

## **Committee 12**

# **Adult Conservative Management**

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# Adult Conservative Management

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## INTRODUCTION

Conservative treatment is any therapy that does not involve pharmacological or surgical intervention. It includes principally, lifestyle interventions, physical therapies, scheduled voiding regimens, complementary and alternative medicines (i.e. those not considered part of the traditional biomedical model), anti-incontinence devices, supportive rings/pessaries for pelvic organ prolapse (POP) and pads/catheters. In some countries a combination of the first three is called “behavioural therapy” (defined as an approach that seeks to alter the individual’s actions or their environment in order to improve bladder control). Conservative therapies are usually low cost, and managed principally by the person with urinary incontinence (UI) with instruction/supervision from a health professional. They differ from other forms of incontinence and prolapse management, in that they have a low risk of adverse effects and do not prejudice other subsequent treatments. Consequently conservative measures should be included in the counselling of patients who suffer from either UI or POP regarding their management options. As the prevalence of UI and POP is high, and with the current constraints on most healthcare economies, conservative treatment constitutes the principal form of management at the primary care level. It is also indicated for those patients for whom other treatments, in particular surgery, are inappropriate, for example, those who are unwilling to undergo or who are not medically fit for surgery and women who plan future pregnancies (as these may adversely affect surgery). Other indications include patients awaiting surgery or who wish to delay surgery and those whose symptoms are not serious enough for surgical intervention.

To date, however, only a relatively small number of intervention studies of adequate size have been carried out to assess the effectiveness of conservative management of UI and POP. This chapter reviews the main types of conservative management (excluding anti-incontinence devices and pads/catheters; see

report of Committee 20: Management using continence products) with regard to their ability to prevent and treat UI and POP effectively. Comment is also made on the effect of conservative management on other lower urinary tract symptoms (in addition to UI) and also factors affecting outcome, in particular age. This information will assist in the counselling of neurologically ‘normal’ adults regarding these treatment options (readers are directed to the chapters on children, the frail elderly and neuropathic patients for discussion on the effect of conservative management in these specific groups). A systematic review of the literature has been carried out, principally of randomised controlled trials (RCTs), resulting in some recommendations for practice based on the level of evidence available (see preface) and suggestions for future research.

Notes to the reader: For ease, all studies are cited using the first author and year. Where summary statistics are presented, the raw data from which these are derived can be found in the trial reports and systematic reviews cited in the chapter. Readers who are interested in the conservative management of faecal incontinence are referred to the chapter on faecal incontinence.

## A. UI IN WOMEN

Female UI is a distressing condition with significant social implications. It is common – the median level of prevalence estimates gives a picture of increasing prevalence during young adult life (prevalence 20-30%), a broad peak around middle age (prevalence 30-40%), and then a steady increase in the elderly (prevalence 30-50%) (see report of Committee 1: Epidemiology). Although the proportions of different types of UI are difficult to estimate, approximately half of all incontinent women are classified as stress incontinent, a smaller proportion as mixed incontinent and urge urinary incontinence is the smallest category. The various types most likely reflect different pathologies and aetiologies.

Stress urinary incontinence (SUI) is thought to occur due to a lack of bladder neck support and/or poor urethral closure. As a result the urethral lumen is not closed effectively during activities that increase intraabdominal pressure with consequent involuntary leakage during effort, exertion, sneezing or coughing. If during urodynamic assessment there is involuntary urine loss synchronous with a rise in intra-abdominal pressure and in the absence of an involuntary detrusor contraction this is described as urodynamic stress incontinence. Urge urinary incontinence (UUI) can be due to a rise in intravesical pressure due to involuntary detrusor contraction, a condition known as detrusor overactivity (DO). This is further subclassified as idiopathic (cause unknown) or neurogenic (where there is a known neurological cause for detrusor muscle overactivity). Some women experience urgency with or without leakage, usually with urinary frequency and nocturia. This constellation of symptoms is called the overactive bladder (OAB) syndrome. Mixed urinary incontinence (MUI) is used when the person has evidence of both SUI and UUI. This chapter addresses the effect of conservative management in women and men with stress, urge (idiopathic), and mixed urinary incontinence, and OAB syndrome.

Where able, the authors of the chapter have differentiated the effects of interventions by diagnosis (such as SUI, UUI, OAB, and MUI). This diagnostic distinction was not made or not reported in some of the studies reviewed; where it was not possible to distinguish effect by diagnosis the more generic term urinary incontinence (UI) is used in summaries and recommendations.

## I. LIFESTYLE INTERVENTIONS

Various lifestyle factors may play a role in either the pathogenesis or, later, the resolution of UI. While published literature about lifestyle factors and UI is sparse, alterations in lifestyle are frequently recommended by healthcare professionals and lay people alike. However, to date, most studies about lifestyle report associations only and do not assess the actual effect on UI of applying or avoiding the behaviour in question. Currently, only a relatively small number of RCTs have been carried out to assess the effect of a specific lifestyle change on UI. This section will examine the evidence for the association and use of lifestyle interventions in the management of female UI. A summary of the search strategy and inclusion/exclusion criteria is given in the appendix.

### 1. PREVENTION

No RCTs assessing the effect of lifestyle interventions on UI prevention were identified.

### 2. TREATMENT

Where RCTs are available, these are reviewed. Where

there are no RCTs for a particular lifestyle intervention, other types of evidence are considered.

#### a) Weight loss

Two RCTs were found that specifically recruited incontinent women [1, 2]. Another RCT focused on the effect of intensive lifestyle intervention in overweight women with diabetes [3]; the bulk of this intervention was weight loss. Four prospective cohort studies [4-7] evaluated the effect of weight loss. Other study designs were cross-sectional [8-14], retrospective cohort [15], or case-control studies [16].

#### 1. QUALITY OF DATA

Sample sizes for the intervention studies were 12 [5], 138 [6], 10 [4], 48 [1], 338 [2], 1,957 [3] and 101 [7]. Sample sizes for observational studies that assessed the association between obesity and UI ranged from 193 [15], 3536 [13], 27,936 [11] to 83,355 [14]. The case control study had a sample size of 108 cases and 108 controls [16].

Participant blinding was not possible in any of the three RCTs. Of 48 randomized in one trial, 40 remained in the study at the time of assessment [1]. Another trial [2] is in abstract form and full details have not been published. In the large RCT with diabetes as the primary focus, 2191 women were enrolled and 234 were excluded because data about UI were not available; the number that dropped out before the endpoint is not detailed for this subpopulation of women.

The outcome measure in most studies was subjective, determined by either validated or non-validated questionnaires. Studies by Bump (1992) and Subak (2002, 2005, 2007) also used objective measures including urodynamics, bladder diary and a standardised fluid loss quantification test.

Follow-up periods for the interventional studies were one year after gastropasty surgery [5] and laparoscopic Roux-en-Y gastric bypass [7], six months after completion of weight reduction, either by means of low calorie liquid or reduced calorie solid diet [4], three months after completion of a very low calorie liquid diet and exercise [1], six months after completing an intensive group weight intervention programme that included lifestyle and behaviour changes [2], mean 2.9 years after beginning the intervention [3], and not stated [6].

#### 2. RESULTS

Many researchers [8-11, 13-20] have reported an association between increased weight, or increased body mass index (BMI, kg/m<sup>2</sup>), and UI. This association held after controlling for age and parity. In one multivariate analysis, Brown (1996) reported that the prevalence of daily UI increased by an odds ratio of 1.6 per 5 BMI units. In a multivariate analysis

of a different population, Brown (1999) found that the prevalence of at least weekly SUI increased by 10% per five units BMI. Similarly, Foldspang (1995) reported an OR of 1.07 for UI prevalence per BMI unit, after controlling for other factors [21]. Hannestad (2003) described a dose-response type relationship between BMI and severe UI. Compared to women with a BMI < 25, OR's for the following groups were: BMI 25-29, OR 2.0 (95% confidence interval (CI) 1.7 to 2.3); BMI 30-34, OR 3.1 (95% CI 2.6 to 3.7); BMI 35-39, OR 4.2 (95% CI 3.3 to 5.3); BMI 40+, OR 5.0 (95% CI 3.4 to 7.3). Danforth (2006) reported that in women with a BMI of 30 or higher, the odds of severe UI were 3.1 times that of women with a BMI between 22 and 24. Similarly, Melville (2005) found that women with a BMI of 30 or higher had a 2.39 fold risk of UI compared to normal weight women.

Three groups [5-7] reported resolution of UI in the majority of cases after massive weight loss in morbidly obese women undergoing surgical weight reduction procedures. While obesity is commonly considered a risk for SUI, in Bump's (1992) study, women with UUI were as likely to experience post-operative continence as women with SUI. In the Burgio (2007) study, mean BMI decreased from 48.9 (standard deviation (SD) 7.2) pre-surgery to 35.3 (SD 6.5) at six months and 30.2 (SD 5.7) at 12 months post-surgery. Prevalence of UI decreased from 67% pre-surgery to 41% at six months and 37% at 12 months (95% CI for change 18.6 to 40.0%,  $p < 0.001$ ). Reduction in prevalence of UI was significantly associated with decreases in BMI ( $p = 0.01$ ). Among incontinent women who lost 18 or more BMI points, 71% regained urinary continence at 12 months. In a cross-sectional study of 1800 Swedish women [12], incontinent women were slightly more likely than continent women to report at least a five kg weight loss in the preceding five years (15% versus 11%, respectively;  $p = 0.05$ ). This may be secondary to intentional weight loss as a treatment for UI, rather than some effect of weight loss itself.

In Subak's pilot study (2002) of 10 women, all six of the women achieving a weight loss of at least 5% had at least a 50% reduction in incontinent episodes compared to one out of the four women with <5% weight loss. In the 2005 RCT [1] reporting on 48 participants, median baseline weight (95 kg) and number of incontinent episodes (21 per week) were similar between the groups. Compared to controls (wait list) that did not participate in a weight loss programme, women in the weight loss (liquid diet) group lost 15kg (SD 7) (compared to 0kg (SD 4)) and experienced a 60% reduction in weekly incontinent episodes (compared to 15%). The Programme to Reduce incontinence by Diet and Exercise (PRIDE) [2] randomised 338 overweight incontinent women in a 2:1 ratio to an intensive 6-month group weight intervention programme or usual care, consisting of four information sessions. Women in the intervention

group lost a mean of 8kg compared with 2kg in the usual care group. Forty one percent of women in the intervention group decreased the weekly number of Incontinence episodes by at least 70% compared to 22% in the usual care group.

The RCT from the Diabetes Prevention Programme [3] reporting on 1957 participants found that overweight diabetic women assigned to intensive lifestyle therapy (consisting of low-fat diet, moderately intense exercise for at least 150 minutes per week and a behavioural and educational curriculum) were less likely to be incontinent compared to those assigned to placebo drug with standard lifestyle advice or metformin alone (38.3% versus 45.7% and 48.1%, respectively;  $p = 0.001$ ).

## SUMMARY

Obesity is an independent risk factor for the prevalence of UI. Massive weight loss (15 to 20 BMI points) significantly decreases UI in morbidly obese women. (Level of Evidence: 2). Moderate weight loss also results in decreased UI. (Level of Evidence: 1).

## RECOMMENDATIONS

For morbidly and moderately obese women weight loss is a useful treatment to reduce UI prevalence (Grade of Recommendation: A). Based on the current evidence, maintaining normal weight through adulthood may be an important factor in preventing the development of UI. Given the high prevalence of both UI and obesity in women, the dual issues of weight loss and prevention of weight gain should receive high research priority.

### *b) Physical forces (exercise, work)*

No RCTs exist in which UI prevalence is compared between subjects assigned to heavy work or high impact activity versus sedentary activities.

#### 1. QUALITY OF DATA

A case-control study compared the incidence of surgery for UI and/or prolapse between 28,619 population based controls and 1,652,533 nursing aids [22]. Bø (1989) and Nygaard (1994) evaluated the difference in UI prevalence between 305 and 144 women, respectively, engaged in high versus low impact activities [23, 24] Bø (2001a) compared 572 athletes ages 15-39 years with 574 controls [25]. In a retrospective cohort study, Nygaard (1997) reported UI prevalence in 104 high-impact and low-impact former Olympic athletes [26]. Caylet (2006) compared UI prevalence between 157 elite female athletes and 426 women from the general population between ages 18 and 35 [27]. Kruger (2007) conducted a case-



control study exploring mechanisms by which athletes might be more likely to experience SUI and compared pelvic organ descent and pubovisceral muscle volume between 24 elite nulliparous athletes and 22 age and BMI matched controls [28]. Eliasson (2005) compared UI at 36 weeks gestation and one year postpartum between 665 primiparous women participating in high-impact, low-impact or no activity [29].

Several small case series described UI in women doing specialised activities. Davis (1996) described a series of nine women who became incontinent after parachute jumping [30]. Larsen (2007) compared UI and POP in 37 soldiers that completed paratrooper training versus 79 that completed other summer military training [31]. Benjamin (2000) studied the prevalence of UI in 25 women aviators exposed to high gravitational forces [32].

Several cross-sectional studies compared the prevalence of UI with the self-reported level of physical activity. The Norwegian EPINCONT study compared both any and severe UI in 27,936 women according to three levels of high impact physical activity [11]. Kikuchi (2007) compared UI prevalence in 676 men and women age 70 years and older participating in three physical activity groups; physical activity was assessed by a single-item questionnaire [33]. Nygaard (2005) compared UI prevalence and severity in 3,364 women according to physical activity level as assessed by the International Physical Activity Questionnaire [34].

Using women enrolled in the Nurses Health Study, two prospective studies assessed the risk of incident UI according to physical activity level, reported as metabolic equivalent task hours per week, in 2,355 women ages 54 to 79 years [35] and 30,135 women 37 to 54 years at risk of incident UI [36]. Another study measured physical activity by questionnaire and electronic motion sensor in 69 women before and one year after successful treatment for UI [37].

## 2. RESULTS

Minimal SUI is common in young exercising women [23, 38, 39]. College athletes participating in high impact activities are more likely to report the symptom of SUI during exercise than those participating in low impact exercise [24]. Bø (2001a) found no difference in UI prevalence between elite athletes and controls. Caylet (2006) found that 28% of elite athletes reported UI compared to 10% of controls. There was no difference in UI prevalence between physically active and sedentary controls. In the prospective study of pregnant and postpartum women, high-impact physical activity before pregnancy was associated with more urinary leakage one year postpartum compared to low-impact activity [29].

There is little available information on whether strenuous exercise or activity causes the condition of UI later in life. In a study of 104 women who were

Olympians approximately 25 years ago, those who competed in gymnastics or track and field were not more likely to currently report daily or weekly UI than Olympians who competed in swimming [26]. Certain provocations may cause SUI; one report described nine nulliparous infantry trainees who developed SUI and pelvic floor defects for the first time during airborne training, which included parachute jumping [30]. The precise number of total trainees is unknown but is estimated to be approximately 500. Larsen (2007) found no difference in UI prevalence between female paratroopers and women that completed regular summer training, but paratroopers were more likely to demonstrate stage II prolapse on examination (OR 2.7 ; 95% CI 1.4 to 5.4). In 25 women aviators, self-report of UI was not found to increase at high gravitational forces [32]. Compared to a control group, athletes that participated in high-impact, frequent intense training had a higher mean diameter of the pubovisceral muscle, greater bladder neck descent and a larger hiatal area on Valsalva manoeuvre [28].

The EPICONT study reporting on 27,936 women found no difference in either any UI (that is, mild or greater) or severe UI in women that reported high impact physical activity one to two hours per week or three or more hours per week compared to those that reported exercising less than one hour per week (after adjusting for age, BMI, parity, coughing and wheezing) [11]. In contrast, Nygaard (2005) reported that UI with physical activity was more common among highly active than less active women (15.9% versus 11.8%;  $p=0.01$ ). Additionally, after adjusting for age, parity, comorbidities and other factors, women with very severe UI were more likely to be insufficiently active than continent women (OR 2.64). In Kikuchi (2007), compared to people in the lowest physical activity group, those in the middle and high level activity groups were less likely to report UI (adjusted OR of 0.71, 95% CI 0.47 to 1.09, and 0.58, 95% CI 0.35 to 0.96 respectively).

In older women enrolled in the Nurses Health Study, total physical activity (i.e. top versus bottom quintile of metabolic equivalent task hours per week) was significantly associated with a reduced risk of new UI (OR 0.81) in analyses adjusted for confounders. Walking constituted about half of the total physical activity among the participants and was related to a 26% lower risk of developing UI. Total physical activity was not related to the incidence of UUI [35]. These findings were mirrored in younger women enrolled in the same study [36]: the risk of at least monthly UI decreased with increasing quintiles of moderate physical activity (relative risk (RR) 0.80, 95% CI 0.72 to 0.89 comparing extremes of quintiles). Note that few women in either study did strenuous physical activity. Stach-Lempinen (2004) found no difference in exercise habits after successful treatment for UI.

Surprisingly little information is available on the

relationship between stressors in the workplace and UI. Danish nursing assistants, who are exposed to frequent heavy lifting, were more likely to undergo surgery for genital prolapse and/or UI than women in the general population (RR 1.6, 95% CI 1.3 to 1.9); the study did not control for parity [22].

## SUMMARY

Strenuous exercise is likely to unmask the symptom of SUI during the provocation. There is currently no evidence that strenuous exercise causes the condition of UI although in a small number of women without other known risk factors, extreme provocations such as parachute jumping may cause UI.

There is good prospective cohort information suggesting that moderate exercise decreases the incidence of UI in middle-aged and older women; this effect may be mediated by weight control (Level of Evidence: 2).

There are scant uncontrolled data that suggests that women engaged in occupations with heavy lifting may be predisposed to genital prolapse and/or UI (Level of Evidence: 3). In spite of the fact that healthcare professionals commonly advise restricting exercise and heavy lifting following UI or prolapse surgery, there is no published evidence that this improves surgical outcome.

## RECOMMENDATIONS

Given the large proportion of women who are employed in various occupations that require heavy lifting and the paucity of data about the association of such exertions and UI, this association should be investigated further. Specifically, research must establish whether heavy exertion is an etiologic factor in the pathogenesis of UI, and whether changing exertions can alleviate established UI.

### c) Smoking

Understandably, there are no RCTs investigating the effect of smoking on UI. There are no trials of the effect of smoking cessation.

#### 1. QUALITY OF DATA

One case-control study compared incontinent smokers with incontinent non-smokers [40], while a second compared smoking behaviour between continent and incontinent women [41]. Seven large cross sectional studies evaluated multiple risk factors for UI, including smoking [8, 11, 14, 42-45]. One case-control study evaluated smoking as a risk factor for failure of SUI surgery [46]. One trial of women planning surgery for SUI assessed the association between smoking and

severity of UI, defined by mean number of Incontinence episodes per day on a bladder diary [47]. An in vitro study assessed the effects of nicotine on bladder muscle contraction [48]. Sample sizes were 189 [40], 1761 [42], 160 [41], 199 [46], 7949 [8], 7338 [43], 1761 [42], 3302 [44], 5,488 [45], 27,936 [11], and 83,355 [14].

## 2. RESULTS

Smokers were more likely to report UI than non-smokers in some studies [11, 14, 41, 43, 44], but not in others [8, 42, 45]. Amongst women with SUI, current smoking was positively associated with UI severity after adjusting for confounders [47]. After adjusting for age, parity, type of delivery, and pre-pregnancy BMI, smokers had a 1.3 fold higher RR (95% CI 1.0 to 1.8) of reporting UI at 16 weeks gestation than non-smokers [43]. The adjusted OR for moderate or severe UI among women reporting UI was 1.38 (95% CI 1.04 to 1.82) in current smokers, after adjusting for perimenopausal status, BMI, diabetes and ethnicity [44]. In the large population based study by Hannestad et al [11], smoking increased the odds of severe UI (OR 1.4, 95% CI 1.2 to 1.6) but not of mild UI. In the case-control study, after adjusting for confounders, smoking was a protective factor (OR 0.26, 95% CI 0.09 to 0.81) against recurrent UI after anti-incontinence surgery [46]. Incontinent smokers were found to have stronger urethral sphincters and lower overall risk profiles than incontinent non-smokers [40]; therefore, it was proposed that more violent coughing promotes anatomic defects, which allow UI.

In potential support of nicotine as a risk factor for UI, Hisayama (1988) and Koley (1984) found that nicotine produces phasic contraction of isolated bladder muscle probes in vitro [48, 49]. However, Milsom (1993) reported an apparent paradoxical local estrogenic effect of nicotine on the vagina, resulting in a decrease in vaginal pH and an increase in lactobacilli [50].

## SUMMARY

Current data suggest that smoking increases the risk of more severe UI (Level of Evidence: 3). Smokers may have a different mechanism causing their UI than non-smokers).

## RECOMMENDATIONS

Further prospective studies are needed to determine whether smoking cessation prevents the onset, or promotes the resolution, of UI.

### d) Dietary factors

No RCT was identified that addressed dietary changes. In a prospective questionnaire study, Dallosso (2004a) studied the impact of dietary risk factors on the one-year incidence of SUI [51] and OAB symptoms [52,

53] in women. Participants completed a 130-item validated food frequency questionnaire. Anecdotal evidence suggests that eliminating dietary factors such as artificial sweeteners and certain foods may play a role in continence; however, no treatment trials have tested this hypothesis.

In a large postal survey, 6037 men and women responded to questions about tea, soft drink and alcohol consumption, as well as whether or not they had UI [54].

One RCT [55] assessed the effects of a caffeine reduction intervention upon frequency, urgency and UUI. Subjects were those with urinary symptoms who consumed more than 100mg caffeine daily. Those randomised to the experimental group received bladder training and a caffeine-fading method to decrease caffeine intake to less than 100mg per day, while the control group also received bladder training but no caffeine reduction information. Another RCT [56] used a crossover design to evaluate the effect of caffeine restriction and of increasing and decreasing fluid intake on urinary symptoms over a four-week period in women with urodynamic SUI or DO.

One study compared women with DO with continent women who received caffeine tablets [57], while another compared caffeine intake between women with DO and those without [58]. The effect of decreasing caffeine intake in a small cohort of incontinent women was examined in a prospective fashion [59]. Large epidemiologic trials using multivariate analyses assessed the effect of coffee drinking [8], alcohol consumption [9] and tea, coffee, and alcohol intake and UI [11]. A smaller cross-sectional analysis assessed the association between symptoms and lifestyle factors, including caffeine intake [60].

In one RCT, women with UI were randomly assigned to one of three groups: increase fluid intake by 500 cc, maintain fluid intake at baseline level, or decrease by 300 cc. Participants kept fluid intake and output diaries for five weeks [61]. Wyman (1991) analysed the correlation between mean daily oral fluid volume intake and mean daily voids and Incontinence episodes in 126 women aged 55 and older that kept diaries for one week [62].

## 1. QUALITY OF DATA

It was not feasible to blind participants in any of the three RCTs, with dropout rates of 22% (26/58) [55], 37% (41/110) [56], and 45% (25/58) [61]. The numbers completing each study were 30 [57], 32 [61], 34 [59], 69 [56], 74 [55], 126 [62], 159 [58], 297 [60] 2764 [9], 6037 [54], 7949 [8], 27,936 [11], and 6,424 women [52] and 4887 men [63].

## 2. RESULTS

**(a) Diet:** After adjusting for age, physical functioning,

SUI at baseline, obesity, smoking and certain dietary factors, the incidence of SUI at one year was increased in women consuming more total fat, saturated fatty acids and monounsaturated fatty acids, as well as those that consumed more carbonated beverages, zinc or vitamin B12 at baseline [51, 52]. The incidence of SUI was reduced in those that ate more vegetables, bread and chicken at baseline [52]. Higher intake of vitamin D, protein and potassium were associated with decreased risk of onset of OAB in women [53].

**(b) Caffeine:** One RCT found a clinical effect of decreasing caffeine, while the other did not. Bryant (2002) reported that women in the intervention group decreased daily caffeine consumption to a mean of 96.5mg, compared to 238.7mg in the control group. The experimental group had statistically significant reduction in urgency episodes (61% versus 12%); the number of Incontinence episodes decreased as well (55% compared to 26% in the controls) but this was not statistically significant ( $p=0.219$ ). In contrast, while Swithinbank (2005) found effect of decreasing fluid intakes (see below), changing from caffeine containing to decaffeinated drinks produced no improvement in symptoms.

Other study designs generally found mixed effects of caffeine on bladder function. Following caffeine intake, women with DO had increased detrusor pressure on bladder filling, while continent women had no such abnormality [57]. In a population of 259 consecutive women presenting for urodynamics, 131 women with DO had a significantly higher mean caffeine intake (484mg/day, SD 123) than women without this diagnosis (194, SD 123) [58]. This association persisted after controlling for age and smoking. In 34 women with symptoms of UI (mostly mixed) who decreased caffeine intake (from 900mg/day to 480mg/day), episodes of daily urine loss also decreased (from 2.3 to 1.0 per day) [59]. In a multivariate analysis, Brown (1996) found no association between coffee drinking or alcohol drinking and daily UI. In the Norwegian EPINCONT study, tea drinkers had a slightly higher odds for all types of UI (OR 1.2, 95% CI 1.1 to 1.2) for up to two cups per day compared to none and OR 1.3 (95% CI 1.2 to 1.5) for three or more cups per day compared to none, while no association was found between either coffee (at any dosage) or alcoholic beverages (three or more drinks per two weeks compared to none to two drinks per two weeks) and UI [11]. Bradley (2005) reported that, after adjusting for confounders, coffee drinking was associated with bladder symptoms of difficulty emptying (OR 8.6, 95% CI 1.4 to 55.0) and weak stream (OR 5.3, 95% CI 1.5 to 19.0).

**(c) Alcohol:** After adjusting for age and gender, no association was found between UI and consumption of alcohol [54]. After adjusting for age and fluid intake, consumption of wine, beer or spirits did not increase the incidence of either SUI or OAB (there was a trend



towards less SUI in beer drinkers; OR 0.75 (95% CI 0.56 to 1.01) for weekly drinkers versus those that drank beer less than monthly) [52]. Similarly, in a large cross-sectional study, there was no association in either unadjusted or adjusted analyses between alcohol consumption and UI [9].

**(d) Fluid intake:** In incontinent women over age 55 years, there was a modest positive relationship between fluid intake and severity of incontinence in women with SUI; fluid intake accounted for 14% of the explained variability in number of incontinent episodes [62]. No such correlation was found in women with DO. In a RCT, 32 women were assigned to one of three groups: increase fluid intake by 500cc over baseline, decrease by same amount, or maintain baseline level [61]. While non-adherence to the protocol made results difficult to interpret, the authors reported that 20 women who had fewer incontinent episodes at the end of the trial attributed this to drinking more fluids. Another RCT that used a cross-over design found that when fluid intake was decreased, 39 women with SUI decreased the number of incontinence episodes; similarly, 30 women with DO significantly decreased voiding frequency, urgency and incontinence episodes [56].

#### SUMMARY

Fluid intake plays a minor, if any, role in the pathogenesis of UI. Caffeine consumption is pervasive in many societies and may play a role in exacerbating UI. The data on caffeine intake and UI are conflicting. While large cross-sectional surveys indicate no association (Level of Evidence: 3), small clinical trials do suggest that decreasing caffeine intake improves continence. (Level of Evidence: 2).

#### RECOMMENDATIONS

Given the fact that decreasing fluids may lead to urinary tract infections, constipation, or dehydration, this intervention should be reserved for patients with abnormally high fluid intakes (Grade of Recommendation: C).

A reduction in caffeine intake is recommended for those with incontinence symptoms (Grade of Recommendation: B). Larger RCTs to assess the effect of caffeine and other dietary factors are feasible and important.

#### e) Constipation

No published RCTs were found which assessed the effect of regulating bowel function on UI. An observational study compared the self-report of straining as a child with urogynaecological symptoms as an adult [64]. Population-based studies assessed multiple risk factors for UI [65, 66].

#### 1. QUALITY OF DATA

Sample sizes range from 73 for the observational study [64] to 213 in a study correlating the surrogate measures of perineal descent and pudendal neuropathy [67] to 1154 and 1051 in the population-based studies [65] respectively.

#### 2. RESULTS

In a small observational study, 30% of women with SUI and 61% of women with uterovaginal prolapse reported straining at stool as a young adult, compared to 4% of women without urogynaecological symptoms [64]. In a large population-based study of 1154 women over age 60 years, those with UI were slightly more likely to report constipation than those who were continent of urine (31.6% vs 24.7%) [65]. After adjusting for demographic and obstetric confounders, women who reported straining at stool were more likely to report SUI (OR 1.9, 95% CI 1.3 to 2.6) and urgency (OR 1.7, 95% CI 1.2 to 2.4) [66]. There appears to be an association between straining and pudendal nerve function. The mean pudendal nerve terminal motor latency increased after straining, correlated with the amount of descent, and returned to resting by four minutes after a strain [68]. Others found evidence of pudendal neuropathy in only 25% of women with abnormal perineal descent; in this large group of patients with defecating dysfunction no relationship was seen between neuropathy and pelvic descent, leading to the conclusion that pelvic descent and neuropathy may be two independent findings [67].

#### SUMMARY

There is some evidence to suggest that chronic straining may be a risk factor for the development of UI. (Level of Evidence: 3). There are no intervention trials that address the effect of resolving constipation on UI.

#### RECOMMENDATIONS

Further research is needed to delineate the role of straining in the pathogenesis of UI. If the association holds, public education, particularly of parents and paediatricians, is needed to make an impact on the common problem of straining due to constipation in children.

#### f) Other

There are many other lifestyle interventions suggested either by healthcare professionals or the lay press for the treatment of UI, including reducing emotional stress, wearing non-restrictive clothing, utilising a bedside commode, decreasing lower extremity oedema, treating allergies and coughs, wearing cotton underwear, and increasing sexual activity. There is no evidence to support these interventions for UI; support for these interventions is all anecdotal in

nature. One study has assessed the value of postural changes in a laboratory setting [69].

### 1. QUALITY OF DATA

In the urodynamics laboratory, 65 women underwent a series of standing cough stress tests in each of four postures: standing, crossing the legs, bending forward from the hips, and a combination of crossing legs and bending forward [69].

### 2. RESULTS

The mean loss was 12.3g (95% CI 8.5 to 16.1) in the standing position; this was significantly reduced to 1.3g (95% CI 0.5 to 2.1,  $P < 0.001$ ) with crossed legs and to 4.7g (95% CI 1.4 to 7.7,  $P < 0.01$ ) by the combination of crossing the legs and bending forward. Bending forward alone did not reduce fluid loss (10.2g, 95% CI 6.5 to 13.9). No study has evaluated whether postural changes are a satisfactory form of treatment outside of the laboratory setting.

### SUMMARY

Crossing the legs and bending forward may reduce leakage during provocation, but this has not been tested in a clinical environment (Level of Evidence: 3). There is no evidence about whether many other recommended lifestyle intervention prevent or are effective treatments for UI.

### RECOMMENDATIONS

Crossing the legs and bending forward might be useful in reducing leakage during coughing or other provocation (Grade of Recommendation: C). High quality studies evaluating the effect of many other lifestyle interventions on UI are warranted.

### 3. OTHER LUTS

Most published data on the effect of lifestyle interventions (in particular, dietary factors) on other LUTS pertain to males only, and thus, are not included in this review. In one study of a geriatric population ( $n=128$ ), there was a strong relationship between evening fluid intake, nocturia, and nocturnal voided volume; this relationship was weaker for diurnal intake and voiding [70]. Bladder training combined with caffeine reduction significantly reduced the number of voids in 24 hours compared to bladder training alone (35% versus 23%) [55]

Future work should separately evaluate the impact of lifestyle interventions on nocturia, diurnal frequency, urgency and UUI to delineate whether certain interventions preferentially affect different areas of OAB.

### 4. FACTORS AFFECTING OUTCOME

RCTs are sparse in this field of lifestyles advice, and none of those available specifically describe the impact of age or any other variable on outcome.

## II. PELVIC FLOOR MUSCLE TRAINING (PFMT)

One of the principal therapeutic uses of pelvic floor muscle training (PFMT) is the prevention and treatment of UI. Because pelvic floor muscle (PFM) integrity appears to play an important role in the continence mechanism (see report from Committee 4: Pathophysiology), there is a biological rationale to support the use of PFMT in preventing and treating UI.

PFMT has been part of exercise programmes in Chinese Taoism for over 6,000 years [71]. It first entered modern medicine in 1936; a paper by Margaret Morris describing tensing and relaxing of the PFM introduced the use of PFMT as a preventative and treatment option for urinary and faecal incontinence to the British physical therapy profession [72]. However, PFMT as a treatment for SUI did not become widespread until the 1950's after American gynaecologist Arnold Kegel reported on the successful treatment of 64 cases of female SUI using PFM exercises with a pressure biofeedback perineometer [73].

### • Biological rationale for PFMT for SUI

The biological rationale is three-fold. Firstly, an intentional, effective PFM contraction (lifting the PFM in a cranial and forward direction) prior to and during effort or exertion clamps the urethra and increases the urethral pressure, preventing urine leakage [74]. Ultrasonography and MRI studies have demonstrated the cranial and forward movement of the PFM during active contraction and the resulting impact on the urethral position, which supports this rationale [75, 76]. Miller (1998) named this counter-balancing PFM contraction prior to a cough the 'knack' and assessed its effectiveness in an RCT [77]; they demonstrated that a voluntary PFM contraction before or during coughing can reduce leakage after only one week of training. Other published research, employing the term 'PFM functional training', recommends pre-contracting the PFM not only during a cough but for any daily task that results in increased intra-abdominal pressure [78].

Thus, research suggests that the timing of a PFM contraction might be an important factor in the maintenance of urinary continence. However, the optimal strength required to clamp the urethra and prevent urine leakage has not yet been determined. In healthy continent women, activation of the PFM before or during physical exertion seems to be an automatic response that does not require conscious effort [79-81]. There is some evidence that this PFM 'reflex' contraction is a feed-forward loop and might precede bladder pressure rise by 200-240 milliseconds [82, 83]. For incontinent women, learning to rapidly

perform a strong, well-timed PFM contraction may actively prevent urethral descent during an intra-abdominal rise in pressure [84].

Secondly, the bladder neck receives support from a strong, toned PFM (resistant to stretching), thereby limiting its downward movement during effort and exertion, preventing urine leakage [74, 85]. Bø has suggested that intensive strength training may build up the structural support of the pelvis by permanently elevating the levator plate to a higher position inside the pelvis and by enhancing the hypertrophy and stiffness of its connective tissues [85]. In line with and supporting this hypothesis, differences in the anatomical position of the PFM have been demonstrated between continent and incontinent women [86, 87]. Additionally, dynamometric studies have shown that SUI and MUI women demonstrate less PFM tone, maximal strength, rapidity of contraction and endurance as compared to continent women [88, 89]. Further, in an uncontrolled MRI reconstruction study, a significant reduction in the internal surface area of the levator ani was observed after PFMT suggesting an increase in passive stiffness of the levator ani, which is indicative of the state of PFM tone [90]. Griffin (1994), using a pressure probe inside the vagina, also showed a significant difference in subjects' PFM resting pressure three to four weeks after starting PFMT and increased resting pressure after PFMT was completed [91]. Furthermore, Balmforth (2004) reported increased urethral stability at rest and during effort following 14 weeks of supervised PFMT and behavioural modifications [92]. Thus, there is a growing body of evidence to support the rationale that PFMT improves PFM tone and that it may facilitate more effective automatic motor unit firing of the PFM, preventing PFM descent during increased intra-abdominal pressure, which in turn prevents urine leakage [93].

Thirdly, PFM may be activated with a transversus abdominus (TrA) muscle contraction; this has implications for coordination of muscle activity in and around the pelvis/abdomen during everyday activity. An increasing body of evidence suggests that the active contraction of the TrA muscle is associated with co-activation of the PFM. This has been demonstrated by US, EMG and MRI studies [94-98]. However, a TrA muscle contraction does not appear to elevate the PFM in all women [99] and when it does, it does not appear to be as effective as a direct PFM contraction [97, 98]. Recent studies suggest that the relationship between PFM and TrA muscle differs between continent and incontinent women with the PFM being displaced less during a TrA muscle contraction in SUI women as compared to continent women [98]. More research is needed to better understand the relationship between the TrA and the PFM muscles as well as the effect on incontinence of rehabilitating the interaction between TrA muscle and the PFM.

Given the above biological rationale, for SUI the objective of PFMT is usually to improve the timing (of contraction), strength and stiffness of the PFM.

#### • **Biological rationale for PFMT for UII**

PFMT can also be used in the management of UII. The biological rationale is based on Godec's observation that a detrusor muscle contraction can be inhibited by a PFM contraction induced by electrical stimulation [100], and Burgio (1985) has demonstrated that detrusor contraction can be inhibited by a voluntary contraction of PFM [101]. De Groat (1997) demonstrated that during urine storage there is an increased pudendal nerve outflow response to the external urethral sphincter increasing intraurethral pressure and representing what he termed a 'guarding reflex' for continence [102]. Additionally, Morrison (1995) demonstrated that Barrington's micturition centre excitatory loop switches on when bladder pressures are between five to 25mmHg while the inhibitory loop is predominantly active above 25mmHg [103]. Inhibition involves an automatic (unconscious) increase in tone for both the PFM and the urethral striated muscle.

Thus, voluntary PFM contractions may be used to control UII. After inhibiting the urgency to void and the detrusor contraction, the patient can learn to reach the toilet in time to avoid urine leakage. However, the number, the duration, the intensity and the timing of the PFM contraction required to inhibit a detrusor muscle contraction is not known. This focus on urge suppression by voluntary PFM contraction, combined with PFMT, is commonly called behavioural training.

#### • **Principles of skeletal muscle strengthening**

The aim of any strengthening programme is to alter muscle morphology by increasing the cross-sectional area, increasing the number and frequency of motor neuron excitations, and improving tone and stiffness. When muscles engage in intense, repetitive tasks that exceed the normal demands of daily activities this stimulates an increase in the muscle fibre size (hypertrophy), which in turn increases muscle bulk [104]. However, hypertrophy is not immediately evident as a training response. An increase in strength is evident long before visible hypertrophy. Early improvements in strength result from neural adaptation, including a greater number of activated motor units, an increased rate of motor unit excitation, more synchronised motor unit firings and more persistent activation of type II motor units [105-107]. Hypertrophy begins only after a minimum of eight weeks of regular and intense strength training [108]. With increased overload, hypertrophy may continue for some years.

There are four principles of strength training: specificity, overload, progression and maintenance [93]. Strength training is specific to the muscle(s) being trained and requires overload (that is, exposing the muscle(s) being trained to a gradual increase in resistance,

repetitions or repetition speed). Progression is the extension, through increased resistance, intensity and volume of training, of the initial exercise programme. Finally, maintenance refers to the extent to which the muscle is able to maintain a continued level of strength. In order to achieve an effective strength training programme, the American College of Sports Medicine recommends that all these elements be addressed [109].

#### • Terminology and method of review

In this section, PFMT is defined as any programme of repeated, voluntary PFM contractions taught by a healthcare professional. This definition allows for variations in the end-goal of PFMT, the supervision (e.g. individual or group sessions) and the exercise programme (e.g. variations in frequency, intensity, number of contractions and duration of training). Thus, PFMT in the context of this chapter may also include the use of pelvic floor muscle contractions for urge suppression, and preceding changes in intra-abdominal pressure to prevent stress leakage; interventions that may also be called behavioural training. PFMT is used in preference to other previously used terms such as Kegel's Exercises, pelvic floor exercises and PFM exercises. The term 'Kegel's Exercises' is no longer appropriate because it refers to his original exercise programme of 500 contractions per day [73]. Advances in strength-training research (see above) indicate that fewer contractions, with a higher load are more effective, making current PFM programmes very different from that which was originally prescribed by Kegel (1948). Terminology that fails to include a reference to the muscle also seems inappropriate, as it is the muscular component of the pelvic floor that is the primary focus of the training. Ideally, it should also be clear that it is the PFMs, not pelvic muscles in general, which are the target of the intervention. Further, training is viewed as a more appropriate word than exercise. The term exercise is commonly interpreted as one training episode or a single muscle action, whereas, training means repeated exercises over time. Therefore, the term Pelvic Floor Muscle Training (PFMT) is used throughout this chapter.

PFMT was the primary intervention in the studies discussed in this section; however, some also included PFMT complemented by additional strategies related to urge and/or frequency. Trials that combined PFMT with urge and/or frequency strategies were included unless these were clearly part of a bladder (re)training programme or a timed or scheduled voiding programme. Trials were excluded if the primary intervention was clearly a combination of two or more treatments (e.g. PFMT with bladder training, PFMT with oestrogen). The exceptions were biofeedback (BF) and intravaginal resistance devices as these adjuncts are not stand-alone interventions.

This section will examine the evidence for the use of PFMT in the prevention and treatment of UI in women. Questions addressed are:

- Is PFMT effective in the prevention of UI?
- Is PFMT better than no treatment, placebo or control treatments for treatment of UI?
- Is one PFMT programme better than another in the treatment of UI?
- Is PFMT better than other treatments in the treatment of UI?
- Does the addition of PFMT to other treatments add any benefit in the treatment of UI?
- What factors might affect the outcome of PFMT in the treatment of UI?
- What is the effect of PFMT on other lower urinary tract symptoms?

#### • Evidence for PFMT for UI in women

A systematic search of studies to November 2007 was carried out (see appendix). Only papers published in English or in a language for which a translator could be found were included. Relevant systematic reviews and reports of RCTs and quasi-RCTs were included. Therefore, only Level 1 evidence is considered in this section. Recommendations are based on the findings of existing systematic reviews, where they were up-to-date, or systematic reviews and more recent RCTs.

In this section, the pre-specified primary outcomes of interest were 1) self-reported UI (for prevention studies), 2) self-reported cure or 3) cure and improvement in UI symptoms (for treatment studies). Secondary outcomes of interest were 1) leakage episodes (treatment studies) and 2) quality of life (prevention and treatment studies).

With regard to assessment of study quality the Consort Statement Checklist was used [110]. Empirical evidence indicates that two elements of trial quality, allocation concealment and double blinding, are important in estimating treatment effect with precision. Trials with inadequate or unclear concealment of allocation appear to overestimate treatment effect by about 30% and trials that are not double-blinded overestimate effect by about 15% [111]. Therefore, trials that reported adequate allocation concealment have been noted. Although it is often difficult or impossible to blind patients to PFMT, trials that reported blinding of the outcome assessment were also noted. Readers may wish to consider these factors in their interpretation of the data.

### 1. PREVENTION AND TREATMENT (PREGNANT AND POSTNATAL WOMEN ONLY)

This subsection specifically considers PFMT for the prevention and treatment of UI in pregnant and



postnatal women (called childbearing women in this section). As the physiological changes of childbearing can affect PFM function, it is possible that the effect of PFMT might differ in this group compared to non-childbearing women.

