Tension-Free Vaginal Tape Surgery versus Polyacrylamide Hydrogel Injection for Primary Stress Urinary Incontinence: A Randomized Clinical Trial

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Abbreviations and Acronyms

PAHG = polyacrylamide hydrogel
PVR = post-void residual urine
SUI = stress urinary incontinence
TVT = tension-free vaginal tape
VAS = visual analogue scale

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Purpose: We evaluated whether polyacrylamide hydrogel is noninferior to tension-free vaginal tape to treat women with primary stress urinary incontinence.

Materials and Methods: In this controlled noninferiority clinical trial patients with primary stress urinary incontinence were randomized to tension-free vaginal tape or polyacrylamide hydrogel treatment. The primary outcome was patient satisfaction and secondary outcomes were effectiveness in reducing urinary leakage and complications at 1-year followup. For statistical power significance was considered at 5%, power was set at 80% and the noninferiority limit was 20% with a 10% expected dropout rate.

Results: A total of 224 women with primary stress urinary incontinence entered the study between September 28, 2015 and March 1, 2017. Of the women 111 were randomized to tension-free vaginal tape and 113 were randomized to polyacrylamide hydrogel. At 1 year a satisfaction score of 80 or greater on a visual analogue scale of 0 to 100 was reached in 95.0% and 59.8% of patients treated with tension-free vaginal tape and polyacrylamide hydrogel, respectively. Thus, polyacrylamide hydrogel did not meet the noninferiority criteria set in our study. As secondary outcomes, the cough stress test was negative in 95.0% of tension-free vaginal tape cases vs 66.4% of polyacrylamide hydrogel cases (difference 28.6%, 95% CI 18.4-38.5). However, most perioperative complications, including those in 19 tension-free vaginal tape cases vs 3 polyacrylamide hydrogel cases (difference 16.0%, 95% CI 7.8-24.9), and all 6 reoperations due to complications (difference 5.9%, 95% CI 1.2-12.4) were associated with tension-free vaginal tape.

Conclusions: Mid urethral tension-free vaginal tape slings were associated with better satisfaction and cure rates than polyacrylamide hydrogel in women with primary stress urinary incontinence. However, complications were mainly associated with tension-free vaginal tape. Thus, tension-free vaginal tape should be offered as first line treatment in women who expect to be completely cured by the initial treatment and are willing to accept the complication risks. Since polyacrylamide hydrogel treatment also provides high satisfaction and cure rates, women with primary stress urinary incontinence can be offered polyacrylamide hydrogel as an alternative treatment.

Key Words: urethra; urinary incontinence, stress; suburethral slings; hydrogels; risk

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One of 3 adult females experiences SUI, defined as involuntary leakage upon exertion, sneezing or coughing.[1,2] Pelvic floor muscle training is first line treatment of SUI. If this fails, mid urethral sling surgery with retropubic TVT has been considered the gold standard surgical option. While TVT efficacy is as high as 90%, complications or side effects may develop in up to 20% to 30% of patients.[2] Furthermore, long-term complications of mid urethral slings such as erosion and pain have been poorly studied and appear to be under reported.[3] Due to these potentially serious complications and an increasing number of legal claims[4] medical authorities in countries such as the United States and the United Kingdom have published warnings about the use of mid urethral slings.[5,6] In England the new NICE (National Institute for Health and Care Excellence) guidelines advise considering mid urethral slings only if alternative surgical procedures are not suitable.[7] Thus, other treatment options are warranted.[8]

An alternative treatment option for SUI is bulking. Bulking agents create an artificial mass in the urethral submucosa to improve urethral coaptation and restore continence.[9] Currently 2 types of bulking agents are used.[10] The first type contains particles which cause inflammation and this reaction gives support around the urethra. The second type of bulking agent is a homogenous gel without particles. Transurethral PAHG (Bulkamid®) is a homogenous gel that has been used for more than 10 years to treat SUI in women and it has proved to be a safe intervention.[11] However, PAHG injections have been typically done as salvage treatment with the subjective success rate varying from 50% to 70%.[12–14]

Although PAHG is also gaining popularity in younger women, its true long-term efficacy or efficacy in the treatment of primary SUI is not established.[10] Thus, we performed a randomized trial comparing TVT and PAHG treatments in women with primary SUI.

