An Adjustable Sling in the Management of Recurrent Urodynamic Stress Incontinence after Previous Failed Midurethral Tape

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Objective: The aim of this prospective study was to evaluate the feasibility and outcome of an adjustable sling system AMI in patients with recurrent urinary stress incontinence after failed suburethral sling insertion. **Patients and Methods:** Twenty-five patients with recurrent urinary stress incontinence treated with an adjustable sling system AMI were analyzed for feasibility and outcome. Patients' incontinence bother was quantified using the Visual Analogue Scale (VAS) from 0 to 10. Multichannel urodynamics and pad tests were pre- and postoperatively performed. Time of adjustment, time of the surgical intervention, and clinical outcome were also recorded. **Results:** Twenty-five patients were treated with the adjustable sling system AMI. Median time of adjustment was 3 days (range 1−8) and a median follow up time of 12 months. Twenty-one out of 25 patients were continent, four patients suffered from persisting incontinence. One patient was put on clean intermittent self-catheterization (CISC). Detrusor pressure at maximum flow rate (pdet/Qmax) increased significantly as did the maximum urethral closure pressure (MUCP). Patient satisfaction improved significantly. **Conclusion:** Adjustable slings in women with stress urinary incontinence might be indicated in difficult situations after surgical failure. As we present a selective group of patients these findings may not apply to other patients with recurrent stress incontinence. *Neurourol. Urodynam.* © 2009 Wiley-Liss, Inc.

Key words: adjustable sling; feasibility; urinary incontinence

INTRODUCTION

In 1995, surgical treatment for stress incontinence was drastically changed with the introduction of a new concept, the tension-free midurethral support described by Ulmsten and Petros.[1] In the past decade, suburethral slings have become the preferred technique for the surgical treatment of female stress urinary incontinence.

Particularly since the largest randomized trial comparing Burch colposuspension with Tension-free Vaginal Tape (TVT) showed equality of results with a significantly more rapid recovery suburethral slings have been widely accepted as gold standard of incontinence surgery.[2]

Whilst high success rates up to 81.3% were reported over a follow-up period of 7 years,[3] the erosion of these synthetic meshes (both mono-filament and multifilament) is also a well-described complication happening in 0.3−23% for all sites.[4] Other complications include bladder injury and myositis.[5−8]

Overall, both the retropubic route and the transobturator routes appear to be equally effective for the treatment of female stress incontinence.[9]

Major complications are rare although reports of bleeding, urinary retention, de novo urgency, vaginal mesh extrusion, urethral erosion, abscess formation, vascular injury, nerve injury, and bowel injury have been reported.[10]

There is a paucity of data on how to deal with recurrent stress incontinence after sling insertion.

In spite of improvement in techniques and devices, there is a subset of patients refractory to standard anti-incontinence procedures. Those patients may benefit from adjustable slings[11] that can possibly be more obstructive. Excessive tension may result in obstruction and may create more problems and irritation.

Aim of the current study was to evaluate the feasibility, clinical, subjective, and urodynamic outcome after the insertion of an adjustable suburethral sling system in patients with recurrent urinary incontinence.

PATIENTS AND METHODS

Between December 2003 and March 2008, 25 patients with recurrent urodynamic urinary stress incontinence were included in this prospective study. The study was performed in a tertian referral setting of the Department of Urogynaecology, Gynaecology, Inselspital Bern.

Patients gave consent to the study.

All patients had a history of at least one surgical intervention for urinary stress incontinence and a positive preoperative cough test.

Obstruction was defined according to Blaivas[12] and retention was defined according to Dorflinger.[13]

A patients' history was taken and symptoms were noted. Patients were gynaecologically examined before surgery and 12 months after surgery.

Urodynamic investigations were performed prior to and 12 months after surgery according to ICS recommendations.

