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Review

# Contemporary diagnostics and treatment options for female stress urinary incontinence



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**Abstract** Stress urinary incontinence is not a deadly disease, but for the large population of women suffering from it, it is a very important issue. Especially in the continuously aging population all over the world, there is more and more need for treatment of this serious medical condition. Treatment of female stress urinary incontinence exists already for ages. In the 20th century invasive treatments like Burch colposuspension and pubovaginal slings were the mainstay of surgical treatments. The introduction of the midurethral sling made the procedure less invasive and accessible for more caregivers. Luckily there are many options available and the field is developing quickly. In recent years many new medical devices have been developed, that increase the number of treatment options available and make it possible to find a suitable solution for the individual patient based on subjective and objective results and the chances of complications. This manuscript provides an introduction to the therapeutical options that are available nowadays for female stress urinary incontinence.

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## 1. Introduction

Stress urinary incontinence (SUI) is defined as “the involuntary loss of urine on effort or physical exertion or on sneezing or coughing” [1]. It is a common medical condition

with a severe impact on quality of life. Symptoms of urinary incontinence are prevalent in 25% of the female population above 20 years [2], 50% of which are stress incontinence symptoms. The main risk factors for development of SUI are higher age, parity and obesity [3]. In white, non-Hispanic women SUI is more common than in other ethnic groups [4]. Other (chronic) comorbidities like physical inactivity [5], diabetes, asthma and angina pectoris are also known to negatively influence incontinence [3].

In this article an overview of the current therapeutical options of this bothersome medical condition is given.

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Information is presented in a historical context, with personal experience from the authors. The data are supported by recent literature found in PubMed, Cochrane and Embase databases and the European Association of Urology (EAU) [6] and International Consultation on Incontinence (ICI) [7] guidelines on incontinence.

## 2. Diagnostics

When initiating treatment for female SUI, assessment of the type of incontinence, either stress-, urge- (UUI), or mixed urinary incontinence (MUI), is necessary first. Investigations to distinguish between these types include patient history, physical examination, voiding diaries, imaging techniques, pad weight testing and urodynamic investigation.

### 2.1. Medical history taking

In medical history taking one should ask when incontinence occurs. SUI occurs at moments of increased abdominal pressure, during coughing, sneezing and/or straining. If incontinence occurs after a feeling of urgency, without abdominal pressure rise, urge-incontinence can be assumed. By thoroughly asking for the symptoms, medical history taking can for a large part distinguish between the various forms of incontinence. In 20%–36% of patients MUI is present, which consists of both forms of incontinence [8]. Because high-quality evidence is not available about the ideal treatment of MUI, in these patients conservative treatment of the most prominent form of incontinence is recommended [8].

### 2.2. Physical examination

To support medical history taking, thorough physical examination is essential. During inspection of the female genitals it is important to look at signs of vaginal atrophy, pelvic organ prolapse and whether urethral hypermobility is present or not.

Vaginal atrophy is found in post-menopausal women after lowering of estrogen levels. Local or systemic estrogen suppletion can help improve continence, as it will increase the thickness of the urethral and vaginal mucosal tissue, which in turn will lead to a better closing mechanism. Treatment with estrogens might furthermore help to improve the quality of the tissue. Although improved quality and thickness of the vaginal wall suggests a more easy procedure during pelvic surgery, no strong evidence exists yet for advantages of pre-operative hormone replacement therapy [9].

Assessment of pelvic organ prolapse is also an important part of physical examination. It can be classified according to several quantification-systems, for example the Pelvic Organ Prolapse Qualification (POP-Q) score. The POP-Q score assesses the position of the anterior and posterior vaginal wall and the uterus compared to the hymenal ring and quantifies this. A vaginal prolapse, especially from the anterior wall, almost always leads to a decreased urethral support, which in turn might lead to (stress) incontinence. By supporting the urethra/anterior vaginal wall during

physical examination and performing a cough test simultaneously, one can mimic the effect after (surgical) correction of this situation. Sometimes this effect can also be seen after placing a pessary and these devices can be used as a treatment for SUI in this way. Contradictory, incontinence can develop after surgical correction of a prolapse, because urethral kinking is made undone. The straightened urethra is more vulnerable for developing SUI, because the physiological mechanism of urethral closure is impaired. Although prolapse and incontinence are closely related to one another, we will not further discuss the treatment of prolapse in this article.