Five systematic reviews investigating the effect of PFMT on the prevention and treatment of UI in childbearing women have been published [112-116]. The review by Hay Smith (2002) did not separate data from childbearing and other women. Critical evaluation of the trials included in the four reviews reveals that women were often recruited to trials without regard to previous continence status.

Based on these prior reviews, three main groups of trials in childbearing women are of interest: 1) trials of PFMT for prevention of UI; 2) trials where it was not possible to differentiate prevention from treatment effects; 3) trials of PFMT for treatment of UI. Based on the latest Cochrane review [116], the primary outcome of interest was self-reported UI. The secondary outcomes of interest were condition specific quality of life (e.g. King's Health Questionnaire, Incontinence Impact Questionnaire), or any other quality of life or health status measure (for example Short Form-36); symptom severity and number of leakage episodes.

#### ***a) Is PFMT effective in the prevention of UI in childbearing women?***

There are three grades of prevention: primary, secondary and tertiary [117]. Primary prevention aims to remove the causes of a disease. Secondary prevention focuses on the detection of asymptomatic dysfunction and provides treatment aimed at stopping its progression. Tertiary prevention focuses on existing symptoms to prevent the progression of the disease through treatment. This subsection addresses the question of PFMT effectiveness for primary and secondary prevention of UI in childbearing women. Clinically it can be difficult to effectively screen trial participants to ensure that a disease process is altogether absent (for primary prevention studies) or present, although asymptomatic (for secondary prevention). In many cases, there are no reliable and valid clinical tests. Trials investigating prevention of UI usually enrol people purely on the basis of the absence of symptoms. Thus, in all likelihood the trials in this section probably represent a combination of primary/secondary prevention effects. No attempt was made to distinguish between primary and secondary prevention effects.

Five trials addressed prevention of UI in childbearing women [118-122]. Two of these studies were combined prevention/treatment studies, but published or unpublished data were available for women who were continent at recruitment [118, 121]. In the study by Sampsel (1998), 54 of 72 women were continent based on a standing stress test at 20 weeks gestation.

After drop outs, unpublished data were available from 37 previously continent women (16 PFMT and 21 controls). Mørkved (2003) published data for 207 of 301 women who were continent before pregnancy and at 20 weeks gestation. After dropouts, data were available from 193 previously continent women (94 PFMT and 99 controls). Neither study was powered to detect differences in the previously continent subgroup; the subgroup sizes were small.

Four studies recruited nulliparous or primiparous women during pregnancy, and one "pregnant women" [120]. Reilly (2002) recruited primigravid women without a pre-pregnancy or current history of UI, but with bladder neck hypermobility at 18 to 20 weeks gestation. Sampsel (1998), Mørkved (2003) and Gorbea Chavez (2004) also recruited primigravidae, at 18, 20 and 28 weeks gestation respectively.

In all five trials, PFMT began during pregnancy while controls received the usual antenatal care, which may have included advice on PFMT from their maternity caregivers [118, 119, 121] or were asked not to do PFMT [120, 122]. There were some variations in the PFMT parameters (intensity and supervision):

- Eight to 12 near-maximal voluntary PFM contractions, held for six to eight seconds with a six-second rest, followed by three to four fast contractions at the end of each contraction, twice daily from 20 weeks gestation. Also a weekly exercise class from weeks 20 to 36 [121].
- Eight to 12 PFM contractions, held for six seconds with a two second rest, three sets twice daily, from 18 weeks gestation. Also individual PFMT with physiotherapist during monthly visit [119].
- Up to 30 near-maximal PFM contractions per day from 20 weeks of gestation [118].
- 10 PFM contractions; held for eight seconds each followed by three fast one second contractions; a six-second rest between contractions; for up to 20 weeks. PFMT taught one-on-one with physiotherapist. Weekly clinic appointments (one hour each) for eight weeks, then weekly phone calls [122].
- PFMT not described. Participants were seen twice monthly throughout pregnancy, and every three months postpartum for one year [120].

Mørkved (2003), Sampsel (1998), and Gorbea Chavez (2004) stated that a correct voluntary PFM contraction was checked prior to training.

#### **1. QUALITY OF DATA**

Allocation concealment appeared adequate in four trials [118, 119, 121, 122] and the outcome assessors were blind in four of the five trials [118-121]. Dropout rates ranged from 4% [121] to 14% [119] and 36% [118]. Stothers (2002) did not report any losses to

follow up. Mørkved (2003) and Reilly (2002) measured outcomes at 34 and 36 weeks gestation then at three months postpartum. Sampselles (1998) assessed women at 35 weeks gestation, then postpartum at six weeks and six and 12 months; the primary endpoint was 12 months. Gorbea Chavez (2004) measured outcome at 28 and 35 weeks gestation, and six weeks postpartum. Stothers (2002) measured outcome at six and 12 months postpartum. Reilly (2002) was the only trial with long-term follow up, at four years.

## 2. RESULTS

**i) Late pregnancy (34 weeks or later):** Pooled data from three trials [118, 121, 122] showed that women in the antenatal PFMT group were 56% less likely to report UI than the controls (RR 0.44, 95% CI 0.30 to 0.65). Statistically significant heterogeneity was observed in this comparison. While the point estimates in all three studies favoured PFMT these differed considerably between the trials (RR of 0.86, 0.46 and 0.03 in the studies by Sampselles 1998, Mørkved 2003, and Gorbea Chavez 2004 respectively). A possible reason why the difference between PFMT women and controls is more pronounced in the study by Gorbea Chavez (2004) is that the comparison group was asked not to do PFMT, whereas in the other two studies the controls had usual care that might have included PFMT.

**ii) Early postpartum (up to 12 weeks):** Pooled data from two trials showed that PFMT women were around 50% less likely to report UI, compared to the controls (RR 0.50 95% CI 0.31 to 0.80; [118, 122].

**iii) Mid postpartum (three to six month postpartum):** PFMT women were still statistically significantly less likely than controls to report UI, although the difference in risk had reduced to about 30% (RR 0.71 95% CI 0.52 to 0.97; [118-121].

**iv) Late postpartum (up to one year postpartum):** Based on the data from a previously continent subgroup of participants in Sampselles (1998), there was no difference in prevalence of UI between PFMT women and controls at 12 months postpartum. This trial had not shown a statistically significant effect of PFMT at any of the three previous time-points (late pregnancy, early and mid-postpartum periods), and was not powered to detect a difference in the previously continent subgroup.

**v) Long term (more than one year):** At four year follow up, Reilly (2002) reported seven of 42 PFMT women and 26 of 58 controls had symptoms of SUI. This advantage for the PFMT group needs to be viewed with caution as less than half of the original sample was followed up.

Regarding secondary outcome measures, four of the five trials reported symptom severity data such as frequency or amount of urine leakage. None of the

measures, or the ways in which they were reported, were common to the four trials. The data suggested that PFMT women with symptoms of UI might have demonstrated less severe symptoms than the controls. Only Stothers (2002) noted adverse events; two of the 43 PFMT women withdrew due to pelvic floor pain.

Only two trials reported treatment adherence data. Gorbea Chavez (2004) reported that 84% of PFMT women attended seven or eight of the eight physiotherapy appointments offered. In the study by Reilly (2002), nearly half the women in the PFMT group exercised for 28 days or more; postpartum similar proportions of women in the intervention and control groups were doing occasional or no PFMT (28% and 34% respectively).

## SUMMARY

Pregnancy and birth appear to be important factors associated with the development of UI in women. Therefore, all women who have had a child or children might be considered 'at risk' of developing UI at a later date.

Continent pregnant women having their first baby who participated in a more 'intensive and supervised' PFMT programme than the PFMT provided as part of usual care were less likely to experience UI from late pregnancy up to six months postpartum (Level of Evidence: 1). There was not sufficient evidence available to be sure whether this benefit persists 12 months or more. There was no evidence investigating the preventive effects of PFMT in pregnant, previously continent, multiparous women.

## RECOMMENDATIONS

Continent pregnant women having their first baby should be offered a supervised (including regular health professional contact) and intensive strengthening antepartum PFMT programme to prevent postpartum UI (Grade of Recommendation: A). The usual or standard approach to PFMT in pregnancy (which is commonly verbal or written instruction without confirmation of correct contraction or supervision of training) needs to be reviewed.

Based on the long term findings of one trial [119] health providers with limited resources may wish to consider whether supervised intensive training would be best targeted at those women who are continent at 18 weeks gestation, but have increased bladder neck hypermobility.

Further, large, good-quality RCTs are needed to investigate the effect of antepartum PFMT on preventing postpartum UI in multiparous women.

**b) Is PFMT effective in the mixed prevention and treatment of UI in childbearing women?**

Eight trials contributed to this comparison. In all these trials, some women did and some women did not have UI at the time of recruitment, i.e. in these studies the effect of PFMT included a mix of prevention and treatment.

Four trials randomised nulliparous or primiparous women to either supervised antepartum PFMT or usual antepartum care [118, 121, 123, 124]. The other four trials randomised nulliparous women during pregnancy [125] or postpartum [126-128] to either postpartum PFMT or usual postpartum care or no PFMT.

**i) Antepartum PFMT versus usual care:** The interventions of the trials by Mørkved (2003) and Sampsel (1998) in pregnant women have been described section B.2.1a. Hughes (2001) recruited nulliparous women at 20 weeks gestation and women randomised to PFMT attended one individual appointment then, between 22 and 25 weeks gestation, a group PFMT session (maximum six women) with a physiotherapist. No details of the training parameters were reported. Women with no palpable voluntary PFM contraction or a flicker of contraction were randomised. Controls received the usual community antepartum care. In Danneker's (2004) study, women in the PFMT group were trained to use an Epi-No device (an inflatable vaginal balloon connected to a pressure gauge for visual feedback), 15 minutes daily; for three to six weeks. Controls received no device. This trial was primarily interested in improving the elasticity of the PFM for delivery rather than continence outcomes.

**ii) Postpartum PFMT versus usual care or no PFMT:** Chiarelli (2002) restricted inclusion to women who had had forceps or ventouse deliveries, or had delivered a baby weighing 4000g or more. Ewings (2005) restricted inclusion to women who had already experienced UI and who were at high risk of UI following childbirth in accordance with the SIFCRAFT risk scale. The control groups received the usual postpartum care, which included an invitation to postpartum classes taught by physiotherapists in Chiarelli's (2002) study; standard ante and postpartum care in Sleep's (1987) study, no PFM re-education from two to 10 months postpartum in Meyer's (2001) study and verbal promotion of PFM exercises supplemented by a leaflet in Ewings' (2005) study. In PFMT groups, women were visited by a midwife or physiotherapist on the postnatal ward and were advised to train as follows:

- PFMT exercises as often as remembered and contractions integrated with daily living activities, plus midstream urine stop. Correct PFM contraction was checked on a second visit at eight weeks postpartum [126]

- PFMT exercises with three to six-second holds, three times a day. A variety of adherence strategies were employed (e.g. red stick-up dots, home or hospital visit after eight weeks) [127]
- PFMT programme including 12 visits with a physiotherapist between two and 10 months postpartum, including a 20 minute BF training session and a 15 minute electrical stimulation session [125].
- PFMT taught one to one with physiotherapist in hospital in addition to an invitation to attend PFMT class at two and four months postpartum; 21 of 284 women participated in the first class (18%) and only 5 (4%) attended both [128].

**1. QUALITY OF DATA**

**i) Antepartum PFMT versus usual care:** Two of the four trials had adequate random allocation concealment [118, 121]. In the other two women were allocated at random but it was not clear if allocation was adequately concealed [123, 124]. Assessors were blinded in two of the four trials [118, 121]. Mørkved (2003) [121] randomised 301 women, Sampsel (1998) 72, Danneker (2004) 144 and Hughes (2001) 1169 women. Dropout rates were 4% [121] at three months postpartum and ranged from 24% [124] to 34% [123] at six to seven months post-partum. At 12 months, the drop-out rate was 36% [118].

**ii) Postpartum PFMT versus usual care or no PFMT:** Random allocation concealment was adequate in the trials by Chiarelli (2002), Sleep (1987) and Ewings (2005), but inadequate in Meyer (2001) where alternate assignment was used. Blinding of outcome assessment was adequate in Chiarelli (2002). Sleep (1987) randomised 1,800 women; Chiarelli (2002) 720; Ewings (2005) 234, and Meyer (2001) 107. Both the Sleep (1987) and Chiarelli (2005) trials measured outcome at three months, with the loss of 191 (11%) and 44 women (6%) respectively. Ewings (2005) measured outcome at six months, with a loss to follow-up of 19%. Finally, Meyer (2001) measured outcome at 10 months with no withdrawal or loss to follow-up.

**2. RESULTS**

**i) Antepartum PFMT versus usual care:** Pooled data from three trials [118, 121, 123] showed that women who were randomised to antepartum PFMT had about 10% less risk of UI in late pregnancy (RR 0.88, 95% CI 0.81 to 0.96). Statistically significant heterogeneity was observed in this comparison. While the point estimates in all three studies favoured PFMT these differed considerably between the trials (relative risks of 0.67, 0.81 and 0.93 in the studies by Mørkved 2003, Sampsel 1998, and Hughes 2001 respectively); the study by Hughes (2001) carried considerable weight in the pooled analysis; most likely because it was the largest study. One of the differences between the studies by Mørkved (2003) and the other two in this comparison was the PFMT intensity and



supervision as reported previously, being more 'intense' in the former.

Prevalence of UI was not statistically significant between PFMT and control groups in the early (RR 0.82, 95% CI 0.48 to 1.40; [118]), mid (RR 0.89, 95% CI 0.78 to 1.02; [118, 121, 123]) or late postpartum period (RR 0.96, 95% CI 0.70 to 1.32; [118, 124]).

Three trials reported data on symptom severity such as frequency or amount of urine leakage, but none of the data suggested that PFMT was superior to control or vice versa at the primary endpoint for each study [118, 123, 126].

**ii) Postpartum PFMT versus usual care or no PFMT:** There was no statistically significant difference in the prevalence of UI in women randomised to postpartum PFMT or control in the mid (RR 0.97, 95% CI 0.85 to 1.09 [126-128]) or late postpartum period (RR 0.94, 95% CI 0.75 to 1.16 [125, 127]). Statistically significant heterogeneity was observed in the combined data for the mid postpartum period, with one study favouring PFMT [127], one neither PFMT nor control [126] and one favouring the control condition [128]. Some potentially important clinical differences were noted between the studies. Firstly, Chiarelli (2002) recommended a PFM strength training programme; neither of the other two studies described their PFMT programme, so it is not possible to determine whether the latter studies could have had an effect or how different the PFMT and control conditions were. Further, Sleep (1987) found only a moderate difference in the proportion of PFMT women and controls doing some PFMT at three months postpartum (58% and 42% respectively) while at three month postpartum Chiarelli (2002) found that about half the controls were doing PFMT (58%) but an even greater proportion of the PFMT group (84%) were exercising. A second difference was that, Chiarelli (2002) recruited women at potentially increased risk of postnatal UI, such as those who had a large baby or a forceps delivery.

## SUMMARY

The effect of antepartum PFMT or postpartum PFMT, in groups of women where some did and some did not have prior UI symptoms, varied by study with some studies showing a benefit of PFMT on UI prevalence whereas others did not (Level of Evidence: 2). The characteristics of the two studies, both methodologically robust, that demonstrated some effect were:

a) For antepartum PFMT: Mørkved (2003) recruited pregnant women having their first baby and used an intensively supervised strengthening PFMT programme; PFMT reduced UI prevalence in late pregnancy and three months postpartum but this was not evident six years after the index delivery.

b) For postpartum PFMT: Chiarelli (2002) recruited primiparous and multiparous women at potentially greater risk of postpartum UI after a large baby or forceps delivery, and used a strengthening PFMT programme; PFMT reduced UI prevalence at three months postpartum but not at one year.

## RECOMMENDATIONS

Health providers should carefully consider the cost/benefit of population based approaches to health professional taught antepartum or postpartum PFMT; that is, health professional instruction to all pregnant or postpartum women regardless of their current or prior continence status (Grade of Recommendation: B).

Where a population approach is used, the 'best' evidence to date suggests the following: (a) an intervention comprising a daily home PFMT and weekly physiotherapist-led exercise classes for 12 weeks, starting from 20 weeks gestation for pregnant women having their first baby, and (b) an individually taught strengthening PFMT programme that incorporates adherence strategies for postpartum women who have had a forceps delivery or a vaginal delivery of a large baby (4000g or more) (Grade of Recommendation: C)

### c) Is PFMT effective in the treatment of UI in childbearing women?

Four studies addressed the treatment of existing UI after delivery [129-132]. One study recruited incontinent women during pregnancy [132], while the other three recruited women three months or more after delivery. All four studies recruited a mix of primiparous and multiparous women.

The control groups in three studies [129, 130, 132] received standard care, which included ante and postpartum advice on PFMT, whereas the control group in Dumoulin's (2004) study received, in lieu of training, relaxation massages at the same frequency as the PFMT treatments.

The PFMT interventions varied as follows:

- Wilson (1998) randomised women in the intervention group to either PFMT, or PFMT with vaginal cones, or vaginal cones (VC). PFMT comprised 80 to 100 PFM contractions per day (a mix of fast and slow), with three home visits by a nurse, healthcare visitor or continence advisor. The VC group received 15 minutes per day of cone therapy while the combined PFMT/VC group received both interventions [129].
- The PFMT programme in Glazener (2001) was the same as Wilson (1998), supplemented by instruction from a physiotherapist on four occasions [130].



- In Dumoulin's (2004) study PFMT included electrical stimulation (EStim) with or without deep abdominal training. PFMT comprised weekly sessions supervised by physiotherapists for eight weeks with 25 minutes of PFMT and 15 minutes of EStim (bi-phasic rectangular form; frequency 50Hz) [131].
- Woldringh's (2007) study included four one to one and half hour sessions with a physiotherapist (three antepartum and one at six weeks postpartum) but details of the PFMT programme were not given [132].

## 1. QUALITY OF DATA

Random allocation concealment was adequate in three of the four trials [129-131] and outcome assessors were blind in two [130, 131].

There were 85 losses to follow-up in the trial by Wilson (1998) with high attrition rates noted in all intervention groups (20/39 PFMT, 24/38 PFMT/VC, 15/36 VC). Glazener (2001) reported 223 (30%) losses to follow-up and Woldringh (2007) 38%. In contrast, Dumoulin's (2004) trial (which included weekly contacts with a physiotherapist for eight weeks) reported a 6% loss to follow-up. Wilson (1998) and Glazener (2001) measured outcome 12 months after delivery, and then 24 to 44 months post-delivery, and six years after the index delivery [133]. Dumoulin (2004) reported outcome nine weeks after intervention began. However as women were recruited at varying lengths of time following delivery (all more than three months postpartum) the data are presented alongside those from Glazener (2001), and Wilson (1998), as long-term post-natal data.

## 2. RESULTS

In the one study of antepartum PFMT for treatment of UI, Woldringh (2007) did not find any statistically significant difference in the prevalence of UI between PFMT and control groups at 35 weeks, eight weeks postpartum, six months and 12 months postpartum.

Pooled data from the three trials of postpartum PFMT found women were about 20% less likely to have UI after treatment compared to the controls (RR 0.79, 95% CI 0.70 to 0.90). Statistically significant heterogeneity was observed. The treatment effect in the study by Dumoulin (2004) was much greater than that in the other two studies. Possible reasons are that the controls in the study by Dumoulin (2004) were asked not to do PFMT, whereas controls in the other two studies received usual care and both interventions and control groups were also doing PFMT (a mean of 20 versus five PFM contractions per day in Glazener 200), and 86 versus 35 in Wilson 1998). Another difference was the intensity and supervision of the PFMT intervention; Dumoulin (2004) used a more intensive PFMT programme with adjunctive electrical stimulation and BF and physiotherapy appointments once a week for eight weeks, whereas in the other two

studies [129, 130] women had three or four appointments with health professional over approximately six months and were asked to do PFMT on their own.

All four treatment trials reported some data on symptom severity such as frequency or amount of urine leakage. None of the measures, or the ways they were reported, was common to the four trials. The data suggested that PFMT women with symptoms of UI might have less severe symptoms than the controls, but this was not a consistent or clear-cut finding. Dumoulin (2004) stated that none of the women in the PFMT group reported any adverse events.

Three trials reported some data related to treatment adherence, one for antepartum PFMT [132] and two for postpartum PFMT [129, 130]. In the antepartum study, at 36 weeks gestation 37% of the PFMT women were exercising intensively compared to 14% of the controls [132]. Glazener (2001) and Wilson (1998) both reported the mean number of PFM voluntary contractions per day at 12 months postpartum. Respectively, the mean number of contractions was 20 (SD 29) and 86 (95% CI 69 to 104) per day in PFMT women, and 5 (SD 15) and 35 (95% CI 30 to 40) per day in the controls.

Glazener and colleagues followed up women six years after the index delivery. The effect of PFMT on UI was not sustained. At six years, 100 out of the 263 in the intervention group and 99 out of the 253 in the control group experienced UI at least once per week [133]. However, the women had had an average of 1.5 deliveries since the index delivery.

## SUMMARY

To date, only one trial has investigated the effect of PFMT for the treatment of UI in pregnant women [132]. This was a moderate-size study that did not report on allocation concealment or blinding of the assessors, and did not describe the type of PFMT programme employed. In the absence of any detail on the PFMT programme it is impossible to judge if the intervention had the potential to be effective. Postpartum women with UI who were randomised to PFMT taught and supervised by a health professional were less likely to be incontinent than controls (standard care or relaxation massage) six to 12 months following delivery (Level of Evidence: 1). Of the three trials, the one that used an intensively supervised strength training programme demonstrated the greatest treatment effect. It is unclear if the benefit of PFMT is maintained over time or with subsequent deliveries (Level of Evidence: 2). For women who have persistent symptoms of UI at three months postpartum PFMT is a more effective treatment than standard postnatal care or relaxation massage;

effects might be greater with supervised and intensive strengthening PFMT (with the addition of EStim). It is not clear if the effect can be sustained over the long-term; there is also no data on the effect of short periodic refresher sessions on long-term effect.

## RECOMMENDATIONS

PFMT should be offered as first line conservative therapy to women with persistent UI symptoms three months after delivery (Grade of Recommendation: A); an 'intensive' PFMT programme (in terms of supervision and exercise content) is likely to increase the treatment effect (Grade of Recommendation: B).

There is a need for at least one large, pragmatic, well-conducted and explicitly reported trial with long term follow-up (five plus years) of postpartum PFMT that investigates the effect of 'intensive' treatment followed by periodic refresher sessions.

## 2. PREVENTION (OTHER WOMEN)

Hay-Smith and colleagues have previously reviewed trials of PFMT and other physical therapies for the prevention of UI [112]. Three main groups of trials were found. The first included trials that investigated the effect of PFMT on PFM activity in women, but did not measure continence related outcomes as so were not relevant for this chapter. The second recruited only childbearing women; these trials were considered in section B.2.1a, which addressed the prevention of UI in childbearing women. The third group included trials for prevention of post prostatectomy UI and these trials are considered in Section C.2.1.

No trials investigating the primary/secondary prevention effects of PFMT for UI in non-childbearing women were found.

## 3. TREATMENT (OTHER WOMEN)

### ***a) Is PFMT better than no treatment, placebo or control treatments?***

Recommendations in this section are based on the updated but as yet unpublished findings (Dumoulin and Hay-Smith 2008, personal communication) of a Cochrane systematic review [134]. Primary outcomes of interest were 1) patient-reported symptom cure or improvement and 2) symptom bother and incontinence specific quality of life assessment. Secondary outcomes of interest included the number of leakage episodes and other quality of life measures (not UI-specific, e.g. Short Form 36).

Seventeen RCTs comparing PFMT with no treatment for women with UI were found, of which five were

excluded. Two were excluded because they compared supervised with unsupervised PFMT [135, 136]; for these trials see B.2.3b. One trial, reported only as a conference abstract, was excluded because it was unclear if it was a RCT and it lacked adequate data [137]. Finally, two more trials were excluded because the PFMT versus sham PFMT comparison was considered to be confounded by the choice of sham PFMT [138, 139]. In both trials, sham PFMT consisted of strong isometric hip abductor contractions and according to EMG, dynamometric and MRI studies, both hip abductions and external rotations result in a synergic contraction of the PFM [80, 97, 140]. These two trials probably compared a direct versus an indirect approach to PFMT; for this comparison see B.2.3b.

Of the 12 included trials, nine recruited women with SUI only [77, 141-148]. One included women with SUI, with or without UUI. However, the proportion with MUI was small (9%) and it was thus analysed with the SUI studies [149]. One included older women with UUI with or without SUI (with urge as the predominant type) [150]. The remaining study recruited women with a range of diagnoses [151].

Four studies gave no details about the PFMT programme used [142, 143, 146, 148]. Of the eight remaining trials, five stated that a correct voluntary PFM contraction was confirmed prior to training [77, 141, 145, 147, 150] and in all cases PFMT was taught by a health professional. Based on the description of training programmes, two trials had PFMT programmes that clearly targeted coordination [77] or strength training [145]. It was more difficult to categorise the other PFMT programmes, because they were either a mixed (i.e. strength and endurance) programme or did not provide enough information on the exercise parameters.

The 'control' groups received no treatment, [77, 141, 142, 146, 147, 149] placebo drugs, [150] sham EStim, [143], sham PFMT with placebo drug [148] or a non-active control intervention such as the use of an anti-incontinence device [145] or advice on incontinence pads [143].

The potential to consider the combined results from individual studies was limited by: 1) lack of consistency in the choice of outcome measures chosen by the researchers and because many did not use any of the pre-specified outcomes of interest for the review; and 2) poor reporting of outcome data (i.e. mean reported without a measure of dispersion) which meant the data could not contribute to a pooled analysis.

### **1. QUALITY OF DATA**

The brevity of the reporting in three trials, which were published as conference abstracts, made it difficult to assess the quality [142, 146, 148]. Only Bø (1999) reported adequate random allocation concealment. Seven trials reported using blinded outcome assessors [77, 144-146, 149-151].

## 2. RESULTS

Twelve RCTs, involving 670 women, compared PFMT (353 women) with no treatment, placebo, sham or other non-active control treatments (317 women). In the six trials contributing data, the two comparison groups comprised 175 and 184 women, respectively. Two trials reported data on cure and both found that PFMT women were statistically significantly more likely to report cure [145, 150]. The size of effect was quite different in the two trials; SUI women receiving PFMT were about 17 times more likely to report cure compared to controls (RR: 16.80, 95% CI 2.37 to 119.04) [145], whereas PFMT women in the study with urge predominant UI were about two-and-half times as likely to report cure (RR: 2.34, 95% CI 1.11 to 4.94) [150].

With regard to patient-perceived cure or improvement the two trials in women with urodynamic SUI [143, 145] suggested more likelihood of cure or improvement than the single study in women with UUI with or without urodynamic SUI [150].

Two trials in women with urodynamic SUI used psychometrically robust questionnaires for the assessment of symptom impact. Bø (1999) used the Bristol Female Lower Urinary Tract Symptoms Questionnaire (B-FLUTS), but only the lifestyle and sex-life domains were reported. Fewer women in the PFMT group reported that UI symptoms interfered with activities or were problematic. Schagen van Leeuwen (2004) reported a mean change in Incontinence Quality of Life score (I-QoL), but it was not clear if the difference in favour of the PFMT group was important as the means were presented without a measure of dispersion.

Four studies used urinary diaries to count leakage episodes. Effect size was greater in the Lagro-Janssen's (1991) trial (MD -2.92, 95% CI -3.74 to -2.10); a possible explanation may be inadequate random allocation concealment, with a resulting overestimate of treatment effect. The point estimates in the other three trials (MD -1.29, 95% CI -2.24 to -0.34) [149], (MD -0.77, 95% CI -1.22 to -0.32) [150], (MD -0.80, 95% CI -1.60 to -0.00) [145] were similar and all were statistically significant. PFMT women experienced, about one less leakage episode per 24 hours compared to the controls.

Few trials had long-term follow up. In all trials, supervision of PFMT stopped at the end of the treatment period except where the controls were then offered supervised training. Because of this 'crossover' of controls to training, follow up data were usually presented for all women in the trial, rather than by group allocation. Three trials have published long-term follow up results, at three and six months [149], nine months [141], and one and five years [152].

Burns (1993) found that those experiencing mild

leakages were more likely to have a return of symptoms in contrast with those experiencing moderate to severe leakages, who were more likely to continue to improve with PFMT. At nine months Henalla (1989) reported that three of the 17 women (from the 25 originally allocated to PFMT) had recurrent symptoms. Lagro-Janssen reported data from 88 women of an original 110 [152]. The proportion of continent women was the same after five years (25%), but more had severe UI (increased from 3% to 18%). Leakage had also increased significantly ( $p = 0.009$ ), with a mean increase of 2.7 episodes per week (95%; CI 0.7 to 4.6). Two thirds (67%) remained satisfied with the outcome and did not want further treatment, although women with UUI or MUI were less likely to be satisfied and SUI women were less likely to report that their condition had worsened. Nearly half (43%) who had done PFMT were no longer training at all, while 39% were training daily or "when needed".

## SUMMARY

PFMT is better than no treatment, placebo drug or inactive control treatment for women with SUI, UUI, or MUI (Level of Evidence: 1). Women treated with PFMT were more likely to report cure or improvement and have fewer leakage episodes per day than the controls. Condition-specific quality of life might also be better after PFMT, but this finding needs confirmation through further studies. The trials suggested that treatment effect might be greater in SUI women who tended to be younger (in their 40s and 50s) and participated in a supervised PFMT programme for at least three months. These hypotheses need further testing. The limited evidence from follow up after treatment means that the long-term outcomes of PFMT are less clear, although continued treatment effect is probably associated with continued training.

It seems likely that treatment effect will be enhanced if PFMT is based on sound muscle training principles: such as, specificity, overload and progression, correct contraction confirmed prior to training, and if women are supported to maintain treatment adherence (Level of Evidence: 4).

## RECOMMENDATIONS

Supervised PFMT should be offered as first line conservative therapy for women with stress, urge or mixed urinary incontinence (Grade of Recommendation: A).

### *b) Is one PFMT programme better than another?*

A number of factors may influence the outcome of the PFMT programme, such as the way in which it is taught and supervised, the exercise parameters, and adherence to training. In this section, different



approaches to PFMT were considered. The review is based on a Cochrane systematic review (in preparation) comparing different approaches to PFMT (Hay-Smith, Dumoulin and George 2008, personal communication).

Twenty-eight trials were identified, and three were excluded for the following reasons. In one study, electrical stimulation (EStim) was added to the biofeedback arm only, and in a second study EStim was added to both treatment arms. In both studies the addition of EStim rendered the trial ineligible for inclusion [137, 153]. Another study reported outcomes by diagnosis and not by intervention group [154]. The included trials compared:

- Health professional supervised PFMT versus self-directed PFMT [135, 136, 155];
- Direct versus indirect (such as PFM contractions facilitated through abdominal or gluteal muscle work) PFMT [138, 139, 156, 157];
- Different exercise parameters (such as strength versus endurance training) [158-160];
- PFMT with repeated episodes of BF versus PFMT without BF [147, 149, 161-167].
- PFMT with intravaginal resistance versus PFMT without resistance [168];
- PFMT with adherence strategy (such as alarm or diary) versus PFMT without strategy [169, 170];
- PFMT with more versus less health professional contact [171-173].

**i) Health professional (HP) supervised PFMT versus self-directed PFMT:** Three trials made this comparison. Burgio (2002) compared written instruction on PFMT and urge suppression strategies (no HP contact) versus HP taught and supervised PFMT with urge strategies and anorectal BF versus HP taught and supervised PFMT with urge strategies but without BF. Treatment duration was eight weeks for all three treatment arms with four HP visits in the supervised arms. Goode (2003) compared written instruction on PFMT versus HP taught and supervised PFMT; treatment duration was 10 weeks in both arms with four HP visits in the supervised arm. Williams (2006) compared written instruction on PFMT along with fortnightly nurse visits versus HP taught PFMT with fortnightly visits for 10 weeks.

**ii) Direct versus indirect PFMT:** Four trials compared direct with indirect approaches. One arm of each trial was PFMT. The other arm was hip abductor contractions in two trials [138, 139]; Pilates in one trial [157] and 'Paula method' in another [156]. The 'Paula method' focuses on strengthening the circular muscles (such as the pubococcygeal muscle, the anal sphincter, and grip) based on the hypothesis that all sphincters in the body work simultaneously. Thus,

exercising circular muscles in one area of the body might strengthen other sphincters. Treatment duration was 12 weeks in both arms of all four trials.

**iii) Different exercise parameters:** Three trials made this comparison; each comparison was different. Johnson (2001) compared near maximal (10 minutes three times a day at 90% of maximal PFM) versus sub-maximal PFMT (15 minutes three times a day at 60% of maximum contraction intensity) for six weeks. Hay-Smith (2003) compared motor relearning PFMT (being PFM contractions in different body positions, preceding and sustained during different provocative activities) versus motor relearning with strengthening PFMT programme (10-12 near maximal PFM contractions, six to eight second hold with equivalent rest, three times a day, at least three days a week). Both groups trained for 18 to 20 weeks. Borello-France (2006) compared 12 weeks of twice daily PFMT in supine versus the same programme performed in supine, sitting and standing.

**iv) Addition of BF (Figures 1 and 2):** Studies used either home or clinic based BF. Potentially, home based BF offers women more opportunity to make use of this adjunct and it might be expected that any BF effects would be greater in these studies. Clinic and home based BF trials were therefore considered separately.

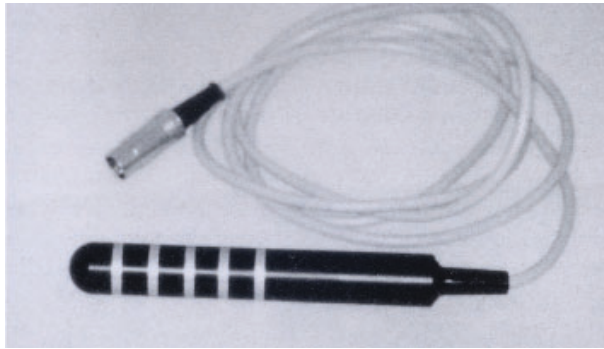
Five trials used clinic based BF. In four of them the home PFMT programme was the same in both groups, with the addition in one arm of clinic BF once a week [149, 163], twice a week [167], or three times a week [162]. Treatment durations in both arms were four weeks [162, 163], eight weeks [149] and 12 weeks [167]. In the fifth trial there were some differences in the PFMT as well as the addition of clinic based BF in one arm. Pages (2001) compared PFMT (group PFMT five times per week for four weeks and daily home PFMT) versus daily home PFMT and clinic BF five times per week for four weeks; in both groups this was followed by eight weeks of home PFMT. Glavind (1996) had a greater amount of supervisory HP contact with the BF group than with the PFMT alone group.

Four trials used home-based BF. In all of them the home PFMT programme was the same in both groups, with the addition in one arm of home BF. Treatment durations in both arms were six weeks [161], eight weeks [147], 12 weeks [164], and six months [166].

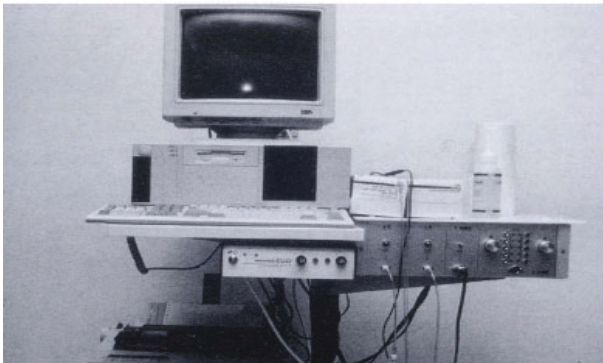
**v) Addition of intravaginal resistance (IVR):** One trial compared daily home PFMT versus PFMT daily at home with intravaginal balloon device for resistance; treatment duration was six weeks in both arms [168].

**vi) Addition of adherence strategy:** Two trials investigated the use of adherence strategies. In both trials the daily home PFMT programme was the same in both groups, with the addition in one arm of an





**Figure 1 : Surface EMG electrodes on vaginal probe**



**Figure 2 : Biofeedback from vaginal probe in clinic (PFM contraction shown on screen)**

adherence strategy or device. These were a device that beeped in the rhythm that contractions were to be performed and participants pressed a button on this device to record their PFM contractions [170], or audiotape of exercise instructions, counting aloud 25 consecutive PFM contractions [169]. Treatment duration was four to six weeks [169], or eight weeks [170].

**vii) More versus less health professional (HP) contact:** Three trials contributed to this comparison. In all three studies both groups did the same daily home PFMT programme with the addition in one arm of a weekly 45 minute group exercise sessions [171], weekly supervised training session in groups of five [173], or twice weekly phone calls from a registered nurse monitoring progress [172]. Treatment duration was the same in both arms of each study, being 12 weeks [173], or six months [171] and [172].

## 1. QUALITY OF DATA

**i) HP supervised PFMT versus self-directed PFMT:** One trial reported adequate random allocation concealment [155]. Outcome assessment was blind in Burgio (2002). The number of women allocated to each group was between 60 and 80 in all three trials. Dropouts were 7/75 for the self-directed group, 11/73 and 9/74 in the HP led groups in Burgio's (2003) study. In Goode's (2003) study, 25/67 in the self-directed

group and 12/66 in the HP led PFMT group withdrew. In Williams's (2006) study, 3/79 in the self-directed group and 3/79 in the HP group withdrew.

**ii) Direct versus indirect PFMT:** Two of the four trials reported adequate random allocation concealment [139, 157] and two reported blind outcome assessment [139, 157]. The number of women allocated to each group was less than 10 [157], between 20 and 30 [138, 156] and between 40 and 50 [139]. Losses to follow-up were less than 10 % in three trials [138, 156, 157] and was 20% in one [139].

**iii) Different exercise parameters:** One trial reported adequate allocation concealment and blind outcome assessment [159]. Two trials randomised less than 25 women to each group [158, 160] and Hay-Smith (2003) randomised about 60 per group. Four percent of women withdrew from the trial by Hay-Smith (2003), while 14% dropped out from Johnson's (2001) trial and 18% in Borello-France's (2006) trial.

**iv) Addition of BF:** Of the five clinic based BF trials, two had adequate random allocation concealment [162, 167] and two had blinded outcome assessors [149, 162]. Two trials randomised between 25 and 50 women to each comparison group [149, 167] while others randomised less than 25 women per group [162, 163, 165]. There were no withdrawals or losses to follow up in one trial [162] less than 10% in one [149], less than 15% in two [163, 167], and 22% in the other [165]. In the latter trial all the dropouts were from the BF group [165]. All women were assessed post-treatment; further follow up was conducted by Burns and co-workers [149] at three and six months, and by Glavind (1996) at three months and two to three years.

Of the five home based BF trials, random allocation concealment was adequate in just one [166], and outcome assessors were blind for some or all of the outcomes in three trials [161, 166, 174]. The number of women allocated to the comparison groups was 20 or less in three trials [147, 161, 174]. Laycock (2001) randomised women in a ratio of 2:1, so there were 40 women in the BF group and 20 in the PFMT only group. Mørkved (2002) randomised 50 women or more to each group. Three trials had complete data sets on trial completion [147, 161, 174], Mørkved (2002) reported 9% withdrawal, and 33% dropped out of the trial by Laycock (2001). One trial reported a one-year follow up [175].

**v) Addition of IVR:** It was not clear if allocation concealment was adequate or outcome assessors were blind. There were 10 women in each intervention group and it seemed there were no dropouts. Women were assessed post-treatment and followed up at 12 to 24 months [168].

**vi) Addition of adherence strategy:** Both trials had inadequate allocation concealment, and neither stated if outcome assessors were blind to treatment allocation

[169, 170]. Less than 25 women were randomised to each comparison group and the dropout rate was 11% in Sugaya's (2003) study. In Gallo's (1997), 43 women were allocated to each comparison group and the drop out rate was 13%.

**vii) More versus less HP contact:** Only one of the three trials reported adequate allocation concealment [171]. It was not clear if outcome assessors were blind in two trials [171, 172] and in the third, outcome assessment was not blind [173]. The number of women allocated to intervention groups was less than 25 in two trials [172, 173] and between 25 and 50 in the third [171]. Losses to follow up were less than 10% in one trial [171] and more than 20% in two other trials [172, 173]. Women were assessed post treatment at twelve weeks [172, 173] and six months [171]. Further follow up was conducted at six months [172] and at five and 15 years (intensive supervision group only) [176].

## 2. RESULTS

**i) HP supervised PFMT versus self-directed PFMT:** None of the three trials reported data on cure; two trials reported cure/improvement. Burgio (2002) found that women in both HP led PFMT groups were statistically significantly more likely to report they were improved than women doing self-directed PFMT (about 60% in the former versus approximately 30% in the latter). Goode (2003) reported similar findings (57% were improved in the HP led group versus 30% in the self directed group). Symptom bother was measured in all three trials, and although less bother was reported improvement was not different between treatments in any of the three trials. In addition, although leakage episode in 24 hours were reduced after intervention, there were no significant differences between the groups in any of the three trials.

**ii) Direct versus indirect PFMT:** Two trials reported data on cure/improvement. Ramsay 1990) found no statistically significant difference in the proportion of SUI women reporting cure/improvement between groups (12/22 in both groups). Ghoneim (2005) using a patient global impression of improvement index did not find statistically significant difference between direct and indirect PFMT training in SUI women. Interestingly, data from 'completers' showed more women in the direct PFMT group were very much better (71% versus 46%). Incontinence Quality of Life scores (I-QOL) were not statistically significantly different between groups in two studies [139, 156], and a comparison of the King's Health Questionnaire (KHQ) scores in the fourth study was not done because of the small sample size [157].

**iii) Different exercise parameters:** Hay-Smith (2003) compared combination strength and motor relearning PFMT with motor relearning PFMT alone for SUI women. There were no statistically significant differences between the groups for self-reported cure

(RR 0.25, 95% CI 0.03 to 2.21), cure/improvement (RR 0.88, 95% CI 0.59 to 1.31), or the number of leakage episodes in 24 hours (MD -0.2, 95% CI -0.55 to 0.15). Nor were there consistent differences in the nine domains of the KHQ. Johnson (2001) compared near maximal PFM contractions (strengthening programme) with sub-maximal PFM contractions (endurance programme) for women with urodynamic SUI. After six to seven weeks of training there was no statistically significant difference between the groups in the number of leakage episodes per day (MD -0.36, 95% CI -1.85 to 1.13). Borello-France (2006) compared PFMT in lying versus lying and upright positions for SUI women. There was no statistically significant difference in improvement in Incontinence Impact Questionnaire (IIQ) scores between the two groups, or differences in the weekly reduction in leakage or amount of urine lost during the pad test.

