

The treatment of female stress urinary incontinence: an evidenced-based review

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Objective: To review the literature on the surgical and nonsurgical treatment options for stress urinary incontinence in women, focusing exclusively on randomized clinical trials and high quality meta-analyses.

Materials and methods: A computer-aided and manual search for published randomized controlled trials and high quality meta-analyses investigating both conservative and surgical treatment options for stress urinary incontinence. In the case of a treatment that is not studied in these formats large case series have been used.

Results: Articles were reviewed and the results summarized on pelvic floor physical therapy, pharmacotherapy, bulking agents, and surgery (open and minimally invasive).

Conclusion: There are numerous high quality studies in the literature. It can be difficult to make definitive conclusions on the most appropriate treatment options due to the variability in the outcomes used to define success in these articles. There is also a dire lack of studies evaluating and comparing the surgical options for patients with intrinsic sphincter deficiency.

Keywords: stress urinary incontinence, conservative and surgical treatment

Introduction

Urinary incontinence is defined as the involuntary loss of urine, which is objectively demonstrable, with such a degree of severity that it is a social or hygienic problem.¹ It is estimated that the US alone spends US\$10 billion annually on therapeutic management, absenteeism, and disability related to urinary incontinence. Stress urinary incontinence (SUI) is the most common form of urinary incontinence with an estimated prevalence of 8% to 33%.² Studies on the treatment of SUI are plagued by the lack of a universal definition of success. Some authors measure patient reported outcomes utilizing validated incontinence questionnaires, pad weights, or repeat urodynamics while others utilize simple improvement rates. The success rate is highly dependent on the definition of cure, hence one cannot compare results utilizing different outcomes.³ A literature search was performed in the PubMed database in February of 2011 using the keywords stress urinary incontinence, mid urethral sling, urethral bulking agents, pelvic floor muscle training, open surgical treatment for stress urinary incontinence, and behavioral therapy and weight loss. We focused almost exclusively on randomized clinical trials or high quality meta-analyses.

Pelvic floor muscle training

Pelvic floor muscle (PFM) training (two systematic reviews)^{2,4} is currently the accepted term, replacing Kegels and pelvic floor exercises. There are currently 24 RCTs in

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the literature. It is defined as “any program of repeated pelvic muscle exercises treated by a health care professional”.⁴ This therapy is intended to improve the function and strength of the pelvic floor muscles. The patient is taught by digital vaginal examination to properly isolate or recruit the pubococcygeus without using other muscles.⁵ Physical therapists are well trained in this assessment and teaching of these exercises with the goal of strengthening and gaining control over the pelvic muscles.⁵

The common biofeedback techniques are different forms of manometry or electromyography used to measure vaginal muscle or external anal sphincter activity. In a systematic review,² 24 randomized controlled trials (RCTs) were identified, and 11 RCTs were of sufficient quality to be included. There is strong evidence to suggest that PFM exercises are effective in reducing the symptoms of SUI. They found no evidence that PFM exercises with biofeedback were more effective than pelvic muscle training alone (Table 1).

A large number of studies have investigated PFM training, but it is difficult to draw any conclusions for a number of reasons. There is great variation in the treatment regimens with different types of exercises, the number and frequency of exercises, the confirmation of the correct technique, and the use of biofeedback. The patient population often varies in the type and severity of incontinence.

Summary

Pelvic floor physical therapy is effective at reducing, but infrequently curing, SUI and the addition of biofeedback does not improve PFM exercise's effectiveness. Pelvic floor therapy regimens and the quality of instruction vary considerably hence it is best to refer to therapists with training in female pelvic floor therapy. Since this is a noninvasive and low-risk therapy it is reasonable to discuss this therapy with all women with SUI. Level 1 evidence.

Weight loss

In an RCT, Subak et al sought to determine whether a behavioral weight-reduction intervention for overweight and obese women with incontinence would result in greater reductions in the frequency of incontinence episodes at 6 months compared with a control group: 338 women participated in this trial with a BMI of 36 ± 6 . There was an 8% reduction in weight in the study group compared to 1% in the control group. Both stress incontinence and urge incontinence were reduced more in the weight-loss group than in the control group, but there was a significant difference only in the stress

urinary incontinence. A higher proportion of the intervention group than of the control group had a clinically relevant reduction of 70% or more in the frequency of all incontinence episodes ($P < 0.001$), stress-incontinence ($P = 0.009$), and urge-incontinence episodes ($P = 0.04$).⁶

This study was then extended to examine the longer term effects of the weight loss intervention.^{7,8} Outcome measures were collected at 12 and 18 months. Both groups continued to show decreases in weekly incontinence episode frequency from baseline, but differences between the groups were no longer significant at 18 months. The authors attributed this to a decrease in the difference of weight loss at 18 months, and an increasingly large reduction in incontinence in the control group. The improved stress urinary incontinence rates were sustained at 18 months in the treatment group. (Table 1).

