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ORIGINAL ARTICLE

A randomized controlled trial comparing two voiding trials after midurethral sling with or without colporrhaphy

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Abstract

Introduction and hypothesis To compare the force of the stream (FOS) voiding trial with the standard voiding trial (SVT) after outpatient midurethral sling (MUS) whether or not colporrhaphy was performed.

Methods This is a randomized controlled non-inferiority trial of patients scheduled for MUS or colporrhaphy. Sample size of 102 patients was calculated for 80% power. Patients were randomized to FOS or SVT. Primary outcome was the number of unexpected postoperative visits (UPOVs) for voiding dysfunction (VD) or urinary tract infection (UTI). Voiding dysfunction was defined as urinary retention or post-void residual (PVR) > 200 cc. Subjects rated FOS using a visual analog scale (VAS). Criterion for non-inferiority was an upper limit of < 10% for the 95% CI. Analyses were performed using SAS version 9.4 (SAS Institute. Cary, NC).

Results One hundred two subjects were included (49 FOS, 53 SVT). Immediate postoperative catheterization for FOS and SVT was 8.2% ($n = 4$) and 9.4% ($n = 5$), respectively. Recovery time was significantly less for FOS versus SVT ($p = 0.0002$). Total UPOVs were five (10.2%) and two (3.8%) for FOS and SVT, respectively. Two FOS subjects who had MUS + colporrhaphy passed their VT and had subsequent UPOVs for VD. No evidence of non-inferiority was noted when comparing FOS to SVT for total UPOVs: CI: 6.0% (−5.2, 17.2) for postoperative VD [CI: 6.1% (−4.0, 16.2)] or UTIs [CI: 0.3% (−9.4, 10.1)].

Conclusions No evidence of non-inferiority was noted comparing FOS with SVT for unexpected postoperative visits for voiding dysfunction or UTI. This study shows the need for larger studies to assess the use of the FOS method in patients undergoing surgery for prolapse with or without MUS.

Keywords Force of stream · Postoperative voiding trials · Pelvic organ prolapse · Midurethral sling · Voiding dysfunction

Introduction

Stress urinary incontinence (SUI) often occurs with concomitant pelvic organ prolapse (POP) [1]. Surgical correction of anterior or posterior compartment prolapse and SUI is commonly performed in the ambulatory setting. To assess for voiding dysfunction or urinary retention, it is recommended that patients undergo a postoperative voiding trial (VT).

Postoperative catheterization after MUS is a concern for both patients and surgeons. Twenty-five percent of urologists surveyed reported they routinely discharged patients with a catheter, and 31% placed admission orders or 23-h observation for postoperative MUS patients. Of those patients, 42% were admitted for the primary purpose of facilitating the VT the following day [2]. Published catheterization rates after MUS and pelvic surgery can approach 58% [2, 3]. Temporary catheterization does not pose a significant medical risk, but can increase UTI risk, can be negatively received by the patient and has been described as the "worst" aspect of surgery [3–5].

No universal protocol for postoperative VT currently exists. Generally, SVT success is based on a percentage of instilled fluid that is voided. Methods and criteria for passing VT vary depending on hospital or practice protocol [6, 7]. Kleeman et al. found that a voided volume ≥ 68% predicted adequate bladder emptying in 100% of patients [7]. Using a similar criterion of voiding 2/3 of the instilled volume, Pulvino et al. also determined this threshold to be successful [8]. In a departure from criteria solely based on voided volume, Ingber et al., in the Force of Stream After Sling Trial (FAST), found that patient assessment of urinary force of stream (FOS) via the visual

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analog scale (VAS) is efficient and safe for assessment of postoperative voiding after MUS only [9]. More recently, a randomized controlled trial (RCT) expanded on the FAST trial by randomizing patients to FOS or SVT; no overall difference in catheterization rates after MUS was found [5].