**iv) Addition of BF:** With regard to clinic BF, pooled data from Pages (2001) and Wang (2004) did not find any statistically significant difference in the proportion of women reporting cure after treatment with or without BF (RR 1.06, 95% CI 0.70 to 1.61) in women with SUI or OAB (OAB) respectively. Similarly, there was no statistically significant difference for cure/improvement. At one to two years after treatment Glavind (1996) found five of 19 BF women and none of 14 PFMT women with urodynamic SUI reported cure (RR 8.25, 95% CI 0.47 to 137.94). Pooled data from three trials did not find any statistically significant difference in the number of leakage episodes per day between the BF and PFMT only groups (weighted mean difference (WMD) -0.11, 95% CI -0.32 to 0.10) [149, 162, 167]. No trial individually demonstrated a statistically significant difference between the groups. The trials recruited women with urodynamic SUI, urodynamic SUI or MUI, and OAB respectively. Wang (2004) measured quality of life using the KHQ; there were no statistically significant differences between the groups on any of the nine subscales. With regard to adverse events, Berghmans (1996) stated that women reported none. Pages (2001) similarly stated there were no adverse events, but they excluded 22% of BF participants after randomisation because the women were unable to use a vaginal probe (e.g. prolapse). Wang (2004) reported two women had allergic reaction to the BF lubricant.

For the home BF trials, it was difficult to interpret or combine the data, principally because data were not reported in useful ways. Pooled data from Shepherd (1983) and Mørkved (2003) found no statistically significant differences between the groups for self-reported cure (RR 1.54, 95% CI 0.95 to 2.50) or self-reported cure/improvement (RR 1.17, 95% CI 0.93 to 1.47). Both trials recruited women with urodynamic SUI. Interestingly, at one-year, cure/improvement was 68% in the home BF group compared to 53% in the PFMT group; this difference did not reach significance

[175]. Mørkved (2003) did not find any statistically significant differences between the groups on the Social Activity Index post treatment. Mørkved (2003) stated that no women reported an adverse event, while Aukee (2004) found that a small number of women could not use a vaginal probe due to discomfort or reported discomfort with PFMT without a probe.

**v) Addition of IVR:** The single trial did not collect any data for the pre-specified outcomes of interest.

**vi) Addition of adherence strategy:** Sugaya (2003) found that SUI women who used an electronic device to cue PFMT were more likely to be satisfied with treatment outcome (RR 3.17, 95% CI 1.02 to 9.88), but there was no difference between device and no device groups for the number of leakage episodes per day post treatment (MD -0.50, 95% CI -1.55 to 0.55). Gallo's (1999) study did not measure any continence outcomes although an interesting finding was that SUI women who used the audiotape of exercise instructions were more likely to be performing the PFMT exercises twice daily as per instruction (RR 7.05; 95% CI 2.78 to 17.88).

**vii) More versus less HP contact:** Bø (1990) found no statistically significant difference in the proportion of SUI women reporting cure (RR 6.25, 95% CI 0.31 to 124.10). Pooled data from two trials found SUI women having more HP contact were more likely to report cure/improvement (RR 1.80, 95% CI 1.34 to 2.43) [171, 173]. Konstantinidou (2007) found that SUI women in the more contact group had significantly fewer leakage episodes in 24 hours (MD -1.39, 95% CI -2.04 to -0.73) and were less likely to report high scores on a study specific UI quality of life score where lower scores reflected better quality of life (RR -1.90 95%CI -2.93 to -0.87). Lin (2004) found that worry about leakage was reduced in the more contact versus less contact group (OR 0.57, 95% CI 0.36-0.92). Finally, in a 15 year follow up study with response rate of 90%, Bø (2004b) reported no differences in any urinary outcomes of interest between the two study groups [176]. Half of both groups had SUI surgery during the 15-year follow up period. Twenty-eight percent performed PFM training at least weekly. None of the papers mentioned adverse events.

## SUMMARY

Considering the number of trials that compared one approach to PFMT versus another it is disappointing there were so few data for analysis. Many trials collected no data for the pre-specified outcomes of interest, collected data for only one of these outcomes, and/or did not report the collected data appropriately (e.g. presented mean without measure of variance).

With regard to HP supervised PFMT versus self-directed PFMT women were more likely to report cure/improvement, fewer leakage episodes and better quality of life if PFMT was taught and supervised by

a HP (Level of Evidence: 1). Although women in self-directed PFMT programmes reported improvements, improvements in the HP led group were greater.

The four trials that compared direct versus indirect PFMT methods made different comparisons; none found an indirect method better than direct PFMT (Level of Evidence: 2).

Three trials also compared different exercise parameters, but none made the same comparison. For SUI women there may be no difference in the number of leakage episodes per day after six weeks of strength versus endurance PFMT; the training period was probably not long enough to be sure about the lack of difference (Level of Evidence: 2). For SUI women, combination strength/motor relearning PFMT versus motor relearning PFMT alone as well as supine versus a combination of supine, sitting and standing exercises seemed equally effective (Level of Evidence: 2).

With regard to clinic based BF it seemed that there were no statistically significant differences between BF assisted and non-BF groups for self-reported cure, cure/improvement, or leakage episodes per day or quality of life (Level of Evidence: 1). This pattern appeared to be consistent across trials that recruited SUI women only, women with urodynamic SUI, MUI, or OAB. There were a similar number of trials addressing the effect of home BF, but fewer data. In a single robust trial, there were no statistically significant differences between home BF and non-BF groups for self-reported cure, cure/improvement, or quality of life for women with urodynamic SUI (Level of Evidence: 2).

Based on a single poor quality trial, SUI women might be more satisfied with the outcome of PFMT if accompanied by an exercise cue, this may not be reflected in differences in number of leakage episodes (Level of Evidence: 2).

Self-reported cure or cure/improvement in SUI women was more likely with more HP contact during PFMT (Level of Evidence: 1). More contact also appeared to lead to better quality of life and fewer leakage episodes for UI women. Based on follow up from a single trial, the initial benefit of intensively supervised PFMT may not be maintained 15 years later when training adherence is low.

## RECOMMENDATIONS

Clinicians should provide the most intensive HP led PFMT programme possible within service constraints because HP taught and supervised programmes are better than self-directed programmes, and more HP contact is better than less (Grade of Recommendation: A). There does not appear to be any benefit of adding clinic (Grade of Recommendation: A) or home based BF (Grade of Recommendation: B) to a PFMT programme.



There are many hypotheses that need further testing, such as:

- Whether any indirect method of PFMT (Paula method, transversus abdominus training, hip abductor or adductor exercise) might be as effective as direct PFMT, or add benefit to a direct PFMT programme.
- Different types of PFM exercise (strengthening, endurance, co-ordination, functional training) may be as effective as each other.
- BF may benefit certain women, such as those with a weak PFM or with difficulty contracting the PFM in isolation.
- IVR adds benefit to PFMT. Given the evidence for the effect of vaginal cones on UI (see B.3) and the fact that PFMT most commonly aims to strengthen the PFM, there seems to be some biological rationale for the use of IVR devices.
- Cues to exercise are useful.

### **c) Is PFMT better than other treatments?**

Trials were considered for inclusion in this section if they compared PFMT with another stand-alone intervention, e.g. vaginal cones, bladder training, drug therapy. Thirty RCTs comparing PFMT with another stand-alone treatment were found. Four trials were excluded. Two were reported as conference abstracts and contained no useable data [177, 178], one was reported in two conference abstracts with inconsistent data [179], and the fourth compared PFMT and vaginal cones versus electrical stimulation [180].

The 26 trials addressed the following comparisons:

- PFMT versus vaginal cones (VC) [129, 145, 155, 164, 177, 181-183]
- PFMT versus electrical stimulation (EStim) [141, 143, 145, 167, 184-187]
- PFMT versus bladder training (BT) [151, 188, 189]
- PFMT versus drug [139, 141, 142, 150, 190, 191]
- PFMT versus surgery [192]

**i) PFMT versus VC:** Eight trials compared PFMT with VC in women with SUI [129] or urodynamic SUI [129, 145, 155, 164, 177, 181-183]. Three trials recommended using VC once a day for 10 minutes [164] 15 minutes [181] and 20 minutes [145]. Four trials asked women to use cones twice a day for 15 minutes [129, 177, 182, 183]. The remaining trial suggested using cones two to three times a day for 10 to 15 minutes at a time [155]. All the VC programmes asked women to retain the heaviest cone possible, and programmes were progressed by increasing the cone weight. The lightest cone weights were 10g [155], 20g [129, 145, 177, 183] or 50g [181, 182] progressing

to 60g [155], 70g [145, 177, 182], 80g [181] or 100g [129, 183]. Laycock (2001) did not describe the cone weights or progression. One study also asked women to perform 20 maximal PFM squeezes with a 65g weight once a day, progressing after two months to 100g [181].

The PFMT programmes varied too, as follows:

- 50 maximal PFM contractions per day [183].
- 10 daily sessions of five PFM contractions [177].
- 10 brief forceful PFM contractions and 10 sustained PFM contractions for 10 seconds, repeated as able [182].
- 100 fast and slow PFM contractions daily [129].
- eight to 12 near-maximal PFM contractions with six second hold and six to eight second rest, with three to four fast contractions at the end of every contraction, thrice daily, and a weekly group session [145].
- 20 maximal PFM contractions, 15 sub-maximal PFM contractions, and one static two minute sub-maximal contraction, twice daily [181].
- 10 minutes of personalised fast and slow PFM contractions [164].
- personalised individual PFMT four times a day [155].

Treatment duration was the same in both arms of all studies, and ranged from four weeks [183], to 10 weeks [177], 12 weeks [155, 164, 182], four months [181], six months [145] and 12 months [129]. The number of HP contacts was the same in both groups in Arvonen (2001), Laycock (2001), Haken (1991), Wilson (1998), greater in the VC than PFMT groups in Peattie (1988), Cammu (1998), but greater in the PFMT than VC group Bø (1999) and Williams (2006).

**ii) PFMT versus EStim:** Eight trials compared PFMT with EStim in women with UI [186], SUI [145, 184, 185], urodynamic SUI [141, 143], mixed UI [187] or OAB [167]. There were different PFMT and EStim protocols in each study.

Two trials used interferential current. Laycock (1988) compared interferential (two to three times weekly, 30 minutes, 10-50Hz) to PFMT (weekly PFM exercise courses and daily home exercises), for four to six weeks. Henalla (1989) compared interferential (20 minutes weekly for 10 weeks, 0-100Hz, at maximal tolerated intensity) to PFMT (five PFM contractions with five second holds, hourly, every day for 12 weeks). Another trial used external (extra-vaginal and lumbar) electrodes to deliver an unknown type of current (10 minutes, three times weekly, intensity increased until noticeable PFM contraction and patient added voluntary PFM contraction) versus PFMT (no details given), for six weeks [143].



The remaining trials all delivered the stimulation using a vaginal electrode. The comparisons were, in approximately ascending order of duration of EStim:

- 20 minutes, twice weekly, biphasic symmetric intermittent current at 10Hz, pulse duration 400 microseconds, duty cycle 10 seconds on and five off, maximum tolerated intensity, versus PFMT (no details given), for 12 weeks [167]
- 30 minutes, three times weekly, biphasic intermittent current at 50Hz, pulse duration one millisecond, two second contraction, duty cycle one to two, at maximal tolerated intensity up to 100 mA (for predominant SUI) or the same stimulation at 20Hz (for predominant UUI), versus PFMT (no details given), for eight weeks [186]
- 30 minutes daily, biphasic intermittent current at 50Hz, pulse duration 0.2 milliseconds, individualised duty cycle depending on ability to hold PFM contraction, at maximal tolerated intensity up to 120mA, versus PFMT (three times daily, eight to 12 near-maximal PFM contractions with six second hold and six to eight second rest, with three to four fast contractions at the end of every contraction in addition to weekly exercise class), for six months [145]
- up to 60 minutes, twice daily, asymmetric balance biphasic intermittent current at 12.5 and 50Hz, pulse duration 300 microseconds, five second contraction time with two second ramp up and one second ramp down, duty cycle one to two, intensity to 80mA, versus PFMT (daily, 60 slow and quick PFM contractions), for four months [187]
- six to eight hour per night, intermittent current at 12, 20 or 50Hz, versus PFMT (six to eight times daily, five to 10 maximal PFM contractions with five second hold and five seconds rest, and one sub-maximal contraction with 30 to 40 second hold), for six months [184].

Amount of HP contact was the same for both groups in one trial [141], greater for EStim in two [143, 185], and greater for PFMT in another [145]. Any differences were not clear in the other four trials.

**iii) PFMT versus BT:** Three trials compared PFMT with BT in women with SUI [189], SUI and/or DO [188] or UI [151]. BT was not described in the conference abstract of the study by Sherburn (2007); in both the other trials BT comprised a voiding schedule with weekly progression. Wyman (1998) also included urge inhibition techniques (affirmations, distraction and relaxation).

Sherburn (2007) did not describe PFMT. In the other two trials BT was compared with:

- PFMT with clinic based BF, and a twice daily home PFMT programme of five fast (three second holds)

and 20 sustained (10 second holds with 10 second rests) PFM contractions, PFM contraction for urge suppression and with increases in intra-abdominal pressure [188].

- PFMT with clinic based BF, and daily home PFMT of 30 PFM contractions for strength and endurance (12 second holds) [151].

Treatment duration, and amount of HP contact, was the same in both arms of all three trials, with treatment duration ranging from eight weeks [151], to 12 [188] and 20 weeks [189].

**iv) PFMT versus drug therapy:** Six trials compared PFMT to drug therapy in women with UUI [150], SUI [139, 141, 142, 190, 191].

The trials by Henalla (1989, 1990) compared Premarin (conjugated equine oestrogens) 2g per night for six [142] or 12 weeks [141] versus PFMT. In Henalla (1989) the PFMT comprised a daily home programme of five PFM contractions with five second holds per hour, but in Henalla (1990) PFMT was not described. All the other trials used different drugs.

Wells (1991) compared phenylpropanolamine hydrochloride (50mg qd for two weeks, increasing to bid for two weeks if leakage continued) for four weeks versus six months of PFMT (90 to 160 PFM contractions with 10 second hold and 10 second rest distributed throughout the day). Ishiko (2000) compared clenbuterol (20mg bid) versus PFMT (10 minutes daily), for 12 weeks.

Ghoniem (2005) compared duloxetine (4mg bid, plus sham PFMT) versus PFMT (four times weekly, three sets of 10 six to eight second contractions and two sets of 10 one to two second contractions), for 12 weeks. Burgio (1998) compared oxybutynin chloride (2.5mg tid, progressed to maximum 5mg tid) versus PFMT (15 PFM contractions thrice daily, 10 second hold, plus PFM contraction with increased intra-abdominal pressure and urge strategies), for eight weeks.

Four trials had the same amount of HP contact in drug and PFMT groups [139, 141, 150, 190]; in Henalla's (1990) trial, this was not clear. Wells (1991) assessed treatment effect after four weeks in the drug group, and six months in the PFMT group.

**v) PFMT versus surgery:** Only one trial compared PFMT and surgery. For women randomised to surgery, Klarskov (1986) chose a surgical technique based on the type of defect identified; Burch colposuspension for anterior suspension defects and vaginal repair for posterior bladder descent.

Women with both defects had a combined Burch and vaginal repair procedure. No details on the PFMT parameters were provided; women had five or more group sessions with a physiotherapist.

## 1. QUALITY OF DATA

**i) PFMT versus VC:** Bø (1999), Cammu (1998), Wilson (1988) and Williams (2006) reported adequate allocation concealment. Bø (1999) stated that outcome assessors were blind, and in the trials by Wilson (1988) and Williams (2006) some but not all outcome assessment was blind. Bø (1999), Cammu (1998) and Williams (2006) randomised 29, 30 and approximately 80 women per comparison group, while Wilson randomised 39 to the PFMT group and 36 to the VC group. There were dropouts from both PFMT and VC groups in all trials except Cammu (1998), where all the dropouts were from the VC group. Drop out rates were higher in the VC group for Arvonen (2001), Cammu (1998), Haken (1991) and Laycock (2001) but higher in the PFMT group for Bø (1999), Peattie (1988), Wilson (1988) and Williams (2006). None of the trials reported follow up beyond the post treatment evaluation.

**ii) PFMT versus EStim:** Of the eight trials, two reported adequate random allocation concealment and blinding of outcome assessors [145, 167]. Three trials randomised approximately 10 women per comparison group [143, 184, 187], and the remaining trials between 20 and 35 women per group. Four trials appeared to have no dropouts [141, 143, 184, 187], with 5% [186], 12% [145], 13% [167] and 19% [164] reported in the others. All women were assessed post treatment; Henalla (1989) and Hahn (1991) also followed-up longer term, at nine months, and one to four years respectively.

**iii) PFMT versus BT:** Sherburn (2007) reported adequate random allocation concealment. Yoon (2003) and Sherburn (2007) reported blinding of outcome assessors while Wyman (1998) stated that outcome assessors were not blinded. Sherburn (2007) randomised 43 women to PFMT and 41 to BT, and Wyman (1998) randomised nearly 70 women per group. The trial by Yoon (2003) was smaller with approximately 15 to 20 women per group. Dropouts were approximately 4% for Wyman (1998) and 12% for Yoon (2003) and not mentioned by Sherburn (2007). All women were assessed post treatment, and Wyman (1998) followed-up three months later (i.e. six months after treatment began).

**iv) PFMT versus drug therapy:** Random allocation was concealed in only one of the six trials [139]. Outcome assessors were blind in the Burgio (1998) and Ghoniem (2005). Three trials randomised 25 women or fewer per group [141, 142, 190]. Ghoniem (2005) randomised approximately 50 per group. The two largest trials randomised about 80 [191] or 85 women per group [150]. Dropouts were not reported [142], none [141], 14% [150], 16% [190], 25% [191] and 36% [139]. All women were assessed post treatment, and Henalla (1989) also followed-up nine months later by questionnaire.

**v) PFMT versus surgery:** It was not clear if random allocation was adequately concealed, or if the outcome assessors were blinded [192]. Klarskov (1986) randomised approximately 25 women to each comparison group. It appears there were no dropouts at four months (post treatment assessment). There was further long-term follow-up at one year, then four to eight years.

## 2. RESULTS

**i) PFMT versus VC:** Results of the individual studies were inconsistent. For cure, the trials favoured PFMT (RR 0.39, 95% CI 0.16 to 0.94, Bø 1999), neither PFMT nor VC (RR 1.00, 95% CI 0.56 to 1.81, Wilson 1998; RR 1.73, 95% CI 0.53 to 5.67, Williams 2006), or VC (RR 9.47, 95% CI 0.55 to 164.35, Arvonen 2001). Pooled data from the four trials showed no statistically significant difference in cure (RR 0.98, 95% CI 0.63 to 1.52); the pooled data showed statistically significant heterogeneity. For cure/improvement, pooled data showed no statistically significant difference (RR 0.99, 95% CI 0.84 to 1.16, in five trials). PFMT was better than cones in terms of daily leakage episodes (WMD -0.61, 95% CI -1.05 to -0.16, three trials). Williams (2006) reported on the cost of intervention; PFMT was more expensive than VC, £338 versus £305 per person because of the amount of time spent with the therapist. With regard to adverse events, Arvonen (2001) and Williams (2006) stated that no women using VC reported any, while Bø (1999) and Cammu (1998) found that VC were associated with adverse events such as inability to use cones, pain, vaginitis, bleeding, and women finding cones unpleasant to use.

**ii) PFMT versus EStim:** Pooled data from three trials in SUI women found self-reported cure was more likely with PFMT (RR 2.67, 95% CI 1.53 to 14.26) [145, 184, 187], although only Bø (1999) found a statistically significant difference when data from the trials was considered individually. It was not clear if the cure data reported by Hofbauer (1990) were derived from a symptom scale or a voiding diary; these data were therefore excluded. Pooled data from three trials in SUI women also found self-reported cure/improvement was more likely in PFMT women (RR 1.72, 95% CI 1.05 to 2.81) [145, 184, 185]; again only Bø (1999) found a statistically significant difference when trial data were considered individually. Only Bø (1999) measured leakage episodes and quality of life (Social Activity Index). There was no statistically significant difference between the groups for either outcome. At nine months post treatment, Henalla (1989) found that three out of 17 PFMT women and one out of eight in the EStim group reported recurrent symptoms. Three trials reported side effects related to EStim, including vaginal irritation and/or bleeding [145, 184, 187].

Spruijt (2003) recruited women with SUI, UUI or MUI,

and did not find a statistically significant difference between the groups for self-reported cure/improvement (RR 0.99, 95% CI 0.45 to 2.16). The trialists reported that EStim produced “physical and emotional stress” in the elderly women in their sample. Wang (2004) recruited women with UUI, and did not find any statistically significant difference between the groups for self-reported cure (RR 0.74, 95% CI 0.38 to 1.42) or cure/improvement (RR 0.84, 95% CI 0.48 to 1.46). PFMT women had statistically significantly fewer leakage episodes per day (MD -1.22, 95% CI -2.37 to -0.07). On the KHQ there were no statistically significant differences in general health perception, incontinence impact, role limitation, physical limitation, social limitation, and personal relationship, but the EStim group had statistically significantly better scores for emotions, sleep/energy and severity measures. Some women using EStim reported discomfort during treatment.

**iii) PFMT versus BT:** Unfortunately, Yoon (2003) did not report any data for the outcomes of interest. Wyman (1998) recruited women with SUI, UUI or MUI. While more women in the PFMT group reported symptomatic improvement or fewer leakage episodes the difference did not reach statistical significance post-treatment (RR for symptomatic improvement 1.73, 95% CI 0.83 to 3.60; MD for leakage episodes -0.14, 95% CI -0.83 to 0.55) or three months later (RR 1.96, 95% CI 0.97 to 3.94; MD -0.09, 95% CI -0.73 to 0.55). Nor were there statistically significant differences in Incontinence Impact Questionnaire (IIQ) or Urogenital Distress Inventory (UDI) between the groups at either time point. Sherburn’s (2007) trial recruited women with SUI only. However, Sherburn (2007) found in SUI women, a significant difference between the two groups in the ICI-Q SF ( $p=0.003$ ), leakage episodes ( $p=0.03$ ) and the VAS ( $p=0.009$ ) in favour of the PFMT group, although the generic health related QOL did not differ between the two groups. No adverse event data were reported in either trial.

**iv) PFMT versus drug:** Neither of the two trials comparing vaginal oestrogens versus PFMT in urodynamic SUI women reported data for the outcomes of interest [141, 142]. Of those that responded to a follow-up questionnaire at nine months, three out of 17 PFMT women and three women using oestrogens reported recurrent symptoms. Adverse events were not reported in either trial.

Two trials compared an adrenergic agonist and PFMT in women with SUI or MUI. Ishiko (2000) did not find any statistically significant difference in the proportion of women reporting no leakage episodes (cure) after treatment (RR 0.68, 95% CI 0.41 to 1.15), and Wells (1991) did not find any statistically significant difference for self-reported cure/improvement (RR 0.92, 0.77 to 1.10). Wells (1991) reported data for leakage episodes per day in SUI women only; PFMT women had statistically significantly more leaks per day than

women in the drug group (MD 0.08, 95% CI 0.02 to 0.14). Ishiko (2000) reported that the drug side effects were sufficient for some women to withdraw; others discontinued the drug, but remained in the trial. Wells (1991) did not report data on drug side effects.

In the comparison of PFMT and oxybutynin in women with DO (DO), or DO with urodynamic SUI, Burgio (1998) reported no statistically significant difference for the number of women who were dry (cured) (RR 1.31, 95% CI 0.73 to 2.34), but PFMT women were more likely to report they were much better than women receiving the drug treatment (RR 1.46, 95% CI 1.08 to 1.97). PFMT women also had fewer leakage episodes per day (MD -0.41, 95% CI -0.80 to -0.02). Some women taking oxybutynin reported side effects (dry mouth and inability to void in particular).

Ghoniem (2005) reported that duloxetine had a significantly greater impact in decreasing Incontinence episodes than PFMT (57% versus 35% median decrease in UI episode frequency between drug and PFMT respectively,  $p=0.004$ ), but there were no significant differences between the treatments with respect to Incontinence Quality of Life (I-QoL).

**v) PFMT versus surgery:** At four months PFMT women with urodynamic SUI were less likely to report cure than women who had surgery (RR 0.20, 95% CI 0.07 to 0.61), although there was no statistically significant difference in the proportions reporting cure/improvement (RR 0.80, 95% CI 0.60 to 1.07). At 12 months, 10 out of the 24 women from the PFMT group were satisfied with the initial therapy, versus 19 out of the 26 women randomised to surgery. Long-term data (four to eight years) were not presented by group allocation. All reported adverse events were associated with surgery; women reported new UUI, retropubic or pelvic pain, or dyspareunia [192].

## SUMMARY

Eight trials compared PFMT with VC in SUI women. No consistent pattern emerged in the data; data on self-reported cure were inconsistent (four trials), there was no difference in pooled data from four trials for self-reported cure/improvement, but there were fewer leakage episodes per day with PFMT in pooled data from three trials (Level of Evidence: 1). Treatment with VC may be inappropriate in some cases due to side effects such as bleeding, and some women appear to find them unpleasant to use.

Eight trials compared PFMT with EStim in SUI women. Pooled data demonstrated that self-reported cure and cure/improvement were more likely in PFMT than in EStim groups (Level of Evidence: 1). It is worth noting that only one trial individually demonstrated a statistically significant difference in these outcomes and there was more health professional contact in the PFMT arm. There were no statistically significant differences between PFMT and EStim groups for



leakage episodes or quality of life, based on a single trial (Level of Evidence: 2). In the one trial that recruited women with SUI, UUI or MUI self-reported cure/improvement rates were not statistically significantly different (Level of Evidence: 2). Self-reported cure and cure/improvement rates were not statistically significantly different in a trial in women with UUI, although PFMT women had fewer leakage episodes per day, and women in the EStim group had better quality of life in three of the nine domains measured (Level of Evidence: 2). Some women reported adverse events attributable to ES.

Three trials compared PFMT and BT, but only two reported data of interest. In women with SUI symptomatic improvement, leakage episodes and quality of life were statistically significantly better in the PFMT group (Level of Evidence: 2). In contrast the study that recruited women with SUI, UUI and MUI did not find statistically significant differences between the groups for these outcomes (Level of Evidence: 2).

In the absence of useful data there is insufficient evidence to determine if PFMT is better than vaginal oestrogens. Neither trial that compared an adrenergic agonist with PFMT in women with SUI or MUI found a difference in self-reported cure/improvement, although in one study women who took the drug had fewer leakage episodes per day (Level of Evidence: 2). Adrenergic agonist side effects were sufficient to discontinue treatment in some women. One trial of PFMT versus oxybutynin in women with DO or DO with urodynamic SUI found PFMT women were more likely to report improvement and had fewer leakage episodes per day after treatment (Level of Evidence: 2). Some women taking oxybutynin reported drug-related side effects. One trial compared a serotonin-norepinephrine reuptake inhibitor (duloxetine) with PFMT and while women who took the drug had fewer leakage episodes, there was no difference in terms of quality of life between the two groups (Level of Evidence: 2). Serotonin-norepinephrine reuptake inhibitor drug side effects were sufficient to discontinue treatment in some women.

Based on one trial it seemed self-reported cure was more likely after surgery than PFMT for women with urodynamic SUI; although there was no statistically significant difference in the proportion of women reporting cure/improvement (Level of Evidence: 2). There was insufficient detail about the PFMT programme to make a judgment about how effective it might have been.

## RECOMMENDATIONS

For women with SUI:

- PFMT is better than EStim as first line conservative therapy, particularly if PFMT is intensively supervised (Grade of Recommendation: B).
- PFMT is better than BT as first line conservative therapy (Grade of Recommendation: B).

- PFMT and duloxetine are both effective in first line therapy, although PFMT is better because of the side effects experienced with the drug (Grade of Recommendation: C).
- PFMT and surgery are both effective therapies, although PFMT is better as first line therapy because it is less invasive (Grade of Recommendation: C).

For women with SUI or MUI:

- PFMT is better than VC as first line conservative therapy (Grade of Recommendation: B).
- PFMT is better than clenbuterol or phenylpropanolamine hydrochloride as first line therapy because of the side effects experienced with the medications (Grade of Recommendation: B).

For women with UUI or MUI:

- PFMT and BT are both effective first line conservative therapy (Grade of Recommendation: B).
- PFMT is better than oxybutynin as first line therapy (Grade of Recommendation: B).

Larger, good quality trials are needed to address each of the above comparisons if these are of interest to women. In planning comparisons researchers should consider carefully the potential impact of different levels of supervisory intensity between groups, particularly in comparisons of conservative therapies. A comparison of surgery and PFMT might be least useful, because PFMT is usually first-line therapy with surgery reserved for those in whom PFMT was unsuccessful or is not the treatment of choice.

## **d) Does the addition of PFMT to other treatments add benefit?**

To be included, trials needed to investigate the effects of PFMT combined with therapy A versus therapy A alone, to address the additive benefit of PFMT over therapy A. Nine RCTs were found, and of these three were excluded. Jeyaseelan et al (2002), a conference abstract, did not report any useable data [178]. Millard (2004) included men and women and the data were not reported separately by sex [193]. Dowell (1997) used a combination BT/PFMT programme [194].

**i) PFMT/VC versus VC:** Two trials, in women with urodynamic SUI [195] or SUI [129], compared combined PFMT/VC versus VC. In both arms of each study the recommended VC regime was twice daily for 15 minutes, with cone weight progressing from 20g to 70g [195] or 100g [129]. Both PFMT programmes asked women to do 100 PFM contractions per day; Wise (1993) recommended 10 contractions 10 times a day, and Wilson (1998) recommended a combination of fast and slow contractions. Treatment duration was 12 weeks in both arms of both studies.



**(ii) PFMT/Estim versus Estim:** In women with urodynamic SUI, Hofbauer (1990) compared Estim (10 minutes, three times weekly, sufficient intensity to provoke a visible contraction to which the patient added their own PFM contraction, extravaginal and lumbar electrodes) to PFMT/ES (daily PFMT home programme (not specified) and a twice weekly exercise class plus the same ES programme). Treatment duration was six weeks in both arms.

**iii) PFMT/BT versus BT:** In women with urodynamic SUI, or urodynamic SUI with DO, Wyman (1998) compared BT (progressive voiding schedule, advice on urge inhibition techniques such as affirmations, distraction and relaxation) to PFMT/BT (twice daily PFMT, maximum of 10 fast contraction with three second holds and 40 sustained contractions with 10 second holds in addition to bladder training as above). The combined PFMT/BT group began with BT and added PFMT in the 3rd week of the intervention. Women in both groups received the same preliminary education programme and treatment duration was 12 weeks in both arms.

**iv) PFMT/drug versus drug:** Two trials compared PFMT/drug to drug alone in women with SUI [139, 190]. Ishiko (2000) compared drug (oral beta(2)-adrenergic agonist (clenbuterol) 20mg bid) to PFMT/drug (clenbuterol as above plus daily 10 minutes of PFM contraction programme, no further detail of training was given). Ghoniem (2005) compared drug (duloxetine, 4mg twice daily plus sham PFMT) to PFMT/drug (duloxetine as above plus PFMT four times a week comprising three sets of 10 long contractions held six to eight seconds and two sets of 10 rapid contractions held one to two seconds). Treatment duration was 12 weeks in both arms in both studies [139, 190].

## 1. QUALITY OF DATA

**i) PFM/VC versus VC:** Wilson (1998) reported adequate allocation concealment and some outcome assessment was blind. Neither of these was clearly reported in the study by Wise (1993). There were approximately 39 women in each comparison group in Wilson (1998) and approximately 20 women in each comparison group in Wise (1993). In Wilson (1998) 63% of the women in the PFM/VC group dropped out compared to 41% in the VC group while in Wise (1993) 30% of the PFM/VC group dropped out compared to 9% in the VC only group.

**ii) PFMT/Estim versus Estim:** It was not clear if random allocation concealment was adequate or whether assessors were blind [143]. There were only 11 women in each comparison group. There did not appear to be any dropouts.

**iii) PFMT/BT versus BT:** It was not clear if random allocation concealment was adequate and outcome assessors were not blind [188]. There were 68 women

in the BT group and 67 in combination therapy. There were fewer than 10% dropouts after 12 weeks of treatment. Further follow-up was reported at six months and approximately three years after study entry.

**iv) PFMT/drug versus drug:** Although adequate allocation concealment and blinded assessors were used in Ghoniem (2005) it was not clear in Ishiko's (2000) trial. In Ishiko's (2000) trial, there were 18 women in the drug group, and 23 in the combination therapy group. Five (27%) and four (17%) women dropped out of these groups respectively, principally because of drug-related side effects. Ghoniem (2005) randomised approximately 50 SUI women to each group; some 30% of whom dropped out of both treatment groups.

## 2. RESULTS

**i) PFM / VC versus VC:** In this comparison, neither of the two trials identified any statistically significant differences between the groups (for patient reported cure, improvement as measured by a Visual Analogue Scale or pad test) and all of the confidence intervals were wide [129, 195].

**ii) PFMT/Estim versus Estim:** Although Hofbauer (1990) reported cure/improvement, it was not clear whether this was based on data from a symptom scale or a urinary diary. There were no data reported for the other outcomes of interest.

**iii) PFMT/BT versus BT:** Wyman (1998) did not find a statistically significant difference between the combination versus single therapy in the number of women reporting they were much better, however more in the combination group reported they were much better, six months after treatment began (RR 0.61, 95% CI 0.39 to 0.94). There was no statistically significant difference in the number of leakage episodes per day between the groups after treatment or at six months. With regard to quality of life the combination therapy group had statistically significantly better scores on UDI (MD 31.10, 95% CI 13.26 to 48.94) and IIQ (MD 25.50, 95% CI 1.05 to 49.95) after treatment, but there was no statistically significant difference in either measure six months after treatment had begun. Approximately three years later, a similar number in each group had sought further treatment for UI (19 of 48 BT, 18 of 48 PFMT/BT). Of the women who had not sought further treatment, fewer were free of leakage episodes in the BT group (four of 22 in BT group versus eight of 16 in the combination group). Adverse events are not mentioned.

**iv) PFMT/drug versus drug:** Ishiko (2000) did not report data for any of the primary outcomes of interest. They did state that 10 of the 13 women in the drug group, and 17 of the 19 in the combination therapy group had no leakage episodes per week post treatment, and some women reported drug-related side effects sufficient enough to withdraw from

treatment. Ghoniem (2005) reported that the combined treatment was not significantly different from the drug-only-treatment in terms of frequency of incontinence episodes, quality of life (IQOL) and Patient Global Impression of Improvement Scale.

## SUMMARY

There were few trials addressing the effect of adding PFMT to another therapy, and only three of the eight studies reported useful data. The findings of Wilson (1988) and Ghoniem (2005) did not suggest any benefit of adding PFMT to VC or duloxetine respectively in women with SUI (Level of Evidence: 2). The study of Wyman (1998) suggested there is a benefit to adding PFMT to BT for women with USI or USI with DO in the short term (three months), but it is not clear if this benefit persists at six months or more (Level of Evidence: 2). There is not sufficient evidence to be sure if there is any benefit in adding PFMT to EStim.

## RECOMMENDATIONS

For women with SUI or MUI a combination of PFMT/BT may be better than PFMT alone in the short-term (Grade of Recommendation: C). If a woman is taking duloxetine or using VC, it may not help to add PFMT (Grade of Recommendation: C). However, these recommendations are based on single trials of variable quality and larger, good quality trials are needed to address each of the above comparisons if these are of interest to women.

## 4. OTHER LUTS

Only two of the many trials included above reported data for other LUTS, e.g. frequency, nocturia, bladder pain.

Lin (2004) looked at the effect of a PFMT programme on frequency, nocturia and urgency in women with MUI [172]. Based on self report of symptom bother both frequency and nocturia improved significantly more in the PFMT group (OR for frequency 0.57, 95% CI 0.35 to 0.95; OR for nocturia 0.52, 95% CI 0.30 to 0.93), while urgency persisted (OR: 0.73, 95% CI 0.456 to 1.17).

A secondary analysis of Burgio (1998) looked at the effect of PFMT versus drug therapy on nocturia in older women with UUI or MUI [150]. The PFMT group reduced nocturia by a median of 0.5 episodes per night; this was significantly more effective than drug treatment (median reduction 0.03 episodes per night;  $p=0.02$ ).

## 5. FACTORS AFFECTING OUTCOME

Apart from differences in effect attributed to PFMT or comparison interventions, there might be other factors affecting treatment outcome. Of particular interest is

the effect of older age; this and other factors are considered here.

### a) Age

Firstly we looked for trials included above that specifically recruited older women; there were six. Women were aged 55 or more [135, 149, 150, 191], or 65 or more [186, 189]. The average age of women in these trials was between 60 and 70 years [135, 149, 150, 191], or over 70 years [186, 189], compared with a mean age of 40 to 55 in most other included studies. It was not possible to compare the data from older women with data from younger women for the following comparisons: PFMT versus EStim [186], PFMT versus drug [150, 191], and PFMT versus BT [189].

For three comparisons (PFMT versus no treatment, [149] PFMT versus placebo/sham/control, [135, 150] BF assisted PFMT versus PFMT alone, [149] there were no clear differences in the size or direction of effect when the data from the trials in older women were compared with data from other trials. The recommendations arising from these comparisons appear to apply to older women. Namely, that PFMT should be offered, as first-line therapy, to all women with SUI, UUI or MUI, and that there does not appear to be added benefit of BF assisted PFMT over PFMT alone.

Secondly, the methods of included trials were checked for use of regression or other methods to investigate association between baseline characteristics (specifically age) and outcome. The literature search also located some papers that reported secondary analysis of data from the included trials. Papers that reported an association between age and outcome, but did not describe the methods of testing association are not discussed here.

Two reports detailed the testing of independent associations between patient characteristics (including age) and outcome [159, 196]. Burgio (2003)[196] used data from PFMT groups in three RCTs [135, 136, 150]. The individual trials restricted entry to women 55 years and older [135, 150] or 40 years and over [136]. In multivariate analysis, age was not a significant predictor of reduction in leakage episodes for PFMT women with SUI, UUI or MUI. Hay-Smith (2003) investigated the associations between leakage on paper towel test and patient characteristics using data from a trial that compared two approaches to PFMT for SUI women. Older age was associated with more leakage in univariate models, but was not significant in multivariate analysis.

One further trial [188] used correlation methods, and one study [197] categorised women as successes or failures, to investigate the association between age and outcome. In a secondary analysis of data from the trial by Wyman (1998) there was no statistically

significant correlation between age and reduction in leakage episodes or change in PFM activity after PFMT or BT in women with SUI, UUI or MUI [198]. Bø characterised participants in the intensive PFMT group from the Bø (1990) trial as treatment responders or non-responders [197]. Treatment responders were statistically significantly older than borderline responders; there were no non-responders.

Considering the number of included trials, there were few that restricted entry to older women and/or investigated the association between age and treatment outcome. Only two studies have used the most appropriate methods to test independent associations. More research is needed to investigate the association between age and treatment outcome. Neither study using multivariate models found an association between age and outcome, nor was there a reported correlation in another. The two studies that categorised women as treatment successes or failures had conflicting results.

#### SUMMARY

There is no good evidence to date to suggest that 'healthy' older women with UI do not benefit from PFMT as much as younger women.

#### *b) Other*

Aside from age, other factors have the potential to mediate treatment outcome, e.g. baseline UI severity and duration of symptoms. Trial reports, and subsequent publications of the included trials, were checked for methods investigating the association between baseline characteristics and treatment outcome. Some of the included studies reported predictors of outcome that appeared to be based on researcher observation, but did not describe the methods for checking the association; these data are not discussed here. Seven reports of interest were found [149, 159, 191, 196-199]. A wide range of patient characteristics were considered in these papers; it is not clear whether it is more important to know which baseline characteristics might be predictors of outcome, or which ones might not. To eliminate long lists of non-significant associations, a pragmatic choice was made to report only significant associations although this creates a false impression of some consistent associations. None of the variables discussed here has demonstrated a consistent association with outcome, and all are worthy of further investigation.

Two reports described the testing of independent associations between patient characteristics and outcome [159, 196]. Burgio (2003) used data from PFMT groups in three RCTs [135, 136, 150]. In multivariate analysis of data from PFMT women with UUI or urge predominant MUI, a 75% reduction in leakage episodes was more likely if women did not

use protection (e.g. pads) prior to treatment. Continence (100% reduction in leakage episodes) was more likely if women had fewer Incontinence episodes at baseline and had a lower educational level, but less likely if they had prior UI surgery. For PFMT women with SUI or stress predominant MUI a 75% reduction in leakage episodes was less likely if women had previously been evaluated for UI or had more than 10 leakage episodes per week pre-treatment. Hay-Smith (2003) investigated the associations between patient characteristics and two outcomes (leakage on paper towel test, self-reported improvement) using data from a trial that compared two approaches to PFMT for SUI women. In multivariate models increasing parity was associated with less improvement in leakage symptoms and more risk of leakage on a paper towel test. Shorter symptom duration and higher body mass index were both associated with more improvement in symptoms. Leakage once or more per day was associated with greater risk of leakage on a paper towel test; the reverse was true for women with a history of constipation.

Theofrastous (2002) used correlation methods to investigate the association between patient characteristics and outcome in a secondary analysis of data from the trial by Wyman (1998). There was no statistically significant correlation between any of the baseline characteristics listed and the two outcomes (reduction in leakage episodes or change in PFM activity).

One study categorised women as successes or failures, to investigate the association between patient characteristics and outcome. Bø (1992) characterised participants in the intensive PFMT group from the Bø (1990) trial as treatment responders or non-responders. Treatment responders had statistically significantly longer symptom duration, higher body mass index, stronger PFM, and were more motivated (clinician judgement) than borderline responders; there were no non-responders.

Few included studies investigated the association between patient characteristics and treatment outcome. Even fewer used appropriate methods. More research is needed to test for independent associations between patient characteristics and outcome. No consistent pattern emerged from the available data. Given the few data available, and the methodological limitations of some papers, any patient characteristic described above that was associated with outcome should be considered as a possible rather than established prognostic factor.

#### SUMMARY

It is not clear if there are any reliable predictors of PFMT outcome. Too few trials have appropriately investigated the association between patient characteristics and outcome to be sure.



