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ORIGINAL ARTICLE

Retrospective review of intra- and post-operative complications with minimal versus large space of Retzius infiltration at the time of retropubic TVT placement

Lamees Ras[1] · Suzanne Frederika Nicoline Roskam[2] · Petrus Frans Kruger[1] · Stephen Trembarth Jeffery[1]

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Abstract

Introduction and hypothesis A concern when using the retropubic tension-free vaginal tape (TVT) for stress urinary incontinence (SUI) is bladder perforation. This article describes a technique hypothesised to reduce the risk of intra-operative bladder perforation, termed the large space of Retzius infiltration (LSORI) technique. A large volume of infiltration of 360 ml saline-vasoconstrictor solution (180 ml × 2) into the space of Retzius (LSORI) at the time of retropubic TVT insertion will reduce the incidence of intra-operative bladder perforations.

Methods This was a retrospective study reviewing the medical records of 89 women who underwent the retropubic TVT procedure at two urogynaecology Units. The intra- and post-operative characteristics associated with minimal (MSORI) versus large retropubic space of Retzius infiltrations (LSORI) were examined.

Results Eighty-nine patients undergoing SUI surgery met the inclusion criteria. Forty-one patients had MSORI (volume range 20–60 ml bilaterally) versus 48 who had the 180-ml bilateral LSORI. No bladder perforations (0%) occurred in the LSORI group versus four in the MSORI group (9.8%), found to be statistically significant ($p = 0.013$). All other outcomes examined had no statistical difference. The TVT-related pain incidence: 8.3% (LSORI) versus 9.8% (MSORI). Post-operative urinary retention incidence was 6.3% (LSORI) and 14.6% (MSORI). Retropubic haematoma incidence was 0% (LSORI) and 2.4% (MSORI). Post-operative UTI rate was 12.5% (LSORI) and 17.1% (MSORI).

Conclusions This retrospective review revealed the potentially beneficial effect of the large (180 ml × 2) bilateral SORI with retropubic TVT placement in terms of the reduction in risk of bladder perforation. It also showed no potential added risk of post-operative complications.

Keywords Stress urinary incontinence · Incontinence surgery

Introduction

Since the launch of the retropubic TVT 2 decades ago, there has been a rapid evolution in the surgical management of stress urinary incontinence (SUI). Additional minimally invasive options have been developed, which include the transobturator and single-incision slings. Newer bulking agents have also become available, and more recently we have seen vaginal laser treatment being performed for SUI. The retropubic tape, however, is still one of the most efficacious options, and it remains the gold standard. In a 17-year follow-up study of the retropubic TVT by Nilsson, the long-term objective cure rate for the TVT procedure was 91% and showed no decline between 5 and 17 years [1]. The subjective cure rate or improvement was 87%, with a perceived worsening in symptoms in the last 6 years, thought to be secondary to urge incontinence and not due to the recurrence of stress incontinence [1]. When transobturator slings were compared with retropubic slings, a meta-analysis for both objective and subjective cures found retropubic slings to be superior [2].

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✉ Lamees Ras
lameesras@gmail.com; lamees.ras@uct.ac.za

[1] University of Cape Town, Cape Town, South Africa

[2] Academic Medical Centre, Amsterdam, The Netherlands

Intrinsic sphincter deficiency is a particularly troublesome cause of stress urinary incontinence as it results in severe SUI and lower surgical success rates. Schierlitz found that the retropubic approach to the mid-urethral sling superseded the transobturator approach in terms of outcomes. The study found that the risk ratio of repeat surgery was 2.6 (95% CI 0.9– 9.3) times higher in the transobturator tape group than the in retropubic group. One in every six women who had undergone the transobturator tape procedure requested repeat surgery compared with 1 of every 16 retropubic tape procedure patients [3].

Despite the better continence outcomes with the retropubic approach, many surgeons prefer to use either a transobturator or single-incision sling. This is mainly due to the perceived increase in complications with the retropubic sling, with intra-operative bladder perforation being the major concern.

A wide range of bladder perforation rates are reported in the literature, with a prospective, randomised, multicentre study reporting an incidence as high as 24% [4]. Independent risk factors for bladder perforation included surgeon experience, previous colposuspension or caesarean section, BMI < 30 kg/m^2 and rectocele. The risk of urethral injury was 0.2% [5]. Concerning other complications, postprocedural haematomas occurred in up to 16.1% of women following the retropubic approach compared with only 2.4% for transobturator slings [2]. In the same study, bowel (0.00–1.57%), vascular (0.00–0.09%) and nerve injuries (0.00–0.07%) were reported to be low [2].