MATERIALS AND METHODS

This randomized, controlled, parallel group trial comparing TVT and PAHG for primary SUI was performed at Helsinki University Hospital. The study was approved by the Helsinki University Hospital Ethics Committee (IRB No. 19/13/03/03/2015) and patients provided written informed consent.

We recruited patients with primary SUI between September 28, 2015 and March 1, 2017. Study inclusion criteria included SUI not responsive to conservative treatment, patient age greater than 18 years, no previous incontinence procedure, a positive cough stress test without urge-type leakage, PVR volume less than 100 ml and bladder capacity greater than 300 ml.

In addition to the clinically used cough stress test, we used a pad test to confirm SUI.[15] Patients were requested to complete a 2-day micturition diary and the detrusor instability score was calculated to exclude symptoms of urge urinary incontinence. Urodynamic testing was not mandatory but it was done if the SUI diagnosis was not confirmed, eg there was no positive cough or stress pad test.[16] Exclusion criteria were body mass index greater than 35 kg/m^2, neurogenic disease, use of anticholinergics or mirabegron, illness or another condition causing a risk of complications during the TVT operation, active malignancy, urinary tract infection, more than second degree urogenital prolapse, pregnancy or future plans for pregnancy, or inability to understand the purpose of the study.

Patients were randomized 1:1 to TVT or PAHG using a computer assisted, random block system and R (https://www.r-project.org/). This was done by an assistant outside the study. Randomization cards were sealed in opaque, sequentially numbered envelopes and opened by the recruiting physician together with a nurse after the patient signed the consent form. This trial was open label, in that participants or investigators were not masked to treatment. However, followup visit assessments were performed by personnel other than the operating surgeon.

All primary procedures were done in an outpatient operating room. As a mid urethral sling we used the Gynecare TVT Exact® system as originally described.[17] Briefly, the TVT was inserted with the patient under local anesthesia using 70 to 100 ml 0.25% prilocaine with epinephrine. Cystoscopy with a 70-degree optic was performed during the operation to detect possible bladder perforation. The sling was adjusted to avoid retention using the cough test (200 to 300 ml saline in the bladder), allowing a few drops of saline to escape on vigorous coughing.

PAHG (Bulkamid®) was injected with the patient under local anesthesia with periurethral lidocaine (10 ml) injections. Under endoscopic control at 1.5 cm from the vesicourethral junction hydrogel was injected at the 10, 2, 5 and 7 o'clock locations with the aim that the hydrogel cushions would meet at the midline. This 4-injection site method differs from the previous technique in which only 3 PAHG injection locations were used (fig. 1).[13] The 4-injection site method was used to apply a lower volume in each cushion and maintain sufficient coaptation should 1 cushion become disrupted and disappear. Patients treated with TVT and PAHG were discharged home after successful micturition with PVR less than 200 ml.

The study nurse telephoned the patients 1 month after the initial procedure. While PAHG cushions are injected under endoscopic control, optimal results are sometimes not achieved with the initial injections. Thus, as part of the study protocol 1 more PAHG injection (an addition or top up) after the initial PAHG treatment was offered if the patient was not satisfied. PAHG additions were scheduled for the first postoperative visit at 3 months and done based on filling up or replacing a missing cushion. Patients who elected TVT after the initial procedure were also treated within 3 months upon request. After the 3-month visit patients were instructed to contact the study nurse if still unsatisfied.

A primary outcome was patient satisfaction with treatment measured on a VAS of 0—extremely unsatisfied to 100—extremely satisfied at postoperative visits with patient satisfaction of 80 or greater defined as a good satisfaction level.[14,18,19] We selected this cut point with