### III. WEIGHTED VAGINAL CONES (VC)

Weighted vaginal cones (VC) were developed by Plevnik as a method for testing PFM function and to provide overload for PFM strengthening exercises [183, 200]. The cones are inserted into the vagina, above the PFM. Theoretically, when a cone is inserted into the vagina, the sensation of 'losing the cone' provides strong sensory feedback prompting the PFM to contract in order not to let the cone slip. Starting with a weight held inside the vagina for at least one minute in the standing position, women train by building up to the ability to keep the cone in place for at least 20 minutes. When the woman is able to walk around for 20 minutes without losing the weight, she then moves on to progressively heavier weights, advancing towards overload of the muscles over the course of the exercise programme [183, 200].

Since their introduction, a variety of cones have been developed encompassing different sizes, shapes and weights (**Figure 3**). However, the effectiveness of the VC training method has been questioned over the years. First, the PFM contraction is not the only reason why the cone stays in place. As the orientation of the vagina is not vertical, it is possible for some women to retain the cone without contracting the pelvic floor; the transverse lie of the cones has been shown by radiology [201]. Moreover, depending on the axis of her vagina, a woman will need to produce different force intensities to retain the cone. Therefore, using the cone as a measurement of PFM function does not appear to be valid. Additionally, retaining the cone in the vagina for 15 minutes requires sustained low load contractions, which is not congruent with the principles of strength straining used in most pelvic floor rehabilitation [84]. Conversely, VC training may actually favour endurance, which could be important in retraining the pelvic floor. Finally, for some women, it may be impossible to insert the cone because of narrowed vaginal opening or to retain it because of either an enlarged vaginal opening or insufficient PFM contraction to hold even the lightest cone.



**Figure 3 : Weighted vaginal cones**

This section will examine the evidence for the use of VC for the prevention and treatment of UI in women. Questions addressed are:

- Are VC better than no treatment, placebo or control for the prevention of UI?
- Are VC better than no treatment, placebo or control for the treatment of UI?
- Are VC as effective as any other treatment for the treatment of UI?
- Are VC combined with PFMT better than PFMT alone for the treatment of UI?

To address these questions, the literature was searched for reports of relevant systematic reviews, RCTs and quasi-RCTs. Therefore, only Level 1 evidence is considered in this section. Recommendations are based on the findings of two systematic RCTs reviews undertaken by Hay-Smith (2002) on UI prevention and by Herbison (2004) who reviewed management of UI with cones [112, 202]. Pre-specified outcomes of interest were urinary continence (for prevention studies), patient symptoms, quality of life measures and pad tests (for treatment studies).

#### 1. PREVENTION

No trials investigating the primary/secondary prevention effects of training with VC for women with UI were found. The literature search revealed two reviews on the prevention of UI [113, 203]. Only Hay-Smith (2002) considered VC prevention trials, but none of the trials measured the effect on UI; all the measures were of PFM activity. Because no continence related outcomes were measured, these trials were not reviewed here. The current Cochrane review of VC does not consider prevention [202], and our own searching has not revealed any new RCTs on VC for prevention.

#### 2. TREATMENT

The literature search revealed one systematic review that specifically addressed the effects of VC in the treatment of UI in women [202]. The review, together with one RCT published after the review, is the basis of this subsection [155].

##### **a) Are VC better than no treatment, placebo or control treatments?**

Three RCTs compared VC with control treatments for women with UI [129, 145, 155]. Wilson (1998) compared VC with standard postnatal care in women with symptoms of UI three months postpartum (controls were requested to continue with their normal postnatal PFMT programme).

Bø (1999) compared VC with a control treatment (use of Continence Guard, Coloplast AG) in women with urodynamically proven SUI.



Williams (2006) compared VC with standard care (leaflet detailing PFM anatomy and exercises). Women in the trial by Bø (1999) used cones for 20 minutes once a day, progressing through three cone weights (20, 40, 70g) according to their ability to hold the cones. Postnatal women in the trial by Wilson (1998) received one training session and three follow up visits. They used cones for 15 minutes twice a day, progressively increasing cone weight when able (20 to 100g), for up to nine months. Women in the trial by Williams used cones for up to 15 minutes twice a day, progressively increasing cone weight when able (10 to 60g) whilst undertaking the most strenuous activity (from lying to exercise) for up to three months.

## 1. QUALITY OF DATA

All trials reported adequate randomisation concealment and blinded outcome assessors. Two randomised about 30 women to VC; however, while Bø (1999) randomised a similar number to the control group, Wilson (1998) had around 100 women in the control group (factorial design). Williams randomised about 80 women in each group.

Dropout rates were 3% [155], 12% [145] and 40% [129]. There were more dropouts from VC (42%) than the control group (22%) in the latter.

## 2. RESULTS

Pooled data from all three trials for self-reported cure showed suggested women in the VC group were more likely to report they were cured than controls (RR 1.98, 95% CI 1.21 to 3.23).

Pooled data from two trials for self reported improvement or cure showed statistically significant heterogeneity. Individually, one trial favoured VC (RR 18.89, 95% CI 2.68 to 132.58 [145]) and the other neither control nor VC (RR 0.95, 95% CI 0.76 to 1.19 [155]). Bø (1999) also reported that VC were better than the control for the Leakage Index but there were no statistically differences in the 24 hour pad test or the Social Activity Index.

## SUMMARY

There is evidence from three good RCTs suggesting that VC is better than control treatments (for subjective reporting of cure or cure/improvement) in the treatment of SUI (Level of Evidence: 1). Treatment with VC may be inappropriate in some cases due to side effects such as bleeding, and some women appear to find them unpleasant to use.

## RECOMMENDATIONS

For women with SUI, VC can be offered as first line conservative therapy to those who can and are prepared to use them (Grade of Recommendation: B); VC may be inappropriate in some cases due to side effects and discomfort.

## b) Are VC as effective as any other treatment?

VC have been compared with PFMT, and with EStim, but not with other therapies such as drugs, BT or with surgery.

**i) VC versus PFMT:** Eight trials compared VC with PFMT [129, 145, 155, 164, 177, 181-183]. This comparison has been addressed previously and for details of the trials (quality and results) readers are referred to section B.2.3d.

**ii) VC versus EStim:** Four trials compared VC with EStim [145, 195, 204, 205]. Important differences were noted in all the VC and EStim interventions. Delneri (2000) compared VC (25 to 35 minutes daily progressing through cone weights of 20 to 70g) to EStim (30 minutes daily with bipolar low-frequency current of 50Hz for 15 minutes and 20 Hz for 15 minutes, four seconds on and eight seconds off). Treatment duration was four weeks in both arms. Bø (1999) compared VC (20 minutes daily progressing through three cone weights of 20, 40 and 70g) to EStim (30 minutes daily with a low-frequency bipolar current of 50 Hz, 0.2ms pulse width at an intensity of between 0-120 mA). Treatment duration was six months in both arms. Olah (1990) compared VC (15 minutes twice daily progressing through cone weights of 20 to 100 grams) to EStim (15 minutes, three times per week with interferential current of 0-100Hz, at maximum tolerated intensity); treatment duration was four weeks in both arms. Wise (1993) compared VC (15 minutes twice daily programme progressing through cone weights of 20 to 70g) to EStim (20 minutes daily of continuous stimulation of 20MHz frequency and 0.75ms pulse width at the maximum tolerated intensity of 0-90mA). Treatment duration was 12 weeks in both treatment arms.

## 1. QUALITY OF DATA

**i) VC versus PFMT:** refer to section B.2.3d.

**ii) VC versus EStim:** Bø (1999) reported adequate random allocation concealment and blinding of outcome assessors, but this was not clear in the other three trials. Dropout rates were higher in the VC group for Delneri (2000) and Olah (1990), but higher in the EStim groups for Bø (1999) and Wise (1993).

## 2. RESULTS

**i) VC versus PFMT:** refer to section B.2.3d.

**ii) VC versus EStim:** There was no statistically significant difference between VC and EStim in pooled data from two trials or either self-reported cure (RR 1.00, 95 CI 0.89 to 1.13, Bø 1999 and Wilson 1998) or cure/improvement (RR 1.45, 95% CI 0.90 to 2.33, Bø 1999 and Olah 1990). Bø (1999) did not find a difference in leakage episodes per day (MD 0.10, 95% CI -0.66 to 0.86). Confidence intervals were wide in all studies. Additionally, Delneri (2000) found no statistically significant difference in terms of overall discomfort between VC and EStim.

## SUMMARY

In summary, eight trials compared PFMT with VC in SUI women. No consistent pattern emerged in the data; data on self-reported cure were inconsistent (four trials), there was no difference in pooled data from four trials for self-reported cure/improvement, but there were fewer leakage episodes per day with PFMT in pooled data from three trials (Level of Evidence: 1).

Pooled data demonstrated no statistically significant differences between VC and EStim groups for self-reported cure, cure/improvement or leakage episodes (Level of Evidence: 1). Both VC and EStim groups reported adverse events. Two trials had to exclude some women prior to randomisation because they could not use VC (e.g. wedging of the cone).

## RECOMMENDATIONS

PFMT is better than VC as a first choice for conservative therapy, because some women cannot or do not like to use cones (Grade of Recommendation: B). VC and EStim seem equally effective in the treatment of SUI and MUI, but the usefulness of VC and EStim in practice might be limited because of side effects and discomfort (Grade of Recommendation: B).

### ***c) Are VC combined with PFMT better than PFMT alone?***

Two trials compared a combined PFMT/VC to PFMT alone [129, 206]. Pieber (1995) compared PFMT (100 PFM contractions daily supplemented by an initial visit with a physiotherapist and additional visits at intervals of two to four weeks) versus PFMT/VC (the same PFMT programme combined with 15minutes of VC daily progressing through cone weights of 20 to 70g). Treatment duration was 12 weeks in both treatment arms. Wilson (1998) compared PFMT (100 fast and slow PFM contractions daily supplemented with one training session and three follow up visits) versus PFMT/VC (the same PFMT programme combined with 15minutes of VC twice daily progressing through three cone weights of 20 to 100g). Treatment duration was 12 months in both treatment arms. None of the outcomes used in the two trials overlapped.

#### **1. QUALITY OF DATA**

Wilson (1998) reported allocation concealment and some outcomes had blinded assessors, but neither was clearly reported by Pieber (1995).

#### **2. RESULTS**

No statistically significant difference detected for cure

(RR 1.21, 95% CI 0.63 to 2.32) [129], cure/ improvement after six weeks (RR 1.41, 95% CI 0.81 to 2.45) [206], cure/improvement after 12 weeks (RR 0.92, 95% CI 0.51 to 1.64) [206], but confidence intervals were wide. Dropout rates were higher in the combined PFMT/VC group in both trials.

## SUMMARY

The limited evidence available suggested no benefit from adding VC to PFMT for SUI women (Level of Evidence: 2)

## RECOMMENDATIONS

If the combination of VC with PFMT is an intervention of interest for women, then more research is needed to confirm or refute the effect of this combination.

## 3. OTHER LUTS

None of the trials included in this section on VC reported other LUTS data.

## 4. FACTORS AFFECTING OUTCOME

None of the included trials addressed the effect of age or any other factors on outcome of VC training. However, it is worth noting that in the 16 trials included in this section on average 23% of the women being treated with VC (range 0 to 63%) withdrew or dropped out. Although few trials examined the reasons for dropping out, those who did reported low compliance, motivation problems, unpleasantness, aesthetic dislike, discomfort, bleeding and vaginal prolapse. However none of these were predominant.

## IV. ELECTRICAL STIMULATION (EStim)

The literature concerning EStim in the management of UI is very difficult to interpret, due to the lack of a well-substantiated biological rationale underpinning the use of EStim. However, the theoretical basis of stimulation interventions is emerging with increasing understanding of the neuroanatomy and physiology of the central and peripheral nervous systems. It is also becoming clear that the mechanisms of action may vary depending on the cause(s) of UI and the structure(s) being targeted by EStim, e.g. PFM or detrusor muscle, peripheral or central nervous system. In general, the aim of EStim for women with SUI appears to be to improve the function of the PFM, while for women with UUI the objective seems to be to inhibit DO (DO). Overall, studies poorly report the biological rationale underpinning the application of EStim being tested [207, 208].

EStim is provided by clinic based mains powered machines or portable battery powered stimulators

(**Figure 4**). EStim also offers a seemingly infinite combination of current types, waveforms, frequencies, intensities, electrode types and placements (**Figure 5**). Without a clear biological rationale it is difficult to make reasoned choices of EStim parameters. Additional confusion is created by the relatively rapid developments in the area of EStim and a wide variety of stimulation devices and protocols have been used even for the same condition. For example, in the last 25 years or so women with SUI have been treated using anything from a single clinic based episode of maximal EStim under general anaesthetic for 20 minutes with vaginal and buttock electrodes [209], to 10 sessions of interferential current at 10 to 40 Hz with perineal body and symphysis pubis electrodes [180], to eight weeks of home-based stimulation using a “new pattern of background low frequency and intermediate frequency with an initial doublet”, for an hour a day [210, 211], to six months of low intensity stimulation at 10 Hz using a vaginal electrode [212].

Finally the nomenclature used to describe EStim has been inconsistent. Stimulation has sometimes been described on the basis of the type of current being used (e.g. faradic, interferential), but is also described on the basis of the structures being targeted (e.g. neuromuscular), the current intensity (e.g. low-intensity, or maximal stimulation), and the proposed mechanism of action (e.g. neuromodulation). In the absence of agreement of how best to classify EStim the authors of this chapter have made no attempt to do so. The authors were also reluctant to use any existing system to group the EStim protocols as many were poorly described and could therefore be erroneously classified.

In this review only non-surgical or non-invasive EStim (i.e. stimulation without implanted electrodes) is considered. The questions to be addressed are:

- What evidence is there that EStim can prevent UI?
- What is the most appropriate EStim protocol for treatment of UI?



**Figure 4 : Mains and battery powered (portable) electrical stimulators**

- Is EStim better than no treatment, placebo or control treatments for UI?
- Is EStim better than other treatments?
- Does the addition of EStim to other treatments add any benefit?
- What is the effect of EStim on other LUTS?
- What factors might affect the outcome of EStim?

This section is underpinned by a Cochrane review of non-invasive EStim (submitted, Berghmans et al, personal communication) and four published systematic reviews [93, 112, 213, 214]. The review reported here is based on the trials included in prior systematic reviews with addition of trials completed after publication of the reviews and/or located through additional searching (see appendix). To be included in this section a study needed to (a) be a RCT, (b) include women with UI, and (c) address one of the questions listed above. Published abstracts were included but reports of trials in progress were excluded.

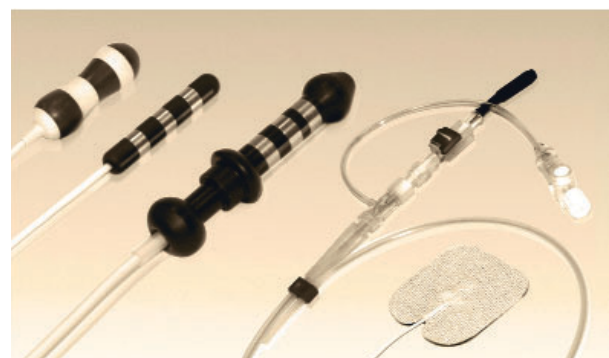
## 1. PREVENTION

It seems EStim has not been investigated for either the primary or secondary prevention of UI or LUTS; no published trials were found.

## 2. TREATMENT

### ***a) What is the most appropriate EStim protocol for treatment of UI?***

On the basis of trial reports to date it appeared that there was considerable variation in EStim protocols with no consistent pattern emerging. EStim protocols are often poorly reported, lacking detail of stimulation parameters, devices and methods of delivery. Therefore, one plausible explanation for differences in the findings of trials included in this section may be differences in the effectiveness of the wide range of protocols that have been tested. Equally it may be that some populations or subgroups of women benefit from EStim more than others. For example, anecdotal



**Figure 5 : Vaginal, rectal (anal), and skin electrodes for electrical stimulation**

evidence suggests that EStim is used with particular effect for women who are unable to perform a voluntary PFM contraction on initial assessment. However, this observation has not been investigated to date. Interestingly, there are also clinical questions about EStim that have not yet been investigated in trials, such as whether 'active' EStim (i.e. the patient voluntarily contracts the PFM during stimulation) is better than 'passive' EStim.

As the biological rational and purpose of EStim might be different depending on diagnosis, the EStim protocols from the trials included in this section are presented below for women with SUI (Table 1), women with urgency, UUI or DO (Table 2), and trials that recruited women with SUI or UUI or MUI (Table 3). There was a single trial in women with MUI only [215].

Amaro (2006) used a vaginal electrode to deliver an alternating current at 4Hz, with a bipolar square wave, 0.1msec pulse duration, a 1:2 duty cycle (2 seconds on and 4 off), at maximum tolerable intensity, for 30 minutes, three times a week for seven weeks.

It is clear there is no consistency in the EStim protocols used for women with SUI, or UUI, or MUI, or DO. It was not possible to identify an optimal set of EStim parameters. Some approaches to treatment are now rare, such as the use of faradic current or external electrodes. There seems to be a trend to use maximal tolerable current intensity, and in women with SUI some trials used a combination of EStim with a voluntary PFM contraction.

Rather than repeating the detail of stimulation parameters throughout this section, readers are referred back to these tables.

#### • Comparison of EStim protocols

Three studies compared one approach to EStim versus another, one in women with SUI [212], two in women with DO and sensory urge [218, 222].

#### 1. QUALITY OF DATA

Random allocation concealment was adequate in one [212] of the three trials. Blinding of assessors and patients was reported in one trial [222], but not in the

**Table 1. EStim protocols for trials that recruited women with SUI**

Parameters	Variations	Trials
Current	interferential faradic (i.e. low frequency interrupted direct) alternating	141, 180, 185, 205] [179, 216] [136, 143-145, 174, 184, 195, 209, 210, 212, 217-223]
Pulse shape		Alternating bipolar square wave [217], alternating square [223].
Frequency	single frequency, Hz two frequencies, Hz  frequency range, Hz	20 [195, 217]; 50 [145, 184, 219, 223]. 10 and 35 [212, 220]; low and intermediate [210]; 12.5 and 50 [221]. 10 to 50 [209]; 0 to 100 [141, 205]; 10 to 40, and 1Hz and 40Hz [180]
Pulse duration	duration, msec	0.08 [220]; 100 [217]
Duty cycle	single, ratio  alternating, ratio	1:1 [136, 212, 220]; 1:2 [217, 219]; 1:3 [222] 1:1 and 1:2 [221]
Current intensity	maximum tolerable intensity  noticeable muscle contraction EStim + voluntary PFM contraction	[136, 145, 180, 195, 205, 217, 221, 223]. [209] 212] (only in maximal stimulation group), [136, 143]
Electrodes	single vaginal electrode  vaginal & buttock electrodes external electrodes only	[136, 184, 195, 212, 216, 217, 219, 221, 222] [144] [174, 180, 220]
Treatment duration	daily at home  every other day at home twice-daily at home clinic-based treatments, number of sessions	4 weeks [223]; six weeks [220], eight weeks [210]; 6 months [145, 184, 212] 8 weeks [136] 8 weeks [217]; 12 weeks [219, 221] 10 [141, 180]; 12 [205]; 16 [212]; 18 [209]



**Table 2. EStim protocols from trials that recruited women with urgency or UUI or DO**

Parameters	Variations	Trials
Current	alternating (not further specified) alternating	[146, 218, 222, 224-227] Biphasic [228]; bipolar [217]; biphasic pulsed [187]
Pulse shape	rectangular square asymmetric	[228] [217, 224, 225] [187]
Frequency	single frequency, Hz  two frequencies, Hz frequency stochastic range, Hz	10 [222, 224, 225]; 20 [217, 226]; 150 [222] 12.5 and 50 [187] 4 to 10 [228]
Pulse duration	pulse duration, msec	0.001 [217]; 0.2 [222, 226, 228]; 0.3 [187]; 1.0 [224, 225]
Duty cycle	single, ratio	1:2 [187, 217]
Current intensity	progressive, mA maximum tolerable intensity to pain threshold tickling sensation	5 to 25 [187] [217, 222, 224, 225, 228] [227] [226]
Electrodes	single vaginal electrode vaginal & anal electrodes transcutaneous self-adhesive electrodes external electrodes	[187, 217, 224, 225, 228] [218, 227] [226] [222]
Treatment duration	daily at home  twice daily at home  single episode	6 hours a day for 6 weeks [226]; 4 months [187] 4 weeks [224]; 8 weeks [217]; 9 weeks [146, 228]; 12 weeks [227] [222]

**Table 3. EStim protocols from trials that recruited women with SUI or UUI or MUI**

Parameter	Variations	Trials
Current	alternating biphasic	[186, 229]
Pulse shape	asymmetric	[229]
Frequency, Hz	predominant SUI predominant UUI	50 [186, 229] 20 [229]
Pulse duration	pulse duration, msec	0.3 [229] 1.0 [186]
Duty cycle	ratio	1:2 [186] 1:1 [229]
Current intensity	maximum tolerable intensity	[186, 229]
Mode of delivery current	single vaginal electrode	[186, 229]
Treatment duration		3 times a week for 8 weeks [186]; 20 minutes twice daily at home for 12 weeks [229]

other two. Fewer than 25 women were allocated to each comparison group in all three trials; in Bower (1997) sample size was based on a power calculation. Bower (1997) had no dropouts or losses to follow up, with 12% [218] and 19% [212] lost to post-treatment follow-up in the other two studies. Two trials had longer term follow up, one [218] to six months [212] after treatment ended; in the latter 28% had dropped out by six months.

## 2. RESULTS

**i) Women with SUI:** In a small trial comparing maximal clinic based (n=20) versus low intensity home based (n=19) EStim in women with SUI, Knight (1998) found a significant difference in patient perceived recovery (OR 4.44, 95% CI 1.08 to 18.36) and pad test (WMD -12.40, 95% CI -16.64 to -8.16). After treatment more women in the low intensity home based EStim group reported cure or great improvement (80% home versus 47.3% clinic for cure,  $p=0.034$ ; 85% versus 44.8% for improvement,  $p=0.009$ ), although intention to treat analysis reduced the apparent success of treatment (66.7% versus 36%).

Long term follow up (12 months) suggested that women in both groups continued to improve subjectively, and this was most noticeable in the group of women who had received low intensity stimulation.

**ii) Women with DO or urgency:** Bower (1997) compared 10 Hz (sacral electrodes) versus 150 Hz (symphysis pubis electrodes) in women with DO (n=49) or sensory urgency (n=31). The same proportion (44%) of women in each stimulation group demonstrated a 'stable' bladder post stimulation and only the 150 Hz group showed a statistically significant improvement in the threshold volume ( $p=0.037$ ).

Lobel (1998) did not find any statistically significant differences in leakage episodes and quality of life between the groups. Although more than half the women in the study were improved symptomatically, only 25% were sufficiently satisfied with outcome that they did not wish for further treatment.

## SUMMARY

There were three small trials comparing different EStim protocols; the clinical heterogeneity meant it was not appropriate to pool the data from the studies. Based on a single trial low intensity home based stimulation may be more effective than maximal clinical based stimulation (Level of Evidence: 2). The other two studies did not find clinically important differences between stimulation groups; the studies were small and may have been underpowered. Further comparisons of EStim protocols are needed.

## RECOMMENDATIONS

For women with SUI low intensity home based EStim daily for six months might be better than 16 sessions of maximal clinic based EStim (Grade of Recommendation: C). There is a need for studies to elucidate the purpose and biological rationale for EStim in different diagnostic groups, so these can then be tested and compared in clinical trials.

### **b) Is EStim better than no treatment, sham or control treatments for treatment of UI?**

#### **• EStim versus no treatment, or control treatment**

Three trials were included [141, 145, 228]. Data were also gathered from two conference abstracts [214, 230] of the full publication by Berghmans (2002).

#### **1. QUALITY OF DATA**

Random allocation concealment was adequate, and outcome assessment was blind, in two of the trials [145, 228]. Henalla (1989) stated that outcome assessors were not blind. In two studies the size of the study population was based on a power calculation [145, 228]. Group sizes were less than 25 women per group in Berghmans (2002), and from 25 to 49 in the other two studies [141, 145]. The proportion of dropouts was less than 10% in one trial [141], and about 12 % in the other two [145, 228]. Henalla (1989) followed women up beyond the post treatment evaluation for six months.

## 2. RESULTS

**i) Women with SUI:** Henalla (1989) compared interferential stimulation with no treatment. In addition to the EStim and no treatment arms there were two other arms in the study. Eight of the 25 women receiving EStim were had a negative pad test or more than 50% reduction in pad test at three months, versus none of the 25 controls. Bø (1999) compared 50Hz daily EStim for six months versus the offer of the Continence Guard (Coloplast AS); the Continence Guard was used by 14 out of 30 women. There was no statistically significant difference between the groups for women reporting symptoms were "unproblematic" after treatment; 28/30 controls and 19/25 in the EStim group wanted further treatment. Two of 30 controls were cured (< 2g leakage) on pad test with standardised bladder volume compared to 7/25 in the EStim group, and the EStim group had less pad weight gain than controls (MD -6.60g, 95% CI -8.60 to -4.60). Leakage Index score was better in the EStim group (MD -1.60, 95% CI -1.79 to -1.41), but did not retain significance with intention to treat analysis. In Henalla (1989) no side effects were reported, but Bø (1999) reported that two out of 25 women in the EStim group had smarting and/or discomfort.

**ii) Women with DO:** In a four arm RCT in 68 women with DO, Berghmans (2002) investigated the effect of no treatment (n=14) versus nine weeks of 4 to 10Hz twice daily EStim at home (n=17). There was more improvement in Detrusor Overactivity Index score (DAI, lower score better) in the EStim group compared to controls (p=0.032), and less self reported symptom impact on the Dutch Incontinence Impact Questionnaire (DI-QOL). There were no reports of side effects or adverse events.

## SUMMARY

Single trials suggest that EStim might be better than no treatment in women with SUI, and women with DO (Level of Evidence: 2). These findings need to be confirmed in further trials.

## RECOMMENDATIONS

For women with DO nine weeks of 4 to 10Hz twice daily EStim at home, and for women with SUI six months of 50Hz daily EStim at home, might be better than no treatment (Grade of Recommendation: C). However, these are single small studies, and the recommendation should be viewed with caution until the findings are supported or refuted in further trials; it would be particularly useful if further trials used a validated and reliable quality life measure as a primary outcome.

### • EStim versus sham EStim

Fourteen trials were included. The sham stimulation comprised a device that:

- delivered a limited output that the trialists considered would have no treatment effect [187, 210, 220, 221].
- appeared to be working but there was no electrical output [180, 209, 217, 219, 222, 224, 227-229].

In the remaining trial placebo stimulation was not described at all [231].

Eight of the 14 trials specifically reported that some attempt was made to remove the participants' expectations of the physical sensations that might accompany stimulation in an effort to mask participants to their allocation to active or sham stimulation [180, 217, 219, 221, 222, 224, 228, 229]. In one trial the stimulation was delivered under general anaesthesia [209].

## 1. QUALITY OF DATA

Random allocation concealment was adequate in seven of the 14 trials [209, 210, 217, 219, 221, 228, 229]. Blinding of assessors was clearly stated in eight trials [209, 219-224, 231]. One trial stated that outcome assessors were not blinded [180].

In six studies the size of the study population was based on a power calculation [210, 215, 219, 221, 222,

229]. Two trials randomised more than 50 women to each comparison group [209, 217]. In three trials the group sizes ranged from 25 to 49 [219, 221, 224], and the remaining nine trials allocated less than 25 women to each comparison group.

Three trials had no dropouts or losses to follow up [180, 187, 222]. The proportion of dropouts was less than 10% in two trials [220, 223] and in the remainder it varied from 11% [210] to 12% [209, 224] to 21% [226, 227].

Eight trials followed women up beyond the post treatment evaluation [180, 187, 209, 215, 220, 223, 224, 229]. The length of follow-up varied from six weeks [209] to six months [187, 220, 229]. Yamanishi [223, 224] only followed up those participants who had improved with treatment, monthly for several months.

Readers should note that the trial by Yamanishi (1997) included men and women with UI. It is possible that the effects of stimulation might be different between sexes (due to difference in electrode placement for example) so this study has not contributed to the analysis where the trialists did not differentiate the effects of treatment in women versus men.

## 2. RESULTS

**i) Women with SUI:** Eight trials compared EStim with sham stimulation in women with urodynamic SUI [143, 180, 210, 219-221], or men and women with urodynamic SUI [223], or reported a subgroup analysis of women with SUI [217]. Blowman (1991) compared EStim plus PFMT versus sham EStim plus PFMT and for the purposes of analysis this trial was considered to be a comparison of EStim with placebo EStim, as there is currently no evidence that PFMT enhances the effect of EStim. Two trials contributed no data to the analysis. Hofbauer (1990) provided minimal detail of participants, methods and stimulation parameters, and it was not clear how 'cure' was defined (self report or urinary diary). Yamanishi (1997) did not report any subgroup data for women.

Two trials were reasonably similar with regard to EStim. Both Sand (1995) and Luber (1997) used twice daily alternating current at home for 12 weeks at 50Hz [221] or 12.5 and 50Hz [219]. Sand (1995) found that the EStim group had significantly greater changes in patient perceived recovery (OR 2.76, 95% CI 0.66 to 11.44), but Luber (1997) did not find any statistically significant difference between EStim and sham (OR 0.81, 95% CI 0.21 to 3.10). The same two trials also had contradictory findings for leakage episodes; Sand (1995) reported a statistically significant difference in the number of leakage episodes in 24 hours (MD 0.90, 95% CI 0.83 to 0.97) whereas Luber (1997) did not (MD 0.10, 95% CI -0.87 to 1.07). A third study, that also used twice daily home stimulation but at 20 Hz (rather than 50) and for eight weeks (rather than 12),

had similar findings to that of Sand (1995) with a significant difference in patient perceived recovery (OR 2.63, 95% CI 1.11 to 6.20) and fewer leakage episodes (MD 2.80, 95% CI 1.06 to 4.54) in favour of EStim; this was a subgroup analysis of 60 women with SUI in a larger trial [217]. Finally, Lubner (1997) did not find any statistically significant difference between active and sham groups for health status (SF-36).

Two trials used daily home alternating current for six [220], and eight weeks [210], at 10 and 35Hz [220] or a "low" frequency (to target the slow twitch fibres) and "intermediate" frequency (to target the fast twitch fibres). Neither study found a statistically significant difference in leakage episodes between active and sham groups, nor did Jeyaseelan (2000) find statistically significant difference in pad test findings or UDI scores.

Laycock (1993) used clinic based, short-term (10 treatments) maximal stimulation with an interferential current, and did not find a significant difference in leakage episodes between the groups post treatment.

With regard to side effects, three studies collected this data but no adverse events or side effects were reported [219-221].

**ii) Women with DO or UUI:** The three trials were sufficiently heterogeneous with respect to EStim and sample populations their results are described separately. A fourth study reported a subgroup analysis of women with DO from a larger trial [217].

Abel (1996) randomised 28 postmenopausal UUI women to maximal anal or vaginal alternating current for 20 minutes once a week for 12 weeks, or sham. In both groups there was a significant improvement in subjective parameters (VAS) but not in objective measurements (24 hour pad test and incontinence episodes per day).

Bower (1997) in a three arm study used a single stimulation episode of alternating current (either 10 Hz, sacral electrodes or 150 Hz, symphysis pubis electrodes) given after the voiding phase of cystometry and before repeat bladder filling.

The results were reported separately for women with DO and those with urgency. In DO both stimulation groups showed statistically significant improvements in urodynamic measures when compared with sham although the clinical relevance of this in terms of benefit felt by patients remains unclear. In women with urgency between group comparisons were not reported.

Yamanishi (2000a) investigated maximum intensity alternating current delivered daily for four weeks in men and women with DO. For the one outcome reported separately for women, more women in the EStim group reported cure/improvement than women in the sham group ( $p=0.0091$ ).

In a subgroup analysis of 61 women with DO (DO alone, or DO with urodynamic SUI), Brubaker (1997) found that after bipolar alternating current 16 of 33 women with pre-treatment DO had post treatment DO. In contrast 24 of 28 women in the sham group had persistent DO, although there were no statistically significant differences between the EStim and sham groups with respect to post treatment urodynamic diagnosis of DO ( $p=0.22$ ).

**iii) Women with MUI:** Amaro (2006) compared intravaginal EStim with sham in 40 women. Leakage was evaluated using a 60 minute pad test, and was statistically significantly reduced in both groups (mean 6.9g SD 3.5 and mean 1.1g SD 0.5 before and after EStim respectively; mean 3.1g SD 3.6 and mean 1.1g SD 0.5 before and after sham respectively).

Although the authors stated that there was no significant difference between groups, our re-analysis revealed a small difference, favouring EStim (MD 3.89, 95% CI 2.58 to 5.20). There were fewer micturitions in 24 hours in the EStim group than sham group post treatment (MD 3.00, 95% CI 1.74 to 4.26). Eighty percent of the EStim group and 65% of the sham group were satisfied with their final result.

**iv) Women with SUI or UUI or MUI:** EStim and sham stimulation were compared in two trials that included women with symptoms of SUI ( $n=42$ ), UUI ( $n=26$ ) or MUI ( $n=39$ ) [209] or urodynamic diagnoses of SUI ( $n=60$ ), UUI or DO ( $n=28$ ) or MUI ( $n=33$ ) [217].

Shepherd (1984) suggested a slightly higher likelihood of patient perceived cure in the EStim group than in the sham group (MD 1.38, 95% CI 0.59 to 3.20), although neither trial found any significant differences between the stimulation and sham groups for a range of outcomes including frequency, number of leakage episodes, quality of life.

## SUMMARY

Due to the clinical heterogeneity of the studies, in terms of EStim protocols and diagnoses, it is difficult to interpret the findings of trials comparing EStim with sham. For women with urodynamic SUI the findings of two trials using similar stimulation protocols were contradictory (Level of Evidence: 2). There was insufficient evidence (small trials, different EStim protocols) to determine if EStim was more effective than sham in other groups of women.

### c) Is EStim better than other treatments for UI?

EStim has been compared with magnetic stimulation (MStim), PFMT, VC, and drugs. The comparisons of EStim versus PFMT, and EStim versus VC, have been addressed previously (see B.2.3d and B.3.2b respectively). Two of the trials comparing EStim with another treatment included men and women [225,



226], and these studies have not contributed to the analysis where they did not differentiate the effects of treatment in women versus men.

#### • **EStim versus MStim**

In the single, small trial intravaginal EStim was compared with MStim; stimulation was applied continuously at 10 Hz in both groups [225]. Neither of the interventions was well described.

#### **1. QUALITY OF DATA**

Random allocation concealment was adequate. It was not clear if outcome assessors were blind or if there were any dropouts or losses to follow up.

#### **2. RESULTS**

Bladder capacity at first desire to void and maximum cystometric capacity increased significantly in both groups, and maximum cystometric capacity was statistically significantly greater in the MStim group (114.2ml SD 124.1 versus 32.3ml SD 56.6).

#### **SUMMARY**

With only one single small trial comparing EStim with magnetic stimulation there is insufficient evidence to determine if EStim is better than magnetic stimulation in women with DO.

#### • **EStim versus medication**

Henalla (1989), in a four arm trial, compared EStim (interferential) versus vaginal oestrogen (Premarin) in 104 women with urodynamic SUI [141]. Smith (1996) compared EStim with propantheline bromide in 38 women with OAB [187].

Soomro (2001) compared transcutaneous electrical nerve stimulation (TENS) with oxybutynin in both men and women with DO in a crossover design [226]. Results were not separately presented by gender, which meant it was not possible to draw any conclusions from this study about the effect of TENS in women with DO.

#### **1. QUALITY OF DATA**

Outcome assessment was not blind in either trial, and random allocation concealment was unclear in one study [141] and inadequate in the other [187]. There were few dropouts in either study, and Henalla (1989) followed women up at nine months.

#### **2. RESULTS**

***ij) Women with SUI:*** Eight of 25 women in the EStim group reported they were cured or improved versus 3/24 in the oestrogen group [141]. Nine month follow-up found that one of the eight women in the EStim group who had reported cure/improvement post treatment had recurrent symptoms, as did all three women in the oestrogen group once oestrogen therapy

ceased. Differences in leakage on pad test, and maximum urethral closure pressure did not reach statistical significance. There was no report of side effects or adverse events.

***ii) Women with DO:*** There was a statistically significant difference in patient perceived recovery in favour of the EStim group (OR 0.38, 95% CI 0.10 to 1.49), but no difference in leakage episodes [187].

#### **SUMMARY**

With only single trials, with small numbers per comparison group, there is insufficient evidence to determine if EStim is better than vaginal oestrogens in women with SUI, or propantheline bromide in women with DO.

#### ***d) Does the addition of EStim to other treatments add benefit for the treatment of UI?***

#### • **EStim with BF assisted PFMT versus BF assisted PFMT alone**

One study was found, investigating EStim with BF assisted PFMT versus BF assisted PFMT alone in women with SUI, or MUI [136].

#### **1. QUALITY OF DATA**

Random allocation concealment was adequate; blinding of assessors was not reported. Goode (2003) reported a power calculation and randomised more than 50 patients to each group. The dropout rate was 22.5%.

#### **2. RESULTS**

Intention-to-treat analysis showed similar perception of improvement between the comparison groups (OR 0.98, 95% CI 0.06 to 16.08), and there was no difference between the groups for leakage episodes. The authors reported no adverse events, but there were side effects in four women; problems were vaginal irritation, slippage of the EStim probe resulting in a pinching sensation, and reaction to the conduction gel which resolved after changing brands.

#### **SUMMARY**

A single trial found that the addition of EStim to a BF assisted PFMT was no more effective than BF assisted PFMT in women with SUI, or MUI (in which stress leakage was the predominant symptom) (Level of Evidence: 2). A few women experienced side effects with EStim.

#### **RECOMMENDATIONS**

The addition of EStim to a BF assisted PFMT programme does not appear to add benefit (Grade of Recommendation: C); this hypothesis needs to be investigated further with high quality trials if it is a clinical/research question of interest to women.

### • EStim with PFMT versus PFMT alone

Four trials compared EStim combined with PFMT versus PFMT alone in women with SUI [143, 179, 212, 216]. Tapp (1987, 1989) used faradic stimulation in combination with PFMT in two small trials reported in conference abstracts, and another small trial gave minimal detail of participants, methods and stimulation parameters [143]. Knight (1998) combined clinic based maximal intensity alternating current with PFMT.

In a four arm RCT with 68 women with proven DO Berghmans (2002) investigated the effect of PFMT alone, alternating biphasic EStim alone, and EStim in combination with PFMT in comparison with no treatment [212, 228].

#### 1. QUALITY OF DATA

Of the five trials random allocation concealment was adequate in two [212, 228], a blind outcome assessment clearly stated in just one [228]. The trials were generally small, with only Berghmans (2002) reporting a power calculation. Group size was less than 25 in four [143, 212, 216, 228] of the trials, and between 25 to 49 in the fifth [179]. Two trials had no dropouts or losses to follow up [143, 216], and two followed women up six months post treatment [143, 212].

#### 2. RESULTS

*i) Women with SUI:* Three of the four trials were small and poorly reported; none of them reported statistically significant differences between the groups receiving combined ES/PFMT and PFMT alone [143, 179, 216]. The fourth trial was also small although better reported [212]. In this study 10 of 21 women in the PFMT group and 16/24 in combination therapy group reported cure or great improvement; a difference in favour of combination therapy (OR 0.23, 95% CI 0.05 to 0.93), but there were no statistically significant differences in improvement in pad test or vaginal squeeze pressure. Neither Hofbauer (1990) nor Knight (1998) recorded any adverse events from stimulation.

*ii) Women with DO:* No data were provided on the comparison of combined PFMT/EStim versus PFMT. No women had any side effects or adverse events

#### SUMMARY

For comparisons of EStim with PFMT versus PFMT alone the reporting was very poor in three of the four trials in women with SUI, and only a single trial that did not report any data for the comparison of interest was found for women with DO. There is insufficient evidence to draw any conclusion about the effect of adding EStim to PFMT.

### 3. OTHER LUTS

No studies were identified that analysed the effect of EStim on lower urinary tract symptoms alone, i.e., frequency of voiding, urgency and/or nocturia.

### 4. FACTORS AFFECTING OUTCOME

#### a) Age

This section considers the effect of EStim in older age, from studies recruiting independent, community dwelling elderly; the frail elderly are considered in the chapter on the elderly.

Only one of the trials in this section on EStim specifically recruited older women [186]. Spruijt (2003) compared the effectiveness of eight weeks of vaginal EStim in women aged more than 65 years with symptoms of SUI, UUI or MUI with a daily pelvic floor muscle training (PFMT). This comparison of EStim and PFMT was considered in the section on PFMT (see B.2.3d). No statistically significant differences between the groups were found for leakage or self reported improvement, but this study was small (n=37) and a post hoc power analysis suggested that the study was underpowered. In view of the likelihood of type II error, the finding of no difference should be treated with caution. In the study report, Spruijt (2003) observed that EStim does not appear to have any serious side-effects in the elderly (apart from interfering with pacemaker activity), but can give an unpleasant vaginal, anal and perineal sensation which can easily lead to a lesser degree of cooperativeness, informed consent and motivation, especially in the elderly. Nevertheless, in general, EStim seems to be a well tolerated and acceptable treatment modality in the older person [186].

One other study included in this section completed a secondary analysis on the basis of age. In a double-blind RCT, Yamanishi (1997) studied EStim compared to a sham device in 68 patients with UUI [223]. EStim was delivered by surface, anal, or vaginal electrodes 15 minutes twice daily for four weeks, using 10Hz and a maximum output current of 60mA. Mean age was 70 years (SD 11) and the secondary analysis considered the effect of treatment in 'older' and 'younger' patients. There was no difference in treatment outcomes based on age (older or younger than 60 years).

In a moderate sized prospective study of 3198 women treated with home-managed EStim in Norway during 1992-1994, there was no association between self-reported improvement and age, although the physicians thought success rates were higher in younger patients [232].

## SUMMARY

On the limited evidence available it seems older women may respond to EStim as well as younger women. On this basis there is no reason to exclude older women from studies of EStim, or not to offer EStim as part of a conservative management programme, except where recognised contraindications such as a cardiac pacemaker are present. More trials need to consider investigating the association between age and treatment outcome.

### b) Other

Aside from age, other factors have the potential to mediate treatment outcome, e.g. diagnosis and underlying cause of UI. A range of other factors are considered below.

#### 1. DIAGNOSIS AND UNDERLYING CAUSE OF UI

It is not clear whether one diagnostic group may benefit more than another from EStim. It has been hypothesised that, in women with SUI who cannot voluntarily contract the PFM to begin a PFMT programme, EStim might help initiate or substitute for a voluntary contraction. However, most studies focusing on the efficacy of EStim do use EStim to initiate or substitute for a voluntary PFM contraction [233]. To date, there has been no trial addressing this hypothesis.

