

Recent advances in surgical management of urinary incontinence [version 1; peer review: 2 approved]

Alison Downey, Richard D. Inman ២

Department of Urology, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF, UK

V1 First published: 31 Jul 2019, 8(F1000 Faculty Rev):1294 (https://doi.org/10.12688/f1000research.16356.1)

Latest published: 31 Jul 2019, 8(F1000 Faculty Rev):1294 (https://doi.org/10.12688/f1000research.16356.1)

Abstract

There have been several recent developments in surgical treatments for male and female incontinence. This article reviews the current options for treatments of urge and stress incontinence in men and women. Treatments for urge incontinence discussed include intradetrusor onabotulinum toxin A, sacral neuromodulation and percutaneous tibial nerve stimulation. For stress incontinence, suburethral mesh, bulking agents, autologous slings, colposuspension, male slings and artificial urinary sphincters are assessed.

Keywords

Surgery, Urinary Incontinence, Bladder, stress incontinence, urgency incontinence

Open Peer Review

Reviewer Status 🗹 🗸



F1000 Faculty Reviews are written by members of the prestigious F1000 Faculty. They are commissioned and are peer reviewed before publication to ensure that the final, published version is comprehensive and accessible. The reviewers who approved the final version are listed with their names and affiliations.

- Wayne J. G. Hellstrom, Tulane University Health Sciences Center, New Orleans, USA
 Pete Tsambarlis, Tulane University Health Sciences Center, New Orleans, USA
- 2 David Waltregny, University Hospital of Liege, Liege, Belgium

Any comments on the article can be found at the end of the article.

Corresponding author: Richard D. Inman (richard.inman@sth.nhs.uk)

Author roles: Downey A: Writing – Original Draft Preparation, Writing – Review & Editing; Inman RD: Formal Analysis, Methodology, Project Administration, Supervision, Validation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: The author(s) declared that no grants were involved in supporting this work.

Copyright: © 2019 Downey A and Inman RD. This is an open access article distributed under the terms of the Creative Commons Attribution Licence, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

How to cite this article: Downey A and Inman RD. Recent advances in surgical management of urinary incontinence [version 1; peer review: 2 approved] F1000Research 2019, 8(F1000 Faculty Rev):1294 (https://doi.org/10.12688/f1000research.16356.1)

First published: 31 Jul 2019, 8(F1000 Faculty Rev):1294 (https://doi.org/10.12688/f1000research.16356.1)

Introduction

Urinary incontinence is defined by the International Continence Society as any involuntary leak of urine¹. Classification of urinary incontinence includes stress incontinence, urgency incontinence, mixed incontinence and continuous incontinence (for example, due to vesicovaginal fistula). This review concentrates on the surgical management of urgency and stress incontinence.

Urge urinary incontinence

Urge urinary incontinence (UUI) is defined as involuntary leakage of urine accompanied or immediately preceded by urgency and is part of the symptom complex of overactive bladder syndrome (OAB)¹. A systematic review of global prevalence and economic burden of UUI estimated a prevalence of between 1.85 and 30.5% in Europe and an annual cost of \$7 billion in Canada, German, Italy, Spain, Sweden and the UK².

Non-surgical management of OAB consists of a stepwise approach. First-line options include lifestyle modifications such as bladder drill (or timed voiding, a self-help regimen designed to increase the interval between voids by using a graduated approach), reducing intake of caffeinated drinks, and preventative measures such as treatment of constipation and weight loss^{3–5}.

If conservative methods are not sufficient, second-line therapies involve adding anticholinergic medications and, more recently, mirabegron, a beta-adrenergic receptor agonist approved in 2012 and recommended as a second-line treatment for UUI by the European Association of Urology (EAU), the American Association of Urology (AUA) and the National Institute for Health and Clinical Excellence (NICE)^{6,7}.

When patients are resistant to or cannot tolerate both conservative and pharmacological treatment, surgical techniques such as intravesical onabotulinum toxin A (oBTXA), sacral neuromodulation, and posterior tibial nerve stimulation are third-line options. In those refractory to all treatments, augmentation cystoplasty or urinary diversion can be considered as a final option.

Onabotulinum toxin A

Injection of oBTXA, a potent neurotoxin, into the bladder wall is now recommended for use in patients who have OAB with or without UUI and who have failed to respond to conservative and drug treatments. It is injected by using a flexible or rigid cystoscope into the detrusor muscle under local or general anaesthetic. The main side effects of treatment are urinary tract infection (UTI), incomplete bladder emptying and urinary retention requiring clean intermittent self-catheterisation⁸.

Substantial high-quality data comparing oBTXA with placebo and anticholinergic medication support the use of oBTXA as a third-line treatment for patients with UUI. In 2017, in a double-blinded placebo-controlled randomised controlled trial (RCT) of nearly 500 patients, Nitti *et al.* compared 100 units of oBTXA with placebo and found that oBTXA significantly decreased the frequency of UUI episodes compared with placebo (by -2.65 versus 0.87)⁹. Complete continence also improved in 22.9% of patients having oBTXA compared with 6.5% with placebo at 24 weeks. Side effects of oBTXA included urinary retention and UTI (Table 1)⁹.

A 2017 systemic review comparing oBTXA with anticholinergics and mirabegron found that 100 units of oBTXA resulted in the greatest reduction in episodes of UUI and of continence (100% reduction in UUI) at 12 weeks, compared with all other licenced medication, although there was no difference in urinary frequency between oBTXA and either solifenacin 10 mg once a day or oxybutynin 10 mg controlled release once a day¹⁰. However, there is currently a lack of direct head-to-head trials of oBTXA compared with anticholinergics and mirabegron.

