# Committee 11 C

# **Surgical Treatment of Incontinence in Women**

# Chairman

A.R.B. SMITH (U.K.)

# **Members**

F. Daneshgari (USA),

R. DMOCHOWSKI (USA),

G. GHONIEM (USA),

G. Jarvis (U.K.),

V. NITTI (USA),

M. PARAISO (USA)

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# **Surgical Treatment of Incontinence** in Women

T. SMITH,

F. Daneshgari, R. Dmochowski, G. Ghoniem, G. Jarvis, V. Nitti, M. Paraiso

### INTRODUCTION

The committee was asked to critically review the literature on the surgical treatment of incontinence in women. The literature on surgery for stress incontinence is large but has many shortfalls. These are detailed and the confounding variables which make it difficult to compare one paper or procedure with another are reviewed.

The remainder of the chapter includes surgery for urethral diverticulae, refractory detrusor instability and non-obstetric fistulae. This literature is almost entirely based on case series making critical review more limited. Whist not under-estimating the difficulty in conducting well constructed, prospective, randomised trials of surgical treatment the review highlights the need for such trials to be performed.

# SURGERY FOR STRESS INCONTINENCE

### 1. HISTORICAL BACKGROUND

Surgery for stress incontinence of urine has been performed on women for over a century. The emphasis in the earlier reports focused predominantly on technical aspects of the surgery. In an attempt to address the problem of failure noted with vaginal continence surgery, (Bailey 1954) first classified types of stress incontinence according to the anatomical relationship between urethra and bladder, using radiographical studies. This classification was simplified by (Green 1973) and further modified by (McGuire 1976). However, by the early 70's the anterior vaginal repair was still the most popular primary procedure for stress incontinence. Failure or recurrence would be followed by a retropubic procedure. Over the last two decades this approach has been criticized because of the high recurrence rates reported for the vaginal repair and the more favourable and sustained results from retropubic surgery.

# 2. LITERATURE SHORTFALLS

The literature on surgery for stress incontinence is extensive. There are many deficiencies in the literature which make it difficult to compare the relative merits of the numerous procedures described. Case selection is varied and often not well described. Pre and post-operative assessment varies from full urodynamics including pad tests to symptoms review alone. The surgical technique and peri-operative complications are often ommitted. It has long been recognised that the risk of recurrence for any procedure is maximal in the first 2 years and continues with advancing age thereafter. Despite this, many reports include short-term follow up thereby producing an over-optimistic view of outcome.

Cure is defined in many different ways, both subjective and objective. The impact of complications from bladder neck surgery has only more recently been studied. What is the value of a procedure which cures stress incontinence but replaces it with urge incontinence or voiding dysfunction? Recent reports which include the social impact of stress incontinence surgery and the effect on Quality of Life help to address this question.

The inclusion of women whose symptoms have "significantly improved" with those who are cured is common. This group is often not well defined yet may greatly affect the apparent merit of a procedure. Research into the relationship between improvement of symptoms and objective parameters is needed.

The majority of surgical reports published, even in recent years, lack clarity in defining many of the variables that may influence outcome. In this chapter we have highlighted a number of confounding variables which might be expected to influence outcome. It is apparent that the level of evidence for most of these is such that no conclusions can be drawn about their level of impact or indeed whether they have any impact at all.

In order that the reader can evaluate the literature more clearly levels of evidence have been included for each of the surgical procedures described.

Ultimately, the role or value of a procedure will depend

on which outcome measure you choose to study. Some women regard absolute continence as the most important outcome. For them, a simple pad test would provide an adequate objective analysis of the chance of success from a procedure. Some women, whilst regarding continence as desirable, prefer to minimize the risk of complications such as voiding dysfunction. For them additional information on the risks is required. How much the complications of continence surgery impact on a woman's quality of life has not been fully studied. This needs to be addressed to determine whether surgery for stress incontinence should be offered on a one operation for all women basis or by selection of the procedure according to the outcome required. Currently most surgeons have a favourite procedure they use for women with stress incontinence. Some surgeons, particularly those with an interest in the field, will attempt to select the procedure according to pre-operative findings. The section on confounding variables highlights the difficulty in doing this accurately or at least on a scientific basis.

### 3. REVIEW OF PROCEDURES

# a) Anterior colporrhaphy (Figure 1)

The anterior colporrhaphy procedure is perhaps better termed the anterior repair with bladder buttress when relating to the surgery for genuine stress incontinence. Anterior colporrhaphy and the Kelly type repair are also a part of pelvic reconstructive surgery for prolapse (vide infra).

Case report literature indicates a wide range of continence rates following this procedure, ranging between 31% and 100% continence (Jarvis 1994a). Meta-analyses of heterogenous studies suggest a continence rate of between 67.8 and 72.0% (Jarvis 1994a,b).

Randomised trials which include anterior colporrhaphy in one arm and generally suprapubic surgery in the other show a continence rate of 66% (Jarvis 1998). Only 257

women received anterior repair and were compared, in seven trials, with 454 comparable women randomised to another intervention.

The anterior colporrhaphy procedure remains in contemporaneous use largely because of the relatively low morbidity of the procedure. The 'serious complication rate' is in the region of 1%, the incidence of de novo detrusor instability is not greater than 6%, and compared with colposuspension there may be a shorter hospital stay and a 50% decrease in blood loss. The incidence of long-term voiding disorders following this procedure approaches zero (Jarvis 1994b, Beck 1991, Jarvis 1981, Loughlin 1982).

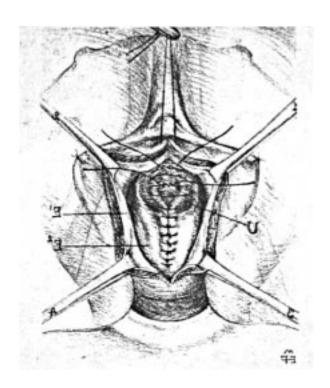


Figure 1: The anterior repair is conventionally performed through a midline anterior vaginal wall incision. The diagram illustrates the creation of a layer of endopelvic fascia to provide additional support to the urethra.

Long-term results decrease with time such that a 63% cure rate at 1 year of follow up fell to 37% at 5 years of follow up (Bergman 1995). Long term follow up beyond the first year was only available in 3 randomised control trials (RCT). (Bergman 1989), (Liapis 1996), (Colombo 2000).

The view of the American Urological Association is that 'Anterior repairs are the least likely of the four major operative categories (anterior repair, suburethral sling, colposuspension, long needle suspension) to be efficacious in the long-term' (Leach 1997).

The literature regarding the anterior vaginal repair has also been reviewed fully by the Cochrane Library (Glazener 2000)

### CONCLUSION

The view of the First International Consultation on Incontinence was 'Perhaps the major indication for bladder buttress in contemporary practice must be the patient who prefers to sacrifice some degree of chance of becoming continent for a reduced chance of complication' (Jarvis 1998)(Level 1). There is no scientific information which should lead to a revision of these opinions. (Recommendation Grade A)

# b) Colposuspension (Figure 2)

Sixteen substantive articles were reviewed. Two of the studies are prospective randomised trials and 9 are prospective non-randomised studies. These articles report the treatment outcome on a total of 1363 women who underwent Burch colposuspension for stress urinary incontinence, mean age of 51 years. Among these women, 267 patients had had a previous anti-incontinence surgery. The mean cure rate (as defined by a combination of subjective and objective evidence) was 79% with an improvement rate of 90%. The follow up duration was 9 months to 16 years. The immediate and longer term results from colposuspension suggest that the procedure remains effective with time. There are two studies which report 5+ years cure rates of 82% (Alcalay 1995, Bergman 1989) Bergman (1995) reported a 90% continence rate at 8 years whilst Kjolhede (1994) reported only 55% cure at 10 years. Alcalay (1995) reported a gradual decline in success rate from 88% at 2 years to a plateau of 69% once 12 years or longer had been reached.

Voiding dysfunction has been reported in a mean of 10.3% of women after colposuspension (range 2-27%). De novo detrusor instability has been described in a mean of 17% women (range 8-27%). Genito-urinary prolapse (enterocoele, rectocoele or cystocoele has been reported in colposuspension follow up at 5 years in an average of 13.6% women (range 2.5-26.7%). This is reviewed later in the section under stress incontinence and prolapse. Other complications are reviewed in a separate section on complications. There was no reported mortality as a direct consequence of the procedure. The summary of the data is presented in table-1.

### • MARSHALL-MARCHETTI-KRANTZ

The Marshall-Marchetti-Krantz (MMK) retropubic procedure was a common anti-incontinence procedure between 1950-90's. Krantz (Krantz 1980) described a personal series of 3861 cases with a follow up of up to 31 years and a 96% subjective cure rate. The success of MMK in treating SUI in women is reviewed in 58 articles that are predominantly retrospective studies between 1951-1998. The preoperative assessment was mainly with history and physical examination, with few studies reporting on other objective data such as urodynamic or pad test. These articles reported the treatment outcomes in a total of 3238 cases. The reported cure rate (mostly subjectively defined) was 88% (2850 patients). The improvement rate is reported as 91% (2946 patients). As a primary procedure in 1211 cases, the MMK had a success rate of 92%. In 1046 repeat cases, the success rate was 84%. The remaining 981 procedures could not be classified as primary or repeat.

The mortality was 0.2%, with 22% overall complication rate. The one complication which would appear to limit the use of this procedure is osteitis pubis, a complication in 2.5% of these patients who undergo a MMK procedure (Mainprize 1988).

The longer term follow up data is limited. In the largest long term follow up series published, McDuffie reported a subjective continence rate of 89.7% at one year, 85.7% at 5 years and 75% at 15 years (McDuffie 1981)

### CONCLUSION

Retropubic suspension can be expected, in primary or secondary surgery, to generate a mean cure rate of 79% and an improvement rate of 90% (Level 2). A decrease in continence rate is observed with time (Level 3).

# c) Paravaginal repair

The concept of a paravaginal defect repair is, at least in theory, a logical one. It was first described by White in 1909 (White 1909) but the type of repair described by Kelly four years later (Kelly 1913) became more popluar. The Kelly type of anterior repair for genuine stress incontinence provides some central support but if there is deficiency in lateral support, then a central repair can only be of a limited benefit. It would be more logical to find the defect in the endopelvic fascia and repair it either in isolation or in combination with other procedures. Such defects in the fascia have been identified unilaterally and bilaterally, medially and laterally.

Individual cohort studies have suggested a subjective cure rate of 97% in patients undergoing a paravaginal repair (Schull 1989). However, there is as yet only a single published randomised comparison of colposuspension with paravaginal defect repair. In this study 36 patients were identified at the time of surgery when they were randomly allocated to treatment by either colposuspension or defect repair using non-absorbable suture material. At follow-up six months after surgery, there was an objective cure rate of 100% for those patients undergoing colposuspension but only 72% for those undergoing paravaginal repair (Colombo 1996).

# **CONCLUSION**

Whilst there is some eveidence that repair of paravaginal defects may result in cure of stress incontinence (Level 2) there is also Level 1 evidence that paravaginal repair, performed abdominally, is less effective than colposuspension. Thus, at the current state of knowledge, the importance of recognition or repair of paravaginal defects is uncertain.

Table 1: Summary of reported data on Retropubic suspension procedures for treatment of SUI in Women

Reference	Type of Op	No of Pts	Duration Follow up	Median age	Success criteria	Cure rate	Success rate
Alcalay M	Burch	109	13.8 yrs	46.6	Subjective -Objective clinically or on UD	70%	N/A
Bergman A 1989	Burch	101	1 yr	57	ICS criteria	87%	N/A
Bergman A 1995	Burch	33	5 yrs	55	UD and subjective cure	71%	N/A
Colombo M 1996	Burch	18	3 yrs	47.8	Subjective - Dry	100%	N/A
Feyereisi J 1994	Burch	87	5-10 yrs	49.9	Success of Fail – Dry or not	81.6%	N/A
Enzelberger H 1996	Burch	36		59.8	Dry	86%	N/A
Pentinen J) 1989	Burch	24		47	Dry, subjective satisfaction 9	6%	96%
Richmond D.H 1989	Burch	15		0	Dry	N/A	87%
Galloway N.T.M 1987	Burch	50		0	VUD	84%	N/A
van Geellen J.M 1988	8 Burch	34		46	Subjective satisfaction, VUD	75.8%	90%
Mutlu N 1997	Burch	98		0	Dry and Subjective	N/A	67%
Maher C1999	Burch	53		0	Women had no or occasional stress or urge incontinence	N/A	89%
Drouin J 1999	Burch	79		0	By Questionnaire Subjective	56%	81%
Akpinar H	Burch	50		0	Dry, subjective satisfaction	52%	82%
Maher C	Burch	50		0	No or occasional ( <one episode="" per="" td="" week<=""><td>2) 72%</td><td>89%</td></one>	2) 72%	89%
Lee RA 1975	MMK	36		0	Dry	96%	N/A
Riggs JA 1986	MMK	490		0	Dry and Subjective	N/A	93%
Fatthy H	Lsc Burch	37 37	1.5 yrs				88% Lsc 85% Oper
Summit RL	Lsc Burch	34 28	1 yr		Dry and Objective	93% Ls 88% Op	
Su TH	Lsc Burch	46 46	1 yr			80% Ls 96% Op	
Burton G	Lsc Burch	30 30	5 yrs		Urodynamic studies	57% Ls 90% Op	
Persson J	Lsc Burch	83	1 yr		Pad test and subjective	83%	

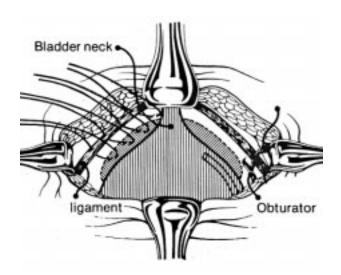


Figure 2: The diagram illustrates the location of colposuspension sutures lateral to the urethra and bladder neck. A minimum of two sutures are normally placed bilaterally.