#### 2. PATIENT SELECTION

EStim is reported to be unsuccessful in patients with major descent of the vagina and prolapse of the uterus [219]. Also denervated PFM muscles might not respond to EStim [234]. This means that in patients with no or reduced integrity of the relevant nerve pathways EStim provides no or little chance of cure/improvement [207]. It has also been reported that EStim will fail if EStim does not increase urethral pressure profile [235], although age, oestrogenisation, and urethral mobility are also affect urethral pressure profile and may influence therapeutic outcome [235]. It is unfortunate that it is difficult to assess patients easily in the clinical setting with regard to integrity of the sacral arc, and other factors, to determine the suitability of EStim as a treatment modality.

#### 3. TREATMENT ADHERENCE

As with all conservative therapy modalities one of the key factors to success or failure of EStim is treatment adherence. Three trials made some comment about adherence or reported adherence data. Barosso (2004) stated that adherence to EStim was satisfactory, and attributed this to the ability of the doctor to motivate patients to continue with EStim if the considered stopping prematurely. Bø (1999) found that adherence to EStim (75%) was less than that for PFMT (93%), and the reasons for non-adherence to EStim were a

lack of motivation (four women) and smarting or discomfort (two women). Sand (1991) reported that 80% adherence was achieved by 61% of the active EStim group and 89% of the sham group.

One of the main factors that may influence adherence is side effects of the treatment. Some of the studies included in this section noted some women had side effects attributable to EStim, others stated no side effects were reported by women, and some trials did not mention side effects at all. None of the side effects reported were serious, and all could be resolved with cessation of treatment or some other treatment adaptation (such as change of conduction gel). In a prospective study of about 1300 women in Norway, Indrekvam (2001) found that the most common side effects of EStim included pain (20%), soreness/local irritation (26%), and psychological distress (7%) were the most common side effects but none of the side effects reported was serious [232]. It seemed users of maximal stimulation experienced more pain than users of long-term stimulators (25% versus 15%).

## SUMMARY

It is possible that diagnosis, other factors such as neural pathway integrity, and treatment adherence, will affect treatment outcome. None of these have been adequately investigated to date.

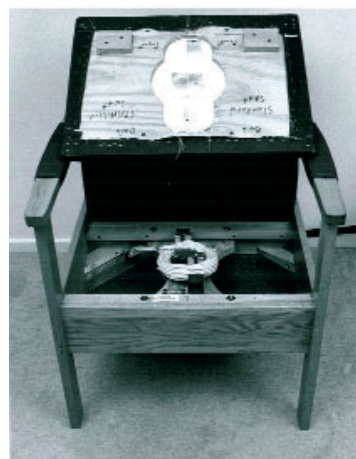
## V. MAGNETIC STIMULATION (MSTIM)

MStim has been developed for stimulating both central and peripheral nervous systems noninvasively [236]. MStim for the treatment of UI was reported for the first time in 1999 by Galloway (1999) [237]. In contrast to EStim, extracorporeal magnetic innervation (more commonly called magnetic stimulation) stimulates the PFM and sacral nerve roots without insertion of an anal or vaginal probe [238, 239]. For treatment, the patient is positioned in a chair. Within the seat is a magnetic field generator (therapy head) that is powered and controlled by an external power unit (**Figure 6**). A concentrated steep gradient magnetic field is directed vertically through the seat of the chair. When seated, the patient's perineum is centred in the middle of the seat, which places the PFM and sphincters directly on the primary axis of the pulsing magnetic field (**Figure 7**). Because of this all tissues of the perineum can be penetrated by the magnetic field. Galloway (1999) says that no electricity, but only magnetic flux enters the patient's body from the device. Goldberg (2000) has suggested that, in contrast to electrical current, the conduction of magnetic energy is unaffected by tissue impedance, creating a theoretical advantage in its clinical application compared to EStim as structures such as sacral roots or pudendal nerves can be magnetically stimulated without patient discomfort or





**Figure 6 : Magnetic stimulation chair with external power unit (Courtesy of Professor Kate Moore and Dr Alastair Morris, University of Sydney, Australia)**



**Figure 7. Magnetic stimulation chair with seat lifted to show magnetic field generator (Courtesy of Professor Kate Moore and Dr Alastair Morris, University of Sydney, Australia)**

the inconvenience of a vaginal or rectal probe. Conventional magnetic stimulators deliver, at frequencies of 10 to 50 Hz, repetitive pulses of current lasting less than 100  $\mu$ sec [238] and 275  $\phi$ s [237] in duration. Size and strength of the magnetic field is determined by adjustments of this amplitude by the therapist [237].

Possible advantages of MStim are that it is performed through full clothing, needs no probes, skin preparation, or physical or electrical contact with the skin surface. On the other hand, the need for repeated clinic based treatment sessions is a potential disadvantage. In contrast to EStim, MStim lacks portability, although in 2003 But reported the development of a small electromagnetic device (Pulsegen) for home use [240]. Further, because both the depth and width of magnetic field penetration is proportional to coil diameter, the present technology is still best suited for stimulation of a field, rather than a narrowly focused target as the sacral roots or the pudendal nerve [238].

MStim of the sacral nerve roots and pelvic floor is said to be effective for both UUI and SUI [238], although the mechanism of action is not fully understood [241]. Some authors have suggested that in SUI stimulation of the PFM causes external sphincter contraction [242], acts as a passive Kegel exercise [243], and increases maximal urethral closure pressure [240]. In UUI, MStim might suppress DO through activation of pudendal nerve afferents blocking parasympathetic detrusor motor fibres at the spinal reflex arc, activation of inhibitory hypogastric sympathetic neurons, or a combination of both mechanisms [244]. Stimulation of sympathetic fibres maintaining smooth muscle tone within the intrinsic urethral sphincter and modulation of pudendal nerve afferent branches stimulating an inhibitory spinal reflex at the S3 nerve root, are also suggested to play a role in this mechanism of action [244].

This section will examine the evidence for the use of MStim for the prevention and treatment of UI in women. Questions addressed are:

- Can MStim prevent UI?
- Is MStim better than no treatment, placebo or control treatments for UI?
- Is one type of MStim better than another?
- Is MStim better than other treatments?
- What factors might affect the outcome of magnetic stimulation?

A literature search for reports of relevant systematic reviews and reports of RCTs and quasi-RCTs, e.g. alternate assignment (see appendix) was performed. No other types of study design were considered.

## 1. PREVENTION

No trials investigating the primary or secondary prevention effects of MStim for women with UI were found.

## 2. TREATMENT

The literature search revealed three reviews, two in English and one in the German language, that addressed the indications for and the use of MStim and provided an historical overview of the therapeutic application possibilities of this treatment modality for UI [202, 241, 245].

These reviews were used to provide some background information regarding MStim, but did not otherwise contribute to the review.

Seven trials were found [225, 240, 246-250]. One report was an abstract; the trial has not yet been fully published [249]. Since the 3<sup>rd</sup> ICI two new trials have been published [246, 247].

**a) Is MStim better than no treatment, placebo, or control treatment?**

Six RCTs comparing MStim with sham for women with UI were found [240, 246-250].

But (2003) compared MStim from a home device (Pulsegen) with sham (identical but inactive device) in women with SUI, UUI and MUI [240], and subsequently in a sample with MUI [246]. In active and sham groups in both trials women were asked to wear the Pulsegen device day and night for two months; in the active group the device produced a pulsating magnetic field of  $B=10 \text{ } \mu\text{T}$  intensity and a pulse frequency of 10Hz [240] or 18.5Hz [246].

Fujishiro (2000) compared a single session of MStim with sham in women with SUI [248], and subsequently women with urinary frequency and UUI [248]. In both trials the active group received 15Hz repetitive MStim of the sacral roots with 50% intensity output for five seconds per minute for 30 minutes. MStim was performed with the patient prone using a rapid rate stimulator with a Rapid circular coil. The coil was fixed over the sacrum to cover the bilateral third sacral foramina. The sham group received exactly the same treatment except the sham stimulating coil did not induce any electromagnetic field.

Gilling (2001) recruited SUI women, and compared MStim of the pelvic floor to sham, using a chair with an inbuilt magnetic coil (Neocontrol device) for 20 minutes [249]. A total of 16 treatments (three per week) were performed over six weeks. Both groups were also asked to do home PFMT.

Morris (2007) compared active MStim (Neocontrol device) with sham (an identical looking/sounding device containing a deflector plate to degrade the magnetic field). Treatment comprised 20 treatment sessions over six weeks, with at least 36 to 72 hours between sessions. Each session comprised two 10 minute periods of stimulation, at individual maximum tolerance, separated by two minutes rest. Frequency was 10Hz. The sham stimulation, with deflector in place, was run at a fixed intensity of 25% in order to provide the same noise as with the active device and to stay below the level required for patient perception.

**1. QUALITY OF DATA**

Random allocation concealment was adequate in three of the trials [240]. Patients were blind in five of the trials [240, 248, 250], and blind outcome assessors were used by But (2003, 2005) and Morris (2007).

Only Morris (2007) based the size of the study population on an a priori power calculation, but due to a high dropout rate the analysis included only 29 of the 40 women needed. Fujishiro (2000) included 62 women (31 in each group) whilst Gilling (2001) randomised 70 women (35 in each group). In the

studies by But, group sizes were 30 [240] and 23 [246] in the active and 22 [240] and 16 [246] in the sham group.

The proportion of dropouts was less than 10% in two trials [240], 34% in Morris (2007), and in the remainder this was not reported adequately. Two trials followed women up beyond the post treatment evaluation; Morris (2007) followed women up for six weeks, and Gilling (2001) reported six and 12 month follow up in their conference abstract but did not report these data in the full publication.

**2. RESULTS**

**i) Women with SUI:** Fujishiro (2000) compared one session of sacral root MStim with sham in 62 women with SUI [248]. Active treatment was statistically significantly better than sham for leakage episodes ( $p=0.0023$ ), leakage on pad test ( $p=0.037$ ), and quality of life ( $p=0.0126$ ). Based on these three measures 3% and 32% of the sham group were considered cured and improved respectively, versus 13% and 74% in the active MStim group, with more cured or improved in the active group ( $p=0.0009$ ).

Gilling (2001) compared MStim with sham in 70 women with SUI and found no statistically significant difference between the active and sham groups at eight weeks for any outcome, nor between baseline and eight weeks in either group. A posthoc subgroup analysis suggested the women with poor PFM tone at baseline did better with active treatment than sham. The authors reported that follow-up was ongoing, but no data have been published.

**ii) Women with UUI:** Fujishiro (2002) compared a single session of sacral root MStim with sham in 48 women with urinary frequency and UUI. Active treatment was statistically significantly better than sham for voided volume/day ( $p=0.04$ ), number of leakage episodes in three days ( $p=0.04$ ), and quality of life score ( $p=0.01$ ). No adverse effects were noted.

Morris (2007) found no between group differences for mean number of daytime voids, maximum interval, volume of leakage on pad test, number of leakage episodes, or quality of life. The only statistically significant difference was in the mean number of urge episodes per day ( $p=0.003$ ); this difference favoured the MStim group.

**iii) Women with MUI:** But (2005) compared home-based MStim with sham in 39 women with MUI. Within group comparison suggested greater improvement in daytime frequency, nocturia, and pad use in favour of active MStim. Between group comparison showed statistically significant differences in favour of active MStim for time to first sensation of bladder filling ( $p=0.003$ ), maximum cystometric capacity ( $p=0.0004$ ), and self reported treatment success ( $p=0.021$ ). There were no adverse effects in either group.

**iv) Women with SUI, UUI, or MUI:** But (2003) included 52 women of whom 21 had MUI, 22 UUI, and nine SUI, and compared MStim with sham. There were statistically significant differences in favour of MStim for pad use ( $p=0.0017$ ), pad weight ( $p=0.038$ ), power and duration of PFM contractions ( $p=0.0071$  and  $p=0.038$  respectively), self reported improvement in symptoms ( $p=0.00012$ ).

## SUMMARY

There was little duplication of MStim interventions, or sample populations, in the six small trials so it was not thought appropriate to combine study findings. For women with SUI one session of sacral root MStim might be better than sham (Level of Evidence: 2), but 16 sessions using a chair based MStim might not be better than sham (Level of Evidence: 2). Similarly in women with UUI, one session of sacral root MStim might be better than sham (Level of Evidence: 2), but chair based MStim might not be better than sham (Level of Evidence: 2). Home-based MStim might be better than sham in women with MUI (Level of Evidence: 2), and women with SUI, UUI or MUI (Level of Evidence: 2). No adverse events were reported.

## RECOMMENDATIONS

Of the MStim protocols investigated to date, it seems that both sacral root MStim and home-based MStim, are worthy of further investigation in women with UI.

### ***b) Is one approach to MStim better than another?***

No studies were found addressing this question.

### ***c) Is MStim better than other treatments?***

A single trial was found that addressed this comparison; intravaginal EStim was compared with MStim in 17 women and 15 men with DO; stimulation was applied continuously at 10 Hz in both groups [225]. This trial was described and discussed in section B.4.2c. With only one small trial or poor methodological quality, in men and women with UI, it is not clear whether there is any difference in effect of MStim compared to EStim.

## **3. OTHER LUTS**

No studies were found that reported the effects of MStim of other LUTS.

## **4. FACTORS AFFECTING OUTCOME**

None of the included trials addressed the effect of age, or any other factor, on outcome of MStim. Sand (1999), in a prospective multi-centre study investigated factors predicting success of MStim [251]. Treatment success was associated with no prior hysterectomy,

no prior anti-incontinence operations, UI symptoms for less than 10 years, and no use of medications known to cause UI. Brodak (1993) has suggested that detrusor response to stimulation might be better in 'thin' patients (presumably due to a shorter distance between the stimulating coil and the sacral nerve roots) and at low bladder volumes [252]. Overall, little is known about the factors affecting outcome of MStim.

## **VI. SCHEDULED VOIDING REGIMENS**

This section examines the evidence on use of scheduled voiding regimens in cognitively intact, non-institutionalised women with UUI, SUI, and MUI and provides recommendations for their use in clinical practice. A summary of the search strategy and inclusion/exclusion criteria for selecting studies for review is provided (See appendix). See the chapter on the Frail Elderly for a detailed discussion of scheduled voiding regimens that are used in the management of UI in cognitively impaired, institutionalised, or homebound older adults, and the chapter on Neurogenic Incontinence for those voiding regimens appropriate for individuals with UI secondary to central nervous system or spinal cord disease.

### **• Scheduled Voiding Regimens**

Bladder training is a term that has been broadly and sometimes inaccurately applied to any type of a scheduled toileting intervention. This has created conceptual confusion in interpreting research reports where few details are provided other than the statement that bladder training was used. The types of scheduled voiding regimens can be categorised as: bladder training, timed voiding, habit training, and prompted voiding [253]. Although these regimens share a common feature of a toileting schedule, they differ on the basis of adjustments to the voiding schedule; the active or passive involvement of the patient; the nature of patient education including the teaching of strategies to control urgency and prevent stress leakage, the use of reinforcement techniques, and the nature of the interactions between clinicians and patients. In practice, however, scheduled voiding regimens may share aspects of one or more of these features.

### **• Bladder training**

Bladder training (also referred to as bladder drill, bladder discipline, bladder re-education, and bladder retraining) involves a programme of patient education along with a scheduled voiding regimen with gradually progressive voiding intervals. Specific goals of bladder training are to correct faulty habit patterns of frequent urination (if present), improve control over bladder urgency, prolong voiding intervals, increase bladder capacity, reduce incontinent episodes, and restore



patient confidence in controlling bladder function. The underlying mechanism of how bladder training achieves its effect is poorly understood. Several hypotheses have been proposed including improved cortical inhibition over detrusor contractions; improved cortical facilitation over urethral closure during bladder filling; improved central modulation of afferent sensory impulses; altered behaviour resulting from better individual awareness of the lower urinary tract function and circumstances that cause UI, and increasing the “reserve capacity” of the lower urinary tract system [188, 254, 255].

#### • Timed voiding

Timed voiding is a fixed voiding schedule that remains unchanged over the course of treatment [253]. The goal of timed voiding is to prevent UI by providing regular opportunities for bladder emptying prior to exceeding bladder capacity. Timed voiding has been recommended for patients who cannot participate in independent toileting [256]. It has been primarily used in institutional settings as a passive toileting assistance programme where a caregiver takes the patient to void every two to four hours including at night, and for patients with neurogenic bladders associated with spinal cord injuries (see Neurogenic chapter) [257]. However, it has applicability for use in outpatient settings with incontinent women who have infrequent or irregular voiding patterns [258] (and men who are independent in their voiding function [259]).

#### • Habit training

Habit training is a toileting schedule that is matched to the patient’s voiding pattern. Using the patient’s voiding chart, a toileting schedule is assigned to fit a time interval that is shorter than the patient’s normal voiding pattern and precedes the time period when incontinent episodes are expected. Thus, the voiding interval may be lengthened or shortened throughout the day depending on the patient’s voiding pattern with the goal to pre-empt UI. Habit training is usually implemented by caregivers, but patients may also be encouraged to suppress the urge to void until the assigned time. Habit training has been used primarily in institutional settings with cognitively and/or physically impaired adults, but it has also been tested in homebound older adults [260]. It is potentially useful for adults without cognitive or physical impairment, who have a consistent pattern of UI [258].

A Cochrane review on habit training was published in 2004 [261]. Prior to this, the last literature review was published in 1986 [253]. The Cochrane review identified three trials that described the effects of habit training combined with other treatment components compared to usual care on the frequency and severity of UI [260, 262, 263]. Participants were primarily care-dependent women with cognitive and/or mobility impairment, and thus, did not meet the criteria for this

chapter. No studies were located that investigated habit retraining in independent-living women.

#### • Prompted voiding

Prompted voiding refers to a caregiver education programme in combination with a scheduled voiding regimen, typically every two hours. It is used to teach people with or without cognitive impairment to initiate their own toileting through requests for help and positive reinforcement from caregivers when they do so [264]. Although it has been used primarily in institutionalized settings with cognitively and physically impaired older adults, prompted voiding has applicability for use with homebound older adults (see the chapter on the Frail Elderly for a full review).

This section will examine the evidence for the use of timed voiding and bladder training for the prevention and treatment of UI in non-institutionalised women of all ages without cognitive or mobility impairments. However, the majority of evidence available pertains to bladder training thus the effects of bladder training are the focus of this section.

Questions addressed are:

- Can scheduled voiding regimes prevent UI?
- What is the most appropriate bladder training protocol?
- Is bladder training better than no treatment, placebo or control treatments?
- Is bladder training better than other treatments?
- Can any other treatment be added to bladder training to add benefit?
- Does the addition of bladder training to other treatments add any benefit?
- What is the effect of bladder training on other LUTS?
- What factors might affect the outcome of bladder training?

This section is based on previously published systematic reviews, including Cochrane reviews, and additional searches of the literature. Studies that were excluded from prior systematic reviews, due to the inclusion criteria for the review or restriction to RCTs or quasi-RCTs, were also considered. Conference abstracts were considered where adequate information was available.

### 1. PREVENTION

No trials were identified that examined scheduled voiding regimens as a sole intervention in the prevention of UI.

### 2. TREATMENT

Four systematic reviews on bladder training were

located that provided descriptive synthesis with evidence grading [214, 256, 265, 266]. The Cochrane Collaboration published a review in 1998 that has been updated in 1999, 2004, and 2007 [265].

#### **a) What is the most appropriate bladder training (BT) protocol**

No trials were identified that compared two or more methods of bladder training (BT). In the absence of trials comparing two or more approaches, a content analysis of the protocols used in trials investigating the effects of BT was performed. Fifteen trials on BT involving a total of 1, 774 women were identified. Six of the trials provided no or minimal details regarding the specific BT protocol used [151, 267-271]. In trials that did provide some description, BT protocols were implemented in several ways.

All protocols involved some type of patient education, namely:

- Brief verbal instruction [268, 269]
- Brief written instructions [272]
- Verbal, written, and audiovisual instruction [188, 255]
- Participants were introduced to an individual who successfully completed BT [270]
- If specified, the education was provided by nurses [151, 188, 255, 267, 273, 274], or general practitioners [275].

Scheduling of voids varied in the following ways:

- Assignment of the initial voiding interval varied from 30 minutes to two hours, with one hour being the most common interval based upon the participant's voiding pattern or 30 minutes beyond the participant's average voiding interval [276].
- Adjustments to the voiding interval varied from 15 to 30 minutes, with 30 minutes the most common interval. Increases were made daily for inpatient regimens [271], after 48 hours of dryness [277], every four to five days [276], or weekly if schedule was well-tolerated [188, 255].
- Goals for optimal voiding interval varied from three to four hours.
- Voiding was 'mandatory' with restriction of voiding in between assigned toileting times even if UI occurred [271], a scheduled voiding regimen that allowed interruptions in the schedule if urgency became unbearable [188, 255, 273], or self-scheduling of voiding with a target goal to reach [272].
- Voids were not scheduled (allowed) during sleeping hours [271]; none of the other protocols identified how voids were handled during sleeping hours.

In some protocols the scheduled voiding regimen was supplemented by specific strategies to control urgency and/or stress leakage, including distraction and relaxation [188, 255, 272, 273], and pelvic floor muscle contraction [188, 267]. In other studies there was encouragement to suppress urge but it was not clear what strategies were used [55, 269, 275]. Feedback techniques included self-monitoring [188, 255, 268, 270, 273], goal setting with feedback of progress [274], and positive reinforcement [188, 255, 276].

Several protocols included use of adjunctive treatments:

- Fluid and caffeine adjustments [55, 273]
- Fluids allowed up to a certain level (1,500 ml) [277]
- No fluid modifications [188, 255, 272, 275]
- Advice on constipation prevention [273]

Finally, both in and outpatient BT programmes have been used. Early inpatient BT programmes involved five to 13 days of hospitalisation to ensure strict protocol adherence [271]. Outpatient programmes are more commonly described and the amount of health professional contacted had ranged from weekly visits for six weeks with fortnightly telephone calls for six additional weeks [188], to weekly visits [151, 255], fortnightly visits [276], and monthly visits [277].

Overall, there is a lack of consistency in BT protocols. Based on the BT protocols described in the literature to date it seems that a reasonable outpatient BT protocol would include:

an initial voiding interval typically beginning at one hour during waking hours, which is increased by 15 to 30 minutes per week depending on tolerance of the schedule (such as fewer incontinent episodes than the previous week, minimal interruptions to the schedule, and the woman's feeling of control over urgency and confidence to expand the voiding interval), until a two to three hour voiding interval is achieved. A shorter initial voiding interval, e.g. 30 minutes or less, may be necessary for women whose baseline micturition patterns reveal an average daytime voiding interval of less than one hour.

education about normal bladder control and methods to control urgency such as distraction and relaxation techniques and PFM contraction.

self- monitoring of voiding behaviour using diaries or logs in order to determine adherence to the schedule, enhance self-awareness, evaluate progress, and determine whether the voiding interval should be changed (**Figure 8**).

a supervising clinician to monitor progress, suggest adjustments to the voiding interval, and provide positive reinforcement to women undergoing BT at least weekly during the training period.

If there is no improvement after three weeks of BT, re-evaluation is warranted and other treatment options would be considered. Inpatient BT programmes may follow a more rigid scheduling regimen with progression of the voiding interval on a daily basis.

## SUMMARY

There is no trials evidence to suggest the most effective method or specific parameters of BT. For those undertaking BT it is likely that more health professional contact will be better than less, based on the developing evidence for PFMT, which like BT requires behavioural change. The literature suggests several variables that could be investigated in future trials including the instructional approach, supervisory intensity, strategies for controlling urgency, scheduling parameters, frequency of schedule adjustments, length of treatment, and use of adjunctive treatments.

**Monday**

**Continence Program For Women**  
Treatment Log

Chart No. \_\_\_\_\_ Date \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Midnight to Noon

AM

Noon to Midnight

PM

Weekly Voiding Interval 1 1/2 hours

---

Treatment Number <u>2</u>	No. of Scheduled Voidings Interrupted <u>2</u>
No. of Scheduled Voidings <u>12</u>	Nocturnal Frequency <u>1</u>
No. of Scheduled Voidings Missed <u>1</u>	Incontinent Episodes <u>2</u>
	Day Missed (Y/N) <u>N</u>

**A**

Instructions: Use this side to indicate all unscheduled voidings including interruptions in schedule, nighttime voidings, and incontinent episodes.

TIME	URINATE IN TOILET	LEAKING ACCIDENT	COMMENTS
12-1 AM			
1-2 AM			
2-3 AM	✓		
3-4 AM			
4-5 AM			
5-6 AM			
6-7 AM			
7-8 AM			
8-9 AM			
9-10 AM	✓	✓	strong urge
10-11 AM			
11-12 NOON			
12-1 PM	✓		
1-2 PM			
2-3 PM			
3-4 PM		✓	cough
4-5 PM			
5-6 PM			
6-7 PM			
7-8 PM			
8-9 PM			
9-10 PM			
10-11 PM			
11-12 PM			

Awake Time 6:30 A Bed Time 11 P # of Pads Used 2

**B**

**Figure 8 : Self-monitoring of voiding behaviour**  
(Courtesy of Dr Jean Wyman, University of Minnesota, USA)

## RECOMMENDATIONS

It is not clear what the most effective BT parameters are. Clinicians and researchers are advised to refer to the operant conditioning and educational literature to provide a rationale for their choice of BT parameters or approach (Grade of Recommendation: D). Clinicians should provide the most intensive BT supervision that is possible within service constraints (Grade of Recommendation: D). More research is needed to investigate which BT parameters, supervisory intensity, and adjunctive treatments are most effective. Future trials should include outcomes that matter to patients including the length and frequency of supervisory contact.

### **b) Is BT better than no treatment, placebo or control treatments?**

BT as the sole therapy has been used in the treatment of DO, urodynamic SUI, MUI, UI, UI with a stable bladder, and OAB syndrome (also called urgency-frequency syndrome). Individual RCTs that met inclusion criteria and the Cochrane review [265] were used to address the question of whether BT is better than no treatment, placebo, or control treatments for UI.

Five RCTs reporting on 515 women were identified that compared the effect of BT to no treatment or control [151, 255, 270, 273, 275]. In one trial, it was not possible to identify the effect of BT alone, because results of participants in the treatment group who received BT (those with UI or MUI) were combined with those who also received PFMT (SUI participants) [275]. However, in the Cochrane review, additional data were provided by the lead author to describe the women with DO who were randomised to BT versus control. In another trial with three consecutive treatments (self-monitoring, BT, and PFMT; with the decision for which treatments were implemented being based on participants' goals), it was difficult to discern the effect of BT alone as compared to a control group, because some participants had already undergone lifestyle modifications (caffeine and fluid modifications and constipation advice) and diary keeping in a prior self-monitoring condition [273]. Thus, this trial is not discussed further in this section.

In the four trials with analysable data, Jarvis (1980) investigated the effect of an in-patient BT programme in 60 women aged 27 to 79 years with a diagnosis of DO or coexisting SUI, whereas three trials [151, 255, 275] examined the effect of an outpatient programme. Fantl (1991) studied the effect of a six week outpatient programme in 123 women aged 55 to 90 years with urodynamic SUI, DO, or both who reported at least one incontinent episode on a weekly voiding diary. Yoon (2003) examined the effect of an eight week outpatient programme in 50 women aged 35 to 55

years with UI (type not identified) who had pad test weights at least 1g or more and 14 or more voids during a two day diary. Lagro-Jansen (1992) studied the effect of an outpatient programme in 18 women aged 20 to 65 years who reported UUI twice or more per month and had urodynamically confirmed DO.

## 1. QUALITY OF DATA

In one trial random allocation concealment was inadequate [275]; in the remainder it was not clear if concealed. One trial used stratification based on urodynamic diagnosis of urodynamic SUI and/or DO [255]. Blinding of outcome assessors was described in only one trial [151].

Sample sizes in the four analysable trials were 50 [151], 60 [270], 123 [255], and 18 [275]. Fantl (1991) reported a power calculation although details were not described. Losses to follow up were none in one trial, although it was not clear if this was due to having no dropouts or due to lack of reporting [270]. In the other two analysable RCTs, loss to follow up was 6% [255] and 14% [151]. Dropout rates at the immediate follow-up time point seemed similar between the BT and the control groups; they ranged from 8% versus 5%, respectively [255] to 10% versus 14%, respectively [151]. No trials reported whether analyses were based on intent-to-treat principles. Follow-up periods ranged from six weeks [255] to eight [151] and 12 weeks [270, 275], with an additional evaluation six months [270] and nine months [255] after initiation of treatment. Two trials noted whether there were adverse events with BT [255, 270]. No trial reported on adherence.

All of these RCTs, with the exception of the one by Jarvis (1980), were considered in the Cochrane review [265]. The Cochrane reviewers based their conclusions on data available from 172 women in the other three trials.

## 2. RESULTS

Three of the four RCTs reported statistically significant improvements in the BT group as compared to an untreated control group with respect to incontinent episodes [255, 270, 275]; the fourth did not report data on incontinent episodes [151].

Jarvis (1980) reported that 90% of the participants in the treatment group were continent and 83% were symptom free at six months (method for determination of continence and symptom status was not specified but probably self-report) as compared to 23% of the control group who were both continent and symptom free. All women who were symptom free after treatment reverted to a normal cystometrogram.

Fantl (1991) reported that 12% of participants in the treatment group were continent and 75% had reduced their incontinent episodes by at least 50% or more at six weeks, as measured by a seven day voiding diary, as compared to 3% of controls with no incontinent

episodes and 24% with at least 50% reduction in their incontinent episodes. These results were maintained at six months. Women with DO and those with urodynamic SUI with and without DO had similar improvement rates. Participants in the treatment group also significantly decreased the grams of fluid lost on a retrograde pad filling test by 54% with results maintained six months later; this was more pronounced in those who had DO with or without urodynamic stress UI. While some women did revert back to normal bladder function following BT, no relationship was found between changes in urodynamic variables and the number of incontinent episodes [278].

Lagro-Jansen (1992) reported that eight or nine patients in BT perceived improvement of UI compared to none of nine in the control group. Yoon (2003) reported that there was no difference between the BT and control groups in the amount of leaked urine at an immediate follow-up; however, it was not clear if this referred to pad test weights solely or a UI severity score. Conclusions from this trial are uninterpretable because of insufficient power.

The Cochrane review [265] noted that the few data available tend to favour BT; however, the scarcity of data implies that they should be interpreted cautiously.

## SUMMARY

From the few trials available, there is scant Level 1 evidence that BT may be an effective treatment for women with UUI, SUI, and MUI (Level of Evidence: 1)

## RECOMMENDATIONS

BT is an appropriate first line conservative therapy for UI in women (Grade of Recommendation: A). Additional high quality studies are needed that examine the effect of BT versus no treatment in treatment of women with UUI, SUI, and MUI.

### c) Is BT better than other treatments?

To be included in this section, trials needed to compare BT alone versus another active therapy. For the comparison of BT versus PFMT see B.2.3d. The only other comparison for which trials were found was BT versus drug therapy. Individual trial reports that met inclusion criteria and the Cochrane review [265] were used as the basis of the review of BT versus drug therapy.

Three RCTs were located that compared BT to drug therapy in 322 women [267, 271, 276]. The study by Park and colleagues [267] compared a 12-week BT programme to 2mg tolterodine twice daily in women (ages unknown) with OAB (unclear if UI was present); because there were no findings reported on UI, this trial is discussed in the section on Other LUTS (B.6.3).



The two trials included in this section used a combination of flavoxate hydrochloride and imipramine [271], or used immediate-release oxybutynin chloride [276].

## 1. QUALITY OF DATA

One trial reported adequate random allocation concealment [276]. Sample sizes were 50 [271] and 79 [276]. Neither trial reported a power calculation;

Follow up periods varied from four weeks [271] to six [276] and 12 weeks [271], and six months [276]. Both RCTs evaluated drug tolerability and adverse events. Dropouts were none in one trial; however, it is not clear whether this was a reporting issue [271]. In the other trial loss to follow up was 7% [276]. Neither trial identified whether intent-to-treat principles were followed. The Cochrane review [265] based their conclusions on the same trials.

## 2. RESULTS

One RCT suggested that BT may be superior to drug therapy in women with DO [271]. Jarvis (1981) compared inpatient BT to outpatient treatment of 200mg of flavoxate hydrochloride (three times a day) and 25mg of imipramine (three times per day) in 50 women aged 17 to 78 years with DO, and concluded that BT was more effective. In the BT group, significantly more patients (84%) became continent and symptom free (76%) assessed by self-report, as compared to the drug group where 56% became continent and 48% were symptom free at four weeks. Patients who were symptom free at four weeks were able to maintain their outcomes at 12 weeks. In the analysis by the Cochrane review group, more participants in the BT group perceived that they were cured at the end of the treatment phase and approximately two month after treatment ended (RR 1.50; 95% CI 1.02 to 2.21). Adverse events included dry mouth, dizziness, headache, nausea, vomiting, and drowsiness in participants who received drug therapy; there were none with BT.

Columbo (1995) reported that a six week course of 5mg oxybutynin chloride (immediate release) (three times per day) had a similar clinical cure rate (i.e. self-reported total disappearance of UUI, no protective pads or further treatment) as outpatient BT (74% versus 73% respectively) in 79 women aged 24 to 65 years with DO. 'Clinical cure' was observed in 93% and 62% of patients with DO, 67% and 75% of those with low compliance bladder, and 60% and 81% of those with urgency-frequency syndrome in those randomised to oxybutynin and BT respectively. The relapse rate at six months was higher for the drug group, whereas, those in the BT group maintained their results better. In the analysis by Wallace et al (2007) participants' perception of cure was not statistically significant at the end of the treatment phase (RR 0.99; 95% CI 0.75 to 1.30), but favoured

BT six months after the treatment ended (96.3% vs. 57.1%; RR 1.69; 95% CI 1.21 to 2.34). Perceptions of improvement were also higher in the BT group at the end of the treatment phase (91.9% vs. 81.6%) but this difference was not statistically significant (RR1.13; CI 0.94 to1.35). Adverse events included dry mouth, constipation, nausea and tachycardia in patients who received drug therapy, with none in those who received BT.

## SUMMARY

It is not clear whether BT is more effective than drug therapy for women with DO or UUI (Level of Evidence: 1). This is consistent with the findings of the Cochrane review [265], which concluded that there was not enough evidence to determine whether first line therapy should be BT or anticholinergic drugs.

## RECOMMENDATIONS

In a choice between BT and anticholinergic drug for women with DO or UUI, either may be effective (Grade of Recommendation: B). BT may be preferred by some clinicians and women because it does not produce the side effects and adverse events associated with drug therapy (Grade of Recommendation: D).

### ***d) Can any other treatment be added to BT to add benefit?***

To be included, trials needed to investigate the effects of BT versus BT plus therapy A to address the additive benefit of therapy A to BT. Trials addressing the additional benefit of three other treatments were found: caffeine reduction, PFMT, and drug therapy. The trial addressing the added benefit of caffeine reduction [55] is considered in the section on Lifestyle Interventions (B.1.2d), and the trial addressing the added benefit of PFMT [188] is considered in the section on PFMT (B.2.3e). The trials addressing the added benefit of drug therapy are considered below.

One RCT was found that compared BT alone versus BT with tolterodine (2mg, twice daily) in 99 women with OAB [267]. However, incontinence status of the participants was unknown, and details regarding the study methodology were limited (abstract only). Therefore this trial was not considered further in this section.

A further three RCTs compared BT with placebo drug versus BT with drug therapy in patients with DO. One of these used terodoline (a drug that was withdrawn from the market) [269]. Therefore, this trial was not considered further in this section. In the other two trials the drugs used were imipramine [277] and immediate release oxybutynin [268].

Castleden (1986) studied 34 patients with DO (28

women aged 30 to 91 years and six men). Szonyi (1995) recruited 60 patients aged 70 years and over (56 women, four men). While it is possible that the placebo drug could augment BT, and both these trials included a small number of men in addition to women (and data for women were not reported separately), a pragmatic decision was made to review these two trials in this section.

## 1. QUALITY OF DATA

Neither Castleden (1986) nor Szonyi (1995) reported adequate random allocation concealment, or blinding. In Szonyi (1995) study size was based on a power calculation. Post-treatment follow up periods were variable. One trial evaluated participants at six weeks [268]; 16 were lost to follow up. The other trial did not have a clear endpoint but followed participants for one to 11 months; one participant was lost to follow-up [277].

## 2. RESULTS

It was not possible to discern the treatment effects in women only in these two trials, and the findings were inconsistent. Castleden (1986) found that more patients became dry on BT plus imipramine 25mg or more per day (14 of 19) compared to those in the BT plus placebo group (six of 14), but the authors reported that there was no statistically significant difference in outcome between the two groups. One patient in the imipramine group became confused and another complained that the drug made him feel ill. Several patients taking imipramine reported dry mouth and constipation (data not reported), but none on placebo.

Szonyi (1995) found no difference between BT plus 2.5mg of immediate release oxybutynin (twice daily) compared to BT and placebo for reducing incontinent episodes. Szonyi (1995) concluded, however, that the combined therapy group was superior to the BT and placebo group, because it had greater subjective benefit (86% versus 55%), and adverse events were similar in the two groups at 50%.

## SUMMARY

In two small trials comparing BT plus placebo drug versus BT plus drug in DO, there was a suggestion that the effect of BT might be enhanced by active drug (Level of Evidence: 2). However both trials were small, placebo controlled, conducted in gender mixed sample populations, and the outcomes were not common to both trials. Thus, there is insufficient evidence to derive a conclusion related to the effectiveness of augmenting BT with drug therapy.

## RECOMMENDATIONS

Direct comparisons of BT versus BT with drug are needed to address the question of whether the effect of BT can be augmented by drug therapy.

## e) Does the addition of BT to any other treatment add benefit?

To be included, trials needed to investigate the effects of Therapy A versus Therapy A plus BT to assess the added benefit of BT over Therapy A alone. Trials were located that investigated the effects of PFMT alone versus PFMT plus BT, and drug therapy alone versus BT plus drug therapy.

Wyman (1998) compared the efficacy of BT, PFMT, and combination therapy in 204 community dwelling women aged 45 years and older with SUI and/or DO [188].

Two RCTs were identified that compared BT plus tolterodine (2mg twice daily) [267, 272] to drug therapy alone. In a three arm trial, Park (2002) included 99 women with OAB but it was unclear if UI was present. Therefore this trial was not considered further.

## 1. QUALITY OF DATA

**i) BT plus PFMT versus PFMT alone:** In a three arm RCT (n=204) Wyman (1998) randomised 136 women to PFMT (n=69) or PFMT with BT (n=67). Outcomes were assessed after the 12 week intervention and three months later. It was not clear if random allocation was adequate or outcome assessors were blind. Study size was based on a power calculation. Losses to follow-up were six at 12 weeks, and 16 three months later.

**ii) BT plus drug therapy versus drug therapy alone:** Mattiasson (2003) evaluated "simplified" BT (consisting of a one page instruction sheet) in a single blind study of 501 participants (378 women and 123 men) aged 18 years and over with OAB with or without UUI. Allocation concealment, blinding of assessors, and a prior power calculation were not described. Post-treatment follow-up was 12 weeks, and then 24 weeks. Seven participants were lost to follow-up; five in drug therapy and two in combination therapy. Analyses were based on intent-to-treat principles. However, because of reporting issues, it was not possible to discern the effect of treatment in women alone.

## 2. RESULTS

**i) BT plus PFMT versus PFMT alone:** Post-treatment the combination therapy group had significantly fewer incontinence episodes compared to PFMT alone. More women in the combination therapy group than PFMT group reported cure (31% versus 13% respectively), or 50% improvement or more (70% versus 50%).

The combination therapy group also reported greater perception of improvement and more satisfaction with treatment than PFMT alone. However, three months later between group differences were not statistically significantly different for cure (27% versus 20%), improvement (59% versus 56%), perception of improvement, or satisfaction with treatment.

### **ii) BT plus drug therapy versus drug therapy alone:**

Mattiasson (2003) reported no difference between participants who received brief written BT instructions plus tolterodine versus tolterodine alone with respect to reducing incontinent episodes (median reduction 87% versus 81%, respectively). Data were combined for men and women and most data were not presented separately for those who had UI versus those who did not.

#### **SUMMARY**

A single trial found that combining BT with PFMT improves short-term outcomes compared to PFMT alone, but the added benefit did not persist three months later. There is no evidence for an added benefit of combining brief written BT instructions with tolterodine (2mg twice daily) compared to tolterodine alone for urge incontinence (Level of Evidence: 2), although this trial included men and women and it is not known if one gender did better than the other with respect to outcome.

#### **RECOMMENDATIONS**

For women taking an antimuscarinic drug there may be no clinical benefit in adding brief written instruction in BT (Grade of Recommendation: B). More research is needed using an appropriately supervised BT programme (see B.6.2a) combined with anticholinergic or antimuscarinic drug therapies versus drug alone.

### **f) Timed voiding**

There are anecdotal reports that timed voiding involving a two or three hour schedule may be beneficial in clinical practice. A Cochrane review on timed voiding for management of UI in adults was published in 2007 [257]. A previous literature review was published in 1986 [253].

Ostaszkiwicz (2007) considered randomised and quasi-randomised trials only and identified two trials that compared timed voiding combined with additional interventions (including medications) to usual care. Both trials were conducted in nursing facilities and most participants were elderly women with cognitive impairment, therefore neither study recruited participants that met the criteria of interest for this chapter.

Two non-randomised studies that were not included in the Cochrane review reported findings related to the effects of timed voiding in women with UUI, stable bladders with UUI, and MUI [279, 280]. Klarskov (1986) reported a consecutive series of 20 women aged 27 to 75 years with a double-blind crossover to compare timed voiding plus anticholinergic drug therapy (terodoline) to timed voiding plus placebo. As terodoline has been withdrawn from the market, this study is not considered further.

## **1. QUALITY OF DATA**

Godec (1984) reported a case series report involved 20 women aged 24 to 94 years in women with a mild degree of UI, irregular voiding patterns, and normal urodynamic parameters (UI type not clearly reported) [279]. The voiding schedule consisted of a two hour voiding interval. Follow-up periods ranged from six weeks to eight months after treatment [279].

## **2. RESULTS**

Godec (1984), reported a 79% success rate (not objectively quantified). Fifteen patients became totally continent, one had less leakage, three (with neurogenic diseases) remained unchanged, and one patient was lost to follow-up

#### **SUMMARY**

There are no RCTs, or high quality observational studies, providing evidence on the effects of timed voiding for UI in women. Based upon the data from one small uncontrolled study, it seems a two hour timed voiding schedule may be beneficial in treating women with mild UI, infrequent voiding patterns, and stable bladder function (Level of Evidence: 3).

