

Chapter 6

Male Stress Incontinence

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Background

All health professionals are familiar with the problem of stress urinary incontinence in females. Female anatomy predisposes to incontinence of urine due to sphincter weakness and in particular in association with childbirth. Health professionals however are less likely to be aware of the problem of stress incontinence in males, which does not usually occur as a primary condition. Since a male is not subjected to childbirth, the pelvic floor does not become weak unless it is affected by specific medical conditions. Thus stress urinary incontinence is much less common in males and less likely to present. Men have a tendency to draw less attention to the problem of urinary incontinence. Although a cause of much distress, incontinence in males tends to often remain a hidden condition. Incontinence is a common condition worldwide and leads to much suffering and in addition significant cost to society.

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Incontinence is a distressing condition, and thus an understanding of the causes of male incontinence, its investigation and treatment is essential to those involved in treating male patients. Resolving incontinence brings major benefits in improvement of quality of life.

Male stress incontinence has to be distinguished from other types of urinary incontinence, and the condition alone may be associated with other conditions affecting bladder storage and emptying, which need to be excluded or treated if they coexist.

Male Continence Anatomy

Male continence depends upon an intact and functioning neural system. The bladder needs to be able to store urine to a normal volume (circa 500 ml) and with low filling pressure (less than 15cmH₂O). With these provisos, the male continence mechanisms are an intact and functioning bladder neck mechanism (bladder neck, internal sphincter) and an intact external striated sphincter mechanism (rhabdosphincter). Any changes in any of these structures either from disease or surgery can affect continence. Surgery has had a major effect on the continence mechanisms in men and has lead to an increase in the incidence of male stress incontinence.

Causes of Male Urinary Incontinence

Transurethral prostatectomy and the alternatives are associated with a relatively low incidence of post-operative incontinence. The incidence has reduced significantly over the years and is probably due to advancing technology allowing excellent views of the surgery by camera techniques and more effective supervision of training.

Male stress urinary incontinence has become more common in recent years because of the increase in the use of surgical treatment for prostate cancer by radical prostatectomy. Whether a radical prostatectomy is performed by the open surgical route or by laparoscopic or robotic means, incontinence will occur in a proportion of men due to sphincter weakness. It is not surprising that men become incontinent of urine after a radical prostatectomy. The bladder neck mechanism is lost and the sphincter may be weakened by resection of part of that sphincter. There is also a loss of support to the urethra by division of the puboprostatic ligaments and incision into the endopelvic fascia. Fortunately most men are continent after a radical prostatectomy or regain continence over a period of months. However, there will be men who will have persistent stress incontinence, which will require treatment.

There are few primary conditions that can give rise to male stress incontinence. The principal one being lower motor neurone spina bifida patients, who will have a poor or acontractile bladders and sphincter weakness incontinence. Sphincter weakness incontinence can occur in patients after a spinal cord injury. A lower motor neuron lesion will be associated with pelvic floor denervation. Patients tend to have poorly contractile or acontractile bladders and thus tend to strain to void if not using intermittent catheterisation. They may also have sphincter weakness incontinence or develop stress incontinence with time due to additional pelvic floor weakness.

One potential cause of stress incontinence but hopefully rarely seen follows a pelvic fracture injury where a urethral rupture has led to a stricture treated by a urethroplasty. The sphincter may be weakened by such surgery, and in later life, should bladder neck or prostatic surgery take place, there is a significant risk of incontinence occurring.

Clinical Practice

Clinical Assessment

Symptoms of stress incontinence are those associated with any event that increases intra-abdominal pressure beyond the resistance within the bladder outlet/sphincter mechanism. Thus coughing, sneezing, laughing and movement will give rise to incontinence of urine. In a catastrophically wet patient, continuous incontinence may be present. This can and does occur after a radical prostatectomy or TURP.

Male patients with stress urinary incontinence tend to be continent at night provided the bladder pressure is stable. However, once movement occurs to the upright position, incontinence may develop. Classically, in this group of men, stress incontinence occurs when moving from the sitting to the standing position. Certain activities also make a man wetter, such as playing golf or tennis.

During history taking, it is important to gain information about the patient's bladder function. This is an assessment of urinary frequency, nocturia, urgency and urge incontinence symptoms, which are likely to be due to an overactive bladder or poorly compliant bladder.

Voiding symptoms should be discussed – hesitancy, the state of the stream, terminal and post-micturition dribbling. Straining usually represents a stricture or poor bladder contractility as does a feeling of incomplete emptying.

The degree of urinary leakage with stress incontinence should be assessed. The number of pads used and how wet they tend to be should be assessed. A pad weighing exercise should take place in all men with stress incontinence as it will indicate the degree of incontinence, may affect the choice of surgery and can be used for an assessment of post-treatment success. Some patients will be wearing a conven sheath, which allows a more accurate knowledge of urinary loss.

Diagnostics

The first part of investigation of course is to take a careful history, then perform a clinical examination. What is most useful is to see what sort of pad the patient is wearing and whether it is wet and if leakage occurs with coughing or sneezing. The genitalia should be assessed and look for excoriation from urine wetness. A rectal examination can be helpful in patients with generalised pelvic floor weakness caused by neurological dysfunction, but it is not usually necessary in patients who have had a radical or transurethral prostatectomy.

A frequency volume voided chart is important in assessing fluid intake as reducing fluid intake may reduce incontinence episodes. Volumes voided will give an indication as to whether the bladder is able to store urine, and this particularly can help at night if a patient can hold urine during the night as it is useful for the later management of that patient.

Voiding function should be known and this can be simply assessed with a free flow rate based upon a volume voided more than 150mls and a post-micturition residual assessment. It is essential to know that the bladder is emptying satisfactorily particularly if any surgical intervention is to be considered.

Urodynamic Investigations

Should we use urodynamic investigations in the incontinent male patient? The assessment of bladder function in a patient with stress incontinence by urodynamic studies can be controversial. However, urodynamic studies are very useful in understanding storage and emptying bladder function. If combined with x-ray screening (video urodynamic studies), much useful information can be gained. Filling cystometry will demonstrate whether or not the bladder has overactivity, and this can be useful in providing the start of treatment of a patient with mixed symptoms. Voiding function is assessed by a pressure flow study, and if obstruction is present, this will need to be dealt with before treating stress incontinence. The benefit of video screening of the bladder and outlet during urodynamic testing gives a view of the bladder shape, presence of the competence or incontinence of the bladder neck and whether or not stress leakage is taking place. The site of obstruction during voiding cystometry will be screened. The presence of reflux and assessment of bladder emptying is also seen with video urodynamic studies. It is the author's view that videourodynamic studies have an essential place in the management of the patient with urinary stress incontinence.

Decision to Treat

Any male patient suffering with stress urinary incontinence will be distressed by the symptoms. Most patients are not particularly accepting of urinary leakage. Often there is a concern about urine smell. There is the ongoing problem of wearing pads.

These are expensive to purchase and not always available on prescription. The penis may become sore due to persistent urinary leakage. Most patients are therefore very keen to become dry.

Containing the Incontinence

Containing the urinary loss may be acceptable to some patients. A single pad for a minimally wet patient may be sufficient to contain the leak and be acceptable.

For the patient with a greater degree of incontinence, a convene sheath applied to the penis and a leg drainage bag may be comfortable. For elderly patients, this may be a suitable choice. This may also be suitable for the patient with neurological dysfunction such as a spinal cord injury. The old-fashioned penile clamp is often overlooked and can be beneficial to some patients who would like to be out and about without wearing a pad. Wearing a penile clamp for a short period of time whilst out and about may be acceptable as a short-to-medium-term solution. It is not a solution to the problem but can be a helpful method of containment.

Conservative Options

Conservative options for post-prostatectomy incontinence can be palliative (focused on comfort of the patient, with no aim at curing incontinence itself) or active. The former includes penile clamps, penile sheaths and protections, and the latter includes pelvic floor muscle training and duloxetine.

Palliative Options

Penile clamps have been used for years for post-prostatectomy incontinence management. A clinical trial has compared three types of clamps (Cunnigham device, U-shaped clamp and C3 clamp), in a randomised, open-label study. The devices evaluated have shown high efficacy but variable tolerance among patients. The use of penile clamp is not recommended by currently available clinical guidelines.

