

Urogynecology Section of the Polish Society of Gynecologists and Obstetricians guidelines on the management of stress urinary incontinence in women

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ABSTRACT

Objectives: The aim was to present an interdisciplinary Guideline of the Urogynecology Section of the Polish Society of Gynecologists and Obstetricians (PSGO) for the management of stress urinary incontinence (SUI).

Material and methods: A review of the literature, including current international guidelines and earlier recommendations of the PSGO Urogynecology Section, about the treatment of SUI was conducted.

Results: Management of SUI is presented. Four lines of therapy were identified: line 1 — the so-called ‘conservative treatment’, which should always be attempted, regardless of SUI symptom severity; line 2 — surgical intervention; lines 3 and 4 — reoperations after unsuccessful surgeries from line 2. The literature reports which provided supporting evidence for this Guideline, including the practical aspects, were discussed.

Conclusions: A systematic review of the guidelines and an analysis of SUI management were conducted. The need for an individualized approach was emphasized.

Key words: urinary incontinence, stress urinary incontinence, conservative treatment, physiotherapy, surgical treatment, midurethral sling, colposuspension

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INTRODUCTION

Stress urinary incontinence (SUI) is defined as involuntary leakage of urine on effort or exertion, or with coughing or sneezing [1, 2]. SUI affects a significant number of women and negatively impacts their quality of life. As many as 75% of older, 44–57% of middle-aged, and 25% of young women report symptoms of urinary incontinence [3].

Objectives

The aim of this publication was to develop a Guideline for the management of stress urinary incontinence, based on the available literature, expert knowledge, and everyday practice.

MATERIAL AND METHODS

In 2005, 2006 and 2010, the expert panel of the Polish Society of Gynecologists and Obstetricians (PSGO) developed guidelines for the diagnosis and treatment of urogynecologic conditions. The present publication is an update of those recommendations, based on the literature reports published between 2010 and 2019, as well as the recommendations of the American Urological Association, the International Urogynecology Association, the European Association of Urology, and the Canadian Urological Association [4].

The literature about the management of SUI, including the current international guidelines, was reviewed. Special attention has been paid to the level of evidence and degree of recommendation of the available data sources. If the literature source seemed insufficient, expert opinions and management protocols were included.

GUIDELINES

First-line treatment: non-surgical treatment

At the first stage of the treatment, it is important to inform the patient about the details of the management which aims to minimize the discomfort associated with urinary incontinence, i.e. the smell of urine, skin irritation due to prolonged exposure to urine, and the feeling of loss of control over one's body. The use of personal hygiene products such as pads and sanitary towels is recommended.

The choice of non-surgical methods should be tailored to the individual needs and symptoms of the patient, and her ability to comply with the therapy. Patient motivation to introduce lifestyle changes and compliance positively affect treatment efficacy.

Among the methods of non-surgical treatment of SUI, the following should be considered:

1. treatment of concomitant diseases and drug modification;
2. lifestyle modifications;
3. treatment and prevention of recurrent urinary tract infections;

4. physiotherapy;
5. supportive devices: pessaries, vaginal tampons;
6. pharmacotherapy.

Second-line treatment: first-line surgical interventions

If the conservative therapy proves ineffective or the physical examination reveals high-grade urinary incontinence, with unfavorable prognosis after conservative management, second-line treatment, i.e., surgery, is recommended.

A. MUS (midurethral sling) procedure, during which the sling is placed in the middle part of the urethra, or retropubic colposuspension (Burch) are the most common first-line surgical treatments.

B. If the tape surgery proves unsuccessful, implant removal and the insertion of a new tape is recommended. Some specialists suggest to perform Burch colposuspension in such cases. In patients with persistent SUI symptoms after Burch colposuspension, MUS may be considered [5–7].

Third-line treatment: second-line surgical interventions

If first-line surgical treatment (usually after both surgeries) proved ineffective or in selected cases, the following are used as second-line surgery:

- a) urethral bulking agents
- b) autologous pubovaginal sling

Fourth-line treatment: third-line surgical interventions

If the first- and second-line surgical interventions prove ineffective, an artificial urethral sphincter and an adjustable compression device may be considered in selected cases.