Cystometry was performed in the sitting position with the patient in the 45° upright position with a six French microtip transducer which was introduced into the bladder for intravesical pressure measurement and a water perfused balloon catheter was introduced into the rectum for intraabdominal pressure measurement. Bladder was filled with a rate of 20 ml per minute with saline solution at 37°. Filling was continued until the patient experienced a strong desire to void. A cough stress test was performed every hundred millilitres of filling. At bladder capacity pressure flow studies were performed. Residual urine was measured using a catheter and bladder neck mobility was assessed with perineal ultrasound using a 3.5 MHz curved array probe.[14]

Microtip urethral pressure profile measurements were taken in the 45° upright sitting position with the patient at rest using an 8 French Gaeltec® double microtip transducer and the transducer opening was orientated in the 3 o'clock position with a withdrawal speed of 1 mm/s. Catheter position was observed during the test to avoid change of orientation.

Intrinsic sphincter deficiency was defined as a maximal urethral closure pressure (MUCP) at rest of $<20\,cmH_2O$.

To quantify the subjective severity of the symptoms the visual analogue scale (VAS) 0–10 was used with 0 points being the least bother and 10 points the worst bother by their incontinence.

As sling, A.M.I. slings (AMI; Agency for Medical Innovation GmbH, 6800 Feldkirch, Austria) were used and inserted retropubically. AMI slings are macroporous monofilament slings that can be adjusted postoperatively by pulling or loosening Polypropylene sutures that go through the sling retropubically to tighten and paravaginally to loosen the sling in case of retention (Fig. 1). Sling insertion was performed under spinal or general anaesthetic and intraoperative cystoscopy was performed to exclude bladder and urethral perforation. Intraoperatively, a prophylactic antibiotic (Ampicillin) was initiated and continued until sling adjustment was complete.

Insertion of the sling is analog classical tension-free vaginal tape insertion; the additional Polypropylene sutures are placed retropubically through the incisions that are required for the sling insertion and vaginally lateral to the colpotomy that is needed for the sling insertion. These sutures are then
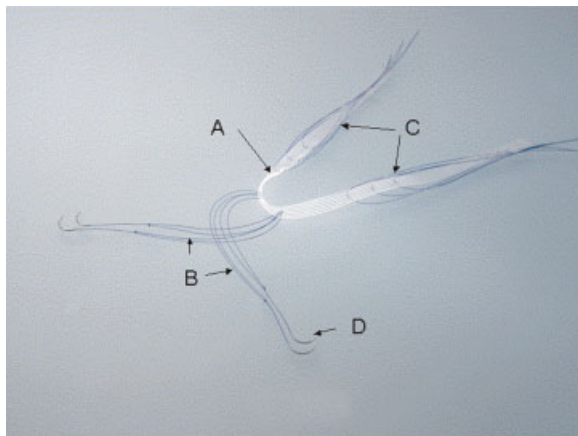

Fig. 1. (A) AMI sling; (B) threads for sling loosening; (C) suprapubic pulling thread for tightening; and (D) needles.

draped and left until they are required for tightening (the retropubic sutures) or loosened (the vaginal sutures).

Adjustment was performed postoperatively depending on the patient's cough test with the bladder at capacity and postmictional residual urine that was measured after removal of the Foley catheter. Sling adjustment was performed with Tramadol® medication 30 min prior to intervention, and after each adjustment cough test and residual urine measurement were repeated. In case of negative cough test, a Pad test was performed as recommended by the ICS.[15]

For tightening, the retropubic Polypropylene sutures were exposed removing the sterile drape and then cautiously pulled until a tightening of approximately 5 mm was achieved. For loosening, the vaginal sutures were exposed and also cautiously pulled until approximately 5 mm of the sling were pulled down. After loosening or tightening, Polypropylene sutures were draped again until the next adjustment took place.

Residual urine was measured using the Aloka SSD-1400 (Aloka® Co Ltd., Japan) with the abdominal 3.5 MHz curved array probe.

Estimation of the sample size of the study was based on a ''null hypothesis value'' for slings a secondary procedure, which is very close to the results published for TVT as a primary procedure, and a proportion (result) of 70%. These values require a sample size 24 patients for a type I error ($P < 0.05$) and a type II error ($P = 0.80$)

For statistical analysis, Prism version 4.0 for windows was used. A two-tailed t-test was performed to compare measurements before and after treatment.