Methods for containment of urine have been extensively reviewed in the literature. In men with post-prostatectomy incontinence, condom catheters are seen as a valuable solution. About protections, there are no reliable data to state whether a type of protection is better than another. Different pads have their advantages and disadvantages; they are chosen depending on the patients' preferences, degree of incontinence and activity.

Lifestyle habits have not proven to substantially modify symptoms. However, abnormal fluid intake or bad habits have to be modified, according to good medical practice.

Therapeutic Options

Behavioural therapy such as pelvic floor muscle training has been evaluated in the field of post-prostatectomy incontinence. It is recommended by the current EAU Guidelines and the ICS document for management of post-prostatectomy incontinence with a level of evidence grade 2. Many different types of pelvic floor muscle training programmes have been described, according to the types of exercises, training and degree of supervision, timing (preoperative, immediate post-operative or delayed), use of biofeedback and associated stimulations. According to a review by the Cochrane collaboration, there is no influence of physiotherapy on the continence rates after one year. However, pelvic floor muscle training can be recommended to fasten continence recovery in a post-operative setting. Early rehabilitation seems the best choice for patients who want to get continence back within a minimal time frame. Supervised training is probably better than alone exercises, but biofeedback has no clear impact on the results. It is thus not routinely recommended when pelvic floor muscle training is prescribed.

Duloxetine has been proposed as a medical treatment of post-prostatectomy incontinence. The rationale for the introduction of this treatment is based on the results obtained in women for stress urinary incontinence management. This drug is a serotonin-noradrenalin reuptake inhibitor, acting on the Onuf's nucleus by blocking the reuptake of noradrenalin and serotonin, thus raising the activity of pudendal motor neurons, leading to increase of striated urethral sphincter tonus and detrusor relaxation. Duloxetine has proven its efficacy in cases series and in one randomised controlled trial at the dose of 80 mg. The drug has been shown to be superior to placebo at an 80 mg/day regimen. However, the use of duloxetine for male post-prostatectomy management is not recommended by current clinical guidelines, because of the paucity of the studies published. It is sometimes used off-label. Moreover, this treatment can lead to numerous side effects, like fatigue, sweat, insomnia, loss of libido, constipation, nausea, diarrhoea, dry mouth, anorexia or psychiatric issues.

Surgical Treatment

Bulking Agents

In some men with mild to moderate SUI, urethral bulking agents are a less effective treatment, with early failure rate of a 50 % and gradual loss of effect with time (LoE: 3; GoR: C). Bulking agents have been used over many years to treat post-prostatectomy incontinence. Collagen was the first material used for treating stress incontinence but had very poor outcomes. There have been a number of other injectable agents used for treating stress incontinence in men. The popular current ones available are Macroplastique and Coaptite. The success rate however with these treatments is relatively poor with only approximately 34 % of men benefiting in the

long term. The only benefit of injectable treatment is that it is a minimally invasive treatment without any incisional surgery, and if this technique works, it can be beneficial and satisfying for the patient. It is important however to warn the patient that the results may not last for long and the incontinence condition can be worsened in a small percentage.

Male Slings

What Do the Guidelines Say?

According to recommendations and available guidelines, the standard surgical management for male stress urinary incontinence is the implantation of an artificial urinary sphincter. Current clinical guidelines mention the use of male slings as an alternative to the implantation of an artificial urinary sphincter, especially in men with mild to moderate symptoms. Overall, all guidelines are in accordance that the level of evidence supporting the use of male slings is rather low, mainly based on cohort studies (generating grade C – level of evidence three recommendations). The current clinical guidelines distinguish the fixed compressive male slings (like InVance™), transobturator repositioning male slings (like AdVance™) and adjustable male slings, like Argus™.

InVance™ is considered as a historical device in some countries where it has been removed from the market. Based on available data, this sling has been shown to lead to heterogeneous cure rates, with a high risk of post-operative infection, erosion and removal of the device. At least 20 different case series have been published about InVance™ according to reviews of the literature, up to midterm follow-up. Infection has been reported being as high as 15 % of cases, and other complications included recurrence of incontinence, acute urinary retention and perineal pain.

Transobturator repositioning AdVance™ male sling has been introduced in 2007, and there has been multiple prospective studies showing the efficacy of this device. After AdVance™ implantation, 50 % of patients are being dry, 25 % are improved and 25 % fail. However, the complication rate has been proven to be very low, with a very limited rate of erosion and infection. The usual complications are rather transient urinary retention (around 10 %) and perineal pain (less than 10 %).

The Argus™ male sling is considered by the current guidelines as an ‘adjustable’ male sling. The guidelines point out the paucity of the data supporting the use of Argus™ system, with published data on a few hundreds of patients and limited follow-up. Based on the available data from the literature, there is grade 3 evidence that Argus™ system can cure SUI (subjective cure rate of around 57 %, but very heterogeneous according to available studies), but the rate of complications (especially sling explantation) is considered as high. External comparison of available cohort studies seems to show that there is no additional benefit with the Argus male sling compared to other types of slings. Recently, a small direct comparative trial between Argus™ and AdVance™ sling has shown no significant difference in efficacy outcomes between after midterm follow-up.

Overall, male slings are reasonable options for management of mild to moderate stress urinary incontinence and are a possible alternative to urinary sphincter implantation. Almost all evidence is level 3, and there is no clear data showing the superiority of a sling over another.

Clinical Practice and Results

Male sling implantation is considered in clinical practice as an alternative to the artificial urinary sphincter in men, particularly for post-prostatectomy incontinence management. Before considering this option, a specialised evaluation is required and includes:

- Complete medical history: date and type of prostatic surgery, alternative causes of urinary incontinence such as neurological diseases, additional treatments (pelvic radiation therapy), cancer status (PSA level).
- Evaluation of the symptoms: a 24 h pad test is welcome preoperatively to check the severity of incontinence (estimation of pad use is also widely used). An objective evaluation by validated questionnaires is useful.
- Endoscopy of the urinary tract: this is often required to check the integrity of the urethra and the vesico-urethral anastomosis. It also permits to rule out a urethral disease (such as stenosis). Some authors have also proposed that endoscopy of the urinary tract make a 'repositioning test' possible, in order to check for residual sphincter function.
- Urodynamic study: this is often required to rule out bladder dysfunction and detrusor abnormalities and identify the intrinsic sphincter deficiency. For some authors, the interest of urodynamics has to be discussed, but a uroflowmetry and post-void residual estimation seem required.
- Urine culture is also mandatory before surgery, as well as the preparation for anaesthesia.

This rigorous and comprehensive preoperative workup sets the basis for a rigorous evaluation, based on patient characteristics. Indeed, some predictive factors influencing outcomes after male sling implantation have been proposed in the literature (mostly reliable for AdVance™ sling). The factors associated with a higher success rate are absence of pelvic floor irradiation, mild to moderate symptoms (leakage of less than 300 g/24 h), absence of history of urethral stricture and good residual sphincter function (checked by the repositioning test). It is however important to state that these factors are not fully consensual and are mostly based on single centre experience.

The AdVance™ male sling has been studied in multiple prospective cohort studies. Mean success rate (no pad use) at medium-term follow-up (around 3 years) is about 60 %. Usually, an additional proportion of patients is improved, and 20–25 % failed. Major complications are exceptional; minor complications occur in 5–15 % of cases and include transient urinary retention, haematoma, perineal pain, urinary tract infection, neurapraxia and superficial wound infection. In the vast majority of cases, these minor complications resolved spontaneously (Table 6.1).

The Argus™ male sling has been evaluated through a limited number of cohort studies. Efficacy has been stated variable in the literature, between 17 and 79 % of patient being cured. The rate of complications has been shown to be quite high with a lot of cases of explantation. Other complications included transient retention, bladder or urethral injury, OAB, haematomas, perineal pain, wound infections and urinary tract infections (Table 6.2).

The InVance™ male sling has shown to have limited efficacy for cure of post-prostatectomy incontinence (with cure rate of around 40–50 %), with a high rate of complications. Explantation rate as well as reintervention has shown to be as high as 30 % (Table 6.3).

Background

Male sling implantation is considered as a case of stress urinary incontinence following prostate surgery (mainly radical prostatectomy and, in a few cases, after surgery for benign prostatic obstruction). The underlying pathophysiology of stress urinary incontinence after radical prostatectomy is not perfectly clear, but deficiency of the external urinary sphincter (rhabdosphincter), associated with anatomical changes (reduction of the length of membranous urethral and loss of periprostatic support), and abnormalities of innervation (consecutive to injury of the neurovascular bundles) have been pointed out as the most important causes. Incontinence following benign prostatic surgery is more often linked to a direct injury of the urethral sphincter.

