Interdisciplinary S2e Guideline for the Diagnosis and Treatment of Stress Urinary Incontinence in Women Short version – AWMF Registry No. 015–005, July 2013

Interdisziplinäre S2e-Leitlinie Diagnostik und Therapie der Belastungsinkontinenz der Frau

Kurzfassung – AWMF-Register-Nummer: 015–005, Juli 2013

Authors

Prof. Dr. C. Reisenauer, LL Koordination (AGUB der DGGG), Dr. C. Muche-Borowski, methodische Betreuung und Moderation (AWMF), Prof. Dr. C. Anthuber (AGUB), PD Dr. D. Finas (AGUB), Dr. T. Fink (AGUB), Prof. Dr. B. Gabriel (AGUB), Dr. M. Hübner (AGUB), Dr. K. Lobodasch (AGUB), Dr. G. Naumann (AGUB), Prof. Dr. U. Peschers (AGUB), Prof. Dr. E. Petri (AGUB), Dr. N. Schwertner-Tiepelmann (AGUB), S. Soeder (AGUB), Dr. U. Steigerwald (AGUB), Prof. Dr. A. Strauss (AGUB), Prof. Dr. R. Tunn (AGUB), Prof. Dr. V. Viereck (AGUB), Dr. T. Aigmüller (AUB), Dr. D. Kölle (AUB), Dr. S. Kropshofer (AUB), Prof. Dr. K. Tamussino (AUB), PD Dr. A. Kuhn (AUG), Prof. Dr. K. Höfner (DGU), Prof. Dr. R. Kirschner-Hermanns (DGU), PD Dr. M. Oelke (DGU), Prof. Dr. Dr. Dr. Dr. C. Klingler (ÖGU), U. Henscher (German Physiotherapy Association)/Consortium for Gynaecology, Obstetrics, Urology and Proctology), B. Junginger (German Federal Association of Independent Physiotherapists)

The Guideline is Supported by the Following Specialist Associations and Consortia

- Consortium for Urogynaecology and Pelvic Floor Plastic Reconstruction (AGUB) of the German Society of Gynaecology and Obstetrics
- ► German Society for Urology (DGU)
- Consortium for Urogynaecology Switzerland (AUG)
- ► Consortium for Urogynaecology and Pelvic Floor Plastic Reconstruction Austria (AUB)
- Austrian Society for Urology
- German Physiotherapy Association/Consortium for Gynaecology, Obstetrics, Urology and Proctology
- ► German Federal Association of Independent Physiotherapists

Note

The long version, including the complete list of references and the guideline report, can be viewed on the AWMF website (www.awmf.org).

1 Definition

Stress urinary incontinence is defined as the involuntary loss of urine during physical exertion, when sneezing or coughing.

2 Diagnosis

2.1 Anamnesis and clinical examination

Patients with urinary incontinence should undergo a systematic examination, including a general anamnesis, urogynaecological anamnesis, physical examination and expectations of examination and treatment (LOE 2, recommendation grade B). The following should be taken into account: storage of urine, bladder emptying, complaints following bladder emptying, type and extent of incontinence, and psychological strain (LOE 3, recommendation grade B).

2.2 Questionnaires

Questionnaires are used to record the patient's symptoms, the severity, and the effects on the patient, as well as to document changes in the symptoms over time, e.g. following treatment. Questionnaires validated in terms of content and language should be used.

There is no scientific evidence that the use of questionnaires to assess urinary incontinence influences the treatment outcome (LOE 4).

2.3 Micturition report/micturition diary

Micturition diaries, which are kept for 3–7 days, are a reliable method of quantifying the average micturition volume and the micturition frequency during the day and night. Micturition reports are used to determine and assess bladder filling and bladder emptying disorders occurring concomitantly with urinary incontinence (LOE 2b).

