

Chapter 3: Outcomes Analysis for the Surgical Management of Stress Urinary Incontinence

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Introduction

This chapter provides the results of the Panel's review of the literature and analysis, presented in outcomes tables, as well as discussions of the outcomes. Two sets of outcomes tables are provided including one set for patients who were treated only for stress incontinence and another set for patients who received treatment for both stress incontinence and some form of pelvic organ prolapse. Since some reports did not segregate patient data accordingly, for the purposes of this analysis if any patient in a group received concomitant prolapse surgery the entire group was included in the category.

Outcomes estimates are presented in two cells for each estimate; the first contains the number of groups of patients followed by the total number of patients (G/P) included in the meta-analysis. A group of patients usually represents the patients in a single study that the received indicated treatment(s). However, if a study had multiple groups with varying factors (e.g. degree of incontinence, details of the procedure used) these patients were analyzed as a separate group in the meta-analysis. In the second cell, the bolded percentage indicates the best estimate of the rate of occurrence of an outcome (median of the Bayesian posterior from the meta-analysis) followed by the 95% credible interval (Bayesian confidence interval) for that estimate. These numbers represent the best estimates that can be made from the existing data and served as the primary basis for the guideline statements presented in Chapter 1.

Efficacy Outcomes

Resolution of Stress Incontinence

The main efficacy outcome was the resolution of the stress incontinence. Cured and dry (cure/dry) was defined by the Panel as the complete resolution of symptoms with no residual leakage under normal and stress situations. Patients reported as having incomplete improvement were considered cure/dry/improved. There were inconsistencies in the reporting of these outcomes in the literature, with some authors distinguishing cured patients from improved patients and others reporting only those cured or improved/cured. The Panel accepted the author's representation (i.e. if a report indicated that a group of patients was cured they were counted as cured) but it is likely that not all patients counted in the cure/dry category were truly dry. If the author defined cured to include some degree of leakage, the patients were counted in the cure/dry/improved category only.

The outcomes were analyzed separately according to the method of incontinence assessment; the "subjective" outcome category included primarily patient reports and diaries and the "objective" outcome category included a variety of formal tests including urodynamics. A separate category ("any") was created for studies that didn't clearly specify how an outcome was assessed or for those using a mixed collection of measures. To make this "any" category complete, outcomes from all studies were included. If a study reported both subjective and objective outcomes, then the subjective outcomes were included in the "any" analysis. If a study reported outcomes from a variety of subjective measures, the one with the highest number of patients was used for both the subjective and "any" analyses.

The outcomes were analyzed by time of last assessment with the following intervals: 12–23 months, 24–47 months, and 48 months or more. If a study reported results for multiple times within one of these ranges, reports closest to 18, 36, and 60 months respectively were used. In this analysis, only studies that had a 12 month minimum follow-up were included; this is in contrast to the 1997 guideline¹ in which studies with a follow-up of less than 12 months were included if the minimum of the range was at least 12 months or the mean or average follow-up was at least 24 months.

Appendices A12-A16 show the results for patients who had no concomitant prolapse surgery for the time intervals 12–23 months, 24–47 months, and greater than 48 months, respectively. Appendices A7 – A11 are arranged similarly and show data for patient groups in which some or all of the patients had concomitant prolapse treatment. Treatments with no available data in are excluded from the tables; thus, not all treatments are presented in all tables.

Urgency

The Panel recognizes the importance of the relationship between surgery for SUI, the complaint of involuntary leakage on effort, exertion, sneezing or coughing (as defined by the International Continence Society [ICS])² or with physical exertion (as defined by the National Institutes of Health)³ and other lower urinary tract symptoms (LUTS; defined as storage, voiding, and postmicturition symptoms by the ICS). OAB syndrome is comprised of the main storage symptoms of LUTS and is defined by the ICS as urgency (the complaint of a sudden, compelling desire to pass urine which is difficult to defer or a strong need to pass urine for fear of leakage (NIH), with or without urgency urinary

incontinence (UUI; involuntary leakage accompanied by or immediately preceded by urgency), usually with frequency and nocturia, in the absence of pathologic or metabolic factors that would explain these symptoms.²