Summary

Even a modest (8% body weight) amount of weight loss improves stress incontinence; unfortunately this weight loss is difficult to maintain and the effectiveness is abolished if the weight is regained. Given the other health benefits of maintaining a healthy weight, all women with SUI should be counseled about modest weight loss to improve SUI. Level 2 evidence.

Pharmacotherapy for stress urinary incontinence

Duloxetine (Cymbalta®, Eli Lilly, Indianapolis, IN) is a balanced and potent inhibitor of serotonin and norepinephrine reuptake.⁹ Its ability to stimulate pudendal motor neurons and increase striated urethral sphincter contractility is thought to be the basis for its efficacy in women with SUI.¹⁰

Dmochowski et al randomized 683 women, 22 to 84 years old, to duloxetine or placebo. There was a significant decrease in incontinence episode frequency with duloxetine compared with placebo (50% vs 27%, $P < 0.001$) with comparably significant improvements in quality of life (11.0 vs 6.8, $P < 0.001$). A greater majority of the placebo treated patients vs duloxetine treated subjects completed the study (87% vs 69%) (Table 1).¹¹ The difference was primarily attributable to a higher rate of duloxetine early discontinuation related to side effects. Nausea was the most common side effect.¹²

Duloxetine has been approved for the treatment of stress urinary incontinence in Europe. Duloxetine is not US Food and Drug Administration (FDA) approved for stress urinary incontinence in the US. The manufacturer and patent holder

Table I Summary of literature review findings

Reference	Study type	Results	Summary
Pelvic floor muscle therapy and weight loss			
Berghmans and Hendriks ²	Systematic review	11 RCT reviewed	Pelvic floor muscle therapy (PFMT) is effective for treatment of SUI. Biofeedback no more effective than PFMT alone.
Subak et al ⁸	RCT	8% weight loss in treatment group. $P < 0.05$ in improvement of SUI in treatment group.	Women with SUI should be counseled about modest weight loss for treatment of SUI.
Pharmacotherapy			
Dmochowski et al ¹¹	RCT	Decrease in incontinence episode frequency compared to placebo. 50% vs 27% ($P < 0.001$).	SUI improved with duloxetine. Only 69% completed the study due to side effects (nausea) of the medication.
Urethral bulking agents			
Lee et al ²⁵	RCT – fat vs placebo	No difference in cure rates 22% vs 21%. 1 death reported.	Fat should not be used as a urethral bulking agent.
Corcos et al ¹³	RCT – collagen vs open surgery	133 females. 12-month success rate after collagen (53%) and surgery (72%).	Collagen is a good alternative for patients unable to tolerate surgery.
Ghoniem et al ²⁷	RCT – Macroplastique vs Contigen	247 females. At 12 months, 61% (Macroplastique) and 48% (Contigen) had improved 1 Stamey grade.	Macroplastique was statistically more effective than Contigen.
Mayer et al ²⁸	RCT – Coaptite vs Contigen	296 females. 63% (Coaptite) vs 57% (Contigen) improved 1 Stamey grade or better.	Both materials are well tolerated. Coaptite required less material.
terMeulen et al ³⁴	Systematic review	2 RCT reviewed (Macroplastique).	More RCTs are necessary to establish the efficacy of Macroplastique.
Keegan et al ²⁶	Cochrane database review	12 RCT reviewed.	The trials were small and of moderate quality. Pending further evidence, injection therapy may represent a useful option.
Open surgery for SUI			
Albo et al ⁴³	RCT – Burch vs fascial sling	655 females. Overall category of success (47% vs 38%, $P = 0.01$) and the category specific to stress incontinence (66% vs 49%, $P < 0.001$) favored the fascial sling.	Success rates were higher with a fascial sling. More UTIs, difficulty voiding, and postop urge incontinence were associated with the fascial sling.
Ward and Hilton ⁴⁴	RCT – TVT vs Burch colposuspension	No significant difference found between cure rates.	Cure rate was the same. Operative time, duration of hospital stay, return to normal activities were longer after colposuspension.
Novara et al ⁵⁴	Systematic review	Colposuspension vs PV sling vs mid urethral tape. 39 RCTs reviewed.	Retropubic tape had higher continence rates than colposuspension. PV sling similar to colposuspension.
Glazener and Cooper ⁴⁶	Cochrane database review	Bladder neck needle suspensions.	Comparable to an open approach. Faster recovery. Vaginal sling procedures offer even greater benefits of minimally invasive surgery and have better outcomes. Effective modality in the long-term. Mid-urethral slings comparable in the short-term.
Dean et al ⁴⁸	Cochrane database review	Laparoscopic colposuspension.	
Lapitan et al ⁴⁹	Cochrane database review	Open retropubic colposuspension.	
Synthetic slings			
Liapis et al ⁶³	RCT	114 patients available at f/u at 12 months.	Objective cure rate was 87% for the TVT-O and 90% for the monarch sling.
Abdel-Fattah et al ⁶⁴	RCT – TOT “outside-in” vs “inside-out”	341 women were randomized. Success rates were 85% (“outside-in”) and 80% at 2-year follow-up.	No significant differences in the objective cure rates and patient reported success rates between “outside-in” and “inside-out” TOT.