In determining the type of stress urinary incontinence, it can be useful to assess the degree of urethral mobility and to diagnose intrinsic sphincter deficiency (ISD). Originally these conditions, which both play a role in the pathogenesis of SUI, were described as “type 1” and “type 3” incontinence respectively. Based on John DeLancey’s hammock theory [10], midurethral hypermobility causes SUI because of a lack of support of the urethral sphincter. The urethral sphincter is not capable to close the urethra during moments of high intra-abdominal pressure resulting in urinary loss. This can be compared to a garden hose, that can easily be compressed against a solid underground, but is hardly compressible in loose sand. Intrinsic sphincter deficiency is, as the name suggests, a failure of the sphincter mechanism of the urethra itself. In these patients stress incontinence can occur without the presence of urethral hypermobility. Stress incontinence based on ISD is more severe and more difficult to treat [11].

The clinical significance of distinguishing between these different forms of SUI is subject of debate. In general, one can state that in case of urethral hypermobility (with or without ISD) treatment with a tension-free vaginal tape is recommended. In case of ISD, one should consider reinforcing the urethral sphincter as well. This can be done with a more compressive sling, an artificial sphincter or – in case the patient is not fit or does not opt for surgery – bulking agents.

Urethral hypermobility is mostly assessed by eyeball observation. Classically it can also be diagnosed by performing a Q-tip test, in which a cotton swab is placed in the urethra. The patient is asked to strain, if the angle of the cotton swab changes more than 30° from the original position, hypermobility is present. In clinical practice, it is not commonly used.

Although the clinical significance of urodynamics in individual cases is disputable, urodynamic investigation can give useful information about the type of incontinence. First it can differentiate between SUI and UUI. Second, it can diagnose ISD if urethral pressure profilometry (UPP) is performed as part of the complete investigation. Generally, an ISD is concluded if the maximal urethral closing pressure (MUCP) is below 20 cmH<sub>2</sub>O (1.96 kPa), but the ranges are wide. There is no consensus about whether the cut-off point of the MUCP is a predictor for success of a possible subsequent surgical procedure [12,13]. Several imaging techniques are available to diagnose incontinence. The most important are X-ray, ultrasound and magnetic resonance imaging (MRI). All can be used to assess bladder neck mobility and/or prolapse, but clinical usefulness for diagnosing SUI is minimal. Ultrasound, especially 4D-dynamic

imaging, seems most feasible as it is cheap, readily available in an outpatient setting and does not have the disadvantage of ionizing radiation. Imaging is to be used in the complicated cases, mainly to get a better understanding of the anatomy.

Voiding diaries and pad weight testing are tools to quantify and objectify urine loss, for the patient as well as for the physician. Though these tests are as objective as possible, inexpensive and non-invasive, less than 10% of the urologists perform this test regularly [14]. The shorter the test (1 h) the better the patient commitment, but longer testing (for 48 or 72 h) gives more reproducible results [14].

Validated questionnaires can add extra information on specific subjective aspects of incontinence, but should always be interpreted with care. A combination of subjective and objective diagnostic tools gives the best insight in the incontinence and can be a guidance for behavioral therapy and the choice for eventual more invasive therapy.

### 3. Conservative management of stress urinary incontinence

Conservative management is defined as any non-surgical intervention for SUI. Whether or not pharmacological treatment is included in this definition is debatable, but this is not relevant considering the relatively small place for medication in the curative treatment of SUI. According to the EAU guidelines on incontinence [6], conservative therapy is usually considered as initial treatment. It carries less risks, is less invasive and often less costly than the more invasive or surgical options. Conservative management can consist of containment, a range of lifestyle interventions and pelvic floor muscle training (PFMT), all with different effectiveness and chance of success.