In prior studies, anterior colporrhaphy with or without incontinence procedure has been shown to result in voiding dysfunction [10, 11]. Additionally, anterior colporrhaphy has been shown to be an independent risk factor for voiding dysfunction at the time of transvaginal tape (TVT) midurethral sling [12]. This has been attributed to postoperative pain and micro-damage to nerves during dissection and repair [13]. Book et al. revealed a higher rate of postoperative voiding dysfunction after posterior colporrhaphy compared with MUS alone with reported VT failure rates of 32 and 15% after posterior colporrhaphy and MUS only, respectively [12]. These studies defined voiding dysfunction by SVT criteria and not the FOS method.

Given the high volume of POP and concomitant SUI, surgeons are likely to encounter patients requiring multiple repairs. To our knowledge, no study has compared FOS with SVT in postoperative SUI/POP patients. The aim of this study was to compare FOS with SVT in patients undergoing MUS whether or not colporrhaphy was performed. Based on prior studies that showed FOS to be safe and effective in the ambulatory setting, our hypothesis was the FOS method is non-inferior to SVT for postoperative assessment of voiding dysfunction.

The primary outcome of this study was the number of UPOVs for voiding dysfunction or UTI within 6 weeks after surgery. Secondary outcomes included the number of patients discharged with a catheter, post-anesthesia care unit (PACU) recovery time and symptom assessment via American Urological Association Symptom Score (AUA-SS) and the Urinary Distress Inventory (UDI-6).

Materials and methods

This was a randomized controlled non-inferiority trial of two postoperative VTs. This study was approved by the Northwell Health Institutional Review Board (#14-667) and registered with clinicaltrials.gov (NCT02400034). All patients scheduled to undergo MUS with or without anterior/posterior colporrhaphy were approached from March 2015 to March 2016 for enrollment in the office or preoperative setting. Patients were excluded from recruitment if they were scheduled for surgical correction of apical prolapse or surgery necessitating prolonged catheterization such as diverticulectomy or autologous sling. Study randomization occurred after enrollment versus postoperatively to prevent exclusion bias. Randomized patients were excluded if they were admitted overnight or sustained an intraoperative cystotomy. After informed consent had been obtained, subjects completed preoperative UDI-6 and AUA-SS questionnaires. Patients were randomized to the FOS or SVT arms of the study with a 1:1 ratio. Permutated computerized block randomization by each hospital site was achieved via https://fimr.northwell.edu/biostatRMS.

All patients underwent a postoperative VT in PACU prior to discharge. A flow diagram delineating the protocol for each VT is shown in Fig. 1. Unless the subject's clinical status caused delay, VTs were performed at 1 h for FOS and within 2–3 h for SVT. This difference in timing was to follow the FOS protocol as previously described by Ingber et al. and the SVT guidelines used in our practice [9]. For all patients, postoperative pain was recorded using a 10-point VAS prior to initiating either VT. In both arms of the study, the bladder was retrograde filled with normal saline or sterile water. Patients were instructed to void within 30 min, given a 100-point VAS and asked to rate the force of their urinary stream. The 100-point FOS VAS scale was collected solely for research purposes in the SVT arm. In the FOS arm, patients who ranked their FOS $\geq$ 50% passed their VT. For those who rated their FOS < 50%, a PVR via bladder scan was obtained. The subject passed her VT if the PVR was $\leq$ 499 cc. If the PVR was $\geq$ 500 cc, the patient failed her VT and was discharged with an indwelling catheter. Criteria for success in the SVT arm were defined as a voided volume $\geq$ 2/3 the amount instilled. Subjects who failed their VT were discharged home with an indwelling catheter and instructed to return to the office in 2–5 days. UDI-6 and AUA-SS were completed at 2- and 6-week postoperative visits. PVR via bladder scan was obtained at both postoperative visits.

Data were collected from the medical record including demographics, preoperative assessments, prolapse stage and intraoperative data (Table 1). VT data and total PACU recovery time were also recorded. Postoperative visit data included questionnaire scores, PVR and assessment for UTI in symptomatic subjects.