The concept of male sling has been developed in the 1970s by Berry, then by Kaufman and Schaefer, as a compressive device. The principle of the surgery was to provide a resistance to bladder outflow, enough to reduce the symptoms of incontinence, but not too much, to avoid urinary retention. This compressive approach has been the only one considered in the past century. The InVance™ male sling is the very last evolution of this concept.

During the last ten years, numerous innovations have been proposed to improve the concept of male slings. The two major inputs were the noncompressive, repositioning concept of the retrourethral transobturator male sling (AdVance™) and the introduction of adjustable device, where the compression is adjustable with time (Argus™).

Several slings can be used. Variations include sling material (synthetic (e.g. polypropylene) or autologous biological material), shape of the sling (length, width), way of anchoring (slings mainly act by self-anchoring in pelvic tissue or are anchored to the bone) and routes in the body for slings placement (retropubic or transobturator). Many brands and types of slings exist, and you urologist will choose the best one according to your case, his habits and sling availability on the market. The principle of male sling implantation is to produce some degree resistance (especially for purely compressive slings), by urethral compression, to the urine output, in order to reduce urinary leakage during efforts but preserving an open urethra to avoid complete obstruction. Some device of different types exist (retrourethral, adjustable, bone anchored) and have never been compared to each other in terms of efficacy.

Table 6.1 Data from the literature related to efficacy and complication following the implantation of AdvVance™ male sling

Authors	N	F-up (months)	Definition of success	Success	Improved	Failed	Major complications	Minor complications
Gozzi (2008)	67	3	No pad	52 %	38 %	10 %	None	Transient AUR (16.4 %)
Davies (2010)	13	6	0 or 1 pad	85 %	–	15 %	None	Transient AUR (15 %) De novo OAB (7 %)
Gill (2010)	33	8.2±17.9	No pad	51 %	20 %	29 %	None	Transient AUR (9 %) Rash (3 %)
Cornel (2009)	33	12	No pad and pad test <2 g	9 %	46 %	37 %	1 infection	Transient AUR (3 %)
Rehder (2010)	118	12	No pad	74 %	17 %	9 %	None	Transient perineal pain (19.5 %), transient AUR (5 %) Groin pain (2 %)
Comu (2011)	136	21±6 (12–36)	No pad	62 %	16 %	22 %	None	Transient voiding difficulties (14 %) Haematoma (1 %) Transient perineal pain (12 %)
Bauer (2011)	126	27 (20–37)	No pad or security pad	52 %	24 %	25 %	2 explantations	Transient AUR (15 %) Transient perineal pain (1 %)
Rehder Eur Urol (2012)*	156	39 (37–4)	No pad or security pad	53 %	23 %	23 %	1 explantation	Transient perineal pain (50 %) Transient AUR (9.6 %) Dysuria (4.5 %) Haematoma (3.2 %) UTI (<1 %) OAB (<1 %) Superficial wound infection (<1 %)
Suskind (2012)	36	19 (1–40)	No pad	38 %	42 %	20 %	NA	NA

Mueller ISRN Urol (2012)	32	9 (3–14)	No pad	56 %	22 %	22 %	1 explantation	Transient AUR (15.6 %)
Li J Urol (2012)	56	24 (17–28)	No pad	39 %	23 %	38 %	None	Rash (3 %) Transient AUR (11 %)
Berger (2012)	26	12	No pad	62 %	27 %	11 %	None	Transient AUR (35 %) Transient perineal pain (19 %)
Kowalik (2015)	30	39 (36–44)	No pad or security pad	60 %	13 %	27 %	None	Transient AUR (30 %) Wound infection (3 %) Neurapraxia (3 %) Chronic pain (6 %)
Collado Serra (2013)	61	26 (12–53)	No pad use	80 %	0	20 %	None	Transient AUR (15 %) Haematoma (4 %) Neurapraxia (10 %) OAB (10 %)

Table 6.2 Data from the literature related to efficacy and complication following the implantation of Argus™ male sling

Reference	N	Median follow-up (months)	Definition of success	Cured	Improved	Failed	Revisions	Major complications	Minor complications
Bochove-Overgaauw	100	27 [14–57]	No pad use or security pad	38 %	30 %	32 %	32 %	Urethral stenosis (12 %) Explantation (11 %)	Transient retention (16 %) Bladder injury (6 %) Transient pain (11 %) OAB (1 %) Haematoma (1 %) Wound infection (6 %) UTIs 2 %
Romano	48	45 [36–54]	No pad use	66 %	13 %	21 %	>11 %	Explantations (19 %)	Perineal pain (4 %) Transient retention (15 %) Urethral perforation (6 %) Transient dysuria (21 %)
Hubner	101	28	20-min pad test of 0–1 g	79 %	ND	ND	39 %	Explantation (16 %)	Transient perineal pain (15 %)
Dalpiaz	29	35 [29–45]	Satisfaction	17 %	11 %	72 %	10 %	Explantation (35 %) Persistent perineal pain (27 %) Erosion (3 %)	Transient retention (35 %) Perineal pain (28 %) OAB (14 %)

Table 6.3 Data from the literature related to efficacy and complication following the implantation of InVance™ male sling

Author	Year	N patients	Follow-up	Cured (%)	Improved (%)	Failed (%)	Reintervention (N)	Infection/Erosion (N)	Explanation (N)
Fassi-Fehri	2007	50	6 (1–22)	50	26	24	1	3	3
Madjar	2001	16	12.2 (4–20)	85	15	0	0	0	0
Comiter	2002	21	12 (5–21)	76	14	10	0	0	0
Ullrich	2004	22	25 (6–42)	60	32	8	0	0	0
Comiter	2005	48	48 (24–60)	65	20	15	2	1	1
Gallagher	2007	31	15 (9–21)	38	37	25	0	2	4
Fischer	2007	62	15 (3–37)	34	24	42	9	5	5
Mouracade	2008	29	4.1 (1–8.5)	37	42	20	0	3	5
Guimarães	2009	62	28 (ND)	65	23	12	1	2	2
Giberti	2009	40	35.2 (2–62)	55	12.5	32.5	1	6	5
Athanasopoulos	2010	43	24.2 (4–38)	30	40	30	14	5	5
Carmel	2010	45	36 (2–64)	36	40	24	0	1	1
Claudon	2011	69	13.7 (8–45.6)	61	34.8	4.2	0	6	6
Crites	2011	41	46 (1.5–112)	31.7	NA	68.3	NA	NA	NA
Castle	2005	42	18 (6–26)	16	24	60	NA	3	NA

Technique

All three devices have specific characteristics that make the surgical steps different for each device. However, for all cases, the preparation of the patient is quite similar, as well as the patient positioning in the operating room. Before the intervention, a urine culture has to be negative or treated by antibiotics if positive. Antiseptic wash of the perineum is done in the operating room, whilst shaving is preferably done before. Anaesthesia can be general or regional, depending on the choice of the patient and the anaesthesiologist. A urinary catheter is put in place at the beginning of the intervention. The main surgical approach is perineal for the three slings.

AdVance™ Male Sling

The AdVance™ male sling has been introduced in 2007 as an innovative therapy. The sling is manufactured by the company American Medical Systems (Minnetonka, Minnesota, USA). The sling is made of precut polypropylene monofilament. In 2010, a new version of the sling, called AdVanceXP™, has been introduced with minor modification of the length/shape of the sling and the ancillary. The results with this new version seem to be comparable to those obtained with the first generation.

Principles

The concept of the retrourethral transobturator male sling has been described in 2007 by Rehder and Gozzi. The sling is put behind the urethra, in contact with the urethral bulb and goes out via transobturator route (Fig. 6.1). It is then fixed to the posterior urethra and when the sling is pulled for tensioning, the urethra is attracted posteriorly and towards the bladder neck (Fig. 6.2). Urodynamic and MRI investigations have postulated that this action results in relocating the proximal urethra and increases functional urethral length. As specified here under, this underlines the need for a significant dissection of the proximal urethra during the surgical approach.

