Urethral Bulking for Recurrent Stress Urinary Incontinence After Midurethral Sling Failure

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Aims: To assess the effectiveness of a polyacrylamide hydrogel (PAHG; Bulkamid®) in treating recurrent stress urinary incontinence (SUI) following a previous midurethral sling (MUS) implant. Methods: This observational study, conducted since 2009, included 60 patients with recurrent SUI or mixed urinary incontinence (MUI) after a previous MUS and who chose to be treated with PAHG. Objective and subjective outcomes were assessed at 1, 6, and 12 months after the initial injection. Patients were classified as cured based on a negative cough test (supine and standing) and <2 g urine on 1-hr pad test and a VAS score improved by ≥90%. Improved were those with the loss of only a few drops of urine during the cough test and 2–10 g urine on 1-hr pad test or a reduction >50% compared with preoperative urine loss and a VAS score improved by ≥75%. Results: The volume of PAHG injected in the current study ranged from 1–3 ml. Cured/improved rates were 93.3% (56/60), 88.3% (53/60), and 83.6% (46/55) at 1, 6, and 12 months, respectively. Patients with MUI had a cured urgency urinary incontinence rate of 36.8%, 47.4%, and 38.9%, respectively. Voiding dysfunction rates were 13.3% (8/60), 8.3% (5/60), and 1.8% (1/55) at 1, 6, and 12 months and urinary tract infection rates were 5% (3/60), 11.7% (7/60), and 3.6% (2/55), respectively. Other adverse events were short-term and/or observed in <4% of patients. Conclusions: PAHG can be used to treat recurrent SUI after MUS failure with good outcome and low complication rates. Neurourol. Urodynam. 36:722–726, 2017. © 2016 The Authors. Neurourology and Urodynamics published by Wiley Periodicals, Inc.

Key words: Bulkamid®; bulking agents; pelvic floor sonography; polyacrylamide hydrogel; recurrent stress incontinence; salvage therapy; tension-free vaginal tape}

INTRODUCTION

The midurethral sling (MUS) is the recommended treatment option for women with uncomplicated stress urinary incontinence (SUI), although patients need to be warned of the complications they might expect, particularly pain, dyspareunia, de novo urgency, or urgency urinary incontinence (UUI). Management of recurrent SUI following primary insertion of a synthetic MUS remains a challenge. Since no consensus is available to favor one treatment over another, treatment selection frequently depends on the experience of the surgeon. Second-line treatment options include a second sling, although it is debated whether this provides inferior outcome compared with first-line sling treatment, or a transurethral bulking agent. A recent survey of members of the International Urogynecological Association (IUGA) found that retropubic sling was the preferred surgical option with transurethral bulking agents being more popular in the absence of urethral hypermobility after a failed sling procedure. Injection of a bulking agent into the submucosal tissues of the urethra is thought to increase the central filler volume and thus the power of the urethral sphincter. PAHG (Bulkamid®; Contura International A/S, Soeborg, Denmark) is a homogenous non-particulate hydrogel (2.5% cross-linked polyacrylamide and 97.5% water), is non-degradable and in situ is migrant resistant, exchanging water, salts, and organic molecules with the host tissue. With time, it gradually becomes fully integrated in the tissue, anchored to the injection site through a fine vessel network. As a first-line treatment in women with SUI or mixed urinary incontinence (MUI), outcome up to 8 years with minimal complications has been demonstrated. Objective response rates of up to 89% and subjective response rate of up to 77% have been reported. The aim of the current observational study was to assess the effectiveness of PAHG in treating recurrent SUI and stress-dominant MUI following a previous MUS treatment.

MATERIALS AND METHODS

This observational study commenced in 2009 and included patients who had a recurrent SUI or stress-dominant MUI after previous MUS. Patients with a tape location severely outside the midurethral zone, with obstructive tape location (too close to urethra), or with a postvoid residual (PVR) volume...
>100 ml were excluded from the study. Treatment options of a repeat sling procedure or a bulking agent were offered to all patients and complication profiles of each type of surgery were discussed. Included in the study are those patients who selected a bulking agent. Ethical approval was obtained (EKLTG 200906/AA02).