#### 3.1. Lifestyle modifications

Obesity is significantly correlated to stress urinary incontinence [15]. In a randomized trial under 338 stress incontinent patients, women with 8.0% weight loss had a significantly greater decrease in stress-incontinence episodes compared to the group with 1.6% weight loss after 6 months follow-up [16]. Interventions in lifestyle aimed at weight reduction are therefore recommended (level of evidence: 1B) [6].

Fluid and/or dietary management in general can be beneficial, albeit mostly on urgency. Reducing the fluid intake reduces the production of urine and with it, it reduces the amount of urine that can be lost because of incontinence. One should however be careful to avoid dehydration and take furthermore into account that no clinical trial has confirmed the effect of fluid management on SUI [17].

Dietary management other than aimed at weight reduction can consist of reduction of caffeine and alcohol intake. Constipation and smoking both have a positive influence on incontinence. Prevention and cessation of these factors respectively can be beneficial for general health, but there is no evidence that treating these factors independently improves symptoms of incontinence [18].

#### 3.2. Pelvic floor muscle training

The oldest form of PFMT are Kegel exercises, named after the urologist Arnold Kegel, who first described these in 1948 [19]. They consist of sets of 8–12 contractions of the pelvic floor that have to be sustained for about 10 s. These exercises require discipline and perseverance of the patients as they should be repeated multiple times a day, for 4–5 months.

There has been ongoing discussion about the effect of PFMT. Dumoulin et al. [20] systematically reviewed the outcomes of 18 studies comparing PFMT versus no treatment. They concluded that 56% was cured after PFMT, in the untreated groups the cure rate was 6%. There is not enough evidence to conclude a long-term effect in this review, because only two articles gave limited information on this topic. Most patients adhered well to the training program for the duration of the studies. Little literature is available about patient adherence after termination of a study. In a Norwegian review two studies with 5 year follow-up were found having an adherence percentage of 10%–70% [21].

There is furthermore no evidence of a benefit of PFMT in addition to other conservative treatments, but this conclusion was drawn based on a Cochrane review of 13 relatively small studies, with a total of 1164 patients [22]. A randomized controlled trial (RCT) published by Labrie et al. [23], in which 460 women were randomized between physiotherapy and midurethral sling surgery, shows that initial surgical treatment with a midurethral sling, gives significantly higher objective (59% vs. 77%) and subjective cure rates (53% vs. 85%) after 1-year follow-up. Even after cross-over from the physiotherapy-group to the surgery-group no additional benefit was found of PFMT.

Superiority of PFMT over electrical stimulation and bladder training has been shown for women with SUI. The long-term effect is dependent on many factors, such as the instructions/education that is given and the supervision that can be provided. Despite the ongoing debate about its effectiveness, it is still recommended (Grade A recommendation) to start with this first-line therapy as it is non-invasive, less costly and safe [6].

Biofeedback can help in training the muscles of the pelvic floor, by giving the patient feedback on how the exercise is performed. There are many “feedback” techniques, from simple manual palpation, to vaginal cones of different sizes that have to be kept in place, to more expensive techniques based on electromyography (EMG). Although it is helpful in some individual cases, addition of biofeedback in any form to adequate PFMT was not beneficial.

### 4. Minimally invasive treatment

#### 4.1. Urethral bulking agents (UBAs)

UBAs or “injectables” are substances – either natural or synthetic – that are injected periurethrally for the treatment of stress urinary incontinence. Classically they have been used in case of ISD. Their function is to increase

urethral resistance by filling the periurethral space, and possibly to increase urethral support [24].

Although a minimally invasive therapeutical option should be attractive for this non-lethal medical condition, bulking agents have up until now never become a great success. There are several reasons for this fact. First, there is a lower success rate compared to the other surgical procedures [25]. Second, their efficacy in the long term is limited [26], leading to reinjections and with it a reduced cost-effectiveness. Finally, many UBAs have been associated with complications like allergic reactions, tissue migration or formation of (sterile) abscesses [26].