RESULTS

Twenty-five patients were included in the study.

In the past, seven patients had had a transobturator tape, 18 a retropubic tension-free vaginal tape (TVT) and one patient repeat collagen injections. At the time of the current study, all patients were stress incontinent and 25 had had sling incisions or sling removal for various problems (18 times obstructive voiding disorders, 7 times urinary retention). One patient had recurrent stress incontinence after Burch colposuspension and retropubic TVT.

Additionally to the midurethral tape, 14 patients had undergone an anterior repair and three a posterior repair.

Table I shows demographic data.

Regarding previous incontinence surgery, five women had had one intervention, six of them had two, four had three, seven had four, and three had five previous interventions for incontinence in the past.

Preoperatively, 18 patients demonstrated intrinsic sphincter deficiency, two patients had an MUCP of even $0\,cmH_2O$ and five patients demonstrated urodynamic stress incontinence with a normotonic urethra.

Preoperatively, 17 patients had a reduced urethral mobility according to the perineal ultrasound findings[14] with a linear dorsocaudal movement (LDM) of <15 mm defined as hypomobility.

TABLE I. Demographic Data

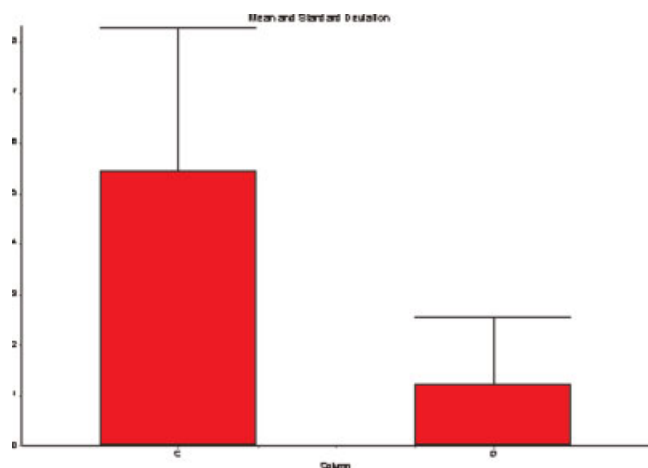|	Age (Years)	BMI (kg/cm^2)
Median	64	29
Range	43–85	24–32

Fig. 2. Pdet/Qmax (cmH2O) pre-(column A) and postoperatively (column B).

Median operating time was 21 min (range 16−31); median blood loss was 45 ml (range 10−120 ml). Intraoperatively, no serious complication was noted.

Median time of adjustment of the sling system AMI were 3 days (range 1−8), and follow-up was 12 months in median (range 3−16 months).

Figure 2 shows pdet/Qmax pre-and postoperatively.

The detrusor pressure at maximum flow rate increased significantly ($P < 0.0063$; two-tailed t-test) postoperatively; however, none of the patients became urodynamically obstructive according to the definition by Blaivas.[12]

Table II summarizes urodynamics and pad test pre- and postoperatively.

Figure 3 shows the subjective symptom bother as measured by VAS before (left column) and after (right column) sling insertion.

Subjective incontinence symptoms improved significantly ($P < 0.0001$, two-tailed t-test).

Twenty-one patients were urodynamically continent and four were still urodynamically stress incontinent at follow-up. Of the latter, one special case needs further description.

A 38-year-old woman presented with urinary stress incontinence after Burch colposuspension and posterior repair in 2005 that had been performed in a district hospital; before that, the insertion of a suburethral sling had been attempted with an iatrogenic urethra perforation. Bladder neck mobility was reduced even after urethrolysis, which was the reason for the adjustable sling. The sling was inserted uneventful but in the postoperative period satisfactory adjustment was not possible: either the patient remained stress incontinent or became obstructive including urinary retention and symptoms of OAB. Detrusor overactivity was confirmed urodynamically.

Anticholinergics were not helpful; because of the difficult situation we discussed with the patient to inject Botox 200 I.E. Botoxinjection was performed uneventfully but detrusor overactivity was not resolved and the patient's residual increased to complete retention.