Several recommendations have been made to reduce the risks of complications when performing TVT procedures. Many of these are obvious and include adequate training of the surgeon, performing a cystoscopy after retropubic TVT insertion to recognise and act upon bladder or urethral injuries and appropriate tensioning of the sling to reduce the chance of voiding dysfunction. A technique performed to reduce the incidence of bladder perforation is infiltration of local anaesthetic-saline solution into the retropubic space. This infiltration displaces the bladder posteriorly and expands this retropubic space to allow the safe insertion of the trocar. Ulmsten, when describing the TVT technique in 1996, recommended that surgeons perform space of Retzius infiltration with 60–70 ml of local anaesthetic [6]. This was however not based on specific evidence. Since then, no literature has been published that provides any evidence for the recommendation of a specific volume for this space of Retzius infiltration.

Methods

The electronic and paper-based health records of all women who had undergone the retropubic TVT procedure for stress urinary incontinence at the Urogynaecology and Laparascopic Clinic at Christiaan Barnard Hospital (CBH) and the Urogynaecology Department at Groote Schuur Hospital (GSH), Cape Town, between October 2015 and February 2017 were reviewed. The retropubic TVT procedures were performed by four locally based urogynaecology surgeons, all experienced in this procedure (performing ≥ 35 of these procedures per annum).

Patients' records were considered eligible for review if they met the following criteria:

(1) retropubic TVT procedure performed for stress urinary incontinence,
(2) received minimal (≤ 70/70 ml—Ulmsten's recommendation) or large (180/180 ml) space of Retzius infiltration,
(3) TVT insertion performed by one of the four experienced surgeons as the primary surgeon.

Patients' records were excluded if:

(1) any other procedure for stress urinary incontinence was performed,
(2) the volume infiltrated into the space of Retzius was not documented,
    - 70/70 ml to 180/180 ml
    - or > 180/180 ml.
(3) TVT insertion performed by a trainee or any surgeon other than the selected four experienced surgeons.

Data gathered from the health records were inserted onto an Excel spreadsheet. Non-identifying study IDs were generated to maintain patient confidentiality. Data were extracted examining demographics of the patient population as well as procedure-related variables, i.e. space of Retzius infiltrations of either large volumes bilaterally (180/180 ml) or small volumes (< 70/70 ml) of SORI, whether any concomitant surgery was performed and the incidence of procedure-related complications.

Space of Retzius infiltration, hypothesised to reduce the rate of bladder perforations, a well-recognised complication of the retropubic TVT procedure, was used as the primary outcome. The secondary outcomes were post-operative pain, urinary retention, retropubic haematoma and urinary tract infections (UTI).

Retropubic injection was performed using a local anaesthetic, 10 mg bupivacaine, with a vasoconstrictor, 2 mg adrenaline (1:200,000), diluted with 400 ml saline. With a transurethral catheter in situ, 180 ml of this solution was infiltrated into the space of Retzius bilaterally using a long large-bore needle (Fig. 1). The amount of infiltration varied depending on the volume chosen, i.e. large or minimal SORI. The site of

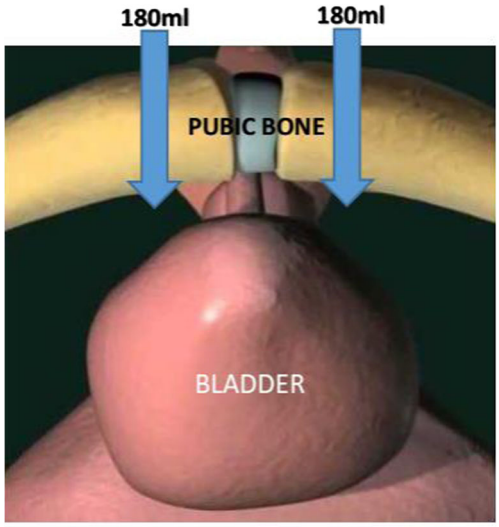

Fig. 1 Space of Retzius infiltration with volumes (180 ml = LSORI)