Surgical Technique

The patient is placed on dorsal lithotomy position. The surgical approach is perineal, median, and should be of 5–6 cm. The first layer (subcutaneous) is dissected with electrocautery, and the bulbospongiosus muscle is opened medially, to expose the urethral bulb. The dissection should be continued enough, posteriorly, until the urethra begins to turn towards the pelvis, so that the corpus spongiosum is free from the central tendon of the perineum. The bulb is thus well exposed; pulling the lowest part of the wound with a retractor is a good means to check that this step is adequately completed. After having made two small incisions at the proximal part of the groin, left ancillary is passed towards the transobturator fossa through the skin and the obturator membrane. A rotation of the hand is necessary to make the end of the needle

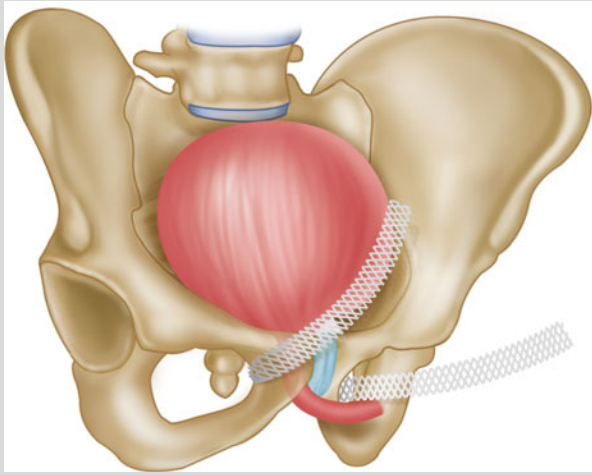


Fig. 6.1 Anatomic position of the retrourethral AdVance male sling (transobturator route)

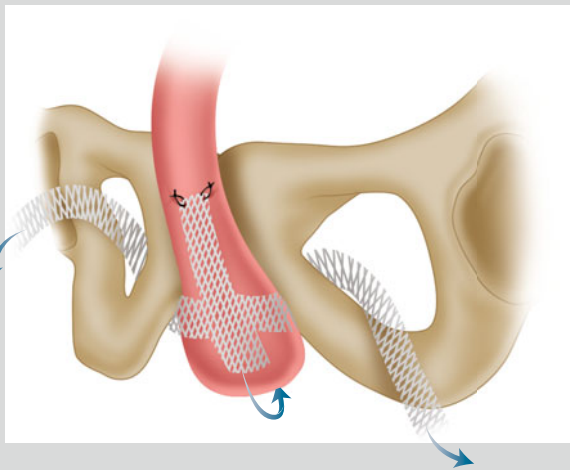


Fig. 6.2 Infero-lateral view of the AdVance male sling; the two arms of the sling are pulled through obturator foramen, and the sling is fixed to the bulbar urethra, leading to relocation of the bladder neck

come out just between the urethra and the origin of the corpus cavernosum (putting a finger laterally in the wound to guide the needle is of great help). The mesh is then attached to the needle by the connector and the sling is pulled out gently. The procedure is repeated on the other side. The central part of the sling is then fixed to the urethra by resorbable sutures. The tension of the sling is then made progressively and carefully, with the surgeon seeing the

urethral bulb going away towards the bladder neck. The wound is then simply closed by layers, including the bulbospongiosus muscle, using resorbable sutures.

Some authors complete the procedure by tunnelling the sling under the skin on each side to prevent slippage post-operatively, but it is not mandatory. Similarly, a urethrocytoscopy immediately after sling placement is fully optional and usually not practiced outside the learning curve.

Post-operative Care

After surgery, the catheter is usually left in place for 24 h, and the patient is discharged at day 1 if bladder emptying is correct without significant post-void residual volume. Oral medications are usually prescribed for post-operative pain management. In the short term, the main secondary effect can include voiding difficulties, wound infection and perineal pain. Other complications are exceptional. Due to the importance of 'repositioning' of the urethra, specific advice is given to the patient in order to avoid intense abdominal efforts and possible sling slippage. Those include rest (incl. work interruption if needed), avoidance of lifting heavy charges and treatment of constipation if any.

Argus™ Male Sling

The Argus™ male sling has been introduced in 2006. The sling is manufactured by Promedon SA (Cordoba, Argentina).

Principles

The concept of the Argus™ sling is presented as an adjustable sling, able to cure post-prostatectomy incontinence by a compressive mechanism. The system is adjustable to permit relief of excessive obstruction of the urethra, as well as re-tensioning in case of lack of efficacy or recurrence of symptoms. Two types of the device are available on the market: Argus™ adjustable male sling system (designed for retropubic approach) and ArgusT™ adjustable male sling system (designed for the transobturator approach that is useful in obese patients)

The system is presented as a single-use kit, containing a rectangular piece of elastomer (the 'pad'), two polydimethylsiloxane elastomer fixation arms (made of multiple conal subunits), two adjustment rings (two sizes), two ring positioners and a ruler. The needles are designed for transobturator approach or retropubic approach. The central pad is compressive, placed behind the urethra. The adjustment rings are placed either on the abdominal wall or the transobturator membrane (Figs. 6.3 and 6.4). The tension has to be smooth enough to minimise the risk of ischaemia or direct injury to the ureter, but strong enough to make a passive coaptation of the urethral walls.

Adjustability is possible intraoperatively and post-operatively.

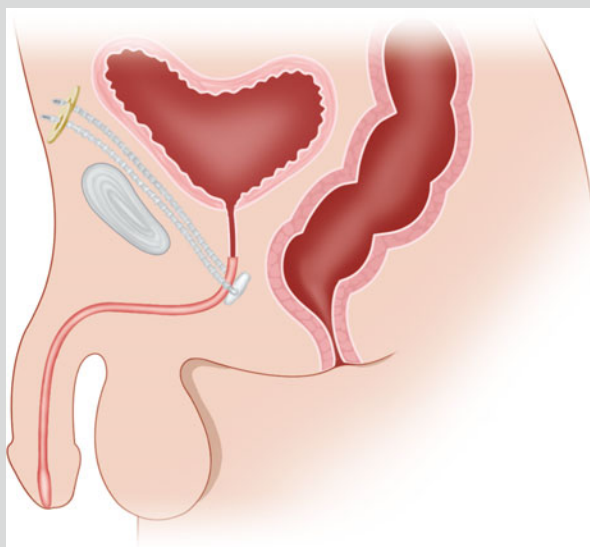


Fig. 6.3 Sagittal view of the Argus male sling system whilst in place. Compression is made posteriorly

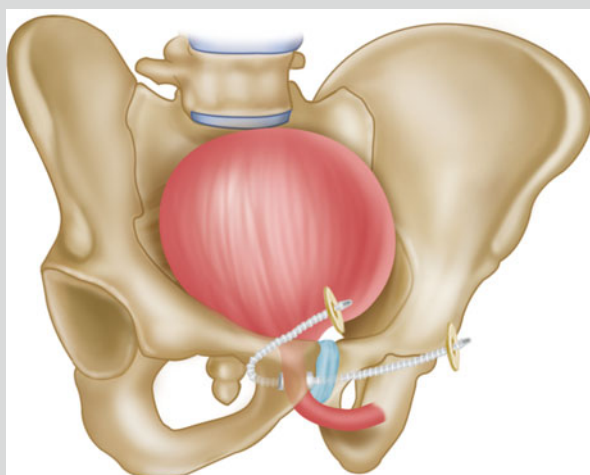


Fig. 6.4 Anterolateral view of the Argus male sling in place

Surgical Technique

The patient is placed on dorsal lithotomy position, under spinal of general anaesthesia. A catheter is usually inserted at the beginning of the procedure, after usual skin preparation. The surgical approach is perineal, median, and should be of 5–7 cm. The first layer (subcutaneous) is dissected with electrocautery, and the bulbospongiosus muscle is kept intact. The space

between the urethral bulb and the ischiopubic ramus, laterally to the root of the corpus cavernosum is dissected. The space towards the edge of the pubis is then dissected.

For retropubic approach (Fig. 6.3), two incisions are made on the abdominal wall and 2 cm over the upper edge of the pubis, until the fascia of rectus abdominis muscle. The 'retropubic' needle is then inserted in the place between the urethral bulb and the corpus cavernosum and passed just behind the posterior part of the pubis to go out by the incisions, repeated on both sides. A cystoscopy is often done at this stage to rule out a bladder perforation. Fixation arms are then connected to the needle and passed on both sides. Adjustment rings are then placed in each abdominal wound. The perineal wound is then simply closed by layers, using resorbable sutures.