(Continued)

Table 1 (Continued)

Reference	Study type	Results	Summary
Latthe et al ⁶⁷	Systematic review	11 RCT comparing TOT or TVT-O vs TVT were reviewed.	Subjective cure rate between TVT-O and TOT were no better than TVT. Bladder injury/voiding dysfunction more prevalent with TVT. Groin pain/erosion with TOT.
Richter et al ⁷⁰	Randomized equivalence trial comparing retropubic vs transobturator slings.	565 (94.6%) completed the 12-month assessment. Objectively assessed treatment success were 80.8% in the retropubic-sling group and 77.7% in the transobturator-sling group. Subjectively assessed successes were 62.2% and 55.8%, respectively.	Objectively assessed successes were equivalent. Subjective successes were similar but not equivalent. Voiding dysfunction more common with retropubic sling. Neurologic symptoms more common with TOT.
Schierlitz et al ⁷¹	RCT	14 of 67 (21%) had urodynamic stress incontinence in the TVT group compared with 32 of 71 (45%) in the transobturator tape group ($P = 0.004$), with nine women in the transobturator tape group having repeat sling surgery compared with none in the TVT group.	Retropubic sling is a more effective operation than the transobturator tape in women with ISD.
Kennelly et al ⁷²	Multicenter prospective evaluation	157 patients available for 1-year analysis. 90.6% had a negative cough stress test and 84.5% had a 1-hour pad weight test less than 1 g at 12 months.	Miniarc sling demonstrated excellent patient tolerability with minimal pain, early return to normal activity and low morbidity.
Ogah et al ⁵⁹	Cochrane database review	62 trials reviewed. The quality of evidence was moderate for most trials.	As effective as traditional suburethral slings, open retropubic colposuspension in the short-term. Objective cure rate increased with retropubic tapes. More complications associated with retropubic tapes.

Abbreviations: RCT, randomized control trial; SUI, stress urinary incontinence; TVT, tension free vaginal tape; TVT-O, TVT obturator; TOT, transobturatortape; ISD, intrinsic sphincter deficiency.

of duloxetine, Eli Lilly, withdrew their FDA application for a new indication of stress urinary incontinence. No other medical therapies have been studied in RCTs to date.

Summary

Currently there is still no good pharmacological therapy available for the treatment of stress urinary incontinence in women. Level 2 evidence.

Urethral bulking agents

Urethral bulking agents have the advantage of being performed in the clinic setting with no need for general or regional anesthetic and minimal risk making them ideal for use in those individuals who are poor surgical candidates due to comorbidities.¹³ They are suitable for women with intrinsic sphincter deficiency since they function by increasing the power of the sphincter mechanism and act as a central filler volume increasing the length of muscle fibers.¹⁴ Injectable therapies are minimally invasive but have been shown to

be 19% less successful than open surgical approaches to cure SUI in one trial. Patient satisfaction and quality of life were similarly improved with an increase in number and severity of complications after open surgery (Table 1).^{13–16} However, their success has been reported to be much worse than this when Macroplastique® (Uroplasty, Minnetonka, MN) and pubovaginal sling were compared with objective cure rates at 6 months being 81% after the sling and only 9% after Macroplastique ($P < 0.0001$).¹⁷ Other limitations of injectable therapies include their biodegradability and need for retreatment, particularly with collagen (Contigen®, CR Bard, Murray Hill, NJ). The unknown long-term risk of urethral complications as well as the possibility of distant migration and antigenicity of these substances is also of great concern. Suspicion among medical providers about the true safety of injectable agents is not unfounded. Teflon urethral injections in animal studies confirmed distant migration and granulomatous reaction in the lymph nodes, lung, and brain.¹⁸ A randomized controlled trial failed to show any

increased risk of complications with Uryx^{®19} which was subsequently FDA approved, but later withdrawn from the market due to 37% urethral erosions in this case series.²⁰ Other agents such as Zuidex[®] have an unacceptably high rate of urethral complications such as pseudo abscess and were less effective than the reference standard of collagen in RCT.^{21–23}

A European trial comparing autologous myoblast and fibroblasts mixed with collagen compared with collagen alone had very high 12-month continence rates, but was retracted due to questionable research practices.²⁴ Other autologous materials, such as fat, have been used in the past and will be described below (Table 1).²⁵

A Cochrane review²⁶ on urethral bulking agents in 2007 included twelvetrials. The data were found to be an unsatisfactory base for practice recommendations, but four higher quality RCT have been published since this review and are included here (Table 1).^{16,23,25,27}

Fat (1 RCT)

One small RCT compared autologous fat to normal saline (placebo) in 68 women. There was no difference in the improved/cure rate between these two groups (22.2% vs 20.7% respectively) at 3 months and one death occurred from a fat embolism.²⁵ Fat should not be used as a bulking agent.