## d) Laparoscopic colposuspension (Figure 3)

Although several case series and cohort studies show similar cure rates between laparoscopic and open Burch colposuspension, four prospective trials show similar or lower cure rates associated with laparoscopic Burch. Fatthy et al (Fatthy 200) and Summitt (2000) et al performed identical procedures by both routes and showed similar cure rates. The main criticisms of Burton's trial (Burton 1999) are that he had not gained sufficient experience with laparoscopic surgery prior to embarking on the study and that the suture used was absorbable with a small needle, which may have included insufficient thickness of tissue. Similarly, Su et al (1997) used three absorbable sutures in the open Burch compared to a single non absorbable suture in the laparoscopic procedure. Persson and Wolner Hanssen (Persson 2000) randomised patients to a one suture versus two suture laparoscopic colposuspension and found a significantly higher cure rate with the two stitch procedure at 1 year, 83% vs 58%. Unfortunately, Summitt et al (2000) and Burton's (1999) trials are published in abstract form only at present. In 2001 Morris et al (Morris et al 2001) reported on the 5 year follow up of a randomised, prospective study of 72 patients in which pre and post-operative subjective and objective assessment was performed. In this study laparoscopic colposuspension produced a cure rate of 77% at 5 years compared to a cure rate of only 48% for open colposuspension on objective testing. It is uncertain how much the experience of the surgeons influenced the results since the majority of the laparoscopic procedures were performed by a single surgeon whereas the open proce-

Figure 3: The picture illustrates the view of the retropubic space seen through a laparoscope, after colposuspension has been performed

dures were performed by a variety of surgeons. During the First International Symposium for Incontinence in Monte Carlo, Monaco, the laparoscopic Burch colposuspension was viewed with reservation because of lack of long-term follow up. The importance of avoiding compromise of the procedure by using tacks and mesh or placing fewer sutures because of technical difficulty of laparoscopic suturing must be stressed. Although quality of evidence is improving, more studies with long-term follow up are still required.

### CONCLUSION

Although there are over 90 articles published on laparoscopic colposuspension the data is influenced by many confounding variables. A meta-analysis of the RCTs published by Fatthy, Summitt, Su and Burton show a continence rate of 80% for laparoscopic colposuspension compared with 90% for open colposuspension (Level 2). If the Glasgow study (Morris et al 2001) is included in the meta-analysis laparoscopic colposuspension is shown to be at least as effective. At this stage we must conclude that there is insufficient data available to determine the value of laparoscopic colposuspension.

# e) Needle suspensions (Figure 4)

Multiple suspension procedures have been described in the past. The first procedure being described by Peyrera (1959). This was a standard needle type suspension. Numerous procedures have subsequently evolved from this including the Gittes procedure (an incision-less



Figure 4: The Stamey needle suspension is illustrated. The Stamey needle and suture is passed through the retropubic space from above and the suture is retrieved through a vaginal wound on each side of the urethra.

needle suspension procedure) and the Stamey procedure (Stamey 1973), utilizing suspending sutures and patch materials. Recently, procedures have evolved to the percutaneous bladder neck suspension utilizing bone anchors and a suspending system. The largest experience with these procedures was obtained by Raz (1992)

However, long-term follow up rates have recently been reported in two large group studies. Trockman et.al (1995) reported 77 patients at mean follow up of 9.8 years. These patients were surveyed by questionnaire means. At mean follow up only 20% of patients reported no incontinence of any type with 51% of patients reporting stress incontinence with or without urgency incontinence. 71% of patients reported significant improvement in incontinence and 73% were satisfied with the long-term success of the procedure.

Further long-term follow up of the percutaneous needle procedure specifically was reported by Tebyani et al (Tebyani), who reported 49 patients who underwent percutaneous bladder neck suspension, of whom 42 were available for interview. Mean follow up was 29 months (range 16 to 52 months). Only 5% of patients were cured of their stress incontinence with 12% significantly improved and 83% considering themselves a failure. In the only randomised controlled trial comparing Peyrera type suspension procedures and retropubic suspensions by Karram and Bhatia (Karram 1992), retropubic suspensions were found to be associated with a higher objective cure rate (98% versus 85% at minimum 1-year follow up). This study has been criticized because of alterations made in the type of suspending suture utilised in the Peyrera procedure performed in the inclusion criteria. Nonetheless, this does represent a randomised controlled trial, which was performed by the authors in an effort to compare these procedures directly.

### **CONCLUSIONS**

The long term data indicates that the initial success rates reported with needle suspension procedures are not maintained with time.(Level 3) The risk of failure is higher than reported with retropubic suspension procedures (Level 1)

There would appear to be few, if any, indications to perform a needle suspension procedure. (Grade A recommendation)

# f) Slings

Suburethral sling procedures were developed initially in 1888, by Schultze. Numerous authors have subsequently modified these procedures including Goebell and Stockell, who utilised pyramidalis muscle to form

a muscular sheath beneath the urethra. This was subsequently modified by Frangheim to utilize strips of rectus fascia, which were left attached to the pyramidalis muscular group. Giordano also proposed utilization of muscle flaps and described the transposition of the gracilis muscle in a suburethral location. Martius utilised the bulbocavernosus muscle and associated fat to provide bulk around the urethra in a further modification of the procedure.

Miller (Miller 1947) utilised strips of rectus to elevate the bladder neck; and Price (Price 1933) used strips of fascia lata and fixed the two ends to the rectus muscles. In 1942 Aldridge (Aldridge1942) utilised rectus sheath strips and reported the technique in one patient and described the procedure as a salvage type operation for those women who had failed prior procedures (Figure 5).

The suburethral sling procedure has since been used predominantly as a treatment for patients who remain incontinent despite previous bladder neck surgery. Used in such an indication, the success rate recorded in the literature would appear to range between 64% and 100% with a mean cure rate in the region of 86% (Jarvis 1994 a, Jarvis 1994 b). The cohort literature relating to the use of a suburethral sling as a first procedure is

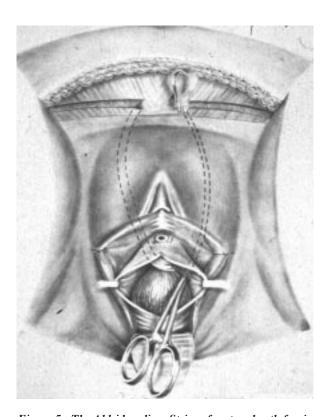


Figure 5: The Aldridge sling. Strips of rectus sheath fascia are passed through the retro-pubic space and fixed under the urethra.

limited but a mean continence rate of 93.9% is quoted (Jarvis 1994 b).

Numerous materials are available for use in a suburethral sling. As a generalisation, autologous material is associated with a greater cure rate and fewer complications than either cadaveric material or synthetic materials (Bidmead 2000). Autologous rectus fascia and fascia lata are probably the commonest materials in use. Allogenic grafts harvested from a cadaveric donor are widely used. They do not seem to carry a risk of erosion and although the short-term results appear satisfactory, there appears to be a longer term material failure rate from fascia lata allografts in excess of 20% (Singla 2000, Fitzgerald 1999). The failure rate ascribed to cadaveric fascia lata is largely from the series reported by Fitzgerald et al (Fitzgerald 1999). This, however, was not replicated in data reported by Elliot and Boone (Elliot 2000), Amundsen et al (Admundson 2000)), Brown et al (Brown 2000), and Wright et al (Wright 1998). There seems to be wide variability in the quality of tissue; depending on its source and processing. Inconsistent fascia may lead to inconsistent results. The rationale for using allo and xenografts for suburethral slings is reinforcement of inherently weak endopelvic fascia. It remains to be seen whether this adds to the body's restorative processes of healing by fibrosis and granulation.

Long-term follow up at 48 months or greater (Morgan 2000) has revealed success rates that are persistent at greater than 90% with time. Morgan (Morgan 2000) reported a 10-year follow up of 247 women with type II and III incontinence. These patients were followed urodynamically, as well as with quality of life questionnaires. At a mean follow up of 51 months, continence rates were 88% overall with a 91% cure rate for type II and 84% for type III. Preoperative urge incontinence resolved in 81 of 109 (74%), while *de novo* urgency developed in 7% of women. Secondary procedures were necessitated in 14 patients for management of incontinence. 235 of the 247 women (95%) completed questionnaire data and 92% reported a high degree of satisfaction with resolution of symptoms.

Synthetic material tends to be associated with a risk of erosion and sinus formation (Duckett 2000). Modifications designed to achieve greater stabilisation, such as anchorage to the pubic bone, are associated with good results in the short-term but carry a longer term risk of osteomyelitis at the site of anchorage (Kovan 1997, Valley 1997).

The most extensive experience has been obtained utilizing Mersilene, which was initially described by Telind. Moir in 1968 (Moir 1968) reported an 83% cure or substantial improvement in incontinence with few complications. Other authors have reported success

rates including the following: Nichols (Nichols 1973) reported 22 patients with a 1 to 2-year follow up with a 95% subjective cure rate without reported complications subjective. Herbertson (Herbertson 1993) reported 44 patients with follow up ranging from 3 to 11 years with a subjective success rate of 73% with 7 patients requiring sling revision for obstruction. Kersey (Kersey 1983) reported 100 patients with a 6-month to 5-year follow up with a 78% subjective cure rate with 2 suture exposures and approximately 23% persistent detrusor instability postoperatively. Recent studies include those of Guner (Guner 1994), who reported 24 patients with a 24-month follow up with a 96% subjective cure rate with a 4% persistent urge incontinence rate. Also, Young (Young 2001) reported 110 patients with a 13-month minimum follow up with 95% subjective and 93% objective cure rates. Two patients experienced vaginal erosions and one patient developed an inguinal sinus. These rates would imply fairly low rates of complications with this material.

Results using Gore-Tex have included Horbach (Horbach 1988) who reported 13 patients with 3 to 18-month follow up and an 85% subjective cure rate with 1 sling revision and 1 sling removal for sinus tract.

Silastic has been utilised by several authors. Chin (Chin 1995), who reported 30 patients with a 3 to12-month follow up and an 83% subjective cure rate, noted 4 sling removals for persistent retention and 1 patient with vesicovaginal fistula, and a 67% rate of de novo detrusor instability.

Overall, with all of these materials the risk of vaginal erosion ranges from zero to approximately 16%. Urethral erosion ranges from zero to 5%. De novo detrusor instability ranges from 3.7% to 66%, and procedures requiring sling revision or removal range from 1.8% to 35% of patients included in these studies.

When compared with colposuspension procedures, the suburethral sling carries a similar success rate (Jarvis 1998). This appears to be true even in patients with low maximal urethral closure pressure (Sand 2000). However, these studies involved small number of patients, short follow up and evaluated patients with a low-pressure urethra. This is not synonymous with intrinsic sphincter deficiency. In addition, the same author (Sand 1987) identified low-pressure-urethra as a risk factor for failure of colposuspension in a previous publication. (See section on urethral occlusive forces).

The intermediate and longer term results for suburethral slings suggest that the 10 year continence rate is not dissimilar from the 1 year continence rate (Jarvis 1988, Chaikin 1988).

Up to 10.8% of patients have some voiding disorder symptoms subsequent to the immediate post-operative

period (Jarvis 1994b, Bidmead 2000). Long-term self-catheterisation has been reported in anywhere between 1.5 and 7.8% of patients, although a figure of 2% may be more realistic (Jarvis 1994 a, Bidmead 2000, Chaikim). De novo detrusor instability may arise in between 3 and 23% of patients and appears to be greater in patients who have urinary urgency but an apparently stable bladder pre-operatively (Jarvis 1994b, Leach 1997, Chaikin 1998).

The American Urological Association considered that 'Retropubic suspensions and slings are the most efficacious procedures for long-term success based upon cure/dry rate. However, in the panel's opinion, retropubic suspensions and sling procedures are associated with slightly higher complication rates, including postoperative voiding dysfunction and longer convalescence. In patients who are willing to accept a slightly higher complication rate for the sake of long-term cure, retropubic suspensions and slings are appropriate choices' (Leach 1997). The First International Consultation on Incontinence concluded that suburethral slings represented 'An effective procedure for genuine stress incontinence in the presence of previous failed surgery' (Jarvis 1998). A recent survey of North American Urological Surgeons showed a significant trend towards surgeons performing suburethral sling procedures in 1999 when they rarely performed such procedures in 1995 (O'Leary 2000). The Editor of the Journal of Urology considered 'Slings - an idea whose time has come' (Loughlin 2000).

### **CONCLUSION**

Long term data suggests that sling procedures, using autologous or synthetic materials, produce a cure rate of approximately 80% and an improvement rate of 90% (Level 3). There is some data which shows that autologous material is associated with a higher cure rate and fewer complications than either cadaveric or synthetic material but there is a need to scientifically study whether the choice of material influences outcome. There is a need to address whether the choice of material influences the outcome. There is some evidence which suggests that placement of a sling without tension reduces the risk of post-operative voiding dysfunction (Level 3).

### g) Tension-free vaginal tape (Figure 6)

The prolene tension-free vaginal tape (TVT) is a relatively new procedure although increasing numbers of cohort studies are being reported. The procedure is of particular importance in understanding the mechanisms by which surgery is effective, given that the suburethral sling is inserted without tension and the site of insertion is the mid urethra. The originator of the procedure



Figure 6: The prolene mesh sling is inserted through a small vaginal incision under the mid-urethra. A needle with mesh attached is passed through the retropubic space on each side of the urethra and bladder and brought through the anterior abdominal wall.

reports that at 3 years 86% of women were 'completely cured', whilst a further 11% were 'significantly improved' (Ulmsten 1999). Others have reported comparable statistics; one series reporting that 80% of women were cured and a further 17.5% significantly improved, whilst a further series reported that 94% of treated women were either continent or significantly improved (Moran 2000, Nilsson 2001). The six month subjective and objective results of a randomised trial between TVT and colposuspension showed a similar cure rate from both procedures (Ward 2001). In this study, where TVT and colposuspension was employed as a primary procedure, the reporting of complete dryness in both groups was 38% and 40% respectively. Dryness with stress was reported in 66% and 68% of women. The 2 year follow up results of this study was reported in abstract form in December 2001. On the basis of a primary outcome measure of a negative cystometrogram and pad test 68% of TVT and 66% of colposuspension patients were cured. If pad test alone was used a cure rate of 75% was achieved in both groups. Over 60% of women were subjectively cured in both groups. This study highlights the difficulty with defining "cure". The only difference in outcomes at 2 years relates to voiding dysfunction and the need for surgery for utero-vaginal prolapse which appear to be more common in the colposuspension group.