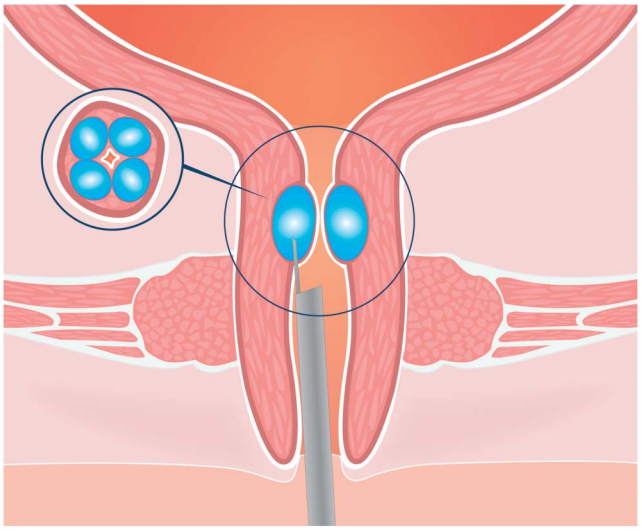

Figure 1. Four-injection site method of PAHG treatment

the assumption that it would represent a generally good level of satisfaction. Secondary outcome measures were treatment effectiveness in reducing urinary leakage and complications, including pain during and after treatment.

Objective cure was defined as a negative cough stress test and pad test. Subjective cure was measured using a 5-point Likert-like scale with incontinence considered 1—cured, 2—improved, 3—no change, 4—worsened or 5—cannot answer. The patient estimation of distress caused by SUI was measured using a numerical rating scale of 0—no distress to 10—very much distress. De novo urgency was defined as the need for anticholinergic or mirabegron treatment. Pain was measured by numerical rating scale. We also classified complications using the Clavien-Dindo grades I to IV, indicating complication severity.[20]

The study was performed as a noninferiority trial according to patient satisfaction. Based on earlier studies we decided that a score of 80 or greater on a VAS of 0 to 100 for patient satisfaction with the treatment result would be a good outcome and we assumed that this would be achieved by 80% of patients the TVT group and 75% in the PAHG group.[14,18,19] Sample size was calculated for a binary outcome noninferiority trial with significance considered at 5%, power at 80% and the noninferiority limit at 20%. Altogether 192 patients (96 per group) were required. Because a 10% dropout rate was assumed, 212 women were planned to be randomized 1:1 for the study but 224 were randomized before the study was closed.

Data are presented on an intent to treat basis with results shown according to the assigned treatment (fig. 2). Data were missing on 4 women (1.9%) who were lost to followup. All 208 patients who attended the 1-year followup visit were included in analysis.

Statistical analyses were performed with SPSS® Statistics for Windows®, version 24.0. Descriptive statistics were used to analyze baseline characteristics. Differences in continuous variables were analyzed by the Mann-Whitney U test for skewed data. The data are presented as the median and IQR with statistical significance considered at $p < 0.05$.