The Panel accepted the author's use of "urge", "urge incontinence" or "urgency" with or without "incontinence" without requiring specific adherence to these definitions. The Panel attempted to distinguish those patients having urge incontinence from those having symptoms of urgency alone in the absence of urge incontinence. However, this distinction was not always reported. Three categories of studies were analyzed: 1) those that included patients with urge incontinence alone; 2) those that included patients with urgency symptoms alone; and 3) those that included patients with unspecified urgency or that combined patients with incontinence and urgency symptoms. Because urgency can occur with stress incontinence and is often resolved with treatment of stress incontinence, the data for urgency are listed in the efficacy section of this chapter; however, urgency occurring de novo after incontinence surgery could also be considered a complication of the treatment. A third category was analyzed for studies not reporting the preoperative urgency status of patients with postoperative urgency and those in which patients with and without preoperative urgency were combined.

Appendix A15 provides the results of the Panel's analyses of urge incontinence, urgency symptoms alone, and unspecified urgency for patients who did not receive concomitant prolapse surgery. Appendix A10 provides the same outcomes in the group of patients where some or all had concurrent prolapse repair. Each table contains three data sets corresponding to 1) continuing urgency in patients with pre-existing urgency; 2) de

novo urgency in patients who did not have preoperative urgency, and 3) unspecified or mixed cases. The format of each entry is the same as for stress incontinence resolution.

The success of surgery for decreased outlet resistance is intimately related to preoperative and postoperative storage and emptying function. The interrelationship of the individual symptoms comprising LUTS (storage and emptying), OAB or urgency/urgency incontinence and of the LUTS to the results of surgery is complex. Patients with SUI may experience no other LUTS or may develop one or more symptoms postoperatively. Alternatively, patients with one or more preoperative LUTS may have symptoms that independently improve, persist, or worsen. In addition, the de novo development, improvement or worsening of symptoms may be acute (temporary) or chronic (permanent). These symptoms may also increase (aging of population, comorbidities) or decrease (resolution of perioperative alterations) over time.

The Panel recognizes the symptoms of “urgency” and “urgency urinary incontinence” as the most commonly reported and most representative of pre-existing or de novo lower urinary tract storage symptoms. Although preoperative cystometry was performed in some studies, postoperative urodynamics were rarely performed in patients regardless of symptoms; thus, patient results are almost universally reported based on symptoms. It is recognized that the symptoms of urgency or UUI may or may not correlate with the urodynamic (cystometric) finding of detrusor overactivity. Additionally, patients may experience detrusor overactivity that is provoked by effort or exertion, or may experience detrusor overactivity without sensation, further confounding the diagnosis and therapy.

Table 1 provides data on patients experiencing postoperative urgency or urge incontinence from the 1997 review¹ and from the current analysis, although these data aren't directly comparable in that the 1997 analysis examined the correlations between urgency and detrusor instability. As mentioned above, the present analysis focused on the development of de novo urgency and urge incontinence and separately analyzed the resolution of these symptoms patients with the presence of urgency and urge incontinence.

OAB is common in women with SUI, occurring in 30%–50% of cases⁴, with surgical treatment of SUI often offering resolution of OAB.^{5,6} Unfortunately, persistence of OAB after SUI surgery has been reported in up to 40% of patients.^{7,8} Persistent OAB has been reported to complicate 8%–25% of all sling procedures,⁹ as well as 7.6%–12% of TVT procedures and 1.4%–16.6% of retropubic urethropexies.¹⁰⁻¹² In the present analysis, persistence of urgency occurred in approximately 15% of those receiving suspension procedures and about 30% of those receiving sling procedures. Moreover in 7%–21% of cases, de novo OAB may occur.^{7,13-16} Possible risk factors for de novo OAB include undiagnosed preoperative OAB, increased bladder wall thickness (induced by or associated with resultant changes in bladder afferent and/or efferent neuromuscular behavior), bladder neck dissection, greater patient age, and postoperative urethral obstruction.¹⁴

Complications

Complications were analyzed similarly to the efficiency outcomes. Because of the wide variation in terms used to describe complications, the Panel grouped complications

together that represented similar or related outcomes (See Appendix A17 for complications groupings). As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Outcomes tables were developed for each group of complications, with separate tables created for the population of patients receiving or not receiving concurrent prolapse treatment. The format of the tables is the same as for the efficacy tables, but the layout is reversed. The treatments are across the top for complications and down the left side for the others.