The sling was then removed completely which surgically was uneventful but the patient returned to severe urodynamically proven stress incontinence. She received an artificial sphincter (AMS 800®, American Medical Systems) recently. She has not been followed-up to date.

Of the other three patients with urodynamically proven stress incontinence, two felt improved and did not require further therapy and one received a transurethral bladder neck injection.

One patient was continent after AMI sling insertion but showed an increased residual of 200 ml after repeat measurements. She was recommended clean intermittent self-catheterization (ICSC) and had the choice to loosen the sling and possibly become incontinent again or to remain on ICSC. She chose the latter.

DISCUSSION

The management of recurrent stress urinary incontinence after previous sling surgery is still a challenging situation for gynaecologists, urogynaecologists, and urologists.

Theoretically, these women could be surgically treated with colposuspension, bladder neck injections, artificial sphincter, or repeat midurethral sling surgery. Colposuspension has a cure rate of 81% when it is carried out after one failed procedure, 25% when it is performed after two failed previous surgeries, and 0% after three previous operations, and it has been suggested to avoid Burch colposuspension after more than one failed intervention.[16]

Bladder neck injections of gluteraldehyde cross-linked collagen of 65% have been reported at 1 year follow-up but their success rate declined significantly to less than 30% at more than 1 year follow-up.[17] Success rates range from 26 to 75% and this procedure is generally not considered that effective.[18,19]

Artificial sphincters are indicated for severe intrinsic sphincter deficiency and normal bladder function with a success rate of 76% and implies the disadvantage of a high amount of artificial material that makes it prone to infection and erosion.[20] Artificial sphincters are major operations.

There are few studies with a small number of patients after failed midurethral sling insertion. A recent study[21] confirmed that the TVT procedure as a second operation after previous failed midurethral tape could provide an overall cure rate of 74% with a low complication rate in female patients; however, in this study, urethral mobility as determined by Q-Tip test was not impaired. In the current study, we had a selection of patients with impaired urethral mobility and intrinsic

TABLE II. Pre- and Postoperative Urodynamics and Pad Test Results

|	Preoperative (median, range)	Postoperative (median, range)	P
First desire (ml)	195 (150−256)	170 (140−220)	0.76
Second desire (ml)	355 (320−420)	320 (190−390)	0.82
Capacity (ml)	388 (290−470)	375 (280−460)	0.78
Maximum flow rate (ml/sec)	23 (18−27)	20 (17−28)	0.49
Residual urine (ml)	30 (0−82)	45 (0−200)	0.67
Maximum urethral closure pressure (MUCP; cmH$_2$O)	10 (0−31)	21 (12−41)	<0.0001
Pad test (gr)	32 (16−89)	4 (0−12)	<0.0001
Linear dorsocaudal movement (LDM; mm)	11 (3−21)	10 (3−10)	0.899
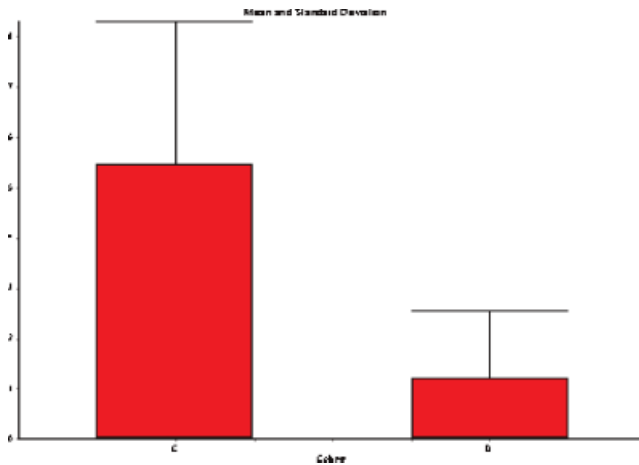
Fig. 3. Symptom bother as measured by VAS before (column C) and after (column D) sling insertion.