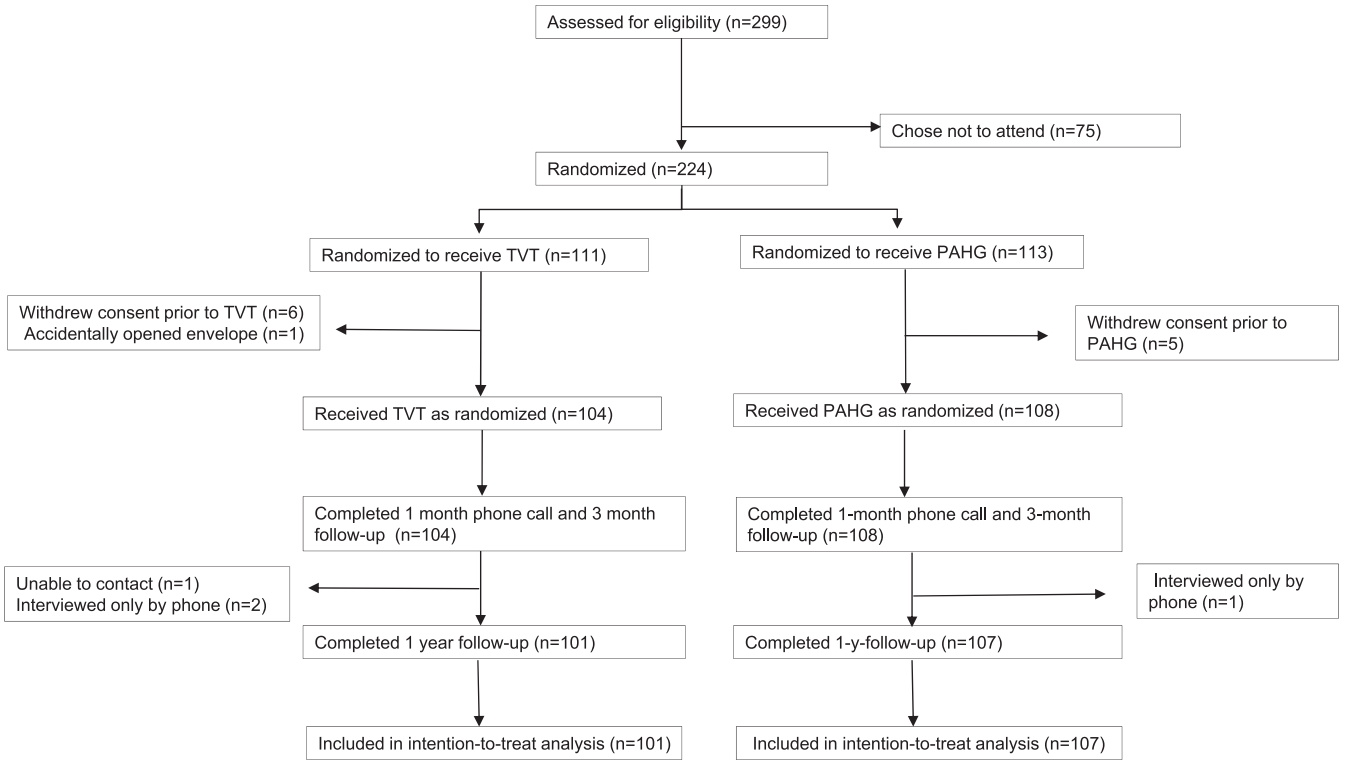

Figure 2. Trial profile

RESULTS

A total of 224 patients were randomized (fig. 2). Prior to treatments 6 women in the TVT group and 5 in the PAHG group withdrew consent. In the TVT arm 1 woman accidentally received 2 randomization envelopes. In addition, 4 women were lost to followup, leaving 208 (101 with TVT and 107 with PAHG) available for the 1-year intent to treat analysis (fig. 2).

Baseline characteristics did not differ between the groups (table 1). For the primary PAHG injections an average of 1.8 ml hydrogel were used. At the 3-month visit 46 women (43%) requested additional PAHG and an average of 1.4 ml hydrogel was added. In the PAHG group 11 women (10%) did not request additional PAHG at 3 months but preferred TVT. Eight women did not believe that adding PAHG would help and 3 had experienced the initial treatment as too painful. Five women underwent TVT surgery after 2 PAHG treatments. In the TVT group 2 women (2%) underwent PAHG treatment but none underwent repeat TVT surgery.

The primary patient satisfaction outcome of a score of 80 or greater on the VAS of 0 to 100 was achieved by 96 vs 64 patients treated with TVT vs PAHG. Thus, PAHG did not attain the noninferiority set in our study (difference 35.2%, 95% CI 24.4-45.1, p <0.001, fig. 3). The median satisfaction score was 99 (IQR 94-100) in the TVT group and 85 (IQR 65-98) in the PAHG group. Per protocol analysis showed similar results with a median satisfaction score of 99 (IQR 94-100) in the TVT group of 99 women and 81 (IQR 63-95) in the PAHG group of 91.

In terms of an objective cure the cough stress test was negative in 96 patients (95.0%) in the TVT group vs 71 (66.4%) in the PAHG group (difference 28.6%, 95% CI 18.4-38.5, table 2). More women treated with TVT than those treated with PAHG would choose that therapy again (98 or 97.0% vs 95 or 88.8%) or recommend it to a friend (100 or 99.0% vs 99 or 92.5%, each p=0.02)

In the TVT group 45 women (44.6%) and in the PAHG group 21 (19.6%) experienced any perioperative and/or postoperative complications (difference 24.9%, 95% CI 12.3-36.6, table 2). Most perioperative complications and all reoperations due to complications were associated with TVT surgery (table 2). Based on Clavien-Dindo grading postoperative complications were more common in the TVT group (table 2).

