

**Committee 18**

**Conservative and Pharmacological  
Management of Faecal Incontinence  
in Adults**

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# Conservative and Pharmacological Management of Faecal Incontinence in Adults

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## A. INTRODUCTION

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A working definition of Anal Incontinence (AI) was adopted at the last consultation [1] as:

“Anal incontinence is the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem”.

It is proposed by this committee that the consultation adopt this definition, with the additional definition of “faecal incontinence” (FI) as identical except excluding flatus. FI is covered in this chapter, except where anal incontinence is specified.

This chapter covers conservative management of FI in adults. Covered elsewhere in the volume are surgical management (Committee 19), and management in children (Committee 11), people with neurological disease or injury (Committee 12) and frail older people (Committee 13). Risk factors and prevention are covered for all groups. Some techniques developed and evaluated in these specific groups may have applications to an adult population, but most have not yet been evaluated.

Conservative management is defined as any non-operative, non-drug intervention designed to improve FI incontinence or prevent deterioration. No studies were found exploring how to select patients for operative versus conservative or drug management, nor comparing the approaches in comparable patient groups, so patient selection remains empirical.

However, the committee recommends a trial of conservative and drug management in the vast majority of patients before considering surgical options because these conservative options are comparatively inexpensive and involve no significant morbidity (see algorithm). Exceptions would be patients with acute traumatic anal sphincter rupture or an endosonographically confirmed major defect in the external anal sphincter in the presence of gross faecal incontinence: these patients would be referred for surgical evaluation.

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## B. RISK FACTORS FOR FAECAL INCONTINENCE AND STRATEGIES FOR PREVENTION

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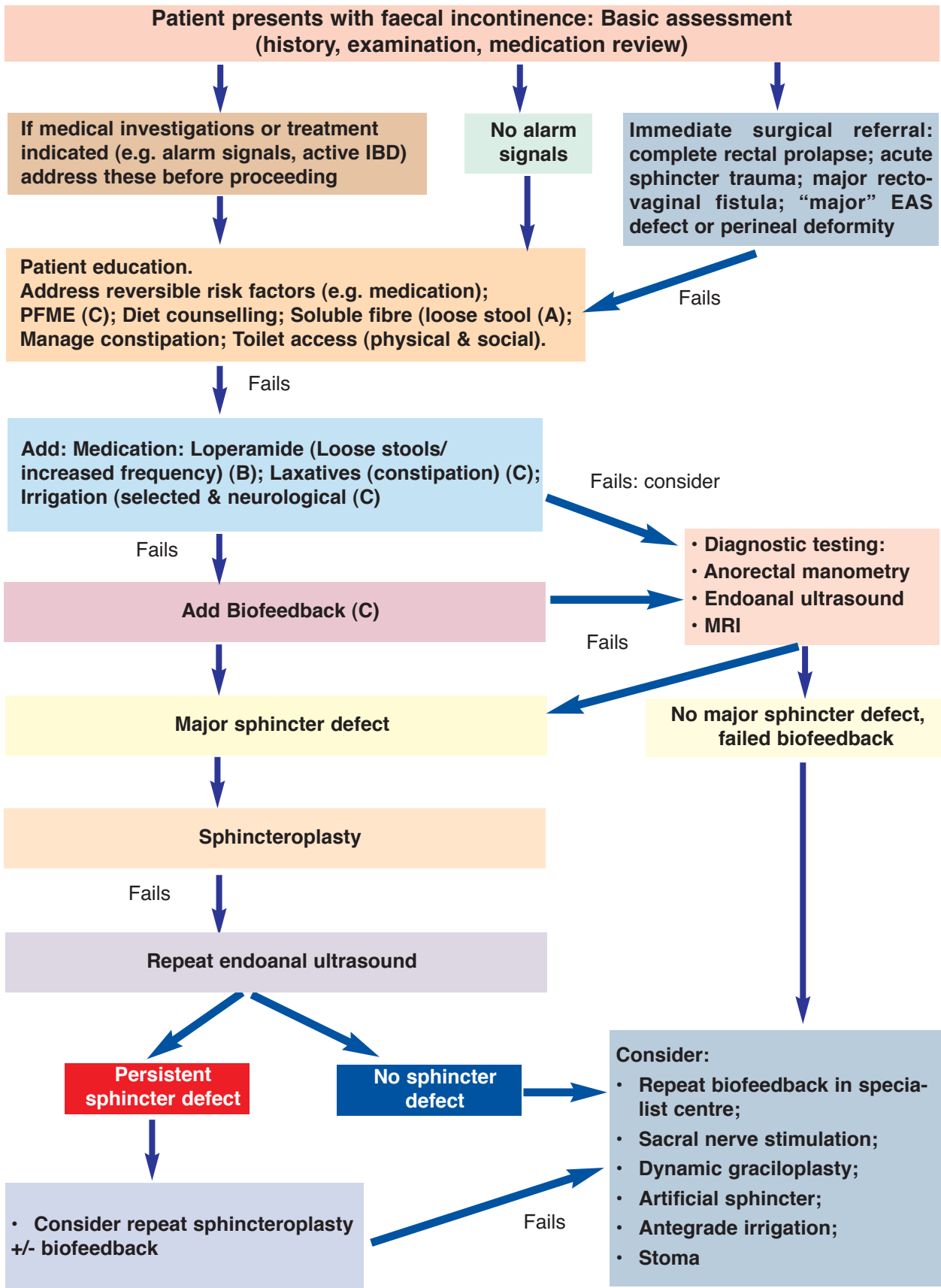
### I. AIMS

The goals of this section are (a) to identify risk factors for faecal incontinence (FI) and (b) to identify and evaluate prevention studies in adults.

#### • Definition of Prevention

Primary prevention is defined as the elimination of risk factors. Examples are fluorination of drinking water and vaccination for diseases. Secondary prevention refers to detecting and treating diseases at an early stage when there may be few or no symptoms, in order to prevent disease progression and possible sequelae. Examples are screening programmes to

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detect mild hypertension, followed by treatment of identified cases. Tertiary prevention refers to the treatment of established disease to prevent or reverse symptoms. The distinction between secondary and tertiary prevention is sometimes blurred. The scope of this section includes a discussion of primary and secondary prevention but does not include tertiary prevention (covered in other sections).

## II. METHODOLOGY

The Medline database was searched for all articles in all languages published in the last 10 years that were captured by the following search terms: epidemiology, risk factors and prevention cross-referenced with faecal incontinence or anal incontinence. These searches captured 459 articles which were reviewed for their relevance to the topic first by titles, then by abstracts, and finally by text of the articles. This search strategy was supplemented by a search of the Cochrane database and by focused searches on disease entities or other risk factors (e.g. haemorrhoids, ulcerative colitis, Crohn's disease) that were not identified as risk factors in the search but that were known to the authors to be associated clinically with FI.

The epidemiological data were evaluated on two primary criteria: representativeness and sample size. We gave preference to population-based studies of at least 1000 subjects for the identification of demographic and other major risk factors (**Table 1**). However, FI is a relatively infrequent condition affecting approximately 2.2% of the population [2, 3] and many of the diseases or conditions that are risk factors for FI are themselves rare (e.g., spina bifida, imperforate anus). Consequently, population based studies are unlikely to identify these risk factors. We therefore also included "enriched" samples which, for example, estimated the prevalence of FI in patients with these disorders. However, we avoided studies in which the method of ascertaining the sample was likely to over-estimate the association of the disease or condition with FI, for example, patients with diabetes who were referred to a gastroenterologist for evaluation.

In some instances we have reported possible risk factors on the basis of small or methodologically flawed studies when better studies were not available. We have identified these instances. **Table 2** gives surveys of prevalence in Nursing Homes.

## III. PREVALENCE OF FI AND RISK FACTORS

The median prevalence of FI among high quality population-based studies is 3.0%, including both men and women, but the range is up to 17% for men and 25% for women [4]. When the data are broken down by type of incontinence, liquid incontinence is 2-3 times more common than solid stool incontinence, and incontinence for flatus is 2-3 times more common than the combination of liquid and solid (5-8). Soiling or staining of underclothes, which is often not included in the definition of FI, was reported to occur in 21% of men and 14.5% of women in one study [9].

### 1. PATIENT CHARACTERISTICS ASSOCIATED WITH INCREASED RISK OF FI

#### a) Age

Nine population-based studies (**Table 1** includes only good quality studies), assessed age as a risk factor: 6 of these studies found age to be a significant risk factor in both men and women [2, 3, 6, 8, 10, 11], one reported it to be significant for women only [9], one found it to be significant in men only [4], and one found no significant association with age [7]. Some of the age-related increase in prevalence of FI may be attributable to age-related declines in general health, muscle strength, mobility, and cognitive functioning, and the increased prevalence of other diseases that may contribute to FI (see below).

#### b) Gender

Of 8 population-based studies that surveyed both men and women (**Table 1**), exactly half [3, 8-10] found a greater prevalence in women. No study reported a significantly greater prevalence in men. A greater preponderance of FI in women, when it has been found, has usually been attributed to obstetrical injury.

#### c) Race

A postal survey carried out in 7,879 women who delivered babies during the same year at three hospitals – one in England, one in Scotland, and another in New Zealand – showed a higher incidence of FI in Asian women than in Caucasians (OR=3.2) [12]. A higher incidence of obstetrical injury in Asian as compared to Caucasian women was reported in two other surveys [13, 14]. The prevalence of obstetrical tears during spontaneous vaginal delivery was also

**Table 1. Population Based Surveys**

Source	Design	Risk Factors	Results
<b>Nelson et al</b> [1995]	Random digit dialing telephone survey in 6,959 community dwelling adults, all ages. FI definition includes flatus.	Age Female sex Physical limitations Poor general health	Adjusted OR=1.01 (CI, 1.01-1.02) OR=1.51 (CI, 1.10-2.11) OR=1.82 (CI, 1.20-2.74) OR=1.64 (CI, 1.48-1.91) Overall prevalence 2.2%
<b>Perry et al</b> [2002]	Postal survey in 15,904 randomly selected community dwelling adults aged ≥40 years. FI definition not include flatus but required frequency of "several times a month."	Age Gender	Significant association No difference Overall prevalence 3.0% age ≥40
<b>Kalantar et al</b> [2002]	Postal survey of 477 randomly selected community dwelling Australian adults, all ages. FI definition excluded flatus and acute diarrhea.	Age Female sex Perianal injury/surgery Loose stool Stool urgency Poor general health Straining, hard stools	Significant association No difference Significant association Significant association Significant association Significant association No association Prevalence 2% solid, 9% liquid
<b>Walter et al</b> [2002]	Postal survey of 2000 randomly selected Swedish community dwelling adults aged 31-76. Distinguished flatus and soiling underwear from loss of solid or liquid. Threshold was at least monthly.	Age Female sex  Loose stools	Significant association in women Significant association for solid or liquid stool. Men reported more soiling of underwear. Significant association Overall prevalence not given
<b>Edwards, Jones</b> [2001]	Interviews in home of 2,818 men and women ≥65 yrs. FI defined by the question, "Do you have any difficulty in controlling your bowels?"	Age Female sex Anxiety & depression Physical disability Urinary incontinence	Significant association Significant association Significant association Significant association Significant association Overall prevalence 3% age ≥65
<b>Nakanishi et al</b> [1997]	Interviews in home of 1,405 men & women ≥65 yrs.	Age Female sex Physical disability Stroke Dementia	Significant association No association Significant association Significant association Significant association Prevalence 8.7% men, 6.6% women
<b>Roberts et al</b> [1999]	Postal questionnaire in age-stratified population sample of 778 men and 762 women aged ≥50 yrs. FI definition did not include uncontrolled flatus.	Urinary incontinence Age	> half of FI men and women had urinary incontinence Significant for men but not women Prevalence 17.0% for men and 24.6% for women
<b>Bytzer et al</b> [2001]	Postal survey of 8657 randomly selected Australian adults (60% response rate), including 423 with self-reported DM.	Diabetes mellitus	FI "Sometimes": 12.8% for DM, 3.8% for controls (p<.001). FI "Often": 2.6% vs. 0.8%, OR=2.74 (CI, 1.40-5.37).
<b>Chen et al</b> [2003]	Door-to-door survey of 1,253 Taiwanese women representative of the population. FI definition included flatus.	POP Parity ≥1 Prior GYN surgery Hypertension Overactive bladder	OR=3.2 (CI, 1.1-8.9) OR=3.4 (CI, 1.2-9.5) OR=1.8 (CI, 1.1-2.9) OR=2.4 (CI, 1.2-4.9) OR=3.2 (CI, 1.6-6.7) Prevalence 2.8% FI, 8.6% flatus
<b>MacLennan et al</b> [2000]	Interviews in homes of 3,010 men & women ≥15 yrs. Distinguished incontinence for flatus from incontinence for stool.	Age Female sex  Parity ≥1 Sphincter repair Vaginal vs. C-section Vaginal vs. Instrumental	Significant association OR=1.7 (CI, 1.3-2.2) for flatus; OR=1.6 (CI, 1.0-2.5) for stool Significant association No association No association No association Prevalence 2.3% for FI & 6.8% for flatus in men; 3.5% for FI & 10.9% for flatus in women
<b>Fornell et al</b> [2003]	Postal survey of 1000 randomly selected 40 year-old and 1000 randomly selected 60 year-old Swedist women. FI defined as leakage >1/month; UI defined as leakage weekly or more often.	3rd or 4th degree tear Parity Vacuum extraction Urinary Incontinence Pelvic Heaviness	OR=9.1 (CI, 3.0-27.3) for solid stool No significant association No significant association OR=5.9 (CI, 2.4-14.6) for solid stool OR=3.3 (CI, 1.6-7.0) for solid stool Prevalence 8.9% FI, 11.4% flatus

**Table 2. Nursing Home Surveys**

Source	Design	Risk Factors	Results
<b>Nelson et al</b> [1998]	HCFA minimum data set for Wisconsin skilled nursing facilities for 1992 & 1993.	Urinary incontinence Tube feeding Loss of ADLs Diarrhoea Truncal restraints Pressure ulcers Dementia Impaired vision Faecal impaction Constipation Stroke Male sex	OR=12.6 (CI, 11.5-13.7) OR=7.6 (CI, 5.6-10.4) OR=6.0 (CI, 4.7-7.7) OR=3.3 (CI, 2.7-4.2) OR=3.2 (CI,4.7-7.7) OR=2.6 (CI, 2.2-3.0) OR=1.5 (CI, 1.4-1.7) OR=1.5 (CI, 1.4-1.7) OR=1.5 (CI, 1.1-2.1) OR=1.4 (CI, 1.3-1.6) OR=1.3 (CI, 1.2-1.5) OR=1.2 (CI, 1.1-1.3)
<b>Johanson et al</b> [1997]	All 388 residents of 5 nursing homes, both skilled & unskilled. Questionnaire was completed by patient if possible, otherwise by investigator or nursing staff. FI defined as any involuntary leakage or soiling.	Diarrhoea Wheelchair dependent Dementia Male sex Age <65 yrs Daily exercise (-) Hard stools (-)	OR=8.0 (CI, 3.0-21.0) OR=2.7 (CI, 1.7-4.0) OR=4.3 (CI, 2.8-6.8) OR=2.5 (CI, 1.5-4.1) OR=2.6 (CI, 1.0-6.5) OR=0.5 (CI, 0.3-0.7) OR=0.2 (CI, 0.1-0.7)
<b>Chassagne et al</b> [1999]	Incidence of new-onset FI in 1,186 residents of nursing homes or long-term care facilities. 234 (20%) developed FI within 296 days. Risk of long-lasting FI reported.	Hx urinary incontinence Decreased mobility Hx dementia MMSE score <15 Associated mortality	OR=2.9 (CI, 1.8-2.6) OR=1.8 (CI, 1.1-3.0) OR=2.1 (CI, 1.2-3.5) OR=2.5 (CI, 1.4-4.4) 16% vs. 6.7% (p<.001)

greater in Hispanic subjects and Filipinos [13]. No published data were found on the relative rates of FI in African Americans compared to Caucasians.