The majority of patients are potentially treatable without general anaesthesia and on a day case basis (Ulmsten 1999). Somewhere between 3% and 15% of patients developed symptoms compatible with the onset of de novo detrusor instability (Moran 2000, Nilsson 2001). Short-term voiding disorder is described in 4.3% of women, although longer term voiding disorder does not appear to be a specific feature (Ulmsten 1999, Moran 2000, Nilsson 2001). Prolene mesh erosion has been reported 2 out of 137 women reviewed at 2 years.

In a multi-centre study, intra-operative bladder perforation was recognised in a mean of 9% of procedures (Ward 2001). A report from Finland (Kuuva 2000) on 1455 TVT procedures revealed 8 cases of significant bleeding, 3.8% chance of bladder perforation, and 2.3% chance of a voiding disorder. It was concluded from this evidence that the "TVT is a safe method for treatment of stress incontinence". There is a need for long-term results and randomised trials involving this procedure. Variations in technique and materials used need further evaluation.

### **CONCLUSIONS**

Two year follow up data from a single RCT demonstrates a similar success rate to open colposuspension (Level 1). Large cohort analysis shows a cure rate of 80% and an improvement rate of 94% (Level 2).

### h) Injectable agents

The cure rate, defined in 15 articles as completely dry, was 48%. The success rate (defined as dry and/or improved) was 76%. Only 8 studies defined intrinsic sphincter deficiency either as VLPP < 60 CM.H2O or through stress video urodynamics to assess bladder neck opening. Parity, BMI, uterovaginal prolapse and family history were not assessed as a potential influence on the outcome in the majority of the studies. Most of the studies include a small number of women and only short term follow up.

A number of bulking agents have been used for the treatment of SUI in women. The bulking agents (collagen, teflon, fat and recently Durasphere) are injected in a retrograde (more common) or antegrade fashion in the periurethral tissue around the bladder neck and proximal urethra. Among the eighteen larger published studies on bulking agents, fourteen are on Glutaraldedehyde Cross Linked Collagen. From the eighteen articles on bulking agents for the treatment of urinary incontinence in women (see Table 2), 8 are prospective nonrandomised studies. A total 1221 patient were included, mean age 61 years. Follow up was between 3 months and 2 years, (mean of 12 months).

Macroplastique (Uroplasty bv.Geelan, The Netherlands) consist of solid polydimethylsiloxane (silicone) elastomer implants in a water-soluble hydrogel carrier suspension. Since its introduction in 1991, more than 20,000 patients with stress urinary incontinence and vesico-ureteral reflex were treated outside the United States.

Koelbl et al (998) found 75% and 60% objective success rates with it in the treatment of Type III stress urinary incontinence on a 6 and 12 month follow-up. Hen-

nalla et al (2000), in a prospective multi-centre trial, reported success rates of 75% on a three month follow-up for treatment of genuine stress incontinence. Radley et al (2001) showed cure or improvement in 60% in a prospective chort of patients with recurrent stress urinary incontinence on a 19 month follow-up. Detrusor instability was an important cause of failures in this study.

Like collagen, it seems that efficacy deteriorate by time (Koelbl 1998) and (Sheriff 1997). Sherrif et al (1997) found success rate at 90% at one month, 75% at 3 months and 48% at 2 years. This raises the possibility of continuous sphincteric function deterioration versus absorption or degradation of the inected materials. RCTs are badly needed for bulking agents.

### **CONCLUSION**

Bulking agents provide a relatively non-invasive method of treatment for stress incontinence. Short term data suggests a cure rate of 48% and an improvement rate of 76% (Level 3). Longer term results suggest a continued decline in success rate (greater than retropubic suspension procedures). It is not known whether the non-absorbable bulking agents last longer although in the short term there is no difference in results. This form of treatment may provide a more acceptable form of treatment for the women who wishes to avoid the complications associated with more invasive surgery.

The lack of morbidity associated with the bulking agents leads some people to believe that they should more meaningfully compared to conservative therapy such as pelvic floor physiotherapy.

# j) Artificial sphincters

The literature related to the use of an artificial sphincter implanted around the proximal urethra is relatively difficult to interpret since most studies contain patients with a range of indications for surgery yet do not break down the result by indication.

There are, however, some studies in which the vast majority, or all, patients have undergone recurrent previous surgery for genuine stress incontinence. In such patients, and providing the detrusor remains stable, high levels of continence can be obtained, such as 92% (Webster 1992). These benefits must be balanced with the potential need for further surgery; in the above series 17% of patients required an average of two revisions each over an eight year follow up for either malfunction of the device or cuff erosion (Webster 1992, Richard 1996).

Table 2: Summary of reported data on use of Bulking agents for treatment of SUI in Women

Reference	No of Pts	Median age	Bulking agent	Success criteria	Cure rate	Success rate
Eckford SD	25	52.3	Glutaraldedehyde CL Collagen	Cured- complete cessation Improved- reduction	64%	80%
Haab F	337	0	Glutaraldedehyde CL Collagen	N/A	N/A	N/A
Lopez A.E	45	63.3	FAT	0-100% subjective improvement	13%	64%
Lopez A.E	22	63.7	Glutaraldedehyde CL Collagen	success - dry 2	4%	62%
Smith D.N	74	54	Glutaraldedehyde CL Collagen	Cure – Completely Continent Success Minimal Pro	54%	76%
O'Connell H.E	94	67	Glutaraldedehyde CL Collagen	Cure - Continent Success Improved < 1 Pad 3	8.3%	67%
Herschon S	44	72	Glutaraldedehyde CL Collagen	cured- dry completely success - not > than 1 pad/	45%	63%
Shortliffe $L \wedge .$ M.D	31	58	Glutaraldedehyde CL Collagen	Cured- dry completely success - not > than 2 pad/d	48%	90%
Stanton S.L	22	75	Glutaraldedehyde CL Collagen	Cured- dry completely success - not > than 1 pad/	N/A	86%
Winters J.C	160	0	Glutaraldedehyde CL Collagen	Cured- dry completely success - not > than 1 pad/	78%	78.4%
Winters J.C	50	0	Glutaraldedehyde CL Collagen	Cured- dry completely success - not > than 1 pad/	70%	48/50
Monga A.K	60	64	Glutaraldedehyde CL Collagen	Cured- dry completely 1 YR success - not > than 1	54%	40/60
Faerber G.J	12	76	Glutaraldedehyde CL Collagen	Subjective cure	83%	100%
Goldenberg S.L	190	0	Glutaraldedehyde CL Collagen	Cured- dry completely	30%	52%
Liu J	17	0	Glutaraldedehyde CL Collagen	Cured- dry completely	47%	82%
Stricker P	50 0		Glutaraldedehyde CL Collagen	Cured- dry completely	42%	82%
Corcos J	22	61	Glutaraldedehyde CL Collagen C	Cured- dry completely	40%	N/A
Henalla SM	10	0	Macroplastique	Subjective	N/A	74.3%

### **CONCLUSION**

A cure rate of 80% and an improvement rate of 90% can be expected when an artificial sphincter is inserted as a primary procedure for stress incontinence (Level 3). Less favourable results are likely in women who have undergone multiple previous procedures (Level 3).

An attrition rate (revision, removal, non-function) of approximately 25% can be expected (Level 3).

# SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

- 1. The major indication for anterior in contemporary practice must be the patient who prefers to sacrifice some degree of chance of becoming continent for a reduced chance of complication' (Level 1). The anterior repair should not normally be recommended as a procedure for the cure of stress incontinence. (Grade A Recommendation)
- 2. Retropubic suspension can be expected, in primary or secondary surgery, to generate a mean cure rate of 79% and an improvement rate of 90% (Level 2). A decrease in continence rate is observed with time (Level 3). The colposuspension can be recommended, on current evidence, as the procedure which produces the best chance of long lasting cure of stress incontinence.(Grade B Recommendation)
- 3. The long term data indicates that the initial success rates reported with needle suspension procedures are not maintained with time.(Level 3) The risk of failure is higher than reported with retropubic suspension procedures (Level 1)

There would appear to be few, if any, indications to perform a needle suspension procedure. (Grade A recommendation).

The results from small studies comparing laparoscopic and open colposuspension are conflicting. Until the data from larger studies are available no conclusions can be drawn about the value of this procedure. The evidence available suggests that the results are surgeon dependent.

- 4. Long term data suggests that sling procedures, using autologous or synthetic materials, produce a cure rate of approximately 80% and an improvement rate of 90% (Level 3). Sling procedures can be recommended as an effective treatment for stress incontinence (Grade C Recommendation).
- 5. 2 year data from a single RCT comparing open colposuspension and the TVT procedure demonstrates a

- similar success rate to open colposuspension (Level 1). Large cohort analysis with the TVT shows a cure rate of 80% and an improvement rate of 94% (Level 2). The short term results for this procedure are promising but it cannot be recommended for use before more data are available from long term studies. (Grade C Recommendation)
- 6. Short term data suggests that bulking agents produce a cure rate of 48% and an improvement rate of 76% (Level 3). Longer term results suggest a continued decline in success rate (greater than retropubic suspension procedures). (Level 3). The role of bulking agents is unclear but they may have a role as a non-invasive form of treatment with a lower chance of cure and a lower risk of complications. (Grade C Recommendation).
- 7. A cure rate of 80% and an improvement rate of 90% can be expected when an artificial sphincter is inserted as a primary procedure for stress incontinence (Level 3). Less favourable results are likely in women who have undergone multiple previous procedures (Level 3). The role of artificial sphincter should be limited to cases in whom previous attempts at surgical treatment have failed (Grade C Recommendation).

# III. INCONTINENCE WITH PROLAPSE

Stress incontinence and prolapse of the anterior vaginal wall often co-exist. In addition prolapse of the uterus and posterior vaginal wall may be found in women with stress incontinence. Pelvic floor weakness is a common denominator to both conditions.

It has long been recognised that some women who are continent with stress prior to prolapse surgery develop stress incontinence after surgery. It has been suggested that if there is loss of support at the level of the bladder neck stress incontinence will occur. If the bladder neck is supported but the bladder base is not supported stress incontinence may not occur probably because of ure-thral kinking. Surgery which elevates the bladder base can then result in development of stress incontinence as urethral kinking is resolved.

Milani et al (Milani 1985) noted that the presence of vaginal prolapse pre-operatively led to a lower cure rate of stress incontinence with either the colposuspension or the MMK procedure; the greater the severity of the prolapse the greater the reduction in cure rate.

Urethro-vesical pressure dynamics have been studied by Richardson et al (Richardson 1983) and Bump et al (Bump 1988). In both studies elevation of the prolapse with a ring pessary led to development of stress incontinence in most cases. Richardson et al (Richardson 1983) demonstrated that women who did not demonstrate stress incontinence had a much higher urethral closure pressure with straining suggesting mechanical dysfunction of the urethra was preventing stress incontinence. Bump et al (Bump 1988) demonstrated a significant drop in pressure transmission and resting urethral closure pressure when the bladder base was supported in women with stress incontinence. These findings suggest that replacing or supporting the prolapse prior to surgery will reveal "latent incontinence" in women who are more likely to develop stress incontinence after prolapse surgery. This theory has not been tested by a rigorous prospective study.

Tanagho (Tanagho 1985) first suggested that prolapse surgery such as anterior repair damaged urethral innervation. Zivkovic et al (Zivkovic1996) found evidence of greater prolongation of nerve latencies in women whose bladder neck surgery had failed to cure their stress incontinence one year after follow up suggesting that surgery may increase denervation. The data on denervation and the role of surgery is not conclusive.

Burch recognised at an early stage that colposuspension led to the development of posterior vaginal wall prolapse in a significant number of women and recommended that a Moschovitz operation should be incorporated into the colposuspension procedure (Burch 1968). Despite introduction of this modification Burch found an 8% incidence of posterior vaginal wall prolapse after colposuspension. Wiskind et al (Wiskind 1992) demonstrated that 27% of women develop symptomatic prolapse within four years of a colposuspension and did not find that correction of prolapse at primary surgery prevented recurrence.

#### CONCLUSION

Surgery for stress incontinence may lead to the development of symptomatic prolapse in up to 27% women. (Level 3) Surgery for vaginal prolapse may lead to the development of stress incontinence (Level 3). The best way to predict or avoid this is not clear.

There is no evidence to support the view that surgery to prevent prolapse performed at the time of incontinence surgery prevents the development of prolapse in future. There is some evidence to suggest that prolapse, when present at the time of incontinence surgery, is associated with a poorer outcome for cure of stress incontinence(Level 3).

There is some evidence that surgery for stress incontinence may increase denervation of the striated muscle of the urethral sphincter (Level 3).

# IV. COMPLICATIONS OF SURGERY

This topic has been comprehensively reviewed by Chaliha and Stanton (Chaliha1999). Complications can be conveniently divided into Immediate (0-24 hours); Short-term (24 hours to 6 weeks) and Long-term (6 weeks onwards).

### 1. IMMEDIATE COMPLICATIONS

# a) Haemorrhage

The perivesical/periurethral venous plexus can be a source of substantial haemorrhage during surgery for stress incontinence. The mean blood loss following anterior repair has been reported as 200 ml compared to 260 ml following a Burch colposuspension. (Van Geeland 1998).

Alcalay et all (Alcalay 1995) in a retrospective review of 109 Burch colposuspensions did not note any difference in blood loss between primary and secondary procedures but a blood loss of more than 1 litre was associated with a higher risk of failure to cure stress incontinence. Haematoma formation following bladder neck surgery may lead to the development of an abscess and possible wound breakdown. However, the relationship between haematoma formation and outcome from surgery has not been studied.

Needle suspension is associated with a lower blood loss (mean 53 ml) (Spencer 1987) and laparoscopic colposuspension is described by authors in cohort series as being associated with minimal blood loss (Liu 1993, Dorsey 1994).