#### **RECOMMENDATIONS**

Timed voiding with a two hour voiding interval may be beneficial as a sole intervention for women with mild UI infrequent voiding patterns (Grade of Recommendation: C). It may also be helpful as an adjunct to other treatment.

## **3. OTHER LUTS**

One trial was excluded from sections above, because it recruited participants with OAB and the continence status of participants was not clear [267]. Park (2002) compared BT versus tolterodine (2mg, twice daily) versus the combination of BT and tolterodine in 99 women with OAB [267]; this study was reported as a conference abstract. Park (2002) found that the tolterodine/BT group had greater reductions in diurnal micturition (32.6%), nocturnal micturition (63.2%), urgency scores (63.2%), and bladder symptom improvement rates (69.3%) than those in BT alone (27.1%, 55.8%, 48.4%, 50%, respectively) or tolterodine alone (30.3%, 61.9%, 62.5%, 58.3%, respectively). However, only the bladder symptom improvement scores were statistically significantly better in the combination therapy group. Thus, it is not clear if BT alone, tolterodine alone, or the combination, is better for LUTS other than UI in women with OAB symptoms.

The most common LUTS, aside from UI, are urgency, daytime (or diurnal) frequency and nocturia. Some trials that contributed to the sections above reported data specifically for these symptoms.



**a) Urgency:** Jarvis (1981) compared BT and drug therapy (flavoxate and imipramine), and 16% versus 44% of participants reported they continued to experience urgency post-treatment. Mattiasson (2003) compared BT with tolterodine versus tolterodine alone and patient rating of urgency was somewhat less in the combination therapy group.

**b) Daytime (diurnal) frequency:** Data on frequency are more commonly collected than data on urgency. Three trials reported diurnal frequency in comparisons of BT with no treatment. Jarvis (1980) reported a small controlled trial of inpatient bladder drill for DO [270]. After BT 17% in the treatment group and 77% in the control group continued to have symptoms of diurnal frequency. Fantl (1991), in subgroup analyses, found a significant reduction in diurnal frequency in participants with urodynamic SUI who had a baseline diurnal micturition frequency of at least 61 per week, and also in participants with DO with or without urodynamic SUI who had at least 57 diurnal micturitions per week [255]. Finally, Yoon (2003) reported that the BT group significantly reduced diurnal micturitions, whereas the control group deteriorated slightly [151].

Two trials compared BT with drug therapy. Jarvis (1981) reported that 24% of the BT group continued to experience frequency as compared to 48% of the drug group (flavoxate and imipramine) [271]. Columbo (1995) found that diurnal frequency was resolved in 18 (56%) of 32 patients taking oxybutynin versus 20 (69%) of 29 BT patients [276].

Another trial compared BT plus placebo versus BT plus drug [268]. Szonyi (1995) found that there was a greater reduction in diurnal micturition frequencies in participants taking oxybutynin alongside BT compared to those on placebo and BT. Similarly, in a trial of BT plus drug versus drug alone Mattiasson (2003) found that "simplified" BT significantly augmented the effect of tolterodine compared to drug alone for voiding frequency (33% versus 25% improvement, respectively;  $p < 0.001$ ).

**c) Nocturia:** Three trials reported data on nocturia in comparisons of BT with no treatment. Jarvis (1980) reported a small controlled trial of inpatient bladder drill for DO. After bladder training, there were 11% in the treatment group and 80% in the control group who continued to have symptoms of nocturnal frequency [270]. Fantl (1991) also found significant reductions in nocturnal frequency [255].

In subgroup analyses, nocturnal micturitions were only significantly decreased in women with urodynamic SUI alone, who experienced at least five episodes of nocturia per week, and not in those who had DO. Yoon (2003) reported that the BT group significantly reduced nocturnal micturitions, whereas the control group deteriorated slightly [151].

Two trials compared BT with drug therapy. Jarvis (1981) reported that the 19% of the BT group continued to experience nocturia compared to 68% of the drug group (flavoxate and imipramine) [271]. Columbo (1995) found that nocturia disappeared in three (27%) of 11 patients taking oxybutynin and 11 (61%) of 18 BT patients [276]. Another trial compared BT plus placebo versus BT plus drug [268]. Szonyi (1995) found no difference in nocturnal micturition frequencies.

## SUMMARY

Scheduled voiding regimens have been implemented in many forms and with a variety of intensities, ranging from strict in-patient regimens to simple instruction sheets. Most research has examined BT, and most of these trials have recruited women with symptoms of UII or OAB. It is therefore disappointing that there is so little data about LUTS other than UI. The indications so far are that BT is effective for reducing UI, as well as frequency of micturition. The scant research comparing BT to drug therapy is inconsistent with some evidence for the superiority of each. It is not yet clear whether drug therapy can enhance BT, or whether BT can enhance UI outcomes from drug therapy, although it appears that reductions in frequency of micturition may be greater with the addition of BT.

## 4. FACTORS AFFECTING OUTCOME

### a) Age

All trials with the exception of two RCTs [151, 275] included older women in their study populations. Three trials specifically recruited elderly women aged 65 to 70 years and over [268, 269, 277]; and two trials recruited women aged 55 years and over [255, 273]. In conducting analyses of factors predicting outcomes of BT alone, two trials reported that age was not a factor in treatment outcome [188]. Similarly, age was also not a predictor of outcome in a trial incorporating an intervention in which three consecutive interventions could be implemented depending on participant goals (self-monitoring, BT, PFMT) [273].

### b) Other

Few BT trials examined other predictors of treatment response. Several trials discussed the effect of diagnosis on treatment outcome. Two trials reported that urodynamic diagnosis did not have an effect on treatment outcome as measured by incontinent episodes and the Incontinence Impact Questionnaire [188, 255]. These RCTs included women with urodynamic SUI, DO, or both diagnoses. BT also led to more clinical cures in one small drug trial. BT in women with sensory urgency (81%) and low compliance bladders (75%) produced better outcomes than in those on oxybutynin immediate release (60%, 67%, respectively); however, oxybutynin led to greater cure rates in patients with DO (93% versus 62%).



## VII. COMPLEMENTARY AND ALTERNATIVE MEDICINES

There is emerging evidence that complementary and alternative medicines (CAMs) may influence both physiologic function and health outcomes. CAMs include those therapies that are not part of the traditional biomedical model, such as meditation, imagery, hypnosis, acupuncture and naturopathic and herbal remedies. While some consider BF part of complementary therapy, we have included BF in this chapter as an adjunct to physical therapies.

A search of AMED (Allied and Complementary Medicine) using the key words randomized controlled trials, and urine or urinary, retrieved 18 records. None of these reported a randomised controlled trial investigating the effect of CAMs that had not already been considered in this chapter.

No trials were found in a similar search when the report for the 3rd Consultation was prepared. A decision was made not to update this section of the report based on further uncontrolled studies.

Given the high placebo response rate in many studies of conservative therapies for UI it is crucial that further studies of CAMs include a control group. When placebo treatment is not possible due to the nature of the intervention, a standard treatment control group should be used.

Interested readers are referred to the report from the 3rd Consultation for the previous summary of the few uncontrolled studies of CAMs found prior to 2005.

## VIII. SUMMARY

Some aspects of the conservative management of UI in women have received the bulk of research attention to date, such as the effect of PFMT. There are other areas, such as the effect of lifestyle interventions, which have received little. Although a reasonable number of trials were found investigating the effects of conservative management of UI in women, the standards of trial conduct and reporting vary considerably and the size of the trials is often small. All these factors contribute to the lack of data that can meaningfully be compared.

### 1. RECOMMENDATIONS FOR PRACTICE

While there are some recommendations underpinned by good and consistent evidence of effect, there are also many recommendations that are essentially hypotheses that need further testing because there is insufficient Level 1 or 2 evidence to be sure about the effect of an intervention.

#### a) Lifestyle interventions

- For morbidly and moderately obese women weight loss is a useful treatment to reduce UI prevalence (Grade of Recommendation: A) (Changed)
- A reduction in caffeine intake may help those with incontinence symptoms (Grade of Recommendation: B) (Changed).
- Given the fact that decreasing fluids may lead to urinary tract infections, constipation, or dehydration, this intervention should be reserved for patients with abnormally high fluid intakes (Grade of Recommendation: C) (Unchanged).
- Crossing the legs and bending forward might be useful in reducing leakage during coughing or other provocation (Grade of Recommendation: C) (Unchanged)

#### b) Pelvic floor muscle training (PFMT): Principal recommendations

The principal recommendations of the committee are that:

- PFMT is offered as first line conservative therapy to women with stress, urge, or mixed urinary incontinence (Grade of Recommendation: A) (Unchanged).
- Clinicians should provide the most intensive PFMT programme possible (in terms of exercise dose and health professional supervision) within service constraints because health professional taught and supervised programmes are better than self-directed programmes, and more health professional contact is better than less (Grade of Recommendation: A) (Changed).
- There does not appear to any benefit of adding clinic BF (Grade of Recommendation: A), or home based BF (Grade of Recommendation: B) to the PFMT programme (Changed).

#### c) Pelvic floor muscle training (PFMT): Other recommendations

The recommendations that follow may help with decision making in specific groups. Most of these are essentially hypotheses that need further testing.

##### Pregnant women expecting their first baby:

- Should be offered an intensive strengthening antepartum PFMT, with regular health professional contact to supervise training, to prevent postpartum urinary incontinence (Grades of Recommendation: A (for women continent at 18 weeks) and B (for population approaches, that is intervention offered whether women are continent or not at 20 weeks gestation)) (Changed).

**Postnatal women, immediately after delivery:**

- Who had a vaginal delivery of a large baby (4000g or more) or a forceps delivery will benefit from an individually taught PFMT programme that incorporates adherence strategies (Grade of Recommendation: C) (Unchanged).

**For postnatal women with persistent symptoms of UI three months after delivery:**

- PFMT is offered as first line conservative therapy (Grade of Recommendation: A) (Changed).
- The 'best' PFMT programmes are 'intensive' with regard to supervision and exercise content (Grade of Recommendation: B) (Changed).

**For women with SUI:**

- PFMT is better than EStim as first line conservative therapy, particularly if PFMT is intensively supervised (Grade of Recommendation: B) (Unchanged).
- PFMT is better than BT as first line conservative therapy (Grade of Recommendation: B) (Changed).
- PFMT and duloxetine are both effective therapies, although clinicians and women may choose to try PFMT first because of the side effects experienced with the drug (Grade of Recommendation: C) (New).
- PFMT and surgery are both effective therapies, although many clinicians and women may prefer PFMT as a first choice therapy because it is less invasive (Grade of Recommendation: C) (Changed).

**For women with SUI or MUI:**

- PFMT and VC are both effective therapies, although it seems PFMT is better as a first choice because of better leakage outcomes and because some women cannot or do not like to use cones (Grade of Recommendation: B) (Changed).
- PFMT is better than clenbuterol or phenylpropanolamine hydrochloride as first line therapy because of the side effects experienced with the medications (Grade of Recommendation: B) (Unchanged).
- A combination of PFMT/BT may be better than PFMT alone in the short-term (Grade of Recommendation: C).

**For women with UUI or MUI:**

- PFMT and BT are both effective first line conservative therapy (Grade of Recommendation: B) (Unchanged).
- PFMT is better than oxybutynin as first line therapy (Grade of Recommendation: B) (Unchanged).

**d) Vaginal cones (VC)****For women with SUI or MUI:**

- VC can be offered as first line conservative therapy to those who can and are prepared to use them (Grade of Recommendation: B); VC may be inappropriate in some cases due to side effects and discomfort.
- VC and EStim seem equally effective in the treatment of SUI and MUI, but the usefulness of VC and EStim in practice might be limited because of side effects and discomfort (Grade of Recommendation: B).

**e) Electrical stimulation (EStim)**

While the usefulness of EStim in practice might be limited because some women cannot use it (due to contraindications), have difficulty using it, or dislike it:

- For women with SUI, (a) six months of 50Hz daily EStim at home might be better than no treatment (Grade of Recommendation: C) (New), and (b) low intensity home based EStim daily for six months might be better than 16 sessions of maximal clinic based EStim (Grade of Recommendation: C) (New).
- For women with DO nine weeks of 4 to 10Hz twice daily EStim at home might be better than no treatment (Grade of Recommendation: C) (New).
- The addition of EStim to a BF assisted PFMT programme does not appear to add benefit (Grade of Recommendation: C) (New).

**f) Magnetic stimulation (MStim)**

- Any clinical use of MStim should only be in the context of a randomised clinical trial as the benefit of this intervention has not been established (Grade of Recommendation: D) (New).

**g) Bladder training (BT)**

With regard to Grade A recommendations for BT:

- BT is an appropriate a first line treatment for UI in women (Unchanged).

Grade B recommendations are:

- Either BT or antimuscarinic drug may be effective (Unchanged), although BT may be preferred by some because it does not produce the side effects and adverse events associated with drug therapy.
- There may be no benefit in adding brief written instruction in BT to drug therapy (New).
- For women with symptoms of SUI or MUI a combination of PFMT/BT may be better than PFMT alone in the short-term (Unchanged).

There are two Grade D recommendations, drawn

from expert opinion and narrative review of the existing literature, being:

- Clinicians and researchers should refer to the operant conditioning and educational literature to provide a rationale for their choice of training parameters or approach (New).
- Clinicians should provide the most intensive BT supervision that is possible within service constraints (New).

#### **h) Timed voiding**

- Timed voiding with a two hour voiding interval may be beneficial as a sole intervention for women with mild UI infrequent voiding patterns (Grade of Recommendation: C) (Unchanged).

## **2. FUTURE RESEARCH DIRECTIONS**

There continues to be much scope for research on the effects of conservative therapies for UI and LUTS in women. Research that is urgently needed, in the opinion of the committee members, is highlighted with the use of *italics*. There are a few recommendations that apply to all further studies in women, namely:

- All future trials must be designed, implemented and reported in ways that maximise their usefulness in practice; this includes evaluation of cost-effectiveness and planned secondary analysis of trial data to investigate factors affecting outcome. Readers are referred to the revised CONSORT statement for guidance.
- Studies need to be larger, with longer follow up.
- Future trials should use a validated and reliable quality life measure as the primary outcome.

#### **a) Lifestyle interventions**

- *The dual issues of weight loss and prevention of weight gain (and the role of exercise in these) should receive high research priority in UI research given the prevalence of both UI and obesity in women.*
- Given the large proportion of women employed in occupations that require heavy lifting the association of such exertions and UI should be investigate further. Specifically research must establish whether heavy exertion is an etiologic factor in the pathogenesis of UI and whether changing exertions can alleviate established UI.
- Further prospective studies are needed to determine whether smoking cessation prevents the onset, or promotes the resolution, of UI.
- *Larger RCTs to assess the effect of dietary factors, in particular caffeine reduction, are feasible and important.*
- Further research is needed to delineate the role of straining in the pathogenesis of UI.

- High quality studies evaluating the effect of all other lifestyle interventions on UI are warranted.
- Future work should separately evaluate the impact of lifestyle interventions on nocturia, diurnal frequency, urgency and UUI to delineate whether certain interventions preferentially affect different areas of OAB.

#### **b) Pelvic floor muscle training (PFMT)**

In antenatal and postnatal women, trials are needed to investigate:

- The effect of antepartum PFMT on preventing postpartum UI in multiparous women.
- The effect of a postpartum PFMT programme (suitable exercise dose and supervision) in the long term (five plus years).
- The effect of periodic refresher sessions after an initial supervised postpartum PFMT programme, in the long term (five plus years).

In all women, trials are needed to investigate:

- The effects of PFMT in the long term (five plus years)
- The effects of different types of PFM exercise (strengthening, endurance, co-ordination, functional training) and supervisory styles (e.g. individual versus group).
- Whether any indirect method of PFMT (Paula method, transversus abdominus training, hip abductor or adductor exercise) might be as effective as direct PFMT, or add benefit to a direct PFMT programme.
- Whether BF may benefit certain women, such as those with a weak PFM or with difficulty contracting the PFM in isolation.
- Whether the addition of any of the following adds benefit to PFMT: intravaginal resistance, cues to exercise, or bladder training.
- Whether the addition of PFMT to either vaginal cones or duloxetine adds benefit.

#### **c) Vaginal cones (VC)**

- If the combination of VC with PFMT is an intervention of interest for women then this combination of therapies could be explored further. VC could be used as an overload progression to active PFM strengthening exercises.

Thus, a VC programme could be offered to women with a demonstrated minimum PFM strength level and could be aimed at either additional strength training by pulling on the cone for three series of eight to 12 contractions daily [181], or endurance training, using a low-load over a sustained period of time.

#### **d) Electrical stimulation (EStim) and magnetic stimulation (MStim)**

- *There is a need for studies to elucidate the purpose and biological rationale for EStim in different diagnostic groups, so these can then be tested and compared in clinical trials.*
- Comparisons of EStim with other treatments that seem to be effective such as PFMT, vaginal cones, and bladder training are more important than comparison of EStim with sham.
- There is also scope for trials of EStim as an adjunct to treatments that seem to be effective such as PFMT, vaginal cones, and bladder training.
- Of the MStim protocols investigated to date, it seems that both sacral root MStim and home-based MStim, are worthy of further investigation.

#### **e) Scheduled voiding regimes, especially bladder training (BT)**

- There are several BT variables that could be investigated in future trials including the instructional approach, supervisory intensity, strategies for controlling urgency, scheduling parameters, frequency of schedule adjustments, length of treatment, and use of adjunctive treatments.
- Although additional studies are needed that examine the effect of BT versus no treatment, more important clinically are trials of BT versus another active treatment such as PFMT or drug.
- The potential benefits of combining BT and anticholinergic/antimuscarinic drug need further investigation, including comparisons of BT plus drug versus drug alone, and BT plus drug versus BT alone.
- Research is needed on habit training in women with a consistent pattern of UI who are ambulatory and cognitively intact.

## **B. URINARY INCONTINENCE IN MEN**

UI in men remains under-reported and under-studied in comparison to studies including women. The report from the 3<sup>rd</sup> ICI indicated that the prevalence of UI and LUTS in men ranged from eight to 23% depending on the method of data collection, population accessed, and location [281]. Despite the prevalence of UI and LUTS in older men, the only aspect which continues to receive systematic consideration with respect to conservative management is post-prostatectomy urinary symptoms. Thus, the focus of this section is the prevention and treatment of UI after prostatectomy for benign or malignant disease. All prostatectomy types and approaches were considered for inclusion

including radical prostatectomy (open radical retropubic or perineal, laparoscopic, and robotic) or endoscopic procedures (such as transurethral prostatic resection, high intensity microwave therapy).

#### **• Aetiology of UI after prostatectomy**

For purposes of the current review, the reader is directed to the report from the 3<sup>rd</sup> ICI [281] in which the aetiology of UI after prostatectomy is covered in detail (see report from Committee 13: Surgery for urinary incontinence in men). In brief, risk factors which have been repeatedly identified for UI after radical prostatectomy and transurethral resection of prostate (TURP) are abnormalities of detrusor contractility [282] and age [283]. Other related factors include neurovascular injury during surgery, previous TURP [284], preoperative radiotherapy, trauma, spinal cord lesion, new obstruction such as prostatic regrowth, bladder neck contracture, urethral stricture, Parkinson's disease [285, 286], dementia, and medications [281].

#### **• Treatment**

The primary conservative treatment for UI after prostatectomy remains physical therapies with or without some form of BF. PFMT, along with anal EStim, BF or transcutaneous electrical nerve stimulation (TENS), MStim, and even pharmaceuticals have all been utilised and reported as modestly successful in some trials and not in others.

A literature search of relevant systematic reviews and reports of RCTs and quasi-RCTs was performed (see appendix). No other types of study design were considered. The report of the 3<sup>rd</sup> ICI [281] identified 14 relevant RCTs on conservative management of UI post radical prostatectomy (n= 12) or TURP (n=2) [287-300]. Seven new published trials and two abstracts [301, 302] were found, all in men undergoing radical prostatectomy [301-309]. One was excluded as it was not published in English and no translation was available [306]; another trial [288] was not an RCT but assigned the first 25 to control and the next 25 to treatment. This trial had been included in the previous ICI report but has been excluded from the current review because of the potential for bias in a non-randomised trial. Thus, one trial was removed and eight trials added to the current evidence base for a total of 20 trials on some aspect of continence treatment after radical prostatectomy and two on treatment after TURP.

## **I. LIFESTYLE INTERVENTIONS**

Typically, as part of standard practice in the treatment of people with UI, lifestyle recommendations are made to stop smoking, maintain a healthy body weight,



avoid or reduce caffeine containing drinks, avoid constipation, and to drink approximately eight glasses of liquid a day. Whether these factors have a direct impact on continence is suggested but not known. To date, no trials have addressed the topic of lifestyle interventions for men with UI. Nevertheless, in practice, it seems reasonable to offer advice on healthy lifestyle choices that may reduce or delay the onset of continence problems.

## II. PELVIC FLOOR MUSCLE TRAINING (PFMT)

The quality of trials included in this update of PFMT has improved from earlier ICI reports although heterogeneity and varying outcome measures continue affect the ability to compare trial findings.

### 1. PREVENTION

Trials in this section addressed the effect of PFMT initiated preoperatively or postoperatively but before continence/incontinence was established. Four new trials were found [301, 303, 305, 309] making a total of nine trials in this category [287, 294, 295, 297, 300, 301, 303, 305, 309].

Two trials utilised preoperative BF assisted instruction in PFMT followed by postoperative self-PFMT at home, and compared this with postoperative verbal instruction [287], or usual postoperative exercise advice [303]. In Bales (2000) (n=100; 93 completing) initial instruction on PFMT was provided using surface BF two to four weeks prior to radical retropubic prostatectomy. The control group received only postoperative verbal instruction; both groups had written information and were encouraged to practice PFMT four times daily once the catheter was removed two weeks after surgery. In Burgio (2006) (n=125; 102 completed), participants had one BF session (rectal probe with three small balloons) two to four weeks preoperatively, plus daily pre and postoperative home exercises. The control group had no therapist contact and practiced postoperative exercises as per standard care (starting and stopping stream). Primary outcome was continence, defined as use of zero or one pad per day [287] or no leaks recorded on bladder diary [303]. In Lilli (2006) (reported only in abstract), 90 participants (all completed) were assigned to PFMT plus BF (method/type not described) or PFMT alone. Both groups were encouraged to do home exercises. Primary outcome was pad use, assessed at one, three, and six months post surgery.

One trial compared active pre- and post-operative PFMT programme to no PFMT instruction [297] and another pre- and post-operative instruction versus post-operative instruction [295]. Participants in Parekh (2003) (n=38; 36 completing) had two pre-operative and four post-operative sessions of anal probe BF

plus post-operative home PFMT using an exercise ball, or no intervention (similar to Burgio (2006) above). Continence was assessed by patient reported number of pads and continence questionnaires at six, 12, 16, 20, 28 and 52 weeks post surgery. Sueppel (2001) randomised 16 men (no dropouts) to two pre-operative and five post-operative sessions of anal probe BF or five post-operative sessions. Both groups were asked to do self directed home PFMT. Continence and quality of life were assessed by AUA symptom score and quality of life questionnaire, pad count, 45 minute standardised pad test, and a leakage questionnaire at six weeks and one year post surgery.

In the study by Mathewson-Chapman (1997) all 51 (50 completing) participants had one session of pre-operative instruction using BF and verbal coaching and were then randomised to intervention or control groups. The intervention group (n=26) practised PFMT daily with a home BF unit (anal probe) from weeks three to 12 after surgery, whereas the control group (n=24) only followed written instructions. Both groups completed questionnaires, pad counts, and 24 hour pad tests at two, five and 12 weeks post-operatively.

Finally, three trials commenced post-operative PFMT immediately after catheter removal [300, 305, 309]. Filocamo (2005) randomised 300 men to a PFMT programme or no formal instruction. Outcomes were ICS Male Questionnaire (ICS MaleQ), pad count, and pad test (one and 24 hours). Overgård (in press 2008) assigned 85 men (80 completing) preoperatively to one of two groups: 42 received weekly 45 minute PFMT guided by a physiotherapist and 43 received one PFMT training session then practiced home exercises. Outcomes were proportion of continent men, defined as self-report of no pads, 24 hour pad test, subject report and PFM strength obtained at six, 12, 24 and 52 weeks post surgery. Immediately after catheter removal, Wille (2003) assigned 139 subjects (128 completing) to one of three active groups: PFMT (method unclear), encouragement to do home exercises, and a three week rehabilitation programme (not described); twice daily PFMT with ESTim taught with surface anal electrodes, or PFMT with ESTim and BF using anal probe. All subjects received three therapist guided sessions immediately after surgery and at three and six weeks plus performed PFMT at home; the two intervention groups also utilised an ESTim or BF device twice daily at home (see also C.3). Outcomes were pad count with continence defined as use of zero to one pad per day or 20 minute pad test (continence was less than 1g urine loss) collected at three and 12 months post surgery.

### 1. QUALITY OF DATA

Of the nine trials in this section, only Burgio (2006) reported adequate random allocation concealment. With regard to blinding of outcome assessment, Bales (2000) attempted to control for bias in outcome

assessment by having a nurse not directly involved in the study interview the subjects. It is not clear whether he/she was blinded to allocation group. Overgård (in press 2008) had surgeons blinded to group allocation. Wille (2003) had data analysed by a professional statistician. Burgio (2006) had outcomes assessors blinded to group assignment. Dropouts were described by Burgio (2006), Filocamo (2005), Overgård (2008), and number of dropouts was provided by Wille (2003) but reasons were not described. Sueppel (2001) indicated incomplete data but did not describe dropouts. Burgio (2006), Filocamo (2005) and Wille (2003) described ITT analysis.

## 2. RESULTS

**i) Preoperative PFMT instruction with postoperative home PFMT versus control [287, 301, 303]:** Burgio (2006) reported a statistically significant difference in favour of PFMT in time to regain continence ( $p=0.03$ ) and proportion of men with severe or continual leakage measured by voiding diary at six months, 32/54 PFMT (59%) versus 40/51 controls (78%) ( $p=0.04$ ); additional data provided by the authors on the 24 hour pad test did not indicate a difference between groups. Bales (2000) found no significant group difference on participant report of number of pads used or time to return to continence. Lilli (2006) did not find a difference between participants who received BF in addition to PFMT at any of the time points; at six months, 32/45 (71%) and 30/45 (67%) respectively were reported as dry and no use of pads. In the Lilli trial both groups received intervention and it is not clear how intensive the pre-operative PFMT instruction was.

**ii) Pre-operative PFMT instruction followed by supervised post-operative PFMT versus post-operative PFMT [294, 295, 297]:** Parekh (2003) found more men continent in the pre and post treatment group at 12 weeks but there was no statistically significant difference at any other time point to 12 months. Sueppel (2001) reported that at one year the pre and post treatment group had less leakage on a standardised 45 minute pad test compared to the postoperative group (mean 2.8g (range 0.0-13.0g) versus 33.3g (range 0 to 194g)); statistical significance was not reported. Mathewson-Chapman (1997) found no statistically significant differences between groups at any of the time points.

**iii) Post-operative PFMT immediately after catheter removal (no pre-operative instruction) [300, 305, 309]:** The Filocamo (2005) trial favoured treatment at three months with 39/50 (78%) versus 105/150 (70%) reporting one or fewer pads a day. At six months 115 in the treatment group and 48 in the control reported themselves as 'completely dry' and at 12 months 134 and 101 were dry respectively. Differences between treatment and control were 96% versus 65% ( $p=0.00001$ ) at six months and at one year 99% and

88% (not significant). There were no significant differences between groups on 24 hour pad test (Filocamo, personal communication). Overgård (in press 2008) reported no difference between groups for proportion dry (no pads) or 24 hour pad test at three months; however, at 12 months, the proportion of continent men was statistically significantly greater in the treatment group (33/36; 96%) versus the control (28/39; 72%) ( $p=0.028$ ). PFM strength and 24 hour pad test results did not differ between groups at any of the time points. Of note is that 20 participants in the treatment group did not receive face to face instruction due to distance from facility but rather followed detailed instructions provided on a DVD. Wille (2003) did not find a difference between groups at three and 12 months but all three groups received some sort of intervention.

## SUMMARY

Nine trials were found addressing prevention of UI in a total of 803 men and used a variety of pre-operative or post-operative PFMT based interventions, or a combination of both. Any differences between experimental and control groups were modest and short term; differences did not appear to be sustained up to 12 months post surgery. A particular challenge in evaluating the trials is that participant reported outcomes in three of the recent studies [303, 305, 309] all indicate some level of improvement in the treatment groups; however, there are no clear differences in pad test results in any of the nine trials. Because all the studies reviewed were generally small, varied in design, and measures differed, it is difficult to interpret them as a whole. Whilst the evidence that therapist delivered PFMT with or without BF before or after surgery improves continence recovery after radical prostatectomy remains inconsistent; a growing number of recent trials suggest that men who undergo some sort of conservative management including PFMT will achieve continence in a shorter time frame than non-treated men but this difference is not significant at 12 months post surgery (Level of Evidence: 2).

Further discussion is needed on the outcomes of most importance. It is possible that the emphasis on quantitative outcomes is not meaningful to participants; men appear to find therapy personally helpful and value the direction provided by a therapist.

## RECOMMENDATIONS

Some preoperative or immediate post-operative instruction in PFMT for men undergoing radical prostatectomy may be helpful (Grade of Recommendation: B); whether this is in the form of 'hands on' therapy of verbal instruction and support

remains unclear. Studies comparing the effectiveness of pre- versus post-operative PFMT, and the number of sessions required, are needed so that practitioners may advise men about pre-operative preparation and budget conscious health boards can make informed decisions on programme funding. In designing such studies, the natural history of UI after radical prostatectomy must be taken into account because the spontaneous recovery rate means that sample sizes must be large to detect any differences between protocols.

## 2. TREATMENT

### **a) PFMT with digital rectal feedback after radical prostatectomy**

Two additional trials were identified [304, 307] resulting in a total of four [292, 293, 304, 307] in which PFMT was taught using digital rectal feedback (DRE) in at least one arm.

Dubbleman (2004) randomised 70 (63 completed) men to physiotherapy (not described) or written material on PFMT. Subjects received nine or fewer therapist-guided PFMT sessions using DRE starting at one week postoperatively. Joseph (2000) randomised a mixed group of 10 men (four radical retropubic prostatectomy and six radical perineal prostatectomy) to weekly verbal teaching plus DRE or BF assisted PFMT over a four week period. Manassero (2007) randomised 107 (94 completed) men to urologist taught PFMT using DRE (unclear how often) plus daily home exercises for up to a year; the control group did not receive any instruction. Participants were assessed at one, three, six and 12 months with a home pad test, VAS and DRE. In Moore (1999) 63 men (58 completed) were randomised to one of three groups: control (written materials only and no therapist contact), PFMT using DRE and abdominal palpation, or PFMT augmented with ESTim via anal probe. Both treatment groups met with the therapist twice a week for up to 12 weeks.

### **1. QUALITY OF DATA**

Only one trial [293] reported adequate random allocation concealment. Data were collected by blinded assessors in one trial [307]. In another, data were collected and outcomes assessed by the primary investigator who had a direct involvement in the trial, although treatment was provided by a therapist blinded to the control group outcomes [293]. Three studies described reasons for dropout [293, 304, 307], but none indicated how withdrawals/dropouts were dealt with in the analysis.

There was considerable variation in the type and intensity of interventions, follow-up ranged from six and a half months to 12 months, and primary outcomes varied from pad test, pad count or subject report.

## 2. RESULTS

Between them, the four trials had a total of 225 participants with complete data. Three of the four studies did not find statistically significant differences between the groups. Dubbelman (2004) found no significant differences at 26 weeks post catheter removal between physiotherapy and written PFMT information groups in one and 24 hour pad tests. Similarly, in the small study by Joseph (2000) no differences were found in outcomes measured by 24 hour pad test, voiding diary or quality of life (IIQ-7) between PFMT and PFMT with BF groups. Moore (1999) found no differences in pad test between PFMT and PFMT with ESTim groups but confidence intervals were wide and subjects began treatment anywhere between eight weeks and 12 months post surgery.

Manassero (2007) reported a statistically significant difference ( $p=0.01$ ) in proportion of continent subjects (<2g on 24 hour pad test) in the PFMT group at three, six and 12 months (54%, 33%, 17% compared to 78%, 60%, and 53% for the controls), with 9/54 versus 21/40 incontinent at 12 months.

### **SUMMARY**

In the most recent and largest trial [307], which compared PFMT taught by DRE or no instruction there was a statistically significant difference in the proportion of continent men (based on 24 hour pad test) in the treatment group at three, six and 12 months. In the three other smaller and earlier trials, in which the control groups had written or verbal instruction on PFMT, there were no statistically significant differences between groups on pad test. (Level of Evidence: 2). Clinical heterogeneity meant that it was difficult to consider the findings from the studies as a whole.

### **RECOMMENDATIONS**

Some instruction in PFMT may be helpful; it is not clear whether PFMT taught by DRE offers any benefit over and above verbal or written instruction (Grade of Recommendation: B). Further well designed studies are needed to test this hypothesis.

### **b) PFMT with BF after radical prostatectomy**

Two new trials were available [308][302] (abstract only), to make a total of six evaluating PFMT with BF compared to a non active or alternate treatment commencing after radical prostatectomy [290, 291, 296, 299, 302, 308].

Three of these trials compared PFMT with BF versus no treatment, placebo treatment, or usual care. Franke (2000) randomised participants ( $n=30$ ; 15 completing) to PFMT with BF versus no treatment. PFMT was delivered via BF from perineal patch electromyography



in weeks six, seven, nine, 11 and 16 postoperatively, supplemented with home exercises. The control group received no written or verbal instruction about PFMT. Outcomes were number of incontinent episodes and 48 hour pad test averaged over 24 hours. Van Kampen (2000) randomised 102 men (98 completing) to PFMT with BF or placebo EStim. Treatment group subjects received detailed instruction on PFMT, received active treatment once a week and practiced home exercises three times a day; the control did not receive any instruction and had weekly placebo EStim. Both groups did home 24 hour pad tests daily until continent and a one hour pad test in the physiotherapy clinic at 12 months. Ribeiro (2008) assigned 73 men (all completed) to PFMT or 'usual care' consisting of instructions to contract PFM (details not provided). Treatment consisted of weekly PFMT up to three months and practiced home exercises. Primary outcome was 24 hour pad test at one, three and six months.

Three trials compared PFMT with BF versus verbal instruction and home PFMT [290, 296, 308]. Floratos (2002) randomised 42 men (all completed) to PFMT with EMG BF, 15 sessions three times a week for five weeks or one session of DRE guidance and verbal instruction starting approximately one week after catheter removal. Both groups practiced daily PFMT at home. Primary outcome was one hour pad test at one, two, three and six months. Moore (in press 2008) compared verbal instruction and written materials on home exercises versus weekly therapist provided PFMT with BF via anal probe plus daily home exercises (n=205; 166 completing). Primary outcomes were 24 hour pad test at four, eight, 12, 16, 28, and 52 weeks post surgery. Opsomer (1994) randomised 43 (39 completing) men to two sessions a week of PFMT with BF plus EStim (method not described) or to one session of verbal instruction on PFMT plus home exercises. Continence was measured by 48 hour pad test.

## 1. QUALITY OF DATA

Two trials appeared to have adequate random allocation and concealment [299, 308], although in the latter treatment was provided by the primary investigator who was aware of group assignment. In Moore (in press 2008), therapists were blinded to the results of the control group; pads were weighed by a person unaware of group assignment; data was entered by a data manager. Van Kampen (2000) had pad weights done directly by the patient at home. Dropouts were accounted for and described fully by Moore (in press 2008) and Van Kampen (2000), partially by Opsomer (1994). There was a high dropout rate in Franke (2000) and these data were not accounted for in the analysis. There were no reported dropouts in the Floratos (2002) or Ribeiro (2008) trials. Floratos (2002), Moore (in press 2008), Van Kampen (2000) all described ITT analysis.

Continence evaluation was different for each study as well as timing of recruitment and intervention, content of intervention and control treatments. Outcomes varied widely: percentage of participants pad free [291], one hour pad test [290], 24 hour pad test (<2g=continent, Ribeiro 2008; Van Kampen 2000; <8g=continent, Moore (in press 2008) and a pad test not described [296]. Follow up ranged from 12 weeks to one year.

## 2. RESULTS

Three trials compared PFMT and BF to a control condition. At 12 weeks, Ribeiro (2008) reported statistically significant difference in 24 hour pad tests (51g, SD 119 versus 197g, SD 269,  $p=0.026$ ), but there was no statistically significant difference at six months post surgery.

In the Van Kampen (2000) trial at eight weeks, there was a statistically significant difference in mean urine loss (30g treatment; 82g control) but by 12 weeks this difference was no longer statistically significant. Van Kampen (2000) also found a statistically significant difference in proportion of treatment group participants reporting continence at three months compared to control (43/50 (88%) versus 29/52 (56%)), but no differences beyond three months. Franke (2000) reported no difference between groups on 24 hour pad test or pad-free rates but sample was small and dropout rate nearly 50%.

None of the three trials that utilised PFMT and BF versus verbal or written instruction on home PFMT showed statistically significant differences between the groups. Outcomes were measured using one hour pad test or number of pads [290], 24 hour pad test, International Prostate Symptom Score (IPSS), or subjective report of continence at eight, 12, 16, 18, or 52 weeks [308], and pad test at 12 weeks [296].

## SUMMARY

Health professional instruction in PFMT with BF when compared with control conditions seemed to reduce the amount of leakage in the early weeks of recovery (up to three months). However, comparisons of PFMT with clinic BF versus PFMT at home did not find similar differences. Based on the current evidence the addition of EStim or BF does not appear to improve continence outcomes over and above PFMT. (Level of Evidence: 2). However, BF may be less difficult for the therapist than DRE.

It seems those who do PFMT compared to no active treatment, might have less leakage in the first three months postoperatively. To the patient, this early improvement may be important in activity, well-being, and socialising. Such concepts require further investigation.



## RECOMMENDATIONS

The use of BF in clinic, over and above home PFMT, is currently a therapist/patient decision based on economics and preference. (Grade of Recommendation: B).

### c) PFMT after TURP

Little study has been dedicated to UI after TURP. In fact, the issue has been largely ignored, perhaps because the incidence of UI after TURP is reported to be very low. Two trials were potentially eligible for inclusion [292, 298], but the latter trial was grouped with studies of PFMT after radical prostatectomy because the 11 participants comprised one following TURP and 10 following radical prostatectomy. No new trials were found on PFMT after TURP. There is one on-going large trial with results anticipated in 2010 [310].

Porru (2001) randomised 58 men booked for TURP. At the baseline preoperative visit, PFM strength, tone and grading were established with a DRE. There were weekly follow up sessions for four weeks post TURP. It was unclear what information, if any, the control group received.

#### 1. QUALITY OF DATA

It was not clear if random allocation was concealed or outcome assessment blinded, and the proportion of dropouts was not stated.

#### 2. RESULTS

While there were statistically significant differences in UI and post micturition dribble as measured by voiding diary and IPSS, there was no statistically significant difference at four weeks.

#### SUMMARY

In the absence of sufficient data from rigorous and well-reported trials it is not known if PFMT reduces UI following TURP. More systematic investigation of the the natural history of UI after TURP is probably needed, to establish the potential cost/benefit of intervention, before further trials are initiated.

### 3. OTHER LUTS

Post micturition dribble (PMD) is an annoying problem experienced by many men of all ages likely due to a failure of the bulbocavernosus muscle to evacuate the bulbar portion of the urethra, causing pooling of urine in the bulbar urethra which then dribbles with movement.

The 3rd ICI identified two RCTs on conservative management of PMD [289, 311] and no further trials were found for the current update. No trials were found on prevention of PMD and it is unlikely that such studies would be undertaken because of the longitudinal nature of such an exploration.

### a) PFMT for post micturition dribble (PMD)

Two RCTs totalling 85 participants who had not undergone prostatectomy have been reported in which PFMT and/or urethral milking were compared to verbal instruction and lifestyle changes [289, 311]. Paterson (1997) assessed men assigned to one of three groups: daily PFMT, urethral milking, or lifestyle changes (consisting of relaxation therapy and oedema management) using four hour pad test at five, nine, and 13 weeks. In a study on erectile dysfunction [289], over 65% (n=36) of participants also complained of PMD. Participants were randomised to PFMT using BF (five weekly treatments plus home exercises) or lifestyle advice addressing smoking, alcohol intake, general fitness, a healthy diet, weight reduction, and saddle pressure. Outcome was patient report using a standardised questionnaire administered by an interviewer unaware of group assignment.

#### 1. QUALITY OF DATA

It was not clear if allocation was adequately concealed in either study. In both studies data collection was done by the researchers but data analysis was done by a separate party.

#### 2. RESULTS

Paterson (1997) found both PFMT and urethral milking were equally effective and better than lifestyle changes. Dorey (2004) found that the PFMT group not only reported a significant improvement in erectile function measured by International Index of Erectile Function ( $p=0.001$ ) but also a significant improvement in PMD measured by standardised questionnaire (67% improved in treatment group compared to 7% of controls;  $p<0.002$ ).

#### SUMMARY

Based on two small studies, it seems that PFMT and urethral milking might both be effective in the control of the annoying symptom of PMD (Level of Evidence: 2).

## RECOMMENDATIONS

Men can be offered instruction to do a strong PFM contraction immediately after voiding, or urethral massage to empty the urethra, to improve symptoms of PMD (Grade of Recommendation: C).

### 4. FACTORS AFFECTING OUTCOME

Based on the current evidence, it appears that time from surgery to implementation of exercises does affect outcome and that by three months after surgery less improvement is noted. Future trials could consider analysis to evaluate the effect of length of time from prostatectomy surgery, co-morbid conditions, prior pelvic surgery, and medications (including smoking and alcohol use) on treatment outcome.

### III. ELECTRICAL STIMULATION (ESTIM)

Electrical stimulation (ESTim) is reported to be effective in the treatment of both UUI and SUI in men [223, 235, 312].

For men with DO and UUI there is often no known cause (idiopathic DO), although in some men symptoms can be associated with neurogenic disorders and to bladder outlet obstruction such as benign prostatic hyperplasia. It is believed that ESTim for UUI acts through reflex inhibition of pelvic efferents or activation of hypogastric efferents through stimulation of the afferent input in the sacral route [225, 312].