Collagen (3 RCTs)

Collagen (Contigen[®]) has served as the standard by which all other injectables are compared and unfortunately will soon be discontinued by its only manufacturer. It was FDA approved as a urethral bulking agent in 1993 and has been well studied with many large case series and had been used as the comparison group in several RCTs^{13,26,28,29} with very few complications other than irritative voiding symptoms and temporary retention (Table 1).

Its major drawback is the need for a collagen skin test 28 days prior to therapy to rule out allergic reaction (4%) and its effectiveness has been shown to deteriorate over time due to resorption necessitating repeat injections.³⁰

One RCT compared collagen injections to open surgery (fascial sling, Burch, or needle suspension) for SUI in 133 women.¹³ At 1 year, 32.8% of patients were not satisfied with their procedure compared with 20.4% in the open surgery group. There were more urological side effects and pain in the open surgery group. Success defined as a negative 24-hour pad weight was significantly higher in the surgery group (72.2% vs 53.1% $P = 0.01$).

Although never studied in RCT there is convincing evidence that there is a very high rate (93% improved or cured) of success with collagen as a salvage procedure after a failed suspension or repair³¹ and this improvement is long lasting in this particular population even with a single collagen injection.²⁹

Coaptite (1 RCT)

Coaptite[®] (Boston Scientific, Natick, MA) is spherical calcium hydroxylapatite (principal constituent of bones and teeth) suspended in a carboxymethyl cellulose gel carrier.³² In animal experiments fibroblast infiltration occurs as the gel carrier degrades over months and heterotopic ossification does not occur. The substance is more viscous than collagen, but can be injected with a 21-gauge needle. An RCT with 296 women with intrinsic sphincter deficiency (ISD) and without urethral hyper mobility compared Coaptite[®] to bovine collagen. At 1 year, 63.5% of the Coaptite patients and 57.0% of the collagen patients ($P = 0.34$) had at least one Stamey grade of improvement in incontinence (39% and 37% cure respectively $P = 0.78$) which confirmed the noninferiority of coaptite.²⁷ 55% less volume of material was injected with the Coaptite group and the material is not felt to be biodegradable. There was no permanent retention with equivalent temporary retention rates (41% vs 33%), but an increase in urgency incontinence following collagen injection (5.7% vs 12%; $P < 0.05$). One patient has a vaginal extrusion of the Coaptite believed to be due to prolonged tissue pressure effect and one patient had dissection of the material under the trigone with no sequelae. There are recent published reports of large urethral mucosa prolapses occurring following injection of this material that required surgical intervention.³³

Macroplastique

This is the most studied of the synthetic injectable agents (four RCTs and one systematic review).^{34–36} It is composed of solid polydimethylsiloxane suspended in inert gel. The systematic review could not recommend Macroplastique due to insufficient evidence,³⁵ but three RCTs have been published since that time (Table 1).^{16,17,34}

In women with urethral hypermobility and SUI, Macroplastique (24 women) had higher cure and improvement rate of 70.8% compared with a pelvic floor exercise program (21 women) 28.5% ($P = 0.029$). This study did not follow both groups past 3 months and with small treatment groups few definitive conclusions can be drawn.¹⁶ A large multicenter RCT comparing Macroplastique with collagen in 247 women with ISD showed improvement in one Stamey grade in 61.5%

of the Macroplastique (36.9% cure) and 48% of collagen (24.8% cure) at 12 months ($P = 0.05$) with similar adverse events (Table 1).²⁶ This group followed those who were cured with Macroplastique for 2 years and found 84% sustained success.³⁵

Permacol (1 RCT)

Permacol® (Covidien Surgical, Mansfield, MA) is porcine dermal collagen that is not reconstituted like Contigen® (bovine collagen), but maintains its original 3-dimensional form and is biocompatible since it is of porcine origin with no skin test required.³⁶ A small RCT with 50 women compared this material injected periurethrally to Macroplastique injected transurethrally.³⁶ There were similar minor adverse events, but no statistical difference in incontinence at 6 months. Higher powered studies with longer follow-up are required before any recommendations can be made for this product.

