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Management of female stress urinary incontinence: A care pathway and update



Giampiero Capobianco^{a,*}, Massimo Madonia^b, Sonia Morelli^a, Francesco Dessole^a, Davide De Vita^c, Pier Luigi Cherchi^a, Salvatore Dessole^a

- ^a Gynecologic and Obstetric Clinic, Dep. of Clinical and Experimental Medicine, University of Sassari
- ^b Urologic Clinic, Dep. of Clinical and Experimental Medicine, University of Sassari
- ^c Chronic Pelvic Pain Centre, Dep. of Obstetrics and Gynaecology, Ospedale S. Maria Della Speranza, Battipaglia, Italy

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ABSTRACT

Stress urinary incontinence (SUI) is a condition characterized by an involuntary loss of urine occurring as result of an increase in intra-abdominal pressure due to effort or exertion or on sneezing or coughing. Estimates of its prevalence in the female population range from 10% to 40%.

A literature search of the Medline, Cochrane library, EMBASE, NLH, ClinicalTrials.gov and Google Scholar databases was done up to July 2017, restricted to English-language articles, using terms related to SUI, medical therapy, surgical therapy and treatment options. The search terms included female stress urinary incontinence, mid-urethral sling, tension-free vaginal tape (TVT) and transobturator tape (TOT, TVT-O). Original articles, reviews and meta-analyses were included.

Surgical therapy should be considered only after conservative therapies (e.g. an exercise programme or topical estrogens) have failed. Synthetic mid-urethral slings are the gold standard for the surgical treatment of SUI according to the 2016 guidelines of the European Society of Urology (ESU) and the 2017 position statement of the European Urogynaecological Association (EUA).

The therapeutic options are numerous but further research into new therapeutic strategies is needed to achieve a better balance between efficacy and adverse events.

1. Introduction

Urinary incontinence is defined as a condition of involuntary loss of urine [1]. The three most common types are: (1) stress urinary incontinence (SUI), characterized by an inadvertent loss of urine occurring as a result of an increase in intra-abdominal pressure due to effort or exertion or on sneezing or coughing; (2) urge urinary incontinence (UUI), denoting involuntary leakage arising for no apparent reason and associated with urgency; (3) mixed urinary incontinence (MUI), denoting the combination of both SUI and UUI.

SUI has a negative impact on social and working life and is associated with poor mental health [2]. According to Hunskaar et al. [2] the prevalence of each type of urinary incontinence in noninstitutionalized women is 49%, 21% and 29%, respectively. Other estimates of the prevalence of SUI range between 10% and 40% of the post-menopausal female population. The reported rate depends on the definition used (e.g. whether the involuntary loss of urine occurs several times in a day or in a week, or whether the last 12 months is specified), on the survey

methodology (e.g. telephone interviews or postal questionnaires) and on differences between study populations (e.g. country of residence).

The objective of this review is to report the state of the art in the management of female stress urinary incontinence.

2. Search strategy

A detailed literature search of the Medline, Cochrane library, EMBASE, NLH, ClinicalTrials.gov and Google Scholar databases was done up to July 2017, restricted to English-language articles, using terms related to SUI, medical therapy, surgical therapy and treatment options. The search terms included female stress urinary incontinence, mid-urethral sling, tension-free vaginal tape (TVT) and transobturator tape (TOT, TVT-O). Original articles, reviews and meta-analyses were included. Studies exclusively of devices no longer available on the market were excluded. Three of the authors (GC, MM and SM) selected the studies independently on the basis of the inclusion criteria. Disagreements among authors over the studies to include were resolved

^{*} Corresponding author at: Gynecologic and Obstetric Clinic, Sassari University, Dep. of Clinical and Experimental Medicine, Viale San Pietro 12, 07100, Sassari, Italy. E-mail address: capobia@uniss.it (G. Capobianco).

by discussion. In cases of duplication, the study with the most recent data was included. For cohort studies with multiple publications, the latest dataset on efficacy was used.

3. Pathogenesis of SUI

Urinary continence depends on a synergy between the structures that constitute the pelvic floor, the sympathetic and parasympathetic nervous systems, and the motor fibres of the pudendal nerves. An alteration in one or more components can lead to an inability of the urethra to counteract increases in abdominal pressure, even minimal increases in the most severe cases. Consequently, involuntary loss of urine can occur during physical exercise, for example.