The most widely used UBA was Contigen, which consisted of bovine collagen. It was used for over 20 years with dry-rates of about 30% (range 10%–83%) [27]. The product has now been withdrawn from the market because of supposed allergic reactions related to the procedure, but several alternatives are currently available. The main differences of the alternatives are the material used, the intended injection location and the route and way of application. No bulking agent has ever been proven to be superior to the other [25], nor has the injection route (either trans- or paraurethral). The preferred position of the bulking agent is at the level of the midurethra [28].

Most of the UBAs consist of a biodegradable carrier gel which contains particles of some sort. The gel is degraded by the body and scar tissue should be formed around the particles to create a permanent effect. Due to the degradation of the gel however, the effect mostly diminishes over time.

Although improvement has been made, the ideal bulking agent has not yet been found. It should be durable, biocompatible, hypoallergenic, deformable, non-immunogenic, with minimal inflammatory response and should cause no migration [29]. Developments in this field are continuously happening and especially in older patients or patients that cannot undergo surgery, this can be a valuable treatment option [30]. The latest EAU-guideline on incontinence gives a grade A recommendation, based on expert opinions, that bulking agents should not be offered to women seeking a permanent cure for SUI [6].

## 5. Surgical interventions

After failure of conservative treatment(s), surgery should be considered as a therapy for female stress urinary incontinence. Traditionally, surgical treatment consisted of (open) colposuspension following a Marshall–Marchetti–Krantz (MMK) or Burch procedure. In case of unsuccessful outcome of these surgical technique, pubovaginal slings were used. Many sling-procedures were performed, the earliest over 100 years ago; McGuire made improvements to the procedure, leading to increased popularity of this method from the late 1970s.

With the introduction of the tension-free vaginal tape in 1996, followed by transobturator tape in 2001, surgical treatment of SUI changed radically. With these relatively simple and highly effective procedures, many women were treated and the midurethral sling soon became the reference standard. As stated before, there are now even studies indicating that in some patients surgical treatment

might be eligible as a primary treatment, even before conservative management like PFMT [23].

Development did not stop after 2001. Driven by the search for less complications and more minimally invasive procedures, mini slings and single incision slings have been developed. Furthermore, in the last years vaginal meshes used for prolapse have developed a negative reputation because of complications, which has reflected upon the synthetic slings used for SUI. Whether justified or not, in the past years there has been a shift to non-synthetic slings and the number of revisions and removals of tapes has increased almost three-fold in the USA [31]. Considering these developments, the need for alternative treatments remains topical.

### 5.1. Bladder neck colposuspension

The bladder neck colposuspension is designed to theoretically stabilize the urethra and reposition the bladder neck and proximal urethra intra-abdominally. By restoring the anatomy, pressure transmission from abdomen to urethra during moments of increased intra-abdominal pressure can be improved, leading to a better continence.

Several procedures and techniques are available. They can be performed either open, laparoscopically or robot-assisted. According to the ICI the medium to short-term outcomes are comparable in terms of subjective outcome (evidence level 2) [7], there is however a lack of long-term data for laparoscopic techniques. Furthermore, the objective outcomes seemed to be inferior [32]. Absorbable or non-absorbable sutures can both be used. The effect of the procedure depends on the fibrosis resulting from it. Some surgeons prefer absorbable sutures, to avoid early resorption, before enough fibrosis has occurred.

The MMK procedure was the first open colposuspension described in 1949 [33]. It is a form of retropubic colposuspension, in which the urinary bladder and urethra are suspended to the periosteum of the symphysis pubis. On both sides of the urethra, three pairs of sutures are placed. The sutures include tissue of the vaginal wall and the lateral urethral wall, whilst sparing the mucosa of both. Although successfully used for a long period of time in the treatment of incontinence, complications did occur in about 20% of the patients [34]. When placed in the wrong place, sutures can damage the urethra, obstruct the bladder neck or they can paradoxically open it, leading to persisting or worsening SUI. The most serious complication observed in 0.9%–3.2% of patients was osteitis pubis [34]. The morbidity associated with the MMK procedure led to the development of modifications of the procedure. As colposuspension according to Burch has become the most performed procedure, we will not discuss the success or failure rates here.