Retention

The Panel defined retention as catheter-dependency for greater than 28 days postoperatively and/or the need to undergo an intervention to correct retention following surgery. Using these definitions, retention estimates ranged from 1%–9% in the population without prolapse treatment and from 1%–10% in the population with concurrent prolapse treatment (Appendices A9 and A14). As a group, those undergoing retropubic procedures had retention estimates of 4% for the non-prolapse group and 1% for the prolapse group. Patients undergoing sling procedures were more likely to experience retention with the highest rates observed in those undergoing synthetic slings at the bladder neck without bone anchors. In these groups, the estimates were 9% and 10% for the non-prolapse treatment and the prolapse treatment populations, respectively. The lack of a standardized definition of retention and the failure of many studies to provide data regarding postoperative urinary retention were limitations to this analysis. Yet, from the present analysis it may be concluded that retention affects 1%–10% of

women postsurgically and varies by procedure, with sling procedures having higher rates of retention than retropubic procedures.

Genitourinary Complications

With regard to genitourinary complications, the Panel analyzed these events as intraoperative complications (events occurring during the surgical procedure or in the immediate perioperative period) or other complications (events occurring after the immediate perioperative period). The purpose of this distinction was to identify complications that may be unique to the technical aspects of a particular procedure or complications that may be related to the consequences of or materials utilized in the procedure.

Intraoperative complications

Bladder injury was reported with 3%–8% of procedures (Appendices A11 and A16).

Although the overall incidence was low, it appeared that bladder injury was more frequent in patients receiving SUI procedures with concomitant prolapse repair. This trend may be the result of the more extensive dissection needed when doing a simultaneous prolapse repair, however the trend did not reach significance and therefore may be not representative of actual experience as well. In addition, the risk of bladder injury was somewhat higher (not statistically significant) in procedures utilizing synthetic materials at the midurethra, particularly when compared to autologous slings and retropubic suspensions. This finding may have been a result of more stringent data recording in the use of synthetic materials or possibly related to technical aspects of

certain midurethral slings. Trocar placement into the retropubic space in the absence of advanced mobilization of the bladder and urethra may predispose to a higher incidence of bladder and urethral injury. Urethral injury was only identified in association with synthetic slings placed at the midurethra or laparoscopic retropubic suspensions. This may be related to technical aspects of the midurethral sling procedure that may predispose to these types of injuries. However, the small cohort of patients did not allow a direct comparison with other procedures. Ureteral injuries occurred during less than 5% of the procedures in most series; however, they were reported in 4%–11% of laparoscopic suspensions, which seemed to the Panel to be higher than expected based on their experience. Many of the reported cases of laparoscopic suspensions reflected the early experiences of surgeons and perhaps this could explain the increased risk of laparoscopic suspensions when compared with other procedures.

Other complications

With the many different techniques and materials utilized in the surgical correction of SUI, surgeons must remain diligent in obtaining long-term outcomes data to understand the effects of these techniques and materials on quality-of-life and potential complications. Of major contemporary concern is the resurgence of the use of mesh materials in the surgical correction of SUI, particularly with the recent emergence of the tension-free midurethral sling procedures using synthetic materials. Early experience with synthetic mesh materials in pubovaginal sling and prolapse surgeries was associated with a considerable risk of mesh complications. Erosion rates of 20%–30% were reported in patients following implantation of Dacron™, Mersilene™, and Marlex™ mesh

materials.¹⁷⁻¹⁹ In these early procedures, larger incisions with more extensive dissection may have increased the potential for bacterial exposure, and increased tension may have promoted tissue ischemia. The woven, multifilamentous nature of these mesh materials may have limited the ingrowth of host tissue, leading to erosions, draining sinuses, and fistulas. These early experiences forced many surgeons to abandon the use of synthetic material in pelvic reconstructive surgery.

