Guideline-Based Strategies in the Surgical Treatment of Female Urinary Incontinence: The New Gold Standard is Almost the Same as the Old One

Leitlinienbasierter Ansatz der operativen Therapie der weiblichen Harninkontinenz: Der neue Goldstandard ist fast wieder der alte

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Key words
- stress urinary incontinence
- bulking agents
- colposuspension
- retropubic tape
- transobturator tape

Schlüsselwörter
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Abstract

The modern sling procedures for treating female stress urinary incontinence encompass numerous methods, materials and manufacturers. On the basis of the current S2e guidelines, the methods used most frequently in the diagnosis of and therapy for stress urinary incontinence in women are critically illustrated. An individualised procedure is necessary for the choice of the surgical method, especially in the presence of accompanying pathologies. This article is intended to help the treating physician to carry out quality-assured diagnostics and therapy for the patient and to offer the best possible urogynaecological management. In addition to the complications and chances of success of the surgical options, the legal aspects of therapy planning are also taken into consideration.

Zusammenfassung

Die modernen Schlingenverfahren zur Behandlung der weiblichen Belastungsinkontinenz variieren heute zwischen zahlreichen Verfahren, Materialien und Herstellern. Basierend auf der aktuellen S2e-Leitlinie werden die am häufigsten angewendeten Verfahren bei der Diagnostik und Therapie der Belastungsinkontinenz der Frau kritisch beleuchtet. Bei der Wahl der Operationsmethode ist ein individualisiertes Vorgehen erforderlich, insbesondere, wenn Begleitpathologien vorliegen. Der Beitrag soll den behandelnden Ärzten helfen, die Diagnostik und Therapie der Patientinnen qualitätsgesichert durchzuführen und die bestmögliche urogynäkologische Versorgung anbieten zu können. Dabei werden neben den Komplikationen und Erfolgsaussichten der operativen Möglichkeiten auch juristische Aspekte bei der Therapieplanung berücksichtigt.

Introduction

The present contribution provides an up-to-date review on the diagnostics and treatment of stress urinary incontinence and is based on the guidelines for diagnosis and therapy of female stress urinary incontinence, last updated in July 2013 and valid until July 2018 [1], the revised guidelines on genital prolapse in women (submitted), as well as the guidelines on sonography in urogynaecology that were updated in 2013 [2]. As a result of the developments in the past few years, surgical treatment has become more differentiated and personalised and this is reflected in the current recommendations. Besides the procedure and positioning of the sling, other factors such as the correct choice of material are important for a successful treatment.

Not only in the German but also in the English guidelines [3] conservative treatment options are recommended in the first line. A current Dutch study [4], however, revealed for the first time in a multicentred, randomised setting that a direct, that is, primary sling management is superior to physiotherapeutic treatment not only with regard to patient satisfaction but also to the subjective and objective cure rates after one year. Depending on the procedure, informing the patient is especially important in order to exclude liability claims within the framework of the new laws on patients' rights [5].

As a result of the warnings issued by the FDA in 2008 and 2011 [6] on the use of meshes in the framework of prolapse surgery, the manufacturers had no option but to also stop the production and marketing of mesh-supported products for the treatment of urinary incontinence. Thus, as the first company, ASTORA Women's Health announced the termination of their entire product portfolio on 29.02.2016.

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Survey/Review

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Definition, anatomy, pathophysiology

Stress urinary incontinence is defined as the involuntary loss of urine during physical exertion, such as sneezing, walking or climbing stairs. The cause for this is an elevated intravesical pressure in combination with a disorder of the urethral occlusion pressure. The reasons for these problems are a weakness of the urethral sphincter and the pelvic floor muscles, defects of the connective tissue supporting systems or atrophy of the epithelium.

Diagnostics according to the guideline recommendations of the DGGG

At first a systematic case history and physical examination should be undertaken **(LOE 2)** [1]. For this a micturition protocol or diary can be helpful **(LOE 2b)** whereas, in contrast, the use of questionnaires has no direct influence on the therapeutic results **(LOE 4)**. Questionnaires are recommended to effectively document the objectification of the patients' reports.