The primary analyses were based on intention to treat (ITT). Non-inferiority testing for the rate of UPOV, UTI and re-catheterization was done using a two-tailed 95% confidence interval for the difference between groups. If the upper confidence limit was $< \delta$ ($\geq \delta$), we concluded that the FOS is non-inferior (inferior) to SVT (Fig. 2).

The sample size of 102 subjects was based on study investigators' estimate of UPOVs for voiding dysfunction or UTI. Based on postoperative catheterization rates in our practice for ambulatory surgery, we assumed the upper limits for catheterization rates in both groups would be equal at 4.5% for a power of 80%. If we assume that the underlying rate of UPOVs using SVT = 4.5% and FOS = 4.5%, a target of 51 subjects per group ($n = 102$ in total) would yield 80% power to determine that the FOS is not inferior to SVT derived from a two-sided α level of 0.05 (i.e., using the upper 2.5% tail of the confidence interval) and a non-inferiority margin of 10%.

A two-sample t-test was used to compare questionnaire data. Nonparametric data were analyzed via the Mann-

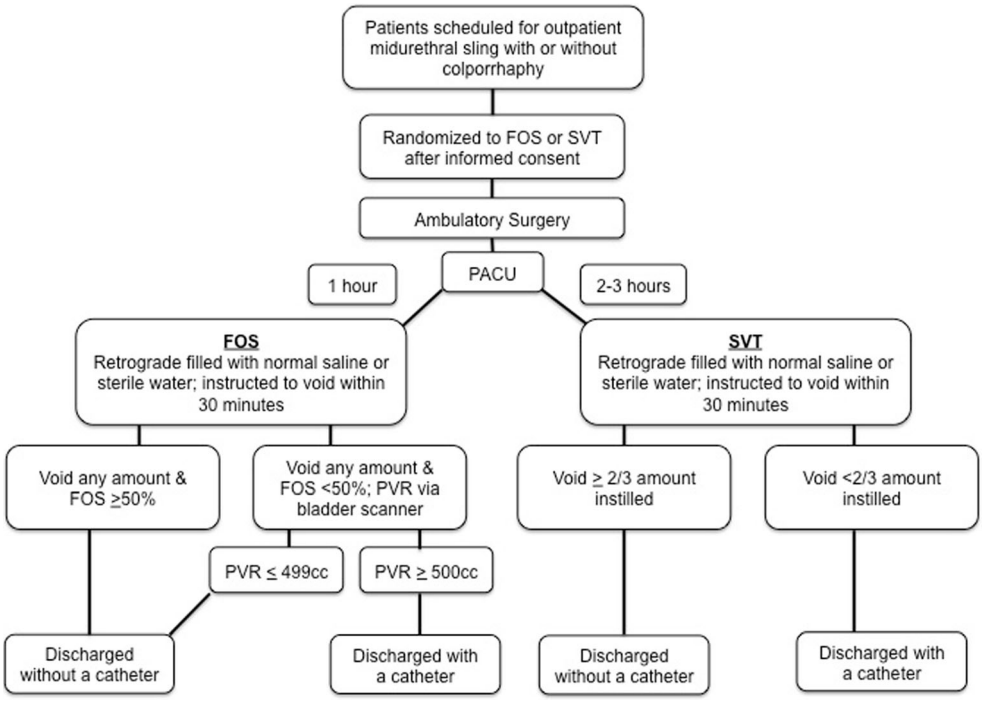

Fig. 1 Study protocol. *FOS* force of stream VT; *SVT* standard VT; *MUS* midurethral sling. [a]FOS measured via 10-point visual analog scale. [b]Post-void residual (PVR) measured with a bladder ultrasound

Whitney test, and Kaplan-Meier survival analysis was used to compare recovery times. Statistical significance was at $p < 0.05$. All analyses were performed using SAS version 9.4 (SAS Institute. Cary, NC).