infiltration was identified as 2 cm lateral to the midline suprapubically, with the needle aimed towards a finger placed vaginally, laterally and slightly distal to the palpable urinary catheter balloon. The needle is then walked posteriorly on the pubic bone until the retropubic space is identified, hugging the pubic bone as the needle is advanced. While introducing the infiltration into the space of Retzius, the catheter bag is disconnected from the catheter, allowing free drainage of urine. This step is important to detect the site of the infiltration after the bladder has been emptied. If minimal fluid drains, the site is correct (in the space of Retzius). However, if large amounts of fluid drain, the infiltration needle is likely to be in the bladder. If the needle is in the incorrect position, it can be removed and repositioned. This technique pushes the bladder in a posterior direction, dorsally away from the pubic bone, by infiltration of the (potential) space of Retzius. This in turn is thought to hypothetically reduce the chance of perforating the bladder as well as possibly reducing the rate of retropubic haematomas. Catheter-guided deviation of the urethra was not performed with this technique.

Statistical analysis was performed using IBM SPSS Statistics version 24 statistical software. Two-by-two tables and Fisher's exact tests were used to analyse the data examining the primary and secondary outcomes (see the Results section).

Ethics

Ethical approval for this retrospective review was obtained through the Human Research Ethics committee at the University of Cape Town (HREC no. 100/2017). Patients' confidentiality was preserved by using a password-protected computer for data storage. Anonymity was maintained with the use of folder numbers and removal of all identifying information.

The concept of non-maleficence was adhered to as the surgeons performing the procedure were experienced surgeons, deemed experts in their field. The intent of this study was to be of benefit to the population involved in the retropubic TVT procedure for SUI, both patients and surgeons.

Results

A total of 192 patients who underwent SUI-related surgery were identified from the Christiaan Barnard Hospital and Groote Schuur Hospital Urogynaecology (Training centre) units. Of these, 103 patients were excluded based on the above-mentioned exclusion criteria, i.e. patients undergoing other non-retropubic TVT surgery, undocumented or exclusionary SORI volumes, and procedures performed by surgeons other than the four experienced surgeons. Two patients who received 120 ml bilateral SORIs were excluded as the volumes infiltrated did not fall into the inclusionary ranges. In total, the records of 89 patients were included in this review (Fig. 2).

Of the 89 patient records reviewed, 48 patients had received large space of Retzius infiltration (LSORI) of 180 ml of a dilute local anaesthetic-vasoconstrictor bilaterally. Forty-one patients had received the minimal space of Retzius infiltration, i.e. infiltration volumes < 70 ml bilaterally. The mode for the range of volumes of SORI in this group was 60 ml bilaterally ($n = 17$), with a mean volume of 48 ml bilaterally. The smallest volume of infiltration recorded bilaterally was 20 ml, and the largest volume infiltrated was 60 ml. The range of volumes of infiltration in the MSORI group and their frequencies are shown in Fig. 3.

Patient demographics

Baseline variables were analysed for patients in the two groups, LSORI vs. MSORI, based on age, whether they smoked, whether they had any previous SUI surgery, previous pelvi-abdominal surgery (including caesarean section; vaginal, abdominal or laparoscopic hysterectomy; anterior or posterior vaginal repair; sacrospinous fixation; sacrocolpopexy; abdominal uterine surgery) and whether they had concomitant surgery with TVT insertion. BMI was not adequately documented in the medical records and therefore could not be commented upon. No statistical difference was found in the baseline characteristics of patients in the two groups (Table 1).