**d) Diarrhoea**

The only two population-based studies to assess loose stools as a risk factor [6, 9], reported an association between loose stools and FI. This is consistent with reports that FI is more prevalent in patients with irritable bowel syndrome [15], patients with illnesses that produce diarrhoea [16-18], and in people who run long distances for exercise [19]. The association between FI and diarrhoea is even more robust in nursing home studies [20, 21] Whenever the frequency of FI is reported separately for solid, liquid, and gas, liquid incontinence is found to be more frequent than solid stool incontinence, and gas is found to be the most common type of incontinence [5, 8, 22].

Potentially preventable causes of diarrhoea, which is a major risk factor for FI, include drugs, dietary supplements, and some foods. Drugs known to cause diarrhoea as a side-effect include antibiotics, especially the erythromycin analogs, tegaserod, the 5HT4 agonist used to treat constipation-predominant irritable bowel syndrome, the serotonin reuptake

inhibitor class of antidepressants, digoxin, and laxatives. Chronic laxative dependence or abuse may cause frequent diarrhoea. Food supplements that have been reported to cause diarrhoea include lactose (in lactase deficient individuals), fructose, sorbitol, aspartame, and other artificial sweeteners that are poorly absorbed, and fat substitutes such as olestra. Some natural foods such as prunes and figs may also cause diarrhoea. The research literature has not established that these foods, food additives, and drugs cause FI, but it has established a link to diarrhoea.

**e) Constipation**

Constipation was found to be a significant positive risk factor for FI in one nursing home survey [21], but in another study, hard stools appeared to be protective [20]. Constipation is considered to be the most common aetiology for FI in children (often referred to in the paediatric literature as encopresis when there is no recognized structural anomaly to explain the incontinence) [23, 24] The mechanism that is presumed to explain constipation-related faecal incontinence is overflow: a mass of hard stool in the rectum or sigmoid blunts sensitivity for perceiving the movement of new stool into the area and also reflexly dilates the internal anal sphincter allowing liquid stool to seep out [23].



#### *f) Poor general health*

In population-based surveys, poor general health is a risk factor for FI that is independent of diarrhoea [6]. FI is associated with increased mortality both in community dwelling older subjects [11] and in nursing home patients [25].

#### *g) Physical limitations*

Three population-based surveys assessed physical limitations and found them to be risk factors for FI [3, 10, 11]. In nursing home patients, mobility impairment is consistently found to be a predictor of FI [20, 21, 25].

#### *h) Cognitive impairment*

Dementia is also a significant predictor of FI both in the community [11] and in nursing homes [20, 21, 25]. Stroke, which may be associated with either cognitive impairment or focal lesions in the neurological pathways responsible for reflex and voluntary control mechanisms, is also a risk factor for faecal incontinence [11, 21]. The prevalence of FI in those with mild learning disability is little different from that of the general population, rates for those with moderate and severe learning disability are higher than population norms and are similar to each other, prevalence is substantially higher in those with a profound learning disability [26]. Nevertheless, around half of those with a profound disability will acquire bowel control by adulthood.

#### *i) Physical exercise and work*

Exercise has been found to increase propagated colonic contractions [27, 28], which is the presumed mechanism for runner's diarrhoea. Exercise is often recommended as a means of promoting a regular bowel habit with complete evacuation, but exercise may not be feasible for people with mobility difficulties. The epidemiological literature is consistent in showing less constipation in people who report that they exercise [29]. It is known that endurance running is associated with diarrhoea and FI in over 10% of individuals [30]. There are no studies on prevention of runner's diarrhoea and faecal incontinence, although presumably avoiding the activity is an option.

Excessive exercise may also be a factor in rectal prolapse. This is seen in young women with anorexia nervosa who combine excessive exercise with extreme nutritional impairment, presumably thus compromising tissue quality. Women whose jobs involving a lot of heavy lifting are more likely to need vaginal prolapse surgery than the general population (OR

1.6) [31], but it is not known if they are also at increased risk of FI. It is not known if avoidance of heavy lifting would prevent FI development in an at-risk population.

#### *j) Weight*

Overweight or obese body mass index (BMI) is associated with an increased risk of anal and faecal incontinence in women, with a BMI over 30 having an OR of 1.8 for gas incontinence, 2.5 for loose stool incontinence and 1.3 for solid stool incontinence when compared to women with a normal BMI [i.e. <25] [5]. It is not known whether weight loss would improve FI in obese women, nor if weight gain prevention strategies would contribute to preventing FI in adults.

## **2. OBSTETRICAL AND OTHER INJURIES TO THE PELVIC FLOOR**

Table 1 shows population-based studies some of which assessed obstetrical history, and **Table 3** shows surveys of samples enriched by recruitment from obstetrical hospitals or urogynaecology clinics.

#### *a) Parity*

Three out of 4 surveys found that parity was a risk factor for FI. The first vaginal delivery carries the greatest risk of new onset FI [32], and each subsequent delivery adds to that risk [5, 7, 8, 33].

#### *b) Forceps delivery*

Three of 4 studies show that forceps delivery is a risk factor for FI, and one of two studies shows that forceps delivery is a risk factor for sphincter tear.

#### *c) Vacuum extraction*

The evidence here is more equivocal, one of three studies show that vacuum extraction is a significant risk factor for FI, and one (of one) study shows that vacuum extraction increases the risk of sphincter tear.

#### *d) Episiotomy*

Two of two studies showed a significant association between midline episiotomy and sphincter tears, but the single study looking at the risk of FI found no significant association with episiotomy.

#### *e) Large baby*

Two of two studies [32, 34] assessing the effects of having a large baby on sphincter tears were positive, as was a study of the effects of gestational age [32], however, a single study examining the impact of baby size on the risk of FI showed no association [33].



**Table 3. Obstetric Samples**

Source	Design	Risk Factors	Results
<b>MacArthur et al</b> [2001]	Postal questionnaires sent to all women delivered during 1 year at 3 hospitals: one in Scotland, one in England, and one in New Zealand. Questionnaires completed 3 months post-partum. N=7879 (71% response)	Forceps delivery C-section Age >35 yrs Asian origin Vacuum extraction Episiotomy Body mass index	OR=1.94 (CI, 1.30-2.89) OR=0.58 (CI, 0.35-0.97) OR=1.75 (CI, 1.04-2.94) OR=3.21 (CI, 2.04-5.05) No association No association No association
<b>Faltin et al</b> [2001]	Questionnaire study in 666 women from general outpatient clinic, 298 from antenatal clinic, 264 from urogynecology, and 984 from a population sample. FI definition was solid, liquid, or flatus at least monthly.	Parity Anal sphincter tear Baby over 4 Kg Operative delivery	OR=3.1 (CI, 1.6-6.0) OR=4.4 (CI, 2.0-9.1) No association Univariate but not multivariate association
<b>MacArthur et al</b> [1997]	Home interview by midwife about 10 months after delivery in 906 women. Assessed new onset FI for solids or liquids.	Vacuum extraction Forceps delivery C-section (elective)	Significant association Significant association Trend favoring protective effect
<b>Fenner et al</b> [2003]	Medical chart review of 2,858 primiparous mothers delivered vaginally at U. Michigan. Assessed risk of 3rd & 4th degree lacerations. Questionnaire also mailed at 6 months but response rate was only 29%.	Age Baby wt >4 Kg Forceps delivery Vacuum delivery Midline episiotomy	OR=1.04 (CI, 1.02-1.06) OR=2.19 (CI, 1.61-2.99) OR=4.75 (CI, 3.43-6.57) OR=3.51 (CI, 2.64-4.66) OR=2.24 (CI, 1.81-2.77)
<b>Zetterstrom et al</b> [1999]	For dependent measure of sphincter tears, hospital records of 845 women evaluated. FI was assessed by postal questionnaire at 0, 5, & 9 months postpartum, but data on relative risk were not presented.	First delivery Gesta age >294 days Fundal pressure Midline episiotomy Increasing foetal weight	OR=9.8 (CI, 3.6-26.2) OR=2.5 (CI, 1.0-6.2) OR=4.6 (CI, 2.3-7.9) OR=5.5 (CI, 1.4-18.7) OR=1.3 (CI, 1.1-1.6)

### 3. SEQUAE LAE OF GI SURGICAL PROCEDURES

#### a) Colectomy and ileoanal anastomosis

Because ulcerative colitis and familial polyposis both convey a high risk of colon cancer, the colon is often removed prophylactically. While a number of variations in surgical technique have been described, the commonest procedure is to create a neorectum from loops of ileum sewn together to create a pouch and to connect this to the anal canal. A temporary ileostomy is usually performed to give the pouch time to heal. Post-operatively, 25-35% of these patients have daytime FI [35-38] and 32-52% have nocturnal FI [35, 35, 36]. Fazio and colleagues [38] reported that the preoperative frequency of FI was as great in their series of patients as was post-operative FI. The mechanisms that lead to FI in this population include frequent bowel movements (8 or more per day), high pouch pressures that exceed anal canal pressures, and high amplitude contractions of the pouch [39]. Such pouch contractions are recorded in continent as well as incontinent patients with an ileal pouch because the pouch is constructed from inner-vented bowel, however, the contractions produce

higher pouch pressures in the incontinent patients.

When it is possible to preserve the rectum, the ileum can be sutured directly to the rectum, substantially reducing the risk of FI [40]. When bowel resection is performed for the treatment of colon or rectal cancer, some or the entire colon may be preserved, and the remaining colon may be sutured directly to the anal canal or it may be used to create a pouch that is connected to the anal canal. This is associated with a lower incidence of FI (estimated at 18%) according to some authors [41, 42], but others [43] reported a rate of 49% FI following colo-anal anastomosis.

One randomised controlled study has investigated the use of daily irrigation of a colonic J-pouch prior to ileostomy closure. Irrigation was not found to improve post-closure nocturnal continence or defaecation frequency [44].

#### b) Internal anal sphincterotomy

Patients with chronic anal fissure or haemorrhoids may be offered internal anal sphincterotomy (slit in the internal anal sphincter for 50-60% of its length to reduce anal canal pressures). In a large series of 585

patients with chronic anal fissures treated in this fashion at the Mayo Clinic, 45% developed FI at some point in their recovery. However, this tended to improve with time from surgery, and at follow-up an average of 72 months after surgery, 11% reported FI [45].

#### ***c) Radical prostatectomy for prostate cancer***

Published prevalence rates of FI following radical prostatectomy alone range from 9% [46] to 15% [47]. In the largest survey, Bishoff and colleagues [48] reported that prostatectomy by the retropubic approach was associated with FI in 17% of cases whereas prostatectomy by the perineal approach was associated with FI in 32% of cases, the loss of moderate to large amounts of stool was reported by 4% and 10% respectively. Rates of FI are higher when prostate cancer is treated by radiation therapy [47]. However, these differences may be confounded by differences in severity of disease before treatment, extent of resection, and dose of radiotherapy. However, in some large unpublished series FI has not been noted as an adverse event (Wein A.J., personal communication) and other studies do not mention FI at all.

#### ***d) Haemorrhoidectomy***

A large series of 507 patients who received the Milligan-Morgan surgical treatment for haemorrhoids were followed up by postal questionnaire 2-11 years after surgery (average of 6 years). A total of 33% [139/507] reported anal incontinence including 72 who were incontinent of gas only, 56 who were incontinent to liquid faeces, and 11 who were incontinent to solid faeces [49]. Other reports of surgical treatment for haemorrhoids list a lower incidence of FI [50], but only cases with loss of liquid or solid stool are usually reported.

### **4. SEQUELAE OF RADIOTHERAPY FOR CANCER**

The prevalence of FI following external beam radiation therapy for prostate cancer ranges from 14% [46] to 21% [47]. One group estimated the prevalence at up to 46% for a mixed group most of whom had been treated with both surgery and radiotherapy [51]. Radiotherapy for cervical cancer is associated with FI in 25% of cases compared to 8% for cervical cancer patients treated exclusively by surgery [52]. The mechanism through which radiotherapy contributes to FI is believed to be a decrease in rectal compliance [53], leading to increases in symptoms of urgency and loose stools [52][47].

### **5. DISEASES THAT PREDISPOSE TO FI**

#### ***a) Urinary incontinence and pelvic organ prolapse***

In community-based surveys, urinary incontinence is strongly associated with FI [4, 5] and overactive bladder [7] in both men and women. Among nursing home patients, urinary incontinence is an even stronger risk factor for faecal incontinence [21, 25]. Pelvic organ prolapse is also a significant risk factor for FI [5, 7]. Further research is needed to understand these associations. The comorbidity of FI with urinary incontinence and pelvic organ prolapse may reflect involvement of the whole pelvic floor, or alternatively, the comorbidity of urinary incontinence with FI may help to identify patients whose FI is related to dementia or mobility impairment.

#### ***b) Diabetes mellitus***

Bytzer and colleagues [54] carried out a large population-based postal survey in 8,657 adults including 423 with self-reported diabetes mellitus (DM). The response rate was 60.0%. When patients with DM were contrasted to the remainder of the sample the frequency of faecal incontinence occurring at least "sometimes" was 12.8% vs. 3.8% ( $p < .001$ ) and the prevalence of faecal incontinence occurring "often" was 2.6% vs. 0.8%. The odds ratio (after adjusting for confounders) was 2.74 (CI, 1.40-5.37). The prevalence of faecal incontinence was shown to be related to self-reported degree of glycaemic control. These results were confirmed by two other studies that contrasted patients from a diabetes register [55] or a diabetes clinic [22]. The risk of faecal incontinence among patients with DM is known to be related to weakness of anal canal resting and squeeze pressures and impaired sensation in the rectum [56, 57], and these physiological defects are related to duration of DM and the presence of microcirculatory abnormalities and autonomic and peripheral neuropathies [56].