Bibliography

DOI http://dx.doi.org/ 10.1055/s-0033-1350871 Geburtsh Frauenheilk 2013; 73: 899–903 © Georg Thieme Verlag KG Stuttgart · New York · ISSN 0016-5751

Correspondence

Prof. Dr. med. Christl Reisenauer

University Women's Hospital Tübingen Calwerstraße 7 72076 Tübingen, Germany christl.reisenauer@ med.uni-tuebingen.de

DGGG-Leitliniensekretariat

Prof. Dr. med. Matthias W. Beckmann, DGGG-LeitlinienbeauftragterFrauenklinik

Universitätsklinikum Erlangen Universitätsstraße 21–23 91054 Erlangen Tel.: 09131-85-33507/44063 Fax: 09131-85-33951

2.4 Urine examination

Urinary incontinence occurs more frequently in women with urinary tract infections. In contrast to symptomatic urinary tract infection, asymptomatic bacteriuria seems to have little influence on urinary incontinence.

2.5 Measuring of residual urine

Residual urine is the amount of urine remaining in the urinary bladder at the end of micturition. There is no standard definition of a pathological quantity of residual urine.

Sonography of the urinary bladder after micturition provides a precise estimate of the quantity of residual urine. The quantity of residual urine should be determined using sonography (LOE 1b, recommendation grade A).

The quantity of residual urine should be determined in female patients with urinary incontinence or micturition problems (LOE 1b, recommendation grade B).

The quantity of residual urine should be determined in female patients receiving treatment that can potentially cause or exacerbate bladder emptying problems (LOE 1b, recommendation grade B).

2.6 Pad test (sample weighing test)

The pad test serves to quantify the loss of urine and can be used as a follow-up and to assess the success of treatment.

2.7 Urodynamics

Urodynamic examinations serve to objectify and quantify the symptoms, to correctly classify symptoms and pathophysiology, as well as identify risk factors that have a key influence on the success of treatment or possible complications and unwanted sequelae.

Preliminary urodynamic testing does not influence the success of conservative urinary incontinence treatment. A routine urodynamic examination is not indicated prior to conservative treatment for urinary incontinence (LOE 1a, recommendation grade 0).

Prior to surgical interventions – in particular, recurrent interventions – a urodynamic examination should be performed to advise the patient with the greatest possible care and introduce the right treatment (LOE 3, recommendation grade B).

An assessment of urethral function should be taken into account within the urodynamic investigation into stress urinary incontinence (LOE 3, recommendation grade B).

In patients with higher-grade genital prolapse without symptoms of stress urinary incontinence, a stress test should be performed following prolapse repositioning. To assess concomitant hidden stress urinary incontinence and/or detrusor dysfunction, urodynamic testing should be carried out with prolapse repositioning (LOE 3, recommendation grade B).

2.8 Imaging

When using imaging to depict the morphology and function of the lower urinary tract, sonography and magnetic resonance imaging are increasingly superseding X-ray investigations.

Cystography and micturating cystourethrography are not indicated for the primary diagnosis of uncomplicated stress urinary incontinence (LOE 4, recommendation grade O).

Introitus sonography and perineal sonography are used when performing a topographical and functional assessment of the urinary bladder, urethra and pelvic floor musculature. Sonography now has an established importance in relation to the diagnosis and further treatment algorithm in women with stress urinary incontinence (LOE 2). Its use in the event of unsuccessful treatment, in particular, can be very helpful clinically.

Within the scope of conservative treatment, rehabilitative ultrasound imaging (RUSI) has become established as a visual biofeedback tool in physiotherapy.

2.9 Endoscopy

Urethrocystoscopy is recommended for stress urinary incontinence if additional urge symptoms, emptying disorders, relapsing urinary tract infections or haematuria exist, in order to rule out morphological causes such as urinary bladder tumours or stones, urethral stenosis or chronic changes to the mucous membrane of the bladder (LOE III).

3 Treatment

3.1 Conservative treatment

3.1.1 Oestrogen

Patients should be informed prior to systemic oestrogen substitution that this can lead to the occurrence or exacerbation of urinary incontinence (LOE 1a, recommendation grade A).