As a result of the high-quality data available, most guidelines recommend oBTXA for refractory OAB symptoms. NICE now recommends offering oBTXA to patients with proven detrusor overactivity at an initial dose of 200 units; however, EAU guidelines recommend an initial dose of 100 units^{6,7}. Patients should be counselled about the 5% risk of urinary retention requiring clean intermittent self-catheterisation, the requirement for repeat injections every 6 to 9 months and the increased risk of associated UTI.

Sacral neuromodulation

Sacral neuromodulation (SNM) involves the placement of an electrode into the third sacral (S3) foramen which is connected to a generator and battery, electrically stimulating the nerve root and suppressing the reflexes responsible for involuntary detrusor contractions. Currently, sacral nerve stimulation (SNS) is recommended in those who have failed or cannot tolerate

Table 1. Comparison of onabotulinum toxin A versus placebo in treating urge urinary incontinence.

At 12 weeks	Placebo	100 units of onabotulinum toxin A	P value
Reduction in frequency	-0.87 (12%)	-2.65 (49%)	<0.01
Continent	6.5%	22.9%	
Urinary tract infection	9.2%	24.5%	
PVR of 200 mL or increase of 200 mL from baseline PVR	0%	8.7%	
PVR of 200 mL or greater requiring CISC	0.4%	5.8%	

Data are from Nitti et al.º (2017). CISC, clean intermittent self-catheterisation; PVR, post-void residual urine volume.

conservative and pharmacological treatment, as an alternative to oBTXA $(EAU^{\rm 6})$ or those unsuitable for oBTXA.

Historically, implantation of a permanent SNS generator was preceded by a trial of percutaneous electrode linked to an external stimulator for a trial of stimulation, and success was defined as more than 50% clinical improvement after 1 to 2 weeks. At a later date, a permanent tined lead and battery were implanted.

Recently, in 2015, a permanent tined electrode was inserted initially for the trial period and a permanent generator was implanted 2 weeks later without removal of the tined lead if the trial was successful¹¹. Comparison of the two implantation techniques has shown that the two-stage technique results in a higher rate of generator implantation and this is probably due to the improved stability of a permanent tined lead (50.9% versus 24.1%)¹¹.

In a 2018 systematic review of neuromodulation, Tutolo *et al.* showed that, in those with UUI, between 43 and 56% of patients were dry and 54 to 59% were improved and that the long-term results are maintained at 4 years¹². SNS is a safe procedure; the commonest side effects are pain at the implantation site in 15 to 42%, revision surgery in 9 to 33% and wound infections in 3 to 6%. Despite the promising results, studies of SNS have often not blinded assessors to treatments and patient allocation has been open to bias.

However, the recently reported ROSETTA (Refractory Overactive Bladder: Sacral NEuromodulation vs. BoTulinum Toxin Assessment) trial was a good-quality multi-centre open-label randomised study comparing oBTXA (200 units) with SNS in 386 women¹³. oBTXA treatment had a small but statistically significantly increased reduction in mean number of UUI episodes (-3.9 versus -3.3) at 6 months. The oBTXA group had a higher rate of UTI (35% versus 11%) and requirement for self-catherisation (8% at 1 month and 2% at 6 months). Although there was a statistical difference in results between SNS and oBTXA, the clinical relevance is uncertain, particularly with the difference in adverse events.

In 2017, Noblett *et al.* reported the results of a prospective multicentre study to evaluate sacral neuromodulation over a period of 12 months and found that 80% of patients underwent permanent SNM implantation following a test period¹⁴. Patients with UUI had a mean reduction of 2.2 \pm 2.7 leaks per day following implantation (P < 0.0001)¹⁴. In 2014, Peeters *et al.* found that SNM was effective in the long term; the success rate was 70% after a mean follow-up of 46.88 months in patients with UUI¹⁵. A summary of SNS and PTNS is provided in Table 2.

Currently, NICE guidelines recommend offering SNM to patients if they have not responded to conservative management, including drugs, and they are unable to perform clean intermittent catheterisation (that is, they would be unsuitable for oBTXA) whereas EAU guidelines recommend offering SNM to patients who have UUI refractory to anticholinergic therapy^{6,7}.
 Table 2. Sacral nerve stimulation versus percutaneous

 nerve stimulation in urge urinary incontinence.

	Sacral nerve stimulation	Percutaneous nerve stimulation
Improvement in lower urinary tract symptoms	61–90%	54–79%
Failure	4–64%	40–44%
Revision surgery	9–33%	

Data are from Tutolo et al.¹² (2018).

Percutaneous tibial nerve stimulation

Percutaneous tibial nerve stimulation (PTNS) involves stimulating the sacral nerve plexus for 30 minutes weekly for 12 weeks by placing a needle percutaneously into the posterior tibial nerve peripherally¹⁶. A 2018 systematic review of PTNS found rates of success (cure or improvement) of between 54 and 79%, depending on the definition of success¹². An RCT comparing PTNS with tolterodine found that 79.5% of patients with PTNS had a subjective cure or improvement in symptoms at 12 weeks compared with 54.8% of the tolterodine group, suggesting that PTNS may be a reasonable alternative to anticholinergics¹⁷. MacDiarmid et al. followed up the patients who had responded to PTNS, further treatment being given "on demand", and found that the effects of PTNS were sustained between 3 and 12 months¹⁸. Despite encouraging data, long-term data for PTNS are sparse; most studies provide data to 12 weeks only and use varying definitions of success.

Conclusions

Although initial results for PTNS are encouraging, high-level evidence and long-term follow-up data are lacking. It is recommended by NICE as an option only for patients who fail conservative management and do not want or cannot tolerate botulinum toxin or sacral neuromodulation following multi-disciplinary team discussion. SNS treatment for UUI symptoms in OAB is safe and effective in both the short and long term. The ROSETTA trial has shown a statistically significant reduction in UUI with use of oBTXA and SNS. Although the oBTXA group had a significantly increased effect on UUI compared to SNS, the clinical significance remains unclear, particularly as oBTXA has a different side effect profile. At present, both EAU and NICE guidelines recommend that either can be used equally for patients with refractory UUI^{6,7}.