Sling procedures which may involve more extensive dissection may be associated with haemorrhage requiring surgical drainage, Morgan et al (Morgan 2000) required drainage in 2.1% of cases. In a randomised prospective study comparing TVT and colposuspension blood loss was 50 ml and 135 ml respectively. (Ward 2000)

### b) Urinary tract and visceral injuries

Bladder ureteric and urethral injuries have been reported during surgery for stress incontinence. Mainprize and Drutz (1988) reported 0.7% bladder injury in nearly 3,000 women undergoing an MMK procedure. Up to 6% of women may sustain injury to the bladder or ureter at open colposuspension. Reports on laparoscopic colposuspension note a risk of bladder injury in up to 10% cases (Smith 1998) In a randomised trail comparing open colposuspension with the TVT procedure an average of 9% bladder perforation was reported in the TVT group compared to 2% in the open colposuspension group (Ward 2000). Urethral injury during anterior repair appears to be uncommon but may follow the opening of an undetected urethral diverticulum.

Laparoscopic surgery when performed through a transperitoneal approach will also carry a risk of injury to intra-peritoneal viscera, particularly when previous surgery has been performed through the anterior abdominal wall. Suprapubic catheterisation, when performed blind, also carries a risk of bowel injury (Noller 1976, Louhglin 1990, Cundiff 1995).

Urinary tract infection is not uncommon following surgery for stress incontinence. Its frequency will increase with the duration of catheterisation at a rate of 6 to 7.5% per day (Foucher 1983). Anderson et al (Anderson 1985) compared suprapubic and transurethral catherisation in a randomised trial and reported a lower incidence of bactiuria on the 5th post-operative day following suprapubic catheterisation (21% versus 46%). A similar difference was reported by Bergman et al following a needle suspension procedure (Bergman 1987).

### 2. SHORT TERM COMPLICATIONS

### a) Infection

Wound infection appears to be uncommon or unrecognized following vaginal surgery. Vaginal hysterectomy however is associated with a vault haematoma in one in four women (Tincello 1998). There is no direct evidence that wound infection influences the cure rate for stress incontinent surgery, although infection in the presence of synthetic support materials may lead to removal. Mundy (Mundy 1983) removed 16% of Dacron Stamey buffers. Erosion rates of up to 21% have been reported with synthetic pubo-vaginal slings (Beck 1988, Bent 1993, Bryans 1979, Muznai 1992). Granuloma and abscess formation have been reported following peri-urethral injection (Politanoi 1974, Politano 1982, Lotenfoe 1993). Infection of artificial sphincters has been reported in up to 9.5% of cases (Appell 1988, Light 1988, Scott 1989).

Osteitis pubis is discussed within the section on MMK procedure but it has also been reported after needle suspension (Green 1986).

# b) Voiding dysfunction

Voiding dysfunction is discussed under each of the operative procedures.and Section 6 on Post Surgical Outlet Obstruction Surgery.

# c) Uro-genital fistulae

As described later in the Chapter, fistulae most commonly follow gynaecological surgery in the developed world. Fistulae may also develop following surgery for stress incontinence. Beck et al reviewed a series of over 500 women who underwent anterior repair and found two cases of urethro-vaginal fistula (Beck 1991). Fistulae have also been reported following needle suspension procedures (Guam 1984) MMK (Mainprize 1988) and sling (Kersey 1983).

Nerve injuries - No direct injuries have been reported to nerves following the anterior colporrhaphy but the abduction and flexion of the thigh in the lithotomy position may lead to femoral nerve injury. (Wang 1993). Denervation of the urethral sphincter may occur (see section on prolapse). Nerve injuries after needle suspension have been reported to the common perineal, sciatic, obturator, femoral, saphenous and ilio-inguinal nerves (Karram 1992). Seven cases of ilio-inguinal nerve entrapment were described following 402 needle suspension procedures. In three cases the suture was removed which led to resolution of the pain in two cases (Miyazaki 1992).

The 'post-colposuspension syndrome' has been described to include women who have pain in one or both ilio-inguinal regions following colposuspension (Galloway 1987).

### 3. Long term complications

Detrusor instability and uro-genital prolapse are discussed under the relevant procedures and also in the section for surgery for stress incontinence and prolapse.

Dyspareunia is seldom mentioned in reports on surgery for stress incontinence. It may be produced by the vaginal wound itself through scarring or vaginal narrowing. Erosion of synthetic material may also lead to dysparuenia in either partner. Alteration of the vaginal axis and the development of prolapse may lead to difficulty with intercourse. Dyspareunia has been reported in up to 40% of women after colposuspension. (Galloway 1987, Eriksen 1990), but less frequently after needle suspension 1.5% (Raz 1991).

# a) Quality of life issues

There are only two studies in the literature which have looked at the quality of life after surgery for stress incontinence. Surgeons have tended to assume that the most significant outcome measure for surgery for stress incontinence is whether complete continence is achieved. This is despite evidence that patients may be satisified with the outcome without complete continence. Given that surgery for stress incontinence does not always produce continence and that this procedure can produce significant complications, it may be more relevant to consider the overall impact on the quality of life of the surgery rather than the single issue of continence. In the prospective cohort study of 442 women undergoing surgery for stress incontinence by various techniques, 68% of women declared themselves satisfied with the outcome of the surgery at one year follow up. However, 7% of women reported a deterioration in their general health by this time and 25% reported a deterioration in their mental health. Only 28% of these women achieved total continence. (Black 1997). Berglund et al (Berglund 1996) reported, in a prospective chohort study that, in addition to age and duration of symptoms, increased patient neurotiscism had a significant assocation with poorer outcome from surgery for stress incontinence.

It appears that clarification about most significant factors which influence satisfaction and improved quality of life after surgery for stress incontinence is required.

# V. CONFOUNDING VARIABLES

The following variables which may impact on the outcome of surgery will be reviewed:

- 1. Age and activity
- 2. Race
- 3 Medical illness, psychiatric illness and drugs
- 4. Obesity
- 5. Parity
- 6. Previous history of continence surgery
- 7. Hysterectomy at the time of continence surgery
- 8 Severity and duration of symptoms
- 9. Detrusor instability
- 10. Urethral occlusive forces
- 11. Surgical factors

If the selection of a surgical procedure includes factors which may influence outcome, bias will be introduced. The degree of bias may be difficult to measure because the influence of factors such as age is not well defined. The influence of these confounding variables can be minimized by random allocation of treatment or structured non-randomised studies. Unfortunately there is a dearth of prospective randomised studies in incontinence surgery.

### 1. AGE AND ACTIVITY

There is some evidence that advancing age is associated with a poorer outcome from surgery for stress incontinence (Berglund et al 1997). The chapter on treatment of incontinence in the elderly covers the influence of age on the outcome from incontinence surgery in detail.

There is no evidence that activity after surgery influences the cure rate following incontinence surgery. An early return to normal activity following surgery may have benefits such as reducing thrombo-embolic events but may also influence the strength of healing after surgery. Women are often advised to avoid high impact activity following incontinence surgery. There is no evidence to support this advice.

### CONCLUSION

There is Level 3 evidence that advancing age is associated with a poorer outcome from surgery. There is no evidence that post-operative physical activity influences the outcome from surgery.

## 2. RACE

There are no studies on the influence of race on the outcome of surgery for stress incontinence. A clinical and urodynamics study by Bump (Bump 1993) comparing black and white women in Virginia USA, demonstrated a different distribution of symptoms, different conditions causing incontinence and different risk profiles for their condition despite an equal prevalence of prolapse.

### **CONCLUSION**

There is no evidence that race influences the outcome from surgery.

# 3. MEDICAL ILLNESS, PSYCHIATRIC ILLNESS AND DRUGS

A patient with chronic obstructive airways disease might be expected to have a less favourable outcome from incontinence surgery. There is no data avilable about the influence of this or other medical illness on outcome from incontinence surgery. There is some evidence that the psych-neurotic state may influence the cure rate from continence surgery. A high degree of neuroticism, psychic anxiety and somatic anxiety was found in women who reported failure from their continence surgery (Berglund et al 1997). Obrink et al (1979) detected higher levels of neuroticism and depression in women who reported failure of their continence surgery at long term review even without objective evidence of stress incontinence. Some women have been found to have improved psychological status after successful surgery but a deterioration was found in women in whom the surgery was not successful. (Rozensweig et al 1991)

One might expect that some forms of drug therapy such as steroids might influence the outcome from surgery however there is no evidence on this issue.

### CONCLUSION

There is Level 3 evidence that the psychiatric of the patient may influence the outcome from surgery. There is no data on the influence of other medical disease on surgical outcome.

# 4. OBESITY

There are no studies reported which prospectively evaluate the influence of obesity on outcome from surgery for stress incontinence. Alcalay et al (Alcalay 1995) in a longitudinal retrospective study noted that women over 80 kg had a lower cure rate (46%) than women less than 80 kg (76%). The heavier women were also more likely to have had a hysterectomy and large blood loss at surgery which was also found to be associated with a lower success rate. Zirkovic et al (Zikovic 1999) performed a 5 year review on 198 women who were available for follow up. Obese women, defined as BMI>30 did not have a different cure rate than overweight (BMI 25-30) or normal women(BMI <25), although the authors assess that the statistical power was only 26% for the hypothesis that BMI does not influence surgical outcome. A record review of 16 women, classified as morbidly obese (200% or more than ideal weight) suggested that since there were only two surgical failures such women can undergo surgery with a good chance of success (Cummings 1998). Three needle suspension series (Varner 1990, O'Sullivan 1995, Bueger 1992) suggest that obesity is associated with a lower cure rate.

There are no studies which demonstrate a better cure rate in women who are overweight

### **CONCLUSION**

There is conflicting evidence on the impact of obesity on outcome from surgery. There is no data on morbidity associated with surgery on obese patients.

### 5. Parity

There is evidence that the prevalence of incontinence increases with advancing parity. There is no direct evidence that parity influences the outcome from continence surgery although duration and severity of incontinence and age are related factors which may influence outcome.

# **CONCLUSION**

There is no direct evidence that parity influences outcome from surgery but increased parity is associated with increased age, severity and duration of incontinence.

# 6. Previous history of incontinence surgery

It is widely believed that the first surgical procedure performed for stress incontinence is the most likely to be successful. Certainly most surgeons would prefer to operate in an area where no surgeon has previously been.

Hodgkinson (Hodgkinson 1978) notes "There is little doubt that the first operation for stress incontinence is the primary one and that every subsequent operation that fails lessens the chance of eventual success". However, in the final sentence of this paper he also writes "In the series of 205 patients with recurrent stress incontinence now under investigation, normal urinary control has been established in more than 90% control".

In 1978 Stanton et al (Stanton 1978) compared clinical and urodynamic features of 45 women whose stress incontinence was caused by colposuspension with 15 women in whom surgery had failed. A greater incidence of failure was found in the previous incontinence surgery group but detrusor instability was also more common in this group.

Stanton & Cardozo (Stanton 1979) reported on a 2 year follow up of colposuspension in 43 women. No difference in cure rate between women who had and had not undergone previous continence surgery was found.

Milani et al (Milani 1985) reviewed the outcome of 86 women who had undergone either a colposuspension or MMK procedure. Sixteen women had undergone a previous anterior repair which did not appear to influence the cure rate. Kjolhede et al (Kjolhede 1994) reviewed the 5 year cure rate of 236 women who underwent incontinence surgery and reported a 33% cure rate at 5 years in women who had undergone previous surgery compared to an overall cure rate of 68%. Jarvis, in a meta-analysis of surgery for stress incontinence demonstrated a trend towards lower cure rates with repeat surgery apart from when injectable agents are used (90% vs 83%). (Jarvis 1994).

# CONCLUSION

The data available suggests a trend towards lower success rates with repeat surgery although the level of significance is in need of clarification.

# 7. HYSTERECTOMY AT THE TIME OF CONTINENCE SURGERY

In a retrospective review of 147 women who underwent a MMK procedure with hysterectomy Green (Green 1975, Green 1978) noted an improved success rate compared to 47 women who underwent MMK alone. These series largely involved vaginal hysterectomy which may have produced a bias to women with uterine prolapse. Further retrospective reviews by Stanton and Cardozo (Stanton 1979) and Milani et al (Milani 1985) did not show any advantage to performing an

abdominal hysterectomy at the same time as a colposuspension or MMK procedure. Langer et al (Langer 1988) demonstrated no advantage with respect to outcome of urinary symptoms when an abdominal hysterectomy was performed at the time of colposuspension in a prospective randomised control trial of 45 women. The women who underwent hysterectomy also had a Moschowitz procedure performed which appeared to offer some protection against enterocoele formation (three in the no Moschowitz group compared to none in Moschowitz group).

### **CONCLUSION**

There is no evidence that hysterectomy performed at the time of incontinence surgery influences the outcome of the surgery.

# 8. SEVERITY AND DURATION OF SYMPTOMS

A woman who experiences urinary incontinence over many years is likely to be older. Over time the incontinence is also more likely to have had an impact on her quality of life and may have impacted on her psychological state. Berglund et al (1996) demonstrated that older women who had experienced stress incontinence for a longer duration were less likely to have a favourable outcome from surgery. Hitchings et al (1998) in a prospective cohort study, demonstrated that women with more severe pre-operative incontinence have a greater liklihood of improvement in their ability to perform activities of daily living than women with mild pre-operative incontinence. Surgery in women with more severe stress incontinence pre-operatively was also found to have a more favourable impact on the woman's social activity. These findings highlight the fact that outcome depends on which measure you chose to study

## CONCLUSION

There is Level 3 evidence that women with more severe incontinence of longer duration have a lower chance of cure from surgery. However, there is Level 2 evidence that women with more severe incontinence are more likely to gain benefit in terms of activities of daily living from surgery.

## 9. Detrusor instability

There are no prospective randomised trials which compare the outcome of colposuspension in women with and without detrusor instability. Colombo et al (Colombo 1996) performed a retrospective cohort study and compared 44 stress incontinent women with detrusor over-activity with a matched group of women with

stress incontinence and a stable bladder. A cure rate of 95% in the stable group compared to 75% in the unstable group two years after surgery was reported. These results, although showing a less favourable outcome in women with stress incontinence with detrusor instability, show a more favourable outcome than cure rates of 24-43% shown in other series (Stanton 1978,Lose 1988, Milani 1995).