In case of transobturator approach, the two lateral incisions are made in the inguinal region a few centimetres below the insertion of the adductor magnus muscle, until the external obturator muscle fascia. Helicoidal needles are inserted on both sides according to an out-in movement, towards the finger placed in the triangular space between the urethral bulb and the corpus cavernosum. The arms are then passed and the rings are placed in contact with the fascia of the external obturator muscle. Some authors recommend to place the arms in the prepubic area through a subcutaneous tunnel, upwards and parallel to the inguinal fold towards the midline, and not below the inguinal fold.

Adjustments are made by moving the rings on the cones that are all along the arms. It can be done during the intervention or afterwards, by simply reopening the lateral/suprapubic wounds under local anaesthesia.

Post-operative Care

After surgery, the catheter is usually left in place for 24 h, and the patient is discharged at day 1 if bladder emptying is correct without significant post-void residual volume (checking the correctness of bladder emptying is mandatory). Oral medications are usually prescribed for post-operative pain management. In the short term, the main secondary effects are perineal pain, retention and dysuria, local inflammation and wound infection. Other less frequent complications are infection, necrosis or erosion of the urethra, sometimes requiring removal of the sling. Patients are usually advised not to practice intense exercise during 6 weeks and abstain from sexual intercourse during 4–6 weeks.

InVance™ Male Sling

The InVance™ male sling has been introduced in the early 2000s. The sling is manufactured by the company American Medical Systems (Minnetonka, Minnesota, USA). Its clinical use has progressively decreased after the introduction of the AdVance™ male sling concept, and there are some countries/institutions where the bone-anchored male sling is not more marketed.

Principles

The InVance™ male sling system is a compressive device for the urethra, using a mesh sling anchored with small bone screws fixed on the pubic ramus. The system is presented as a single-use kit, containing a single-use inserter, battery powered, driving the screws at low speed in the bone. Titanium bone screws are delivered with pre-attached polypropylene sutures to fix the device accurately. The sling is a silicone-coated polyester mesh. Compression is achieved by providing a local support to the urethra that is kept anterior to the mesh (Fig. 6.5).

Surgical Technique

Three screws are placed on each side of the descending ramus to act as six fixation points for the InVance sling. Each of the screws has sutures attached. The sutures are passed through the sling pores and tied tightly. The patient is placed on dorsal lithotomy position, under spinal or general anaesthesia. A catheter is usually inserted at the beginning of the procedure, after usual skin preparation. The surgical approach is perineal, median, and should be of 3–4 cm. The first layer (subcutaneous) is dissected with electrocautery, and the bulbospongiosus muscle is kept intact. Dissection is continued laterally to expose the pubic bone (pubic rami). The screws (with their sutures) are positioned on each side, on the pubic ramus, the first one being placed close to the pubic symphysis. Screws are separated from each other by a one-centimetre interval. The mesh is then placed and sutured to the screws after having tested the good tension (either by cough test if patient is awake or by evaluating the retrograde leak point pressure). The perineal wound is then simply closed by layers, using resorbable sutures.

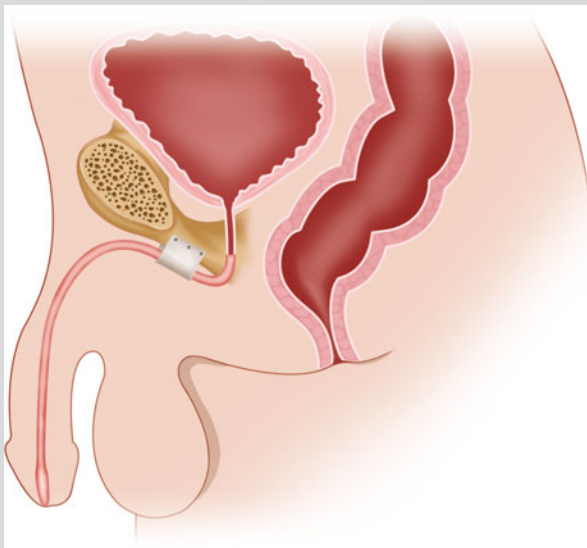


Fig. 6.5 Sagittal view of the InVance, bone-anchored male sling

Post-operative Care

After surgery, the catheter is usually left in place for 24 h, and the patient is discharged at day 1 if bladder emptying is correct without significant post-void residual volume (checking the correctness of bladder emptying is mandatory). Oral medications are usually prescribed for post-operative pain management. In the short term, the main complications are perineal pain, retention and dysuria, local inflammation and wound infection. Other less frequent complications are infection, necrosis or erosion of the urethra and osteitis, sometimes requiring removal of the sling. Patients are usually advised not to practice intense exercise during 6 weeks.

Points of Interest

- Male sling are a reasonable option for mild to moderate post-prostatectomy incontinence. However, there are no valuable comparative study available, including compared to artificial urinary sphincter. This field is moving with studies underway.
- AdVance male sling is regarded as the most widely used sling with the most important clinical experience, but numerous new slings are ready to be marketed.
- Preoperative evaluation before a male sling is also being reconsidered nowadays with new prognostic factors evolving. MRI data are of great interest and may have a future role for patient selection.

AMS 800

Brief History

The artificial urinary sphincter (AUS) has been used in clinical practice since 1972. In the first one and a half decades, several technical improvements of the device have been made, such as the introduction of kink resistant tubing. In 1987 the device reached its current design with the development of quick snap connectors and the narrow back cuff. Over the last 27 years, no major technical changes have been made on the AMS 800. In recent years, the addition of antibiotic coating on pump and cuff and also the introduction of 3.5 cm cuff were the most important novelties.

It is estimated that to date more than 150,000 patients worldwide have been implanted with an artificial urinary sphincter type AMS 800.

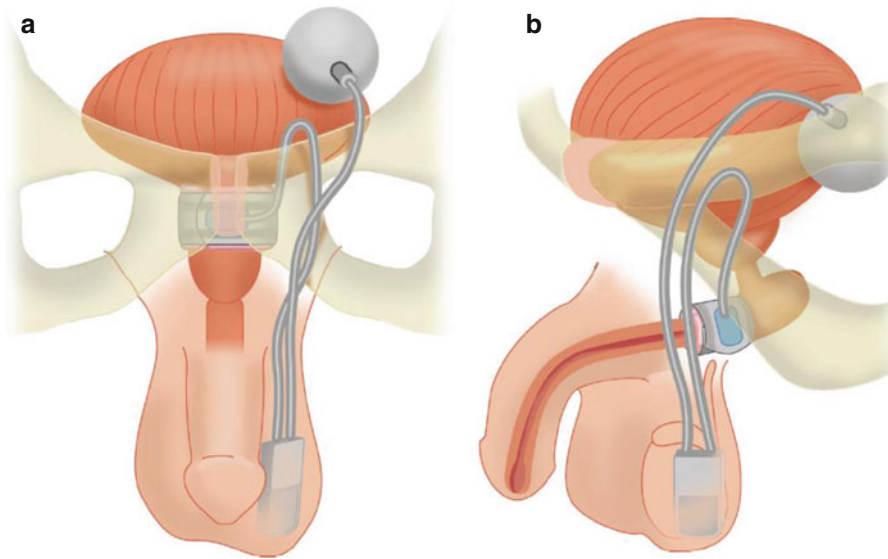
As such the AMS 800 is by far the most implanted device to treat urinary incontinence. Also the length of clinical follow-up is unseen in other devices.

Working Mechanism

The AMS 800 is a complete hydraulic system.

After implantation of the separate parts (cuff, pressure balloon and control pump), the system is filled with an iso-osmotic fluid and connected using quick snap connectors.

At rest, the cuff is inflated and closes the urethra by gentle external pressure (in accordance with the type of pressure balloon used, generally 61–70 cm H₂O). When the person needs to void, he stabilises the pump with one hand at a level of the tubing and pushes 1–3 times at the distal part of the pump. One can feel the fluid movement in the system during this manoeuvre. Fluid is now transferred from the cuff to the balloon by means of a one-way valve inside the pump. After this manoeuvre, the cuff is opened and the patient is able to void. The fluid inside the system will automatically return to the cuff in the following seconds to minutes because of the pressure balloon. The patient doesn't need to close the device Klijn (1999).



The Ideal Candidate

The AMS 800 is mainly implanted in patients with post-prostatectomy incontinence.