A preoperative sonographic measurement of residual urine as an additional method is useful for patients with urinary incontinence or micturition difficulties and, in general, for patients under a drug therapy that is associated with the problem of voiding disorders **(LOE 1b)**.

The pad test is a possible method for the objectification of progress and control of success. A urodynamic examination on the other hand is not routinely required prior to conservative therapy and for cases of uncomplicated stress urinary incontinence **(LOE 1a)**. When done preoperatively it can, however improve counselling and therapy **(LOE 3)**. Also in some cases of prolapse **(LOE 3)** a supplementary urodynamic examination is useful for evaluation of a masked stress urinary incontinence and estimation of detrusor function.

In the meantime sonographic imaging of the pelvic floor has gained an established place in the diagnostics and within the framework of the treatment algorithm **(LOE 2)**. In cases of therapeutic failures sonography is indispensable.

In cases with urge symptomatics, urge and mixed urinary incontinence as well as voiding disorders, recurrent urinary tract infections or haematuria, cystoscopy can be extremely useful **(LOE 3)**. Its routine use, however, is not necessary.

Conservative treatment – a MUST

The updated guidelines recommend a primary conservative therapy for stress urinary incontinence. This includes local oestrogen therapy, weight reduction, drug treatment with duloxetine* and/or a pessary therapy. In addition, physiotherapeutic treatment is also very helpful, not only as a single therapy but also as a conservative pre-treatment and follow-up treatment after a surgical intervention. On account of its highest evidence level **(LOE 1a),** a supervised pelvic floor training for more than three months combined with bladder training is recommended.

Surgical measures are only recommended after having exploited these conservative options. In the ideal case, this means that surgical therapy should always be combined with the conservative therapy since the long-term postoperative results can be unequivocally improved in this way.

Which operation for which indication?

If conservative therapy ends with no or only a slight success, the question arises as to the choice of the surgical method. In principle the suburethral sling procedure is the method of choice, followed by the classical colposuspensions and sling plasties. The sub- or intraurethral injection methods are only offered as a third-line therapy. The artificial bladder sphincter or neobladder as very last resort should remain an exception.

According to the guidelines, the suburethral sling system should be offered primarily with the retropubic approach being the gold standard against which all other methods must be measured. These other procedures are very diverse in nature of approach (retropubic, transobturator, minisling) and materials used (polypropylene/other alloplastic tissue, elastic/stiff, wide/narrow, pore size, length, adjustable/not adjustable). The question thus arises of whether or not this enormous number of products provides superior results to the classical method introduced by Ulmsten. In other words, is there a definite field of indications for which only certain types of slings are suitable? Does the gold standard TVT still remain the gold standard?

The classic TVT operation was introduced in Scandinavia in 1995 by Ulmsten and then spread rapidly to other countries. In the course of time various factors and innovations have led to higher success and lower complication rates. The originally published method was based, for example, on a urethral length of 35.5 mm [7]. With this assumption, the scattering of the relative sling position was very high on account of individual variations in urethral length. This often led to complications or a lack of success [8]. The introduction of pelvic floor sonography by Kociszewski and Viereck optimized tape placement [9]. Thus, in their report they demonstrated that the individual length of the urethra had to be taken into account and that the classical TVT sling should be placed in the transition zone from the distal to the middle third of the urethra [8].

In the follow-up data published in 2013 on the classical TVT according to Ulmsten [10], the objective postoperative cure rate amounted to 91% and remained practically stable between 5 and 17 years. In the case of retropubic slings (TVT) the perioperative risks are somewhat higher than for transobturator slings (TVT-O), but in the long-term, TVT generates less dyspareunia and fewer pain in the operated region.