The preoperative evaluation of SUI and MUI as well as objective and subjective outcome assessments were done according to the standard operating procedures for incontinence surgery applied at the clinic and included completion of a 3-day micturition diary and as recommended by Ulsten et al. a stress provocation test, a pad test, and a self-administered incontinence questionnaire. The stress provocation test (cough test) was performed in the supine and standing positions with a comfortably filled bladder (300 ml bladder volume recorded by ultrasound). The 1-hr pad test consisted of a standardized exercise regimen combined with assessment of an UUI component (hand washing). In the questionnaire, patients self-evaluated their incontinence severity on a visual analogue scale (VAS) score (VAS score 0–10; 0—without leakage of urine, completely dry). In order to confirm the diagnosis of SUI and MUI prior to second-line treatment, all study patients underwent clinical and invasive urodynamic assessment (comprising of cystometry, urethral pressure profilometry, and uroflow studies). Multichannel urodynamic testing was performed on Sedia SE-6 (Sedia AG, Givisiez, Switzerland) with a microtip catheter pulled by the electric puller. Urethral sphincter function was obtained during profilometry after inflating 300 ml saline into the bladder.

Preoperative ultrasonography was conducted to assess urethral length, so that the mid-point could be determined for injection of the bulking agent and at the same time the position of the previous sling placement, which was left in position, was assessed (Fig. 1A). Intraoperative single shot antibiotics (Cefuroxim, a second generation cephalosporin) were administered as well as local anesthesia with or without sedation (Propofol and Fentanyl). The bulking agent was injected under endoscopic guidance. The cystoscope used for injection included a stop point rubber ring around the sheath (Fig. 1B) that was positioned halfway according to the patient’s individual urethral length to ensure correct midurethral placement of bulking agent (same plane for all three depots) and to ensure that it was not moved back and forth over the injection site. The cystoscope was connected to a 0° optic and the rotating sheath over the cystoscope allowed the modified 22 gauge × 12 cm needle to rotate 360°. The needle itself was a modification of a previous version such that it had a blunt end to limit the depth of penetration (Fig. 1C). The material was also released from a side opening allowing the bulking agent to be delivered laterally to the needle rather than forward in order to improve the accuracy of placement.

Three PAHG injections were given at the mid-urethral position to achieve coaptation of the urethra (Fig. 2). The first at the 6 o’clock position was the key site and approximately 1 ml material was delivered to ensure that a good “cushion” was achieved. The two other sites were at three and 9 o’clock and included injection of approximately 0.5 ml each. Postprocedure at 1, 6, and 12 months a cough test (supine and standing) was conducted as well as ultrasound to check the number and positions of the depots. Patients were discharged from the clinic on the next day following confirmation of a PVR volume <100 ml and successful voiding. Antibiotics were administered postoperatively if intermittent catheterization (with an eight Charrière catheter) was required, and transient cholinomimetic treatment (Bethanechol) if voiding difficulties persisted. In cases of urinary retention, the size of the depot was reduced by mechanical compression using a 20 Charrière foley catheter for 30 min. Voiding dysfunction was defined in accordance with the International Continence Society as slow stream and/or staccato micturition plus a continual PVR volume of >100 ml.

Objective and subjective outcomes were assessed at 1, 6, and 12 months using the cough test, the 1-hr pad test and a patient visual analogue scale (VAS) score (see above). Patients were classified as cured based on a negative cough test and <2 g on