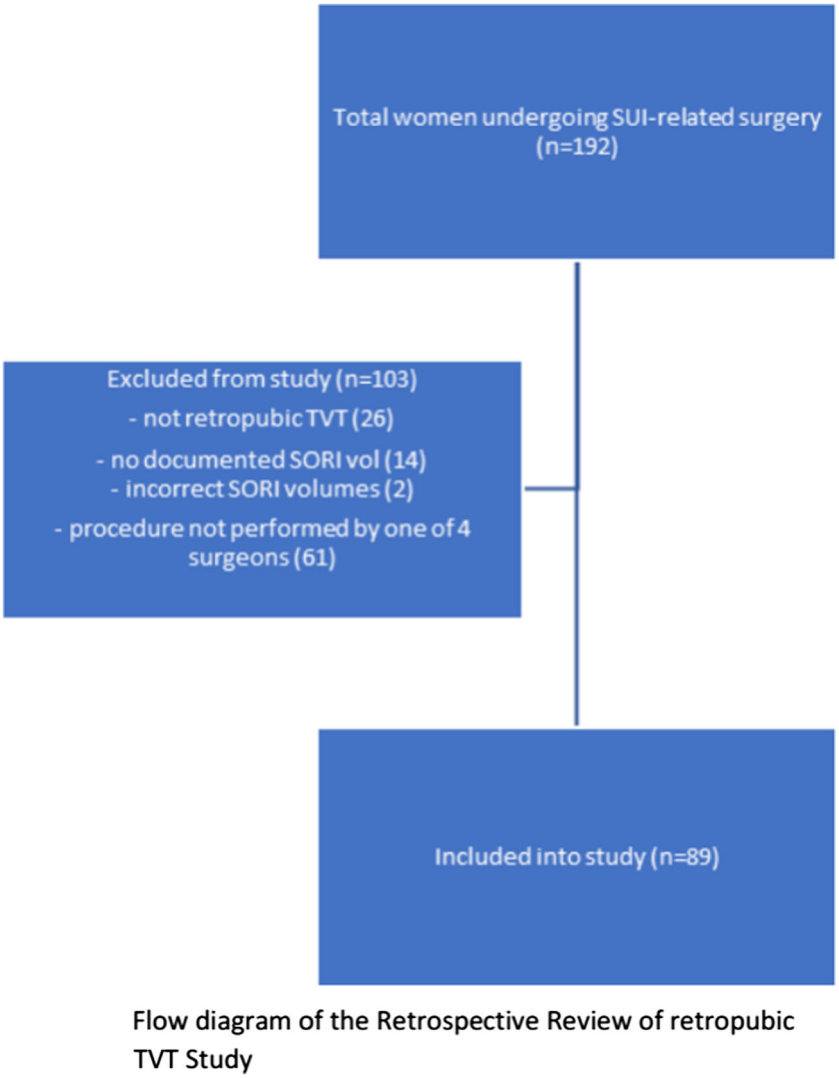

Fig. 2 Flow diagram of the retrospective review of retropubic TVT study

Primary outcome

Bladder perforation

Bladder perforation can occur at the time of retropubic TVT insertion. This was diagnosed intra-operatively using a cystoscope. No delayed diagnoses were recorded. The bladder perforation rate in this study was 4.5% (4/89) for the entire group. Of the 41 patients in the small volume MSORI group, the bladder perforation rate was 9.8% (4/41). Three of these patients in whom the bladder was perforated during the procedure had a volume of 60 ml SORI bilaterally, with the other while using 20 ml bilateral infiltrations. The 60-ml bilateral infiltrate was, however, the most frequently used MSORI volume used. One patient in the MSORI group sustained a bladder injury at the time of a TLH and therefore was not included in the data as it did not occur as a result of the TVT procedure. This patient was not included in the TVT-related bladder injuries.

In 48 patients the LSORI volumes were infiltrated (180 ml × 2). No bladder perforations occurred in this group (0%) (Table 2).

Secondary outcomes

Post-operative pain

Post-operative pain was defined as pain beyond what would be considered appropriate for the surgical procedure undergone, requiring extra analgesia. It was also pain that would be directly attributed to the TVT procedure or related complications and not concomitant surgery. A total of eight patients (9%) experienced pain related to the retropubic TVT procedure (Table 2). Four patients in the MSORI group had post-operative pain (9.8%). One of these patients had sustained a bladder injury at the time of the TVT insertion with