OVERVIEW OF THE RECOMMENDATIONS

The literature offers a number of effective therapies for SUI, including various types of non-surgical and surgical treatments. Conservative management should be the first stage of SUI therapy [8].

Non-surgical treatment

Conservative management should be attempted in many patients, even if surgical treatment had already been planned. The effectiveness of non-surgical treatment is typically evaluated after 8 to 12 weeks.

The use of protective materials (high absorbency pads and sanitary towels, intravesical catheters which allow for external urine collection) can improve the short- and long-term patient comfort [9]. Appropriate sanitary products are well-tolerated, and women of all ages use them willingly. Product diversity enables the users to adjust the size

as well as the following features: absorption, odor control, anti-allergic properties, etc. (LE 1b).

1. Drug modification may reduce the symptoms of SUI in patients treated for concomitant diseases, e.g., metabolic syndrome, cardiovascular diseases, respiratory system diseases, chronic renal failure, degenerative syndromes, including multiple sclerosis, mental diseases, and depression [10].
2. Educating the patient about lifestyle modifications often results in significant improvement. It also allows the patients to better understand the nature of the disease and, consequently, to treat it more effectively.
 - a) Consumption of fluids containing caffeine or theine (coffee, tea, carbonated drinks) and alcohol beverages

The literature offers no evidence of a linear association between caffeine intake (equivalent to one cup of coffee/day) and the prevalence and severity of urinary incontinence. Only reduction of caffeine intake combined with behavioral therapy was demonstrated to reduce urgency, but it did not reduce urinary incontinence as compared to behavioral therapy alone [11]. Therefore, lower caffeine intake does not reduce symptoms of urinary incontinence (LE2). It is recommended to reduce fluid intake (including fluids which increase diuresis) two hours before bedtime, especially in patients with early morning and night urinary incontinence.

- b) Treatment of overweight and obesity

Overweight and obesity are confirmed risk factors for the development of urinary incontinence. SUI is believed to occur even 4.2-fold more often in obese women as compared to their normal body weight peers [12]. The loss of at least 5% of the initial weight is recommended. According to NICE, weight reduction should be recommended to women with the BMI of $>30 \text{ kg/m}^2$ [13, 14]. Even a slight reduction of the body weight can improve urinary continence in overweight and obese women [15] (LE 1a).

- c) Treatment of constipation

Constipation is a common occurrence in patients with urinary incontinence. According to an observational study in women with urinary incontinence, women with POP, and controls, history of constipation was associated with both, pelvic organ prolapse and urinary incontinence [16]. However, no evidence supports the alleviation of SUI symptoms after reduction of constipation (LE 4).

- d) Physical activity

Regular physical activity can positively affect pelvic floor muscles and reduce urinary incontinence episodes. Resistance training with additional load, high-intensity jumping, e.g., trampolining, as well as high-intensity running should be excluded. Various studies demonstrated elevated risk for developing SUI in active women, especially sportswomen.

There is evidence that women who do sports experience urinary incontinence later in life (LE 3 recommendation) [17, 18]. Nevertheless, proper body weight and higher mobility when accessing the toilet are undeniable benefits of engaging in regular physical activity.

- e) Smoking cessation

No relationship between smoking cessation and improved urine control has been demonstrated. However, smoking-associated cough may increase the intra-abdominal pressure and intensify the symptoms of urinary incontinence [19].

- f) Bladder training

Controlled voiding, scheduled micturitions with gradually extended time intervals between voiding and correct urination habits are elements of bladder training. These techniques are typically used in the management of urgency urinary incontinence, but they also proved to be effective in SUI therapy [20].

3. Comprehensive diagnosis, treatment and prevention of urinary tract infections are important elements of managing patients with lower urinary tract symptoms.
4. Physiotherapy.