Table 1. *Intent to treat data on 212 women who received TVT or PAHG treatment*

	TVT	PAHG
No. pts	104	108
Median age (IQR)	48 (42—57)	49 (42—60)
No. postmenopausal (%)	44 (42.3)	48 (44.4)
Median kg/m^2 body mass index (IQR)	24 (22—26)	25 (22—27)
No. smoking (%)	14 (13.5)	10 (9.3)
No. socioeconomical status (%):		
Working	83 (79.8)	86 (79.6)
Upper white collar	29 (27.9)	28 (25.9)
Lower white collar	44 (42.3)	40 (37.0)
Blue collar	12 (11.5)	19 (17.6)
Student	0	3 (2.8)
Other	19 (18.3)	18 (16.7)
Median No. parity or delivery (IQR):	2 (2—3)	2 (2—3)
0	7 (6.7)	4 (3.7)
1	16 (15.4)	17 (15.7)
2	54 (51.9)	59 (54.6)
3 or More	27 (26.0)	28 (25.9)
Vaginal	93 (89.4)	101 (93.5)
Cesarean section only	4 (3.8)	3 (2.8)
No. previous pelvic surgery (%):	44 (42.3)	49 (45.4)
Hysterectomy	20 (19.2)	22 (20.4)
Anterior colporrhaphy	6 (5.8)	9 (8.3)
Posterior colporrhaphy	7 (6.7)	11 (10.2)
Other	14 (13.5)	14 (13.0)
No. yrs incontinence (%):		
More than 1—less than 2	1 (1.0)	4 (3.7)
2—5	64 (61.5)	65 (60.2)
More than 5	39 (37.5)	39 (36.1)
Median VAS incontinence distress (IQR)*	8 (8—9)	8 (7—9)
No. pos stress test (%):		
Cough	103 (99.0)	105 (97.2)
Pad†	96 (93.2)	101 (94.4)
Urodynamics	8 (7.7)	14 (13.0)

* Data missing on 1 patient in PAHG group (VAS range 0 to 10).
† Data missing on 1 patient in TVT group and 1 in PAHG group who micturated before test.

DISCUSSION

After the 1-year followup women with TVT reported better satisfaction and, thus, PAHG did not meet the noninferiority criteria set in our study. While TVT provided higher satisfaction and cure

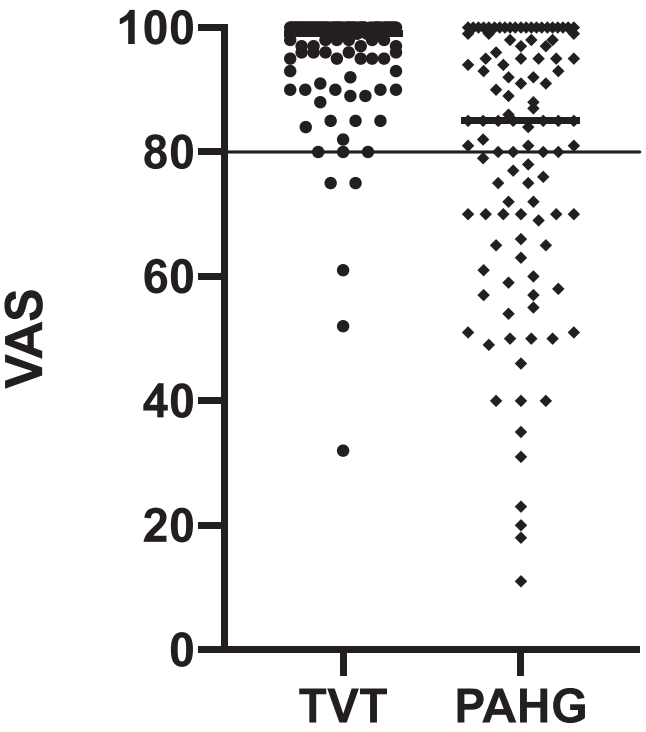

Figure 3. Patient satisfaction on intent to treat analysis 1 year after TVT or PAHG treatment.