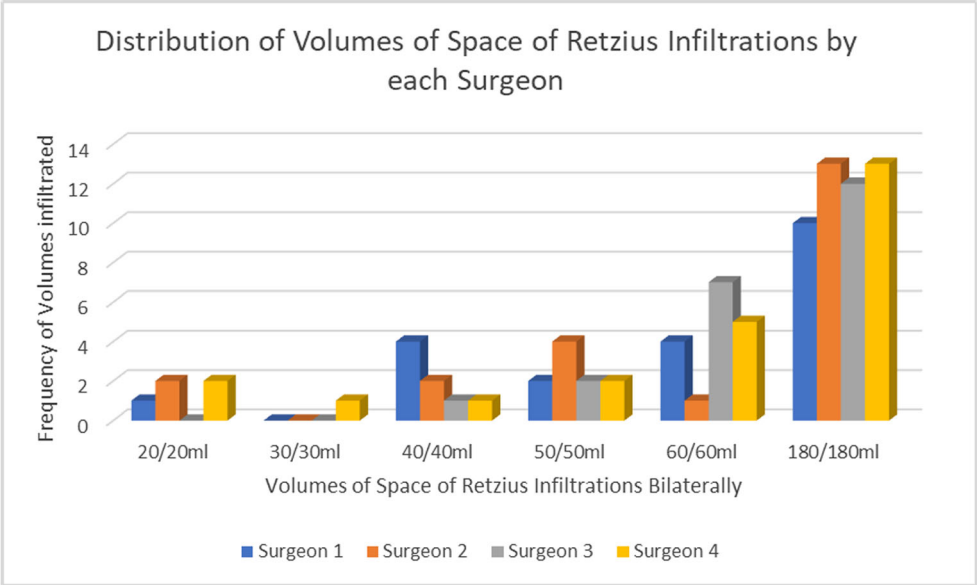

Fig. 3 Distribution of volumes of SORI stratified to surgeons ($p = 0.499$)

subsequent urinary retention and pain that improved over time. The other two patients in this group had post-operative pain that subsequently resolved; one of these patients was a smoker with unexplained suprapubic pain and the other with unexplained lower abdominal pain. Both these patients had previous unsuccessful transobturator tape procedures. Four of the 48 patients in the LSORI group reported pubic or suprapubic post-operative pain, a rate of 8.3%, with no statistical difference between the two groups (Table 2). One of the patients with post-operative pain in the LSORI group had pain attributed to a urinary tract infection. The second patient had pain associated with urinary retention that resolved as retention improved. The third patient had a previous transobturator tape that was removed because of an erosion.

Urinary retention

Urinary retention was defined as a post-void residual > 150 ml when > 300 ml of urine was passed or retention > one third of the total urine volume compared with the volumes voided. Of all the patients undergoing the retropubic TVT procedure, 9 of 89 patients (10.1%) experienced post-procedural urinary retention. This was a rate of 14.6% in the MSORI group ($n = 7$) compared with a rate of 6.3% in the LSORI ($n = 3$) group with no statistical difference (Table 2). In the MSORI group, all six patients with urinary retention had concomitant surgery at the time of retropubic TVT insertion, two of whom sustained bladder injuries. Concomitant procedures included posterior vaginal repairs, perineorrhaphies, vaginal hysterectomy, anterior vaginal repair and a sacrospinous fixation. Two patients had an associated urinary tract infection and one patient a retropubic haematoma. None of the three patients with urinary retention in the LSORI group had concomitant surgery. Five of the nine patients in the study with urinary retention had undergone previous procedures for SUI, i.e. transobturator tapes (one had previous excision for erosion and the other concomitant excision) and a previous Burch colposuspension. Six of the nine patients had previous hysterectomies (LAVH, VH, TLH and other prolapse-related procedures). One patient required a return to theatre for loosening of a retropubic tape that had resulted in urinary retention. All patients with urinary retention improved/resolved after 5–7 days with an indwelling catheter.

Table 1 Baseline characteristics of patients in the MSORI and LSORI groups

Baseline variables	Study population ($n = 89$)	MSORI ($n = 41$)	LSORI ($n = 48$)	*P* value (MSORI vs. LSORI)
Age (years) (mean, IQR)	59 (48.5–70)	57 (50.5–68)	62 (47.3–70.8)	0.736
Smoking (%)	11 (12.4)	5 (12.2)	6 (12.5)	0.965
Previous SUI surgery (%)	14 (15.7)	8 (19.5)	6 (12.5)	0.365
Previous pelvi-abdominal surgery (%)	47 (52.8)	24 (58.5)	23 (47.9)	0.317
Concomitant surgery (%)	51 (57.3)	25 (61)	26 (54.2)	0.517

Table 2 Outcome comparisons between patients with MSORI and LSORI (Fisher's exact test)

	TVT study population n = 89	MSORI n = 41	LSORI n = 48	P value
Bladder perforation (%)	4 (4.5%)	4 (9.8%)	0 (0%)	0.013
Post-op pain (%)	8 (9%)	4 (9.8%)	4 (8.3%)	0.635
Urinary retention (%)	9 (10.1%)	6 (14.6%)	3 (6.3%)	0.191
Haematoma (%)	1 (1.1%)	1 (2.4%)	0 (0%)	0.277
UTI (%)	13 (14.6%)	7 (17.1%)	6 (12.5%)	0.543

Haematoma

Haematomas specifically refer to retropubic haematomas occurring during the retropubic TVT insertion. These were suspected by excessive groin bruising, pain or voiding dysfunction and confirmed on ultrasound. One patient in the MSORI group (2.4%) developed a retropubic haematoma (Table 2). No haematomas occurred post-operatively in the LSORI group. The patient who developed a retropubic haematoma had 60 ml of SORI placed bilaterally, concomitant posterior vaginal repair and perineorrhaphy, with a bladder perforation at the time of TVT insertion with subsequent post-operative pain and urinary retention requiring catheterisation for 1 week.