The success of the TVT procedure introduced surgeons to several principles that have seemingly facilitated the safe use of synthetic material in pelvic reconstruction. The use of small incisions and minimal dissection decreases the potential for bacterial exposure. The avoidance of tension on the mesh material limits local tissue ischemia while the use of macroporous monofilament mesh materials promotes host tissue ingrowth and biocompatibility. Incorporating these principles, the synthetic tension-free slings have become one of the more commonly used procedures in the surgical management of SUI. The reported incidence of mesh erosions and complications with these procedures appears quite low, although the true incidence is not known. A recent report analyzing the United States Food and Drug Administration Manufacturer and User Facility Device Experience database (U.S. FDA MAUDE)²⁰ which collects data on U.S. FDA approved medical devices, suggests that these complications are indeed underreported.²¹ In addition to mesh materials, permanent suture materials, tacking devices and laparoscopic instrumentation may also be associated with lower urinary tract or vaginal injuries.

Erosions and extrusions may also occur with the use of foreign materials such as mesh. For the purposes of this review, the Panel has defined erosion as the presence of a

foreign body in the lumen of the urinary tract (bladder, urethra or ureter) whereas extrusion was defined as the exposure of mesh in the vagina. Urinary tract erosion has been reported subsequent to all SUI procedures, but overall this does not appear to be a common event. In this meta-analysis (Appendices A11 and A16), erosion into the urethra and bladder occurred following 2%–4% of vaginal sling procedures. Erosions appear to occur more frequently following synthetic sling procedures; however, the method of reporting varies widely. Some authors have reported that “erosions” occurred but were not specific as to location and type. For example, 17% of erosions resulting from synthetic slings placed at the bladder neck were not classified. The incidence of urethral and bladder erosions appears to be higher following placement of synthetic slings at the bladder neck when compared to autologous slings. These data might suggest that synthetic slings have a higher rate of erosion than autologous or cadaveric slings. Based on these findings, the Panel believes that discussion of urinary tract erosion should be part of the informed consent process, particularly when selecting synthetic slings. The Panel also concludes that urinary tract erosion is a risk of any surgical procedure used in the treatment of SUI, with the risk appearing highest for synthetic slings, particularly when placed at the bladder neck.

Vaginal extrusion occurred in 1-8% of cases following synthetic slings. In this meta-analysis, the unexpectedly high risk of vaginal extrusion associated with cadaveric slings (23%) probably represents an anomaly resulting from the fact that few studies of cadaveric slings mentioned extrusion and the one study reporting this complication was small. Since the small number of series may affect the overall data reporting and incidence rates, this result is likely artifactual.

General Medical Complications

General medical complications captured in this analysis included cardiovascular, dermatologic, febrile, infectious (local, systemic, and urinary tract), neurologic, and pulmonary complications as well as subjective complications such as pain and sexual dysfunction (Appendices A11 and A16). In addition, transfusion was analyzed as a separate category. There was variable and limited reporting of most general medical complications, with many authors not reporting any complications data. These findings reinforce the need for standardized reporting of complications, particularly as related to general medical complications.

Urinary tract infections were the most commonly reported infectious complication, with estimates following retropubic surgery of 13% for those not undergoing concurrent prolapse procedures and 17% for those receiving such procedures. Patients undergoing sling procedures were less likely to experience urinary tract infection, with estimates of 4%–16% for the no prolapse treatment groups and 1%–9% for the prolapse-treatment group. However, the majority of authors did not report specifically on the presence or absence of urinary tract infections and caution must be used in interpreting these data.

There was very little uniformity in reporting other infectious complications. Febrile morbidity estimates were between 0%–14% of patients depending upon the procedure. The highest estimates were noted in the retropubic groups with rates of 8%–11% for the non-prolapse and prolapse treatment groups, respectively. Patients undergoing sling procedures were less likely to have a febrile morbidity reported and this

was true for both treatment groups. The reported estimates of febrile morbidity ranged in those populations between 2%–8%.