Durasphere® (2 RCT)

Durasphere® (Coloplast, Denmark) is composed of pyrolytic carbon-coated zirconium oxide bead suspended in a 2.8% glucan (a polysaccharide used in wound healing) carrier gel.^{37,38} It was found to be equally effective as collagen in 355 women with stress incontinence and leak points less than 90 cm H₂O with improvements in one Stamey incontinence grade at 1 year from baseline in 66.1% of the Durasphere and 65.8% of the collagen ($P = 0.162$) treated women. An equal number of injections was required (1.69 vs 1.55) and the adverse events were similar for both groups with a slight increase in acute retention lasting less than 7 days and urgency in the Durasphere group. This trial showed no evidence of antigenicity and pelvic X-rays taken postprocedure and at 1 and 2 years follow-up showed no migration of particles.³⁷

Significant particle migration into the urethral mucosa and both regional and distant lymph nodes has been observed in nonrandomized trials and high pressure injection is believed to be the cause.^{39,40} Durasphere in its original formulation (particle size 200–550 μm) was difficult to inject due to viscosity and required high pressures, but recently Durasphere-EXP (95–200 μm) has been introduced to resolve this issue. To avoid particle migration the minimum size should be $>80 \mu\text{m}$.¹⁸ Periurethral masses have also been reported following Durasphere treatment requiring surgical drainage or excision in 2.9%.⁴⁰

Stem cell therapy

Stem cell therapy is not FDA approved, but there are promising results for stem cells injected alone without collagen in pilot studies performed in North America.⁴¹

Summary

With the disappearance of collagen, Macroplastique and Coaptite have emerged as safe and effective bulking agents with no antigenicity or distant migration. Macroplastique can be difficult to inject and requires a specialized instrument, but has the most data on its safety. The new Durasphere has not been evaluated in RCT. Level 1 evidence.

Traditional open surgical approaches

Recently, several large RCT have been performed to evaluate the success of open slings and enough information has been accrued to perform adequate Cochrane reviews of the various techniques (Table 1).^{42–44}

Artificial urinary sphincter (AUS) (0 RCT)

This is frequently used in the male population for the treatment of SUI, however, there are to date only case series to describe its use in the female population.⁴⁵ The surgical technique requiring bladder neck placement, the high risk of erosion, and the need for revisions have limited its use and study. Currently evidence is insufficient to make recommendations.

Anterior repair (10 RCTs, 1 systematic review)

This is a purely vaginal approach to SUI that aims to correct urethral hypermobility. The vaginal mucosa overlying the urethra is dissected and sutures are placed in the periurethral tissue and pubocervical fascia to support and elevate the bladder neck (Kelly plication). This is typically done in conjunction with a cystocele repair. A thorough Cochrane review was done on this intervention and was updated in 2009.⁴⁶ Ten trials were reviewed including 385 women who had an anterior repair for SUI. Compared with retropubic suspension, failure rates were doubled in the anterior repair groups at 1 year (29% vs 14% in six trials), between 1 and 5 years (38% vs 17% in six trials) and longer than 5 years (38% vs 21% in four trials). There were few differences in the urological and overall morbidity. With these poor results and no advantage to this procedure it has almost been abandoned as a primary treatment for SUI.

Bladder neck needle suspensions (10 RCTs, 1 systematic review)

These are performed by passing a suture on a needle passer from the vagina to the anterior abdominal fascia via an abdominal or vaginal approach. The three basic techniques are: Pereyra, Raz, and Stamey and each of these has been

modified to utilize slightly different techniques or different suture material, but all have the goal of correcting urethral hypermobility. A Cochrane review was performed and was up to date as of 2009 on this procedure.⁴⁷ Ten trials were evaluated that contained 375 women who had needle suspension and 489 who had other procedures. The perioperative risk was similar comparing needle suspensions to retropubic suspension (seven trials), but the failure rate was increased 1 year and beyond (29% vs 16%). These procedures are rarely performed today due to their poor long-term success and the availability of other minimally invasive options.

Laparoscopic colposuspension (22 RCTs, 1 systematic review)

Was developed as a minimally invasive approach to female SUI and is performed in essentially the same way as a Burch procedure. A Cochrane review up to date as of 2009 reviewed 22 trials.⁴⁸ Ten articles compared laparoscopic with open Burch and found slightly worse results in the laparoscopy arms, but with fewer complications and shorter hospital stay. Eight studies compared the laparoscopic surgery to synthetic mid-urethral slings and found similar subjective cure, but better objective cure rates in the slings. With the shorter operative time and comparative simplicity of midurethral slings, laparoscopic Burch is currently rarely performed.