#### ***c) Spinal cord injury***

Traumatic spinal cord lesions result in substantial or complete denervation of pelvic floor muscles and loss of voluntary control over the external anal sphincter. However, many of these patients avoid faecal incontinence because they are constipated due to delayed whole gut transit and/or hyper-reflexia of the external anal sphincter. Occasional faecal incontinence is reported by 33-66% [58-60] but frequent FI (more than monthly) is limited to 11% [61] to 14% [60, 62]. Approximately 70% require mechani-

cal or manual assistance to initiate defaecation [62]. In patients with congenital spinal cord lesions (spina bifida), anorectal dysfunction may be more common: 53% report that they soil regularly [63]. As with traumatic spinal cord lesions, the majority of patients with spina bifida are constipated, which reduces the frequency of faecal incontinence that would otherwise occur in these patients who have partial or complete disruption of the efferent innervation to the pelvic floor muscles [64].

#### **d) Stroke**

Two large studies have assessed the incidence of faecal incontinence following stroke. In the Copenhagen Stroke Study of 935 consecutive admissions for stroke [65], 34% were fully incontinent and 6% were partially incontinent on admission to the hospital, 6 months later, 5% were fully incontinent and 4% were partially incontinent. In a study of 1069 patients taken from the South London Stroke Register [66], 29.7% were faecally incontinent 7-10 days after stroke, 10.8% were still incontinent at 3 months, 10.9% at one year, and 15.0% at 3 years. These data suggest that faecal incontinence is transient for the majority of patients affected, but the prevalence of faecal incontinence remains elevated compared to population norms at one year and shows little further improvement. A study of 186 stroke patients in Spain showed a similar pattern: 56% had FI at admission, and 22% remained incontinent 6 months later. Risk factors for FI include age, severity of stroke, diabetes, and comorbidity of other diseases [65].

#### **e) Traumatic brain injury**

An excellent study [67] of the prevalence of FI following traumatic brain injury was carried out in 1,013 patients consecutively enrolled in any of 17 acute rehabilitation facilities. Prevalence rates were 68% at admission, 12.4% at discharge, and 5.2% at one year follow-up. The risk of incontinence at each time point was significantly related to all measures of the severity of brain injury including Glasgow Coma Scores and length of stay. In addition, at discharge from the rehabilitation facility, FI was significantly associated with pelvic fracture, urinary tract infection, and patient age (older patients were more likely to be incontinent). At one-year follow-up, FI was significantly associated with urinary tract infection and patient age. Patients with FI were more likely to be discharged to an institution rather than to return to their homes.

#### **f) Multiple sclerosis**

FI is reported by 29% [68] to 38% [69] to 51% [70]

of multiple sclerosis patients living in the community, and it is frequent in 5% [68] to 25% [70]. Among 14,000 nursing home residents with multiple sclerosis, FI was present in 58% and occurred more than twice a week in 7.5% [71]. Incontinence in this group is associated with weak strength of contraction of pelvic floor muscles, a low threshold for elicitation of the internal anal sphincter inhibitory reflex, and impaired sensation for rectal filling [72, 73]. Approximately half of patients with multiple sclerosis are also constipated, but constipation seems to occur about equally often in multiple sclerosis patients with and without FI [70].

#### **g) Imperforate anus**

High anal atresia is associated with faecal incontinence 85% of the time and low anal atresia about 57% of the time [74]. The surgical correction of high anal atresia involves identifying the striated external anal sphincter and pulling the healthy portion of the bowel down through this sphincter to create an anus. Contributing causes of incontinence are absence of an internal anal sphincter (passive barrier to soiling), weak contraction of the external anal sphincter, and decreased compliance of the neorectum [75-78]. The outcome of surgical repair is improving with improved surgical techniques and the use of the Malone antegrade colonic enema technique, but 10-30% of these patients remain totally incontinent for faeces [79].

#### **h) Haemorrhoids**

A significant number of patients with prolapsing haemorrhoids (Grade 3 and 4) experience faecal soiling, although this has not been the specific focus of any study. Johansson and colleagues [49] reported that 21% of 507 patients treated for haemorrhoids listed hygiene or soiling as an indication for seeking treatment. Following treatment with the Milligan-Morgan procedure, 24% of patients who had not listed soiling or hygiene as an indication for surgery developed new onset FI.

#### **i) Ulcerative colitis and Crohn's disease**

Faecal incontinence is more common in patients with inflammatory bowel disease, although the precise prevalence has not been the focus of study and is not known. Two mechanisms are recognized for this association: Both ulcerative colitis and Crohn's disease are associated with diarrhoea, which is a risk factor for faecal incontinence. Crohn's disease is also associated with the development of anal fistulae that may drain liquid stool to the skin surface and that may create anatomical defects in the external anal sphincter.

## IV. PRIMARY PREVENTION

**Table 4** summarizes the modifiable risk factors identified by our literature review, all of which are potential targets for primary prevention. The first of these targets, preventing the spread of infectious causes of diarrhoea, is largely achieved in developed countries by providing safe water and sewage disposal in urban areas and by inspecting wells and sewage treatment facilities in rural areas. This remains a major problem in developing countries, however.

*Table 4. Targets for Primary Prevention*

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Infectious causes of diarrhoea
Obstetrical practices: episiotomy
Internal anal sphincterotomy for anal fissures or haemorrhoids

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Episiotomy, especially midline episiotomy, has been shown to increase the risk of sphincter laceration rather than to reduce it, and some urogynecologists now recommend avoiding episiotomy [80].

Vaginal childbirth is itself a significant risk factor for sphincter lacerations leading to FI, and this risk is augmented when forceps or vacuum extraction are required. There is evidence from retrospective studies that Caesarean delivery reduces the risk of postpartum FI [12], although other, smaller retrospective reports failed to show any significant benefit from Caesarean section [81]. There is also evidence for a small but significant increase in the risk of maternal morbidity and mortality associated with Caesarean delivery [82]. A published decision analysis concludes that elective Caesarean delivery should be offered to women as an option, and surveys suggest that a sizable minority of obstetricians would prefer elective Caesarean delivery to vaginal delivery for themselves [83, 84]. However, this issue is very contentious [85]. There is one randomised controlled trial on this issue: in the Term Breech Trial [86], 1940 women from 110 centres worldwide who had a single foetus in breech position at term were randomised to elective Caesarean or vaginal delivery, resulting in 725 Caesarean deliveries and 456 vaginal deliveries. There were no differences in the rate of FI (0.9% for C-section vs. 1.1% for vaginal delivery) or flatus incontinence (10.8% for C-section vs. 9.1% for vaginal delivery) at 3 months postpartum

follow-up. There is currently no consensus among gynaecologists and obstetricians as to whether elective Caesarean section should be offered as a means of primary prevention of obstetrical trauma to the pelvic floor and FI.

Primary prevention of FI secondary to obstetrical injury could also take the form of providing pelvic floor muscle training prior to or immediately following childbirth. Pelvic floor muscle training is often recommended by obstetricians as preparation for childbirth, but no published studies have evaluated their benefit for primary prevention. However, see below for studies of pelvic floor muscle training used as secondary or tertiary prevention.

Pelvic floor muscle training was investigated as a primary prevention measure for patients undergoing colectomy with ileoanal pouch procedure [87]. Twenty-six patients were randomised to receive either 5 weeks of exercises or no additional treatment prior to their surgery. There was no significant difference in the incidence of FI following surgery, although there was a trend favouring the group that performed exercises. This study may have been underpowered to detect a clinically significant benefit.

Internal anal sphincterotomy—slitting the internal anal sphincter longitudinally to reduce anal canal pressure – may be used to treat anal fissures, haemorrhoids, or Hirschsprung’s disease. Nyam and colleagues [45] have shown that this procedure is associated with a high incidence of FI. It is possible that conservative guidelines for minimizing the use of sphincterotomy would reduce the incidence of FI, but none have been proposed or tested.

Diarrhoea is a major risk factor for FI, and a number of drugs, food supplements, and foods can cause diarrhoea. In patients who are at increased risk of FI for other reasons such as age or history of obstetric injury, it would be appropriate to screen for these agents and to eliminate them. However, there are no published data on the benefits of this approach.

## V. SECONDARY PREVENTION: EARLY DETECTION AND TREATMENT

The greatest obstacle to secondary prevention is the reluctance of patients to report their FI to physicians and to request care. The proportion of patients with FI identified through surveys who report they have



discussed this problem with their doctor ranged from 5% to 27% [6, 33, 88].

**Table 5** identifies a variety of patient characteristics, diseases, surgical procedures, and radiological treatments that are associated with a substantial risk of FI. Since patients are reluctant to report FI and to seek help, physicians should be alert to the possibility of FI in these patient groups, they should routinely inquire about FI and should offer treatment or referral.

**Table 5. Targets for Secondary Prevention Through Early Recognition**

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**Patient characteristics:**

Dementia/cognitive impairment

Physical limitations/ impaired mobility

**Diseases and disorders:**

Urinary incontinence

Pelvic organ prolapse

Haemorrhoids, grade 3 and 4

Irritable bowel syndrome

Diarrhoea

Constipation

Diabetes mellitus

CNS injury: stroke, head injury, Alzheimer's,

Spinal cord injury: traumatic cord injury, spina bifida

Multiple sclerosis

Congenital anorectal anomalies: imperforate anus

**Surgical interventions:**

Vaginal delivery with sphincter laceration

Instrumented vaginal delivery

Colectomy, with or without ileal reservoir

Internal anal sphincterotomy for anal fissure, haemorrhoids, Hirschprung's disease

Radical prostatectomy, especially by perineal approach

**Drugs and Diet**

Drugs that cause diarrhoea as a side-effect

Foods that cause diarrhoea: dairy products in lactase deficient individuals, some fruits

Food additives that cause diarrhoea or gas: artificial sweeteners

**Radiological treatment of pelvic cancer**

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Pelvic floor muscle training and education have been evaluated as secondary/tertiary prevention strategies in a small number of studies. Glazener and colleagues [89] compared nurse assessment plus reinforcement of pelvic floor muscle training and bladder training to standard management in 747 women with urinary incontinence 3 months following deli-

very. FI was present as a comorbid condition at baseline in 57/371 in the active treatment group and in 54/376 in the standard care condition. At follow-up 12 months after delivery, the prevalence of FI was significantly lower in the active intervention group compared to the control group (4.4% vs. 10.5%,  $p < .012$ ). However, other studies have suggested no benefit for the treatment of early onset FI with pelvic floor muscle training: Meyer and colleagues [90] performed a prospective, randomised controlled trial in which half of 107 primiparous women received 12 weeks of pelvic floor exercises with biofeedback and electrostimulation beginning 9 weeks after delivery. Assessment was at 10 months after delivery. The incidence of FI was low in this study (4-5%) and was not significantly different in the group receiving biofeedback. Two other studies whose primary aim was to treat urinary incontinence with pelvic floor exercises and education, reported that these exercises did not reduce the incidence of FI relative to the control group [91, 92].

Further research is needed to evaluate low-cost and widely available treatments (e.g., patient education, pelvic floor exercises) that could be employed by community-based health care providers for both primary and secondary prevention. These studies need to be adequately powered (large), they need to characterize the at-risk population that is being targeted (e.g., different prevention strategies may be appropriate for childbirth, frailty, and dementia), they should employ large samples of at-risk individuals, and they should include direct and indirect health care costs as secondary outcome measures. Further research is also needed that could identify early precursors of FI such as straining to defaecate over a period of many years, such studies may help to explain the late onset of FI in some patients and may identify preventable risk factors.

**Recommendations for Primary Prevention**

1. Encourage and support public hygiene measures to reduce diarrhoeal diseases (Grade A).
2. Discourage episiotomy except in restricted circumstances (Grade B).
3. Discourage the use of internal anal sphincter myectomy for treatment of anal fissure and haemorrhoids (Grade A).
4. Continue the debate on elective Caesarean delivery to prevent sphincter laceration, but no recommendation is given by this working team.

### Recommendations for Secondary Prevention

1. Because less than 1/3 of patients with FI report this to their physician, we recommend that health care providers aggressively investigate all patients for FI who present with the most common risk factors: urinary incontinence, pelvic organ prolapse, diarrhoea, vaginal delivery with sphincter laceration, multiparity, mobility impairment, dementia, and other neurological conditions. See Table 2 for other, less prevalent conditions that are associated with a high risk of FI (Grade C).
2. In patients with frequent, loose stools, screen for drug side-effects, lactose intolerance, and high intake of artificial sweeteners or other foods likely to cause diarrhoea (Grade C).
3. Research is needed to assess the benefits of pelvic floor muscle training for the prevention of FI in women undergoing vaginal delivery.

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## C. EDUCATION & “LIFESTYLE”

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Most patients do not know how the bowel works and what might improve bowel function. Many also have attitudes to defaecation that are influenced by stigma and taboos prevalent in their particular family and wider cultural group within a society [93].

Expert opinion supports the use of general health education, patient teaching about bowel function and advice on lifestyle modification [94, 95], but the evidence base does not exist. Unlike urinary incontinence, there have been few “lifestyle” associations identified with FI and little is known about whether interventions designed to reduce potential risk factors might improve FI. Diet and fluid intake are covered below.

The following databases were searched using the keywords “faecal incontinence” and the relevant intervention: Cochrane library, AHMED 1985-2004, BNIID 1994-2004, EMBASE 1974-2004, MEDLINE 1951-2004, PsychInfo 1987-2004. All seemingly relevant articles were retrieved in hard copy, and the reference lists searched for further studies.

## I. PHYSICAL EXERCISE AND WORK

One study in a nursing home population had found that a structured daily exercise programme, combined with increased fluid intake and regular toileting opportunities, significantly improved FI and increased the percentage appropriate toilet use compared with controls [96, 97]. No studies on the impact of physical exercise on FI or bowel habit in non-institutionalised adults were found. Abdominal massage in the direction of colonic peristalsis is often recommended [98].

## II. SMOKING

Nicotine is thought to slow upper gut motility and increase total transit time [99], but it seems that it can speed recto-sigmoid transit [100], and this stimulation of distal colonic motility may exacerbate a tendency to faecal urgency. This fits with many anecdotal reports that smoking a cigarette facilitates initiation of defaecation. Smoking is a known risk factor for urinary incontinence and genital prolapse (OR 2.9) [101], presumably via chronic coughing. No association has been found between antenatal smoking and postnatal FI [102]. Smoking cessation is anecdotally reported to be useful for reducing urgency of defaecation, but no formal studies were identified.