Factors that predispose to SUI are age, parity (especially with vaginal delivery) and obesity, as they are associated with a weakening of the pelvic floor support structures, resulting in urethral hypermobility. Parity can further predispose to SUI through its effects on bladder and urethral innervation, resulting from the stretching or compression of nerves during the passage of the fetus through the birth canal [3,4].

4. Conservative treatment of SUI

Fig. 1 shows the initial management of urinary incontinence in women and Fig. 2 the specialized management as recommended by the European Association of Urology (EAU) in its guidelines [5]. The main options include exercises aimed at restoring the strength and muscle tone of the pelvic floor, and estrogenic therapy. An intervention that has proven to be effective as a first therapeutic step is triple therapy with vaginal *Lactobacilli acidophili* and estriol plus pelvic floor exercises [6]. Fig. 3 shows the care pathway for women with SUI.

4.1. Drugs for SUI (duloxetine)

Duloxetine has been approved in Europe for the treatment of SUI. Its adverse effects include mental health problems and suicidality. Duloxetine has been shown to be effective for SUI in women but the associated harms are reported to outweigh the benefits [7].

Furthermore, the UK National Institute for Health and Care Excellence recommends that duloxetine should not be used as a first-line treatment or routinely offered as a second-line treatment for stress

urinary incontinence, given that pelvic floor muscle training is more effective and less costly than duloxetine and that surgery is more cost-effective than duloxetine [8].

4.2. Laser therapy

Laser therapy has been introduced as a non-invasive treatment of SUI. It is also used for the treatment of vaginal disorders associated with menopause, notably vaginal atrophy. The lasers used in gynaecology are mainly of two types, the $\rm CO_2$ laser and the vaginal erbium ER:YAG laser (VEL) (so-called because it uses an erbium yttrium-aluminium-garnet medium). The latter, although it lacks the microablative function of $\rm CO_2$ lasers, can induce changes in genital tissues that counter vaginal dryness and dyspareunia. It has been used in the treatment of mild and moderate SUI, with a significant reduction in self-reported symptoms [9–12].

The mechanism of action is attributed to the remodelling which occurs due to a thermogenic effect on the collagen that constitutes the pelvic floor; with menopause, a drastic reduction in the production of collagen occurs, thus resulting in a decrease in its physiological function of support, causing not only urinary incontinence but also the onset or aggravation of prolapse of the genital organs. The thermogenic effect induces in the target tissues a neoangiogenesis, neoformation of collagen; it also increases epithelial thickness and the cellular glycogen content. This ensures greater support for the urethra. All these tissue changes are detectable for at least six months after treatment [10].

The first studies of laser therapy in the treatment of SUI were done by Fistonić's research group [11]. They used the Incontinence Questionnaire—Urinary Incontinence Short Form (ICIQ-iu SF) to evaluate the efficacy and safety of the ER:YAG laser and found that even in severe SUI there was a significant improvement in symptoms, without any particular adverse events being recorded. The efficacy of the treatment is apparent after a single session, but increases with three sessions, and the benefits last for at least six months [11].

Although there not enough studies that have investigated the long-term efficacy of laser therapy, it appears clear that it does represent a therapeutic option, as it is minimally invasive and objective benefits have been demonstrated, with regard not only to SUI but to the whole spectrum of symptoms of the genitourinary syndrome of menopause (GSM).

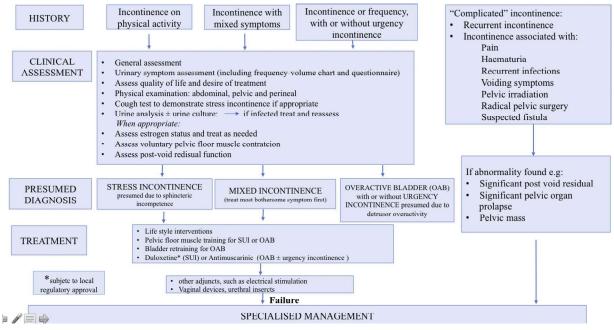


Fig. 1. Initial management of urinary incontinence in women [5].

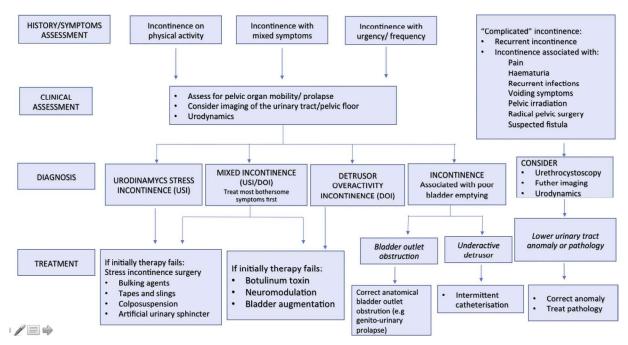


Fig. 2. Specialized management of urinary incontinence in women [5].