Table 1 Patient characteristics and demographics

Patient characteristics[a]	FAST [$n = 49$]	Traditional [$n = 53$]	p value
Age (years)	54.0 (55.3 ± 10.7)	51.0 (52.4 ± 11.9)	0.1121
BMI	29.2 (29.4 ± 5.2)	27.1 (28.1 ± 5.5)	0.1388
Parity	2.0 (2.1 ± 1.2)	2.0 (2.5 ± 1.1)	0.0905
CCI[b]	2.0 (1.5 ± 1.1)	1.0 (1.7 ± 1.8)	0.7911
Race			
Caucasian	40 (81.6%)	31 (58.5%)	0.0506
African American	2 (4.1%)	5 (9.4%)	
Hispanic	6 (12.2%)	10 (18.9%)	
Asian	1 (2.0%)	7 (13.2%)	
Anticholinergic medications	4 (8.2%)	2 (3.8%)	0.4237
Nocturia	19 (38.8%)	22 (41.5%)	0.7784
Preoperative urinary frequency	33 (67.4%)	36 (67.9%)	0.9503
Preoperative urinary urgency	34 (69.4%)	34 (64.2%)	0.5751
Diabetes mellitus	3 (6.1%)	6 (11.3%)	0.4907
Surgical procedure:			
MUS only	18 (36.7%)	14 (26.4%)	0.3456
Anterior repair + MUS	9 (18.4%)	18 (34.0%)	
Posterior repair + MUS	19 (38.8%)	18 (34.0%)	
Anterior and posterior repair + MUS	3 (6.1%)	3 (5.6%)	
Retropubic/transobturator sling	42 (85.7%)/7 (14.3%)	47 (88.7%)/6 (11.3%)	0.6537

BMI body mass index, *CCI* Charlson Comorbidity Index, *FOS* force of stream, *SVT* standard voiding trial, *MUS* midurethral sling

[a] Continuous data presented as median (standard deviation); categorical data presented as number (%)

[b] Predicts 10-year mortality rate for patient who may have comorbid conditions

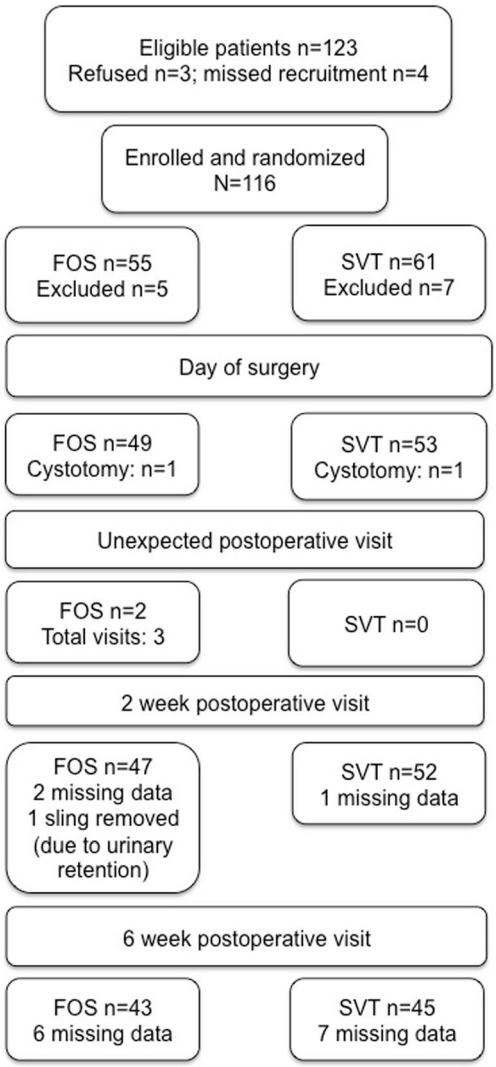

Fig. 2 Flow diagram of subject enrollment and follow-up. *FOS* force of stream VT; *SVT* standard VT