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*Fig. 1. A. Sonographic urethral length measurement to determine the mid-point of the urethra. B. bladder, UL, urethral length. B. Cystoscope with a stop point rubber ring (white ring), which was placed halfway of the patient’s individual urethral length (at the mid-point of the urethra). C. Delivery needle. Top: original needle 12 cm, 23 G with a sharp tip (Contura International A/S, Denmark). Bottom: modified needle with the blunt end tip 12 cm, 22 G (FemoBulk Peter Pflugbeil GmbH, Germany) used in the study.*
1-hr pad test and a VAS score improved by $\geq 90\%$ (i.e., score 0–1). Patients were classified as improved based on the loss of only a few drops of urine during the cough test and 2–10 g urine on 1-hr pad test or a reduction $\geq 50\%$ compared with preoperative urine loss and a VAS score improved by $\geq 75\%$ (i.e., score 2–3). Failure was defined as urine loss during the cough test, $>10$ g on the 1-hr pad test or a VAS score $>3$. Intra- and post-operative complications up to 12 months were recorded. De novo urgency was defined as post-operative development of the symptoms of urgency, which were not present before surgery and persisted for at least 1 month and were assessed by means of a three day micturition diary. Urinary tract infection (UTI) implied the presence of characteristic symptoms and significant bacteriuria ($\geq 10^5$ CFU/ml). Transient hematuria was defined as the macroscopic presence of blood in the urine, and hematoma as a transient, paraurethral blood collection after surgery, which was confirmed sonographically.

Descriptive statistics were conducted to examine patient characteristics, treatment parameters and the frequency of treatment outcomes, and complication rates. Frequency data of categorical variables was analyzed with the Chi-square-test or the Fisher exact test of the STATA software, with a significance level alpha $\leq 0.05$ (StataCorp LP, IC 13.1, College Station, TX).

RESULTS

The study included 60 women who developed recurrent SUI or stress pre-dominant MUI after one or more previous sling procedures. Patient characteristics and treatment parameters are shown in Table I. In addition to all patients being diagnosed with recurrent SUI, 31.7% (19/60) had MUI and 36.7% (22/60) had intrinsic sphincter deficiency (ISD), defined as an urodynamic maximal urethral closure pressure of $\leq 20$ cm H$_2$O. Patients had also undergone a wide range of gynecological treatments, including a 43.7% rate of colposuspension and 36.7% rate of anterior and posterior colporrhaphy. The volume of PAHG injected in this present study ranged from 1 to 3 ml (median 2 ml). The median volume injected at the key site at 6 o’clock was 1 ml (range 0.5–2 ml). The 9 and 3 o’clock sites had a median of 0.5 ml and ranges from 0.2 to 1 ml or 0.2 to 0.9 ml, respectively. Ultrasound showed that none of the depot injections had relocated from the injection site.

Cure rates of 43.3% (26/60) and 25.4% (14/55) were reported at 6 and 12 months, respectively (Table II). Improved rates were 46.7% (28/60) and 58.2% (32/55) at 6 and 12 months, respectively. This provided cured/improved rates of 93.3% (56/60), 88.3% (53/60), and 83.6% (46/55) at 1, 6, and 12 months, respectively. Of the five patients lost to follow-up at 12 months, one was cured at 1 and 6 months and the other four patients were improved at 1 and 6 months. At 6 months, 49 patients stayed in the same class as the previous visit, while 10 had a worsened condition and 1 changed from improved to cured. Similarly, 43 of 55 patients stayed in the same class at the 12 months visit compared with the previous visit, while 12 had a worsened condition. No difference in the outcome was observed between ISD patients

| Characteristic | (n = 60) |
|----------------|---------|
| Age, mean (SD), years | 71.7 (10.7) |
| BMI, mean (SD) | 28.8 (3.9) |
| Time interval since previous midurethral sling placement or Bulkmid treatment, median (range), months | 18 (1–119) |
| Previous incontinence treatments, n (%) | |
| TVT | 51 (85.0%) |
| TVT-O | 17 (28.3%) |
| TVT-S, mini sling | 5 (8.3%) |
| Sling incision | 9 (15.0%) |
| Partial sling extirpation | 5 (8.3%) |
| Bulkmid | 2 (3.3%) |
| Colposuspension | 25 (41.7%) |
| Other previous surgeries, n (%) | |
| Vaginal urethrolysis | 6 (10.0%) |
| Abdominal hysterectomy | 21 (35.0%) |
| Vaginal hysterectomy | 12 (20.0%) |
| Prolapse surgery | 11 (18.3%) |
| Anterior colporrhaphy | 8 (13.3%) |
| Anterior and posterior colporrhaphy | 22 (36.7%) |
| Mesh anterior | 12 (20.0%) |
| Mesh posterior | 3 (5.0%) |
| Sacrocopexy | 26 (43.3%) |
| Fistula | 2 (3.3%) |
| Vulvectomy | 1 (1.7%) |