Local oestrogen therapy should be recommended for all postmenopausal patients with urinary incontinence. The duration of treatment and the best mode of application are unclear (LOE 1a, recommendation grade A).

3.1.2 Body weight

Being overweight is a risk factor for stress urinary incontinence in women. Weight loss of more than 5% improves incontinence symptoms (LOE 1b).

Weight loss (>5%) should be recommended to overweight patients with urinary incontinence (LOE 1b, recommendation grade A).

3.1.3 Duloxetine

Duloxetine does not cure incontinence, but instead reduces episodes of stress and urge urinary incontinence (LOE 1b). Duloxetine causes significant adverse effects affecting the gastrointestinal and central nervous systems (nausea, vomiting, mouth dryness, constipation, dizziness, insomnia, fatigue), which lead to high rates of treatment discontinuation (LOE 1b).

Duloxetine should be offered to women who aim for a temporary improvement in incontinence symptoms (LOE 1b, recommendation grade A).

Due to the high number of adverse effects, duloxetine treatment should be started gradually (LOE 1b, recommendation grade A).

3.1.4 Pessary treatment

Pessary treatment should be offered as a treatment option to female patients with stress urinary incontinence (LOE 1b, recommendation grade B).

3.1.5 Pelvic floor exercise

In the event of stress urinary incontinence, guided pelvic floor exercise over more than 3 months, combined with bladder training, should be implemented (LOE 1a, recommendation grade A). Pelvic floor exercise should be used to prevent and treat incontinence during pregnancy and after the birth (LOE 1a, recommendation A).

Pelvic floor exercise should be instructed individually and can be implemented as an individual treatment, in a group or within independent training (LOE 1b and 2b, recommendation grade B). Pelvic floor exercise should also be carried out by older patients (LOE 1b and 2b, recommendation grade B).

Active pelvic floor exercise should be preferred to electrostimulation on its own (LOE 1b, recommendation grade B). A combination of both measures can be more effective than pelvic floor exercise on its own (LOE 1b).

To assess pelvic floor activity, vaginal palpation or a perineometer should be used **(LOE 2b, recommendation grade B)**.

Vibration treatment using a base plate with a side-alternating vibration leads to an improvement in continence when used in combination with physiotherapy (LOE 2).

3.2 Surgical treatment

Surgical treatment for stress urinary incontinence should only be considered once conservative treatment options have been exhausted

Each surgery should be preceded by a detailed discussion with the patient, during which she is informed about the reasons for and objectives of the surgical intervention, the benefits and possible complications. It is equally important to review the advantages and disadvantages of alternative treatment options, where these are available.

When there are no incontinence operations in the anamnesis, no neurological symptoms and no symptomatic genital prolapse or desire for children, the stress urinary incontinence is known as uncomplicated. In contrast, if women are affected by one or more of the aforementioned criteria, it is known as complicated stress urinary incontinence.

3.2.1 Surgical treatment for uncomplicated stress urinary incontinence

3.2.1.1 Open colposuspension

Systematic reviews have shown that open colposuspension (Burch) and the autologous fascial sling procedure are equally effective in treating stress urinary incontinence in women over the short term (after 5 years) (LOE 1b).

The efficacy of colposuspension declines after 5 years. In the 1st postoperative year, the continence rate was still 85–90% following open colposuspension. The failure rate (persistent incontinence/recurrent incontinence) was 17% within the first 5 years and then rose to 21%. A genital prolapse occurred more frequently following colposuspension than following other incontinence operations. The autologous fascial sling procedure involves higher perioperative complication risks than open colposuspension, above all caused by bladder emptying disorders and postoperative urinary tract infections (LOE 1b).

3.2.1.2 Laparoscopic colposuspension

Laparoscopic colposuspension demonstrates an equally high efficacy as open colposuspension in curing stress urinary incontinence 2 years postoperatively (LOE 1a).

Laparoscopic colposuspension is associated with less postoperative pain, a shorter time taken to resume normal activities, a shorter stay in hospital, and shorter catheterisation time than open colposuspension (LOE 1a).