Stress urinary incontinence in women

Stress urinary incontinence (SUI) is the involuntary loss of urine on effort or physical exertion, including sneezing or coughing¹. In women, prevalence ranges from 29 to 75%, depending on age, and two broad pathophysiological mechanisms are proposed: urethral hypermobility (weakness in the supporting mechanism of the urethra) and intrinsic sphincter deficiency (defective urethral sphincter mechanism).

Initial management of SUI includes weight reduction, pelvic floor muscle training and biofeedback^{4,5}. Incontinence pessaries

have been used in the past for women who are poor surgical candidates, as has duloxetine, a serotonin and noradrenaline reuptake inhibitor, but neither is recommended by NICE. If conservative management for SUI fails, patients may be offered surgical treatment⁷. Surgical options for women include ure-thral bulking agents and bladder neck suspension procedures, including mid-urethral mesh procedures, pubovaginal slings, colposuspension, and the artificial urinary sphincter (AUS).

Urethral bulking agents

The injection of bulking agents into the urethral submucosa is a minimally invasive treatment for SUI, improving mucosal coaptation and thus increasing urethral outlet resistance. Several agents are available for use (Table 3) whereas others have been withdrawn because of adverse events (Zuidex, Uryz, Polytef and autologous fat). The procedure may be performed in the outpatient day case setting under local anaesthetic. Complications include urethral discomfort, overactive bladder syndrome, temporary urinary incontinence and UTIs²².

High-quality long-term evidence for the use of urethral bulking agents as first-line agents is limited. A Cochrane Review in 2017 found only 14 trials of moderate quality which were not suitable for meta-analysis²³. Bulking agents were compared with placebo, surgical management or collagen in the trials assessed. In the short term, injectables (Macroplastique) provided a better improvement in continence than conservative treatments²⁴. In two trials which compared surgical treatments with Macroplastique or collagen, surgery resulted in a better objective cure than injectables^{25,26}. No clear-cut conclusions could be taken from trials comparing different injectable agents.

According to EAU guidelines on urinary incontinence, bulking agents should not be offered to women seeking a permanent cure but may provide short-term improvement in symptoms. Repeat injections may be required⁶. NICE supports the short-term use of intra-urethral bulking agents but noted that the benefits diminish with time but may be repeated⁷.

Burch colposuspension

The Burch colposuspension was initially described in 1961 and involves suspending the anterior vaginal wall to the ileopectinal ligament (Cooper's ligament). This was the gold-standard surgical approach for many years and can be performed by using the open or laparoscopic approach. Complications include bladder perforation, haemorrhage, *de novo* overactive bladder syndrome and prolapse.

An updated Cochrane Database Review in 2017 of 55 trials involving 5517 women found that the overall continence rate for colposuspension was between 85 and 90% at 1 year after procedure and that 70% of patients remained dry at 5 years. Patient-reported incontinence rates were not significantly different between open and laparoscopic colposuspension, but laparoscopic surgery was found to have a lower rate of complications and a shorter length of stay in hospital²⁷. AUA and EAU guidelines also suggest that open and laparoscopic colposuspension have comparable cure rates.

EAU guidelines suggest offering colposuspension (open or laparoscopic) if a mid-urethral sling (MUS) cannot be considered⁶. NICE guidelines state that colposuspension, mid-urethral tape or autologous fascial sling can be offered as first-line surgical options but that laparoscopic colposuspension should be offered only by an experienced laparoscopic surgeon working within a multi-disciplinary team⁷.

Autologous fascial sling

The autologous fascial pubovaginal sling (PVS) was first popularised by McGuire and Lytton in 1978 and involves harvesting a strip of rectus fascia which is placed suburethrally by using a vaginal incision. In 2007, the Stress Incontinence Surgical Efficacy Trial (SISTEr) reported the results of randomly assigning incontinent women to either PVS or colposuspension. At 24 months, the rate of success (no self-reported SUI, negative stress test and no retreatment) was higher for autologous PVS compared with colposuspension (66% versus 49%), although side effects and need for intervention were more likely²⁸. At 5 years, patient satisfaction remained high (PVS 83% versus 73%) for both procedures, although continence rates had decreased (PVS 30.8%, colposuspension 24.1%)²⁹.

Schimpf *et al.* found autologous PVS to be superior to Burch colposuspension when comparing subjective cure rates (odds

Bulking agent	Commercial name	Current usage
Autologous fat	Autologous fat	Trial terminated (serious adverse event)
Carbon coated zirconium beads	Durasphere	Recommended by NICE
Polyacrylamide hydrogel	Bulkamid	
Calcium hydroxlapatite	Coaptite	Approved by FDA
Glutaraldehyde X linked with bovine collagen	Contigen	Requires skin test (commonest comparator in trials)
Hyaluronic acid with dextranomer	Zuidex	Withdrawn in 2009
Porcine dermal implant	Permacol	
Silicone particles	Macroplastique	Recommended by NICE, approved by FDA
Autologous myoblasts	Experimental preparations	Research (not licenced)

Table 3. Periurethral bulking agents for stress incontinence.

FDA, US Food and Drug Administration; NICE, National Institute for Health and Care Excellence.

ratio [OR] 1.65) and to have a lower incidence of UTI, groin pain and bladder/vaginal perforation³⁰. However, MUS was found to be superior to autologous PVS for subjective cure rates (OR 0.40) and to have a lower incidence of overactive bladder symptoms and retention³⁰.