BMI, body mass index; ISD, intrinsic sphincter deficiency; TVT, transvaginal sling; TVT-S, tension-free vaginal sling-Secur; TVT-O, transobturator sling.
Salvage Bulking Therapy After MUS failure

No severe AEs were reported in the current study. The cases of persistent UUI can be attributed to the high number of patients with MUI included or could be due to the fact that 41.7% of patients had undergone colposuspension. In comparison to repeat MUS, Stav et al.\textsuperscript{3} reported voiding complications including de novo urgency (30%), persistent urgency (70%), de novo UUI (22%), persistent UUI (69%), and voiding difficulties (4%). Lee et al.\textsuperscript{4} also reported the following complications after repeat MUS: bladder perforation (3.4%), de novo urgency (13.0%), and voiding difficulties (10.3%).

Very few studies have been published on the use of bulking agents as salvage therapy following a previous MUS. A retrospective study of the bulking agents Macroplastique\textsuperscript{6} and Durasphere\textsuperscript{6} as salvage therapy conducted in 23 women reported a cure rate of 34.8% at 10 months.\textsuperscript{2} Patients in that study had undergone one previous sling procedure and eight of them had undergone a hysterectomy. Kim et al.\textsuperscript{21} reported a 40% (22/56) success rate with Durasphere\textsuperscript{6} after failed MUS procedures at an average time of 64.3 months.

Salvage therapy with a sling following failed first-line sling treatment has been reported. Kardin et al.\textsuperscript{7} conducted a retrospective multicenter study of 245 women who were treated with TVT for genuine stress urinary incontinence (GSI) (157 for primary and 88 for recurrent GSI); the mean (SD) duration of follow-up was 38 (16) weeks. Cure rates among patients with recurrent versus primary GSI were similar (85% and 87%, respectively; \( P = 0.23 \)). These findings are in line with other reports.\textsuperscript{24} In contrast, Stav et al.\textsuperscript{3} reported subjective stress incontinence cure rates 86% (n = 1035; mean 51 months) and 62% (n = 77; mean 40 months) with primary and repeat MUS, respectively (\( P < 0.001 \)). Lee et al.\textsuperscript{4} conducted a retrospective analysis of 29 patients who underwent a second sling procedure following a failed MUS. The original slings were not removed. At 12 months follow-up cure and improvement rates were 75.9% (22/29) and 6.9% (2/29), respectively. These cure rates were lower than for the initial sling, with cure rates of 86.8% at 13 months reported at the same institute.\textsuperscript{25}

A retrospective study has compared salvage therapy conducted between 2008 and 2011 involving a repeat sling (n = 165) or a bulking agent (Coaptite\textsuperscript{8}, Macroplastique\textsuperscript{6}, and Contigen\textsuperscript{9}; n = 67).\textsuperscript{26} Failure rates were 11.2% and 38.8% in MUS and bulking groups, respectively (\( P = 0.004 \)). However, due to the retrospective nature of the study it did not include validated measures of subjective or objective failure or standardized follow-up intervals. There were no differences in perioperative complications or AEs between the groups.

There are currently no established guidelines on salvage therapy following previous MUS and studies on effectiveness and safety of different therapy options are needed. Patients with recurrent SUI after previous MUS are likely to be difficult to treat patients with often a wide range of previous surgeries, thus making it harder to identify an association between salvage therapy and continence outcome due to potential confounders. The patients included in this report had undergone several previous gynecological procedures as the objective was to determine whether continence could be achieved in this complex patient group.

Even though we did not limit PAHG treatment to certain subgroups of patients, for example, presence of low urethral pressure or hypermobility, a potential selection bias cannot be excluded. Other weaknesses of this study are the relatively small sample size and that we did not follow the group with repeat sling procedure as this was not set up as a randomized controlled trial. Nevertheless, this study adds an analysis of a salvage population for recurrent SUI and stress-predominant MUI.