3.2.1.3 Suburethral tension-free tape

Suburethral tension-free tape was quickly adopted into the primary treatment of stress urinary incontinence due to its efficacy, low invasiveness, and the rapid postoperative recovery of the patient.

The NICE (National Institute for Health and Clinical Excellence) Clinical Guideline 2006 recommends the use of synthetic, macroporous type-I tape in the treatment of stress urinary incontinence in women.

A comparison of suburethral tension-free tape and colposuspension

Retropubic tape operations demonstrate the same subjective and better objective stress urinary incontinence cure rates in comparison with colposuspension 12 months postoperatively (LOE 1a). Transobturator tape operations show the same subjective and objective cure rates in stress urinary incontinence in comparison with colposuspension 12 months postoperatively (LOE 1a). Following a suburethral tape operation, fewer de novo urge syn-

Following a suburethral tape operation, fewer de novo urge syndromes and bladder emptying disorders occurred than following colposuspension (LOE 1a).

In the meta-analysis by the European Association of Urology (EAU), the subjective cure rate 12 months following suburethral tape operations was 75%. Long-term follow-ups up to 5 years later show no efficacy differences compared with colposuspension. Bladder emptying disorders occurred more rarely following suburethral tape operations in comparison with colposuspension. Bladder perforations occurred more frequently during the insertion of suburethral tape than during laparoscopic colposuspension or open colposuspension.

Transobturator versus retropubic approaches

The meta-analysis by the EUA showed equally high subjective and objective stress urinary incontinence cure rates 12 months following insertion of a transobturator suburethral tape compared with retropubic suburethral tape operations (LOE 1a). The transobturator tape technique is associated with a lower risk of bladder perforation and a lower risk of bladder emptying disorders than the retropubic tape technique (LOE 1a).

In contrast, there is more frequent pain around the inside of the thighs and groin and more frequent vaginal injuries in the region of the sulci following the transobturator implantation technique. With regard to arrosion, no significant differences appear to exist.

Bladder injuries, retropubic haematomas, bladder emptying disorders, and symptoms of the lower urinary tract occur more frequently following retropubic tape insertion.

12 months after the insertion of a transobturator tape, patients have a higher risk of urethral perforation and chronic perineal pain (LOE 1a).

If a hypotonic urethra is the cause of stress urinary incontinence, the continence rates following insertion of a retropubic tape are better than following insertion of a transobturator tape (LOE 2).

Outside-in vs. inside-out techniques.

A comparison of retropubic and transobturator techniques The outside-in technique for retropubic suburethral tape insertion is less effective than the inside-out technique (LOE 1a). The outside-in technique for retropubic tape is associated with a higher risk of postoperative bladder emptying disorders (LOE 1b). The outside-in approach for transobturator tape is equally as effective as the inside-out approach. However, the outside-in path

is associated with a higher rate of bladder emptying disorders and bladder injuries.

Single-incision slings (called mini slings)

Mini slings were developed to further reduce the invasiveness of incontinence operations. Various macroporous polypropylene tapes are use to stabilise the middle third of the urethra. The insertion points for mini slings are the retropubic tissue or the obturator membrane/musculature. The mini slings have the aim of preventing complications resulting from the tape passage through the retropubic space or through the adductors of the thigh as well as injuries to the obturator nerve.

Single-incision slings show an equally high stress urinary incontinence cure rate as retropubic and transobturator tape up to 12 months postoperatively (LOE 1b). It has not yet been possible to demonstrate this equivalence in a longer follow-up.

The loss of blood is less and postoperative pain occurs less often following single-incision slings than following suburethral tape insertion (LOE 1b). There is no evidence that other complications occur less often or more frequently following single-incision slings than following suburethral tape insertion (LOE 1b).

Adjustable slings

Adjustable slings enable the tension of the implanted slings to be altered intra- and postoperatively, thus optimising the balance between continence and bladder emptying.