Urinary tract infections

Urinary tract infections were suspected according to symptoms and urine dipsticks and confirmed on urine culture. A total of 13 patients (14.6%) had UTIs after having the retropubic TVT procedure with almost equal distribution between the two groups. Seven patients in the MSORI group (17.1%) developed a UTI and six patients in the LSORI group (12.5%). Eleven of the 13 patients with bladder infections had concomitant surgery, one of whom had a TVT-unrelated bladder injury, three with excessive post-operative pain and two with urinary retention.

No major vascular, bowel or urethral injuries were noted throughout the period reviewed in either group.

Surgeons' outcomes

The surgeons' infiltration volumes and procedural outcomes were examined, assessing for any possible surgeon-related confounding factors. There was a fairly even distribution of volumes of infiltration between surgeons regarding MSORI vs. LSORI (Fig. 4). When examining the frequency of specific volume administrations, no surgeon showed a predilection for large or small infiltration volumes. Surgeons' infiltrations were further stratified to specific volumes, with no statistical difference found between the surgeons (Fig. 3). When further assessing surgeons' performance with the procedure in terms of complications, i.e. primary and secondary outcomes, no statistical difference was found (Table 3).

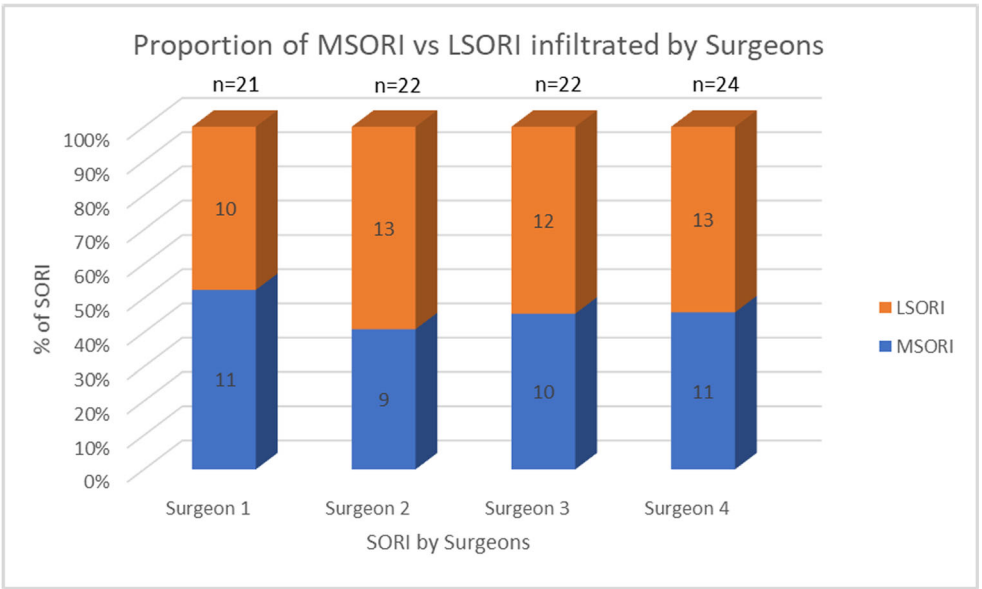

Fig. 4 Proportion of MSORI vs. LSORI infiltrated by surgeons ($p = 0.811$)

Table 3 Primary and secondary outcomes stratified by surgeons

Outcomes		Surgeon 1 *n* = 21	Surgeon 2 *n* = 22	Surgeon 3 n = 22	Surgeon 4 *n* = 24	P value
Bladder injury	Yes	1	1	2	0	0.243
	No	20	21	20	24	
	%	4.8%	4.5%	9%	0%	
Post-op pain	Yes	1	2	2	4	0.592
	No	20	20	20	20	
	%	4.8%	9%	9%	16.7%	
Urinary retention	Yes	1	3	2	3	0.768
	No	20	19	20	21	
	%	4.8%	13.6%	9%	12.5%	
Retropubic haematoma	Yes	0	0	1	0	0.379
	No	21	22	21	24	
	%	0%	0%	4.5%	0%	
UTI	Yes	4	4	3	2	0.722
	No	17	18	19	22	
	%	19%	18.2%	13.6%	8.3%	