## III. MEDICATION SIDE-EFFECTS

Medication used specifically to treat FI is covered in section F below. A vast number of drugs have direct or indirect effects on the gastrointestinal system, tending to cause constipation, diarrhoea, or either in different people. A careful drug history (including all over the counter or “herbal” preparations) should be taken in each person with FI. It is beyond the scope of this chapter to review drug effects in detail, and prescribers should be aware of unintended side-effects on faecal incontinence. No studies were identified that evaluated the benefits of changing the patient’s drug regimen on FI.

One single case report was found reporting that a combination of olestra in the diet and orlistat given to treat obesity led to symptoms of FI, which resolved when the olestra was stopped [103]. Patients reporting soiling while on treatment with orlistat for

obesity have been found to have pre-existing impaired anorectal function, thus predisposing them to symptom development [104].

## V. TOILET FACILITIES

In individuals who have physical or mental impairments, adverse physical or social environments may impair the ability to maintain continence. This is particularly relevant to those in institutional settings (see Committee 13). Adverse environmental factors include: (a) toilet facilities that are inaccessible or that lack privacy so that the person avoids using the toilet, (b) care providers who are insensitive to the individual's needs and bowel habit, (c) clothes which are difficult to manipulate in a hurry, and a variety of other factors which vary with abilities of the individual. The toilet itself may be too high, leaving the feet dangling and thus making abdominal straining difficult. The toilet may be too low, making sitting and rising difficult for those with immobile hips. A social environment in which care-givers are overworked and harassed may lead the patient to repeatedly ignore the call to stool, in the hope of finding a quieter time later.

There are many adaptations that can be made to a toilet to facilitate access and stability in use [105]. Effective bowel evacuation is helped by sitting well-supported, with feet slightly raised to enable appropriate use of abdominal effort if needed, and leaning forward slightly [106]. Horizontal grab rails assist pushing up from a seated position, while vertical ones can enable pulling up. A raised seat or foot blocks can adjust the height as needed. For lateral transfer from a wheelchair, both seats need to be at the same height. Where it proves impossible for a person to use the toilet, alternative commodes or chemical toilets are available with appropriate features for the individual's needs. No studies were found examining the effect of modifying the physical or social environment in treating FI.

## VI. PATIENT AND CARE-GIVER EDUCATION AND ATTITUDES

The strongest data on education and lifestyle comes from a single RCT randomising patients to nurse-led education and advice alone, or with the addition of exercises, biofeedback or home biofeedback. The

education and advice group showed reduced frequency of FI and was as effective as biofeedback or exercises [107]. Other support for the benefits of patient education comes from a study reported in abstract form [108] which showed that education and standard medical care, when provided systematically to a group of FI patients who had failed prior attempts at medical management, led to a successful outcome in 38%. Success in this trial was defined as a patient's report that they had experienced adequate relief of bowel symptoms. Another randomised study examined the efficacy of a nurse-administered single session education and advice intervention in patients with bowel problems following stroke and found improved bowel function up to one year later [109, 110].

For people with dementia or other severe intellectual impairments, expert opinion holds that the attitude and management methods adopted by carers is as important as bowel function in maintaining continence [150]. No controlled studies on this subject were found. However, one quasi-experimental study examined care-givers' knowledge and compliance before and after an educational intervention [111]. Forty home care-givers of people with dementia, over half of whom had some degree of FI, completed a study-specific questionnaire before and after receiving a videotape and information booklet entitled "a practical approach to maintaining bowel control in people with dementia". Ninety percent of the care-givers accessed the information and there was an improvement in post-intervention knowledge scores measured on a 55-point scale, with the mean score increasing from 23 pre-test to 32 post-test ( $p < 0.001$ ). However, it is not known if this improved knowledge translates into improved care or reduced FI.

## VII. COMPLIMENTARY THERAPIES

Hypnotherapy has been found to improve urinary incontinence associated with detrusor overactivity [112]. However, no hypnosis treatment study was found which included FI as an outcome variable. Psychotherapy does not appear to enhance the effectiveness of behavioural intervention for FI in children [113], but no studies were found in adults. Likewise, there have been no studies of the use of acupuncture, reflexology, homeopathy or any other complimentary approach reported in the literature.



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## D. DIET AND FLUID INTAKE

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### I. RATIONALE FOR DIETARY INTERVENTIONS

The basis for investigating diet modification as a strategy for managing faecal incontinence comes from anecdotal reports by persons with faecal incontinence and clinicians, as well as from physiological principles of gastrointestinal (GI) function. People with faecal incontinence report anecdotally that they manipulate their diet and eating patterns as a strategy for managing their faecal incontinence [114]. Dietary manipulation is frequently employed by the approximately 20% of patients with irritable bowel syndrome (IBS) who also have faecal incontinence [95, 115] and by the approximately 19% to 40% of patients with inflammatory bowel disease who have faecal incontinence [15, 95, 116-119].

The way many patients with FI cope is to avoid eating anything on days they are going to be away from home: “nothing in, nothing out”. They also avoid any food that they suspect may cause loose stools or gas. One survey of faecal incontinence and self-care practices for faecal incontinence administered to community-living elderly people showed that the respondents changed their diet and skipped meals. Changing diet was a significantly more common practice among women (35.4%) compared to men (12.5%) [120]. Bliss et al. [114] compared the nutritional profile of the usual diets of persons with faecal incontinence to the usual diets of age and gender matched controls with normal bowel function and found few significant differences. However, the group with faecal incontinence had a greater intake of carbohydrates, manganese and vitamin B1.

#### 1. FLUID INTAKE

Constipation is a recognized risk factor for FI (see section 2). Approximately 30% of elderly residents in long-term care institutions have faecal impaction [121, 122] and general clinical recommendations for faecal incontinence management in these cases are for an adequate intake of fluid to prevent hard stool consistency and constipation. However, there is no empirical data to support the recommendation of increased fluids either for constipation or for FI, and there is no evidence that the diets of patients with FI or constipation are deficient in fluids.

#### 2. DIETARY FIBRE, PREBIOTICS, PROBIOTICS, AND SYNBIOTICS

A prebiotic is a general term describing a food ingredient that is not digested in the human intestine and thus stimulates the growth and/or activity of one or more types of bacteria in the colon that have the potential to improve the health of the host. Because of its ability to stimulate growth of bacteria in the colon, dietary fibre can be considered a prebiotic. Fructo-oligosaccharides and galacto-oligosaccharides are popular prebiotics. A probiotic is a general term for a supplement (available as a tablet, powder, or food) containing live non-pathogenic and non-toxic microbes that have the potential to affect the balance of colonic microbes or improve the host's health. Bifidobacteria and lactobaccilli are the most commonly used probiotics, and yogurt which has active microbial cultures can be considered a probiotic. A synbiotic refers to a product that combines a prebiotic and probiotic. Probiotics have been investigated for their ability to prevent or reduce diarrhoea associated with antibiotics, ulcerative colitis, in acute infant dehydration due to diarrhoea and in treating *Helicobacter pylori* infections [123]. However, there are no published data on the use of probiotics or synbiotics to treat FI.

Dietary fibre is the non-starch, polysaccharide component of plant cell walls and lignin that resists digestion by human intestinal enzymes. Dietary fibre supplementation has been shown in an RCT to reduce FI associated with loose stool (see Section 4.5). Moreover, persons with normal bowel function who had diarrhoea inducing by administration of phenolphthalein reported that they had fewer days with urgency to defaecate or fear of FI when they ingested the soluble fibre psyllium compared to wheat bran, calcium polycarbophil, or placebo in an unblinded manner [124]. On the other hand, there are reports that dietary fibre may exacerbate FI in some patients. It has been observed that some patients with FI benefit from moderating their intake of foods containing largely insoluble fibre, such as whole grain breads and cereals, nuts, beans, fruits and vegetables with skin, and sweet corn [125]. One clinical letter reported that treating constipation in elderly immobile people with a supplement of insoluble fibre and bran, resulted in faecal incontinence in half of them [126].

#### 3. LACTOSE, YOGURT, SORBITOL, FRUCTOSE, CAFFEINE, AND ALCOHOL

Certain dietary components such as lactose, sorbitol,

fructose, caffeine, and alcohol may cause loose stools that can potentially aggravate FI. A deficiency of the small intestinal enzyme, lactase, prevents hydrolysis of the disaccharide lactose and its absorption. The presence of lactose creates an osmotic shift of intestinal water into the small intestine and increased transit. In the large intestine, fermentation of lactose by colonic bacteria typically results in flatulence, distension, diarrhoea, and cramps. However, the majority of adults who have lactase deficiency can tolerate a small amount of lactose in foods [127]. Yogurt is usually well tolerated by lactose maldigesting individuals because the lactose is partially digested by the beta-galactosidase of the bacteria used to ferment the yogurt. However, yogurt has not been found to aid the digestion or tolerance for additional lactose simultaneously consumed with it [128].

Due to its prevalence in approximately 25% of the population, lactose maldigestion is currently regarded as a normal physiological pattern rather than a disease [129]. It occurs in 6% to 19% of whites, 53% of Mexican Americans, 62% to 100% of Native Americans, 80% of African Americans, and 90% of Asian Americans [129, 130].

Malabsorption of fructose and sorbitol results in osmotic diarrhoea and adverse symptoms, similar to lactose. A diet reduced in fructose and sorbitol content is suggested for some patients with irritable bowel syndrome to reduce adverse GI symptoms [131].

Caffeine, of which coffee is a popular source, has numerous effects on the GI system, it reduces lower esophageal sphincter pressure, stimulates acid and gastrin secretion as well as secretion from the small intestine, and induces a desire to defaecate [132-136]. Caffeine has also been observed to stimulate defaecation urgency in some patients with FI [125].

Chronic consumption of alcohol has been associated with accelerated gastric emptying and small bowel transit in animal studies whereas a single large dose has an inhibitory effect on these parameters [137-139]. Excessive alcohol consumption leads to injury of the duodenal and upper jejunal mucosa and inhibition of sodium and water absorption. There is an increased prevalence of bacterial overgrowth in the small intestine of alcoholics, which may contribute to loose stools, diarrhoea, incontinence, and other GI symptoms.

## II. LITERATURE SEARCH STRATEGY

The following databases were searched for studies to include in this review of dietary interventions for faecal incontinence management: Medline (1966 to 2004), CINAHL (1982 to 2004), BIOSIS (1996 to 2004), PUBMED (1950 to 2004), Cochrane Library of Controlled trials (4th quarter 2004) and the Cochrane Library of Systematic Reviews (3rd quarter 2003). The following key words were linked with faecal incontinence and used in the database searches: food, diet, dietary therapy, dietary fibre, fibre, prebiotic, probiotic, synbiotic, caffeine, lactose, yogurt, fructose, sorbitol, fluid, fluid intake, and fluid therapy. The Table of Contents of major journals on gastroenterology, digestive diseases, colon and rectal surgery, nutrition, and wound, ostomy and continence nursing were searched for relevant articles from November 2003 to January 2004. Reference lists were scanned from the systematic reviews of the Cochrane Collaboration, practice-related articles, or review papers about treatment of faecal incontinence from 2000 to 2003, and relevant papers were retrieved.

## III. CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### 1. TYPES OF STUDIES

Only studies in the English language were reviewed. Systematic reviews and meta-analyses of randomised controlled trials and full-length manuscripts reporting individual studies published in a peer-reviewed journal were considered. Individual studies or reports were required to have one of the following designs as defined in the ICUD review guidelines: randomised, controlled trial, prospective, non-randomised cohort, case-control, or recommendations from an expert consensus panel or Delphi process.

### 2. TYPES OF STUDY PARTICIPANTS

Studies that involved people who were 18 years or older, had faecal incontinence, and received a dietary intervention were included. People who were tube-fed or had an intestinal ostomy of any sort were ineligible.

### 3. TYPES OF DIETARY INTERVENTIONS

A dietary intervention was defined as any type of food, supplement, dietary product, or fluid that is purposefully consumed or restricted, limited or avoided to manage faecal incontinence. Studies were excluded if it was not possible to distinguish any direct effect of the dietary intervention from other interventions introduced simultaneously. For example, a study was excluded if it combined pelvic floor muscle training and a dietary intervention and compared it to another intervention such as drug therapy making it impossible to determine the effect of the dietary intervention alone.

### 4. TYPES OF OUTCOME MEASURES

Faecal incontinence was required to be a primary outcome measure of the studies. Studies which focused primarily on the outcomes of stool consistency or form, stool amount, volume or bulk, defaecation frequency, diarrhoea, or constipation without including any measure of faecal incontinence were excluded.

## IV. METHOD OF REVIEW

The reviewer examined the list of citations and abstracts yielded from the electronic search strategy. Potentially relevant papers were retrieved in full text. The reviewer was not blind to the journal titles, authors' names or their institutional affiliations. The quality of the studies was evaluated using the checklist accompanying the CONSORT statement available at <http://www.consort-statement.org>. The levels of evidence for therapeutic interventions developed by the 3rd ICI 2004 were adopted.

## V. FINDINGS

### 1. GENERAL DESCRIPTION AND SETTING

One study was found that met the inclusion criteria for this review [140]. Subjects were community-living people with incontinence of loose or liquid stools in the United States. The intervention was supplementation with one of two soluble dietary fibres compared to placebo.

### 2. METHODOLOGICAL QUALITIES OF STUDIES

#### *a) Study Design.*

The study design was a randomised, parallel-group, placebo-controlled, single blind trial. A block sche-

me resulted in equal numbers in each group. Details of the procedures for random assignment and allocation concealment were not provided. The participants, statistician, and participants' clinicians were blinded [141]. The interval for data collection during the baseline and intervention periods was equal.

#### *b) Participants and Follow-Up.*

Participants were adults who had faecal incontinence of loose or liquid stool at least weekly. The cause of their faecal incontinence, if known, was not reported. The inclusion and exclusion criteria were reported. Thirty-nine (8 men, 31 women) of 42 people completed the study. Drop-outs occurred during the baseline period before any fibre supplementation, and reasons for attrition were reported. Follow-up was completed by 95%. There were 13 participants in each group. How sample size was determined and the power of the study was not explained. The characteristics of the groups were comparable in the baseline period.

#### *c) Dietary Intervention.*

Participants consumed one of the following soluble fibre supplements mixed into fruit juices: 25 g of psyllium source/day, 25 g of a gum arabic source/day, or placebo (0.25 g of a pectin source/day). Based on the percent of fibre in each of the sources, the amount of dietary fibre that was administered in the supplements could be calculated as follows: 7.1 g of psyllium/day, 21.5 g of gum arabic/day, and 0.2 g of the pectin placebo. The timing of supplement consumption and periods of administering the supplements and follow-up were defined. The supplements were taken in addition to usual diet intake, which was determined by a prospective diet record for 8 days in each period. Adherence to taking the supplements was determined by self-report of the participants. There were attempts to control concomitant treatments, e.g., none of the participants was taking biofeedback training for pelvic muscle exercises, those who were taking anti-diarrhoeal medications were instructed not to alter the type or amount of medication taken, anti-diarrhoeal compliance was determined by self-report of the participants. Measures of stool characteristics were made using standard, objective laboratory procedures.