There is a small amount of evidence that adjustable suburethral slings are effective in treating stress urinary incontinence in women (LOE 3). However, there is no evidence that adjustable slings are superior to suburethral tape (LOE 4).

3.2.1.4 Bulking agents

Bulking agents are injected into the urethral submucosa of the proximal urethra/the external sphincter and have the aim of improving continence through coaptation of the urethral wall.

The periurethral injection of a bulking agent leads to a short- or medium-term improvement in symptoms, depending on the materials used. There are no long-term data available (LOE 2a). Repeated injections are often required in order to achieve lasting,

There is no evidence that one type of bulking agent is superior to another. However, the substances differ considerably in terms of adverse effects (LOE 1b).

yet sometimes only short-term, treatment success (LOE 2a).

Bulking agents are less effective in curing stress urinary incontinence than colposuspension or autologous fascial slings (LOE 2a). The percutaneous approach to the urethral mucosa is associated with a higher residual urine risk in comparison with the transurethral approach (LOE 2b).

The use of bulking agents is particularly suitable for a patient collective with limited operability (LOE 2b).

3.2.2 Surgical treatment for complicated stress urinary incontinence

The failure rate following incontinence operations differs widely and is linked to the definition of surgical failures. Failure can occur immediately following surgery (persistent incontinence) or years after the operation (recurrent incontinence). Persistent stress urinary incontinence or recurrent stress urinary incontinence should be clearly differentiated from urge urinary incontinence or incontinence with another cause (incontinence as a result of a fistula, neurogenic incontinence, overflow incontinence, etc.).

Open colposuspension or autologous fascial sling insertion are equally effective in treating recurrent stress urinary incontinence following anterior colporrhaphy (LOE 1b). No statistically significant connection between previous surgical treatment and treatment success following colposuspension or an autologous fascial sling (LOE 2) can be found. A systematic literature review showed that the risk of treatment failure for a stress urinary incontinence operation is higher in women who had already undergone an incontinence or prolapse operation (LOE 2). The implantation of a suburethral tape can be less effective in the secondary treatment of stress urinary incontinence than in primary treatment (LOE 2). Due to the present data, no recommendation can be made to remove the primary suburethral tape prior to a further incontinence operation.

Artificial sphincter

There is only insufficient evidence with regard to the use of an artificial sphincter in women. In case series with a follow-up of 1 month to 25 years, most of the patients report an improvement in stress urinary incontinence. The subjective cure rate is between 59–88%. Complications comprise mechanical failure with revision operations within 10 years in up to 42% of cases and explantation rates of 5.9–15%. Risk factors for a failure were age, a previous colposuspension or radiotherapy of the lesser pelvis. Injuries to the urethra, bladder or rectum were risk factors for the explantation of the artificial sphincter.

The implantation of an artificial sphincter can improve or cure complicated stress urinary incontinence in women (LOE 3). Mechanical failure and the necessity of sphincter explantation or sphincter replacement are typical risks of an artificial sphincter (LOE 3).

Suburethral tape, colposuspension and autologous fascial slings are options for the surgical treatment of persistent or recurrent stress urinary incontinence in women. The choice depends on the prior interventions and the preference of the patient or the surgeon.

3.2.3 Surgical treatment of stress urinary incontinence in women with mixed urinary incontinence

Following surgical treatment of stress urinary incontinence, preexisting urge symptoms (urgency) can improve, remain the same or become worse (LOE 3). Women with mixed urinary incontinence and urodynamically verified detrusor hyperactivity have lower satisfaction rates following suburethral tape insertion compared with women with stress urinary incontinence alone. Women with mixed urinary incontinence with dominating stress urinary incontinence components have a significantly better outcome following surgical treatment for stress urinary incontinence than women with dominating components of urge urinary incontinence.

3.2.4 Summary

Recommendations for surgical treatment of uncomplicated female stress urinary incontinence

Suburethral tape insertion (retropubic and transobturator) should be offered to women with uncomplicated stress urinary incontinence as a primary surgical treatment option (recommendation grade A).