In a series of 46 women with urodynamically proved mixed incontinence Scotti et al (Scotti 1998) noted a significantly higher cure rate in women whose primary symptoms had been stress incontinence. A retrospective review of 36 women who underwent a sling procedure for stress incontinence and Valsalva induced detrusor instability revealed a cure rate of stress incontinence of 92% and urge incontinence of 75%.(Serels 2000). Pow-Sang et al (Pow-Sang1986) demonstrated in a retrospective study that high pressure detrusor instability is associated with a poorer outcome from bladder neck surgery. Further studies are required to clarify what type of detrusor over-activity is most likely to influence the surgical outcome. Since de novo detrusor instability is not uncommon after all forms of bladder neck surgery the relationship between pre and post-operative bladder function and pelvic surgery appears to merit further study.

# CONCLUSION

There is Level 3 evidence that women who have detrusor instability pre-operatively are more likely to have a less favourable outcome from surgery.

## 10. URETHRAL OCCLUSIVE FORCES

Several authors have reported a lower success rate for surgical treatment of stress incontinence in women with a maximum urethral closure pressure of < 20 cm (Sand 1987, Stanton 1979). Sand et al (Sand 1987) compared two similar groups of women who underwent colposuspension for stress incontinence. The group of women with a resting maximum urethral closure pressure (MUCP) of 20 cm water were less likely to be cures of stress incontinence if they were under 50 years of age but in women over 50 years the MUCP was not a discriminatior. All but three of the 86 women in this study had urethral hypermobility. McGuire et al (McGuire 1980) demonstrated that maximum urethral closure pressure measurement was not a reliable prediction of surgical outcome and more important was the identification of proximal urethral weakness by radiological studies. McGuire has suggested that such patients (classified as Type III incontinence) are best managed by a pubovaginal sling procedure. McGuire further reported (NcGuire 1993) no correlation between MUCP and clinical severity or the type of stress incontinence. In a series of 125 women with stress incontinence an inverse correlation between the abnormal pressure required to cause leakage and the grade and type of incontinence was demonstrated.

Bump et al (Bump 1997) studies urethral competence in 159 women with stress incontinence by measurement of maximum urethral closure pressure, Valsalva leak point pressure and straining urethral axis (urethral hypermobility). They found that a composite of a MUCP of < 20 cm water, a Valsalva leak point pressure (VLPP) of < 50 cm water and a stress urethral axis < 20 degrees was required to reliably diagnose intrinsic sphincter deficiency. Only low MUCP and VLPP had a significant association with the severity of incontinence.

Bump et al (1988) studied bladder to urethra pressure transmission ratios in addition to urethral pressure profilometry and demonstrated that an operative procedure producing a transmission ratio close to 100% was most likely to cure stress incontinence. This is consistent with other studies suggesting that stabilising urethral position is important for successful continence surgery (Hertogs1985, Bergland 1982 and Iosif 1982).

McGuire and Appell (McGuire 1994) reported that injection of a bulking agent improved the ability of the urethra to resist raised intra-abdominal pressure and therefore recommended such treatment for women who have intrinsic sphincter weakness with no urethral hypermobility. Kreden and Austin (Kreden 1996) demonstrated better cure rates with injectable agents in women without urethral hypermobility and concluded that injectable agents were only suitable for women with ISD in whom urethral support was satisfactory. Only 4 women were treated with ISD and urethral hypermobility for this study. Other groups have also used injectables on women with and without urethral hypermobility and found similar cure rates (O'Connell 1995 and Monga 1995)

### **CONCLUSION**

Whilst there appears to be some growing consensus on the diagnosis and classification of types of incontinence in relation to urethral sphincter occlusive forces and urethral mobility there is conflicting data on whether this type of classification either influences outcome or should influence the type of surgical treatment.

# 11. SURGICAL FACTORS

The seniority and experience of the surgeon is rarely mentioned in reports on continence surgery. It is therefore not known whether these factors are important in determining the outcome. Over the years many techniques have been described by their inventor which produce results that no other author manages to reproduce. The generalisability of a procedure is an important factor in assessing its value to the surgical community. There is some evidence in the literature on laparoscopic surgery that the learning process for this type of surgery may be longer and more difficult than open surgery. This is clearly of importance if a procedure is to be used by surgeons who have no familiarity with laparoscopic surgery.

The surgical technique and the materials used are little described in the literature. Burch used chromic catgut for his colposuspension in the series published in 1968 (Burch 1968) Only four suspension failures were described indicating that the suture material strength did not play an important role in the effectiveness of the procedure. It is difficult to evaluate the robustness of Burch's evaluation. Many surgeons now use non-absorbable sutures for colposuspension because they believe that the long-lasting support provided is important. There is no proven benefit of non-absorbable suture material and there is a potential risk of suture erosion.

Newer techniques such as testing for stress incontinence during the surgical procedure (and adjusting sling tension) need proper evaluation. It would be helpful to know whether local, regional or general anaesthesia influences the outcome of surgery. There are many techniques that have only anecdotal value and need proper evaluation.

### **CONCLUSION**

There is no data to support the view that surgical technique or the experience of the surgeon influence the outcome from surgery or the associated morbidity.

# VI. POST-SURGICAL OUTLET OBSTRUCTION SURGERY

The incidence of bladder outlet obstruction (BOO) and associated voiding dysfunction after anti-incontinence surgical procedures is not known but has been estimated to be between 2.5% and 24%. In table 3 the details of most recent six largest series reported in the English literature are summarized. As seen in this table, any of the retropubic, needle suspensions or pubovaginal sling procedures can cause BOO.

A newer cause of BOO is injection of Collagen. Since its introduction in late 1980s, glutaraldehyde cross-linked bovine dermal collagen has been used as a bulking agent for treatment of intrinsic sphincteric deficiency (ISD) in women with stress urinary incontinence.

Table 3: BOO after previous anti-incontinence surgery

Author	No Pts	S/p surgery	Time interval	Diagnostic clue	Type of urethrolysis	Re-suspension	Results	Follow-up
Webster	15	6MMK 6 Stam. 2 Raz 1 Burch	2-24 7.6 mean	chronology of symptoms	Abd	Obturator shelf on all pts	93% success	N/A
Foster	48	Vaginal NS 19 sling 10 rpbns 17	2m-35 yr 11 months median	combination of sx, cysto and UDS	Vaginal	various types on 24 pts	65%	2-67 mean 17 m
McGuire	13	rpbns 6 vbns 4 sling 3	28 months	sx & UDS	Vaginal	various type in 4	77%	1-4 yrs
Zimmern	13	MMK 13	1-6 yr mean 3.5 yr	sx & UDS	vaginal	Raz in all	92%	12-44 m mean 20
Nitti	41	MMK 18 AP 7 Raz 7 Stamey 4 Burch 1	3-194 m mean 54 m	sx & UDS	vaginal	Raz in all	71%	3-78 m mean 21 m
Austin	18	average of 2.7/pt various procedures	at least 6 m	sx & UDS	vaginal	sling in 16	60% and 33%	N/A

Although its use has been reported to be safe with minimal or no complications, later reports have mentioned up to about 10% rate of urinary retention with subsequent urinary tract infection. The most recent report suggested 13% incidence of urgency with urge incontinence among 337 patients treated with collagen as early evidence of increased bladder outlet resistance.

According to Raz (Raz 1989) three distinct group of patients with BOO symptoms after previous anti-incontinence procedures exist. These groups are: 1) obstructed only- the patients who produce pdet>35 cm H2O without urinary flow. This group will benefit only from urethrolysis, 2) poor detrusor function- the patients who would continue to have problems post urethrolysis, and 3) obstructed and incontinent- the patient in whom an additional resuspension procedure seems appropriate. Many surgeons reserve urethrolysis for patients in whom intermittent self-catheterisation (ISC) is an unacceptable alternative. The use of ISC avoids the risk of return of the stress incontinence which can occur after urethrolysis.

# 1. DIAGNOSIS

# a) Symptoms

Women with BOO present with a variety of urinary symptoms. The most common of the presenting symptoms are frequency, urgency, urinary incontinence and nocturia. A similar constellation of symptoms in men has recently been termed as lower urinary tract symptoms (LUTS) with the underlying etiology ranging from simple benign prostatic hyperplasia (BPH) to severe bladder outlet obstruction. Classical symptoms of outflow obstruction such as poor urinary flow, hesitancy, abdominal straining or feeling of incomplete bladder emptying are less common. As a reaction to the obstructive mechanism, the detrusor muscle can become overactive and unstable resulting in frequency, urgency and urge incontinence, or even progress to the phase of detrusor decompensation heralded by urinary retention, recurrent urinary tract infections (UTIs) or overflow incontinence.

In table 4 the frequency of symptoms presented in women with BOO after anti-incontinence surgery is summarized.

In order to help reliably identify patients with voiding dysfunction use of questionnaires has increasingly become popular. Such a questionnaire is the Urogenital Distress Inventory developed by Uebersax and colleagues. With this questionnaire, a total score of >9 out of 18 usually points out to a underlying voiding dysfunction including BOO.

# b) Voiding Diary

Urinary symptoms of women with suspected BOO could primarily be assessed through two methods:

Table 4: Reported symptoms of BOO in women

Author	no of pts	frequency	urgency	nocturia	urge incontinence	new onset UI	inability to void	residual SUI
Webster	15	13	13	13	0	8	7	0
Foster	48	13	32	11	32	32	29	9
McGuire	13	N/A	N/A	N/A	N/A	N/A	5	N/A
Zimmern	13	4	4	N/A	N/A	N/A	2	3
Nitti	41	30	30	30	16	N/A	29	19
Austin	18	13	13	13	N/A	N/A	5	2

	pain	recurrent UTI	decreased force of stream	dysuria	post void dribbling	PVR	CIC
Webster	n/a	n/a	n/a	n/a	n/a		
Foster	10	8	6	6	6	63%	25%
McGuire	N/A	N/A	N/A	N/A	N/A	N/A	6/13
Zimmren	N/A	4	N/A	N/A	N/A	100%	2
Nitti	N/A	N/A	N/A	N/A	N/A	29	19
Austin	N/A	N/A	N/A	N/A	N/A	13	5

patient recall during history taking, and self-monitoring of voiding behavior using a diary. Although both methods have pitfalls in terms of providing reproducible information, voiding diary has been shown to be more accurate in demonstration of patient's symptoms. Seven-day diary does not provide any advantage over the three-day diary.

# c) Physical examination

The physical examination of patients with suspected BOO should include: a general abdominal exam, a focused neurological exam including a back exam, and a detailed and a combined perineal/vaginal examination. During vaginal exam, careful investigation of possible anatomical causes for BOO including the urethrovesical angle should be performed. The entire length of urethra should be palpated carefully for any tender spot or mass. Periurethral scarring usually becomes apparent by a combination of observation and palpation of the urethra. In the case of excessive scarring, most of the urethra appears to be "cemented" in the anterior vaginal wall.

The value of urethral calibration in the management of BOO in women is difficult to assess. There is no agreement in the literature regarding the normal calibre of the adult female urethra, which ranges between 12 and 24 F. It has been determined however that restriction of the urethra to 10 F or less must be present to produce an obstructive urodynamic pattern (Tanagho et al 1971, Gleason et al 1969).

Partial or total urinary retention may be seen in women with bladder outlet obstruction. During the abdominal examination of a non-obese patient a minimal of 150 cc is needed in the bladder to make it palpable. In contrast to conventional thinking, urinary retention or large postvoid residuals in women more commonly are the result of a poor detrusor contractility rather than bladder outlet obstruction, although poor detrusor contractility does not rule out the presence of BOO in women. Incomplete bladder emptying is often associated with significant cystoceles.

### d) Urodynamics

Interpretation of the results of urodynamic studies is the cornerstone of the diagnosis of BOO in women. Various elements of urodynamic studies can be used in the evaluation process depending on the guides received from history and physical examination.

# e) Uroflowmetry

Despite its ease of use, wide availability and inexpensive nature, the uroflow information should be interpreted with caution. For an accurate interpretation of uroflowmetry data in men, the voided volume should be in excess of 150 ml. Although this data has never been replicated in women, it is commonly used in interpretation of uroflow data in them. Maximum flow rate (qmax), voiding time and the uroflow curve are other important elements in accurate interpretation of a noninvasive uroflow test. The caveat in uroflow inter-

pretation is that it cannot distinguish between an obstructive process with a high-pressure detrusor contraction or impaired detrusor contractility as the cause of a weak stream. Following uroflowmetry, measurement of post voiding residual (PVR) is needed to determine the bladder capacity.

### • Pressure-flow studies

The simultaneous measurement of detrusor pressure and urine flow during voiding offers the best objective evidence for diagnosis of BOO in women. This is based on the physical principles that obstruction exists in a fluid-transporting system if an elevated pressure is required to transport the usual rate of flow through a relative narrowing. During the filling phase of the study, bladder compliance, presence or absence of detrusor overactivity/instability, and maximum bladder capacity are evaluated.

Filling and voiding cycles may be repeated twice to assure the persistency of the obtained values. Generally, the distinction between an unobstructed from an obstructed voiding pattern is made based on the following characteristics: a) the maximum flow rate (qmax) is lower; b) detrusor pressure at maximum flow (pdetqmax) is higher; c) the timing of void is longer and d) the slope/curve is of flattened or interrupted. In men, a number of pressure-flow plots have been created. These plots graphically show the changing pdet for each value of the flow rate as it rises and falls throughout a whole void. Based on this demonstration, patients voiding pattern is categorized to obstructed, unobstructed or equivocal.