Results

One hundred twenty-three patients were eligible for enrollment, and 113 subjects were randomized to either arm of the study. After randomization, nine patients were excluded from the final analysis because of surgery cancelation ($n = 3$), overnight admission ($n = 5$) and incorrect randomization ($n = 1$). Intraoperative cystotomy occurred in two patients (1 FOS, 1 SVT); thus, 102 subjects were included in the final analysis (49 FOS, 53 SVT). Data were complete at 6 weeks for 88 subjects (43 FOS, 45 SVT). Demographic characteristics, prolapse stage, urodynamics (UDS) findings, concomitant colporrhaphy and type of MUS were similar between the two groups. Fifty-two patients in the SVT arm had UDS.

There was no correlation among MUS type ($p = 0.3216$), concomitant prolapse repair ($p = 0.4843$) and catheterization rate. Distribution of type of surgery between groups was not significant (Table 1). Estimated blood loss (EBL) was expectedly higher (110.0 ± 52.6) in patients who had MUS with both anterior and posterior colporrhaphy (MUS + AP) ($p = 0.0001$). There was no statistical difference in immediate postoperative catheterization rates for failed VT with a rate of 8.2% ($n = 4$) and 9.4% ($n = 5$) in the FOS and SVT group, respectively ($p = 1.000$) (Table 2).

Total UPOVs were five (10.2%) and two (3.8%) in the FOS and SVT groups, respectively (Table 2). Four UPOVs occurred for UTI (2 FOS, 2 SVT). No SVT subjects ($n = 0$) had UPOVs for voiding dysfunction. Two FOS subjects ($n = 2$) had voiding dysfunction and returned for UPOVs ($n = 3$). One subject underwent MUS with anterior and posterior colporrhaphy (MUS + AP) while the other underwent MUS with anterior colporrhaphy (MUS + A). Both subjects developed frequency/dysuria on POD2 and were treated empirically for UTI over the phone. Both developed voiding dysfunction/urinary retention after 2 days of empiric antibiotic treatment. Voiding dysfunction resolved 48 h after placement of an indwelling Foley catheter in one subject. The other subject received an indwelling catheter, was then taught clean intermittent catheterization and returned to the operating room for sling revision on POD 9. No evidence of non-inferiority was noted when comparing FOS to SVT for total UPOVs: CI: 6.0% (−5.2, 17.2) for postoperative VD [CI: 6.1% (−4.0, 16.2)] or UTI [CI: 0.3% (−9.4, 10.1)] (Table 2).

As expected, median total recovery time (hours) was significantly less for FOS subjects [2.1 (1.9, 2.4)] than for SVT subjects [3.2 (2.8, 3.6)] ($p = 0.0002$). Those who failed their VT ($n = 9$) had significantly longer recovery times at 4.13 (1.9, 5.42) hours than those who passed ($n = 93$) [2.7 (2.3, 3)] ($p = 0.0120$). Preoperative AUA-SS and UDI-6 improved in both groups at 2 and 6 weeks postoperatively ($p = 0.0001$). Preoperative survey totals were not predictive of a successful VT.

There was no significant correlation in pain VAS compared with volume voided ($r_s = 0.17$, $p < 0.0926$) or force of urinary stream VAS ($r_s = -0.13$, $p < 0.1807$) in either group. Furthermore, there was no significant difference ($p = 0.4914$) in pain VAS for subjects who failed their VT ($n = 9$) compared with those who passed ($n = 93$).

Discussion

This is the first RCT comparing FOS with SVT and including patients who have undergone MUS and concomitant colporrhaphy. Based on our findings, there is no evidence of noninferiority comparing the FOS method to SVT based on UPOVs for voiding dysfunction or UTI in this patient population. This is consistent with prior studies comparing these two methods after MUS only. Nonetheless, FOS resulted in six patients discharged without a catheter who would have otherwise been catheterized if the SVT criteria were implemented.