The device should only be offered to and implanted in persons with adequate dexterity and mental capacity to use the device. The need for future endoscopy should be limited to a minimum, because of the risk of urethral damage and subsequent cuff erosion. Therefore untreated urethral strictures or bladder neck contractures are relative contraindications. They should be diagnosed and treated prior to implant. Untreated detrusor overactivity will also have a negative impact on the efficacy of the device. Ideally it should also be diagnosed and treated prior to implant. Low bladder compliance of the bladder is a contraindication. In order to diagnose detrusor overactivity and low compliance, urodynamic study is a crucial step in the preoperative workout.

It is to be expected that several patient factors will influence the efficacy of the artificial urinary sphincter. Prior irradiation, current smoking, diabetes mellitus, prior treatment of urethral strictures or bladder neck contractures and all other conditions that influence tissue oxygenation, vascularisation, fibrosis and wound healing can theoretically increase erosion and urethral atrophy rates. These factors are at most relative contraindications, since many large cohort series have proven the safety and efficacy of AMS 800 implants in patients with these characteristics. As in every candidate for an artificial urinary sphincter, these patients should be adequately counselled about the high revision rates but acceptable success rates after implantation of an AMS 800 device.

Work-Out Prior to Implant

A detailed history is mandatory to confirm the presence of invalidating stress urinary incontinence. This is preferentially completed by a micturition diary with recording of the amount of urine loss (e.g. pad weight). A clinical examination to look for chronic skin conditions, scars and other abnormalities should also be performed.

A cystoscopy prior to implant of an AUS is mandatory to confirm the absence of bladder neck contracture or urethral strictures and to evaluate a normal bladder aspect. Coincident treatment of strictures with an implant has been described in literature but increases the risk of complications. Also future treatment of these problems with an AMS 800 in situ increases the risk of complications and should be avoided as much as possible.

Urodynamic study is usually performed to determine the cystometric bladder capacity and to confirm the absence of detrusor overactivity and compliance loss. The latter two might mandate other therapy before embarking on AMS 800 implant. A low cystometric bladder capacity can predict frequency and urgency complaints after implant. As such, urodynamic study is a good tool to counsel your patient and to set the right expectations.

In the days before the implantation, a urine culture can be checked to exclude the presence of bacteriuria. If present, directed antibiotic prophylaxis is advisable. If a patient is using an indwelling catheter or a condom catheter, these should be removed 1 week prior to implant to reduce the risk of bacteriuria.

Implant Technique

The patient is placed in lithotomy position. The perineum is shaved immediately before surgery. Prophylactic antibiotics are administered (e.g. 2 g cefazoline). The operating field is disinfected with alcoholic solution and draped. A transurethral 16 French catheter is placed. A perineal incision is made over the bulbar urethra. After incision of the subcutaneous fat, the bulbocavernosus muscle is split in the midline and the bulbar urethra is dissected laterally from the muscle and dorsally from the corpora cavernosa. The urethra is sharply dissected circumferentially until the measuring device can be tunnelled underneath. The ideal location is the proximal bulbar urethra where the corpora diverge. The catheter is removed before measuring the cuff size. In normal circumstances, a 3.5 to 5 cm cuff will be measured.

A right inguinal incision is made, and after dissection, the oblique fascia is incised. The Retzius space is entered by perforating the transversal fascia, and using blunt dissection, a small space for the balloon is made in the Retzius space. Using a clamp or Hegar dilators, a subdartos scrotal pouch is made from the inguinal incision just above the oblique fascia.

The different components of the devices (cuff size as measured, 61–70 cm H₂O balloon and control pump) are prepared and placed in the dissected areas. The cuff tubing is tunnelled to the inguinal incision. All tubes are flushed and connected with the quick connectors.

The operating fields are rinsed with aqueous solution (+/- antibiotics) during the procedure. Care is made to place the device directly from the preparation table, directly into the patients without placing it on wet drapes, patient skin or penis. The different wounds are closed in layers. It is very important to deactivate the device after implant.

The device will only be activated after several weeks, to allow for healing of local tissues. Early activation will increase erosion rates.

Learning Curve

The vast majority of patients receiving an AMS 800 implant are operated by surgeons early in their learning curve. Sandhu and colleagues showed that the learning curve for AMS 800 implant is steep. A patient operated by a surgeon that has performed <5 previous AMS 800 implants has got 24 % chance of needing reoperation vs. 18 % for a surgeon with an experience of <100 implants and 13 % for a surgeon with an experience of <200 implants. Possible explanations for this persisting learning curve are the need for adequate measuring and filling of the device and correct placement of the bulbar cuff.

Alternative Techniques

Over the years, alternative techniques have been proposed for several indications. Hereunder, we briefly report the most important alternatives.

Transverse Scrotal Incision

A transverse scrotal incision has been advocated, at first in the setting of revision surgery and later as an alternative to the classical perineal approach as described above. The so-called penoscrotal approach is proclaimed to be faster and easier as compared to the classical perineal approach. It also allows for bulbocavernosus muscle-sparing surgery. It is an ideal approach in the case of a combined implant with an inflatable penile prosthesis.

Whether the cuff position after a penoscrotal approach is comparable to the position after a perineal approach is under debate. Sceptics of the technique believe that the cuff is rather located in a distal bulbar position. It has also been reported that dry rates of this alternative approach are inferior to the classical perineal approach. Advocates of the technique claim that adequate dissection of the bulbar urethra is possible to place the cuff in a comparable position.

Transcorporal Implant

In cases where the urethra is very thin or when an increased risk of cuff erosion exists (such as patients who had a previous erosion or urethroplasty), a transcorporal technique can be chosen. Instead of dissecting the urethra from the corpora, risking urethral injury and/or a thin barrier, the tunica albuginea of the corpora is incised bilaterally 3–5 mm lateral to the urethra and through blunt dissection, both corporotomies are connected. As such a ‘patch’ of corpora cavernosa is left on the bulbar urethra at the dorsal side. This technique has proven its efficacy and its safety in the above-mentioned high-risk population, although long-term follow-up are lacking and the experience is limited to relatively small numbers of patients.

Ectopic Balloon Placement

Especially in the scarred retroperitoneum, it can be interesting to avoid perforating the transversalis fascia. By blunt dissection, a space is created above the transversalis fascia. The reservoir is positioned at the lateral aspect of the penis and medial of the spermatic cord. This technique has been described in 2005 and has been found quicker and easier than the classical positioning in the Retzius space. Avoiding the perforation of the transversalis fascia decreases the risk of perforating blood vessels and underlying organs. It is important to close the opening in the neighbourhood of the inguinal ring with an absorbable suture to prevent migration of the balloon on Valsalva.

Double Cuff

The use of a double cuff has been popularised 20 years ago in order to diminish the number of patients that had persistent urinary leakage after single cuff implant. Where initial reports were very optimistic and presented improved outcome in

terms of dry rates, longer follow-up has learned that double cuff placement might not be superior to single cuff implants and is also associated with a higher risk of complications. As always, there exists no well-designed prospective trial, and this data is drawn from cohort studies, limiting the power of the evidence. The existing evidence does not support the use of double or tandem cuff in a routine setting.

High- and/or Low-Pressure Balloon

There is no published data that specifically addresses the results and complications of the different pressure reservoirs that are on the market (51–60 cm H₂O, 61–70 cm H₂O and 71–80 H₂O). It is generally accepted that low-pressure balloons (51–60 cm H₂O) result in lower dry rates. The use of high-pressure balloons (71–80 cm H₂O) on the other hands will increase erosion rates. Therefore, it should be noted that the standard of care consists of using a 61–70 cm H₂O balloon. As a matter of fact, there is no reason to use another pressure balloon.

Early Complications

Surgical Perforation of Urethra

During dissection of the urethra, inadvertent perforation of the urethra can occur. When the perforation is clear, cuff implant should be abandoned. Undiagnosed urethral perforation will result in early cuff erosion or infection. Whenever in doubt, a control of urethral integrity should be performed. One way to do this is to inject a coloured (e.g. isobetadine) aqueous solution in the urethra and check for abnormal leakage in the operating field.

Bladder Perforation

During perforation of the fascia transversalis and creation of the space for the pressure reservoir, the bladder can be accidentally perforated. Undiagnosed bladder perforation will again result in early infection of the prosthesis and will require early removal. When bladder perforation is diagnosed during surgery, the procedure can continue, but the reservoir needs to be relocated to the intraperitoneal space of to the above-mentioned ectopic location. Whenever in doubt of bladder perforation, a control of bladder integrity should also be performed, for example, by injection of a coloured aqueous solution in the urethra and check for abnormal leakage in the operating field.