Gambacciani et al. [12] evaluated the effects of ER:YAG laser therapy on the symptoms associated with menopause and found that the patient-reported subjective benefits were confirmed by objective assessments using the Vaginal Health Index. The therapy was very well tolerated, results could be achieved quickly and the benefits lasted for up to 24 weeks [12]. According to that study, ER:YAG treatment is indicated not only for all women who present the classic symptoms associated with menopause, such as dryness and vaginal atrophy, but also for those women with mild to moderate SUI where hormonal treatments (topical estrogens—see below) are contraindicated, as is the case for women with a history of breast cancer [12].

4.3. Combination therapy: vaginal topical medical therapy and pelvic floor rehabilitation

Estrogen receptors are present throughout the genitourinary tract and in the pelvic floor musculature [13]. Estrogens have an important role in the mechanism of urinary continence since they affect the synthesis of collagen; their topical vaginal administration can also act by reducing the frequency and amplitude of detrusor contractions, by increasing the sensory threshold of the bladder and by promoting relaxation of the detrusor muscle [14]. These estrogen-dependent mechanisms explain why with the fall of estrogen levels after the menopause, disorders of the urogenital apparatus, including SUI, become so

Care pathway of female Stress Urinary Incontinence (SUI) Characterisation severity of the condition Careful medical history Women with stress urinary Exclude UTI, diabetes incontinence (SUI) Quality of life assessment and bladder diaries Urodynamics In moderate to severe SUI: first step local therapy and pelvic floor rehabilitation for at Lifestyle modifications, pelvic floor rehabilitation and local least 3 months. therapy for at least 3 months in mild SUI When failure, depending on patient condition: Laser therapy in mild-moderate SUI Bulking agents in patients whit comorbidities that preclude Surgical therapy with midurethral sling surgery

Fig. 3. Care pathway for urinary incontinence in women.

frequent. Estrogenic therapy, in particular estriol, has been shown to be of value in the treatment of urogenital disorders [15]; moreover, it is free of proliferative effects on the endometrium. Intravaginal local therapy with estriol has proven to be effective in the treatment of urogenital atrophy, recurrent infections of the lower urinary tract and SUI after the menopause [16,17], especially when combined with exercises aimed at improving pelvic floor muscle tone [17]. But the effects of combination therapy are not probably not long term.

5. Surgical therapy

The first surgical options included: the retropubic Burch colposuspension (initially abdominal but superseded by the laparoscopic approach) [18], which was widely used until about 15 years ago; anterior colporrhaphy; and needle suspension. These have now mostly been replaced by new minimally invasive surgical techniques (see below) of mid-urethral slings (MUSs), as well as retropubic tension-free vaginal tape (TVT) and trans-obturator (TVT-O) tape, which are not considered further in this review because of a lack of recent data. Neither have we included in this review autologous fascial slings, because there have been no recent high-quality publications relating to these. Another surgical therapeutic option is the injection of urethral bulking agents (UBAs).

The treatment of the SUI should be individualised with careful assessment of symptoms and concomitant factors that may preclude the use of surgery, even minimally invasive techniques. Preoperative counselling should include discussion the benefits and potential harms of the procedure.

5.1. Mid-urethral slings (MUSs)

The most effective approach, after conservative therapies have been unsuccessful, are mid-urethral slings, which were introduced in the 1990s. These have similar efficacy to the laparoscopic Burch colposuspension but have the advantages of a shorter period of hospitalization and fewer postoperative complications [19].

The slings can be made of autologous material, formed from tissue taken from the fascia lata or from the rectus abdominis fascia, or artificial meshes, usually polypropylene monofilament macroporose; in both cases they are introduced by a small vaginal incision and placed "tension free" in order to guarantee support of the middle urethra. The current trend is to use artificial meshes, as these produce lower rates of reaction and postoperative complications [20].

The two most common current techniques use tension-free vaginal tape (TVT), introduced in the 1990s by Petros and Ulmsten [21,22], in which the mesh is introduced by vaginal incision, then directed towards the retropubic space, and then passed out from the abdominal wall into the suprapubic area. More recently, trans-obturator tension-free vaginal tape (TVT-O) has been used, in which the mesh passes through the obturator foramen. Depending on how the needles are inserted during the placement of the sling, we can characterize the TVT-O (trans-obturator) technique as inside—out (as the needle, bilaterally, goes from the vaginal incision through the obturator membrane, and then comes out laterally in the genitocrural fold), and the TOT technique as out—inside (as the needles go from an incision a few centimetres from the genitocrural fold and come out in the vaginal incision).