Most important for the choice of sling is an evaluation of the paraurethral sulci and the urethral mobility. With flat paraurethral sulci and a mobile urethra, both slings can be used. With a less mobile urethra and high-lying sulci it is only possible to create the needed tension with a retropubic sling and so reduce the danger of erosion [11]. Also, the localisation of the external urethral orifice (meatus urethrae internus [MUI]) has an influence on the choice of surgical treatment. If the MUI is higher than the lower symphysis margin line, only the retropubic procedure is able to guarantee the corresponding support for the urethra. In addition, there are the many young patients and women with regular cohabitation, to whom one should offer the best validated methods with the lowest erosion rates. Here also the retropubic slings are superior to the transobturator slings.

If there are general contraindications to a sling procedure such as that of a pronounced rotary urethral prolapse with possibly also the existence of kinking or if these methods fail in spite of a sonographically confirmed optimal sling placement, the colposuspension or autologous fasciae sling can be offered as alternatives.

For "minislings" the principle is that, on account of the currently available data, they should at present only be used within the

* Approved in the EU since 2004, not approved in certain countries such as, e.g. Switzerland and USA.

framework of clinical trials. First follow-up data after 1 to 3 years have recently been published [12–17]. According to these reports a similar efficiency to that of the traditional slings seems to be possible. Most experience is available for the TVT-SECUR™ produced by ETHICON and the MiniArc™ made by ASTORA. However, both are no longer available on the market due to the production stop. Thus, for a conclusive evaluation, on the one hand, the follow-up time is too short and, on the other hand, there is a shortage of reliable data on the efficiency of the less investigated slings. Thus, at the moment the minislings do not offer an alternative to the classical TVT slings.

Also, the products for suburethral injection procedures were in recent years only commercially available for a short time, so that long-term studies on their tolerability and efficiency are largely lacking. At present, suburethral injection procedures are generally not recommended for first-line therapy or are recommended only with strict reservations and certainly not for routine use. However, their place value is currently being investigated in detail in randomised controlled studies, among others, in a large Finnish study comparing the retropubic TVT sling with the bulking agent Bulkamid®.

Material properties

Beside the approach employed, the properties of the used sling materials play a decisive role for success of the therapy. The NICE guidelines [3] recommend synthetic, macroporous type slings of polypropylene.

But, even within this group, there are large differences with regard to the individual parameters: tensile strength, mesh elasticity, porosity, surface and weight. The importance of tensile strength and mesh elasticity is obvious. The pore size determines the extent of a possible ingrowth of connective tissue and is thus a decisive parameter for long-term success. They should amount to more than 2.5 mm. Since bacterial colonisation is proportional to the surface of the graft, the surface area should be as small as possible; a monofilament structure and filaments with small radius are thus to be preferred. For slings, the weight is of subordinate importance as long as the other mentioned criteria are fulfilled.

The used slings should not be considered as equals to the mesh grafts used in prolapse operations and so the FDA warnings [6] are not applicable for incontinence surgery. Even so, these warnings, as mentioned above, have also had an effect on the production of incontinence slings.

General complications

Tension-free, suburethral slings currently constitute the so-called gold standard for incontinence surgery. Twelve months after surgery the subjective cure rates for retropubic and transobturator slings practically correspond to those of colposuspension. The objective cure rates are equal (TVT-O) or even better (TVT). Perioperative bladder perforations, however, occur more frequently in the course of TVT operations. If the techniques are compared with each other, bladder voiding disorders and perforations as well as retropubic haematomas occur more frequently with the retropubic technique than with the transobturator technique. In contrast, pain in the groin and inner thigh as well as vaginal injuries in the region of the sulci (erosion) are reported more often in TVT-O. One year after a transobturator intervention the risks for vaginal skin perforation and chronic perineal pain are higher. In transobturator sling placement we distinguish between an inside-out procedure and an outside-in procedure. Both approaches are reported to be equally effective but the outside-in approach leads more often to complications like bladder voiding disorders and bladder or urethra injuries.