The most common physiotherapeutic methods used in the management of SUI in women include pelvic floor muscle training — PFMT (the so-called 'Kegel exercises'), biofeedback, ultrasonography feedback, EMG biofeedback, electrostimulation (superficial, vaginal), and pelvic floor manual therapy [1, 3, 4, 8, 10, 21]. Incorrect physiotherapy may intensify urogynecological symptoms. Professional urogynecological physiotherapy should be initiated after the functional diagnosis. Its effectiveness depends on therapy duration and expert supervision over the therapeutic process [22]. PFMT includes different protocols and principles of this branch of physiotherapy. Separate guidelines for physiotherapeutic management of SUI in women have been presented elsewhere.

5. Supportive devices.

- a) pessaries

Silicone pessaries (urethra and cerclage), with a thickening near the urethra, are usually recommended in SUI therapy. The desired effect is obtained when the thickening of the pessary supports the transition of the bladder and the urethra. The rim of the pessary must be sized so that it does not move and rests along the posterior wall of the vagina. If those pessaries prove ineffective, a cube-type pessary may be used. In such cases, the upper edge of the pessary should be placed under the urethra for support and urine control. A gynecological examination and adjustment of the material, durability, size and shape to the anatomic conditions are necessary to select the appropriate vaginal tampon or pessary. All the measures can be used periodically or remain the only form of conservative therapy (with

the recommendation to change daily). In SUI therapy, the pessaries may be used during the day or whenever needed (LE 2a) [23–25].

b) vaginal tampons

Tampons made of special, flexible, and delicate medical material — PVA (vinyl polymer-polyvinyl alcohol) in the shape of a cylinder or a cube, are used in SUI therapy. The tampon is inserted under the urethra for support. It is recommended to use vaginal tampons only when necessary, which might mean only during sport activities or dancing for some patients, or throughout the day for others [25].

6. Pharmacotherapy of SUI.

Duloxetine, which inhibits the presynaptic re-uptake of serotonin (5-HT) and norepinephrine (NE), can be used in SUI therapy. A meta-analysis of four randomized, placebo-controlled clinical trials reported to the European Medicines Agency, demonstrated that duloxetine was more effective than placebo as far as the rates of weekly incontinence episodes were concerned [26]. Level LE 1a recommendation for duloxetine has been reported by the experts from the European Association of Urology, whereas in the USA, the FDA suspended the registration of this drug for SUI therapy [27]. Duloxetine is not registered for the treatment of SUI in Poland ('off label' use).

A review of the Cochrane database and the available literature indicated improved continence control in a short-term evaluation for vaginal estrogen use (LE 1a). The method of application is easy and safe for the patient. The degree of absorption and of systemic activity is so low that it can be used for short periods even in women after breast cancer treatment. The optimal duration of the therapy has not been determined and should be adjusted to the individual needs of the patient [28–30].

Systemic estrogen-progestogen replacement therapy may intensify the symptoms of urinary incontinence as compared to placebo [31].

Second-line treatment: first-line surgery

First-line surgical treatment of SUI includes: midurethral sling, during which the sling is placed in the middle part of the urethra, or retropubic colposuspension (Burch).

The choice of the procedure should be tailored to the individual needs of the patient, based on the symptoms and diagnostic results, as well as the expert knowledge and surgical experience of the physician. The scope of preoperative diagnostics depends on the symptoms, findings of the clinical examination and the additional tests, the experience of the physician and common practice in a given medical center. It is necessary to evaluate pelvic organ prolapse and the possible treatment methods before or during SUI surgery [32, 33]. These issues have been discussed elsewhere, in the guideline for the surgical management of POP.

MUS

Currently, sling implantation under the middle part of the urethra is based on the use of macroporous tape (type 1 according to Amid's Classification) [34–37]. The tape parameters allow to significantly reduce the risk of exposure as compared to multifilament and microporous materials (higher risk of infection). With the advancements in this area, new materials will likely be used in the future. The method of sling implantation has been modified: the tape can be inserted from the suprapubic side down to underneath of the urethra (rarely used) or passed through the retropubic or the obturator space [38]. Some studies indicated the possibility of improved outcomes of SUI therapy after MUS surgery if the procedure is individualized using pelvic floor sonography (PFS). The choice of the implantation site is determined by urethral length and mobility and the type of sling [39–43].