Open abdominal retropubic suspensions (46 RCTs, 1 systematic review)

These procedures are performed via a Pfannenstiel incision whose goal is to correct urethral hypermobility. The retropubic space is exposed and permanent sutures are placed in the anterior vaginal wall around the bladder neck and proximal urethra and are sutured to ileopectineal ligament in the case of a Burch colposuspension, or the bladder neck is suspended to the fibro cartilage of the symphysis in the Marshall-Marchetti-Krantz (MMK). The paravaginal repair or the vagina-obturator shelf repairs are variations of the Burch with more lateral placement of the sutures.

A Cochrane review published in 2009 reviewed 46 trials with 4738 women total.⁴⁹ Overall they concluded that open retropubic suspensions are effective with 1 year 85% to 90% success and approximately 70% 5-year dry rate. Compared with both needle suspensions and anterior repair (eight trials) there is a lower failure rate both in the short- and long-term.

Four small trials compared MMK with Burch with very limited data available. Overall in the short- and medium-term

there were fewer surgical failures in the Burch group (23 vs 34%).

Six trials compared retropubic suspension to pubovaginal sling (PVS), but only two of these utilized autologous fascia.⁵⁰ Demirci and Yucel compared the pubovaginal sling and Burch colposuspension in 46 women with high valsalva leak point pressures (>90 cm H₂O).^{50,51} At 1 year there were no differences in complications; one patient in each group developed de novo detrusor over activity and on physical exam. In the Burch group only, there were two new significant pelvic organ prolapses and one surgical failure. Albo et al compared autologous PVS and Burch in a large, well designed trial that since the publication of the Cochrane review has undergone multiple sub analysis.⁴⁴ This trial evaluated multiple outcomes both objectively and subjectively in 655 women who had relatively high val salva leak point pressures (average <115 cm H₂O).⁵² At 24 months the PVS group had greater overall (47% vs 38%; $P < 0.001$) and stress specific (66% vs 49%; $P < 0.001$) continence rates. The low success rates overall compared with prior trials are explained by the extremely rigorous definition of success utilized in this trial, which required all objective and subjective measures of continence to be met for a patient to be deemed cured. More women in the sling group had voiding dysfunction, urinary tract infections and all 20 women who required surgical revision due to urinary obstruction were in the PVS group. Women were 1.7 times as likely to need treatment for urgency incontinence after PVS,⁵² but sexual function improved and was not different between these groups.⁵³ Only 3.5% of the recruited women had ISD with (Valsava Leak Point Pressure) <60 cm H₂O so that these results cannot be extrapolated to that population.

Ten trials in the Cochrane review⁵⁰ compared Burch colposuspension with tension-free vaginal tape (TVT), but most were of very small size and of short follow-up except one trial by Ward and Hilton in 2002.⁴⁵ In all time periods these combined studies showed no significant difference in success rates between TVT and retropubic suspension. Operative time was shorter for the TVT as was hospital stay and cost was 25% less, but there is a slightly higher rate of vaginal or bladder perforation. Another systematic review was performed evaluating Burch and mid urethral slings and did find a slight advantage in cure rates with the latter (Table 1).⁵⁴

In general, retropubic suspensions are very effective at correcting stress urinary incontinence in women with urethral hypermobility and higher leak point pressures. The risk of developing voiding dysfunction is very low after retropubic suspension, but there is an 8-fold risk of developing new

or recurrent pelvic organ prolapse compared with any sling procedure.⁵⁰ Given the morbidity of the open incision and the widespread belief, despite minimal evidence, that synthetic midurethral slings are equally effective, a Burch is often only performed in conjunction with a concomitant pelvic surgery such as abdominal sacrocolpopexy where the incision has already been made.⁵⁵

Pubovaginal slings (27 RCTs, 2 systematic reviews)

These slings are placed via a combined abdominal Pfannenstiel incisions and vaginal incision. A strip of material is passed under the proximal urethra/bladder neck and tunneled up to be tied above the rectus fascia. The pubovaginal sling is designed to treat ISD, but is also effective at treating incontinence due to urethral hypermobility. The material utilized is typically abdominal rectus fascia harvested from the same incision, but autologous fascia latta from a separate incision is also used as have porcine dermis, cadaveric fascia, Teflon, Gore-Tex, Marlex, silastic, and Mersilene. A Cochrane review of traditional suburethral slings is newly available.⁵⁶ In this review there were 26 trials with 2284 women included. The quality of these studies was only modest with small sample sizes, apart from the previously mentioned study by Albo et al, and follow-up was short ranging from 6 to 24 months.

The trials comparing Burch with autologous PVS showed superior cure rates at the expense of a higher voiding dysfunction and obstruction with the PVS and are discussed in the section above.

Twelve trials have compared PVS and midurethral slings in the review. Only short- and medium-term results are available, but at both time points there is no difference in patient reported incontinence between these slings.