Infection

Early infection in general is clinically apparent by the classical dolor, tumor, rubor and calor and can also be accompanied by fever. These sign will mandate prompt removal of the prosthesis. There have been reports of ‘salvage procedures’ where a

new device is implanted in the same time after thorough rinsing the operating field with antibiotic or antiseptic solutions. The majority of implanters will however advise explant followed by a reimplant at a later stage (in terms of months). Most important underlying causes of early infection are probably perioperative inoculation of bacteria or unrecognised perforation of bladder or urethra. It is of course mandatory to perform implants under appropriate antibiotic prophylaxis. We know that a course of 24 h antibiotics diminishes infection rates in orthopaedic surgery. It is thus wise to continue antibiotics for 24 h. It is unclear whether longer antibiotics are useful. Nevertheless, many implanters will currently prescribe a longer course of antibiotics. Also irrigation of the operation field with aqueous solution (+/- antibiotics), shaving immediately prior to implantation and placing the prosthesis directly from the preparation table directly into the patients without placing it on wet drapes, patient skin or penis are believed to diminish infection rates, again not supported by strong evidence.

Early infection rates are not often reported separately from late infections or from erosions. The rate of infection and erosion in contemporary series with a follow-up of at least 12 months is believed to be around 8.5 % with a wide variability in reported series.

Late Complications

Urethral Atrophy

When recurrent stress urinary incontinence occurs during follow-up of patients with an implanted AMS 800 device, urethral atrophy is suspected. Due to the chronic compression of the urethral cuff, tissue hypoxia occurs, which in turn results in tissue atrophy. This is also an explanation why radiation, which can result in obliterative endarteritis, is believed to favour urethral atrophy. This has however not been proven in current literature. Current atrophy rates are reported to be around 8 %. In a prospective study, urethral atrophy occurred at a median of almost 30 months after implantation. Other series have reported atrophy to occur from 3 up to 23 months after implantation.

Erosion/Infection

Erosion and infection of implants usually occur within 24 months after implant surgery. As stated above, early infections probably arise from perioperative inoculation of bacteria or unrecognised perforation of bladder or urethra. Infection and erosion have been reported to occur even after more than 7 years after implantation. Patients can have years of satisfactory results of the device and nevertheless present with late erosion. Low-grade infection or repetitive injury of the prosthesis material in the tissue might be causative factors. As mentioned above (in the early infections section), the rate of infection and erosion in contemporary series with a follow-up of at least 12 months is believed to be around 8.5 % with a wide variability in reported series.

Mechanical Failure

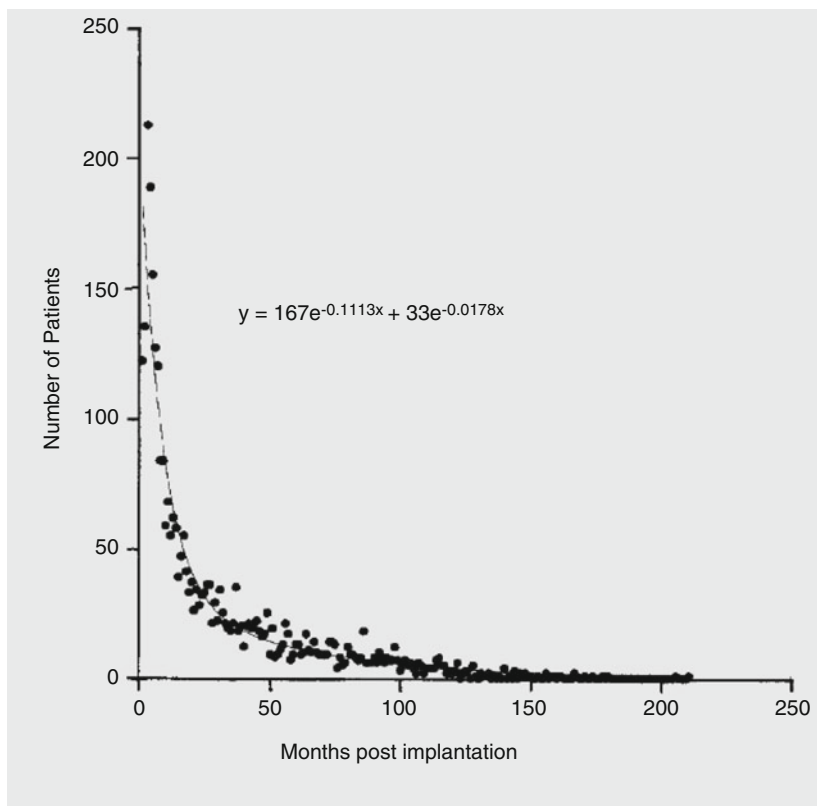
Mechanical failure can occur within each of the different components of an artificial urinary sphincter (balloon, control pump or cuff), in the tubing or in one of the connections. It is well known that implanted artificial urinary sphincters can remain functional for very long periods, way over 10 years. The actuarial 5-year survival rates of these devices have however not been well described. In literature, rates of mechanical failure vary between 2.0 and 13.8 % with a mean of 6.2 % after a follow-up of at least 2 years. It is clear that the rate of mechanical failure is dependent of the follow-up period.

AUS implant in severe non-neurogenic male stress incontinence ^a	Risk (no comparator)	<i>N</i> of participants (<i>n</i> of studies)	Quality of evidence (grade)
Infection/erosion	8.36 % (range 3.3–27.8 %)	754 (13)	Low
Mechanical failure	6.4 % (range 2.0–13.8 %)	754 (8)	Low
Urethral atrophy	11.6 % (range 1.9–39.7 %)	601 (8)	Low
<i>N</i> patients with reinterventions	28.0 % (range 14.8–44.8 %)	719 (12)	Low
<i>N</i> reinterventions	79 interventions in 52 patients that needed revision (mean of 1.5 reinterventions/patient)	52 (5)	Low
<i>N</i> patients social continent (≤1 pad/24 h)	82.4 % (range 60.9–100 %)	425 (8)	Low
<i>N</i> patients completely dry (0 pads/24 h)	48.4 % (range 4.3–85.7 %)	409 (8)	Low
Quality of life	VAS scoring impact of incontinence preoperative 5.0 vs. post-operative 1.4	40 (1)	Low

^aMean follow-up was not extractable from the different subgroup datasets, but all included studies have a follow-up from >24 months

Revision Rates

The overall reintervention rate for patients undergoing artificial urinary sphincter implants is an important comparator to other techniques and offers important information to counsel a patient prior to proceeding with implantation. In a recent pooled analysis of published data, the mean reintervention rate for all causes after AMS 800 implantation was 26 %. It has been shown that 50 % of reinterventions occur in the first 8 months and that 90 % of reinterventions occur in the first 3 years after implantation of the artificial urinary sphincter. Patient satisfaction seems to be mainly linked to the presence of a functioning device, rather than the necessity to re-intervene. The majority of patients (up to 98 %) will have a functioning device at more than 2 years follow-up, independent of the need for revision.



Efficacy

The efficacy of the AMS 800 device can be measured in terms of continence rates and in terms of quality of life.

When continence is defined as being dry (no pad use), the dry rates vary from 4.3 to 85.7 %. The high variability shows that more standardisation is necessary in the evaluation of the efficacy of the AMS 800 device. Improvement of incontinence is seen in the vast majority of patients, up to 100 % in certain series. A recent small prospective study suggest that about half of all patients implanted with an AMS 800 device will be dry and that 90 % of patients will report a markedly improved continence. Failure seems to be linked to infection and subsequent removal of the device and to reduce to bladder compliance on preoperative urodynamic study.

Quality of life is not well studied in this patient population. All studies that the use-specific quality of life measures have shown a very significant impact of the AMS 800 device on the quality of life. As said before, the number of reinterventions does not seem to have an important impact on the final quality of life, as long as patients have a functional AMS 800 device after revision.

Risk Factors for Failure

Although one would expect that risk factors for failure of AMS 800 are well known and described, because of the long-standing service of this device, these relations are not always well established. Risk factors such as diabetes and irradiation do not necessarily have a negative impact on patient's outcome. Several cohort series have reported similar outcome for irradiated patients vs. nonirradiated patients. In some of these series, however, this was at cost of a higher revision rate in the irradiated patient group. Previous erosion of a sphincter, previously treated urethral stricture disease or bladder neck contractures have been associated with higher failure rates in several series. On the other hand, some small series have also shown good results in these difficult patient cohorts.