### 5.2. Burch colposuspension

Colposuspension according to Burch is a modification of the MMK procedure, first described in 1961. In this procedure the paravaginal fascia is not attached to the periosteum of the pubic symphysis, but to Cooper's ligament. This decreases the risk of osteitis pubis.

Both procedures have relatively high subjective and objective cure rates. In a recent Cochrane review (2016) about open retropubic colposuspension, which included 55 trials and 5417 patients, the cure rates were 70%–90%. The effect tends to diminish from 85% to 90% after 1 year to 70% after 5-year follow-up [35]. Because of less complications, the Burch procedure has become the colposuspension of first choice and made the MMK procedure obsolete. The MMK is therefore no longer recommended for treatment of SUI by the 5th ICI consultation on incontinence (2013) [7]. Together with pubovaginal slings, Burch colposuspension is recommended (Grade A) by the latest EAU-guidelines as a treatment in case midurethral slings (MUS) are not eligible [6].

### 5.3. Pubovaginal slings (PVS)

Although used for over more than 100 years, PVS have never been a treatment of first choice. They have classically been used after failure of colposuspension or nowadays the (synthetic) midurethral slings. There remains however an indication for the use of this type of sling, especially considering the negative publicity around complications of synthetic material used for reconstruction of the female pelvic floor. PVS can be used in case of intrinsic sphincter deficiency, regardless whether urethral hypermobility is present or not.

Many different techniques have been described, using many different materials. Materials can be autologous, allograft, xenograft or synthetic. The autologous materials most commonly used as a graft are the rectus fascia or fascia lata, of which a sling of >8 cm length and >2 cm width is obtained. They are placed at the bladder neck, in contrary to the newer generation of midurethral slings, leading to urethral coaptation and a better continence.

Because the pubovaginal slings are usually applied more firmly than the tension free alternatives, it is advisable to teach patients clean intermittent catheterization before surgery and to keep at least a space two fingers wide between the sutures of the sling and the fascia used. Furthermore one should perform urethrocytostcopy after the procedure to check for possible bladder perforation [36].

Available literature shows a good effect of these procedures on incontinence. In a summary of the results of 23 studies with 2341 patients, a cure rate of 46%–97% was found with autologous slings [37]. The sling made from autologous rectus fascia seems to be an effective and durable treatment. For many other PVS there is not enough reliable data available to draw any conclusions about the effect or feasibility of these procedures. In the latest Cochrane review of 2011 [38], seven studies compared PVS with Burch. Although evidence was in most cases poor with a short follow-up, the cure rates were comparable for both interventions. A systematic review and meta analysis from Schimpf et al. [39] showed evidence that PVS has a superior cure rate compared to Burch colposuspension based on 4 RCTs. This was not the case when PVS was compared to (retropubic) MUS. Based on five lower-quality RCTs, an inferior subjective cure with PVS is observed. In contrary, a recent British multicentre RCT between tension free vaginal tape (TVT), autologous fascia sling (AFS) and

xenograft sling in 201 women, concluded no differences in long-term success rates between AFS and TVT. There was however some evidence that the long-term dry-rates of the AFS may be superior. When comparing the outcomes of MUS and PVS one should of course take into account that the PVS procedure is more invasive because of harvesting of the graft material and more time consuming.

The main complications of the PVS are erosion and extrusion to urethra and vagina and *de novo* urgency and urge incontinence. With autologous or biomaterial grafts the risk for erosions is considerably lower than with synthetic slings.

In recent years there has been an increase in PVS procedures performed, especially in the USA [31]. Due to the non-inferior clinical outcomes compared to synthetic slings and Burch and the fact that autologous material is preferred above synthetic, the pubovaginal slings have an ever relevant place in the treatment of female stress urinary incontinence.

### 5.4. Midurethral slings

#### 5.4.1. Retropubic tapes

Introduced in 1996, this first version of a midurethral tape has become a revolutionary success in the treatment of female SUI. Based on the integral theory posed by Petros and Ulmsten [40], the tape is positioned on the middle, high pressure part of the urethra, mimicking the function of the pubourethral ligament. As the name suggests, the arms of the slings are positioned in the retropubic space. The majority of tapes consist of polypropylene, a material that shows less erosion than previously used materials like polyethylene or polytetrafluoroethylene. The sling should furthermore be macroporous, with a pore size of >75  $\mu\text{m}$ .