Table 2. *Objective and subjective cure on intent to treat analysis 1 year after TVT or PAHG treatments, and perioperative and postoperative complications*

	No. TVT (%)	No. PAHG (%)	% Difference (95% CI)	p Value
Overall	101	107	—	—
		Cure		
Objective:				<0.001
Cough stress + pad tests neg	92 (91.1)	58 (54.2)	36.9 (25.3—47.2)	
Cough stress test neg	96 (95.0)	71 (66.4)	28.7 (18.4—38.5)	
Pad test neg	96 (95.0)	68 (63.6)	31.5 (21.0—41.4)	
Subjective:				
Cured	84 (83.2)	25 (23.4)	59.8 (47.5—69.1)	<0.001
Improved	17 (16.8)	73 (68.2)	−51.4 (−61.5 − −38.8)	<0.001
Cured or improved	101 (100.0)	98 (91.6)	8.4 (3.0—15.2)	0.003
		Complications		
Periop:	19 (18.8)	3 (2.8)	16.0 (7.8—24.9)	0.000
Hematoma	6 (5.9)	0	5.9 (1.2—12.4)	0.012
Bladder perforation	7 (6.9)	0	6.9 (2.0—13.6)	0.006
Acute urinary retention	10 (9.9)	3 (2.8)	7.1 (0.3—14.7)	0.045
Less than 3 mos postop:	10 (9.9)	9 (8.4)	1.5 (−6.6—9.8)	0.709
Vaginal tape extrusion	3 (3.0)	0	3.0 (−1.0—8.4)	0.113
Reoperation due to hematoma	1 (1.0)	0	1.0 (−2.6—5.4)	0.486
Reoperation due to retention	3 (3.0)	0	3.0 (−1.0—8.4)	0.113
Urinary tract infections	7 (6.9)	9 (8.4)	−1.5 (−9.1—6.3)	0.689
12 Mos postop:	23 (22.8)	10 (9.3)	13.4 (3.5—23.4)	0.008
Vaginal tape erosion	2 (2.0)	0	2.0 (−1.8—6.9)	0.235
Reoperation due to erosion	2 (2.0)	0	2.0 (−1.8—6.9)	0.235
Pelvic/implantation site/tape pain	5 (5.0)	0	5.0 (0.5—11.1)	0.026
Dysuria	3 (3.0)	0	3.0 (−1.0—8.4)	0.113
PVR 150 ml or greater	1 (1.0)	0	1.0 (−2.6—5.4)	0.486
Difficulty emptying bladder	9 (8.9)	0	8.9 (3.5—16.1)	0.001
De novo urgency	6 (5.9)	10 (9.3)	−3.4 (−11.1—4.3)	0.357
Clavien-Dindo grade:				
None	60 (59.4)	84 (78.5)	−19.1 (−30.9 − −6.5)	0.003
I	13 (12.9)	1 (0.9)	11.9 (5.3—19.9)	0.001
II	21 (20.8)	20 (18.7)	2.1 (−8.7—13.0)	0.704
III*	5 (5.0)	0	5.0 (0.5—11.1)	0.020
IV†	1 (1.0)	0	1.0 (−2.6—5.4)	0.486

* Tape extrusion repair repeatedly using local anesthesia, acute urinary retention with tape loosening and ultimately cutting, blood transfusion and laparotomy due to hematoma and acute urinary retention with tape loosening in 2 patients under local anesthesia.
† Postoperative ischemic heart symptoms possibly related to local anesthesia.

rates than PAHG, all major perioperative and followup complications were associated with the TVT operation.

The TVT sling has become the most common operative treatment in women with SUI and to date more than 5 million mid urethral sling operations have been performed worldwide.[21] TVT has been thoroughly studied at our unit and by other groups,[2,22,23] which showed high objective and subjective cure rates ranging from 80% to 90%. In the current study we confirmed that TVT is an effective treatment in women with primary SUI. However, as in any surgery, complications develop and this is also true for the TVT procedure.[24]

In our trial perioperative complications were in line with those in previous studies.[2,22,23] Recently, long-term complications of mid urethral slings, particularly chronic pain and dyspareunia, have become a major concern.[4,6] Furthermore, since most legal claims have involved retropubic SUI slings, the new NICE guidelines advise considering mid urethral slings only if alternative surgical procedures are not suitable.[7]

Only a few studies have addressed chronic pain with an incidence ranging from 0% to 31%.[4] In our trial 5.0% of patients with TVT reported pain at the 12-month followup while after PAHG treatments no patient reported pain. Other TVT complications included vaginal sling extrusion and/or impaired healing in 3.0% of cases, erosion in 2.0% and difficulty emptying the bladder in 8.9%, which were in line with previous studies.[2] None of these complications were detected for PAHG treatment and de novo urgency was detected at a similar rate in the 2 groups. Followup in our study will be extended to 5 years, which will reveal long-term complication rates.