In conclusion, whenever a patient suffers severe incontinence, he should be offered the possibility of an artificial urinary sphincter implant, even in the presence of risk factors. Adequate counselling and explanation of the risk for revisions is obviously a mandatory step prior to implant.

Summary

The AMS 800 device has been used in its current form for more than 25 years. Therefore, it is by far the most well-known surgical technique to treat severe incontinence. After implantation of an AMS 800, the vast majority of patients will have improved continence and quality of life. Not all patients will be completely dry however. A non-negligible proportion of the patients will require revisions, but this will result in improved continence and quality of life again. Only a small proportion of patients will be left incontinent without further possibilities for prosthesis surgery.

Tips and Tricks

1. Discuss the high success rate and also the high revision rate of this surgery with your patient prior to implant.
2. Pay attention to the dexterity and cognitive function of your patient.
3. If you perform only a few implants a year, consider referring your patient to a high-volume centre.
4. Plan the surgery in advance, but be prepared to change technique when encountering difficulties (e.g. ectopic balloon placement, transcorporeal cuff placement,...).
5. An infected/eroded AMS 800 should be explanted without significant delay. Antibiotics will not cure the patient but will result in delay and possible increased damage of the urethra. This might diminish the chances for a second implant.

Stress Urinary Incontinence in Neurogenic and Irradiated Patients

Irradiated Patients

Radiation therapy is increasingly offered to patients after radical prostatectomy in the course of treatment of their prostatic carcinoma. Radiotherapy prior to implantation of AUS or male slings in men with SUI is assumed to cause morbid changes to the irradiated bladder and urethral tissue. This morbid effect may finally lead to worsening of the continence status in these patients. Radiation endarteritis obliterans of small blood vessels leads ischaemic changes in the irradiated tissue. Cellular radiotoxicity causes fibrotic changes to the detrusor muscle, disturbs its function and decreases its compliance. Radiation hemorrhagic cystitis may necessitate multiple endoscopic interferences that is quite a problem after insertion of AUS. Similar changes are assumed to take place in the bulbar urethra – even though it is not involved in the radiation field – due to compromised vascularity.

Studies that have addressed the effect of radiation therapy – prior to implantation of AUS or male slings – on the surgical outcome in this particular patient population are not that many. Manunta et al. (2000) reported higher complication and reoperation rate in the irradiated group of patients. Sathianathen et al. (2014) reported a higher incidence of coexisting urethral stricture in the irradiated patients. Walsh et al. (2002) found that revision due to urethral atrophy, erosion and infection occurred more frequent in the irradiated patients and that complete resolution of incontinence was significantly higher in the unirradiated group.

In a group of 37 male patients with post-prostatectomy incontinence who received AdVance male sling, Torrey et al. (2013) reported statistically significant higher frequency of pad usage in the subgroup of patients who underwent external beam irradiation (3.5 pads vs. 0 pads, $p=0.007$). Three of the seven irradiated patients experienced worsening of their incontinence status compared to 1 of 30 patients without irradiation. About 63 % of unirradiated patients became pad free, whilst none of the seven irradiated patients achieved complete dryness.

Neurogenic SUI

Management of neurogenic stress urinary incontinence (NSUI) is one of the challenging topics in daily urological practice. A substantial number of school aged patients with bifid spine and patients with infrasacral spinal cord injuries (SCI) have weak urinary sphincteric mechanism and, therefore, suffer from SUI. Looking at the literature, although so many studies have investigated various approaches to treat patients with NSUI – such as artificial urinary sphincter (AUS) and suburethral slings – there is no single, blinded, randomised trial to standardise an optimal surgical approach dealing with such specific patient population.

Neurological assessment and further investigations reveal an underactive sphincteric mechanism; this should be accompanied by assessment of the functionality of the detrusor muscle whether it is normal, overactive or underactive. This is of utmost importance to assess the gravity of the condition and to plan the future treatment. The neurological assessment of the patient should include testing of the integrity of sensations in the urogenital area and the assessment of anal sphincter tone and the ability to voluntarily contract the anal sphincter and pelvic floor muscles. This gives indirect information about the functionality of the external urinary sphincter. Part of the clinical assessment of a male patient with NSUI is to complete a bladder diary, generic (SF-36) and I-QOL to assess the amount of incontinence and its impact on patient's quality of life. Urinalysis helps reveal any urinary tract infection. Imaging and renal function test can detect any deterioration of the upper urinary tract, especially after surgeries that aim to increase the urinary bladder outlet resistance as they might result in development of DO or decrease in bladder compliance in some cases.

Filling cystometry and videourodynamics have a particular role in patients with NSUI, both preoperatively and during follow-up of patients after surgery. They help the urologist to document the presence of incontinence, sphincteric underactivity and any coexisting DO and/or low bladder compliance and the impact of these findings on the upper urinary tract. Urethral pressure measurement is used at some functional urology centres around the world; however, according to the EAU Guidelines, it has a very limited role in neuro-urological disorders.

The EAU Guidelines for the treatment of NSUI highlight some priorities, particularly protection of the upper urinary tract, improvement of urinary continence status, restoration of lower urinary tract function and improvement of patient's quality of life. Management of a male patient with NSUI is challenging; in many cases, the NSUI is accompanied by DO and/or low bladder compliance that may be part of the pathogenesis of the underlying neurological deficit or may develop later after surgery. Therefore, a thorough clinical assessment and further specific investigations are mandatory, with close follow-up of the patients after surgery to ascertain achievement of the above-mentioned urological priorities. Moreover, some additional surgical procedures are mandatory to guard against deterioration of the upper urinary tract function by increasing the capacity of the bladder, e.g. bladder augmentation.

Drug treatment in NSUI is not recommended and should not be prescribed (LE: 4, GR: A). Whenever possible, suprapubic catheters and indwelling transurethral catheters should be avoided (LE: 3, GR: A). Urethral lengthening and bladder neck procedures such as Young-Dees-Leadbetter approach can help regain continence in patients with NSUI due to sphincteric incompetence. However, these procedures are invasive and quite challenging with success rate of about 50 % in primary procedures. Less invasive procedures are available and should be tried out in the first place. These procedures are urethral bulking agents, suburethral slings and artificial urinary sphincters (AUS). The use of AUS is recommended by the EAU Guidelines for the treatment of men with NSUI (LE: 3, GR: A).

However, none of the studies, on which the above-mentioned recommendation is based, was a randomised, controlled trial. Only one systematic review was found in the literature that comprehensively described the surgical outcomes and quality of

reporting of 30 studies that applied less invasive surgical procedures to correct NSUI. All studies were either cohort prospective or retrospective of level 3 evidence with overall quality of reporting 43–81 %. The analysis included 849 patients, of whom 525 were males, median age of 21 years (range 3–80). The majority of cases were incontinent because of spina bifida (69 %) or SCI (22 %). About 47 % of patients used intermittent catheterisation to empty their bladders. A total of 322 male patients (60 % of males) received AUS, 108 males (21 %) received suburethral slings, 82 males (16 %) received urethral bulking agents and 13 males (3 %) received Pro-ACT implant.

A follow-up of the patients for 48 months (range 12–62) revealed an overall successful treatment in 64 % of patients, 16 % improved whilst 20 % of patients experienced no change in their continence status after surgery. The overall success rate in this systematic analysis showed no correlation with the type of neurological deficit or the associating bladder augmentation procedures in the course of treatment of the patients.

Surgical complications were reported in 20 % of male patients. About 25 % of the patient underwent one or more reoperation, whilst 5 % of patients received an additional urethral procedure – other than the original one – to achieve continence.

Further analysis of the surgical outcomes of this systematic review revealed that the studies where AUS was applied reported the highest rate of success (77 %) and the lowest rate of failure (10 %), followed by suburethral slings which had a success rate of 58 % and failure rate of 22 % and urethral bulking agents (27 % success and 50 % failure).

However, AUS studies reported the highest complication rates (32 %) and the highest rate of reoperation (51 %), whilst slings had 14 % complication rates and 7 % reoperation rates. Finally, the bulking agents had only 4 % complication rates and 12 % reoperation rates.

Points of Interest

- Filling cystometry and videourodynamics have a particular role in the assessment of male patients with NSUI.
- AUS shows higher success rate in achieving continence in male patients with NSUI compared to slings and urethral bulking agents.
- AUS implantation is technically feasible in patients with previous radiotherapy.

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