Open or laparoscopic colposuspension or autologous fascial slings should be offered to women with stress urinary incontinence if suburethral tape insertion (retropubic or transobturator) is not possible. Colposuspension can also be useful for concomitant traction cystocele, or if a laparoscopic/open approach was already chosen for other reasons **(recommendation grade A)**.

Patients with stress urinary incontinence who are offered a retropubic sling should be informed about the higher perioperative complication risk compared with transobturator sling insertion (recommendation grade A).

Patients with stress urinary incontinence who are offered a transobturator sling should be informed about the higher risk of dyspareunia and pain over the long term (recommendation grade A).

Patients with stress urinary incontinence who receive treatment with an autologous fascial sling should be informed about the high risk of bladder emptying disorders and the necessity for intermittent self-catheterisation; it should be ensured that they are capable of this and in agreement with this (recommendation grade A).

Intraoperative urethrocystoscopy should be performed for every retropubic suburethral tape insertion and difficulties during transobturator suburethral tape insertion (recommendation grade B).

Patients with stress urinary incontinence who are offered a mini sling (single-incision sling) should be informed that this could be less effective than a suburethral standard sling and the efficacy after one year has so far not been definitively determined (recommendation grade B).

Adjustable suburethral slings should only be offered in the primary treatment of stress urinary incontinence as part of studies (recommendation grade B).

Periurethral bulking agents should not be offered to women who aim for a cure for stress urinary incontinence (recommendation grade A).

Recommendations for surgical treatment of complicated stress urinary incontinence in women

The selection of surgical treatment to treat recurrent stress urinary incontinence should only take place following a careful evaluation of each patient (recommendation grade B).

Patients should be informed that the surgical success of a recurrent intervention is inferior to that of primary treatment, both in terms of a reduced benefit and also of an increased intraoperative risk of injury (recommendation grade B).

An artificial sphincter should only be offered as a treatment option for complicated stress urinary incontinence if the long-term medical supervision of the patient is ensured and the patient is able to operate the sphincter herself. The higher risk of mechanical failure and the necessity for explantation in the event of complications should be discussed prior to the operation (recommendation grade B).

4 Complications

During the patient briefing, the risks of the suggested operation and the alternative interventions should be discussed and, in the event of realisation, the specific effects on the further lifestyle of those affected should be explained.

As stress urinary incontinence operations aim to cure/improve the symptoms and thus improve quality of life, the risks and possible complications of the interventions must be balanced particularly carefully against the prospects for success on an individual basis.

Possible complications that occur in association with the surgical treatment of stress urinary incontinence include: overactive bladder, formation of residual urine, urogenital complications (bladder injuries, urethral injuries, erosion of foreign material in the urethra, bladder or vagina, urethrovaginal and vesicovaginal fistulas), general complications (cardiovascular, dermatological, febrile, infectious, neurological and pulmonary complications, as well as pain and sexual dysfunctions, etc.), gastrointestinal complications (stomach injury, ileus), vascular complications (injury to major blood vessels), neurological complications.

5 Perioperative Management

Restrictive postoperative recommendations can significantly impair the quality of life of patients. Activities that are discouraged postoperatively (e.g. lifting heavy loads > 5 kg, physical training) do not produce any higher intra-abdominal pressure than everyday, unavoidable activities, such as rising from a chair or standing up from a lying position. It is important here that advice is given on the physiological implementation of the activities. Physiotherapeutic guidance is recommended (LOE 3).

Recommendations to be an active road user should be based on the cognitive abilities and pain treatment of the patient and not concerns regarding wound complications. The resumption of sexual intercourse at too early a stage can result in wound infection and suture dehiscence.

Prospective long-term studies are necessary to investigate the effects of physical activity on the occurrence, progression and relapse of urinary incontinence and genital prolapse.

Deutschsprachige Zusatzinformationen online abrufbar unter: www.thieme-connect.de/ejournals/toc/qebfra.