#### *d) Outcome measurement.*

Participants prospectively reported faecal incontinence on a daily stool diary for 8 days in each period. The proportion of incontinent stools during the baseline and fibre supplementation periods was the primary measure of faecal incontinence.

Secondary clinical measures included stool consis-

tency and frequency (both obtained from the stool diary), stool wet and dry weights, and percentage water content of stool (determined by freeze-drying). Measures of the effects of the fibres on the stools included the water-holding capacity of stool solids, total fibre content of stool, stool pH, and faecal short chain fatty acids.

*e) Adverse events.*

The adverse event of flatulence was monitored daily by self-report of the participants on the stool diary. Flatus did not differ between the baseline and fibre supplementation periods or among fibre groups.

*f) Results*

The rate of faecal incontinence for the groups ingesting psyllium or gum arabic were significantly lower than those taking the placebo. The rate of stools with loose and unformed or liquid consistency for the groups ingesting psyllium or gum arabic were significantly lower than those taking the placebo. The water-holding capacity of stool solids was highest for the group ingesting psyllium. There were no differences among the groups in stool frequency, wet or dry weight of stool, weight of stool solids, total fibre content of stool, stool pH, or short chain fatty acids. A limitation of the study was the relatively small sample size (n=13 per group).

## VI. CONCLUSIONS

The one published study provided level 1 evidence to suggest that dietary fibre can reduce the rate of FI in patients with loose stool. Dietary fibre supplementation appears to be a safe and tolerable intervention (see below). Further studies on the topic are encouraged to build a greater body of evidence.

## VII. RECOMMENDATIONS FOR FUTURE STUDIES ON DIET

Additional studies are recommended that have larger sample sizes and follow participants for a longer period of supplementation. Both dietary fibres administered in the reviewed study appeared to be fermented to a similar extent. Since the fermentability of dietary fibre may be affected by the amount of fibre administered, the role of fermentation on the effectiveness of dietary fibre in managing faecal incontinence warrants investigation.

Future studies could then determine whether there is an optimal type of fibre to use for faecal incontinence and whether there is a dose of fibre beyond which no additional benefit will be seen. Whether dietary fibre can augment other behavioural interventions such as pelvic floor muscle exercises (especially during the period of muscle conditioning) or bowel training needs to be studied further. Studies are needed to elucidate possible mechanisms underlying the benefit of dietary fibre.

The methods of future studies would benefit from a more objective measure of FI. Measuring compliance with a dietary intervention, although very difficult in an incontinent population, would strengthen the design of future studies. Investigators should be attuned to a broad range of symptoms of tolerance to dietary fibre over time.

Recommendation: soluble dietary fibre is recommended for the management of FI associated with loose stool. (Evidence level 1. Recommendation Grade B).

## VIII. OTHER DIETARY INTERVENTIONS

No studies of any other dietary intervention for managing faecal incontinence were found, so no recommendations about other dietary interventions for managing FI can be made.



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## **E. BOWEL MANAGEMENT AND RETRAINING PROGRAMMES**

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Note: Committee 13 has reviewed the evidence for bowel retraining programmes in nursing homes and frail elders. This section is limited to studies in younger adults.

The following databases were searched using the keywords “faecal incontinence” and the relevant intervention: Cochrane library, AHMED 1985-2004, BNID 1994-2004, EMBASE 1974-2004, MEDLINE 1951-2004, PsychInfo 1987-2004. All seemingly relevant articles were retrieved in hard copy, and the reference lists searched for further studies.

### **I. BOWEL HABIT**

Expert opinion supports the importance of attempting to establish a regular predictable pattern of bowel evacuation by patient teaching and adherence to a routine [94, 142]. Because peristaltic contractions of the colon that are associated with defaecation increase in frequency following awakening from sleep and following meals [143, 144] the period after breakfast is the best time for scheduled defaecation, but no studies have evaluated the effectiveness of this in adults. In children with constipation-related FI (encopresis) bowel habit training is effective at reducing the frequency of FI and increasing the frequency of self-initiated bowel movements (see Committee 11). Toileting programmes for assisting dependent older people to access the toilet are covered in Committee 13 and protocols for neurological bowel management are in Committee 12.

### **II. RESISTING URGENCY**

In contrast to urinary incontinence, where a body of knowledge has developed on the efficacy of bladder training techniques, particularly in relation to the overactive bladder syndrome (Committee 14), the possibility of bowel retraining for resisting urgency to defaecate is almost unexplored. Some biofeedback protocols focus on altering rectal sensory thresholds (see below) and some protocols for treating soiling in children focus on establishing a regular bowel routine.

One RCT compared patients who received education, including urge resistance techniques [125], and dietary advice, to a group of patients who received the same training plus anal sphincter exercises with or without home or clinic biofeedback. There were no significant differences in outcomes [107]. However, this study did not assess the effectiveness of the behavioural training compared to an appropriate control group.

### **III. EVACUATION TRAINING**

A common factor in the genesis of pelvic floor problems may be chronic straining with perineal descent from constipation, this may lead to pelvic floor damage (direct or neurological) [145, 146] and may be associated with pelvic organ prolapse or urinary or faecal incontinence. In one small study women who reported straining were more likely to develop urogynaecologic symptoms such as prolapse and stress urinary incontinence [147]. No studies were identified examining the effect of treating constipation or decreasing straining on preventing or treating FI in non-institutionalised adults.

Clinically, many patients with FI are taught evacuation techniques or are encouraged to use laxatives, enemas or suppositories in an attempt to ensure that the rectum remains empty most of the time, thus giving less chance of FI. There is a well-recognised association between rectal loading and FI in both frail elders [148] (Chapter 18) and in children with soiling (Chapter 16).

Children with FI have been found to respond to training to relax the external anal sphincter in order to evacuate effectively, although improvement in sphincter co-ordination does not necessarily equate to symptom change [149]. Laxative regimens reduce FI in institutionalised adults if complete rectal evacuation can be achieved [121]. However, complete evacuation is not easy to achieve (see section F below). Clinically many older women with FI report former constipation as a young adult, but data to support this are lacking. The evidence for treatment options is lacking.

One RCT of a combination treatment package for FI included training on evacuation techniques and noted that patients reported improved ease of evacuation after treatment [107]. No separate data on FI were presented. No studies were found utilising specific evacuation training to treat FI in younger adults.

## IV. BEHAVIOUR MODIFICATION

Toilet training with rewards, either alone or in combination with laxatives has been found helpful in children with encopresis [149] (see Committee 11). It is not known if a similar approach might be applicable to adults with learning difficulties or frail older people in institutional settings, although a behavioural approach to such problems is recommended by expert opinion [150]. Adults with learning difficulties may respond to formal behaviour modification techniques, but only small case series are currently available as evidence [151]. Similarly there are no controlled studies of training in non-retentive encopresis [152].

## V. COMBINATION THERAPIES

It is recognised that in many people the symptom of faecal incontinence is the result of a complex combination of disordered anatomy and physiology, stool consistency and gut motility, emotional and psychological status and restricted access to toilet facilities, amongst other factors (see Committee 5). Hence in clinical practice most patients receive a combined approach addressing diet, medications, lifestyle, muscle function and bowel habit simultaneously, depending on the result of initial assessment [153, 154]. However, with the exception of one study [107] the few well-conducted studies on the conservative management of FI in adults have usually focused on evaluating a single intervention such as biofeedback, often not specifying what other advice (that might confound the results) was given to patients.

Norton et al compared a combination of conservative measures, including patient teaching, advice on diet, medication titration, and bowel retraining, with the same measures combined with anal sphincter exercises and/or biofeedback [107]. No statistically significant differences were detected between the four groups on any of the outcome measures (including diary, symptom questionnaire, manometry, anxiety, depression and quality of life). Over 50% of those randomised (171 patients) reported improved continence. Of those completing the protocol, 74% felt that they remained improved at one year following the end of treatment. The authors of this study suggest that the most effective element may have been education and therapist-patient interaction rather than specific interventions.

An RCT of a combination nurse-led intervention for bowel problems in 146 stroke patients found that a single therapeutic visit with a detailed information booklet improved bowel dysfunction up to 6 months later, and changed diet and fluid behaviour up to one year later compared to controls who received routine care. The intervention group were more likely to have sought professional help from their family practitioner for bowel problems demonstrating a heightened awareness of the possibility of treatment [109, 110]. However, there was no difference in the rates of FI between the intervention and control groups.

In children a combination of behavioural training techniques and laxative therapy is as effective alone as it is when combined with biofeedback [149].

Anecdotally, laxatives may enhance the effect of behaviour modification alone.

## VI. RECTAL IRRIGATION

### 1. ANTEGRADE IRRIGATION

Surgical construction of an irrigation port to allow for the use of antegrade enemas or colonic irrigation is covered in Committee 19. An alternative is the insertion of an artificial irrigation port into the left colon (e.g. percutaneous endoscopic colostomy or PEC [155, 156] or the right colon [157]). Infection at the insertion site may be a problem in the medium to long term [158].

### 2. RETROGRADE IRRIGATION

Anal irrigation to control FI has been reported in a few isolated case series [159, 160] and is reported anecdotally to be widely used in Europe to manage FI symptoms, although there is no published evidence to support this. Irrigation may be by gravity-fill using a stoma irrigation cone [160, 161] or via a rectal tube, or using a stoma irrigation pump with either of these [162]. Some patients find the procedure painful or ineffective, and other discontinue because irrigation is time-consuming (taking between 10 and 90 minutes), but up to two-thirds of patients unresponsive to other non-surgical management methods have been reported to benefit, and those with soiling are more likely to continue than those with major incontinence [160].

Shandling [163] has developed a catheter incorporating an inflatable balloon and reported 100% success with 40% of 112 children with spina bifida, however, he did not make selection criteria clear or state

the length of follow-up [163]. Others are more cautious in their appraisal of retrograde irrigation. Thirty one children with spina bifida aged 3-19 years (mean 9 years) who were dissatisfied with current bowel management were treated by infusing 20ml/kg of saline every 24 or 48 hours through this catheter [164]. There were 6 immediate dropouts and a further 9 had stopped using the catheter by 30 months. Of those who continued to use the catheter the percentage of continent stools rose from 28 to 94% and the percentage of constipated stools dropped from 55 to 15%. The authors suggest that potential adverse effects include bowel perforation, and allergic reaction to latex in the catheter. One group [165] reported that 83 of their 190 patients with spina bifida achieved continence using irrigation daily or on alternate days via a cone in the anus. They used water at 20ml/kg body weight, with evacuation within 30 minutes. The investigators stress the importance of a specialist nurse overseeing the programme. The irrigation did not help with bladder compliance or instability.

Details of the technique are given by Scholler-Gyure and colleagues [165], who use 20ml/kg tap water one hour after the evening meal, run in half the volume and then allow 5 minutes without the cone, then run in the rest of the water, allowing up to 20 minutes for defaecation afterwards. They state that the volume needed varies and is often only found by trial and error. Of 41 patients with spina bifida who had failed other bowel management, 66% were continent at a mean follow up of 33 months, seven had monthly incontinence and 7 weekly incontinence, none had daily incontinence. Side effects included abdominal pain, headaches and poor appetite, but these were rare. Parental satisfaction was high in 63% and good in 37%. 66% of the children rated continence as the most important advantage, but half felt that it took up too much time and energy. Six found irrigation painful and three found it unpleasant, five were dependent on others to help.

There has been virtually no research on the best irrigation regimen, which fluid to use, and in what volumes to promote optimum evacuation either via an artificial port or by rectum. Christensen has evaluated retrograde colonic washout in a laboratory setting, using scintigraphy to assess segmental evacuation [166]. Six patients with FI were found to empty most of the rectosigmoid and descending colon, with fluid reaching on average just beyond the hepatic flexure. However, the clinical significance of this finding has yet to be explored. Gattuso et al [167] found that colostomy irrigation with water at

volumes of 500mls and above (but not at 250mls), produced high-pressure propagated waves of colonic contraction and effective evacuation without subsequent breakthrough. Patients preferred 500mls to larger volumes. This work had not been done with irrigation anally.

Some patients find it impossible to retain fluid instilled rectally. Clinical experience suggests that the response to rectal washout is very individual, and it is worth experimenting with volumes, temperatures and fluids, with or without addition of enemas, to find the optimum for an individual. There is a danger of autonomic dysreflexia in those with a thoracic level spinal lesion, and this will need careful monitoring and patient teaching.

A mechanical pump which introduces warm water in pulses into the rectum has been described [162]. It was reported to clear faecal impaction in 24 of 37 procedures on the first attempt and was well tolerated by most patients. The pump has been shown to be safe in a case series over 6 years [168]. It is not known if continence improved because the main focus of the study was relief of constipation.

### 3. ADVERSE EVENTS

A note of caution has been given about using tap water if a water softening system is in place because electrolyte disturbance may occur in vulnerable individuals such as children [169]. Phosphate enemas or tap water irrigation may also cause volume overload or electrolyte imbalance in patients who have compromised renal function or who retain the fluid for excessively long periods of time [170, 171]. Long-term use of phosphate enemas in irrigation fluid may also cause electrolyte imbalance in vulnerable patients. There is a case report of hyperphosphataemia and symptomatic hypocalcaemia with irrigation via an ACE [172]. Similar problems are theoretically possible with rectal irrigation. Isolated reports of perforation and serious complications are rare, but are a possibility, particularly if extension tubes are used [173].

## VII. DIGITAL OR OTHER STIMULATION

Use of a finger or other stimulator to trigger reflex rectal contraction and anal relaxation is a technique commonly employed to control timing of evacuation after spinal cord injury (see Committee12). Expert opinion suggests that this may work in the non-neurogenic population [142] but no study was found.



## VIII. MANUAL EVACUATION

A controversy has arisen in nursing about using manual rectal evacuation because of possible complications [174]. There is almost no research on this, and no evidence of harmful effects. The majority of patients with lower spinal cord injury and cauda equina syndrome need to use this regularly, although the evidence base is lacking [175, 176]. The Royal College of Nursing in England [174] has reviewed manual evacuation and suggested a procedure and safety points. No study was found evaluating the efficacy of manual evacuation for managing FI.