In 2017, a systematic review of 28 RCTs involving more than 15,000 patients examined comparative data for PVS, colposuspension, tension-free vaginal tape (TVT) and transobturator tape (TOT). Patients undergoing autologous PVS and MUS had similar rates of cure, but MUS had better cure rates than colposuspension. TVT has higher cure rates than TOT though with a higher rate of complications, including bladder perforation, pelvic haematoma, UTIs and voiding symptoms³¹. Recently, in a small study of the results of transobturator insertion of autologous fascial sling, Linder and Elliott found that 80% of patients were dry at 4 months; however, long-term data are required to validate this approach³².

In summary, PVS has high satisfaction rates at 5 years compared with colposuspension, although popularity waned with the introduction of the MUS, which does not require the additional morbidity of harvesting of fascia. Increasing patient and surgeon concern with mesh-related complications has renewed interest in PVS because of the lack of mesh-type erosion and pain-related complications.

Mid-urethral synthetic slings

Mid-urethral synthetic sling insertion has become the most common surgical procedure for SUI and largely superseded colposuspension and PVS as a result of the minimally invasive nature and effective cure rate. Ulmsten described the original retropubic tape procedure in 1996: the TVT. This is inserted in a "bottom up" approach through a suburethral incision in the vagina to the anterior abdominal wall posterior to the pubic symphysis. The SPARC (suprapubic arch) sling system is a "top down" retropubic sling with complications similar to those of the TVT but is not commonly performed in the UK. Transobturator tapes were developed in the early 2000s, when Delorme introduced an "outside in" procedure (TOT), and subsequently an "inside out" procedure (TVT-O) was popularised by de Leval³³. The Cochrane Review of MUS in 2017 reported increased risk of serious intra-operative complications during TVT compared with TOT, including bladder perforation (0.6%

versus 4.5%) and more serious but rare complications such as visceral and vascular injury (Table 4). Post-operative voiding dysfunction was less frequent after TOT, although the incidence of groin pain was higher (6.4% versus 1.3%) but the incidence of suprapubic pain was lower (0.8% versus 2.9%). The risk of vaginal tape erosion/exposure/extrusion was low in both groups, although the evidence was of low quality¹⁹.

Fusco et al. performed an updated systematic review and metaanalysis of the literature to compare the efficacy and safety of MUS with those of Burch colposuspension and pubovaginal slings³¹. They found that MUS was significantly superior to Burch colposuspension for overall (OR 0.51) and objective (OR 0.51) cure rates. They had a similar risk of further incontinence surgery and late complications. Retropubic TVT had a higher subjective cure rate (OR 0.83) and objective cure rates (0.82 OR) compared with TVT-O but this was at the cost of higher rates of intra-operative bladder/vaginal perforation, pelvic haematoma and UTI and lower urinary tract symptoms. There were no significant differences in efficacy and safety between "inside out" and "outside in" TVT-O³¹. There is a risk of intermittent self-catheterisation with both TVT and TVT-O insertion: in a systematic review, Novara et al. reported a 1.5% rate following TVT-O and 3.4% following TVT insertion¹⁹.

Recently, a single-incision mini-sling placed through a single vaginal incision that can be performed under local anaesthetic as a day case was developed³⁴. However, one type of mini-sling (TVT-Secur,,Ethicon, Somerville, USA) was with-drawn from use because of a higher risk of adverse effects and subsequent data have shown a high failure rate at 3 years compared with retropubic MUS. NICE guidance states that mini-slings should not be used unless special arrangements are in place for clinical governance, consent and research⁷.

Mesh safety

In recent years, concerns about complications after the use of synthetic mesh for SUI and pelvic organ prolapse (POP) surgery have been voiced by physicians, regulatory bodies, the media and patient websites. These have identified the risk of complications, including mesh erosion, chronic pain, dyspareunia and infections. In some patients, this has resulted in debilitating symptoms requiring major surgery and in large payouts after successful litigation, particularly in the US.

Table 4. Comparison of transobturator tape and transvaginal tape tapes.

	Transobturator tape	Transvaginal tape	Risk ratio (confidence interval)
Subjective cure 1 year	62–98%	71–97%	0.98 (0.96–1.00)
Subjective cure >5 years	43–72%	51-88%	
Bladder perforation	0.6	4.5	0.13 (0.08–0.2)
Voiding dysfunction	Lower	Increased	0.53 (0.43–0.65)
Groin pain	6.4	1.3	4.12 (2.71–6.27)
Suprapubic pain	0.8	2.9	0.29 (0.11–0.78)
Tape erosion	2.4	2.1	1.13 (0.78–1.65)

Data are from 19.

The Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of SUI and POP in women was reported in March 2017 and concluded that retropubic mesh tape is a valid option to be offered for SUI³⁵. In addition, Morling et al. carried out a cohort study of 16,660 women in Scotland who had undergone a first single incontinence or prolapse procedure with mesh compared with colposuspension³⁶. Mesh procedures were found to have a lower risk of immediate complications (adjusted relative risk of 0.44) and subsequent prolapse surgery. Recent advice from several national bodies in the face of unbalanced reports affecting media, legal and patient perception emphasised that patients should be comprehensively counselled about the risks of mesh implantation, together with conservative options and other surgical options available, before proceeding to mesh implantation, which is supported by good evidence when used in appropriate patients by appropriately trained surgeons.

Artificial urinary sphincter

The AUS has been used for neurological and recurrent stress incontinence in females for several years but is not in widespread use. Laparoscopic and robotic insertion were first reported in 2015³⁷ and since then the overall numbers of patients and reporting centres have remained comparatively small. In a case series of 52 women with intrinsic sphincteric deficiency and a median follow-up of 24 months, 77% patients were cured and 22% required revision surgery³⁸. At the end of a study of 26 women with neurogenic incontinence, 58% of patients still had their AUS and 71% of them were continent after a median follow-up of 7.5 years³⁹.