Male SUI is rare but radical prostatectomy and, rarely, TURP may cause sphincter injury leading to SUI [293, 313-315]. DO, poor compliance and decreased contractility may also be factors related to post-prostatectomy incontinence [293, 316]. For male SUI, ESTim can be used to enhance contractility of the PFMs in the same way as female SUI [317, 318], and may be used as stand alone therapy, as a second-line treatment when other methods have failed, or in combination with PFMT [300, 319]. It has been postulated that continence is regained more rapidly [320] and the duration of the application of ESTim is reduced when PFMT is augmented with ESTim [320, 321]. ESTim is also believed to be more effective in patients who are initially unable to identify and contract the correct PFMs [213]. Interestingly, it is generally agreed amongst those using ESTim that it should be avoided for those with carcinoma of the bladder for fear that ESTim may increase abnormal cell activity [322]. Although there are no data to confirm or refute this, many physiotherapists are unwilling to use ESTim for patients with cancer and, therefore, post radical prostatectomy. Further research is needed to clarify this risk.

This section will examine evidence for the use of ESTim for the prevention and treatment of UI in men. Questions addressed are:

- What is the most appropriate electrical stimulation protocol?
- Can electrical stimulation prevent UI?
- Is electrical stimulation better than no treatment, placebo or control treatments for UI?
- Is electrical stimulation better than other treatments?
- Does the addition of electrical stimulation to other treatments add any benefit?
- What is the effect of electrical stimulation on LUTS other than UI?
- What factors might affect the outcome of electrical stimulation?

A literature search for reports of relevant systematic reviews and reports of RCTs and quasi-RCTs was performed (see appendix). No other types of study design were considered. Since the 3<sup>rd</sup> ICI only one new RCT [323] was identified and included in this chapter. A previous relevant Cochrane systematic review [324] was updated, and the new review [319] contributed to this section.

#### 1. PREVENTION

There have been no studies on the effect of ESTim for prevention of UUI or SUI (including post prostatectomy UI) in men.

#### 2. TREATMENT

One systematic review was identified [319], along with nine RCTs [223-226, 239, 293, 296, 300, 323] of which one was new since the previous report [323]. An abstract of a trial by Ceresoli [325] reported data for men, but the separate effects of ESTim could not be assessed and the study was excluded.

##### *a) Is ESTim better than no treatment, placebo or control treatments?*

No studies were identified that compared ESTim with no treatment or a control. Two placebo controlled trials were identified, and both included men and women. One included 29 men and 39 women with UUI [224], and the other 30 women and five men with SUI [223]. In the latter trial, four men had post-prostatectomy incontinence and one had sphincter deficiency due to sacral cord tumour.

#### 1. QUALITY OF DATA

Both trials blinded patients and doctors to treatment allocation [223, 224]. For ESTim in UUI, three patients (8%) in the active group and one (3%) in the sham group dropped out, and two patients in each group discontinued the treatment due to adverse events (5.4% and 6.5% respectively).

For ESTim in SUI, two of 35 patients (6%) dropped out and none of the patients had adverse events.

#### 2. RESULTS

*i) Men with UUI:* The authors reported statistically significant differences in cure (22% active and 4% sham) and improvement rates (81% active and 35% sham) between the groups; data were not differentiated for men and women [224].

*ii) Men with SUI:* None of the participants in the sham group were cured or improved. One man in the active ESTim group was cured and a second was improved; five men participated in the study but it was not clear how many were allocated to sham and how many to active ESTim.

## SUMMARY

In the absence of sufficient data from rigorous and well-reported trials it is not known if EStim, as a stand alone treatment for male UUI or SUI, is better than no treatment, placebo or control treatments.

### ***b) Is one approach to EStim better than another?***

EStim protocols for men are similar to those for women and like protocols in women vary widely. Intermittent, short-term stimulation (or maximal electrical stimulation) using a portable stimulation device at home [323] or in clinic [239, 293, 300] has most often been used. Rectal or surface electrodes are most common; surface electrodes are positioned over the perineal region [323].

For the treatment of SUI (and post-prostatectomy incontinence) EStim is most often used in combination with PFMT, but also as a monotherapy [239]. Usually a rectal electrode is used, and the stimulation artificially stimulates the pudendal nerve and its branches to cause direct reflex responses of the urethral and periurethral striated muscles [293, 323].

Frequencies of 14Hz have been used for UUI [323], while 20Hz [239], 27Hz [300] and 50Hz [293] have been used for SUI. Pulse form is mostly biphasic; pulse width varies and includes 300 microseconds [239], 250 milliseconds [323], one [293] and five seconds [300]. Duration of the stimulation varies as well, from 15 minutes [300] to 30 minutes [293], and from twice daily [300] [239] to twice weekly [293]. Duration of treatment has ranged from one month [239], to three months [300].

## SUMMARY

So far, no studies comparing EStim protocols have been identified. The most appropriate EStim protocol for different types of symptoms is unknown. EStim protocols for men have been developed from studies in women. The variability in the findings of the trials included in the remainder of this section may in part be due to differences in the effectiveness of the wide range of protocols that have been tested. There are many differences in clinical application that have not yet been investigated. Some populations or subgroups of men may benefit from EStim more than others, but this observation has not yet been investigated.

### ***c) Is EStim better than other treatments?***

Three RCTs have compared EStim with other treatments. In a three arm trial Yokoyama (2004) compared EStim, magnetic stimulation (MStim) and verbal/written instruction in PFMT in men with post-prostatectomy incontinence [239]. Two trials compared

EStim with MStim [225] or medication [226] in men and women with UUI.

## 1. QUALITY OF DATA

Yamanishi (2000b) compared EStim with MStim for inhibition of DO in a urodynamic study of 32 patients (15 males, 17 females; aged 62.3 years, SD 16.6) [225]. Random allocation concealment was adequate; results were not reported by gender.

Yokoyama (2004) compared EStim, MStim and verbal/written instruction on PFMT in men with post-prostatectomy incontinence [239]. This study did not report method of randomisation, whether or not allocation was adequately concealed, or blinding of patients, healthcare providers or assessors. The number of treatments, duration and intensity seemed to be different between groups. Home EStim comprised 15 minutes of twice daily stimulation for one month, at maximum tolerable level of intensity. For MStim, treatment sessions were 20 minutes, twice a week for two months, with stimulating intensity gradually increased up to the tolerable level. PFMT consisted of PFM exercises in supine position with instructions how to contract the anal muscles selectively. Verbal and written instructions for home practice were given to the patients. Patients were followed up for six months.

Soomro (2001) compared EStim (Transcutaneous Electrical Nerve Stimulation, TENS) with medication (oxybutynin) for UUI in 43 patients (13 men, 30 women) with DO using a crossover design [226]. Results were not reported by gender. No information about randomisation procedure, random allocation concealment, blinding of observers, or drop-outs (if any) was given. Oxybutynin was started at a dose of 2.5mg orally twice daily and titrated to 5mg orally three times daily by day seven. Dual channel TENS with two self-adhesive pads connected to the stimulator and applied bilaterally over the perianal region (S2 to S3 dermatome) was used. Stimulation parameters were set at a frequency of 20Hz and a pulse width of 0.2msecs on a continuous mode. TENS duration was up to six hours daily.

## 2. RESULTS

***i) Men with DO:*** In the urodynamic study of EStim versus MStim, bladder capacity at first desire to void and maximum cystometric capacity increased significantly in both groups compared to baseline; the increase in maximum cystometric capacity was statistically significantly greater in the MStim (106%, SD 130) than the EStim group (16%, SD 34) ( $p=0.0135$ ).

Soomro (2001) reported that EStim and medication improved subjective parameters but only oxybutynin showed statistically significant improvements in objective urodynamic parameters such as bladder

volume at first desire to void and at first overactive detrusor contraction.

**ii) Men with post-prostatectomy incontinence:**

Amount of leakage in the 24 hours after catheter removal was 684g, 698g and 664g for the EStim, MStim and PFMT groups respectively. At one month, it was 72g, 83g and 175g (EStim versus PFMT,  $p < 0.05$ ), and at two months was 54g, 18g and 92g respectively (MStim versus PFMT  $p < 0.05$ ). Finally, six months later, the average 24 hour leakage weight was less than 10g in all groups. Quality of life measures decreased after surgery, but gradually improved over time in all groups. No complications were noted in any of the groups. The authors concluded that both MStim and EStim offered earlier continence compared with PFMT after radical prostatectomy.

**SUMMARY**

There were few men in either of the two trials comparing EStim and MStim, the single trial comparing EStim with verbal/written instruction in PFMT, or single crossover trial comparing EStim with oxybutynin. In the absence of sufficient data it is not known if EStim is better than MStim or written/verbal instruction in PFMT or oxybutynin for UI in men.

**d) Does the addition of EStim to other treatments add benefit?**

Four RCTs have been identified investigating the addition of EStim to other treatments for men with post-prostatectomy incontinence [293, 296, 300, 323]. Opsomer (1994) compared intensive PFMT plus EStim (once a week) plus BF versus simple PFMT in 43 men. As it was not possible to differentiate the effects of additive EStim from adjunctive BF this study was not further considered. No trials were found in men with UUI.

**1. QUALITY OF DATA**

Moore (1999) compared standard treatment (verbal and written instructions about PFMT) versus intensive PFMT, versus intensive PFMT plus rectal EStim in 63 men with UI  $\geq 8$  weeks after radical prostatectomy. Randomisation was adequately concealed, there was a power calculation, and adherence to protocol was monitored using patient-recorded diaries. Five patients dropped out, three in PFMT/EStim and two in the PFMT group. In one patient dropout was related to the use of EStim (rectal pain). Intensive PFMT, which focussed on strength, endurance, speed and control, comprised physiotherapy for 30 minutes twice a week for 12 weeks. Initial contractions were of 5-10 seconds with a 10-20 seconds rest, with 12-20 repetitions. Endurance exercises focused on maintaining contractions at 65-75% of maximal strength. In the PFMT/EStim group EStim and PFMT were alternated per session. EStim was provided by a surface anal

electrode, with intensity to induce visual lifting of the levator ani. Stimulation parameters were 50Hz, biphasic pulse shape with one second burst, a one second pulse width and one second pulse trains. All therapy was performed by one experienced physiotherapist.

Wille (2003) compared PFMT alone ( $n=47$ ) versus PFMT plus EStim ( $n=46$ ) versus PFMT plus EStim plus BF ( $n=46$ ) in 139 men who underwent radical prostatectomy. Because in the group with both EStim and BF the results of each treatment modality could not be differentiated, we considered only the data from the PFMT alone versus PFMT plus EStim comparison. Randomisation, blinding of observers, and withdrawal or dropout rates were not described. Patients in the PFMT group received verbal and written instructions about postoperative PFMT from a physiotherapist, intensive postoperative physiotherapy for 20 to 30 minutes for three days, a post-discharge rehabilitation programme for three weeks (not described), and a three month home PFMT programme. In the PFMT/EStim group EStim was provided by a bioimpulser surface anal electrode for 15 minutes. EStim parameters were 27Hz, biphasic pulse shape with one second bursts, a five second pulse width and two second pulse trains. Intensity of current was controlled by each patient from 10-100%.

Hoffmann (2005) compared percutaneous EStim plus PFMT versus anal EStim plus PFMT versus PFMT alone in men with post-prostatectomy incontinence; this trial allocated 60 men per group, the intervention was for four weeks, and each patient was followed up for three months. It was not clear if random allocation was concealed or if observers were blinded. Dropouts were 22/60 in the anal EStim/PFMT group, 4/60 in the percutaneous EStim/PFMT group and 0/60 in the PFMT group. PFMT consisted of a "specialized program" of "continence training", lifestyle changes, osteopathy and "Feldenkrais Lehre" three times/week in the clinic and three times/day at home, with a daily maintenance home programme after finishing the therapy.

**2. RESULTS**

Hoffmann (2005) found that 9/60 men in the anal EStim/PFMT group reported recovery, versus 11/60 in the percutaneous EStim/PFMT group; data were not reported for the PFMT only group. Wille (2003) found more men in the PFMT/EStim group reported recovery compared to PFMT alone, but the difference was not statistically significantly different (OR 0.48, 95% CI 0.21 to 1.09).

Pad test results were not consistent. Using a 24 hour pad test Moore (1999) found a statistically significant difference in decrease of urine loss favouring PFMT over EStim/PFMT (MD -182.00, 95% CI -276.56 to -87.44). Wille (2003) found that 37% in the EStim/PFMT group were continent on pad test versus 29% in the



PFMT alone group immediately after catheter removal. At three months 77% in EStim/PFMT group were continent versus 65% in the PFMT group, with 82% and 77% continent respectively after 12 months. None of these differences at any of the three time points were statistically significant.

EStim was associated with adverse events. In Moore (1999) three out of 19 men in the EStim group dropped out because of bladder neck contractures. Hoffman (2005) reported that the main reason for dropouts was discomfort with EStim (18 of 60).

#### SUMMARY

Three RCTs investigated the addition of EStim to PFMT for men with post-prostatectomy incontinence. Data suggested no further benefit of EStim when added to PFMT over PFMT alone; the numbers in each trial were relatively small. (Level of Evidence: 2)

#### RECOMMENDATIONS

For men with post-prostatectomy incontinence there does not appear to be any benefit of adding EStim to a PFMT programme (Grade of Recommendation: B).

### 3. OTHER LUTS

No studies were identified which addressed this comparison in men.

### 4. FACTORS AFFECTING OUTCOME

#### a) Age

There are no comparisons of the effects of EStim for UI between younger and older men. While many EStim studies include participants over 50 years most studies don't include those over about 80 years [326]. In the studies of EStim for post-prostatectomy incontinence in this chapter the mean age of men is about 66 years. Although post-prostatectomy studies have included older men it may be unwise to extrapolate the effects of EStim in older men with SUI to older men with UUI, because in the former UI is usually as a result of sphincter incompetence whereas in the latter the symptoms are those of an OAB. Further, it is not known whether the efficacy of EStim for UUI in elderly men is similar to that for women [293].

#### b) Other

Many other factors, such as types of electrodes, intensity, frequency and duration of stimulation, electrode positioning, the number of treatment sessions, diagnosis and underlying cause, patient selection, and treatment adherence are plausible factors affecting outcome. Little is known about the effect of any of these and there are no trials investigating these factors in male patients.

## IV. MAGNETIC STIMULATION (MSTIM)

Background information about extra corporeal magnetic innervation, more commonly called magnetic stimulation (MStim), has been given in the section on MStim for women (see B5). MStim has also been used in men; it is unclear whether the mode of action and effects of MStim are similar in men and women. In men, MStim is used to treat UI after radical prostatectomy [239, 327] and for the inhibition of DO [225].

The questions to be addressed are the same as those for women (see B5). A literature search for reports of relevant systematic reviews and reports of RCTs and quasi-randomised trials was performed (see appendix). No other types of study design were considered. Since the 3rd ICI one further RCT has been published. Suzuki (2007) compared the effect of MStim versus sham MStim for UUI in 39 patients (23 females and 16 males). The study was not included in the review below because both groups also received PFMT, and data were not reported separately for men and women [328].

### 1. PREVENTION

No trials investigating the primary or secondary prevention effects of MStim for men with UI were found.

### 2. TREATMENT

Three RCTs were identified; two full manuscripts [225, 239] and one abstract of an ongoing study without data [327]. The trial by Yamanishi (2000b) included both men and women with UI; because the effects of MStim might be different between sexes (due to differences in the underlying aetiology of symptoms) this study has only contributed to the analysis where the researchers' differentiated the effects of treatment in men and women.

#### *a) Is MStim better than no treatment, placebo or control treatment?*

No studies were found addressing this question.

#### *b) Is one approach to MStim better than another?*

No studies were found addressing this question.

#### *c) Is MStim better than other treatments?*

Two studies were identified [225, 239]. Both compared MStim with EStim; the latter also compared MStim and PFMT. Readers are referred to section C.3.2c for a description of these studies, findings, and summary.

### 3. OTHER LUTS

No studies were found.

## 4. FACTORS AFFECTING OUTCOME

None of the included trials addressed the effect of age, or any other factor, on outcome of MStim. The relationship between age (or any other factor, such as treatment parameters, treatment adherence, or diagnosis) and the outcome of MStim has yet to be determined.

## V. SCHEDULED VOIDING REGIMENS

Scheduled voiding regimens include bladder training (BT), timed voiding (TV), habit training and prompted voiding. They are frequently combined to achieve maximum benefits. Although there is evidence to indicate that scheduled voiding regimens, especially BT and TV, are commonly used in the treatment of men with UI and other LUTS, there has been substantially less research that addresses their use in men compared to the literature on their use in women.

### 1. PREVENTION

No trials investigating the preventive effects of scheduled voiding regimens for men with UI were found.

### 2. TREATMENT

Since the 3<sup>rd</sup> ICI, there have been no new reports of BT that have included men in the study population. Five RCTs have included men; however, most included only a small number of men in the sample [55, 268, 269, 272, 277]. Two observational studies, but no RCTs, were found regarding TV. No studies were located that addressed habit training or prompted voiding in men.

#### a) Bladder training

A total of five RCTs involving 142 men met the criteria for inclusion in this review. All trials (previously described in section B6) had predominantly female participants; one RCT compared BT to BT plus caffeine reduction (seven men, 86 women) [55]; and three RCTs compared BT plus placebo drug versus anticholinergic drug therapy available prior to 1995 (six men, 28 women [277]; four men, 30 women [269]; two men, 58 women [268]). The largest RCT compared drug therapy alone (tolterodine) to drug therapy plus BT (123 men, 378 women) [272]. A sixth study was located that compared BT supplemented with drug therapy after three months, but it was excluded from review because the full length report was in Japanese and an English translation was not available [329].

As none of the trials reported outcome data separately for men, and with the proportion of male participants being so small (3%, [268]; 8%, [55]; 12%, [269]; 8%, [277]; 25%, [272], there is insufficient evidence available to comment on the effectiveness of BT in men.

#### b) Timed voiding

There have been two clinical series that investigated timed voiding in men only [259, 330]. In the first, Sogbein (1982) applied TV in incontinent men in a geriatric hospital [330]. In the second study, 20 men (ages 55 to 89 years) with persistent post-prostatectomy incontinence were advised to void every two hours and keep a daily bladder record for two weeks as a run-in to being treated with BF-assisted behavioural training [259]. Outcomes were measured by a two week voiding diary kept at baseline and during two weeks of timed voiding by patients diagnosed with SUI, UUI, and/or continual leakage.

### 1. QUALITY OF DATA

Both studies used a clinical series design and patients in both subsequently received other treatment if they were not adequately improved. In the Sogbein study, nurses checked the patients' clothing for wetness at each two-hour voiding interval and recorded the results. Data in the Burgio study were based on bladder diaries completed by the patients. Reasons for drop-out [330] and non-adherence [259] were provided.

### 2. RESULTS

Sogbein (1982) reported an 85% improvement rate in UI men in a geriatric hospital. Burgio (1989), in men with persistent post-prostatectomy incontinence, found the two hour TV schedule was used with only 12 out of 20 men, because they were either already on a voiding schedule, unwilling to go on a voiding schedule, or results were not presented because the patient was noncompliant. In five men with SUI, TV resulted in a 29% decrease of incontinent episodes; in three men with UUI, two improved and one dramatically regressed producing a 33% increase in incontinent episodes. In four patients with continual leakage, there was no reduction in percentage of wet intervals.

### SUMMARY

With limited Level 3 evidence (and no higher order evidence), there is insufficient evidence available to comment on the effectiveness of TV in men.

### 3. OTHER LUTS

No studies were identified in men.

## 4. FACTORS AFFECTING OUTCOME

#### a) Age

The five RCTs involving BT included older men, as well as women, in their study populations. Three trials specifically recruited elderly adults aged 65 to 70 years and over [268, 269, 277]. The largest trial of men recruited adults aged 18 and over with a median age of 62 years. There was no subgroup analysis related

to age and gender effects, so it is not possible to draw conclusions regarding the effect of BT in older men [272]. Voiding regimens are of particular interest for the elderly, but some are effective in younger patients with UI [253].

### **b) Other**

No studies were identified on other factors affecting outcome of TV or prompted voiding in men.

Patients who appear to benefit most from scheduled voiding regimens are highly motivated individuals without cognitive deficits. Men and women with SUI and UUI have benefited, whereas patients with severe sphincter damage (e.g. after radical prostatectomy) generally do not [253].

## **VI. COMPLEMENTARY AND ALTERNATIVE MEDICINES**

Similar to women, complementary therapies are used for the treatment of male UI. Therapies include relaxation, meditation, imagery, hypnosis and naturopathic and herbal remedies, but only trials of acupuncture therapy have been found in men with UI. Therefore, only acupuncture will be considered in the remainder of this section.

Acupuncture is a traditional Chinese modality and has been used for the treatment of urinary disturbances. Acupuncture has been reported to relieve OAB symptoms including UI due to spinal cord injury [331], and idiopathic DO or MUI [332-334].

### **1. PREVENTION**

No studies were identified on the preventative role of complementary therapies in men.

### **2. TREATMENT**

Acupuncture has been shown to improve urodynamic parameters such as bladder capacity in men with UUI [331, 332]. Acupuncture is a form of somatic sensory stimulation [334]. The mechanism by which acupuncture inhibits DO remains unclear, but suppression of the spinal and supraspinal reflexes that lead to bladder contractions is considered one of the most important mechanisms of acupuncture stimulation. In an experimental study with anaesthetised rats, an acupuncture-like stimulation of the perineal skin and muscles inhibited detrusor contraction [335, 336]. A release of neuropathies (e.g. endorphins) by acupuncture may be another possible mechanism of increasing bladder storage [334].

Acupuncture may also change sphincter activity, which may be useful for men with SUI. Urethral EMG in rats showed excitation when acupuncture-like stimulation was applied to the skin and underlying structures in the rostral half of the body, the hind paw, the perineal area, testis or urethra, while less excitation was seen

when the bulbocavernosus, sacrococcygeus or pubococcygeus muscles were stimulated [337]. Kubista [338] showed a significant increase in the urethral closing pressure. However, there has been no report on the effects of acupuncture for male SUI or post-prostatectomy incontinence.

### **a) What is the most effective acupuncture protocol?**

Acupuncture has been carried out with disposable stainless steel needles (0.3mm in diameter, 60mm in length) inserted into the bilateral BL-33 (Zhongliao) points on the skin of the third posterior sacral foramina [331-333] or several other points (BL-31, 32, 21, 23, SP-6, KI-3, LI-11, CV-1, 2, 4, 5) [339], and usually performed once or twice weekly [331-334, 340]. Acupuncture protocols vary and there is no apparent consensus between investigators. It is not known if any acupuncture protocol is more effective than another.

### **b) Acupuncture versus no treatment, sham acupuncture or any other treatment**

Only one RCT has been identified including both men and women [341], but there is no study exclusively for men. In a randomised, placebo-controlled, single-blind study among 20 elderly patients (three males, 17 females) Ellis (1990) showed that the frequency of voiding at night was reduced after acupuncture [341].

In an uncontrolled study, Kitakoji (1995) treated 11 patients (nine males, two females) with OAB including three participants with benign prostatic hyperplasia [332]. Improvement of symptoms was noted in nine, overactive detrusor contractions disappeared in six and significant improvements in both maximum cystometric capacity and bladder compliance were obtained after the treatment. Acupuncture was benefited all three patients with benign prostatic hyperplasia.

In a second uncontrolled study, Honjo (2000) reported an improvement in UI due to neurogenic DO in 13 patients (11 males, two females) with chronic spinal cord injury [331]. Treatment was repeated once a week for four weeks. UI disappeared in two and decreased to 50% or less compared to baseline in six. Maximum cystometric capacity increased significantly from 76ml (SD 62) to 148ml (SD 82) one week after the fourth acupuncture treatment.

The evidence of the effectiveness of acupuncture for men with UI is limited by the lack of controlled studies. To date, the studies are small, objective measures of UI are not included and long-term follow-up is lacking. Preliminary data from predominantly uncontrolled studies suggest that RCTs of acupuncture of UI in men are warranted.

### **3. OTHER LUTS**

In a RCT in patients with sensory urgency after TURP, Ricci (2004) reported significant improvements by

acupuncture reflexotherapy (EStim of somatic and auricular points) in terms of IPSS, QOL scores, decrease of daytime frequency and nocturia, but no improvements with the use of placebo or oxybutynin [340].

Honjo (2000) reported the effects of acupuncture on mono-symptomatic nocturnal enuresis [331]. Fifteen participants (10 males, five females) with mono-symptomatic nocturnal enuresis were treated, and nocturnal enuresis was improved in six just after the treatment and two months later seven were improved. In the six 'responders' nocturnal bladder capacity increased significantly from 201 to 334ml ( $p < 0.05$ ).

#### 4. FACTORS AFFECTING OUTCOME

Aside from Ellis (1990), reported above, who specifically recruited elderly participants there is a lack of evidence about the effect of any prognostic factor for the outcome of complementary therapies in men.

## VII. SUMMARY

Despite the prevalence of UI and LUTS in older men, the only group that has received much attention in research is men following radical prostatectomy. Overall, the effect of conservative treatment (lifestyle interventions, physical therapies, schedule voiding regimes, complementary therapies) has received much less research attention in men compared to women.

### 1. RECOMMENDATIONS FOR PRACTICE

There is generally insufficient Level 1 or 2 evidence on which to base recommendations for practice, and most recommendations are in effect hypotheses that need further testing in research.

#### a) Lifestyle interventions

- It seems reasonable for health professionals to offer men advice on healthy lifestyle choices that may reduce or delay the onset of continence problems (Grade of Recommendation: D) (New).

#### b) Pelvic floor muscle training (PFMT)

- Some preoperative or immediate post-operative instruction in PFMT for men undergoing radical prostatectomy may be helpful (Grade of Recommendation: B) (Unchanged).
- It is not clear whether PFMT taught by digital rectal examination (DRE) offers any benefit over and above verbal or written instruction in PFMT (Grade of Recommendation: B) (New).

- The use of BF to assist PFMT is currently a therapist/patient decision based on economics and preference (Grade of Recommendation: B) (New).
- Use of a strong pelvic floor muscle contraction immediately after voiding, or urethral massage to empty the urethra, can improve symptoms of post micturition dribble (Grade of Recommendation: C) (Unchanged).

#### c) Electrical stimulation (EStim)

- For men with post-prostatectomy incontinence there does not appear to be any benefit of adding EStim to a PFMT programme (Grade of Recommendation: B) (Unchanged).

## 2. FUTURE RESEARCH DIRECTIONS

There is much scope for research on the effects of conservative therapies for UI and LUTS in men. Research that is urgently needed, in the opinion of committee members, is highlighted with the use of *italics*. There are a few recommendations that apply to all future studies in men, namely:

- All future intervention studies must be designed to allow standardised and comprehensive reporting of results based on the ICS and CONSORT recommendations.
- The natural history of UI after radical prostatectomy must be taken into account in study design as the spontaneous recovery rate means that sample sizes must be large to detect any differences between protocols.
- More research is needed to find out what are the most important outcomes for men with UI, so such measures can be incorporated as the primary outcome measures in further trials.
- Data are needed to establish to the cost, and cost effectiveness, of conservative therapies in men with UI.
- Surgical approaches with laparoscopy or robotics offer promising improvements in visualisation for nerve-sparing procedures; further research should address continence and erectile function after these newer surgical procedures.

#### a) Lifestyle interventions

- To date, no trials have addressed the topic of lifestyle interventions for men with UI.
- *The effects of interventions such as weight and caffeine reduction, both of which show some evidence of benefit in women, are priorities for future research.*



### **b) Pelvic floor muscle training (PFMT)**

- A comparison of preoperative versus postoperative PFMT verbal and written feedback to reduce prevalence and severity of UI following radical prostatectomy is needed.
- Methods of PFMT instruction and supervision require further investigation. Two areas of research interest are:
  - Whether PFMT taught by DRE offers any benefit over and above verbal or written instruction.
  - The effect of group exercise. Because of the peer support that men may receive from participating in a group [342] this might be useful after radical prostatectomy; both Moore [293] and Opsomer [296] reported that support in the post operative period may be important to healthy recovery.
- More systematic investigation of the the natural history of UI after TURP is needed, to establish the potential cost/benefit of intervention, before further trials are initiated.
- The relationship between age, or any other factor, and the outcome of PFMT for UI in men has yet to be determined.

### **c) Electrical stimulation (EStim) and magnetic stimulation (MStim)**

- It is not known if pre or postoperative EStim or MStim has a role in reducing the prevalence of UI after radical prostatectomy.
- RCTs in larger samples, with long-term follow up, are needed to investigate all aspects of the effectiveness of EStim and MStim as a treatment for UI in men, including:
  - Either type of stimulation versus no treatment, sham stimulation or other control conditions.
  - Comparisons of both EStim and MStim protocols.
  - EStim versus MStim.
  - Either type of stimulation versus medication.
  - Whether the addition of either type of stimulation to other treatments adds benefit, in particular the addition of stimulation to PFMT.
- The effect of age, and other factors, on outcome of stimulation. Elderly men may have more co-morbid conditions than young men, such as dementia, changes in the secretion of vasopressin, venous insufficiency, renal disease, heart failure, drug intake, restricted mobility and constipation. A more pragmatic approach to inclusion in EStim studies is needed.

### **d) Scheduled voiding regimens**

*In the absence of trials exclusively in men, or trials that*

*report data separately for men and women, there is a pressing need for high quality RCTs with an appropriate sample size and long-term follow up to address the effects of BT, TV, habit training and prompted voiding in men suffering from UI.*

## **C. PELVIC ORGAN PROLAPSE**

Pelvic organ prolapse (POP) is common and is seen in 50% of parous women [343]. Women with prolapse can experience a variety of pelvic floor symptoms.

Treatments include surgery and conservative management. Choice of treatment depends on the severity of the prolapse and its symptoms, and the woman's general health. Conservative treatment is generally considered for women with a mild degree of prolapse, those who wish to have more children, the frail or those unwilling to undergo surgery. Conservative treatment is defined here as lifestyle interventions, physical therapies, pessaries and complementary therapies.

The aims of conservative treatment in the management of POP include:

- to prevent the prolapse becoming worse;
- to help decrease the frequency or severity of symptoms caused by prolapse (vaginal, backache, urinary, bowel and sexual symptoms);
- to avert or delay the need for surgery;
- to provide a therapeutic/diagnostic aid (e.g. to establish, when it is not clear, whether a patient's symptoms are caused by prolapse; to determine whether urodynamics are indicated prior to prolapse surgery; or to confirm suspected UI).

This section will examine the evidence for the use of conservative treatments in the management of POP utilising information from two recent Cochrane systematic reviews [344, 345], and literature identified via a search strategy summarised in the appendix.

## **I. LIFESTYLE INTERVENTIONS**

Lifestyle interventions include weight loss, reducing exacerbating activities (e.g. lifting, coughing) and treating constipation. These interventions seek to avoid exacerbation of the prolapse by decreasing intra-abdominal pressure. The extent to which any of these lifestyle interventions are effective in managing prolapse is thought to be unknown [346]. Studies that investigated lifestyle interventions for the prevention or treatment of prolapse were searched for.

## 1. PREVENTION

### 1. QUALITY OF DATA

No body of literature about the effects of lifestyle changes for the prevention of POP was found. However, several studies were identified that addressed the association between factors such as occupation (involving heavy lifting/strenuous physical activity), bodyweight and constipation, and POP. These studies are reported here.

**i) Association between POP and occupation:** Two case control studies addressed the association between occupation and surgery for POP [22, 347]. Jørgensen (1994) compared the incidence of surgery for a non-specified degree of prolapse among 28,619 Danish nursing assistants, whose occupation exposed them to repetitive heavy lifting, with 1,652,533 female population controls of similar age. No adjustment for parity was made. Chiaffarino (1999) compared 100 control women with 108 women admitted to undergo surgery for second or third degree uterovaginal prolapse and/or third degree cystocele. Adjustments were made in this study for potential confounding effects, although occupation was collected as a social class indicator and yielded no information about physical effort.

Two further case control studies, conducted in the 1980s, addressed the association between occupations and POP assessed by physical examination [348, 349]. Spornol (1983) and Bao (1989) assessed 200 and 364 women respectively to see whether occupations involving hard physical labour were associated with the risk of development of POP. In Bao (1989) women were classified according to weight carried, however in Spornol (1983) past work history was subjectively assessed as light, medium or heavy work. These parameters were not further quantified nor were the study outcome measures validated. Bodner-Adler (2007), in a case series of 96 women diagnosed and treated for second or third degree uterine prolapse over a three month period at one hospital in Nepal, reported on associated risk factors including heavy lifting/work. [350].

**ii) Association between POP and bodyweight:** Spornol (1983) also investigated the association between bodyweight and risk of POP. Hendrix (2002), in a more recent cross-sectional study of 27,342 postmenopausal women used questionnaires and a pelvic examination to investigate factors (including occupation as assessed in four broad categories, and bodyweight) associated with POP [351]. Although the large study population allowed examination of numerous associations the study was not designed specifically to determine risk factors for POP. Similarly, despite the examination for prolapse being standardised, no validated grading system (e.g. POP-Q examination) was used to measure prolapse. Four

other epidemiological studies, designed to analyse risk factors for prolapse, explored the influence of bodyweight on risk of prolapse [352-355].

**iii) Association between POP and bowel function:** Rortveit (2007) reported risk factors for symptomatic prolapse from the "Reproductive Risks for Incontinence Study at Kaiser", a population study of 2,001 randomly selected, community-dwelling women in California, aged 40 to 69 years [356]. Data were collected by a mix of self-report, interview, physical examination and medical record review. Risk factors assessed included irritable bowel syndrome and constipation. Kahn (2005) and Arya (2005) looked specifically at bowel symptoms and constipation and their relationship to prolapse in a cross-sectional study (n=1,004) and a case-control study (cases n=60, controls n=30) respectively [357, 358]. One limitation of Kahn (2005) was the use of a non-validated bowel symptom questionnaire. Arya (2005) collected data on constipation (Patient Assessment of Constipation Symptom Questionnaire) and dietary fibre intake (National Cancer Institute Dietary History Questionnaire). Jelovsek (2005) studied bowel function and constipation in 302 women presenting consecutively to a urogynaecology clinic with either prolapse or lower urinary tract symptoms [359].

**iv) Association between POP and anaemia:** Scherf (2002) examined and surveyed 1,348 women in rural Gambia, and presented data on the associations between severity of prolapse, and socio-demographic and morbidity variables, including presence of anaemia [360].

## 2. RESULTS

**i) Association between POP and occupation:** All but one [351] of the studies reported above found a positive association between occupations associated with lifting and the presence of prolapse. Danish nursing assistants were 1.6 times (95% CI 1.3 to 1.9) more likely to undergo surgery for POP than general population control women but as noted this analysis did not adjust for parity [22]; Italian housewives were 3.1 times (95% CI 1.6 to 8.8) more likely to undergo surgery for POP than professional/managerial women [347]; 68% of women with uterine prolapse reported a history of medium/heavy work compared to 40% of control women without prolapse (p=0.0001) [348], the increased risk remaining after controlling for childbirth; and female workers that generally lifted more than 20kg were more likely to have uterine prolapse than other workers [349]. Heavy work in the early post-partum period was cited by Bodner-Adler (2007) [350] as a risk factor for uterine prolapse in Nepalese women; 88% with prolapse reported doing such work.

**ii) Association between POP and bodyweight:** Spornol (1983) reported that 77% of women with POP were overweight compared with 45% of women with

no prolapse ( $p < 0.001$ ). Hendrix (2002) reported that being overweight was associated with a significantly higher prevalence of uterine prolapse by 31% (OR 95% CI 1.15 to 1.48); rectocele by 38% (OR 95% CI 1.25 to 1.53) and cystocele by 39% (OR 95% CI 1.28 to 1.51).

Also, obesity was associated with a significant 40% (OR 95% CI 1.24 to 1.59), 75% (OR 95% CI 1.54 to 1.99) and 57% (OR 95% CI 1.41 to 1.74) increase in each of these conditions respectively. Overweight women were also reported to be at increased risk of prolapse in both the British Oxford Family Planning Association Study [352] and the cross-sectional study in menopausal clinics in Italy [355]. This finding however was not confirmed by Rinne (1999) or Samuelsson (1999) who concluded that increased bodyweight/ obesity did not predispose women to genital prolapse [353, 354].

**iii) Association between POP and bowel function:**

In a cross-sectional study, Rortveit (2007) reported that current constipation, experienced monthly or more frequently, was associated with an odds ratio for symptomatic prolapse of 2.5 (95% CI 1.7 to 3.7), after controlling for age, race, education and number and type of delivery. Kahn (2005) found, in women attending for routine gynaecological care, weak relationships between prolapse severity (POP-Q measurements) and bowel symptoms, however straining at stool was found to be associated with anterior vaginal wall (measured by POP-Q point Ba) and perineal descent (POP-Q points Gh + Pb). Arya (2005) found women with prolapse had an increased risk of constipation compared to controls (after allowing for age, prior pelvic surgery and total fibre intake), and this was partially due to their lower intake of dietary insoluble fibre. Jelovsek (2005) found that neither overall POP-Q stage of prolapse nor stage of posterior vaginal wall prolapse was associated with constipation. There was no difference in the prevalence of constipation between those with UI and those with stage III or IV prolapse in this study.

**iv) Association between POP and anaemia:** Scherf (2002) found that 46% of women had prolapse on vaginal examination (most commonly cystocele: 57%), and in those not pregnant at the time, moderate/severe anaemia ( $Hb < 10$ ) was associated with a two-fold increased odds of having prolapse.

**SUMMARY**

No prospective studies of lifestyle interventions to prevent prolapse were found. There is some evidence that occupations involving heavy lifting/hard physical labour or being overweight may play a role in the development of POP (Level of Evidence: 3).

Constipation is a modifiable risk factor which perhaps has potential to impact on development of prolapse symptoms. However, evidence regarding the association between constipation or straining at stool and prolapse was conflicting. Existing studies, particularly older ones, are hampered by their cross-sectional nature, inconsistent definitions of POP and use of unvalidated outcome measures, and failure to adjust for potentially important variables (such as parity and socioeconomic status).

Anaemia is a treatable condition, either through diet or medication, which may be worth considering further in research on prevention of prolapse.

**2. TREATMENT**

No studies have been identified to date that evaluate the effectiveness of lifestyle interventions in the treatment of women with POP.

**II. PHYSICAL THERAPIES**

The primary physical therapy for POP is PFMT, with or without other adjuncts. PFMT may include PFM assessment and education, PFM exercise instruction, and PFM bracing against increased intra-abdominal pressure, for example when coughing and sneezing (termed "The Knack" [361]).

Adjuncts (such as BF) or other physical therapies (such as neuromuscular EStim) may be used. These therapies aim to improve PFM strength, endurance, coordination and function.

The promotion of PFMT for prolapse varies between treatment centres with some providing only a patient information leaflet and others giving individual instruction from a physiotherapist [362]. Research shows that verbal teaching of pelvic floor exercises alone is insufficient [363]. It is suggested that 15% of women are incorrectly 'bearing down' when trying to carry out these exercises [363]. In women with prolapse, this could further add to the strain on the area and worsen the condition.

A Cochrane systematic review has indicated that PFMT should be offered as first-line conservative management for urinary stress, urge and mixed incontinence [134]. However, its role in managing prolapse is not established [364]. Some authors have extrapolated the results of trials relating to UI, implying for example that PFMT would be effective for prolapse. The importance of clarifying the place of PFMT in the prevention and management of prolapse has been highlighted [365, 366].



## 1. PREVENTION

### 1. QUALITY OF DATA

No studies have been identified to date that evaluate the role of PFMT in prevention of POP. This lack of evidence was noted by Harvey (2003) in a systematic review of PFMT during and after pregnancy [113]. A longitudinal 12-year follow-up of women originally enrolled in an RCT of post-natal PFMT is currently underway (<http://www.wellbeingofwomen.org.uk/index.asp?PageID=279>), examining the prevalence of prolapse in this cohort who were randomised to a PFMT intervention or control group. No data are yet available. Borello-France (2007) examined 317 women without SUI, prior to prolapse surgery, to determine PFM function (Brink scale score) and prolapse stage (POP-Q) [367]. The association between PFM strength and severity of prolapse was reported.

### 2. RESULTS

Borello-France (2007) found the Brink Vertical Displacement subscore was significantly higher in women with less severe prolapse. That is, women with stage II prolapse were better able to elevate their pelvic floor than those with stage III or IV. The authors hypothesise that poor PFMs may be a contributory factor in the development of prolapse. Interventions to improve PFM function might thus prevent prolapse. However, conversely, the prolapse itself might contribute to PFM weakness.

### SUMMARY

Currently, there is no evidence from intervention studies regarding the role of PFMT or other physical therapies in the prevention of POP; improved PFM strength could prevent prolapse (Level of Evidence: 3).

## 2. TREATMENT

An evidence-base is now emerging regarding the role of PFMT in the treatment of prolapse, both as a treatment in itself and as an adjunct. Data from five completed trials are now available, two of which had been ongoing at the time of the 3<sup>rd</sup> ICI. In addition three sizeable trials are currently ongoing. Feasibility work for a further trial is in progress.

Five completed RCTs were found that evaluated the effects of PFMT in women with prolapse [368-372]. Piya-Anant (2003), Hagen (2006) and Ghroubi (2008) assessed PFMT alone as a treatment for prolapse, whilst Jarvis (2005) and Frawley (2007) focused on PFMT as an adjunct to surgery.

**i) PFMT alone:** Piya-Anant (2003) assessed the effect of PFMT in elderly women (aged 60 years or more) with genital (anterior) prolapse. This cluster RCT compared 324 control group women with 330

intervention group women; each group included women classified as having no prolapse, mild prolapse or severe prolapse. The intervention group received unspecified PFMT to strengthen the levator and perineal muscles and were instructed to exercise after one meal every day for 24 months. They were also given dietary and fluid advice. Women were followed-up every six months for 24 months allowing comparison with baseline measurements. The main outcome measure in the study, worsening of genital prolapse, does not appear to have been determined using a recognised measure. No allowance appears to have been made in the study for the presence of other types of prolapse i.e. posterior vaginal wall prolapse or prolapse of the apical segment of the vagina.

Hagen (2006) conducted a feasibility study for a RCT of a PFMT intervention in 47 women (23 PFMT, 24 controls) with stage I or II prolapse of any type in two UK centres. The intervention consisted of five physiotherapy appointments over a 16-week period, with an individually-prescribed daily PFM exercise programme. Control women received a prolapse lifestyle advice leaflet by post only. Outcome measures included: blinded prolapse assessment (POP-Q); prolapse-related symptom severity and quality of life via postal questionnaires; PFM strength (modified Oxford grading scale) (intervention group only).