The procedure is less invasive than colposuspension or a pubovaginal sling. Operating time is shorter, recovery time is shorter and the outcome is as good as the more invasive procedures. In a systematic review by Ford et al. [41], 81 trials with 12 113 women were included, who all received a sling treatment for SUI or MUI. The short term subjective success rates of this procedure lie between 71% and 97%. Long-term (>5 years) results based on four articles (714 patients) in this review were lower with 51%–88%. In a French retrospective study in 463 women with a mean follow-up of 71 months 74% reported subjective cure, 12% was improved and 14% had treatment failure [42].

Complication levels after the procedure are acceptable. In a retrospective study after the complications of TVT by Kristensen et al. [43], 778 procedures were analyzed. The most common intra-operative complication was bladder perforation (6.6%). Postoperatively voiding difficulty (56%) and urinary retention (16.6%) were most commonly seen.

#### 5.4.2. Transobturator tapes

In an attempt to decrease the risk of complications associated with the retropubic tape (bladder perforation, vascular injury), the transobturator tape was introduced in the beginning of this millennium. It is, like the retropubic tape, implanted tension-free at the level of the mid-urethra. The arms of the sling are however positioned in the

obturator foramen, puncturing the adductor muscles. It can be introduced outside-in (*i.e.*, introduction through an incision in the groin), or inside-out (*i.e.*, introduction through vaginal incision and exit through groin). None of these techniques is superior to the other [41,44].

The subjective cure rate of the combined transobturator procedures is 62%–98% after a follow-up of 1 year. The long-term effect (>5 years) lies in the range of 43%–92% [41]. In a multicentre prospective study after tension free vaginal tape – obturator (TVT-O) in 160 women, a follow-up of 10 years was reached [44]. In this study, there was a subjective cure rate of 97% and the objective cure rate was 92%. This indicates that satisfying long-term results can be achieved with this procedure.

Compared to more invasive procedures like Burch colposuspension and pubovaginal slings, the risk of complications with MUS is low. However, especially now studies with larger groups of patients with a longer follow-up are being published, there are side effects of these procedures. The complications observed with retropubic and transobturator tapes together are: *de novo* urge and urge-incontinence (8%), postoperative voiding difficulties (6%), chronic pain (5%), vaginal erosion (2%) and bladder perforation (3%) [41]. The clinical effectiveness of both retropubic and transobturator is comparable, as are the route of introduction (inside out or outside in). There is a difference in types of complications. Considering the effectiveness and safety of both procedures, there is no strong indication for either one of the slings or routes. Groin pain and sexual dysfunction are more common after the transobturator approach [45], bladder perforation tends to occur more often using the retropubic route as were post-operative voiding difficulties. It is recommended to discuss the side-effects of both therapies with the patient and to choose a type of sling based on patient preference. Also in redo cases the retropubic route is recommended by most guidelines. Studies show that this can also be highly effective [46].

#### 5.4.3. Single incision mini slings (SIMS)

The SIMS are a shorter version of the conventional mid-urethral slings described earlier. The first mini sling was introduced in 2006 and since that time many different products were marketed. They are all developed based on the theory that they are shorter and require no blind passage of a needle through the obturator foramen or the retropubic area. Furthermore there is need for only one vaginal incision in the midline, no other skin incisions are necessary. These properties should lead to a reduced risk of damaging anatomical structures and the morbidity associated with this damage. The main differences between the mini slings are the lengths and the anchoring systems. Usually the mini slings are anchored to the pubocervical fascia.

After introduction the objective and subjective cure of SIMS at the mid- and long-term first appeared to be inferior to the MUS. This even led to withdrawal of the widely investigated TVT-Secur. Recent reviews do however conclude that there is no significant difference in (midterm) cure for SIMS compared to MUS [47]. The duration of the operation is usually shorter, the recovery is faster and postoperative pain is less, as are intraoperative

complications like erosions and peroperative blood loss, according to the EAU guidelines (level of evidence: 1B) [6].