Two systematic reviews of the performance and safety of AMS 800 AUSs (American Medical Systems, Minnetonka, MN, USA) in female patients were published recently (Table 5)²⁰. The conclusions were based on 12 articles reporting on 886 patients.

At present, implantation of AUS in female patients is restricted to specialised centres but, despite good success rates, has a high risk of significant morbidity. Well-designed trials with specified indications and long-term follow-up measuring quality-of-life outcomes are required to develop guidelines for AUS implantation in women.

 Table 5. Results and complications of artificial urinary sphincter in women.

Intra-operative complications	Results
Bladder neck injury	0–43.8%
Vaginal injury	0–25%
Post-operative results	
Continence	61.1-100%
Follow-up	5–204 months
Erosion	0–22.2%
Explantation	0–45.3%
Mechanical failure	0–44.1%

Data are from 20.

Conclusions

Options for treatment for refractory SUI in women include autologous fascial slings, mid-urethral tapes and open colposuspension. Although historically colposuspension was the gold standard, now most patients are offered an autologous sling or mid-urethral tape. EAU guidelines recommend offering MUS to women with uncomplicated SUI as the preferred surgical intervention. NICE guidance recommended MUS, open colposuspension or autologous PVS. Surgeons must discuss the risks and benefits of the different procedures and involve the patient in the choice of treatment, and there is currently a moratorium on MUS in the UK. The approach to recurrent stress incontinence after initial surgery depends on reassessment, and an individualised approach including the same options as primary surgery, with the additional option of AUS.

Male stress incontinence

Male SUI most commonly occurs after treatment of prostate cancer following radical prostatectomy and less commonly following transurethral resection of the prostate (TURP). Postprostatectomy incontinence (PPI) is likely due to a direct injury to the sphincter or damage to adjacent nerves and soft tissue, whereas post-TURP incontinence is more likely to be due to pre-existing abnormal bladder function. The incidence of male post-prostatectomy SUI ranges from 4 to 74%⁴⁰. SUI may improve within the first 12 months after surgery, and patients should undergo a trial of pelvic floor muscle training. When conservative management fails, the AUS is considered the gold-standard treatment. Recently, alternatives to the AUS have been developed, such as the male sling and adjustable continence devices in an attempt to make treatment simpler and avoid the mechanical failure risks of the AUS.

Artificial urinary sphincter

The AMS 721 was first implanted by Scott, Bradley and Timm in 1972. It consists of three components: a control pump, inflatable cuff and pressure-regulating balloon. The AMS 800 has been the most commonly used device since 1983 and its basic design has largely remained unchanged apart from the introduction of an antibiotic coating, sutureless connectors and smaller cuff sizes⁴¹. The ZSI 375 device (Zephyr Surgical Implants, Geneva, Switzerland) was introduced in 2007 and is a two-part device consisting of a cuff and pump which can be adjusted percutaneously post-operatively⁴⁰.

A systematic review by Van der Aa *et al.* found that social continence rates (<1 pad per day) ranged between 61 and 10% in studies with a mean follow-up of more than 24 months and that 43.5% of patients were dry⁴². Infection rates were 8.5% (3.3–27.8%) and mechanical failure occurred in 6.2% (2–13.8%). Follow-up of patients at more than 10 years has shown overall continence rates of between 59 and 91%⁴². Yafi *et al.* reported that 79% of patients were dry or had improved continence rates with a 90% increase in quality-of-life scores⁴³.

Male slings

Male slings were introduced in 1958 to treat PPI. A wide variety of devices are available; these include bone-anchored, transobturator, adjustable and the newer quadratic sling. Boneanchored male slings (InVance, American Medical Systems) are anchored to the inferior rami of the pubic bone and provide direct compression of the bulbar urethra with reported continence rates of 13 to 66%. The most commonly reported complication was infection (3–15%), a potentially serious complication that ultimately led to withdrawal of InVance from the US market⁴⁰.

AdVance (American Medical Systems) is a transobturator sling device whose proposed mechanism of action is proximal urethral relocation, although some believe that compression of the bulbar urethra may occur since some patients experience post-operative retention. Rehder et al. reported that 76.8% of 156 patients who used the AdVance device were cured or improved at 3 years⁴⁴. Complications include urinary retention (2.7-15.1%) and perineal pain (4-17%)⁴⁴. In 2010, the modified AdVanceXP was introduced, and Bauer et al. published 36-month follow-up data in a prospective multi-centre study showing a 66% cure rate and 22.5% improvement rate⁴⁵. There were no intra-operative or long-term complications and no explantations⁴⁵. Critical success factors for the AdVance sling are good mobility of the sphincter area, and compromising factors to success include radiotherapy, bulking agents, prior TURP and urethral fibrosis.

Adjustable slings allow modification of sling tension post-operatively. The Argus (Promedon SA, Córdoba, Argentina) and Remeex (Neomedic International, Barcelona, Spain) devices provide compression to the bulbar urethra with retropubic traction sutures. Hübner *et al.* showed a success rate of 79% with a median follow-up of 25 months with the Argus device; 39% of patients required adjustment⁴⁶. The Remeex device has reported success rates of up to 65% at 32 months⁴⁷. Complications include infection (5–7%), erosion (3–13%) and explantation in 12 to 35%.

The Adjustable Transobturator Male System (ATOMS) (A.M.I., Feldkirch, Austria) is an adjustable device consisting of a urethral pad with mesh on either side, a titanium port for adjustments and a silicon connection. Friedl *et al.* conducted a retrospective multi-centre study of 287 men who used the ATOMS device with a median follow-up of 31 months⁴⁸. The overall success rate was 90%, and 64% of patients were completely dry. Twenty percent of devices required explanation due to titanium intolerance or leak/dysfunction, and the rate of urinary retention was $3\%^{48}$.