Ghroubi (2008) conducted a trial in 47 women with stage I or II cystocele. Women were randomised to a conservative treatment group (PFM exercises plus advice on healthy living) or a non-treated group. Outcomes included clinical examination, the "Measurement of Urinary Handicap" (MUH) scale, urodynamic tests, the Ditrovie quality of life scale and patient satisfaction.

**ii) PFMT and surgery:** Jarvis (2005) investigated the effect of PFMT, bladder and bowel training on continence, quality of life and general health symptoms of 30 women undergoing surgery for UI and/or prolapse compared with 30 control women who received no training alongside their surgery. The intervention group received pre-operative training in PFM exercises, and correct voiding and defaecation techniques with reinforcement post-operatively. There were no prolapse outcomes measured in this study. Results presented relate to the combined group of study women i.e. those having prolapse surgery, those having UI surgery and those having both.

Frawley (2007) compared physiotherapist-led pre- and post-operative PFMT versus usual care in 48 women undergoing prolapse repair surgery, with or without hysterectomy. Intervention comprised one pre-operative instruction session, and eight post-operative appointments, and a final appointment at nine months post-operatively. PFM strength was measured (manometry and modified Oxford grading



scale) by a blinded investigator at four time points: pre-operatively prior to randomisation, and three, six and 12 months post-operatively.

**iii) Ongoing trials:** In addition, there are three RCTs (two for PFMT alone, one for PFMT as an adjunct to surgery) and one feasibility study for an RCT (PFMT as an adjunct to pessary) ongoing at the time of this review. Following on from the feasibility study by Hagen (2006) a multi-centre trial of the same intervention, in women with stage I, II and III prolapse, is now underway in 17 UK centres (the POPPY Trial, ClinicalTrials.gov Identifier: NCT00476892 ), with additional international centres in New Zealand and Australia. Results are expected in 2010.

Bø and colleagues in Norway are undertaking a single blind RCT involving 100 women with stage I, II or III prolapse evaluating the effects of a PFMT intervention. The intervention spans a six month period, with weekly physiotherapy appointments for three months, then fortnightly appointments for three months, and a structured home training programme (the POP Study, ClinicalTrials.gov Identifier: NCT00271297). A case-control study is taking place simultaneously, including 50 women without prolapse, to assess risk factors for the condition. The results of this study are expected in 2008.

A RCT has just begun enrolling under the direction of the NIH-sponsored Pelvic Floor Disorders Network. This trial will compare two methods of suspending the vaginal vault in women undergoing vaginal surgery for POP and additionally will randomise half of the participants to adjunctive post-operative PFM exercises and behavioural therapy and half to routine care. The analysis will assess whether such adjunct therapy improves both anatomic and symptomatic outcomes two years after surgery. The study is expected to be complete by 2012 (the OPTIMAL trial, ClinicalTrials.gov Identifier: NCT00597935).

A feasibility study (the PEPPY study) looking at the possible effects of PFMT with a vaginal pessary in situ is being undertaken by Hagen and colleagues in three Scottish centres (<http://www.wellbeingofwomen.org.uk/index.asp?PageID=369>). Fifty women with prolapse will be randomised to pessary alone or pessary plus physiotherapy-led PFMT. The study will be complete in 2009.

## 1. QUALITY OF DATA

**i) PFMT alone:** In Piya-Anant (2003) the method of randomisation was not described. It was stated that the assessor was blinded both to the previous assessment results of the participant and to their group status; however the method of blinding was not reported. There was insufficient detail of women lost to follow-up. Hagen (2006) reported an automated telephone randomisation service set up for the study using the minimisation method of randomisation.

Outcome assessment was predominantly by self-reported questionnaire, and women knew the group they had been allocated to. Prolapse severity at follow-up was assessed by a gynaecologist who was blind to the group allocation of the woman. Blinding was not always successful as some women disclosed their group allocation during their assessment. Sufficient information on drop-outs was given. Ghroubi (2008), which was published very recently, is written in French with an English abstract. A translation has been requested in order to allow detailed description of the trial methods and findings.

**ii) PFMT and surgery:** In Jarvis (2005) randomisation was generated by a computer in balanced blocks of 20, and randomisation outcomes were stored in opaque envelopes separate from the clinic. It was stated that the physiotherapist assessing the women at follow-up was blind to their status. Sufficient information on drop-outs was given. No information on the randomisation methods was available from the published abstract of Frawley (2007). The PFM strength measurements were taken by a physiotherapist who was blind to the women's group allocation. Numbers of drop-outs were adequately described.

## 2. RESULTS

**i) PFMT alone:** Piya-Anant (2003) reported that PFMT was effective in elderly women who had a severe degree of genital prolapse. After 24 months of PFMT, the rate of worsening of genital prolapse was 73% in the control group and 27% in the intervention group ( $p=0.005$ ). In the subgroup with 'mild' genital prolapse, the rate of worsening at 12 months was statistically significantly less for PFMT women than controls ( $p=0.02$ ), but there was no difference between the groups at 24 months ( $p=0.1$ ).

Hagen (2006) found that women in the PFMT group were more likely than controls to have an improvement in prolapse stage (Fisher's exact test  $p=0.038$ ). Intervention group women had significantly greater improvement by 26 weeks than controls in their prolapse symptom score (mean score decrease 3.5 versus 0.1,  $p=0.021$ ). There were significant differences between the groups at both follow-up time points in perceived improvement in prolapse (20 weeks,  $p=0.001$ ; 26 weeks,  $p=0.012$ ); PFMT women were more likely to report their prolapse was better now than at the start of the study. A significant improvement in PFM strength was detected in the intervention group; mean muscle strength increased by 0.5 on the modified Oxford scale (95% CI 0.2 to 0.8,  $p=0.008$ ). However, PFM strength measures were not taken blinded to women's group allocation.

Ghroubi (2008) found that immediately post-treatment, pelvic heaviness persisted in five women (19%) from the treatment group compared with fourteen (70%) in

the control group ( $p < 0.001$ ). There were also significant differences in other outcomes, including quality of life and urodynamic measures. It was reported that 20 women from the intervention group retained benefits two years after the treatment had ceased.

**ii) PFMT and surgery:** Jarvis (2005) reported a significant improvement in both quality of life (improvement in score for treatment group 215, 95% CI 124 to 305 versus control group 47, 95% CI -26 to 121;  $p=0.004$ ) and urinary symptoms (difference between groups in symptom score reduction 3.8, 95% CI 0.7 to 6.9;  $p=0.017$ ) when pre-operative physiotherapy was given to women undergoing surgery for UI and/or prolapse compared with women who received no physiotherapy. There was no difference between the groups in SUI measured by pad test. Mean maximum PFM squeeze increased in the physiotherapy group by 2.7 cmH<sub>2</sub>O, and decreased in the control group (-1.8 cmH<sub>2</sub>O) ( $p=0.022$ ). Frawley (2007) reported that despite the tendency towards improvement in the PFMT group over time, there were no significant differences in PFM strength scores between the controls and those who received PFMT at any of the post-operative time points.

Comparing the results for the two surgical trials [369, 371] it is interesting that one found an effect of PFMT on post-operative pelvic floor contraction pressure [369] while the other did not [371]. The latter appeared to have a more intensive intervention protocol (with one pre-operative and eight post-operative physiotherapy appointments up to nine months); however the former included teaching of voiding and defaecation techniques as well as a PFMT programme. In addition the trial populations were not identical, with some women having combinations of prolapse, hysterectomy and UI surgery. The sample sizes in both trials were small ( $n=60$  and  $n=48$  respectively).

## SUMMARY

Given the prevalence of POP and the fact that physical therapies, in particular PFMT, may already be part of the treatment offered to women in many centres [362] the lack of evidence of effectiveness is disconcerting. The results of further trials regarding the effectiveness of PFMT, which is costly in terms of therapist time, are awaited.

These ongoing trials are large, have a control group, are randomised and use recognised objective measurements of prolapse severity, and thus will provide a high level of research evidence to inform practice. The effectiveness of PFMT used in conjunction with other treatments is another area where evidence is lacking [344] but trials to address this are also emerging.

Based on the evidence from one large trial, PFMT may prevent deterioration of anterior prolapse. However this trial had several weaknesses including its failure to utilise a recognised objective measurement of degree of prolapse and its restricted population (elderly women with anterior prolapse only). The results from two small trials provide some additional evidence of a positive effect of PFMT on prolapse symptoms and severity. In the next few years, the completion of two sizeable trials of PFMT for POP might provide a much stronger evidence base for clinical practice. (Level of Evidence: 2)

Pre- and post-operative PFMT may help to improve quality of life and urinary symptoms in women undergoing surgery for POP, but the findings regarding its effects on PFM strength are contradictory. The evidence available however is based on two small trials, one of which included women undergoing surgery for UI and/or prolapse. (Level of Evidence: 2)

## RECOMMENDATIONS

PFMT may help prevent deterioration in anterior prolapse, and may help improve prolapse symptoms and severity more generally (Grade of Recommendation: B). Further trials are needed to confirm these findings.

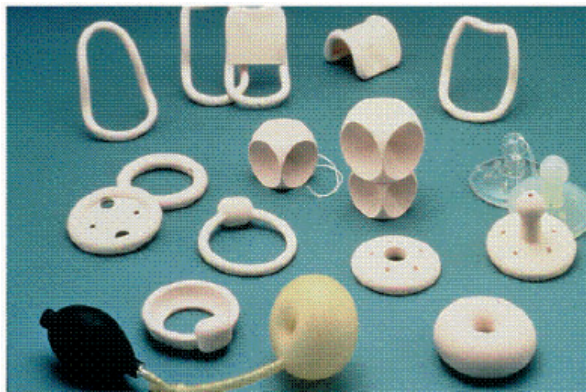
Preoperative PFMT may help improve quality of life and urinary symptoms in women undergoing surgery for prolapse (Grade of Recommendation: C). Larger trials are needed, and prolapse-specific measures should be primary outcomes in such trials.

Future studies of PFMT for POP should aim to reach a consensus on the optimal intervention programme prescribed in terms of the number of repetitions, type and duration of exercises and should also consider comparisons of individualised training with group training. There is also a need for studies of the effectiveness of physical therapies in comparison with surgery and vaginal pessaries.

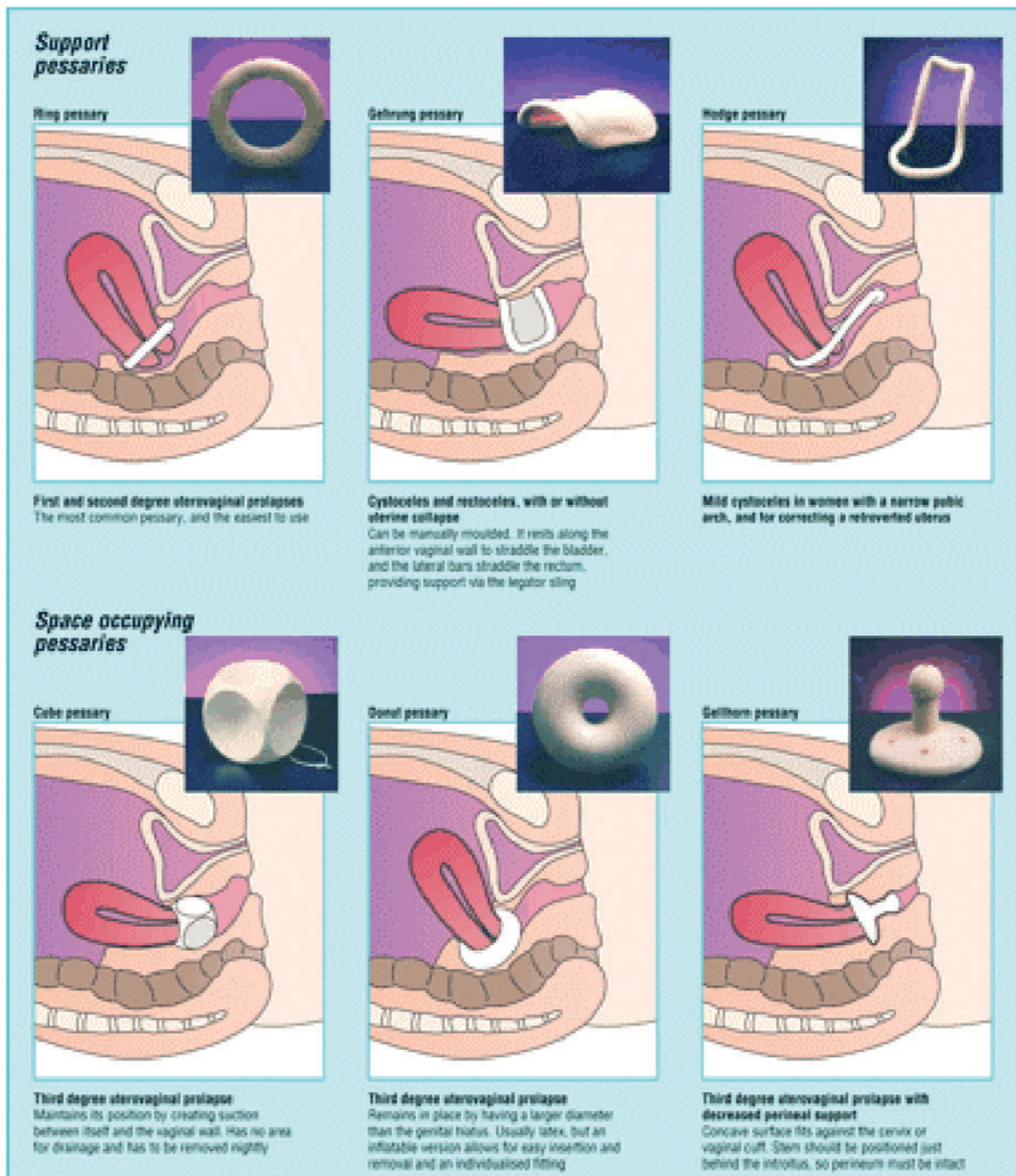
## III. RINGS AND PESSARIES

Pessaries aim to manage POP by supporting the pelvic area. These shaped devices are inserted into the vagina and rest against the cervix. They hold the prolapse inside the vagina, provide support to related pelvic structures and can relieve pressure on the bladder and bowel. Various shapes and sizes (**Figure 9**) and types (**Figure 10**) of pessary exist for use in the treatment of prolapse, a range of which is illustrated by Poma (2000) and Zeitlin (1992) [364, 373]. Modern pessaries are made from a variety of materials





**Figure 9 : Range of pessaries (Courtesy of Mediplus Ltd, UK)**



**Figure 10: Types of pessaries**

including rubber, clear plastic, soft plastic with metal reinforcements and silicone [373]. Until recently only a limited range of these has been available in some countries (e.g. the UK where often the choice is a ring or shelf).

Pessaries have been used for many years in the management of POP but their efficacy in treating this condition is unknown [374]. Surveys of pessary use have shown that 86% to 98% of gynaecologists/urogynaecologists prescribe pessaries [374, 375]. In the Cundiff (2000) survey of members of the American Urogynecologic Society 77% of physicians reported using pessaries as a first line therapy. Ninety two percent of physicians believed that pessaries relieve symptoms associated with POP, while 48% felt that pessaries also had therapeutic benefit in addition to relieving symptoms.

Whilst there are identifiable trends in pessary use there are clear practice differences with respect to choosing a pessary for a specific patient. Similarly there are no clear prevailing removal regimes [375]. Many physicians receive little or no training in the use of pessaries [374] and have limited experience with pessary selection and fitting.

## 1. TREATMENT

Clinical experience suggests a substantial proportion of women with prolapse may be managed safely and effectively with a pessary [373, 376, 377]. Much of the evidence relating to pessaries originates from case reports describing complications arising from pessary use [378-381] and review articles that provide advice, primarily based on clinical experience, on the indications for pessary use, pessary selection, fitting, care and replacement [365, 373, 376, 377, 382-387]. A large number of observational studies relating to pessary use have been published. In addition, two completed intervention studies evaluating pessaries (one a before and after design [388], and one a RCT [389]) have recently been published, bringing some advances to research in this area.

### 1. QUALITY OF DATA

**i) RCT:** Cundiff (2007) reported a multi-centre crossover RCT, comparing a ring with support and a Gellhorn pessary for the treatment of symptomatic POP. One hundred and thirty four women were randomised; 71 to ring pessary with support and 63 to Gellhorn, followed by crossover to the second type of pessary, ring with support (n=54) or Gellhorn (n=54). Women had stage II or greater symptomatic prolapse and had no prior experience of a pessary. Forty eight percent had stage II, 42% stage III and 10% stage IV prolapse. The largest group (51%) had anterior prolapse. Mean age was 61 years, and most were parous and post-menopausal. There were no significant differences between groups in baseline characteristics. Participants were randomised to be

fitted with one of the pessaries for three months, and then were fitted with the second pessary for a further three months. During each three-month period data were collected at one, six and 12 weeks from women who had a successful fit. At one year women had a final appointment to discuss pessary continuation and other treatment needs. Outcomes were measured at enrolment and three-months, including POP-Q, PFDI, PFIQ and a sexual function questionnaire.

Random allocation was by computer-generated random numbers using permuted blocks of variable size. Opaque, sealed envelopes were used to store the random allocation. Participants and clinicians were not blind to the allocation, but data were coded such that analysis was conducted blind.

**ii) Non-randomised intervention studies:** Lukban (2006) described a study of the effectiveness and safety of the Colpexin Sphere device in women (n=39) with prolapse beyond the hymenal ring [388]; all women had grade three or greater prolapse of at least one vaginal compartment (69% cystocele, 44% rectocele, 31% enterocele, 8% vault prolapse, 21% uterine prolapse). This is a spherical intravaginal device, similar to a pessary, which is placed above the levator musculature and requires active PFM contractions to keep it in place. The device has a string attached for easy removal and is available in six sizes. Its purpose is to reduce the prolapse while facilitating PFM strengthening which may treat co-existing bladder symptoms. Women were instructed to use the Colpexin Sphere only whilst in bed for the first week, and to use continuously thereafter, and were taught PFM exercises to be performed twice daily (Kegels and knee squeezes). The intervention period was 16 weeks. Outcome measures included prolapse stage (modified Baden and Walker classification system), PFM assessment (Brink Scale score), and a Pull Test to measure PFM tone and strength (a tensiometer is used to measure the force required to remove a 35mm sphere from above the levator plate). The small sample size, lack of control group and short follow-up were limitations of the study.

Kapoor (2004) reported on a cohort of 104 women attending a gynaecology service with symptomatic prolapse who completed the Sheffield POP symptom questionnaire [390]. Of these women 65 chose to have surgery and 39 chose to be fitted with a pessary. The baseline symptoms of these women were compared. Fernando (2006), using the same questionnaire, compared symptoms at one year follow-up between women (n=104) who chose surgery (n=48) and pessary (n=56) [391]. It is possible that these studies overlap as they take place at the same hospital.

**iii) Observational studies:** Several retrospective and prospective observational studies were identified that evaluated factors contributing to successful pessary fitting and usage, and/or the therapeutic impact of pessary use [390, 392-403].



Sulak (1993) evaluated the therapeutic usefulness of pessaries in a retrospective study of 101 women with pelvic relaxation. Wu (1997) performed a prospective study of 110 women with symptomatic POP to evaluate a protocol for pessary treatment. Handa (2002) described prospectively the course of POP amongst 56 women who used a supportive vaginal pessary for at least one year.

Both Hanson (2003) and Clemons (2004) conducted observational studies of 1043 and 100 women with prolapse respectively, to analyse the factors that contributed to successful pessary use. Hanson subsequently conducted further statistical modelling of their data and updated the study findings [397]. Clemons also published separately on the symptoms and patient satisfaction at two months of 73 out of the original 100 study women who had a successful pessary fit [398], and on continuation with pessary at one year of the sub-group who were satisfied users [399]. Mutone (2005) retrospectively reviewed the records of 407 women with symptomatic prolapse who had been fitted with a pessary in order to determine the factors influencing success at three weeks follow-up. Within the group of women 37% had previously undergone prolapse repair surgery. Bai (2005) reviewed the notes of 104 women who had been fitted with a pessary at one urogynaecology department and who were available for follow-up by questionnaire. Data on indications for pessary use, complications, satisfaction and frequency of removal were collected. Maito (2006) carried out a retrospective review of the notes of women who had been referred to a midwifery pessary clinic. Data on 120 women in whom pessary fitting was attempted were presented, including predictors of successful fitting and pessary continuation.

Fernando (2006) addressed the effectiveness of pessaries in alleviating symptoms associated with POP in a prospective study of 203 consecutive women attending a specialist urogynaecology unit.

Follow-up periods for observational studies varied from one week [396] to three years [393]. Only in some studies [394, 396, 398, 399] was a recognised measure of prolapse used i.e. POP-Q examination, to objectively assess and evaluate the prolapse. No consistent measure of pessary fitting "success" was used throughout studies. Commonly used questionnaires were the Sheffield POP symptom questionnaire, and the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ).

## 2. RESULTS

**i) RCT:** Combining the two trial periods in a crossover trial by Cundiff (2007), there were complete data on the ring pessary from 94 women, on the Gellhorn from 99, and on both pessaries from 85. Results were presented graphically with no mean values reported.

There were statistically significant improvements in the majority of PFDI and PFIQ scale scores for both pessaries, including the prolapse specific sub-scores (POPDI for symptoms and POPIQ for impact). However there were no differences between pessaries in improvement in these two sub-scores (POPDI,  $p=0.99$ ; POPIQ,  $p=0.29$ ). Considering clinically significant differences in scores (improvement of greater than half the baseline standard deviation), all POPDI sub-scores showed clinically significant improvements for both pessaries. However only for the Gellhorn were there clinically significant improvements in impact of prolapse symptoms (POPIQ), and only then for the physical sub-score and the total POPIQ score. Women who were highly satisfied with the Gellhorn also had improvement in a range of symptoms including the POPDI score; no similar significant association was found for the ring pessary with support.

**ii) Non-randomised intervention studies:** Lukban (2006) evaluated use of the Colpexin Sphere in 39 women, of whom 27 completed the 16-week assessment and were included in data analysis. Twenty two women (82%) had an improvement in their prolapse of at least one vaginal compartment. No detail of the magnitude of this improvement was given. Seventeen women (63%) exhibited increased PFM function as measured by the Brink Scale total score; however the statistical significance of this improvement was not reported. The Pull Test force during contraction increased significantly ( $p=0.029$ ) between baseline (mean 1.84lb, SD 1.04) and 16 weeks (2.14lb, SD 1.26). Displacement of the sphere with defaecation was a problem for 72% of women. Only two women (5%) experienced vaginal ulceration, and the problem was mild. Twenty five out of 27 women said they would recommend the device to others for the treatment of prolapse.

Two studies compared symptoms in women having surgery and women having a pessary. Kapoor (2004) found that generally the symptoms present before treatment did not differ between the groups, with the exception of low backache which was significantly more common in the group who then opted for surgery. The surgery group were also significantly younger and more likely to be sexually active. One year post-treatment Fernando (2006) found no significant differences in prolapse, bladder, bowel and sexual symptoms between women who had undergone surgery and those fitted with a pessary. The surgery group had been significantly younger at the outset but parity, ethnicity and menopausal status had been comparable.

**iii) Observational studies:** Study results show that pessary fitting 'success' rates ranged from 56% [393] to 75% [403] of women with POP. Higher success rates for specific types of prolapse (83% for uterine prolapse and 82% for cystocele) were recorded by

Hanson (2003). Comparison of fitting success rates by pessary type was difficult due to use of differing protocols for pessary selection within studies. Wu (1997) used ring pessaries in 96% of women who were successfully fitted. Similarly, ring pessaries were the primary choice of treatment in the studies by Handa (2002), Clemons (2004), Bai (2005) and Fernando (2006), whereas the Gellhorn pessary was primarily used in the study by Sulak (1993). The fitting protocol used by Mutone (2005) specified the ring pessary with support diaphragm in the first instance. Of women who had a successful pessary fitting, ring pessaries were used more often in women with stage II (100%) and stage III (71%) prolapse whereas Gellhorn pessaries were used more often with stage IV (64%) prolapse [396]. Hanson (2006) found significantly greater success with the ring, ring with support and Gellhorn pessaries than other type of pessaries ( $p<0.05$ ), however only 54% of women in this study had prolapse (the remainder had UI).

Parameters reported as associated with a successful pessary fitting were often contradictory. Hanson (2003), Clemons (2004) and Mutone (2005) reported that patient age was not significantly related to the success of pessary fitting whereas Wu (1997) reported that women who were fitted successfully tended to be older ( $p<0.05$ ). Mutone (2005) found that women classed as obese were significantly less likely to have a successful fit, whereas Maito (2006) found weight was not a predictor of successful pessary fit.

Clemons (2004) reported no effect on fitting success of previous surgical intervention. Whereas Wu (1997) reported that a history of pelvic surgery reduced the probability of a successful pessary fitting from 79% to 67%, although this result was not significant ( $p=0.2$ ). Mutone (2005) also showed a significant relationship between previous hysterectomy ( $p<0.001$ ) or prolapse repair ( $p=0.010$ ) and unsuccessful pessary fit. Similarly Maito (2006) reported that having a prior prolapse procedure or hysterectomy predicted unsuccessful fitting ( $p<0.001$ ). Hanson (2006) found a higher fitting success rate in women with previous abdominal genitourinary surgery (71%) compared to those with a history of genitourinary surgery via the vaginal route (60%) ( $p=0.027$ ). Fernando (2006) found 75% retained the pessary at two weeks, and that failure to retain was associated both with increasing parity and hysterectomy in a multivariate logistic regression analysis; site and type of prolapse did not affect success.

Current hormone use did not predict greater likelihood of fitting success [393, 396], whereas use of local oestrogen (with or without systemic HRT) was felt to play an important role in successful pessary fitting [395, 397].

Wu (1997) reported that women with SUI before pessary fitting had a significantly lower success rate ( $p=0.03$ ), whereas Clemons (2004) did not find SUI

to be a risk factor for unsuccessful fitting ( $p=0.60$ ). Maito (2006) found no significant difference ( $p=0.50$ ) in success rates between women with SUI (94%), POP (89%), or both (81%).

Increasing severity of prolapse was not associated with an unsuccessful pessary fit [393, 396, 400]. Neither was large genital hiatus [396, 400] nor severe vaginal atrophy [396]. Clemons (2004) however did find shorter vaginal length and wider vaginal introitus were associated with an unsuccessful fitting. Women with foreshortened vagina were not less likely to have successful fitting than those without in the study by Mutone (2005). Mutone (2005) also found that the location of prolapse was not associated with pessary success. Maito (2006) however found mild posterior prolapse to be a significant predictor of successful fit ( $p=0.002$ ).

Comparison of long term pessary usage rates was difficult due to differing follow-up periods used in the studies reported. In Sulak (1993) the average length of use was 16 months. Maito (2006) reported continued pessary use of on average six months (range one to 17 months); discontinuation of pessary use was associated with severe posterior prolapse ( $p<0.04$ ) after adjustment for age. Fifty percent of women continued to use the pessary at an unspecified follow-up period and 21% discontinued pessary use despite having no surgery [392]. In Wu (1997) 66% of those who used a pessary for more than one month were still users after 12 months and 53% were still users after 36 months. Thirty four percent of women in Handa (2002) continued pessary use for at least one year. Women with greater degrees of pelvic support loss were more likely to continue using the pessary than those with less support loss [392]. The main complaint of patients who discontinued using the pessary was dissatisfaction because symptoms were not adequately relieved or pessary use was inconvenient [392].

With regard to the effect of pessaries on POP symptoms and prognosis, 21.1% (95% CI -0.2% to 43.7%) of women had an improvement in stage of prolapse (measured via POP-Q with pessary removed) and none had worsening after using a pessary for at least one year, although improvement was limited to women with anterior vaginal prolapse [394]. Four months after pessary insertion Fernando (2006) found, in the 97 women with successful fit who completed the four month questionnaire, significant improvements in all prolapse symptoms and in many urinary, bowel and sexual variables (change in Sheffield POP questionnaire responses from before pessary fitted to four month follow-up with pessary still in situ). In Sulak (1993) 82% of women still using the pessary at an unspecified follow-up period described their degree of satisfaction with their symptomatic relief as excellent. Clemons (2004) reported 92% (67/73) of women successfully fitted with a pessary were satisfied with

it at two months. All prolapse symptoms were significantly improved, and half of the baseline urinary symptoms had improved or resolved. However 21% of women without urinary symptoms at baseline developed de novo SUI. The 67 women who were satisfied at two months were evaluated at one year [399]. Fifty nine of these women were available for follow-up, 73% had continued with the pessary for at least one year, and 27% had discontinued (after a mean of 5.9 months) and underwent pelvic reconstructive surgery. Logistic regression analysis revealed that age <65 years ( $p<0.001$ ), stage III or IV posterior vaginal wall prolapse ( $p=0.007$ ), and desire for surgery at first visit ( $p=0.04$ ) were independent predictors for discontinued pessary use and surgery.

Despite Cundiff (2000) reporting that use of pessaries was associated with potential complications no major complications were observed in the studies conducted by Sulak (1993) or Wu (1997). Bai (2005) reported 73% of women had complications such as bleeding or erosion, but that these were not severe and 70% said they were satisfied or very satisfied. Nineteen percent removed the pessary most often because of pessary slippage or discomfort. Based on clinical experience many authors advocate the use of local oestrogen to prevent or treat sores [377, 383-387, 396]. Indeed physicians thought that oestrogen was a necessary adjunct “most times” to pessary usage [374]. Differing advice however was apparent with regard to the frequency and amount of oestrogen applied.

## SUMMARY

In the only RCT of pessaries identified, there was no difference in symptom relief for women between the Gellhorn and the ring with support; however greater clinically significant improvement in prolapse-related quality of life may have been achieved with the former (Level of Evidence: 2). Therefore, despite the fact that pessaries are commonly used in current practice to treat symptomatic POP there is almost no RCT evidence to support recommendations for their use. Whilst pessaries are cheap and complications are rare there is no consensus regarding various aspects of pessary management including indications for different types of pessary, appropriate choice of pessary, pessary fitting procedures, replacement intervals, follow-up care and treatment of complications. Similarly, there is relative little research on the therapeutic benefits of long term use of pessaries for POP although data suggest that they provide symptomatic relief and may prevent worsening of prolapse or indeed promote improvement in prolapse stage.

Pessaries and surgery may equally improve prolapse symptoms, but the types of women who choose these treatment options are likely to be different.

## RECOMMENDATIONS

In a choice between the Gellhorn and the ring with support, either may improve prolapse symptoms and decrease their impact (Grade of Recommendation: B).

There are a rapidly increasing number of studies in this area; however there remains a pressing need for well-designed RCTs to examine the effects of using the wide variety of different pessaries in the treatment of POP. Such trials need to address optimal pessary effectiveness, including the symptomatic and therapeutic benefits of pessaries as well as the indications for use, pessary fit, replacement and care.

These studies need to adopt consistent protocols regarding choice of pessary and allow sufficient follow-up periods. There is also a need for studies to compare the effectiveness of pessaries with surgery, which is a more expensive option that may have additional morbidity, and with physical therapies. PFMT in conjunction with a pessary is an intervention which may warrant evaluation. It is not clear whether women would consent to being randomised to surgery or pessary; women might consider this if surgery was offered after a period of pessary use. If non-randomised studies comparing surgery and pessary are done, then efforts should be made to match the characteristics of the treatment groups.

## IV. COMPLEMENTARY AND ALTERNATIVE MEDICINES

No studies have been found that evaluate the role of complementary and alternative medicines in the prevention and treatment of POP in women. It is not known what scope there might be for such therapies.

## V. SUMMARY

Despite the prevalence of POP in women, which is increasing with the growing elderly population, there has been little attention paid to the effectiveness of interventions for the condition. There are encouraging signs of more rigorous research in this area, with the publication of four RCTs [370-372, 389] in this field since the 3rd ICI.

### 1. RECOMMENDATIONS FOR PRACTICE

There is no Level 1 Evidence, and generally insufficient Level 2 evidence on which to base recommendations for practice, and most recommendations are in effect hypotheses that need further testing in RCTs.



### **a) Pelvic floor muscle training (PFMT)**

- PFMT may help prevent deterioration of anterior prolapse, and may help improve prolapse symptoms and severity more generally (Grade of Recommendation: B) (Unchanged).
- Preoperative PFMT may help improve quality of life and urinary symptoms in women undergoing surgery for prolapse (Grade of Recommendation: C) (New).

### **b) Rings and Pessaries**

- In a choice between the Gellhorn pessary and a ring with support, either may improve prolapse symptoms and reduce their impact (Grade of Recommendation: B) (New).

## **2. FUTURE RESEARCH DIRECTIONS**

There is much scope for research on the effects of conservative therapies for POP in women. Research that is urgently needed, in the opinion of the committee members, is highlighted with the use of *italics*. There are a few recommendations that apply to all future studies in POP in women, namely:

The assessment and measurement of POP be made in a standardised fashion using a validated outcome measure (such as the POP-Q examination).

The assessment of prolapse symptoms is made in a standardised fashion. The choice of a single validated tool is however problematic at present.

### **a) Lifestyle interventions**

- Studies are needed to fully investigate the association between occupation/heavy lifting, bodyweight, constipation and POP. These studies should ensure that:
  - *Occupation, physical activity, bowel function and diet are assessed rigorously, using instruments with sound psychometric properties.*
  - Potential confounding variables are considered.
  - Attempts are made to overcome some of the obstacles in research in this area such as recall bias inherent in assessing lifetime occupational history, or healthy worker bias which is a problem when attempting to compare POP in women currently employed in heavy labour type jobs versus others.
- Only when the links between various lifestyle factors and POP have been more clearly established can good RCTs be set up to investigate the effects that changes in these lifestyle factors can have on preventing POP.
- Anaemia is a treatable condition, either through diet or medication, and further research on its role in prevention of prolapse is warranted.

### **b) Pelvic floor muscle training (PFMT)**

- Studies are needed to fully investigate the role of physical therapies in the prevention of POP. Such studies should:
  - Consider the exact nature and timing of any physical therapies.
  - Ensure that the effects of lifestyle factors and other potential confounding variables are taken into account.
- Further trials are needed to add to the evidence regarding:
  - PFMT alone to improve or prevent deterioration in prolapse severity.
  - The role of PFMT as an adjunct to prolapse surgery.
- There are no trials that address the following comparisons of interest:
  - *Low versus high intensity supervision of PFMT*
  - Individual versus group PFMT.
  - PFMT versus surgery.
  - PFMT versus rings and pessaries.

### **c) Rings and pessaries**

- There remains a pressing need for well-designed RCTs to examine the effects of using the wide variety of different pessaries in the treatment of POP. Such studies need to:
  - *Address optimal pessary effectiveness, including the symptomatic and therapeutic benefits of pessaries as well as the indications for use, pessary fit, replacement and care.*
  - Adopt consistent protocols regarding choice of pessary.
  - Allow sufficient follow-up periods.
- There are no trials that address the following. Randomisation may not be appropriate in such studies but efforts should be made to match the characteristics of the treatment groups being compared. Comparisons of interest are:
  - Rings and pessaries versus surgery; surgery is a more expensive option that may have additional morbidity.
  - Rings and pessaries versus physical therapies.
  - Ring or pessary in conjunction with PFMT. (Note: Feasibility work for a larger RCT is currently underway: (<http://www.wellbeingofwomen.org.uk/index.asp?PageID=279>)).

### **d) Complementary and alternative therapies**

- Any developments in this area should be studied in RCTs.

# APPENDIX

## SEARCH STRATEGIES

### A : Urinary incontinence in women:

#### Lifestyle interventions

We searched Medline (languages English, Scandinavian, German) and the Cochrane Register of Controlled Trials from 1966-January, 2008 using the following keywords which were linked to “urinary incontinence” or “urination disorders” or “overactive bladder” or “urinary urgency”: lifestyle interventions, weight, obesity, weight loss, exercise, work, physical activity, lifting, smoking, tobacco, coffee, caffeine, posture, constipation, bowel function, fluids, fluid restriction, pulmonary status, cough, and diet.

#### Pelvic floor muscle training and weighted vaginal cones

This review drew on the search strategy developed for the Cochrane Incontinence Group. Relevant trials were identified from the Cochrane Incontinence Group Specialised Trials Register, which is also described under the Incontinence Group’s details in The Cochrane Library. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, CINAHL, The Cochrane Controlled Trials Register and hand searching of journals and conference proceedings. The trials in the Cochrane Incontinence Group’s Specialised Register are also contained in The Cochrane Controlled Trials Register (CENTRAL). There was no restriction on language of publication or publication status (that is full publication, grey literature, etc). The date of the last search was 4-10-2007.

#### Electrical Stimulation

Relevant trials were identified from the Specialised Register of Controlled Trials of the Cochrane Incontinence Group. The register contains trials identified from MEDLINE, CINAHL, the Cochrane Controlled Trials Register (CENTRAL) and handsearching of journals. Additional trials were sought from the reference lists of included studies and a broader search of computerized bibliographic databases (EMBASE, EXCERPTA MEDICA, DUTCH NATIONAL INSTITUTE OF ALLIED HEALTH PROFESSIONS), from 1980 – October 2007, was undertaken. In addition, published abstracts presented at the International Continence Society, the European Association of Urology, the American Urogynaecology Society, and the American Urological Association were reviewed from 2003 to 2007, and cross-referenced to find if a full-length report had been published.

Keywords were incontinence, urinary incontinence, detrusor instability, detrusor overactivity, bladder, overactive bladder, stress incontinence, urge incontinence, mixed incontinence, urgency, frequency, nocturia, physiotherapy, physical therapy, conservative management, conservative therapy, non-surgical stimulation, electrostimulation, neuromuscular stimulation, electrical stimulation, electrotherapy, RCT’s, controlled trials, evaluation, effectiveness, efficacy, and outcomes.

#### Magnetic Stimulation

Relevant trials were identified from the Specialised Register of Controlled Trials of the Cochrane Incontinence Group. The register contains trials identified from MEDLINE, CINAHL, the Cochrane Controlled Trials Register (CENTRAL) and handsearching of journals. Additional trials were sought from the reference lists of included studies and a broader search of computerized bibliographic databases (EMBASE, EXCERPTA MEDICA, DUTCH NATIONAL INSTITUTE OF ALLIED HEALTH PROFESSIONS), from 1980 – October 2007, was undertaken. In addition, published abstracts presented at the International Continence Society, the European Association of Urology, the American Urogynaecology Society, and the American Urological Association were reviewed from 2003 to 2007, and cross-referenced to find if a full-length report had been published. Keywords were incontinence, urinary incontinence, detrusor instability, detrusor overactivity, bladder, overactive bladder, stress incontinence, urge incontinence, mixed incontinence, urgency, frequency, nocturia, physiotherapy, physical therapy, conservative management, conservative therapy, non-surgical stimulation, electrostimulation, neuromuscular stimulation, electrical stimulation, electrotherapy, RCT’s, controlled trials, evaluation, effectiveness, efficacy, and outcomes.

#### Scheduled voiding regimens

This review began with reports identified in the previous edition [281], which were predominantly obtained from MEDLINE, CINAHL, BIOSIS, and the Cochrane Register of Controlled Trials from February 1966 to January 2004. Keywords linked to urinary incontinence or overactive bladder consisted of: bladder, bladder training, habit training, timed voiding, behaviour therapy, toileting, rehabilitation, and therapy. This literature was updated by adding reports obtained using the same keyword searches in Pubmed from January 2004 to January 2008. Reference lists were searched from protocols and systematic reviews

published on timed voiding, habit training, and bladder training by the Cochrane Collaboration, the Agency for Healthcare Policy and Research (United States) [256], review articles, and retrieved manuscripts.

To be considered for inclusion, studies had to meet the following criteria:

Prospective research design: randomised controlled or non-randomised controlled trials. If there were non available, then non-randomised cohort studies, case control studies, and case series were reviewed.

Types of participants: cognitively intact, non-institutionalised women and men with stress, urge, and mixed incontinence. Studies involving participants with catheters, urinary tract infections, interstitial cystitis or other pelvic pain syndrome, neurological disorders, or who were pregnant or immediate postpartum were excluded.

Type of intervention: timed voiding, habit training, and bladder training used in the management of urinary incontinence or lower urinary tract symptoms. Studies were excluded where it was not possible to establish any direct effects due to a specific scheduled voiding regimen. For example, studies that compared an intervention that used both bladder training and pelvic floor muscle training to another type of intervention such as drug therapy were excluded because it was not possible to determine the effect of bladder training alone.

Publication type: full published reports in English

#### **B : Urinary incontinence in men:**

##### **Lifestyle interventions, pelvic floor muscle training and complementary therapies**

We searched the Cochrane Incontinence Group Specialised Trials Register, MEDLINE, EMBASE, CINAHL, ERIC, the reference lists of relevant articles and conference proceedings of Wound Ostomy and Continence Nurses Society, International Continence Society, American Urological Association, Canadian Urological Association and Society for Urologic Nurses and Associates from 2004 at the time of the last ICI to January 2008. Search terms included 'incontinence', 'male incontinence', 'prostatectomy/post

prostatectomy', 'continence', 'pelvic floor/muscle exercises/therapy', 'biofeedback', 'quality of life', 'prostate surgery', 'urge incontinence'. Manuscripts in languages other than English were retrieved and translation obtained. Randomised or quasi randomised trials were included; case series were excluded.

For Complementary Therapies, the same electronic sources and years were used, applying the search terms "acupuncture" or "hypnosis" or "complementary therapies" or "alternative therapies" AND "urinary incontinence" or "urination disorders" or "overactive bladder" or "urinary urgency" or "uterine prolapse". Manuscripts that included only children in the study population were excluded.

#### **C : Pelvic organ prolapse:**

##### **Lifestyle interventions, physical therapies, rings and pessaries**

Reports of RCTs evaluating the effect of lifestyle interventions, physical therapies and the use of rings and devices were obtained from a search of the Cochrane Incontinence Group specialised register. This register contains trials identified from MEDLINE, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL) and handsearching of journals and conference proceedings. The date of the last search was November 2007.

Reports of other studies evaluating the effectiveness of the above treatments in the management of pelvic organ prolapse were obtained by searching MEDLINE (January 1966 to November 2007), PREMEDLINE (9 November 2007), EMBASE (1996 to November 2007), CINAHL (1982 to November 2007) and PEDro (November 2007). Key search terms were: prolapse, pelvic organ prolapse, uterine/uterus prolapse, vault prolapse, urogenital prolapse, cervical prolapse, pelvic prolapse, vaginal prolapse, rectocele, cystocele, urethrocele, enterocele, proctocele, sigmoidocele, pelvic dysfunction, pelvic disorder, pelvic relaxation, vaginal defects.

The UK National Research Register (November 2007) and ZETOC database of conference abstracts (November 2007) were also searched.



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