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## F. DRUG TREATMENT OF FI

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### I. GOALS

The goals of this section are to identify the drugs and other medical interventions that have been used to treat faecal incontinence and to evaluate the evidence regarding their efficacy. The medical management of faecal incontinence has focused exclusively on three mechanisms:

- 1 Reduction of diarrhoea. Diarrhoea is consistently found to be a strong risk factor for FI (see Section B above).
- 2 Increasing resting anal canal pressure. Low resting anal canal pressures are a risk factor for passive FI, and are commonly seen following some types of anorectal surgery (e.g. sphincterotomy, ileal pouch procedures, abdominoperineal pull-through for imperforate anus).
- 3 Control of constipation. Constipation is frequently found to be a risk factor for FI, especially in children and the elderly (see Section B above).

### II. METHODS

The Medline database and the Cochrane reviews [149, 177] were searched for studies in any language and any year which matched the following search terms:

- 1 “Faecal incontinence” OR “anal incontinence” AND “drug” OR “medical management” OR “medical treatment.”

- 2 “Faecal incontinence” OR “anal incontinence” AND “loperamide” OR “diphenoxylate.”

- 3 “Faecal incontinence” OR “anal incontinence” AND “laxative” OR “polyethylene.”

- 4 “Faecal incontinence” OR “anal incontinence” AND “phenylephrine gel.”

These search terms captured a total of 347 unique articles. These articles were screened by title, then by abstract, and 148 articles identified as potentially relevant were retrieved and read. Additional articles were identified by examining systematic reviews.

## III. TREATMENT OF DIARRHOEA-ASSOCIATED FAECAL INCONTINENCE WITH ANTIDIARRHOEAL DRUGS

### 1. LOPERAMIDE AND DIPHENOXYLATE

**Table 6** lists all studies found that were judged to be relevant to the topic of drug treatment of diarrhoea-related FI. All the studies that assessed loperamide treatment were rated as level 2 evidence: they were randomised cross-over studies but had methodological flaws which limited generalisability. Some of these studies reported that loperamide was superior to placebo [178-180] while others reported only a trend favouring loperamide [181, 182]. The study by Palmer and colleagues [182] is significant because it directly compared loperamide (average of 4.6 mg per day) to codeine (average of 103 mg per day) and diphenoxylate (average of 12.5 mg per day) in 30 patients with diarrhoea, of whom 19 had FI prior to treatment. However, FI was not the primary outcome measure. Loperamide was superior to diphenoxylate and similar to codeine with respect to decreased stool frequency, improved stool consistency, and reduced side-effects. Although not statistically significant, there was a trend for less FI while taking loperamide compared to diphenoxylate.

### 2. SUCRALFATE

This drug was compared to placebo in a double-blind, parallel group, RCT [183] carried out in 123 patients with diarrhoea that occurred secondary to radiation treatment for pelvic cancer. FI was not required for inclusion and was a secondary endpoint in data analysis. This study showed, contrary to hypothesis, that sucralfate made FI worse.

### 3. VALPORATE SODIUM

Gamma-amino butyric acid (valporate sodium) was

**Table 6 . Trials of Drug Treatment for Diarrhoea-Associated Faecal Incontinence**

<b>Source</b>	<b>Drug tested</b>	<b>Patients</b>	<b>Design</b>	<b>Results</b>	<b>Comments</b>
Harford et al 1980	Diphenoxylate & placebo vs. placebo	15 w/ FI & diarrhoea	Blinded crossover; 3 day treatments, 1 day washout	Decreased BM volume & frequency; tendency to decreased FI	Level 2 evidence. Treatment too short; Too few subjects
Palmer et al 1980	Loperamide 4.6 mg vs. codeine 103 mg vs. diphenoxylate 12.5 mg	30 w/ diarrhoea, of whom 19 had FI	Blinded crossover; 4 week treatments, no washout	Loperamide similar to codeine & superior to diphenoxylate for BM frequency, urgency, & side-effects; trend for loperamide to reduce FI more than comparators	Level 2 evidence. Underpowered. Did not analyze by ITT.
Kekomaki et al 1980	Loperamide 2-6 mg vs. placebo	7 children w/ congenital anomalies	Blinded crossover; 3 week treatments at 3 different doses alternated with placebo	Improved BM frequency, consistency, & FI in dose-dependent way	Level 2 evidence. Too few subjects; mixed aetiologies.
Read et al 1982	Loperamide 12 mg vs. placebo	26 w/ diarrhoea, FI, & urgency	Blinded crossover; 7 day treatments, no washout	Decreased FI, urgency, stool weight, % loose stools, BM frequency; increased resting anal pressures	Level 2 evidence. Treatment period too short
Ambjornsson et al 1986	Loperamide, titrate up	8 children w/ FI 2nd high imperforate anus repair	Open, uncontrolled 6-8 week study	Decreased FI in 7/8; Intolerable constipation in 2.	Level 3 evidence. Uncontrolled study

compared to placebo in a double-blind, randomised crossover study [184] in 17 patients with diarrhoea related FI secondary to colectomy and ileoanal anastomosis. Valproate sodium decrease FI episodes and stool frequency relative to baseline and increased anal canal pressure, whereas placebo did not have these effects. Limitations of the study were (a) small sample size and (b) statistical comparison to baseline rather than to placebo. Valporate sodium is of possible benefit in this population.

#### 4. AMITRIPTYLINE

Santoro and colleagues [185] carried out an uncontrolled study of the tricyclic antidepressant, amitriptyline, given 20 mg at bedtime, in 18 patients with FI, diarrhoea was not required. Thirteen of 18 became continent and 3 reported improvement. The authors attributed the benefits to increased anal resting pressure and decreased numbers of “rectal motor complexes.” This study suggests that amitriptyline and other tricyclic antidepressants are of possible benefit for treating FI.

##### • Mechanism of action

Three possible mechanisms of action have been identified in these studies of the drug treatment of diarrhoea-related FI: Loperamide, diphenoxylate, and amitriptyline appear to work in part by decreasing bowel movement frequency through an effect on motility and absorption. Fibre supplements (reviewed in Section 4 above), on the other hand, work by binding more water into the stools. Resting anal canal pressures were reported to be increased in response to loperamide [178, 179], valporate sodium [184], amitriptyline [185], and phenylephrine gel [186, 187].

### VI. INCREASING ANAL CANAL PRESSURE IN PATIENTS WITH PASSIVE FI

A subgroup of patients with FI have passive incontinence, defined as FI that is not preceded by a sensation of urgency to defaecate and that occurs without awareness. This is believed to be related to decreased resting pressure in the anal canal due to an impaired internal anal sphincter and/or to decreased sensation for rectal distension. A specific aetiology for passive FI is the patient with a colectomy (usually for ulcerative colitis) with a surgically constructed ileal reservoir connected to the anal canal [36].

Phenylephrine gel, an alpha-1 adrenergic agonist, has been investigated for the treatment of passive FI

in patients with ileoanal pouches [187]. This was a double-blind crossover study comparing topical (intraanal) administration of 10% phenylephrine gel to placebo in 12 patients. However, the investigators noted carryover effects and therefore reported only the first treatment period, making this a parallel group study. They found a significant reduction in a faecal incontinence severity score during treatment with the active drug. The same research team reported a second study [188] in which they randomised 36 patients with idiopathic causes of FI (not including ileal pouch procedures) to receive either phenylephrine gel or placebo, and found no significant improvement in either severity of FI (incontinence score) or anal canal pressures. These patients all had structurally intact sphincters. Thus, the clinical utility of phenylephrine gel (if any) may be limited to patients with passive incontinence associated with ileal pouches. Oral preparations have been found to have significant side-effects but this has not been reported in these topical studies.

Loperamide also increases anal canal resting pressure by an unknown mechanism [178, 179], and it has been suggested that this may contribute to the treatment of FI [180]. As reported in the last section, loperamide does decrease the frequency of diarrhoea-related FI [178-180], but it is unknown how much of this effect is due to increased resting pressure in the anal canal as compared to changes in stool consistency. No studies of the effectiveness of loperamide in patients with passive FI were found.

### V. DRUG TREATMENT OF CONSTIPATION-ASSOCIATED FI

Constipation-associated FI, sometimes referred to as overflow incontinence, occurs more frequently at the two ends of the lifespan. The prevalence of FI in children is estimated to be 0.8% [189] to 3% [190] and in 35% (191) to 96% [25] of cases, FI in children is associated with constipation. FI occurs in 46% [192] to 47% [21] of nursing home residents and is more common in those with constipation [193]. However, the proportion of faecally incontinent nursing home residents whose FI is attributable to constipation is not known. Constipation-associated FI is also common in patients with spinal cord injury, occurring in an estimated 33% [58].

Constipation-associated FI in nursing homes is often treated with the prescription of daily or frequent laxatives. However, we found only two RCTs which tested the effectiveness of laxatives for treating FI

associated with constipation in adults. Ryan [194] randomised 87 new admissions to a single nursing home to receive either 15 ml daily of sorbitol for up to 15 days or routine care without the use of a laxative. Patients were enrolled whether or not they had constipation or FI. The outcome measures recorded by nurses were amount of nursing time required for the care of FI and amount of soiled linen. Patients treated with sorbitol were found to have significantly less soiled linen, and they tended to require less nursing time. Limitations of the study included (a) analysing the aggregate amount of soiled linen used by each group rather than the proportion of the subjects in each group who had FI, (b) failure to control for expectancy by providing a placebo treatment to members of the control group, and (c) failure to include all randomised subjects in the data analysis, i.e. failure to use an intention to treat analysis.

A second study [121] compared daily enemas to no treatment in 206 nursing home residents who had FI and documented constipation. This was an open label RCT. Results showed no difference between groups either for frequency of FI or for amount of soiled linen. However, post hoc subgroup analysis showed that patients with complete rectal emptying on digital examination exhibited a significantly greater improvement than the group that continued to have a faecal impaction. Strengths of this study were the large sample size, randomisation, strict inclusion criteria, and assessment of whether the enema regimen in fact eliminated faecal impaction. A weakness was that the post hoc analysis of the physical examination data suggest that the trial is not interpretable since the daily enema regimen did not eliminate faecal impaction in most patients.

Two RCTs were reported for children with FI associated with constipation. In one of these, Nolan and colleagues [195] randomised 169 children who had FI and radiological evidence of stool retention to receive either combined treatment with laxatives plus behavioural toilet skills training or behavioural toilet skills training alone. This was an unblinded RCT. Children treated with laxatives plus behaviour modification were significantly more likely to improve than children treated with behaviour modification alone (63% vs. 43%,  $p < 0.02$ ), and improvement was more rapid. Limitations of the study include (a) failure to blind the study by using a placebo, and (b) analysing the data by symptom completers rather than by intent to treat.

A second RCT in children [196] randomised 40 children with constipation (only 3/4 had FI at enrolment) to one of 3 groups: senokot, placebo tablets, or no

treatment. All children also received toilet training. The authors reported that all three groups improved (i.e. reduced frequency of FI) and there were no differences between groups. However, the study did not have sufficient power to test the hypothesis.

A double-blind RCT testing the effectiveness of the prokinetic drug cisapride in paediatric FI found no evidence for efficacy [197]. Adverse events subsequently led the U.S. Food and Drug Administration to restrict access to this drug. An alternative prokinetic drug, tegaserod, has been approved for the treatment of chronic constipation in adults, but has not been tested for its effectiveness in patients with constipation-associated FI.

Several trials [198, 199], including one high quality RCT [200] have compared laxatives alone to the combination of laxatives plus biofeedback in children with constipation-associated FI. For this indication biofeedback is designed to teach the patient to relax the pelvic floor muscles during attempts to defaecate in order to overcome a tendency to paradoxically contract these muscles and to obstruct defaecation. The RCT by van der Plas and colleagues [200] showed that combined treatment was associated with a higher success rate at the end of training (39% vs. 19%), but by follow-up 12 months later, there were no differences between groups. Other studies support these findings by showing either no difference between the laxative only group and a biofeedback group [198] or faster acquisition of continence in the biofeedback group but no long-term difference in success rate [199]. These trials suggest that laxatives alone are as effective as biofeedback for constipation-associated FI in children in the long term, but they were not designed to show that laxatives are superior to placebo or to no treatment.

## VI. DRUG TREATMENT OF FI: SUMMARY AND RECOMMENDATIONS

Level 2 evidence supports the recommendation of loperamide for diarrhoea-associated FI and suggests that the loperamide may be superior to diphenoxylate. Our recommendation is to treat diarrhoea-associated FI with antidiarrhoeal drugs (Grade B). There is insufficient trial data to recommend phenylephrine gel or loperamide for the treatment of passive FI. For constipation-associated FI, there is level 2 evidence suggesting that daily or more frequent oral laxative regimens may

be effective for the treatment of constipation-associated FI in nursing home residents [194] and children [195], but there are conflicting data [121, 196]. We recommend the use of laxatives to treat constipation-associated faecal incontinence, Grade B. It is important to confirm that the impaction is resolved by the laxative regimen. Additional, well-designed studies are needed to validate the common clinical practice of using laxatives to treat constipation-associated FI.

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## **G. BIOFEEDBACK AND/OR ANAL SPHINCTER / PELVIC FLOOR EXERCISES**

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### **I. INTRODUCTION**

This section reviews all studies published in English of adult research on biofeedback for faecal incontinence. A MEDLINE search was conducted to identify all articles matching "biofeedback and faecal incontinence" published between 1970 and February 2004. The search was supplemented by a crosscheck of citations in the identified papers and other systematic reviews.

### **II. BIOFEEDBACK MODALITIES USED IN THE TREATMENT OF FAECAL INCONTINENCE**

Biofeedback can be defined as the use of an instrument that delivers a concurrent measurement of selected biological responses to enable the individual to alter his/her physiological response in directions associated with improved function [201].

The earliest reported application of biofeedback to treat faecal incontinence used a simple pressure device in the anal canal to reinforce external anal sphincter (EAS) contraction [202], a procedure somewhat analogous to the vaginal perineometer that was used by Kegel to treat stress urinary incontinence [203]. However, the seminal biofeedback procedure [204] for FI, which was followed in a series of studies [57, 205-211], used a 3-balloon manometry probe to reinforce changes in 3 distinct physiological variables rather than just EAS contraction. The responses that

were reinforced with this protocol included, (a) the perception of sensory cues associated with rectal distension and potential loss of stool, (b) a short-latency EAS contraction, and (c) inhibition of activity that would increase rectal pressure (i.e. contraction of the abdominus rectus and diaphragm). The overall goal of this protocol was to strengthen the presumed EAS reflex that normally counters the internal anal sphincter inhibitory response to rectal distension. However, reinforcement for EAS contraction was contingent upon maintaining stable rectal pressure, because increases in rectal pressure during stool urgency can overcome relative sphincter closure pressure, and thus would be counterproductive to retention. Subsequently, the EAS response to rectal distension was determined to be a learned, rather than an involuntary response. As a result, the theoretical basis for the use of operant conditioning (biofeedback) in the treatment of bowel disorders was established [212].