Several groups have attempted to study obstruction in women on the basis of pressure flow analysis. Massey and Abrams defined the BOO when qmax of <12mL/s, pdetqmax of >50 cm H2O, urethral resistance (pdetqmax/qmax)>0.2 and "significant" residual urine. Farrar et al (Farrar 1975) used an arbitrary definition based on qmax of <15 mL/s and pdetqmax of >50 cm H2O. In order to establish the basis of a nomogram in women, Chassagne et al (Chassagne 1998) have recently proposed the pressure-flow cut off values for diagnosis of BOO in women. In a cohort of 35 clinically obstructed and 124 control women, different cutoff values were driven from receiver operator characteristic curves (ROC). Using cut off values of qmax of 15 mL/s or less and 12 mL/s or less, sensitivity of 85.7% and 71.4% and specificity of 78.2% and 90.3% was obtained. Also using cutoff values of pdetqmax of more than 25 and more than 30 cm H2O, sensitivity of 74.3% and 71.4% and specificity 79.8% and 88.7% was obtained. Based on these values, using a combined value of qmax of 15 mL/s or less and pdetqmax of more than 20 cm H2O with resultant sensitivity of 74.3% and specificity of 91.1% was proposed as the pressure-flow cutoff values for diagnosis of BOO in women.

#### • Urethral pressure profile

Urethral pressure profile can be performed as static or dynamic techniques. Its role in investigation of patients with stress urinary incontinence continues to be debated (see above). This test is technically challenging and is not currently recommended by most authors for investigation of patients with BOO. Moreover, some authors have found that UPP did not contribute to prediction of outcome after urethrolysis operation [1] in patients with BOO after a previous anti-incontinence surgery.

# f) Cystourethroscopy

Using a flexible cystoscope with local anesthesia in the office, cystourethroscopy may be used to examine the likely cause of BOO. It is mostly useful in diagnosis of calculi and foreign bodies or suspension sutures in the bladder. However, the gross appearance of the urethra and bladder neck is usually inaccurate in diagnosis of obstruction in the absence of a defined pathology. Although the bladder trabeculation implies persistent detrusor damage, the significance of this finding is still unknown. Bladder trabeculation usually persist despite relief of obstructive process.

# g) Voiding cystourethrogram

The voiding cystourethrogram (VCUG) is a reproducible method to evaluate the female lower urinary tract and may be used in the evaluation of patients presenting with BOO symptoms. The information gained includes angulation of the urethra, the position of urethrovesical junction, and the status of the bladder neck and proximal urethra during the voiding phase of micturition. Observation of post void residual contrast also confirms the incomplete emptying of the bladder.

# **SUMMARY**

In summary, the combination of a) LUTS-like symptoms and continued incontinence in the presence of previous anti-incontinence surgery, b) physical finding of an overcorrected urethro-vesical junction or excessive scar on the urethral, and c) urodynamic confirmation of BOO as defined by high detrusor pressure with low flow rate during voiding phase constitute the foundation of diagnosis of post-surgical BOO in women. The value of imaging modalities has not been proven.

### 2. Treatment

The treatment options for BOO after anti-incontinence surgery in women primarily depends on the cause and the severity of the obstruction but the mainstay of treatment is:

## a) Clean Intermittent Catheterization

Pioneering work of Lapides and colleagues has established clean intermittent catheterization (CIC) as an effective mean of bladder emptying when physiological voiding is not possible. The catheterization is ideally done by the patient herself or in certain cases by a careworker or relative. Its ease, safety and low cost have made it a very attractive alternative for chronic bladder emptying. The recommended frequency varies depending on the patient's situation, but it has been suggested that catheterization volume be kept below 350 to 400 ml to prevent clinical infection.

# b) Alternative treatment are

### • ANTI-CHOLINERGIC MEDICATIONS

In both clinical and animal models bladder/detrusor overactivity develops in response to BOO, and the main neurohumoral pathway of this physiologic response appears to be via acetylcholine-induced stimulation of the muscarinic receptors of the bladder smooth muscle. Anticholinergic agents thus can depress this physiologic response to BOO. The problem with the general muscarinic receptor anticholinergic agents is in their significant side effects on other systems such as salivary glands. The value of these drugs in BOO has not been formally evaluated.

#### • Urethrolysis

Surgical urethrolysis is an option for patients with BOO after a previous anti-incontinence surgery. The options for urethrolysis include retropubic, transvaginal and infra pubic approaches.

Series with either retropubic or transvaginal approaches have shown similar rates of success on the order of 80%. Although some authors have downgraded the importance of recurrent incontinence after urethrolysis and do not recommend resuspension (Foster and McGuire), most other authors do recommend resuspension. The choice of resuspension has varied from needle suspensions, pubovaginal slings, or obturator shelf repair in the case of abdominal approach to urethrolysis.

Several factors appear to have an impact on the outcome of urethrolysis in patients with BOO after an anti-incontinence surgery. A higher failure rate was seen when detrusor instability was demonstrated on the preoperative evaluation (McGuire et al 1989). In the group of patients reported by Nitti and Raz, preoperative postvoid residual was predictive of failure of urethrolysis. The presence or strength of the detrusor contraction preoperatively and pressure-flow analysis did not predict outcome in this report. Austin et al (Austin et al 1996) reported 60% success with urethrolysis and resuspension in 13 patients with highest mean

maximal voiding pressure (MVP), and 33% for 5 patients with lowest MVP. Foster and McGuire have reported higher rate of success of transvaginal urethrolysis following needle suspension and retropubic urethropexy compared to patients with urethral obstruction secondary to pubovaginal sling.

### • URETHRAL INCISION

Transurethral incision of the bladder neck (TUIBN) has been reported with good results in symptomatic patients with BOO after anti-incontinence surgery (Turner-Warwick 1976, Axelrod et al 1987 and Fenster 1990. Because of the vulnerability of the female urethra however, It has been suggested that TUIBN should only be used when a distinct anatomical obstruction exists. In animal studies, distinct differences between histological effects of urethrotomy and urethral dilation in female dogs were noted. The main difference was the prominence of sheared disruption of the musculature in the urethrotomy vs attenuation of circular striated and smooth muscles following dilatation

### • URETHRAL DILATATION

Dilatation of the female urethra has tradionally been used for a variety of lower urinary tract symptoms including BOO after anti-incontinence surgery. This is done by dilating the urethra up to 32 F using female urethral sounds, with or without anaesthesia. Due to lack of poor definition of indications and report of outcome, this option is rapidly falling out of favour. A recent survey by Lemack et al (Lemack et al 1999) showed that only 21% of urologists who have been trained more than ten years ago consider urethral dilatation as a viable option, whereas none of the urologists trained within the last decade consider it as a therapeutic option.

# **SUMMARY**

Post-surgical incidence of BOO have been reported between 2.5-24%. All of the anti-incontinence procedures, including bulking agents can cause BOO in women. The diagnosis is made on the basis of symptoms, physical examinations and presence of high pressure voiding during pressure-flow studies. CIC is normally regarded as the mainstay of management but surgery may be required, particularly when there is marked over-elevation of the urethra and voiding dysfunction is severe.

## VII. URETHRAL DIVERTICULAE

The diagnosis of female urethral diverticula is now being made with greater frequency due to awareness of the condition and its co-existence with incontinence. In a comprehensive videourodynamic study of 58 women with urethral diverticulum, Ganabathi et al (Ganabathi 1994) found that 53% had concomitant stress incontinence and 24% had detrusor instability (8 patients had both). In addition 2 patients (3%) had paradoxic incontinence (loss of urine associated with intermittent drainage of the diverticulum). Videourodynamics and voiding cystourethrography may be helpful to differentiate between true stress incontinence and paradoxic loss of urine (Figure 7).

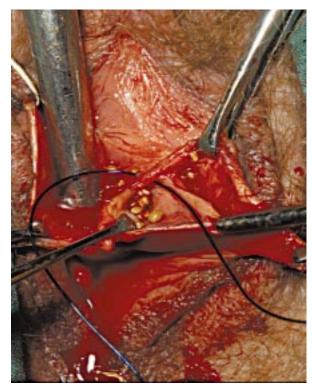


Figure 7: A urethral diverticulum is illustrated. A dilator is placed in the urethra. The diverticulum contains small stones and a suture identifies the communication between the diverticulum and the urethral lumen.

Surgery for stress incontinence may be successfully performed along with urethral diverticulectomy (Table 5). Leach and Bavendam (Leach & Bavendam1987) described simultaneous needle bladder neck suspension in 22 women with stress incontinence. At a mean follow up of 20.5 months, 77% were totally continent and no significant complications were noted. Four of the five failures were secondary to ISD. In 1993, Swierzewski and McGuire (Swierzewski & McGiuire 1993) performed simultaneous autologous rectus fascia pubovaginal sling and urethral diverticulectomy in 14 women. All were cured of stress incontinence and one developed severe detrusor instability. A diverticulum recurred in 1 patient.

### LEVELS OF EVIDENCE

All the evidence available is based on uncontrolled case series and therefore does not qualify for a more advanced level than 4.

# VIII. SURGERY FOR REFRACTORY DETRUSOR INSTABILITY

Detrusor overactivity may be neurogenic (detrusor hyperreflexia) or non-neurogenic in origin. The underlying aetiology of the condition should be identified and appropriate medical therapy given for that aetiology. Surgical intervention for this condition is usually reserved for those patients who have failed conservative therapies, including pelvic floor exercises, bladder retraining, electrical stimulation of the pelvic floor, and pharmacologic treatment.

Surgery is a step of last resort and may be effective when detrusor overactivity is associated with involuntary contractions or diminished bladder compliance. In bladder disease the goal of surgical intervention is to prevent or modulate the development of intramural detrusor fibrosis (Sehn 1978). If it is initiated early enough within the natural history of the disease process poor compliance may be substantially decreased by early surgical intervention. However in patients with idiopathic detrusor instability, the aim is improved continence and preservation of upper urinary tract function.

A variety of surgical approaches have been tried for the management of the overactive bladder, including open and endoscopic approaches.

### 1. Endoscopic approaches

Distension of the bladder utilizing hydrostatic pressure (cystodistension) has been used in the management of detrusor pathologies, including interstitial cystitis, urgency incontinence (Wang et al 1988) and even bladder tumours (Helmstein 1972). Overdistension is thought to reduce bladder dysfunction by causing degeneration of unmyelinated small sensory nerve fibers (c afferent). Success rates have varied from 18% to 77%, with complications including hematuria, urinary retention, and bladder perforation in 5% to 10% (Jorgenson et al 1985, Pengally et al 1978).

There are no long term studies on cystodistension. It may represent an intermediate step before considering more complicated surgical interventions. Although this method represents a very simple form of treatment, it may provoke interstitial fibrosis, leading to a contracted or non-distensible bladder. The proposed mechanism of activity is ischemic damage to sensory nerve endings reducing sensory input (Dunn1975). Initial supportive rates of 75% success have now not been upheld by more prolonged follow-up (Ramsden et all 1976, Delaere et al 1980).

A form of this technique is termed bladder "cycling," in which intermittent self-catheterization is used to increase bladder capacity periodically in an effort to improve

Table 5: Complications of diverticulectomy from published series since 1956 in 872 women

Reference	No. Women	Follow up (mos)	No. Urethro- vaginal Fistula (%)	No. Recurrent Diverticulum (%)	No. Stress Incontinence (%)	No. Urethral Stricture (%)	No. Recurrent Urinary Tract Infections (%)
Wharton and Telinde	58	Not available	7		1.7	5.2	8.6
Davis and Telinde	84	Not available		11.9			13.1
MacKinnon et al	130	Not available	5.4	1.5	Several		10
Boatwright and Moore	48	Not available	8.3		4.2	2.1	
Hoffman and Adams	60	Not available	1.7		6.7	1.7	
Ward	24	Not available	8.3	29.2	12.5		
Davis and Robinson	98	Not available	4.1	1			
Pathak and House	42	Not available					
Benjamin et al	30	Not available	3.3	3.3	3.3		
Peters and Vaughan	32	24	6.3	25			10
Ginsburg and Genadry	52	12-240	1.9	25		1.9	
Rozsahegyi et al	50	Not available	2			2	
Lee RA	108	24-204	0.9	9.3	15	1.9	
Ganabathi et al	56	6 -136	1.8	3.6	16.1	0	0
Leng and McGuir	e 18	Not available	0	0	11	0	0

(Revised and reprinted from Leach GE, Trockman BA. Surgery for Vesicovaginal, and urethrovaginal fistula and urethral diverticulum. In Walsh PC, Retik AB, Vaughn ED, Wein A, eds:Campbell's Urology, 7th ed. Philadelphia, W.B. Saunders Company, 1997, pp1135 – 1153.)

overall bladder volumetric capacity. This technique has been described by Perlmutter for patients undergoing reconstruction of the lower urinary tract after revision of a urinary diversion and/or in transplant patients with a defunctionalized bladder. Although effective for the short-term management, this technique requires anaesthesia, and is usually only temporary in its overall symptomatic control. (Perlmutter 1980)

### 2. OPEN SURGICAL INTERVENTIONS

### a) Denervation

Denervation of the lower urinary tract can be accomplished at several levels:

1. in the bladder by injection of anesthetic or ablative chemicals or by hyperbaric bladder distention,

- 2. peripherally at the level of the pelvic nerves (immediately sub-trigonal, or more proximally at the anterior roots),
- 3. centrally at the level of sacral nerves,

Most of these procedures are associated with a high relapse rate of symptoms (or objective evidence of detrusor dysfunction) within 18 months after the procedure.

• Transvesical phenol injection: The utilization of dilute phenol (6%) injected through the base and trigone of the bladder has been described (Blackford et al 1982). Short term success followed by relapse rates approaching 100% within 18 months have been reported. Complications including vesicovaginal fistula have been reported (Chapple et al 1991, Nordling et al 1986).