The use of the retropubic mid-urethral sling (RP-MUS) with TVT has a higher risk of bladder injury than with TVT-O [23]. Other possible complications of TVT are urinary tract lesions, urinary tract infections and abnormal bladder voiding (defined as a post-voiding bladder residual of more than 150 ml). Occasionally, vascular lesions may occur during the placement of the sling due to the passage of the guide trocar in the retropubic space, or intestinal lesions, the risk of which is increased in women who have had previous abdominal or pelvic surgery. An indication for the retropubic technique is where the SUI is not due to urethral hypermobility, but to intrinsic sphincter deficiency (ISD) with

a fixed urethra: in such cases it was found to be more effective than the trans-obturator technique [24].

A refinement of the MUS is the passage of the sling through the obturator foramen, as in the TVT-O procedure, developed precisely to avoid some of the major complications of the retropubic pathway noted above [25]. Another advantage of TVT-O compared with the retropubic technique is the shorter operation time, only 15 min on average, and a reduction in the period of hospitalization required; on the other hand, patients may report pain more frequently, especially in the inguinal site, than with the TVT technique [26].

A modified form of the TVT-O procedure uses TVT-Abbrevo^{*}, in which a shorter piece of mesh, only 12 cm long, is used with the inside—out technique (from the vaginal incision, coming out laterally to the genitocrural fold). Moreover, in the TVT-Abbrevo^{*} procedure, the obturator membrane [27] is not perforated with the guide scissors. Capobianco et al. [28] studied a sample of 56 patients submitted to SUI correction by the TVT-Abbrevo^{*} technique and followed them up at 12 and 24 months postoperatively. Twelve months after the procedure, 76.6% of patients had regular urodynamic function, 17.86% had a significant improvement in their symptoms and only 1.78% of the patients examined had a "de novo" overactive bladder. The benefits obtained were classified in terms of both the patient's subjective wellbeing and objective measurements with urodynamic studies, Q-tip test, and stress test with cough. Excellent results were noted in the long term and the safety profile was good [28].

Both TVT and TVT-O are associated with high long-term success rates [29], with similar results between the two techniques, as demonstrated by a recent Italian meta-analysis of 49 studies [30]. However, there are differences in the complications associated with the TOT and TVT procedures; for example, retropubic MUS has a higher rate of bladder perforation than TVT-O [23,30]. Moreover, in the UK and elsewhere there has been publicity, and legal action, relating to a small percentage of women undergoing TVT procedures who have had complications such as erosion and pain.

5.2. Single-incision mini-sling (SIMS)

The mini-sling represents the third generation of mid-urethral slings. They require a single vaginal incision for entry and use less mesh. It has been debated whether or not obese patients are suitable for this type of treatment, but a recent study showed that body mass index (BMI) did not affect the outcome (efficacy) of treatment with minislings [31].

5.3. Urethral bulking agents (UBAs)

An alternative to sling surgery is the injection of urethral bulking agents (UBAs), as it is less invasive. This is recommended for the elderly, those at high anaesthetic risk and women who are reluctant to undergo sling surgery [32,33]. Injected into the submucosa, UBAs thicken the urethral walls and elevate the urethral mucosa, thus restoring continence and urethral resistance [33,34].

Many agents are available for injection, but the ideal choice should be biocompatible, durable, non-migratory and hypoallergenic, while evoking healing with minimal scarring [35]. UBAs can used in women who have already undergone surgery without benefit.

The American Urological Association recommended the use of UBAs in elderly patients, in patients at increased risk from anaesthesia and in patients who refused a more invasive procedure [36]. In addition, the National Institute for Health and Care Excellence (NICE) [37] suggests that UBAs are indicated in patients with significant reduction in urethral mobility and in patients who have a history of failure with conservative treatment of their SUI [36].