Another systematic review performed recently evaluating only the biological PVS compared these to midurethral slings and found similar efficacy, but higher bladder injury rates after midurethral sling and higher rates of voiding dysfunction after PVS.⁵⁶

One publication since that review compared porcine dermal slings (Pelvicol®, Bard, Sweden) to autologous PVS and TVT in a RCT with 201 women.⁵⁷ Incontinence was poorly defined in the treatment groups, but the Pelvicol slings had significantly worse outcomes than either the PVS or the TVT at 1 year with only a 22% dry rate (TVT 55%, PVS 48%; $P = 0.001$) suggesting that the material is not durable. Animal studies have explained this phenomenon and shown that in certain individuals Pelvicol is rapidly degraded.⁵⁸ TVT and PVS had equivalent success, but PVS

required a longer hospital stay and more patients required short-term self-catheterization. Unfortunately no RCTs have been performed comparing the PVS to midurethral slings in the treatment of ISD which is the primary indication for a PVS in the current treatment of SUI.⁵⁹

Summary

Anterior repair and bladder neck needle suspensions are inferior surgical approaches to female SUI. Laparoscopic Burch is effective, but invasive when compared with minimally invasive synthetic slings and has similar success. Open retropubic Burch is effective in treating female SUI with high leak point pressures and urethral hypermobility, but does carry the risk of secondary pelvic organ prolapse. The pubovaginal sling is slightly more effective than Burch in this same population with an increased risk of voiding dysfunction. The primary utility of the PVS in treating ISD has not been evaluated in RCT. If a PVS is performed one should try to utilize autologous fascia. Level 1 evidence.

Synthetic slings

In 1990, Petros and Ulmsten described the integral theory. This theory proposes that a physiologic “backboard” is created through fixation of the middle region of the urethra to the pubic bone, via the pubourethral ligaments, and that this factor is critical to the continence mechanism.⁶⁰

The integral theory of female urinary continence led to the development of the tension-free vaginal tape.⁶¹ This was introduced as a commercially available kit by Gynecare® Inc (Menlo Park, CA) and has ushered in a new era of stress incontinence treatment.

Bottom up vs top-down retropubic midurethral slings

The TVT sling is a narrow polypropylene strip, housed within a plastic sheath passed via trocars from a small vaginal incision to a suprapubic exit site at the skin's surface. This is described as a “bottom-to-top” technique. There have been modifications made to the Gynecare® design. SPARC® or (SupraPubic ARC system, American Medical Systems, Inc, Minnetonka, MN) is a similar polypropylene mesh, but this is passed in a “top-to-bottom” fashion. A recent Cochrane review found three RCTs on patient-reported cure showing a significant difference in favor of “bottom-top” vs “top-bottom” at 12 months (85% vs 77%). The combined analysis of objective cure rate also favored “bottom-top” by a smaller margin, 92% vs 87%.⁵⁹

In the study with the longest follow-up, Tseng compared the efficacy and complication rates of TVT and SPARC in

62 patients. They used a negative 1-hour pad test to define postoperative continence. They reported similar continence rates in the two arms (87% vs 80.7%) and similar low complication rates.⁵⁹

The largest published RCT⁵⁹ enrolled 147 patients randomized to TVT and 154 to SPARC. This study showed significantly higher subjective continence rates in the TVT arm (87.1% vs 76.5%). This was a well done study except for the very short follow-up (6–8 weeks). Combining all four studies: TVT outperformed SPARC in terms of subjective cure rate ($P = 0.02$) and objective cure rates ($P = 0.005$) according to any definition.

Transobturator vs TVT-O

The transobturator approach is another method of placement of a midurethral sling.^{61,62} Trocar placement is initiated just lateral to the labium majus and continued through the obturator foramen to a small vaginal incision.⁶² This approach was designed to minimize the risk of complications involving the enteric and vascular structures of the pelvis. A reversed “inside-out” approach also exists.⁶³ Three RCTs directly compare “outside-in” to “inside-out” transobturator slings.^{63–66} These report equivalent cure rates both subjective and objective over the short- and medium-term follow-up (Table 1).

Latthe et al performed a meta-analysis of four RCTs comparing the two different routes of transobturator tape.⁶⁷ (Table 1) Follow-up ranged from 1 to 44 months. The evidence for the equivalent effectiveness of transobturator tape (TOT) and transvaginal tension free tape obturator (TVT-O) when compared with each other was established over the short-term. Bladder injuries and voiding difficulties seemed to be less with inside-out tapes on indirect comparison. Groin/thigh pain (TVT-O, odds ratio [OR]: 8.05, 95% confidence interval [CI]: 3.78–17.16) and vaginal injuries (TOT, OR: 5.82, CI: 1.85–18.3; TVT-O, OR: 1.69, CI: 0.73–3.91) were more common in the transobturator tapes. Authors recommended more long-term follow-up to establish the continued effectiveness of transobturator tapes.⁶⁸

Retropubic vs transobturator approach

A Cochrane Review⁵⁹ evaluated 24 trials that compared retropubic and transobturator midurethral slings. Subjective cure was reported in ten trials with a total of 1281 participants and showed no statistically significant difference between routes.