Compared with sling procedures, de novo urge symptoms and bladder voiding symptoms occur more frequently after abdominal as well as laparoscopic colposuspensions. The occurrence of a genital prolapse after colposuspension is observed more often, especially in the posterior compartment, than after incontinence operations with a suburethral sling. The failure rate for colposuspension due to persisting or recurrent incontinence increases from 10–15% in the first year to 21% after five years. Although the success rates of autologous fasciae slings after five years are as high as those of colposuspension, perioperative complications occur more frequently, in particular due to bladder voiding symptoms and postoperative urinary tract infections.

Expectations on outcome/training the surgeons

The complexity of the clinical entity, the various operations and the employed materials place special demands on the surgeon in order to achieve the best possible outcome for the patient. According to the NICE guidelines, surgeons should perform at least 30 operations using each method per year in order to guarantee the corresponding quality [18]. Surgeons and centres with the required experience and facilities can be found on the internet site of AGUB (www.agub.de). Implementation of the specialty urogynaecology is being planned in German-speaking countries. In Switzerland the specialty “urology for women” was introduced on January 1, 2016. In Austria a subspecialisation for two years following the European model for basic training is being implemented.

Follow-up can be carried out by the surgeon or by a practicing gynaecologist, depending on the individual qualifications and local accessibility. Exact documentation and feedback to the surgeon are very important for quality control.

At present the German government together with the Ministry of Education and Research (BMBF), the Ministry of Health (BMG) and professional societies is preparing an interdisciplinary, central graft register in order to fulfil the documentation requirements for medical products. Already in the current parliamentary term accordingly, a central and binding documentation for all mesh grafts shall be introduced [19]. The first focused discussion on this topic took place on December 10, 2015. A position paper from the “Arbeitsgemeinschaft für Urogynäkologie und plastische Beckenbodenrekonstruktion” (AGUB), the German Society of Residents in Urology (GeSRU) for the “Deutsche Gesellschaft für Urologie” (DGU) and the “Deutsche Gesellschaft für Chirurgie” (DGCH) is currently being prepared and will be published shortly.

Legal aspects

Patient assessment is of special relevance since the surgeon must in individual cases exactly justify his/her choice of intervention. Knowledge of the risks, especially of the different materials, is thus essential. Since the slings are classified as urogynaecological grafts, a graft or, respectively, patient pass must be issued in which the product name and charge/batch number is noted.

Even when the intervention only requires a short time of about 40 minutes and usually can be performed successfully without complications, it is challenging from the point of view of anatomic knowledge and thus is clearly recommended as an inpatient procedure [20]. The average duration of hospital stay as a rule encompasses two postoperative days. In order to achieve the best

functional results and to reduce the complication rates, it is mandatory that the patient is referred to a clinic with sufficient experience.

Conclusions

On account of its safety and efficacy, the suburethral sling management has the highest status in incontinence surgery. The classic retropubic sling placement (TVT) is, also because of the good data acquired over 17 years, the method of first choice. After many years of attempted improvements to this procedure by means of diverse and manifold variants in suburethral sling development, one today comes to the conclusion that the classic method according to Ulmsten should still be chosen as the primary surgical procedure. With the correct indications, it can be used for all cases of stress urinary incontinence and is also effective for mixed urinary incontinence.

The transobturator approach should be reserved for particular indications. This is the case especially for patients with an expected high risk of bladder injury. For minislings (single-incision slings), there is only little available experience and the two products with the highest level of scientific evidence are no longer on the market. Because of the changes in patient rights, in every case alternative methods such as the classic colposuspension and sling plasties should be mentioned and attention paid to a comprehensive clarification and documentation. Decisive for the success of the therapy is, beside the choice of material, above all the expertise of the surgeon.

Conflict of Interest

The authors declare that they were active in part within the past three years in advisory committees of Astellas or pfm, received lecture fees from American Medical System, pfm, Ethicon, Roche or Astellas, or were supported by a research grant (Astellas European Foundation Grant).

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