Virtue (Coloplast, Minneapolis, MN, USA) is a relatively novel sling device with a hybrid design (two transobturator and two pre-pubic arms). The 12 month follow-up outcomes have shown subjective and objective success rates of 70.9% and 79.2% respectively and no severe adverse events or prolonged retention⁴⁹. A summary of a comparison of male slings is provided in Table 6.

In summary, male slings are a less invasive treatment of PPI compared with AUS, which is attractive to patients as mechanical manipulation of a pump is not required when wanting to void. Most clinicians would use male slings in those with mild to moderate incontinence and adequate residual sphincter function. There is no accepted definition of when to perform a sling or AUS. The results of the Male synthetic sling versus Artificial urinary Sphincter Trial: Evaluation by Randomised control (MASTER) trial, where patients are randomly assigned to either AUS or male sling, will inform on the relative indications for each treatment.

Artificial urinary sphincter versus male slings

Crivellaro *et al.* carried out a systematic review of PPI surgical treatments in 2015^{50} . The authors included articles with more than 12 months of follow-up and defined a successful outcome as the use of zero or one pad per day. They found the AUS to be more efficacious than all sling types (65.7% success AUS, 48.2% InVance and 48.8% AdVance); however, AUS had a higher overall rate of post-operative complications (19.4% versus 7.4% InVance; 12.3% AdVance). However, they also found that the overall quality of studies was poor, and although the AUS had a higher complication rate, this may be due to the longer follow-up⁵⁰.

Conclusions

AUS is the gold-standard surgical treatment for male SUI, but the use of male sling procedures is becoming more prevalent.

Sling type Introduced Approach Cure/Dry percentage Explantation percentage Adjustable 15–9 Argus T 2006 Transobturator 60 Reemex 2004 Suprapubic 65 12 ATOMS 2009 Transobtorator 60 20 - 30Non-adjustable Advance 2007 Transobturator 35-66 1 0 Virtue 2009 Transobturator 43-79

Data are from 21. ATOMS, Adjustable Transobturator Male System.

Table 6. Results of male sling surgery for stress incontinence.

Both procedures have been shown to be safe and efficacious; however, there is a lack of good-quality evidence or long-term outcomes or both. Kumar *et al.* have shown that 75% of patients with moderate SUI prefer a sling over AUS, even against surgeon advice⁵¹. The MASTER trial is a multi-centre RCT that is still recruiting. Patients are randomly assigned to either AUS or male sling with outcomes of patient-reported incontinence at 12 months and cost-effectiveness (measured in quality-adjusted life-years at 24 months). The results of this trial should help guide decision making for both patients and clinicians.

Grant information

The author(s) declared that no grants were involved in supporting this work.

Abbreviations

ATOMS, Adjustable Transobturator Male System; AUA, American Association of Urology; AUS, artificial urinary sphincter; EAU, European Association of Urology; MASTER, Male synthetic sling versus Artificial urinary Sphincter Trial: Evaluation by Randomised control; MUS, mid-urethral sling; NICE, National Institute for Health and Care Excellence; OAB, overactive bladder; oBTXA, onabotulinum toxin A; OR, odds ratio; POP, pelvic organ prolapse; PPI, post-prostatectomy incontinence; PTNS, percutaneous nerve stimulation; PVS, pubovaginal sling; RCT, randomised controlled trial; ROSETTA, Refractory Overactive Bladder: Sacral NEuromodulation vs. BoTulinum Toxin Assessment; SNM, sacral neuromodulation; SNS, sacral nerve stimulation; SUI, stress urinary incontinence; TOT, transobturator tape; TURP, transurethral resection of the prostate; TVT, transvaginal tape; TVT-O, transvaginal tension-free vaginal tape-obturator; UTI, urinary tract infection; UUI, urge urinary incontinence

References

- Haylen BT, de Ridder D, Freeman RM, et al.: An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Neurourol Urodyn. 2010; 29(1): 4–20.
 PubMed Abstract | Publisher Full Text | F1000 Recommendation
- F Milsom I, Coyne KS, Nicholson S, et al.: Global prevalence and economic burden of urgency urinary incontinence: a systematic review. Eur Urol. 2014; 65(1): 79–95.
- PubMed Abstract | Publisher Full Text | F1000 Recommendation
- 3. Wood LN, Anger JT: Urinary incontinence in women. *BMJ*. 2014; **349**: g4531. PubMed Abstract | Publisher Full Text
- Dumoulin C, Hay-Smith EJ: Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev. 2010; (5): CD005654.
 PubMed Abstract | Publisher Full Text
- Wing RR, West DS, Grady D, et al.: Effect of weight loss on urinary incontinence in overweight and obese women: results at 12 and 18 months. J Urol. 2010; 184(3): 1005–10.
 PubMed Abstract | Publisher Full Text | Free Full Text
- Burkhard FC, (Chair) Bosch JLHR, Cruz F, et al.: EAU Guidelines on Urinary Incontinence in Adults. 2018. Reference Source
- National Institute for Health and Care Excellence: Urinary incontinence in momen:management. NICE Guideline [CG171]. 2015. Reference Source
- Chancellor MB, Elovic E, Esquenazi A, et al.: Evidence-based review and assessment of botulinum neurotoxin for the treatment of urologic conditions. *Toxicon.* 2013; 67: 129–40.
 PubMed Abstract | Publisher Full Text
- Nitti VW, Dmochowski R, Herschorn S, et al.: OnabotulinumtoxinA for the Treatment of Patients with Overactive Bladder and Urinary Incontinence: Results of a Phase 3, Randomized, Placebo Controlled Trial. J Urol. 2017; 197(2S): S216–S223.
 PubMed Abstract | Publisher Full Text
- F Drake MJ, Nitti VW, Ginsberg DA, et al.: Comparative assessment of the efficacy of onabotulinumtoxinA and oral therapies (anticholinergics and mirabegron) for overactive bladder: a systematic review and network metaanalysis. BJU Int. 2017; 120(5): 611–622.
 PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Brown ET, Reynolds WS, Kaufman MR, et al.: Advances in the Treatment of Urinary Incontinence in Women. Clin MedInsightsUrol. 2015; 8: CMU.S13181. Publisher Full Text
- Tutolo M, Ammirati E, Heesakkers J, et al.: Efficacy and Safety of Sacral and Percutaneous Tibial Neuromodulation in Non-neurogenic Lower Urinary Tract Dysfunction and Chronic Pelvic Pain: A Systematic Review of the Literature. Eur Urol. 2018; 73(3): 406–418, pii: S0302-2838(17)30978-8.
 PubMed Abstract | Publisher Full Text | F1000 Recommendation