Sung et al in a review of six RCTs and 11 cohort studies in 2591 women showed no difference in subjective failure between the two routes (5.7% for transobturator vs 7.8% for retropubic). They did note a lower risk of complications and de novo irritative voiding symptoms for the transobturator group.

They concluded that it would take RCT of 30,000 women to demonstrate superiority of one approach over the other.⁶⁸

TVT-O and TVT were compared in 208 patients with varying severity of SUI. At 1 year of follow-up, incontinence was cured in all mild SUI patients with both techniques. In patients with severe SUI, all were cured with TVT and 66% when treated with TVT-O ($P < 0.001$). They concluded that the severity of SUI is an important parameter that influences results after TVT-O and TVT, and could be used to guide surgeons in selecting the most effective intervention.⁶⁹

In 2010, a multicenter, equivalence trial compared outcomes with retropubic and transobturator midurethral slings in women with stress urinary incontinence.⁷⁰ The primary outcome was treatment success at 12 months according to both objective (negative stress test, a negative pad test, and no retreatment) and subjective criteria (self-reported absence of symptoms, no leakage episodes recorded, and no retreatment). A total of 597 women were randomly assigned in the study and 95% completed the 12-month assessment. Both approaches were considered equivalent (80.8% retropubic slings vs 77.7% for the transobturator slings). The equivalence applies only to objective success. Equivalence between the two procedures could not be definitively shown for subjective success. There were differences in the complications associated with the two procedures with the transobturator sling more likely to have neurologic symptoms, such as leg weakness and groin numbness and the retropubic sling group members were more likely to have postoperative voiding dysfunction (Table 1).

Patients with intrinsic sphincter deficiency (ISD)

ISD represents the portion of SUI that is not due to a support defect or urethral hypermobility. Most of the published data have used a definition of an abdominal leak point pressure of <60 cm H₂O or a maximal urethral closure pressure of <20 cm H₂O. Fortunately, one recent study has evaluated this difficult to treat condition. Schierlitz et al performed an RCT looking at the effectiveness of TVT compared with TOT in women with SUI and ISD.⁷¹ 164 patients were enrolled in the study. On urodynamics 6 months after surgery, of the 138 patients tested, 14 of 67 (21%) in the TVT group had persistent continence compared with 32 of 71 (45%) in the transobturator tape group (Fisher's exact test, $P = 0.004$). Nine of the 67 (13%) TOT group did request further surgical treatment to correct SUI compared with 0 of 71 (0%) in the TVT group. Their conclusion was that, in the treatment of urodynamic stress incontinence with intrinsic sphincter deficiency, the insertion of TVT is the preferable surgical option (Table 1).

Mini-slings vs others

The newest type of sling is the mini-sling, which requires only one incision, and no trocar passage is necessary outside the vagina. These slings are believed to be less invasive than the previously described midurethral slings. There are very limited data available on their safety and efficacy.⁶² These slings use self-fixating tips that provide immediate fixation into the obturator muscles. In January 2011, an RCT on a retropubic transvaginal tape vs mini-sling was performed. A total of 71 patients were randomized to both procedures. Subjective cure rates as well as dual channel subtraction cystometry and pressure flow studies at 6 months were used. The mini-sling was associated with a much higher rate of persistent stress urinary incontinence at 6 weeks and 6 months. The authors state that the mini-sling should be used with caution until more robust studies can be performed (Table 1).⁷²

Summary

Midurethral slings are effective and safe for the treatment of stress urinary incontinence. TVT and SPARC are relatively similar retropubic approaches. Retropubic slings have a slight increase in voiding dysfunction compared with transobturator routes, but have none of the thigh complications associated with obturator approaches. TVT appears to have better efficacy for more severe incontinence or ISD and little data exist for the mini-slings. Until more robust data are available, TVT and TOT remain the standard of care in patients undergoing surgical treatment for stress urinary incontinence. Level 1 evidence.

Conclusion

Many surgical options exist for SUI. Synthetic midurethral slings are minimally invasive, safe, and effective for women with high leak point pressures and hypermobility. There is robust evidence for both the retropubic and transoburator route with slightly different complications. What is missing among all these data is a comparison between surgical approaches for the treatment of intrinsic sphincter deficiency and low leak point pressure stress urinary incontinence, which is the most difficult type of incontinence to cure. What is needed is a large trial to compare surgical approaches such as the pubovaginal sling and the midurethral slings for incontinence in women with ISD and those women who have failed midurethral slings surgical procedures for stress urinary incontinence.

Disclosure

The authors declare no conflicts of interest in this work.

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