### **III. BIOFEEDBACK PROTOCOLS**

There is wide variability (i.e. no standardisation) in the biofeedback literature for FI. Studies use different instrumentation, training procedures, adjunctive strategies, samples, outcome measures, or follow-up periods. Therefore, straightforward comparison of study outcomes and statistical analysis of multiple outcomes is not possible. Most biofeedback protocols can be placed into one of three general categories on the basis of the procedures used for training and include:

- 1 strength training, defined as the reinforcement of sphincter or pelvic floor muscle (PFM) contraction to improve EAS strength without attention to sensation [213-219],
- 2 sensory training, defined as the reinforcement of heightened sensitivity to stepwise reductions in rectal distension volumes without emphasis on improvements in sphincter strength [220, 221], and
- 3 combined training, defined as the reinforcement of rectal sensitivity, a short-latency EAS response in the absence of rectal pressure changes and also sustained EAS contraction to improve sphincter strength [222, 223]. Variations of these procedures include the reinforcement of tolerance to progressively larger volumes of rectal distension and control of urgency [224, 225]. Instrumentation



used to measure and reinforce the changes in biological activity include pneumatic and perfusion manometry, surface electromyography (EMG) and recently transanal ultrasound [226, 227]. Some workers have suggested the use of a multi-variable EMG protocol that mirrors the manometric protocol by substituting surface abdominal EMG electrodes for the rectal pressure balloon to measure extraneous abdominal muscle wall contraction that is associated with increases in rectal pressure. An EMG probe is placed within the anal canal or vagina to measure external anal sphincter or pelvic floor muscle activity [228]. There is limited support for the use of abdominal EMG measures as valid and reliable indices of muscle activity associated with increased intra-abdominal pressure and for the use of pelvic floor EMG measures as indices of pelvic floor and EAS contractile function [229, 230].

#### IV. STUDY SAMPLES

A systematic review found 46 studies in adults published in English from 1974-2000 [231] that included a total of 1364 patients. Another, review assessed 35 studies published from 1973-1999 which met inclusion criteria as being prospective, using 5 or more subjects and included an a description of biofeedback procedures used [232]. Subsequently, 16 additional papers were published from 2000-2004 [90, 107, 226, 233-245].

The majority of patients in all published studies are female. Ages studied range from 6-97 (studies primarily of children were excluded). Aetiology and symptom severity was highly heterogeneous. However, some studies did select subjects according to specific problems such as obstetric injury [90, 245-247], severe pudendal nerve deficit (215), transit time [237], older people [223] or severe FI [235]. Other studies restricted their samples to patients who had undergone ileo-anal reservoir procedures (87), rectosigmoidectomy and creation of a J- pouch [248], and anterior resection of the rectum combined with total colectomy [249]. Subjects in two studies had stomas [224, 241] with treatment provided in preparation for stoma closure, but data was not provided regarding changes in actual faecal incontinence from pre- to post-treatment in these reports.

Two studies restricted their samples to patients with neurological disorders associated with diabetes mellitus [57] and multiple sclerosis [250].

#### V. VARIABILITY IN TREATMENT METHODS

There is considerable variation in the methods used in biofeedback training for FI. Seventeen studies used EMG to improve EAS contraction [213-219, 233, 236, 245, 248, 251-258], two reports used anorectal ultrasound [226, 227] while the remaining reports used pressure sensors, anal rectal manometry, or the method used was not stated. Using manometry, some studies have trained short-latency EAS contractions in response to recognition of rectal distension, while others have also reinforced sustained EAS contraction to improve strength.

Two studies attempted a component analysis to determine whether rectal sensory training or EAS strength training was more effective in reducing faecal incontinence. They concluded that the primary mechanism responsible for symptomatic improvement was increased rectal sensitivity [221, 259]. However, limitations in the applied strength training procedures preclude valid comparisons of strength vs. sensory training methods in these studies [260]. In a between-group design, one study [233] compared out-patient intra-anal EMG strength training to EMG plus sensory training using an intra-rectal balloon, EMG plus home biofeedback training, and EMG, sensory training plus home biofeedback. No added benefit was found when the more comprehensive protocols were used, but small group sizes make this study inconclusive. On the other hand, a protocol that applied well-defined strength and sensory training procedures in the treatment of severe stool incontinence [235] found that responders to treatment improved both EAS squeeze pressure and rectal sensation. However, those that did not respond to treatment showed improvements in squeeze pressure equivalent to those who had responded, but did not show similar changes in rectal sensation, indicating that a certain level of rectal sensation is necessary for the reacquisition of continence.

Between 1 and 28 treatment sessions have been provided over 1 day to one year. Time spent in each treatment session ranged from 30 to 90 minutes or is not stated. Some studies controlled for the use of anti-diarrhoeals [235] or provided specific bowel management interventions prior to active treatment [223]. Other studies simply stated that patients were selected from those who had failed prior medical management. Alternatively, one study using a between-group design of 4 different treatments, compa-

red management and advice that included the use of anti-diarrhoeals to the same protocol plus: EAS exercise, EAS exercise and clinic biofeedback, or EAS exercise, biofeedback and the use of a home trainer [107]. In addition to diet and bowel management, other adjunctive treatments that have been used with biofeedback include electrical stimulation [245-247] and home biofeedback equipment [107, 233].

Most studies report that patients are instructed in home exercises but many do not specify the precise instructions given to the patients. Some studies state that subjects were simply instructed to contract the EAS with any feeling of rectal distension at home, while others provided structured sphincter exercise programmes. Three studies reported the degree of patient compliance to the assigned exercises [107, 235, 238]. However, a clear relationship between long-term improvement and continued exercise was not established. For example in one study, [235] only 26% of the subjects reported that they continued to perform PFM exercise at 12 month follow-up even though all subjects who improved initially (71%) maintained the gains at follow-up.

## **VI. RESPONSE TO TREATMENT: RANDOMISED CONTROLLED STUDIES**

A Cochrane review [261] of randomised or quasi-randomised studies found 5 eligible studies that used biofeedback to treat faecal incontinence [221, 223, 246, 259, 262]. The Cochrane review included the outcome data from a total of 109 patients who were participants in four published papers and a single abstract [261]. Four of the 5 trials were found to have potential methodological bias and only 2 trials provided data in a form suitable for statistical analysis. The reviewers [261] felt that the evidence from the reviewed trials was insufficient to conclude that biofeedback treatments are useful in the reduction of FI. Additionally, the reviewers [261] found limited evidence to support the usefulness of any specific component of the biofeedback protocols tested with the exception of rectal sensitivity, which was consistently found to be associated with improved continence when biofeedback was administered.

Subsequent to the Cochrane review [261], four additional RCTs were published. One [233] study compared 4 different biofeedback protocols but did not have a non-biofeedback control group. Before patients were randomised to the different biofeedback protocols, they underwent medical and bowel

management but the time period of initial intervention was unspecified. Although there was an overall 74% reduction in stool incontinence after biofeedback, no difference in effect was found between the different protocols. However, interpretation of effects was hampered by small group size.

Another study compared manometric biofeedback, anal rectal ultrasound biofeedback and sphincter exercise taught with digital examination alone [226]. All groups showed modest improvements in bowel control with 70% of the subjects reporting improvement. Improvements in bowel control were associated with modest changes in anorectal measures. However, neither manometric or ultrasound biofeedback provided added benefit to digitally taught sphincter exercise on any of the nine outcomes measures.

Another RCT [107] used four groups to compare the effects of a behavioural treatment from a specialized nurse that included advice on bowel management, diet, urge control and the use of anti-diarrhoeal medication, to the same behavioural management but with the addition of: sphincter exercises, exercises plus clinically administered biofeedback, or exercises, clinical biofeedback and home biofeedback. Each group received a median of five (range 1-9), 45-90 minute treatment sessions. No difference was found between groups on ratings of bowel control or physiological measures. These findings suggest that biofeedback did not provide any additional benefit to behavioural and medical management. When outcomes were collapsed across all subjects, modest reductions in symptoms of 54% and 53% were reported to occur in the advice and biofeedback groups, respectively.

Although manometric indices of sphincter function improved across all groups, an unexpected and unexplained numerical decrease in squeeze pressure was reported in one of the biofeedback groups, and minimal change was reported in the other biofeedback group. However, the outcome analysis was appropriately conducted on an intention to treat basis. In this study a 20% drop out rate was reported, which is consistent with other studies that have also reported drop out rate. But unlike Norton [107], most studies have reported outcomes only on subjects completing treatment rather than on an intention to treat basis. As result of the more stringent analysis, the Norton outcomes appear to be lower than many of the other reports.



## VII. RESPONSE TO TREATMENT: UNCONTROLLED STUDIES

Most studies use some form of self-report collected from diaries, symptom questionnaires, or continence scores as the primary dependent variable. Criteria used to determine a successful outcome varies from 90% [205, 263] to 50% [264] reduction in incontinent episodes or subject's ratings of improvement. Most studies report an overall response rate that combines improvement and cure rates. Reported improvement ranges from 0% [215] to 100% [265]. Four studies [215, 234, 266, 267] reported improvements below 50%, 21 reported improvement from 50-75% and 23 studies reported improvement of 75% or greater, with 3 of these reporting improvement over 90%. Thirty studies reported the number of patients that achieved symptom-free or nearly symptom free status after treatment for a total of 353 of 773 (46%) patients fitting in the continent or nearly continent category.

Twenty-three studies specified a mean follow-up period greater than 12 months, 8 studies reported a range or mean follow-up that fell above 3 months and 29 studies reported follow-up less than 3 months or the time was not stated. Some studies reported outcomes at the time that treatment was completed [225, 233, 236, 246]. Of those studies having a longer follow-up, six studies reported follow-up results at 2 or more years [211, 217, 221, 238, 239, 251]. One study reported the results immediately after treatment and then at approximately 3 years follow-up and found that initial responders regressed as a function of time, leading to a conclusion that patients may need follow-up evaluation and treatment to maintain optimal function obtained with the initial treatment [239]. However, compliance to the home programme was not reported in this case. On the other hand, one study found that a majority of patients maintained, and in some cases exceeded, improvements reported immediately after treatment [238]. The long-term positive outcome in this study was attributed to the 83% home exercise compliance during the active treatment phase.

## VIII. MECHANISM OF BIOFEED- BACK TRAINING EFFECTS

Many studies have reported changes in physiological variables such as anal resting and squeeze pressures and changes in rectal sensory threshold volumes as

an outcome of biofeedback training. A few studies also have reported changes in the duration of EAS contraction [107, 222, 245] with researchers concluding that the ability to sustain an EAS contraction is more important than maximum squeeze pressure. For example, two studies found that it was the subjects who learned to extend the duration their sphincter contraction who developed continence [222, 257] after biofeedback training. This notion was supported by a study that compared the EAS fatigue rates of healthy controls to patients with constipation, seepage and stool incontinence and found that the EAS fatigue rate in incontinent patients was significantly increased compared to healthy controls and those with seepage [268].

Several studies report that improved rectal sensation is most consistently linked to improvements in continence as a result of biofeedback training [221, 236, 259]. Conversely, changes in sphincter strength are not consistently found to be associated with reductions in incontinence [210, 221, 224, 255, 267, 269] and in two studies, squeeze pressure was found to increase even in those patients that did not improve in bowel control [235, 263]. These inconsistencies have lead to questions regarding the mechanism(s) presumed to be responsible for symptom reduction as a result of biofeedback treatment [270].

## IX. PATIENT CHARACTERISTICS PREDICTING WHO WILL RESPOND TO TREATMENT

With the exception of rectal sensation [235], there are no established criteria that might predict which patients would most likely benefit from biofeedback therapy. One paper found that in addition to a rectal sensory threshold of 50ml or less, a lower EAS and IAS response threshold and an urge threshold less than 100ml were associated with better outcomes after biofeedback [235]. Another study noted that positive outcomes were associated with those patients 55 years and older and having normal defecation patterns while poorer outcomes were associated with those younger than 55 and having abnormal evacuation patterns [240]. One study noted that the need for more than 3 biofeedback sessions and a poor early response to biofeedback predicted poor long-term improvement at follow-up [217]. Several reports noted that improvements were not associated with the presence or absence of defects found with ultrasound [107, 216, 225, 268] but one study found that less robust improvements were obtained in those having passive incontinence rather than urge inconti-

nence [225]. In the one study that found that no functional improvement was obtained with biofeedback, all subjects had severe neurogenic faecal incontinence and pudendal nerve neuropathy and absent sensation for bowel urge [215]. Another study found that patients with spinal cord lesions were least likely to respond to treatment [205]. On the other hand, one study did find that subjects with pudendal neuropathy could improve bowel control with biofeedback but were less likely to show improvement in EAS strength [267]. However, the effects of bowel management strategies were not controlled. Currently, there is little evidence that shows a relationship between pre-treatment anorectal function as measured by manometry and biofeedback outcomes, with the exception of rectal sensitivity which, if found to be greater than 100ml before treatment, is associated with a poor response to biofeedback [205]. As a result, some studies have excluded patients having rectal sensory thresholds greater than 100 ml.

## **X. PELVIC FLOOR MUSCLE EXERCISES**

Historically, the use of pelvic floor muscle (PFM) exercise without biofeedback has not been used as a primary treatment for FI, unlike its application for UI where PFM exercise has been recommended as an intervention prior to the use of biofeedback. For FI, most exercise protocols have been used secondarily as anal sphincter exercise to augment the biofeedback protocol. Given that PFM exercise has been accepted as a valid treatment for UI, similar protocols may potentially improve FI as well. This is supported by one study [271] that found that levator ani function as measured by an intrarectal dynamometer was more related to severity of FI than EAS squeeze pressures obtained from anorectal manometry. Moreover, improvements in FI after biofeedback were associated with concomitant changes in levator ani strength but not changes in EAS strength. However, the two studies that have directly examined the effects of pelvic floor muscle exercise on FI report inconsistent outcomes [7, 226]. One RCT [226] found that when PFM exercises were prescribed in addition to a comprehensive behavioural management programme, no added benefit was obtained in primarily middle-aged subjects. In contrast, another RCT (7) found that when younger subjects were instructed in PFM exercises 3 months postnatally, the intervention group reported less FI at 12 months follow-up. However, in this study, the effect of PFM

exercise was not studied separately from education. Given the limited data available, there is an obvious need to investigate the effectiveness of PFM exercise alone on FI because there are no known risks associated with its application and its cost is lower relative to biofeedback.