Dermatologic complications were reported only in patients receiving injectable collagen, with an estimate of 5%. The estimates for sexual dysfunction were 4% for retropubic suspensions and 8% for autologous fascial slings. However, the definitions and reporting methods for identifying sexual dysfunction remain extremely variable in the evidence as assessed. Therefore the rates reported may not be representative of the true incidence of this outcome. Standardization of reporting indices is critically needed for a better understanding of the true rates of sexual dysfunction arising from interventions for stress incontinence and pelvic organ prolapse.

Operative Complications

Gastrointestinal complications

All procedures performed adjacent to the peritoneal lining and its contents are associated with risks of injury to the bowel and such injuries have been reported with open, laparoscopic and “minimally invasive” procedures. “Minimally invasive” synthetic-based retropubic procedures had the highest reported risk of bowel complications, with estimates of 1% for synthetic midurethral slings performed without concomitant prolapse repair (see Appendix A16). There were too few reports of bowel injuries resulting from the other procedures for a meaningful comparison.

Vascular complications

Vascular complications were defined as any reported iatrogenic intraoperative injury to a specific major or significant blood vessel not including intraoperative or postoperative bleeding or hematomas. The estimates for vascular complications are found in Appendices A11 and A16. There were no reported vascular complications in over 400 articles reviewed for this meta-analysis involving an anti-incontinence procedure with or without pelvic organ prolapse repair in approximately 40,000 patients. Yet, it is well known that major vascular injuries including iliac, femoral, obturator, and epigastric vessel injury have been reported with the TVT procedure in the FDA MAUDE database.²⁰ The Panel believes that the risk of serious vascular complications with TVT procedures is very low; but nevertheless surgeons should bear this risk in mind when performing this technique.

Neurologic complications

Neurologic complications occurring in association with SUI surgery are rare (see Appendices A11 and A16). A total of five cerebrovascular accidents (CVA) were reported. CVA occurred more frequently in patients undergoing retropubic suspensions (n=3) versus pubovaginal slings (n=1) or midurethral slings (n=1), although the small numbers of these events preclude statistical analysis. No patient required additional surgery as a result of a CVA but CVA was the cause of death in three patients. While all of the CVAs may be attributable to the patient having had an anesthetic and/or surgery, one must take into consideration the age and other comorbidities of patients who elect surgical correction of SUI.

Twelve nerve injuries were reported. In some cases these were listed only as “nerve injury” whereas in other reports they were described by the resulting deficit or as an injury to a discrete nerve. The most common nerve injury cited was to the obturator nerve, which occurred in three patients. There were nerve injuries described with the use of midurethral synthetic slings (n=5); however, none of these patients required additional surgical procedures. Two patients required additional surgical procedures to treat complications related to nerve entrapment. One patient had removal of a suture and a second patient underwent removal of a bone anchor using a hammer and osteotome.

Infectious complications

The panel elected to divide infectious complications into multiple subsets to accommodate the various definitions presented in the literature; these included infection (undefined), infection with local extension, abscess, and osteomyelitis (see Appendices A11 and A16). Osteomyelitis, rarely reported, was observed in procedures with and without bone anchors.

Death

The risk of perioperative mortality following surgical treatment of SUI is very low, although a precise estimate is difficult to achieve due to the paucity of studies that specifically evaluate mortality, compounded by the fact that published studies represent only a tiny fraction of all surgical procedures performed. To gain an estimate of perioperative mortality in the SUI patient population, a combined approach was taken: 1) the raw data from the current analysis were assessed; 2) a Medline search was performed

using the term “perioperative mortality” and reports were obtained for all surgical procedures in the U.S. and also for surgical procedures thought to be of comparable risk to SUI surgery; and 3) reports were obtained that specifically dealt with surgical procedures for SUI and urogynecology (shown in Table 2²²⁻²⁹). Finally, an estimate was determined for the added perioperative mortality from the special circumstances of vascular or bowel injury due passage of trocars from midurethral sling kits.