- Ingelman-Sundberg Denervation: Initially described by Ingelman-Sundberg in 1950 (Ingelman Sundberg 1950), the procedure was utilized during radical hysterectomy for cervical carcinoma. It was subsequently modified as a transvaginal approach for the treatment of patients with refractory detrusor instability. Cespedes et al. utilized a modified technique composed of two steps. The first component was performed through a transvaginal approach to assess whether the patient would benefit from the procedure, utilizing a local anaesthetic block of the sub trigonal plexus. Subsequently, if successful, an open surgical neural ablation was carried out through an anterior vaginal wall dissection. 64% of patients (16) were cured at a mean of 14.8 months from surgery. A vaginal approach through which the terminal branches of the sensory pelvic nerves and postganglionic fibers are divided and/or are cauterised has been described. Cure rates of up to 70% of patients with documented motor instability have been reported, but is considered ineffective in sensory disorders such as interstitial cystitis (McGuire et al 1994).
- *Cystolysis:* Mundy (Mundy 1985) included a transection of the posterior and postero-lateral aspects of the bladder wall. This transection extended to a point approximately 1 cm above the ureteral orifices. In Mundy's study, 74% of patients were symptomatically cured, 12% failed, with 14% improvements at less than 12 months follow up. However, detrusor muscular atrophy occurred between two and five years, decreasing successful control of symptoms from a 65% to 16%. The transection technque has now been abandoned. This technique has given way to enterocystoplasty.
- Sacral bhizotomy: Sacral deafferentation of the bladder by dorsal sacral rhizotomy of the S<sub>2-5</sub> can be accomplished either peripherally or within the dura. A complete section of the anterior and posterior S<sub>2-4</sub> nerves results in permanent ablation of detrusor reflex function. Full rhizotomy, however, results in complete disruption of external anal and urethral sphincteric function, as well as loss of sexual function residing in erections and female lubrication, as well as sensation in the perineum and buttocks. The significant side effects of this technique have substantially limited its use.

Posterior sacral rhizotomy may be combined with anterior root stimulator implant, providing a means of voluntary stimulation of the motor efferents. This technique of deafferentiation and neurostimulation was developed by Brindley (Brindley 1982). Typically, an L4-L5 laminectomy is performed, the dura is opened, and the anterior and posterior sacral roots are identified and isolated using *in situ* stimulation. The posterior roots of S2, S3, and S4 are then transected, and a segment of the roots is removed. The anterior roots are

then placed in an electrode "book", and the electrodes are connected to a Finetech-Brindley stimulator. The stimulator is driven by electromagnetic induction, and delivers intermittent bursts of stimulation to the anterior roots, timed in such a way as to offset the peaks of detrusor contraction and sphincter contraction, allowing the patient to void. The device can also facilitate defecation and erection. Egon et al (Egon et al 1998) recently reported a large series of patients with neurogenic bladder treated with posterior sacral rhizotomy and implantation of Brindley-Finetech sacral anterior root stimulators. Of 90 evaluable patients, 83 voided using their implants, and 82 were continent. Bladder capacity was significantly increased, and vesico-ureteral reflux disappeared. Re-operation was required in three patients with CSF leaks, and another two devices were explanted due to infection. In 1999, Weilink et al (Weilink 1999) demonstrated the potential for considerable health care cost savings in the long run, with positive effects on health status.

• Enterocystoplasty: The utilization of bowel segments to increase bladder capacity has been used for intractable detrusor instability. Some authors have also utilized this technique for interstitial cystitis. The goal of this procedure, like other procedures of this type, is to create a low-pressure, large-capacity reservoir with low-filling pressures (adequate compliance), which protects the upper urinary tract from pressure-related reflux and infection related to this reflux, as well as providing urinary continence. Augmentation enterocystoplasty is often utilized simultaneously with procedures to correct reflux or improve incompetent bladder outlets. Utilization of bowel to augment the bladder has been shown to decrease overall detrusor contractility and also to increase the volume at which the first detrusor contraction related to detrusor overactivity occurs. The bladder may be divided sagittally or transversely. There is still some argument regarding the appropriate configuration of the transected bladder and the type of bowel segment to be utilized. It is generally agreed that it is best to de-tubularize the intestine into a sphere, which will disrupt peristaltic contractions and increase overall bladder capacity. Herschorn and Hewitt (Herschorn and Hewett 1998) reported on 59 patients with neurogenic voiding dysfunction undergoing augmentation cystoplasty. In addition to showing improvement in urodynamic parameters (mean capacity increased from 220 ml to 523 ml and mean detrusor pressure at capacity decreased from 48.9 cmH2O to 15.8 cmH2O) continence improved, 67% demonstrating complete continence and 32% mild incontinence. They also reported patient satisfaction with a standardized questionnaire. Sixty-nine percent of patients were "delighted", 23% were "pleased" and 11% were "mostly satisfied " with the results of surgery. Complications specific to augmentation cystoplasty include: mucus production, which can cause either catheter or voiding obstruction, urinary tract infection, perforation resulting from incomplete or inadequate self-catheterization, and electrolyte abnormalities such as hyperchloremic acidosis. Perforation has been reported in 2-6% of patients in the long-term and surgical revision rates range from 15-36% (Herschorn and Hewitt 1998, Flood et al 1995). *N*-acetylcysteine instillation has been shown to be effective in decreasing mucus production in the bladder (Gillon et al 1989).

Ureterocystoplasty is another method utilizing native urothelium for bladder augmentation. Churchill *et al.* reviewed 16 patients, utilizing a catheterisation kidney ureter in 12 and a catheterisation duplex in 2. Fifteen patients required intermittent catheterisation and one voided spontaneously. This procedure has been modified to protect the distal blood supply with persistent improvements in compliance and capacity.

Gastrointestinal full-thickness segments may be utilized for augmentation or serial muscular graphs with deepithelialized bowel segments may be used either alone or as a support for native urothelium. This was first proposed by Blandy in the early 1960s, and recently has attained new interest. Tissue engineering may provide further benefit in the future for augmentation indications. In Mundy's series (Mundy et al 1985), 37 of 190 patients experienced significant complications early in management, although 67 reported later urinary tract infections and later complications.

• *Detrusor myomectomy:* Detrusor myomectomy involves incising and removing the bladder muscle to allow bladder mucosa to form a pseudodiverticulum. The success of this procedure is incumbent upon removing large segments of muscle to prevent scarification of the muscle over the exposed mucosa.

From the recent literature, it appears that autoaugmentation is more successful in patients with idiopathic overactivity than those with neuropathic hyperreflexia, although success rates as high as 80% have been reported for this latter group (Swami, et al 1998). Seromuscular enterocystoplasty combines autoaugmentation with enterocystoplasty by laying a de-mucosalized detubularized segment of bowel over the exposed bladder mucosa following detrusor myectomy (Bunson, et al 1994). This theoretically avoids the complications associated with exposure of urine to gastrointestinal mucosa, and may prevent the loss in capacity seen over time with simple autoaugmentation. While recent literature cites encouraging results (Shekarriz et al, 2000), this technique remains limited to few centres, and long-term follow-up on significant numbers of patients is still pending.

• *Urinary diversion:* Urinary diversion is rarely needed, but may be useful in those patients with intractable detrusor instability with a very small reservoir. Diversion may be effective for helping the cause of pelvic pain that may be associated with detrusor overactivity. However, it represents a last-step intervention in the surgical management of incontinence resultant from detrusor overactivity.

### **CONCLUSIONS**

- 1. Surgical therapy should only be considered when all conservative methods have failed.
- 2. Long-term results remain disappointing with surgical techniques for bladder overactivity.
- Bladder augmentation appears to have supervened denervation procedures as being a reasonable intervention.
- 4. There is no evidence to support more extensive use of surgery.

### LEVELS OF EVIDENCE

All the included studies in this section are non-randomized case series, usually with no cohort and only historical controls. The evidence available is therefore only Level 4 or 5.

# IX. SURGERY FOR NON-OBSTETRIC FISTULAE

Extraurethral incontinence can be caused by an abnormal communication between the urinary tract, i.e bladder, urethra or ureter, and the vagina. Incontinence is often continuous, but can vary depending upon certain circumstances or patient position. Patients usually have "insensible incontinence" that is loss of urine without increase in abdominal pressure or exertion or an urge. Depending on the size of the fistula, incontinence can range from minimal to complete loss of all produced urine.

# 1. VESICO-VAGINAL FISTULAE

### a) Aetiology

In developing countries birth trauma still accounts for the majority of fistulae. (Arrowsmith 1996). Prolonged labor induces tissue necrosis of the bladder base and urethra which results in tissue loss that can be substantial. Rarer causes include infectious disease (bilharziasis). In contradistinction, in developed countries, modern obstetric care has substantially limited the risk of vesicovaginal fistulae by reducing the duration of labour. In these areas fistulae are usually the consequence of complications of gynaecologic or other pelvic surgery. Regardless of the aetiology, fistulae can cause substantial life disruption for the patient and medical legal consequences for caring physicians. The most common cause of vesicovaginal fistula is abdominal or vaginal hysterectomy and approximately 75% of genitourinary fistulae are produced in this way. (Jonas 1984, Lee 1988; Symmonds 1984; Tancer 1992). Fistulae occurring after hysterectomy are thought to be due to tissue necrosis caused by inadvertent suture incorporation of vaginal tissue from the cuff closure into an unrecognised bladder wall injury. Tissue necrosis promotes fibrosis and induration, finally resulting in an epithelial or mucosal lining of the fistula tract (Kursh, 1988). In 1980 Goodwin reported 32 patients with fistulae as a direct result of gynaecologic surgery. Tancer (1992) noted a similar group of 151 patients and found that 91% (137) were post-surgical with 125 caused by gynaecologic surgery. The most common procedure accounting for fistula was hysterectomy in 73% (110) of cases (99 of which were performed transabdominally). Factors thought to contribute to the risk of fistula formation due to hysterectomy included prior cesarean section, intrinsic uterine disease (endometriosis) and the possibility of prior ablative treatment for carcinomas (pelvic radiation therapy). Similar risk factors were identified by Blandy et al. (1991) The incidence of fistula after hysterectomy is generally accepted to be 0.1 -0.2%. (Harris, 1995) The influence of factors such as the grade/experience of the surgeon and the patient's habitus have not been studied. Other causes of fistulae include malignancy (Kottmeier, 1964), radiation (Cushing, 1968, Stockbine 1970, and Villasanta, 1972), gastrointestinal surgery (low anterior resection) (Cross, 1993), inflammatory bowel disease and urinary tuberculosis (Ba-Thike et al, 1992). Symmonds' experience at the Mayo clinic revealed only 5% of 800 vesicovaginal fistulae to be due to obstetric causes (Symmonds1984). Rarely, foreign bodies such as pessaries, diaphragms, and intrauterine devices also may lead to fistula formations (Goldstein et al, 1990). Iatrogenic CO2 laser therapy for cervical disease has also resulted in bladder fistulae. (Colombel 1995) Autoimmune diseases such as Bechet's disease have also been recently implicated as causative for vesicovaginal fistulae due to extensive vasculitis related bladder wall necrosis. (Monteiro 1995)

# b) Clinical features

The most common presenting symptom of an iatrogenic genitourinary fistula is continuous urinary drainage from the vagina after gynaecological or other pelvic surgery. A fistula may become apparent either immediately or much more commonly after a delay of several days to weeks after surgery. Patients may present while in the hospital with prolonged ileus, excessive pain, haematuria or loin pain (Kursh 1998). If the fistula tract is large enough a significant amount if not all urine drains through the vagina producing total incontinence. In other cases, fistula drainage may be minimal and intermittent and may be initially mistaken for stress incontinence occurring postoperatively. Patients with urethrovaginal fistulae arising from urethral catheter trauma may not develop symptoms until catheter removal has occurred. Incontinence arising from a urethrovaginal fistula may be intermittent unless the fistula extends across the bladder neck, in these cases severe and total incontinence is usually encountered.

# c) Treatment

### 1. Conservative management

Most vesicovaginal fistulae are identified late after the initial surgical intervention. Regardless of the timing of presentation, a trial of conservative therapy may be implemented which uses continuous urethral / suprapubic catheter drainage supplemented with anticholinergics. This management technique is less likely to be successful in the woman with a mature tract (six weeks or longer after inciting event). Tancer et al (1992) reported 3 of 151 patients with spontaneous closure of fistula using this strategy.

Another possible conservative therapy utilizes electrocoagulation or fulguration of the lining of the fistulae tract (O'Connor 1980, Alonso 1985, Molina 1989, Stovsky 1994). In Stovsky's experience 11 of 17 (73%) of patients with small (less than 3mm) fistulae treated with electrofulguration and 2 weeks of catheter drainage resolved. This technique should not be used for large fistulous tracts. The magnitude of current intensity should be minimal. This technique is also not to be used for inflammatory, immature, or malignant fistulae. Another alternative, but similar strategy is the use of metallic objects to physically abrade the tract. The concept of this technique is physical disruption of the tract which instigates an inflammatory response leading to fistula closure. McKay (1997) recently described successful cystoscopically placed suture closure of a vesicovaginal fistula, with no secondary incision.

# 2. SURGICAL THERAPY

# → General concepts

Optimal results for fistula closure are obtained when surgery is performed on a mature fistula tract. It is generally agreed that the first effort at surgical fistula closure is the most likely to succeed. Results approximating 90% are obtainable on the first operative intervention in woman who have not undergone radiation

and do not have active carcinoma as the cause of the fistula. Multiple factors impact upon the success of fistula repair including the duration of fistula communication, the aetiology of the tract, the presence of necrotic tissues, surgical technique, and experience of the operating surgeon.

All suture lines should be watertight, tension-free, nonoverlapping, and exist in an uninfected environment. If the repair is tenuous, interpositional graft materials may be helpful. (Wein 1980, Raz 1992, Raz 2000)

Previously, many authors have advocated a waiting period of at least 3 to 6 months before intervening with surgical therapy (O' Connor 1951, Wein 1980, Blandy 1991). More recently surgeons have advocated an individualized approach without an observational period. Several authors have reported superb results with early interventions (Persky, 1979, Goodwin 1980, Wang 1990, Raz 1992, Blaivas 1995, Raz 2000). Fistulae identified within the first 24 to 48 hours postoperatively can be safely repaired immediately. Those identified days to weeks after surgery require careful planning and selection. Wang and Hadley successfully managed 15 of 16 (94%) high lying (vaginal apical) fistulae through a transvaginal approach, with all 7 patients who were less than three months from initial surgery cured of fistula. (Wang 1990) Surgical judgment is needed since there are no prospective studies to determine the optimal technique for each aetiology.