F F1000 recommended

- F Amundsen CL, Richter HE, Menefee SA, et al.: OnabotulinumtoxinA vs Sacral Neuromodulation on Refractory Urgency Urinary Incontinence in Women: A Randomized Clinical Trial. JAMA. 2016; 316(13): 1366–74. PubMed Abstract | Publisher Full Text | Free Full Text | F1000 Recommendation
- 14. F Noblett K, Siegel S, Mangel J, et al.: Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. Neurourol Urodyn. 2016; 35(2): 246–51. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Peeters K, Sahai A, De Ridder D, *et al.*: Long-term follow-up of sacral neuromodulation for lower urinary tract dysfunction. *BJU Int.* 2014; 113(5): 789–94.
 PubMed Abstract | Publisher Full Text
- Peters KM, Carrico DJ, Wooldridge LS, et al.: Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. J Urol. 2013; 189(6): 2194–201. PubMed Abstract | Publisher Full Text
- Peters KM, MacDiarmid SA, Wooldridge LS, et al.: Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial. J Urol. 2009; 182(3): 1055–61.
 PubMed Abstract | Publisher Full Text | F1000 Recommendation
- MacDiarmid SA, Peters KM, Shobeiri SA, et al.: Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. J Urol. 2010; 183(1): 234–40.
 PubMed Abstract | Publisher Full Text
- Novara G, Artibani W, Barber MD, et al.: Updated systematic review and metaanalysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. *Eur Urol.* 2010; 58(2): 218–38.
 PubMed Abstract | Publisher Full Text
- F Peyronnet B, O'Connor E, Khavari R, et al.: AMS-800 Artificial urinary sphincter in female patients with stress urinary incontinence: A systematic review. Neurourol Urodyn. 2018. PubMed Abstract | F1000 Recommendation
- E Chung E: Contemporary surgical devices for male stress urinary incontinence: a review of technological advances in current continence surgery. Transl Androl Urol. 2017; 6(Suppl 2): S112–S121.
 PubMed Abstract | Publisher Full Text | Free Full Text | F1000 Recommendation
- Leone Roberti Maggiore U, Bogani G, Meschia M, et al.: Urethral bulking agents versus other surgical procedures for the treatment of female stress urinary incontinence: a systematic review and meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2015; 189: 48–54.
 PubMed Abstract | Publisher Full Text
- First Kirchin V, Page T, Keegan PE, et al.: Urethral injection therapy for urinary incontinence in women. Cochrane Database Syst Rev. 2017; 7(Suppl 1):

CD003881

PubMed Abstract | Publisher Full Text | Free Full Text | F1000 Recommendation

- ter Meulen PH, Berghmans LC, Nieman FH, et al.: Effects of Macroplastique 24 Implantation System for stress urinary incontinence and urethral hypermobility in women. Int Urogynecol J Pelvic Floor Dysfunct. 2009; 20(2): 177-83
 - PubMed Abstract | Publisher Full Text
- Corcos J, Collet JP, Shapiro S, et al.: Multicenter randomized clinical trial 25. comparing surgery and collagen injections for treatment of female stress urinary incontinence. Urology. 2005; 65(5): 898–904. PubMed Abstract | Publisher Full Text
- Maher CF, O'Reilly BA, Dwyer PL, et al.: Pubovaginal sling versus transurethral 26. Macroplastique for stress urinary incontinence and intrinsic sphincter deficiency: A prospective randomised controlled trial. BJOG. 2005; 112(6): 797-801
 - PubMed Abstract | Publisher Full Text
- F Lapitan MCM, Cody JD, Mashavekhi A; Open retropubic colposuspension 27. for urinary incontinence in women. Cochrane Database Syst Rev. 2017; 177: CD002912
 - PubMed Abstract | Publisher Full Text | Free Full Text | F1000 Recommendation
- 28. F Albo ME, Richter HE, Brubaker L, et al.: Burch colposuspension versus fascial sling to reduce urinary stress incontinence. N Engl J Med. 2007: 356(21): 2143-55 PubMed Abstract | Publisher Full Text | F1000 Recommendation
- F Brubaker L, Richter HE, Norton PA, et al.: 5-Year Continence Rates, 29. Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence. J Urol. 2012; 187(4): 1324-30. PubMed Abstract | Publisher Full Text | Free Full Text | F1000 Recommendation
- Schimpf MO, Rahn DD, Wheeler TL, et al.: Sling surgery for stress urinary 30. incontinence in women: A systematic review and metaanalysis. Am J Obstet Gynecol. 2014; 211(1): 71.e1-71.e27 PubMed Abstract | Publisher Full Text
- Fusco F, Abdel-Fattah M, Chapple CR, et al.: Updated Systematic 31. Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. Eur Urol. 2017; 72(4): 567–91. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Linder BJ, Elliott DS: Autologous transobturator urethral sling placement for 32 female stress urinary incontinence. J Urol. 2015; 193(3): 991–6 PubMed Abstract | Publisher Full Text
- Imran R, Kearney R: Surgical management of stress urinary incontinence. 33. Obstet Gynaecol Reprod Med. 2016; 26(1): 20-5. **Publisher Full Text**
- 34. Basu M, Duckett J: Three-year results from a randomised trial of a retropubic mid-urethral sling versus the Miniarc single incision sling for stress urinary incontinence. Int Urogynecol J. 2013; 24(12): 2059–64. PubMed Abstract | Publisher Full Text
- Scottish Independent Review of the use, safety and efficacy of transvaginal 35 mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women. accessed 6/5/18. **Reference Source**
- Morling JR, McAllister DA, Agur W, et al.: Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence 36 and pelvic organ prolapse in Scotland, 1997-2016: a population-based cohort study. Lancet. 2017; 389(10069): 629-40. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Biardeau X, Rizk J, Marcelli F, et al.: Robot-assisted laparoscopic approach 37. for artificial urinary sphincter implantation in 11 women with urinary stress