A sensitivity analysis was performed for the two patients who were excluded from the study who received the 120-ml bilateral SORI. The data for these two patients were analysed by including them in the MSORI data set and then in a re-analysis, including them in the LSORI data set. This was done to assess whether there was any significant change in the outcomes by the exclusion of these two patients from the study (Tables 4 and 5). When the two excluded patients where added to the MSORI group for analysis, the results were similar to the results in primary and secondary outcomes where these two patients were excluded. The difference in bladder injury rates continued to be statistically significant ($p = 0.015$) with a rate of 11.6% in the MSORI group and 0% in the LSORI group. All the differences between the secondary outcomes remained non-significant. However, when adding the patients with the 120-ml SORI to the LSORI group, the bladder injury rate was 9.8% in the MSORI group and 2% in the LSORI group. No statistical difference was found for either the primary or secondary outcomes.

Discussion

In this relatively small retrospective study, we have shown a significant reduction in the incidence of bladder perforation with a large-volume retropubic injection (9.8% absolute risk reduction; 100% relative risk reduction, although the numbers are too small for reliable results). The TVT procedure has been accepted as the gold standard in SUI surgical treatment because of its minimally invasive approach, high success and low complication rates. Although the retropubic TVT is thought to be more effective than the trans-obturator TVT, the latter is shown preference because of the concern about complications with the retropubic approach. This concern is seen especially with less experienced surgeons, the main concern being the risk of intra-operative bladder perforation. Large-volume spaces of Retzius infiltrations are thought to displace the bladder posteriorly and cephalad, thus reducing the risk of bladder perforation with the trocar used to insert the retropubic TVT. No evidence-based recommendations exist for the appropriate volumes for infiltration into this space.

Table 4 Outcome comparisons between patients with MSORI and LSORI (chi-square test) (Patients with 120-m1 bilateral SORI placed in the MSORI group)

Variable	MSORI (*n* = 43)	LSORI (n = 48)	P value
Bladder injury	5	0	0.015
Post-op pain	9	6	0.279
Urinary retention	6	3	0.219
Retropubic haematoma	1	0	0.288
UTI	7	6	0.607

Table 5 Outcome comparisons between patients with MSORI and LSORI (chi-square test) (patients with 120-m1 bilateral SORI placed in the LSORI group)

Outcomes	MSORI (n = 41)	LSORI (*n* = 50)	P value
Bladder injury	4	1	0.106
Post-op pain	8	7	0.481
Urinary retention	6	3	0.170
Retropubic haematoma	1	0	0.267
UTI	7	6	0.491

This retrospective study, although reviewing a small population size, aims to assist in the development of the hypothesis of reduced bladder perforation rates with the use of the LSORI. A possible benefit of the LSORI volumes was shown in reducing the risk of intra-operative bladder perforation (LSORI group 0% vs. MSORI group 9.8%). An initial concern with this large volume of infiltration was a possible increased risk of retropubic haematomas, bladder dysfunction/urinary retention and post-procedural urinary tract infections. In this study, there were no increased risks of any of these procedure-related complications.

A wide range of bladder perforation rates are reported in the literature, with a prospective randomised multicentre study reporting an incidence as high as 24% [4]. This is similar to the perforation rate found in the MSORI group. Stav et al. found bladder injuries to be more common when performed by inexperienced surgeons in women with a previous colposuspension or caesarean section, a BMI < 30 kg/m^2 and a rectocele [5]. In this study, all bladder perforations occurred in the group that received the MSORI. Two of the four patients with bladder perforation had previous SUI surgery where both had had trans-obturator mid-urethral slings inserted previously. Three of the four patients had had previous pelvi-abdominal surgery, including previous caesarean sections, previous vaginal hysterectomy, previous prolapse surgery as well as one with a previous laparoscopic-assisted vaginal hysterectomy. The numbers in this group were small and hence definite associations could not be elicited. However, a possible association that may require further interrogation was found in patients who had concomitant surgery. It is important to note that the rates of concomitant surgery in the entire study population was 57.3%. All four patients (100%) who had sustained bladder perforations had additional surgeries at the time of the TVT insertion. These included prolapse surgery (anterior and posterior repair), perineorrhaphy and laparoscopic hysterectomy. Unfortunately, BMI was not adequately documented and hence not discussed. All four patients with bladder perforations had at least 5 days of catheterisation post-operatively, two with high post-void residuals that improved and one with de novo overactive bladder symptoms.