### **→** Surgical approaches

Surgical approaches for vesicovaginal fistulae include: combined abdominal vaginal, vaginal, or abdominal approaches. The approach chosen is dependent upon several factors including location of fistula (position related to apex), quality and mobilty of tissue, the angle of the sub-pubic arch and the surgeon's experience. Vaginal surgery is usually quicker and results in less morbidity (avoiding an abdominal incision) and more rapid recovery. However, the vaginal route may be difficult in patients with a significant degree of fibrosis, pelvic immobility, or with large tracts with possible injury in close proximity to the ureteral orifices. The abdominal approach should be utilised for the poorly visualized tract, the narrow or immobile vagina, and those with close proximity to a ureteral orifice. All approaches should lend themselves to the possibility of interposition grafts. (see later).

# → Vaginal approach

The vaginal approach may utilize the creation of an anterior vaginal wall mucosal flap. Subsequently a tension free closure is performed utilizing a long acting (polyglycolic acid or polydioxanone) suture and non-overlapping multiple closure lines.

If the fistula repair is tenuous or there is concern regarding apposition of suture lines a Martius interpositional graft may be utilised. (see later on interpositional options) If this is not obtainable, alternative graft sources include peritoneal flap (Raz 2000) or interposition graft utilizing gracilis muscle tissue. The peritoneum can be freed from the posterior aspect of the bladder and easily advanced to cover the layers of the closure as well (Raz 1993).

Martius interposition utilizes the fibro- fatty tissues of the labia majora, which are well vascularised (Martius 1928, Raz 1992, Blaivas 1995, Blaivas 2000). The fat pad may be mobilized utilizing either a pudendal or epigastric based pedicle because of the constancy of blood supply. (Hoskins, 1984) After mobilization of the fat pad, the graft is tunnelled under the vaginal wall from labia to vaginal incision and is sutured in place over the fistula repair site with absorbable sutures. The vaginal mucosal flap is then closed over the site. A small Penrose drain is usually placed in the harvest site (the labia) to prevent haematoma accumulation. Several authors have used this graft as an adjunct to repair associated with complicated incontinence with excellent results. (Ghoniem 1995, Carr 1996)

In patients who are poor operative candidates, the Latz-ko (1942) technique of proximal vaginal fistula repair may also be attempted. This technique involves excision of the vaginal epithelium around the fistula site and colpocleisis with several layers of absorbable sutures from anterior to posterior wall obliterating the upper vagina. No actual excision of the fistula tract occurs during this procedure and therefore ureteral reimplantation should not be required (Raz 1992). Vaginal depth is compromised by this procedure but several authors (Raz 1992) have reported no impact on sexual function from this procedure.

The vast majority of vesicovaginal fistulae can be closed in one operation using a vaginal technique. Success rates range from 67-100%. Raz reported a success rate of 92% (64/69) for vesicovaginal fistulae, 2/3 of which had failed 1 to 3 prior repairs using this technique (Raz 1992).

### a) Abdominal approach

All bladder fistulae (except those extending into the urethra) may be approached through the abdomen and this is the preferred approach in those patients requiring bladder augmentation or ureteral re-implantation. Experience in N America was reported by O'Conor (1951, 1973) for abdominal transvesical repair of vesicovaginal fistulae. Omentum may be interposed between the repaired bladder and vagina (Wein 1980;Turner-Warwick, 1976; Kiricuta, 1972). Reported success rates with the abdominal approach are approximately 85% - 90% (Marshall 1979, Wein 1980, Gil-Vernet

1989, Udeh 1985 ,Demirel 1993, Kristensen 1994, Blaivas 1995, Raz 2000). Table 6 summarizes a group published series for success rates and timing of repair. Recently, Nesrallah et al reported a 100% success rate using the O'Conor transabdominal supratrigonal technique in 29 patients. (Nesrallah 1999) Other authors have reported similar results (Table 6).

## **→** Interposition grafts

Some authors feel that the routine interposition of healthy well vascularised tissue between the bladder and vagina is not necessary for uncomplicated fistula repairs, but rather should be reserved for complex cases such as failures, radiation, malignancy, compromised field, etc. Others place such grafts routinely. In a nonrandomised retrospective review of transabdominal fistula repairs, where grafts were placed solely by surgeon's discretion, Evans et al reported a 100% success rate for benign fistulae repaired with an interposition flap, vs. 63% when a flap was not used. Similarly, fistula associated with malignancy success rates were 100% vs. 67%.

Reconstructive techniques have been described utilizing a variety of interpositional tissues including fibrofatty labial interposition tissues, anterior/posterior bladder flaps (autografts), myocutaneous flaps including rectus, sartorius, gluteus, and gracilis muscle flaps as well as combined myocutaneous flaps (Garlock 1928, Byron 1969, Stirnemann 1969, Menchaca 1990, Blaivas 1991, Raz 1992, Candiani 1993, Tancer 1993, Brandt 1998, Raz 2000) as adjuncts to repair of the complex vesicovaginal fistula.

Table 6: Results of fistula repairs, including timing of repair

Author (Date)	Number of patients	Success (%)	Fistula duration before surgery	Surgical technique
Collins (1960)	24	67	20 (<2 mth) 8 (> 4 mth)	24 vag
Eisen (1974)	29	90	29 (> 3 mths)	29 abd
Persky (1979)	7	86	7 (< 10 wks)	6 abd/1
vag Tancer (1980)	45	93	8 – 16 wks	43 vag / 1abd/ 1sp
Wein (1980)	34	88	> 3 mths	34 abd
Keetel (1982)	168	94	> 3 mths	156 vag/ 6 abd/ 6 com
Bisada(1983)	7	100	NS	7 abd
Cruikshank (1988)	11	100	< 1 mth	9 vag/ 1 abd / 1 comb
Lee (1988)	182	98	15 < 2 mths $167 > 2$ mths	15 vag/ 130 vag/ 37 abd
Elkins (1990)	23	91	> 2 mths	23 vag
Wang (1990)	16	94	7 < 3 mths 9 > 3 mths	16 vag
Blandy(1991)	25	100	12 < 1.5 mths 13 > 1.5 mths	25 abd
O'Conor (1991)	77	91	> 2 mths	77 abd
Raz (1993)	19	84	>2 mths	19 vag
Demnirel (1993)	26	88	> 3 mths	8 vag /18 abd
Kristensen (1994)	18	94	>2 mths	18 Abd
Brandt (1998)	80	96	>1 mths	80 abd
Nesrallah (1999)	29	100	> 6 wks	29 abd

Vag = vaginal

Abd = Abdominal

Spon = spontaneous closure

Comb = combined abdominal and vaginal approach

# 2. URETHROVAGINAL FISTULAE

Urethrovaginal fistulae may be very small pinpoint fistulae demonstrated by vaginal voiding or may present as complete urethral and bladder neck loss with total urinary incontinence. This circumstance most commonly results from prior gynecologic surgery, with anterior repair and urethral diverticulectomy comprising the most common inciting procedures (Blaivas 1989, Raz 2000). Additionally, complete urethral loss due to trauma arising from prolonged urethral catheter malposition may occur.

Previously birth trauma was a cause of majority of urethral defects, however in developed nations this is now a rare cause of urethrovaginal fistulae. Prolonged obstructive labor, however remains a major cause of urethral injury in developing nations (Elkins 1994).

Techniques used for urethrovaginal fistula closure are very similar to those utilised for transvaginal vesicovaginal fistula repair (Webster 1984). Complete urethral loss is a more daunting surgical challenge and a multiplicity of techniques has been described for this (Blaivas 1989, Blaivas 1996, Hendren 1980 and 1998, Patil 1980). These techniques usually employ some type of flap utilizing either vaginal, bladder, or alternative tissue in an onlay versus tubularized reconstruction (Blaivas 1989). Simultaneous stress incontinence procedures should be performed to obviate the risk of postoperative incontinence (Blaivas 1990). Preoperative assessment of the degree of urethral loss as well as the function of the intrinsic urethral mechanism should be established prior to surgical intervention.

# **→** Urethral reconstruction

Multiple procedures have been described for urethral reconstruction although many authors now prefer the transvaginal approach. Abdominal approaches previously described include posterior bladder flaps as described by Young and modified by Theiss as well as Ledbetter in 1964. Tanagho in 1981 also described an anterior bladder flap (Tanagho 1981). The abdominal approaches use omentum to reinforce the repair and also allow for simultaneous ureteral re-implantation.

The use of the vaginal approach has been well-described (Goodwin 1980, Blaivas 1991, Elkins 1992) and has been successfully used for all types of urethral bladder neck defects. Elkins also has described a transvaginal neoruethral reconstruction using the anterior bladder wall, however most investigators now use either vaginal flaps alone or in conjunction with Martius labial fascia interposition (Goodwin 1980, Webster 1984, Blaivas 1989 and 1991, Raz 1992, Bissada 1997).

Recently, utilization of rectus abdominis flaps for repair of recurrent urethrovaginal fistulae has been reported as a highly successful procedure. Bruce et al (2000) reported 100% success in 6 women with recurrent fistulae, 5 of whom were continent and able to void. Their technique used a combined abdominal-vaginal approach with rectus interposition. These authors recommended this flap as a salvage procedure after failed Martius graft. Another tissue alternative prior to bladder neck closure is the perineal based flap poincered by Hendren which provides an interpositional graft and also apparently conveys improved continence status possibly due to increased urethral length as compared to standard anterior bladder tube neourethral reconstructions (Hendren 1998).

In debilitated patients or patients with severe local tissue defects, bladder neck closure with a concomitant catheterisable stoma may be indicated (Ziedman 1989). Bladder neck closure should accomplish a tensionf ree circumferential closure of the remnant urethra at the bladder neck by complete disruption of the endopelvic fascia at the bladder neck, and layered inverting closure of the urethral stump.

Urethral incontinence after reconstruction may be a consequence of bladder and/or urethral factors as well as urethral fistula re-formation. Careful examination should help identify this consequence. Periurethral injections may be useful in selective cases (Lockhart 1988, Ganabathi 1994b) however, the quality of the surrounding tissues must be evaluated as the neo-urethral wall no longer has a well defined submucosa for injection. As with diverticulum repair, urethral strictures may result from a too narrow tubularization of the neo-urethra.

Blaivas (1996) reported on 49 women undergoing one stage vaginal flap reconstruction of urethra and/or bladder neck. Overall, 42 of 49 (87%) were continent, 6 of 7 failures were successful after a second procedure. Forty one patients underwent a sling and 5 a needle suspension (3 of whom subsequently required a sling). In 47 women a Martius was used and in one each a gracilis or anterior bladder tube functioned as the neourethra.

# **CONCLUSION**

Surgical repair of non-obstetric vesico-vaginal fistulae may be performed abdominally or vaginally, the latter allowing a quicker post-operative recovery. (Level 4) Use of interpositional grafts may aid successful fistula repair (Level 3) There are no RCT's reported on the optimal method for fistula repair.

# X. RESEARCH RECOMMENDATIONS

- A. There is now a recognition that outcome from surgery for stress incontinence is not simply an issue of cure of stress incontinence. Research is required to understand:
  - 1. What is the optimal measure of a good outcome? Is it cure of stress incontinence? Is it improved quality of life?
  - 2. How do quality of life scores relate to objective measures of outcome?
  - 3. How do symptom scores relate to objective measures of outcome?
  - 4. Can improvement be defined in terms of symptom or QOL scores?
- B. The Chapter has highlighted the large number of confounding variables which may influence outcome. Research is required to define the influence these variables may have on the outcome so that future research on surgical procedures can stratify for these variables if they are important.
- C. Stress incontinence and prolapse commonly coexist. It appears that surgery for either condition commonly results in the development of the other. Research is needed into how to reduce the risk of prolapse developing after surgery for stress incontinence. The techniques used to try to predict "latent" incontinence need evaluation in order to prevent this unfortunate sequel to prolapse surgery.
- D. It is evident from the literature that the risk of stress incontinence recurring after surgery increases with time. Some reports suggest that this risk evens out after approximately ten years. The risk of recurrence needs to be studied prospectively and the factors which influence the risk of recurrence over time should then become more fully understood.
- E. Sling procedures are increasing in popularity. The optimal sling material needs to be determined. The advantages of using synthetic or cadaveric sling materials are obvious in avoiding the need for harvesting from the patient but the evidence to date illustrates the increased risks of infection and erosion. Large studies comparing slings with other retropubic procedures and different sling materials are required.
- F. Pelvic floor physiotherapy is often tried before surgery in the treatment of stress incontinence. There is a need to determine whether pelvic floor physiotherapy *in conjunction with* surgery influences the outcome since the pelvic floor has both muscle and fascial components. Both components have a part to play in the normal continence mechanism.
- G. It is to be hoped that pharmacotherapy will ultima-

- tely improve to the degree that surgery for detrusor instability will become obselete. In the meantime the procedures in current use need more rigorous evaluation than has been performed to date. This includes not only objective measures of continence but also evaluation of quality of life outcome. The magnitude and risks of these procedures is such that more objective analysis is required.
- H. Women who develop a urinary fistula after gynaecological surgery suffer the misfortune of developing a more severe problem than at original presentation. The optimal management of a non-obstetric fistula, including which surgeon performs the repair, needs to be studied to reduce the risk of a chronic incontinence problem.

#### CONCLUSIONS

The medical press is still publishing case series of surgical procedures for stress incontinence that are scientifically flawed in many areas. This does not serve to inform and may mislead, often presenting an over-optimistic view of the outcome.

A minimum data set of information should be included in the assessment of any surgical procedure. Such a data set should include the following domains:

- 1. Anatomical / physiological- structured physical examination and urodynamics (POP-Q)
- 2. Symptoms (Validated questionnaire)
- 3. Urine loss (pad test)
- 4. Quality of Life (Validated questionnaire)
- 5. Full documentation of all confounding variables
- 6. Economic costs

It could be argued that, in complying with the type of scrutiny applied to new pharmacological agents, ethical approval should be sought before embarking on a study of any new procedure. Approval should only be then given if the study is designed in a manner which would have a reasonable chance of providing useful data.

In addition, when a new procedure becomes available for more widespread use, a central register, incorporating the same data set, could be employed to ensure that all the facts about the procedure could be learnt by the surgical community as soon as possible.

There is a recognition by the Research Funding Agencies that the literature on the surgical management of urinary incontinence needs to be improved by well constructed, multi-centre trials. It is up to the clinicians to present such trials for grant approval.

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