## **XI. SUMMARY AND RECOMMENDATIONS: BIOFEEDBACK, EXERCISES AND FI**

In general, the outcomes reported from uncontrolled biofeedback studies for faecal incontinence have been favourable. However, most studies have been small and have a multitude of methodological flaws that include inadequate descriptions of subject characteristics and procedures, the use of heterogenic samples, and limited follow-up data. Only a handful of the non-randomised studies have made efforts to control for non-specific effects. In contrast to the mostly favourable outcomes reported in uncontrolled studies, two randomised controlled trials found no additional benefit when biofeedback was added to either a comprehensive behavioural and medical management programme [107] or to digitally taught sphincter exercise [226]. Although larger and randomly controlled, these trials [107, 226] have limitations.

We still lack precise knowledge of the mechanisms responsible for improvement when biofeedback is used to treat FI, and we do not yet understand the extent to which any specific biofeedback protocol alters parameters of anorectal function. The exception is rectal sensitivity, which is the single physiological parameter that has been reported to most consistently improve with biofeedback. However, not all subjects that show improvements in rectal sensitivity also develop continence. Thus, rectal sensitivity can be considered a necessary but not sufficient variable for continence. In contrast to rectal sensation, EAS strength has not been shown to consistently improve with biofeedback even when protocols have been directed to improve EAS function. Herein lies an essential empirical question for the field that must be answered before we can determine whether biofeedback is a useful tool in the treatment of stool incontinence. For, if changes in sphincter function are not observed when the stated goal of a biofeedback procedure is to improve sphincter strength, the validity of the protocol can be questioned and accordingly, conclusions based on the outcomes must be limited. Protocols then should

be appropriately altered to achieve the stated goal of changing EAS function before it can be adequately tested again. As in the field of psychophysiology from which biofeedback has evolved, a test of biofeedback effectiveness for any disorder cannot be accepted as an adequate evaluation of the treatment without evidence that the targeted physiology has been changed to a valid criterion of function [272]. Accordingly, any biofeedback protocol for faecal incontinence must be shown first to have altered some aspect of anorectal or bowel physiology, before it can be tested as a treatment. Without validation of the biofeedback procedure itself, the analysis of group effects tends to be primarily, a test of non-specific effects.

*In summary, the primary problems in the biofeedback and pelvic floor muscle literature are:*

1. Biofeedback studies for FI have employed a variety of methodologies that range from rectal sensitivity training to sphincter strength training but without standardisation of methodology.
2. Although uncontrolled studies using biofeedback for FI have reported mostly favourable outcomes, results from larger RCTs have not demonstrated a benefit of biofeedback over comprehensively administered behavioural and medical management or sphincter exercises alone.
3. There is a need to conduct further RCTs to determine whether specific biofeedback and pelvic floor muscle exercise protocols can alter physiological parameters of ano-rectal function with concomitant changes in bowel control.

## RECOMMENDATIONS

Because recent RCTs have raised questions whether biofeedback provides a specific benefit relative to education and good clinical management despite a large body of uncontrolled studies supporting its efficacy, the consensus of the committee is that it is possibly effective but currently unproven.

1. The use of biofeedback as a treatment for FI is recommended after other behavioural medical management is tried given the numerous positive outcomes from uncontrolled trials, limitations in the current RCTs and low morbidity associated with its application. (Grade C recommendation)

2. PFM exercises are recommended as an early intervention in the treatment of FI based upon low cost and weak evidence suggesting efficacy (Grade C recommendation).

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## H. EXTERNAL ELECTRICAL STIMULATION FOR FI

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Note: Surgically implanted electrodes are covered in Committee 19.

### I. THE PHYSIOLOGICAL BASIS OF THE EFFECTS OF ELECTRICAL STIMULATION

Anal electrical stimulation (ES) was first described for treatment of faecal incontinence over 40 years ago, firstly as an implanted stimulator [273] and later as needle EMG stimulation [274]. As technology has developed, more comfortable surface electrodes have become available either as skin or intra-anal plug devices with a battery box. ES may be provided by a mains-powered machine or by a portable battery-powered stimulator. The advantage of a small device is that it is easier for the patient to use on a daily basis. Development of vaginal and anal electrodes make it possible for the patient to sit, stand or move during a training programme. There is at present no experimental evidence upon which to select optimum electrical stimulation parameters for different symptoms and clinical conditions.

An electric current of sufficient amplitude will excite nerve and muscle tissue in its field. In addition, the current will alter cell membrane potentials and therefore exert an influence on all living cells. The full extent of this influence is not known but studies have shown an increase in axonal budding following denervation and an increase in vascularisation and muscle bulk when the stimulating electrodes are placed in an area of striated muscles [275]. Also normalisation of the reflex activity of the bladder by using ES has been reported [276].

Maintenance of continence requires volitional cortical control which is dependent upon the sensory feedback from the ano-rectum [277] and the ability to sense rectal distension and impending defaecation and to relax or contract the striated muscles of pelvic

Table 7. Studies of electrical stimulation for FI

Author/year	No. of patients	Gender	Inclusion Criteria	Modality	Frequency	Pulse width	Stim duration
Fynes 1999	40	f	obstetric	anal plug ES + BFB + PFMT vs. vaginal BFB	20 & 50 Hz		5 sec (20 Hz), 8 sec 50 Hz
Jost 1998	30		atrophic muscles	anal plug ES	50 Hz		5 sec
Kientle 2003	70	37f, 33m	prior to stoma closure	anal plug ES + PFMT vs. BFB = PFMT	20 Hz		2 sec
Larpent	13	9f, 4m		anal plug ES			
Lerol 1999	33		self-selected	anal plug ES	50 Hz	1 ms	2 sec
Menard 1997	14	6f, 8m	congenital	anal plug + BFB	20 & 50 Hz		
Mills 1990	39	f		surface	10-33 Hz	80-200 ms	4 sec
Osterberg 1999	24	20f, 4m	idiopathic or "neurogenic"	anal & vaginal plug	25 Hz		1.5 sec
Pescatori 1991	15		partial FI	anal plug ES	20 Hz		10 sec
Peticca 2000	32			ES + BFB + PFMT	10-20 Hz		2 sec
Scheuer 1994	10		total incontinence, poor squeeze	anal plug	27-30 Hz		9 sec
Sylvester 1987	7			interferential current	10-100 Hz		

Author/year	Time off	Treatment frequency	Session duration	Intensity of stimulus	Length of treatment	Length of follow up	Outcome
Fynes 1999	8/30	weekly	15 min		12 weeks	Nil	ES + BFB better than BFB alone
Jost 1998	5 sec	daily	15 min	individual tolerance	3 months		
Kientle 2003	4 sec	1-2x per day	15 min		3 months min		BFB better than ES
Larpent		daily	30 min		10 days	8-25 months	8/13 improved
Lerol 1999	4 sec	2x day	15 min	individual tolerance	4 months		2 responded with loperamide
Menard 1997		2x week-monthly	5-10 min		mean 10 sessions		12/14 improved
Mills 1990	4 sec	daily home	10-60 mins		12 weeks +	3 months	20/39 completed; 17/20 improved
Osterberg 1999	3 sec	daily	20 min	max tolerated	12 sessions in 4-5 weeks		11/24 improved
Pescatori 1991		daily	30 min		10 days		10 responded, anxiety improved
Peticca 2000	4 sec	2x day	5-15 mins	progressively increased	10 sessions	6-35 months	5 dropped out; 11 continent; 8 improved; 8 no change
Scheuer 1994	6-21 sec	2x day	30 min	individual tolerance	12 weeks		2/10 improved
Sylvester 1987		3x week	20 min	individual tolerance	12 sessions	1 month	not effective



floor [278]. The motor control of the pelvic floor muscles is a learned voluntary response albeit often at a subconscious level [212, 279].

Functional electrical stimulation activates both sensory and motor axons. The sensory axons send signals to the brain and it is thought may cause plastic changes in the representational area of a body part. The result of this is enlargement of the representation and improvement of awareness of the stimulated body part. This leads to better control of movements [278]. In theory ES may therefore reinforce weak functional signals that come from the pelvic floor musculature during the treatment [280], although this remains to be demonstrated experimentally.

There are many good studies of the use of ES to improve the function of other striated muscles and this knowledge may be applied to treatment of FI [281]. Stimulation parameters such as stimulation frequency, pulse width, on:off ratios, and current intensity are very important as it is possible to cause fatigue and other problems by using incorrect parameters, too long a treatment time or too high an intensity.

## II. QUALITY OF DATA

There have been few studies of ES in faecal incontinence (**Table 7**). Most studies included small numbers of patients and provided limited details of what was done within the intervention programmes.

## III. RESULTS

One controlled study has been conducted [246]. Forty women with obstetric-related faecal incontinence were randomised to anal biofeedback and exercises with adjunctive electrical stimulation, or vaginal biofeedback and exercises (no electrical stimulation) with a different therapist. Both groups improved symptomatically, with no difference in symptoms between the groups. The stimulation group also improved manometric pressures. However, electrical stimulation was not the only variable in the study, there was no follow up beyond the 12-week study period and the difference in outcome found could have been the effect of a different therapist or biofeedback method. Another attempted controlled study in patients who had FI following repair of obstetric third degree tear abandoned stimulation because it caused discomfort [247].

A prospective study compared biofeedback and electrical stimulation in patients who, in the majority of cases, had so called "potential" faecal incontinence before stoma closure [241]. Forty patients were treated by biofeedback training, and 30 patients were treated by electrostimulation. All patients were encouraged to do pelvic floor exercises in addition to their training program. No description was given of stimulation. The biofeedback group was trained with a manometry-based balloon system. Biofeedback appeared to be more effective in this context than ES. Resting and squeeze pressure and resting and squeeze vector volume all increased significantly after biofeedback training ( $p < 0.05$  and  $< 0.001$ ). Only resting pressure and squeeze vector volume were significantly improved by electrostimulation ( $p < 0.05$  and  $< 0.01$ ). The increase in squeeze vector volume was significantly greater in the biofeedback group ( $p = 0.03$ ). The estimated median time period from commencement of training until stoma closure was 9 months in the biofeedback versus 21 months in the ES group.

Larpernt and his colleagues [282] treated 13 patients with anorectal incontinence by ES in an uncontrolled study. The basal pressure of the external anal sphincter and the squeeze pressure improved significantly ( $p < 0.05$ ,  $p < 0.04$  respectively). Some studies may have used parameters that cause fatigue or a rest period that is too short for weak external sphincters [283]. Improved rectal sensation may be associated with a positive outcome [280]. Patients with the most severe incontinence and muscle impairment might be expected to benefit least [284]. Interferential current has not been found effective [285] and has since fallen out of use in most areas of physiotherapy.

## IV. SUMMARY ON ELECTRICAL STIMULATION FOR FI

A Cochrane review of trials of electrical stimulation for faecal incontinence has concluded that "At present, there are insufficient data to allow reliable conclusions to be drawn on the effects of electrical stimulation in the management of faecal incontinence. There is a suggestion that electrical stimulation may have a therapeutic effect, but this is not certain" [286]. We concur with this conclusion.

Because there is a lack of consistency in electrical stimulation protocols and also a failure to use phy-



biological principles when employing using electrical stimulation, direct comparison between studies is impossible. There are many parameter and clinical applications that have not yet been investigated. We know little about which patients are likely to benefit from ES. Sensory awareness of the body schema and the possibility of improving this cortically by using ES may be important in motor re-learning for those patients with severe sensory loss, but this has not been investigated.

## **V. FUTURE RESEARCH & RECOMMENDATIONS ON ELECTRICAL STIMULATION FOR FI**

Randomised controlled trials with adequate sample sizes are necessary to investigate all aspects of the effectiveness of ES in faecal incontinence. Rectal hyposensitivity is common in patients with constipation and/or faecal incontinence [287]. Functional electrical stimulation combined with daily activities and its effectiveness in changing consciousness of the cortical schemes of the pelvic floor is one of the interesting future areas for research. When planning future research basic knowledge of electrical stimulation parameters and other important factors could be utilised from the other areas where electrical stimulation has been widely used [281].

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## **I. CONCLUSIONS AND RECOMMENDATIONS**

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There is a number of potentially beneficial conservative and drug interventions for faecal incontinence in adults. The evidence base does not at this time provide strong evidence for efficacy or guidance for patient selection.

### **I. RECOMMENDATIONS FOR PRIMARY PREVENTION OF FI**

1. Encourage and support public hygiene measures to reduce diarrhoeal diseases (Grade A).
2. Discourage episiotomy except in restricted circumstances (Grade B).

3. Discourage the use of internal anal sphincter myectomy for treatment of anal fissure and haemorrhoids (Grade A).
4. Continue the debate on elective Caesarean delivery to prevent sphincter laceration, but no recommendation is given by this working team.

### **II. RECOMMENDATIONS FOR SECONDARY PREVENTION OF FI**

1. Health care providers should aggressively investigate all patients for FI who present with the most common risk factors: urinary incontinence, pelvic organ prolapse, diarrhoea, vaginal delivery with sphincter laceration, multiparity, mobility impairment, dementia, and other neurological conditions (Grade C).
2. In patients with frequent, loose stools, screen for drug side-effects, lactose intolerance, and high intake of artificial sweeteners or other foods likely to cause diarrhoea (Grade C).
3. Research is needed to assess the benefits of pelvic floor muscle training for the prevention of FI in women undergoing vaginal delivery.

### **III. LIFESTYLE INTERVENTIONS AND EDUCATION**

At present there is no convincing evidence for these interventions in FI (Level D: possibly effective but unproven).

### **IV. DIET AND FLUID INTAKE**

1. Soluble dietary fibre is recommended for the management of FI associated with loose stool. (Evidence level 1. Recommendation Grade B).
2. No studies of any other dietary intervention for managing faecal incontinence were found.

### **V. BOWEL MANAGEMENT AND RETRAINING PROGRAMMES**

Level D evidence at present: possibly effective but unproven

## VI. DRUG TREATMENT OF FI

1. Loperamide is supported for the treatment of diarrhoea-associated FI (Level 2 evidence, Grade B recommendation).
2. Laxatives can be used to treat constipation-associated faecal incontinence, (Level 2 evidence, Grade B recommendation).

## VII. BIOFEEDBACK AND/OR ANAL SPHINCTER / PELVIC FLOOR EXERCISES

1. The use of biofeedback as a treatment for FI is recommended after other behavioural and medical management is tried given the numerous positive outcomes from uncontrolled trials, limitations in the current RCTs and low morbidity associated with its application (Grade C recommendation).
2. PFM exercises are recommended as an early intervention in the treatment of FI based upon low cost and weak evidence suggesting efficacy (Grade C recommendation).

## VIII. ANAL ELECTRICAL STIMULATION

Level D evidence – possibly effective but unproven.

## IX. OUTCOME MEASURES

The committee noted wide variety and inconsistency in reporting of outcomes. The committee agree with the findings of Committee 6: there is a need for development of validated outcome measures for studies of FI.

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