Baseline variables between the two groups were found to be similar, indicating to a degree generalisability of the results to the population undergoing SUI surgery. There were concerns about confounding factors having an impact on the outcomes of this study. Surgeon factors were considered, and although two of the four bladder perforations occurred with one surgeon, no statistical difference was found. The ratios of infiltration volumes used as well as the profile of other procedure-related complications were all similar, making the surgeon as a confounding factor unlikely in this study. Apart from the difference in SORI volumes, no other factor could be elicited that had an impact on bladder perforation rates.

The incidence of urinary retention in both the MSORI group (14%) and the LSORI group (6.3%) corresponds with the rates reported in a large systematic review in 2014 where rates of 0.00–21.74% were quoted [2]. Although not statistically significant, a trend was found where the incidence of urinary retention in the LSORI group was less than half that of the MSORI group. Again, all six patients in the MSORI group with urinary retention had concomitant surgery at the time of retropubic TVT insertion, two of whom sustained bladder injuries. Remarkably, none of the three patients with urinary retention in the LSORI group had concomitant surgery. All patients required catheterisation for 5–7 days. From the data in this study, the MSORI group had concomitant surgery as a risk factor for retention while the LSORI group had none. Although no direct inferences can be drawn from this, important factors to consider with any future prospective study would be to investigate the impact the large-volume infiltration has on the risk of urinary retention post-operatively. The often-unanticipated catheterisation post-operatively causes some distress and discomfort in patients.

The rest of the secondary outcomes examined in this review correlated with the published literature on this topic. Post-procedural retropubic haematomas were found to be 2.4% in the MSORI group and 0% in the LSORI group, corresponding with the reported rates of 0.0–16.3% [2]. Schimpf et al. reported UTI rates of 0.0–23.3%, similar to the rates found in this review of 12.5% (LSORI group) and 17.1% (MSORI group).

There are several limitations in this study, mainly the study design. A retrospective descriptive study with a relatively small study population does not allow carrying out a detailed statistical analysis that clearly identifies risk or associations. In addition, as data collection was retrospective, there was a paucity of documented information that may have been deemed important from this study's perspective. This relates specifically to accurate recordings of BMI and OAB symptoms, as these have been found to have an impact on surgical outcomes as well as subjective success and patient satisfaction with this procedure.

Two patients were excluded from the study with the 120-ml bilateral SORI, deemed a 'medium' volume, a volume of infiltration that falls between the minimal (MSORI) and large (LSORI) volumes used in this study. A sensitivity analysis was thus performed to assess whether the exclusion of these two patients from the study made a difference to the outcomes by assigning them to the MSORI group and then the LSORI group. When the data of these two patients were added to the MSORI group, no major changes occurred in the statistical differences found, i.e. there was still a significant difference shown in the primary outcome of bladder perforations (11.6% MSORI vs. 0% LSORI), with no differences found with the

secondary outcomes. However, when the data of these two patients were added to the LSORI group, none of the outcomes showed any statistical difference. Importantly, this analysis showed that no significant statistical difference was found between the two groups when assessing the primary outcome of bladder injury (9.8% MSORI vs. 2% LSORI group). This has a great impact on the ability to use these data to generate the proposed hypothesis. One could argue that although the statistical difference has changed with this sensitivity analysis, the difference in rates between the two groups may still remain clinically significant.

This retrospective review, although limited, can be used to generate the hypothesis that the use of LSORI may play a role in reducing the risk of bladder perforations at the time of retropubic TVT insertion. A trend was noted that there was no increased incidence of other known retropubic TVT-related complications, although urinary retention may be a concern (as discussed above). Statements about safety based on the quality of this study design cannot be made, but trends in the data can be noted and used to motivate larger prospective studies. The limitation regarding the sensitivity analysis performed further emphasises the need for a larger prospective trial to further assess this study hypothesis.

Conclusion

Intra-operative bladder perforation at the time of the retropubic TVT procedure is a major dissuasive factor for surgeons opting for the trans-obturator approach instead, despite its reduced efficacy in more severe and complicated cases. This retrospective review, despite the limitation of its study design and deficiency of some data, unveiled a possible benefit of the large space of Retzius infiltration technique in substantially reducing the risk of bladder perforation, while showing trends of maintaining the known safety of the procedure. This retrospective review identifies the need to do larger prospective studies to interrogate the LSORI technique's safety, efficacy and risk reduction potential.

Compliance with ethical standards

Conflicts of interest None.

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