Over the years, several materials have been tested, including paraffin, autologous grease, polytetrafluoroethylene, glutaraldehyde combined with bovine collagen, porcine dermis and plant materials rich in

hyaluronic acid. These substances were then abandoned due to health problems, adverse events, marked hypersensitization reactions and migration from the injection site [38]. The most commonly used substances today are polydimethylsiloxane (Macroplastique[®]) and polyacrylamide gel (Bulkamid*). Both are implanted in the urethral submucosa and exert a mass effect, thus increasing the urethral sphincter pressure and consequently urinary continence. The main advantage of using these agents is that they are less invasive than traditional surgery [39]. For example, polydimethylsiloxane is indicated in the treatment of SUI that is due to intrinsic sphincter deficiency (ISD). The substance is implanted during cystoscopy, about 1 cm from the urethral origin, to restore the urethral sphincter function [40]. The subjective and objective benefits have been recorded with urodynamic studies, 24-h pad tests and number of incontinence episodes during the day [41]. It is also possible to repeat the treatment (after a sufficient interval), either to consolidate the benefits obtained with the first injection or to treat symptoms that have persisted after the first treatment.

Bulking agents are, ultimately, safe in the treatment of SUI and the because of the low incidence of side-effects are indicated for women with comorbidities that preclude sling surgery [42]. Recently, a new silicone-derived elastomer, Urolastic*, was introduced; a few minutes after injection into the paraurethral tissue it undergoes a change from the liquid state to the solid state, thereby supporting the urethra. It has been shown to have good biocompatibility and little risk of migration from the injection site, which means it offers long-term improvement in clinical symptoms [43].

6. Recurrent stress urinary incontinence (RSUI)

The prevalence of voiding dysfunction, including urinary retention, following mid-urethral sling (MUS) procedures, ranges from 2% to 25%, and a surgical intervention is required to resolve the problem in 0–5% of patients, according to Smith et al. [44]. The reported proportion of patients who require a second surgical intervention for RSUI varies, however [45,46]. Jonsson Kunk et al. [45] reported a cumulative recurrence of 14.5% among over 155,000 patients examined nine years after primary surgery; the type of repeat surgery performed was sling (70.5%), followed by bulking agents (20.1%), Burch (6.5%), laparoscopic (1.5%), needle (0.8%), total vaginal hysterectomy (0.5%), and Kelly (0.2%) [45]. Fialkow et al. [46] reported 8.6% recurrence among 40,000 US women who underwent either a sling or retropubic colposuspension (Burch) for SUI. In a recent retrospective study [47] 6% of women were retreated within 5 years of their initial standard anti-incontinence procedure (Burch and sling procedures).

Risk factors for recurrent or persistent urinary incontinence after surgical treatment include age, obesity, medical comorbidities (e.g. diabetes mellitus), previous high-grade incontinence, mixed urinary incontinence and previous failed surgery [48].

Which of the operative techniques for female recurrent stress urinary incontinence is the most efficient and safest is still being debated; there is no consensus and there are few data to guide the choice of type of surgery for persistent/recurrent SUI. The choice of procedure should be individualized and account should be taken of the severity and type of symptoms, medical comorbidities and the type of previous surgery. Nonetheless, a second anti-incontinence procedure is effective in many women with persistent/recurrent SUI.

MUS surgery appears to be a good choice. A meta-analysis of 12 prospective studies with a total of 430 women reported good results, where the women had previously undergone either a sling procedure or other procedures such as Burch colposuspension. The cure rate was 79% after any previous surgery and 73% after a prior mid-urethral sling [48,49]. Cure rates seemed to be higher for TVT than for TOT midurethral slings (80% versus 54% after any prior surgery); however, the numbers undergoing TOT procedures were too small for firm conclusions to be drawn [49].

The previous procedure may play a role in the choice of further

treatment, in that repeated retropubic TVT seems to offer better results than TOT following a failed primary TVT [50,51].

A retrospective study by Cerniauskiene et al. [52] compared 45 women with recurrent SUI after a Burch colposuspension, TVT and TOT. The second surgical intervention was Burch colposuspension, or TVT or TOT procedures. No differences were found in the outcomes with the different techniques. Nevertheless, minimally invasive techniques undoubtedly had many advantages over the Burch colposuspension and nowadays TVT and TOT procedures are the first-choice interventions for recurrent stress urinary incontinence. Repeat surgery seems, though, to be associated with a higher risk of intraoperative complications and a lower success rate than initial surgery [53].

Regarding medical treatments, there is no current evidence on the efficacy of conservative management of SUI for women with persistent/recurrent symptoms after surgical therapy. In general, however, conservative measures are not as effective as surgery and should be mainly considered in women who decline or are otherwise not candidates for surgery.