One of the SIMS with a different approach to placement is the SIMS-Ajust, which is used since 2009. One anchor of the arms of this midurethral sling makes intraoperative adjustment of the tension of the tape possible. After adequate tensioning the tape is secured. In a meta-analysis from 2015, Zhang et al. [48] found five RCTs with a total of 678 patients comparing SIMS-Ajust with TVT-O and TOT. They reported, based on these studies, that there was no significant difference in subjective ( $RR = 0.95$ , 95%CI: 0.87–1.04,  $p > 0.05$ ) or objective ( $RR = 0.97$ , 95%CI: 0.90–1.05,  $p > 0.05$ ) cure rates. The complication rates are also not significantly different, making a shorter operating time the main advantage of this procedure. The long term outcome with the SIMS-Ajust is still unknown.

The latest Cochrane review concludes that there is not enough evidence to make a reliable comparison between SIMS and MUS [49]. More RCTs are necessary, data from one study can not be used to draw conclusions about other products because of different lengths and anchoring techniques. Even if future research shows lower efficacy this does not mean that there is no place for SIMS in the treatment of female SUI. Research shows that if postoperative pain can be prevented by a less invasive procedure, patients are willing to accept slightly lower cure rates [50].

### 5.5. Artificial urinary sphincter (AUS)

The AUS was first developed about 40 years ago. It has gradually evolved to the implantable medical device we know today, that consists of three main items. There is an (mostly abdominal) pressure regulating balloon, a cuff that is placed around the urethra, and a little pump in the labia that can be switched to inflate the cuff. The different parts consist of a silicone elastomer and are connected through a liquid-filled system. By mechanically closing of the urethra, sphincter function is simulated and stress urinary incontinence can be treated.

It is used mostly in case of intrinsic sphincter deficiency and after failure of other less invasive procedures. In male post-prostatectomy, sphincter implantation is much more common. It is estimated that of all the AUS implanted, only 1% is implanted in women. The procedure can be performed transvaginally, retropubically/trans-abdominally and open or laparoscopically. No randomized controlled trials have been performed after the ideal route of transplantation. The retropubic route is however considered the most eligible, as the transvaginal route is associated with higher morbidity and infection rates [51]. Some recent research shows that robot assisted laparoscopic implantation possibly leads to less complications [52].

The overall rates of cure or improvement are 76%–89%. In recent years more data about the long-term effect are being published. After 20 years 11 out of 34 women still had successful outcomes [53]. In the same group of patients 26 out of 34 patients had the implant still in place.

Explantation can be necessary in case of device failure or severe complications. Device failure was reported to be as high as 15% [54]. Complications include among others erosion (15%) and infection (4.8%) [55]. Urethral atrophy

occurs frequently, but for female patients there is a lack of data on the incidence of this complication [55].

Because of the risk of complications and device-failure, an AUS is mostly a therapy of last resort in women. Furthermore implantation is reserved for specialized centers. If it is nevertheless considered, patients should be informed about the risk of complications. In case of successful treatment, the effect can be durable for years. Lifelong follow-up is often necessary.

## 6. Conclusion

The widely prevalent medical condition of stress urinary incontinence has been treated over a century in many different ways. The first non-conservative treatments were large open colposuspensions, later followed by pubovaginal slings. Both techniques were refined to acceptable treatments with a good effect on incontinence, albeit with side effects.

Treatment of SUI changed radically after introduction of the significantly less invasive midurethral synthetic slings. Although also these procedures are continuously being refined by for example development of the single incision mini slings, the MUS is still the reference standard for treatment of uncomplicated SUI. Single incision mini slings still have to prove their – especially long-term – efficacy.

In the last years there is more attention for the drawbacks of the synthetic midurethral slings and the position of the older surgical techniques is reconsidered. This led to an increase in colposuspensions performed and autologous pubovaginal slings placed. These techniques are recommended when slings are not eligible. The artificial urinary sphincter can be a therapy of last resort, that is very rarely placed, mainly due to complications and device failure.

## Conflicts of interest

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