PAHG has been widely used for the last 10 years with good safety data,[13,25] as confirmed in our study. In one of the most comprehensive randomized, controlled studies PAHG and collagen gel were compared in North American women.[25] A quarter of the patients had undergone prior incontinence surgery. At 12 months 77% treated with PAHG considered themselves cured or improved while only 24% were objectively cured, which is consistent with

previous smaller studies.[13,26] In our trial a surprisingly high 91.6% of women treated with PAHG reported subjective cure or improvement and 63.6% were objectively cured according to a negative pad test. Therefore, our results suggest that in patients with primary SUI PAHG performs better than when used as salvage treatment.

Further, the women in our study were mostly younger and leaner than those in previous studies.[13,25] A new 4-injection site technique was also adopted, which could have positively affected results by potentially increasing the propensity to maintain sufficient cushioning to improve urethral coaptation. The difference is not explained by total PAHG volume or the number of repeat injections since each was similar or even less in our study compared to previous studies.[13,14,25]

Our study has limitations. 1) We did not perform invasive urodynamics in all patients. However, most guidelines follow compelling evidence that invasive urodynamics do not offer any further value if a detailed office evaluation is done.[16] 2) We did not segregate patients based on urethral hypermobility or intrinsic sphincter deficiency. PAHG is equally effective for urethral hypermobility and intrinsic sphincter deficiency, likely since each is often present to some extent in typical SUI cases.[9] 3) Our data cannot be extended to the different mid urethral slings or to other bulking agents. 4) In our trial the procedures were done by urogynecologists with a strong background in SUI treatment, particularly TVT.[22–24] This may partially explain the high success rate for each treatment. However, we believe that comparable results are achievable with adequate training and similar procedure volumes.

Our study also has strengths. 1) In a randomized trial setting we provide novel subjective and objective outcome data on PAHG treatment in women with primary SUI. 2) Our primary outcome was patient satisfaction, which is considered an even more important outcome than objective cure in pelvic floor surgery.[27] However, we also assessed objective cure and complications. 3) We had low dropout and loss to followup rates. 4) Our patients with SUI represented a nonselected population of women.

CONCLUSIONS

At the 12-month followup PAHG did not show noninferior patient satisfaction compared to TVT in women with primary SUI. While TVT treatment provides higher satisfaction and cure rates than PAHG, complications were almost exclusively associated with TVT. Since most PAHG treated women also reported high satisfaction and were objectively cured, women with primary SUI can be offered PAHG as an alternative therapy with subsequent TVT in the event of failure. However, in women who expect to be completely cured by the initial treatment and who are willing to accept the complication risks, TVT should be offered as first line treatment.

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EDITORIAL COMMENT

This randomized, controlled trial compared TVT vs Bulkamid, a urethral bulking agent, for primary SUI in women. This is a timely study considering the ongoing controversies regarding use of mesh and, therefore, it must have been a difficult choice for some patients. The trial showed that the urethral bulking agent success rate did not meet noninferiority criteria compared to TVT at 1 year (59.8% vs 95%).

Yet the difference in overall complications is unsettling, especially in the hands of experienced providers, with a significant number of patients who received TVT requiring reoperation for vaginal exposure, erosion or voiding dysfunction. Echoing a prior study from Maher et al,[1] the bulking group had fewer complications and no need for reoperation. It is unclear why the authors used a nonvalidated visual analogue scale with an arbitrary cutoff of 80 as the primary outcome to gauge patient satisfaction instead of any of the many available validated questionnaires. The authors also regrettably failed to describe SUI severity and separate urethral hypermobility from intrinsic sphincter deficiency. This limits the generalizability of their data regarding success rates following urethral bulking agent injection.

The long-term outcomes in these patients will be highly anticipated to determine how these 2 procedures fare with time, especially since there are limited long-term data on urethral bulking agent.[2] As it stands, this study invites renewed caution with TVT and possibly a larger role for urethral bulking agent[3] in the management of female SUI.

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