### TABLE II. Treatment Outcome Assessment at 1, 6, and 12 Months

|                  | 1 month (n = 60) | 6 months (n = 60) | 12 months (n = 55) |
|------------------|-----------------|------------------|--------------------|
| Cured, n (%)     | 34 (56.7)       | 26 (43.3)        | 14 (25.4)          |
| Improved, n (%)  | 23 (38.3)       | 28 (46.7)        | 32 (58.2)          |
| Failed, n (%)    | 3 (5.0)         | 6 (10.0)         | 9 (16.4)           |

(MUCP \( \leq 20 \text{ cm H}_2\text{O} \)) and non-ISP patients (\( P > 0.4 \) for all follow-up visits). Similarly, no difference in the outcome was observed between patients with SUI versus MUI (\( P > 0.5 \) for all follow-up visits). Among the patients with MUI, urgency urinary incontinence was cured in 36.8% (7/19), 47% (9/19), and 38.9% (7/18) at 1, 6, and 12 months, respectively.

Adverse events (AEs) are shown in Table III. After PAHG treatment, UUI persisted in 20%, 16.7%, and 20% of the patients at 3, 6, and 12 months, respectively, whereas before treatment, UUI was reported for 31.7% MUI patients. The eight cases of voiding dysfunction occurred during the first 3 post-operative days and were resolved with catheterisation. Two of these patients received transient cholinomimetic treatment. The size of the depots was reduced in one patient suffering from urinary retention. UTI rates were 5%, 11.7%, and 3.6% at 1, 6, and 12 months, respectively. De novo urgency occurred in 1.7%, 3.3%, and 3.6% at the respective follow-up visits, while no de novo UUI was observed. Other AEs were short-term and observed in less than 2% of patients.

### DISCUSSION

The aim of salvage bulking therapy following a previous MUS is to achieve a better dorsal compression of the urethra by narrowing the distance between the tape and the urethra with the bulking agent. Cure rates reported in the study were 43.3% and 25.4% at 6 and 12 months, respectively, whereas before treatment, UUI was reported for the 31.7% MUI patients. The eight cases of voiding dysfunction occurred during the first 3 post-operative days and were resolved with catheterisation. Two of these patients received transient cholinomimetic treatment. The size of the depots was reduced in one patient suffering from urinary retention. UTI rates were 5%, 11.7%, and 3.6% at 1, 6, and 12 months, respectively. De novo urgency occurred in 1.7%, 3.3%, and 3.6% at the respective follow-up visits, while no de novo UUI was observed. Other AEs were short-term and observed in less than 2% of patients.

Table III. Adverse Events

| Adverse events | <1 month (n = 60) (%) | 6 months (n = 60) (%) | 12 months (n = 55) (%) |
|----------------|-----------------------|-----------------------|-----------------------|
| Persistent UUI| 12 (20.0)             | 10 (16.7)             | 11 (20.0)             |
| Voiding dysfunction\textsuperscript{a}| 8 (13.3)              | 5 (8.3)               | 1 (1.8)               |
| UTI (\(>10^5\) CFU/ml)| 3 (5.0)               | 7 (11.7)              | 2 (3.6)               |
| De novo urgency| 1 (1.7)               | 2 (3.3)               | 2 (3.6)               |
| Hematuria      | 1 (1.7)               | 0                     | 0                     |
| Injection site laceration| 1 (1.7)               | 0                     | 0                     |
| Hematoma       | 1 (1.7)               | 0                     | 0                     |
| Urinary retention| 0                    | 0                     | 0                     |
| Injection site pain| 0                    | 0                     | 0                     |

UTI, urinary tract infection; UUI, urge urinary incontinence.

\textsuperscript{a}Accompanied with residual urine >100 ml.
CONCLUSIONS

PAHG can be used as salvage therapy in patients who have undergone several previous therapies for SUI. The technique used in the current study resulted in a 12 months objective/subjective cured and improved rate of 83.6%, which is comparable to first-line bulking therapy. Although success rates were lower than those reported with salvage MUS treatment, complications were minimal and less than those seen with repeat MUS. Mid-term follow-up will be the topic of a future publication.

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