In contemporary series, overall perioperative mortality for all surgical procedures ranged from 0.02%–1.8% (Table 2). In the Medline search on which this review was based, there were three deaths out of 39,019 patients, for a mortality rate of 0.008%. Waetjen et al²⁶ reported an unadjusted mortality rate of 0.01% in a survey of 135,000 women undergoing incontinence surgery in the U.S. in 1998. However, in that series pubovaginal slings accounted for less than 15% of the procedures; nearly three-quarters had either retropubic suspension or anterior repair. This is probably an underestimation of mortality due to bowel or vascular injury from trocars. No other reports that dealt specifically with mortality after incontinence surgery were identified. Sung et al²⁹ reported an unadjusted risk of death following all urogynecologic procedures of 0.04% and noted that mortality rate increased with age. For women less than 60 years of age, the mortality rate was 0.01%; for those more than 80 years of age it rose to 0.28%. The authors noted that elderly women had a 13-fold increase in the risk of death and a 33% higher risk of suffering postoperative complications compared with younger women, irrespective of their co-morbidities.²⁹ Brown et al²⁷ reported a perioperative mortality of 0.03% after pelvic organ prolapse surgery. In a study of surgical mortality, Pine et al²⁸ reported mortality rates for various surgical procedures. The Panel selected those that

were the most comparable to incontinence surgery for a comparison of perioperative mortality data. The unadjusted mortality rates were 0.11%, 0.41% and 0.20% for hysterectomy, herniorrhaphy, and prostatectomy, respectively (Table 2).

Finally, the Panel estimated the minimal mortality after the TVT procedure by accessing the US FDA MAUDE Database²⁰ (now known as MedWatch) using the terms “TVT,” “transvaginal tape,” “sling,” “pubovaginal sling,” and “suburethral sling” which yielded incident reports that included six deaths. Three of the deaths were associated with bowel perforations and one each resulted from hemorrhage, myocardial infarction and pulmonary embolism. In addition, Panel members have documented at least two other deaths due to vascular injury.

In summary, perioperative mortality after sling surgery in the index patient is low; the Panel estimates it at between 0.01%–0.09%. However, mortality increases with advancing age and comorbidities, with mortality nearly three per 10,000 in patients over 80 years of age. Blind passage of trocars into the retropubic space potentially increases the possibility of bowel or vascular injury that could lead to mortality.

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1 **Table 1. Patients experiencing postoperative urgency or**
 2 **urge incontinence**

	Retropubic Suspensions		Transvaginal Suspensions		Sling Procedures	
	G/P	Median CI (2.5-97.5%)	G/P	Median CI (2.5-97.5%)	G/P	Median CI (2.5-97.5%)
<i>Prior Analysis¹</i>						
Urgency						
+ urgency/+DI*	6/78	66 (50–79)	6/33	54 (35–73)	4/45	46 (24–68)
+ urgency/–DI*	6/319	36 (22–52)			5/110	34 (13–61)
– urgency/+DI*	1/6	4 (0–33)	1/3	7 (0–54)	4/36	20 (5–45)
– urgency/–DI*	8/241	11 (8–16)	6/150	5 (3–10)	7/140	7 (3–11)
<i>Current Analysis</i>						
Urge Urinary Incontinence						
New Onset		10-14				11-22
Pre-existing		22-48				29-52
Urgency						
New Onset		9-11				13 (Grade>1)
Pre-existing		40 (Grade<1)				21 (Grade>1)

3 * Preoperative status

4 Abbreviations: CI, confidence interval; DI, detrusor instability; G/P, number of groups and number of
 5 patients per treatment arm

1 **Table 2. Estimated perioperative mortality for SUI and**
 2 **urogynecologic surgical procedures**

3

Surgical procedure	Mortality rate
Overall perioperative mortality ^{22-25,28}	0.02 – 1.8%
Stress incontinence ²⁶	0.01%
Urogynecology ²⁹	0.04%
< 60 years	0.01%
61 – 69 years	0.05%
70 – 79 years	0.09%
> 80 years	0.28%
Hysterectomy ²⁸	0.11%
Pelvic organ prolapse ²⁷	0.03%
Herniorraphy ²⁸	0.41%
Prostatectomy ²⁸	0.20%

4