Table 2 Inferiority testing for FOS compared with SVT

Outcome total study time	FOS ($n = 49$)	SVT ($n = 53$)	Difference (95% CI)[a]
Failed voiding trial (discharged with catheter)	4 (8.2%)	5 (9.4%)	−1.3% (−11.1, 8.5)
Total unexpected postoperative visits for voiding dysfunction and UTI	5 (10.2%)	2 (3.8%)	6.0% (−5.2, 17.2)
Unexpected postoperative visits for UTI	2 (4.1%)	2 (3.8%)	0.3% (−9.4, 10.1)
Unexpected postoperative visits for voiding dysfunction	3 (6.1%)	0 (0.0%)	6.1% (−4.0, 16.2)

FOS force of stream, *SVT* standard voiding trial, *CI* confidence interval

[a] The criterion for non-inferiority was an upper limit of < 10% based on the upper 2.5% tail of the 95% confidence interval

Although this includes FOS subjects ($n = 2$) who presented for UPOVs, 66% ($n = 4$) avoided necessary catheterization per SVT criteria and thus benefitted from the FOS method.

This study is the first RCT to follow the FOS protocol as originally described by Ingber et al. and included patients with pelvic organ prolapse. We utilized PVR only for an FOS < 50% on the VAS scale as previously described [9]. This differs from a prior RCT in MUS-only patients where all patients were catheterized, independent of PVR, if their FOS was < 50%, which could contribute to the catheterization rate of 26% in this study [5].

This study adds to the literature on postoperative VTs and shorter recovery time when using FOS. However, we acknowledge that this can be attributed to our protocol design, which timed the administration of TOV differently for each. Our decision on timing was made according to our current practice for SVT starting 2 h postoperativley versus 1 h for FOS as described by Ingber. Despite the differences in timing of VT, we found similar pass rates in VT between the two groups ($p = 0.0$). Therefore, it is possible that SVT could be performed starting 1 h postoperatively resulting in shorter recovery times. This could be a topic of further investigation as expedited assessment and discharge may decrease hospital time and resources.

A potential weakness of our study is that patients were not stratified by colporrhaphy and not all patients underwent concomitant colporrhaphy. There was no difference between the two groups for type of surgery as surgical procedures were evenly distributed (Table 1). Another potential weakness is that patients were randomized preoperatively after consent and not in PACU. This was done to exclude selection bias based on surgeon concern about the type of VT implemented regarding EBL or other potential intraoperative events. Additionally, a PVR via bladder ultrasound was not obtained on all subjects. It may have been useful to assess PVR via bladder scan in all subjects vs. calculated PVR. However, as stated by Ingber et al., PVR via bladder scan was not shown to effect patient outcomes in their study [9].

Our study contributes to the literature on postoperative VTs and demonstrates the need for larger multi-center trials to assess the role of subjective assessment of voiding in patients after MUS whether or not colporrhaphy is performed. Based on our findings, no evidence of non-inferiority was noted for FOS compared with SVT in rates of UPOVs for voiding dysfunction. Despite this, FOS was similar to SVT in rates of VT failures and UPOVs for UTI and led to six patients passing VT who otherwise would have failed using the SVT criteria (Table 2). We support using the FOS for assessment of postoperative voiding dysfunction. We recommend that patients who call after ambulatory surgery and complain of UTI be referred for evaluation for possible urinary retention.

Conclusion

In this study population, there was no evidence of non-inferiority comparing the FOS method with SVT for unexpected postoperative visits for VD or UTI after MUS whether or not colporrhaphy was performed. Larger studies on the FOS method in patients after colporrhaphy are needed to assess the generalizability of these data. As voiding trials are often performed following many urogynecologic and urologic surgeries, it may be unwise to assume one VT criterion is ideal for all procedures. With patients expressing concern regarding postoperative catheterization, identifying and standardizing the safest and most effective VT will aid in preoperative counseling and postoperative catheter management.

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Compliance with ethical standards

Conflicts of interest Harvey A. Winkler, MD, is a consultant for Contipi and Boston Scientific and an expert witness for Johnson & Johnson. All other authors report no conflict of interest.

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