UBAs are an option for women with persistent SUI. They are normally reserved for women who wish to avoid or cannot tolerate an invasive procedure. In a retrospective review of 165 women who had recurrent SUI after undergoing a synthetic mid-urethral sling procedure, UBAs had a higher risk of failure than a repeat sling procedure [54]. UBAs were used in the treatment of 67 patients, while the other 98 underwent a repeat sling procedure. The former group had a worse outcome (38.8% failure rate) than those who underwent a repeat sling procedure (11.2%) [54]. Furthermore, injections often need to be repeated to maintain continence.

7. Experimental therapies for SUI

There are insufficient clinical data about the use of stem cells (autologous myoblasts, muscle-derived stem cells and autologous fibroblasts) injected into the urethra to treat the intrinsic sphincter deficiency [55].

The artificial urinary sphincter [56] in women has not yet been extensively tested or evaluated with controlled randomized clinical trials. This technique is not recommended as a first-line surgical therapy for SUI [56–58].

8. Conclusions

Currently, according to the 2016 guideline from the European Society of Urology and the 2017 position statement from the European Urogynaecological Association (EUA), synthetic mid-urethral slings are the gold standard for the surgical treatment of SUI [59,60]. A recent systematic review and meta-analysis of 28 controlled clinical trials with a total of 15855 patients showed that mid-urethral slings are more effective than the Burch colposuspension and that studies comparing retropubic and trans-obturator sling procedures have shown a higher rate of subjective and objective cure rates with the retropubic technique but also greater risk of complications, such as intraoperative bladder and vaginal perforation (OR: 2.4, p = 0.0002), pelvic hematoma (OR: 2.61, p = 0.002) and urinary tract infections (OR: 1.31, p = 0.04). There was no statistically significant difference in efficacy between the trans-obturator inside-out technique and the outside-in technique, though the risks of vaginal perforation were lower with the inside-out technique [61]. A recent Cochrane Database systematic review by Ford et al. [26] concluded that mid-urethral slings are as effective as retropubic colposuspension, but have a shorter operation time and a lower risk of postoperative complications.

Surgical therapy should be indicated only after conservative therapies (an exercise programme or topical estrogens) have failed.

Further research into new therapeutic strategies is needed in order to achieve a better benefit—risk balance.

There are insufficient data on the long-term efficacy of new

Table 1
Take-home messages on management of female stress urinary incontinence.

Take-home messages	Grade of recommendation
For morbidly and moderately obese women, weight loss helps to reduce UI symptoms Medical therapy and rehabilitation should be the first step of treatment Midurethral slings (MUSs) are the gold standard for surgical treatment TVT and TVT-O have high long-term success rates Urethral bulking agents are recommended in elderly patients, in patients with increased anesthesiological risk and in patients who refuse a more invasive procedure The best therapeutic approach for recurrent stress incontinence (RSI) after a sling failure should be individualized. The best choice could be to	A ⁵ A ⁵ A ^{5,26,59,60} A ⁵ B ^{5,36}
counsel a repeat MUS (retropubic or transobturator) or bulking agents to women with RSI	

A: Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial.

B: Based on well-conducted clinical studies but without randomized clinical trials.

C: Made despite the absence of directly applicable clinical studies of good quality.

interventions, such as laser therapy, but they do appear to have a potential role in the treatment of IUS.

Table 1 shows take-home messages [62].

8.1. Practice points

- SUI is highly prevalent after the menopause.
- Surgical therapy should be considered only after conservative (rehabilitative, local estrogenic) therapies have failed.
- Synthetic mid-urethral slings (TVT and TVT-O) are the gold standard for the surgical treatment of SUI.
- Urethral bulking agents are recommended in the elderly, those at increased risk from anaesthesia and in women who do not wish to undergo a more invasive procedure.

8.2. Future research

- Investigate preventive measures for SUI.
- Define new therapeutic strategies for SUI in order to achieve an ever better balance between benefits and risks.
- Test lighter mid-urethral slings.
- Investigate whether there is a role for stem cells (autologous myoblasts, muscle-derived stem cells and autologous fibroblasts) injected into the urethra to treat the intrinsic sphincter deficiency.

Contributors

Giampiero Capobianco conceived and designed the review, and drafted the manuscript.

Massimo Madonia conceived and designed the review.

Sonia Morelli analyzed and interpreted the data.

Francesco Dessole contributed to the literature review.

Davide De Vita contributed to the literature review.

Pier Luigi Cherchi contributed to data collection and review.

Salvatore Dessole contributed to data collection and review.

Giampiero Capobianco and Massimo Madonia contributed equally to the review.

Conflict of interest

The authors declare that they have no conflict of interest.

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