sphincter deficiency who had had problems with suburethral slings in the past; this is why we chose an adjustable system. Symptom bother as determined by the VAS significantly improved and 80% of the patients in the present study were objectively dry; other studies without adjustable slings report a far lower cure of 40% in patients with decreased urethral mobility and intrinsic sphincter deficiency.[22]

Adjustable systems facilitate the adjustment of sling tension under physiological conditions, e.g. when the patient is not anaesthetized and in the operating theatre but in the upright position during the cough test; however, as this study shows, we are mistaken if we expect 100% continence. In the current study, the patients were almost exclusively low-pressure fixed urethra subset of patients with stress incontinence, and our findings may not apply to a broader group of women with recurrent stress incontinence.

Adjustable slings are not new, and various systems are currently available: Palma published in his series of 16 patients with recurrent urinary stress incontinence after a transobturator sling procedure a success rate of 93.7% using the Safyre system.[23,24] Iglesias[25] inserted the Remeex system in 21 stress incontinent women with a success rate of 90% determined by patient satisfaction but this was not in recurrence after suburethral sling insertion; however, 62% had had incontinence surgery in the past. Petros[26] found an 80% subjective cure rate in 37 stress incontinent patients using an adjustable bone anchor system; his group of patients had a median of 0.8 previous incontinence procedures in the past but were not objectively assessed. In comparison to the Reemex system, the AMI sling cannot be adjusted after removal of the Polypropylene sutures, which is probably a negative aspect of this sling system.

Generally, adjustable slings implement an increased amount of foreign material that may lead to infection; none of our patients suffered from infections but all patients received prophylactic antibiotics during adjustment. However, the AMI sling has only four to eight additional Polypropylene strings that are removed when sling adjustment is satisfactory and no additional material is left inside compared to non-adjustable slings.

The overall goal of the placement of an adjustable sling is to produce adequate urethral resistance to prevent stress incontinence whilst ideally allowing voluntary and complete

bladder emptying. A common problem of sling surgery is excessive tension and bladder outlet obstruction.[27] Despite the adjustable system, one patient presented with significant residual urine requiring intermittent self-catheterization, and we were unable to reach full continence without residual urine in that case.

None of the patients presented with obstructive voiding or de novo urgency, but we had one patient who was either stress incontinent or showed detrusor overactivity that lead finally to sling removal, so we do not think at all that adjustable slings are the general solution for all problems in difficult cases. Due to adjustment, that patient probably developed detrusor overactivity due to obstruction, as the system allows rather rough adjustment only we were unable to find the proper balance of non-obstructive voiding and continence.

Detrusor pressure at maximum flow rate increased significantly in the current study, so despite nobody being obstructed according to the Blaivas definition we consider that there might be obstruction to some degree. MUCP increased significantly, and this may be a result of the tension that is applied to the urethra during the process of adjustment. Careful follow-up of these patients is required to detect urethral erosion early. In patients with any symptoms of the lower urinary tract, recurrent infections and/or persisting pathologic urine specimen erosion of the sling should be anticipated and urethrocystoscopy performed.

A weak point of the study is the small number of patients; however, these patients were a selection of women who had been operated before unsuccessfully, and the majority showed intrinsic sphincter deficiency and an impaired urethral mobility. We consider it important to report our experiences despite the small number and the mixed outcome as there is no clear guidance on which approach would offer the best outcome.

This is a non-comparative study; Kuuva[28] has found equally good findings with the classical TVT procedure in 51 patients with recurrent stress incontinence. The objective and subjective cure rate was 90 and 80%, respectively.

During the classical TVT-procedure, a cough test is performed intraoperatively as described by Ulmsten[1] and in the current study, the cough test was performed postoperatively in the wake unanaesthetized patient. The latter may be the more physiological situation to test the sling result.

When recurrent urinary stress incontinence occurs, a multimodal assessment in a specialist center is necessary.

A point that seems crucial is that extensive counseling of the patients on the lack of published data in secondary surgery and its results, and even promising systems have failures.

Surgeons who treat patients must not forget that meeting patients' expectations and goals, especially those of female patients with surgical failure, is a responsibility of our profession.[29]

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