Retropubic colposuspension

Colposuspension is usually performed in patients with paravaginal lateral defect and excessive mobility of the bladder neck, which causes SUI. Colposuspension may be performed in patients after MUS. MUS implantation is also often recommended after unsuccessful colposuspension [7, 44].

Colposuspension is associated with the rate of urinary incontinence correction ranging from 85–90% for the follow-up (FU) of 1–5 years after surgery to 70% for FU of > 5 years. A comparison of colposuspension and MUS revealed no differences in the subjective or objective efficacy of SUI therapy, regardless of the time factor [45, 46] (LE 1a). Likewise, studies comparing the results of MUS from the retropubic versus obturator access (1–5 years FU and > 5 years FU), found no differences in the subjective recovery rate (LE 1a). FU of > 5 years showed the recovery rate of 51–88% for the retropubic and 43–92% for the obturator access [47]. The obturator access was associated with more frequent groin pain (6.4% vs 0.6%), while the retropubic access with a higher rate of bladder perforations (4.5% vs 0.6%), difficulty passing urine, and organ and vessel injury (LE 1a).

Third-line treatment: second-line surgery

a) urethral bulking agents

The procedures which 'seal' the urethra consist in the administration of bulking agents, submucosally delivered via the transurethral or transvaginal route, which reduces the urethral lumen. The agents are typically injected into the submucosa surrounding the bladder neck or mid-urethra [48].

Due to the variety of the available bulking agents and lack of long-term observations, it is challenging to present unequivocal guidelines for their use in SUI therapy. Only

short-term observations demonstrated improved urine control (1b) [49]. Therefore, bulking agent injection, despite being minimally invasive, should be treated as an alternative procedure for SUI: in the next stage of treatment, in patients with systemic diseases who do not want to undergo the classic procedures (2a) [50].

b) Autologous fascial sling, pubovaginal sling, bladder neck slings

This procedure uses a piece of the fascial tissue which stabilizes the urethra on the vaginal side. The most used sling is the autologous fascial sling, originating from the rectus sheath or the fascia lata of the thigh. It is not recommended as first-line treatment and should be used only in case of recurrent urinary incontinence after earlier procedures proved ineffective, in patients with internal sphincter deficiency, after prior radiotherapy, MUS failure, and after urethral injury. A comparison with MUS synthetic sling revealed that the procedures have similar efficacy [51]. Nevertheless, MUS seems to be more beneficial considering the increased risk for postoperative urination disorders, abnormal wound healing, and procedure duration which are associated with autologous slings.

Fourth-line treatment: third-line surgical treatment: artificial urinary sphincter (AUS) and adjustable compression therapy (ACT)

Implantation of an artificial urethral sphincter involves transabdominal insertion of a system which replaces the normal functions of a urethral sphincter. It is the final solution for patients with no urine control and after other surgical procedures proved unsuccessful (LE3) [52].

Future course: regenerative medicine

Autologous muscle-derived stem cells obtained by skeletal muscle biopsy and injected into the area of the urethral sphincter were shown to be effective in Phase I/II trials [53–55]. Randomized phase III trials (Clinicaltrials.gov Identifier: NCT01893138) are currently in progress. The proclaimed mechanism of action consists in promoting tissue remodeling by in situ secretion of growth factors and cytokines, which helps to restore the sphincter structure and its function [56] (LE 4).

SUMMARY

The implementation of targeted therapeutic management of SUI must be preceded by a thorough diagnostic process. Details about patient eligibility and correct qualification will allow to choose the optimal treatment and obtain urine control.

Surgical intervention (tailored to the individual needs of the patient) should be considered only after conserva-

tive treatment and personal hygiene measures have been exhausted and SUI persists.

Importantly, guidelines are only an indication for the specialist treatment and will not replace clinical knowledge when making individualized therapeutic decisions, which in some cases may prompt the experts to deviate from the recommendations.

Conflict of interest

All authors declare no conflict of interest.

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