incontinence: surgical technique and initial experience. Eur Urol. 2015; 67(5): 937-42. PubMed Abstract | Publisher Full Text

- Ferreira C, Brychaert PE, Menard J, et al.: Laparoscopic implantation of 38. artificial urinary sphincter in women with intrinsic sphincter deficiency: Midterm outcomes. Int J Urol. 2017; 24(4): 308-13.
- PubMed Abstract | Publisher Full Text | F1000 Recommendation 39
- Phé V, Léon P, Granger B, et al.: Stress urinary incontinence in female neurological patients: Long-term functional outcomes after artificial urinary sphincter (AMS 800[™]) implantation. Neurourol Urodyn. 2017; 36(3): 764-9. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Ostrowski I, Śledź E, Ciechan J, et al.: Current interventional management 40 of male stress urinary incontinence following urological procedures. Cent European J Urol. 2015; 68(3): 340-7. PubMed Abstract | Publisher Full Text | Free Full Text
- James MH, McCammon KA: Artificial urinary sphincter for post-prostatectomy incontinence: A review. Int J Urol. 2014; 21(6): 536-43. PubMed Abstract | Publisher Full Text
- F van der Aa F, Drake MJ, Kasyan GR, et al.: The artificial urinary sphincter 42 after a quarter of a century: A critical systematic review of its use in male non-neurogenic incontinence. Eur Urol. 2013; 63(4): 681-9. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- F Yafi FA, Powers MK, Zurawin JP, et al.: Contemporary Review of Artificial 43. Urinary Sphincters for Male Stress Urinary Incontinence. Sex Med Rev. 2016; 4(2): 157-66. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Rehder P, Haab F, Cornu JN, et al.: Treatment of postprostatectomy male 44 urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3-year follow-up. Eur Urol. 2012; 62(1): 140-5. PubMed Abstract | Publisher Full Text
- F Bauer RM, Grabbert MT, Klehr B, et al.: 36-month data for the AdVance XP® 45 male sling: results of a prospective multicentre study. BJU Int. 2017; 119(4): 626-30. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Hübner WA, Gallistl H, Rutkowski M, et al.: Adjustable bulbourethral male 46 sling: experience after 101 cases of moderate-to-severe male stress urinary incontinence. BJU Int. 2011; 107(5): 777-82. PubMed Abstract | Publisher Full Text
- Trost L, Elliott DS: Male stress urinary incontinence: a review of surgical treatment options and outcomes. Adv Urol. 2012; 2012: 287489. PubMed Abstract | Publisher Full Text | Free Full Text
- F Friedl A, Mühlstädt S, Zachoval R, et al.: Long-term outcome of the 48 adjustable transobturator male system (ATOMS): results of a European multicentre study. BJU Int. 2017; 119(5): 785–92. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Comiter CV, Rhee EY, Tu LM, et al.: The virtue sling--a new quadratic sling 49 for postprostatectomy incontinence--results of a multinational clinical trial. Urology. 2014; 84(2): 433-8. PubMed Abstract | Publisher Full Text
- F Crivellaro S, Morlacco A, Bodo G, et al.: Systematic review of surgical 50 treatment of post radical prostatectomy stress urinary incontinence. Neurourol Urodvn. 2016: 35(8): 875-81. PubMed Abstract | Publisher Full Text | F1000 Recommendation
- Kumar A, Litt ER, Ballert KN, et al.: Artificial urinary sphincter versus male sling 51. for post-prostatectomy incontinence--what do patients choose? J Urol. 2009: 181(3): 1231-5.

PubMed Abstract | Publisher Full Text

Open Peer Review

Current Peer Review Status:

Editorial Note on the Review Process

F1000 Faculty Reviews are written by members of the prestigious F1000 Faculty. They are commissioned and are peer reviewed before publication to ensure that the final, published version is comprehensive and accessible. The reviewers who approved the final version are listed with their names and affiliations.

The reviewers who approved this article are:

Version 1

1 David Waltregny

Academic Department of Urology, University Hospital of Liege, Liege, Belgium *Competing Interests:* No competing interests were disclosed.

2 Wayne J. G. Hellstrom Department of Urology, Tulane University Health Sciences Center, New Orleans, LA, USA Pete Tsambarlis Department of Urology, Tulane University Health Sciences Center, New Orleans, LA, USA

Department of Urology, Tulane University Health Sciences Center, New Orleans, LA, USA *Competing Interests:* No competing interests were disclosed.

The benefits of publishing with F1000Research:

- Your article is published within days, with no editorial bias
- You can publish traditional articles, null/negative results, case reports, data notes and more
- The peer review process is transparent and collaborative
- Your article is indexed in PubMed after passing peer review
- Dedicated customer support at every stage

For pre-submission enquiries, contact research@f1000.com

F1000Research