

GYNECOLOGY

Serious complications and recurrences after retropubic vs transobturator midurethral sling procedures for 2682 patients in the VIGI-MESH register

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BACKGROUND: Midurethral slings are the gold standard for treating stress urinary incontinence, but their complications may raise concerns. Complications may differ by the approach used to place them.

OBJECTIVE: This study aimed to compare serious complications and reoperations for recurrence after midurethral sling procedures when using the retropubic vs the transobturator route for female stress urinary incontinence.

STUDY DESIGN: This analysis was of patients included in the French, multicenter VIGI-MESH register since February 2017 who received a midurethral sling for female stress urinary incontinence either by the retropubic or the transobturator route and excluded patients with single-incision slings. Follow-up continued until October 2021. Serious complications (Clavien-Dindo classification $\geq$ grade III) attributable to the midurethral sling and reoperations for recurrence were compared using Cox proportional hazard models including any associated surgery (hysterectomy or prolapse) and a frailty term to consider the center effect. Baseline differences were balanced by propensity score weighting. Analyses using the propensity score and Cox models were adjusted for baseline differences, center effect, and associated surgery.

RESULTS: A total of 1830 participants received a retropubic sling and 852 received a transobturator sling in 27 French centers that were placed

by 167 surgeons. The cumulative 2-year estimate of serious complications was 5.8% (95% confidence interval, 4.8–7.0) in the retropubic group and 2.9% (95% confidence interval, 1.9–4.3) in the transobturator group, that is, after adjustment, half of the retropubic group was affected (adjusted hazard ratio, 0.41; 95% confidence interval, 0.3–0.6). The cumulative 2-year estimate of reoperation for recurrence of stress urinary incontinence was 2.7% (95% confidence interval, 2.0–3.6) in the retropubic group and 2.8% (95% confidence interval, 1.7–4.2) in the transobturator group with risk for revision for recurrence being higher in the transobturator group after adjustment (adjusted hazard ratio, 1.9; 95% confidence interval, 1.2–2.9); this surplus risk disappeared after exclusion of the patients with a previous surgery for stress urinary incontinence.

CONCLUSION: The transobturator route for midurethral sling placement is associated with a lower risk for serious complications but a higher risk for surgical reoperation for recurrence than the retropubic route. Despite the large number of surgeons involved, these risks were low. The data are therefore reassuring.

Key words: complication, mesh erosion, midurethral sling, recurrence, sling removal, stress urinary incontinence, urinary retention

Introduction

Stress urinary incontinence (SUI) affects about two-thirds of middle-aged females and may severely impair their quality of life.¹ After failure of conservative first-line treatment options,² surgery proved to be effective decades ago.³ Consequently, 10% to 15% of females will

undergo surgery for SUI during their lifetime.^{4,5}

By the start of this century, surgery to insert synthetic midurethral slings (MUS) was the most common procedure for SUI,⁶ and the retropubic approach has been monitored the longest.^{4,6} The transobturator approach was developed to avoid the pelvic organs by passing the sling through the obturator foramen.⁷

MUS procedures can cause serious complications or sequelae, including chronic pelvic pain, voiding dysfunction, and mesh erosion.^{8,9} After issuing restrictions on the use of transvaginal meshes for prolapse surgery in the United States and Europe, health authorities subsequently issued warnings about the safety of MUS surgeries. Some

countries have proposed limitations on MUS surgery because of their uncertain risk-benefit ratio.¹⁰ In the United Kingdom, the National Institute for Health and Care Excellence (NICE) guidelines do not recommend MUS as a first-line treatment for SUI and state that the transobturator route should be avoided.¹¹ Canada and Australia have also restricted the use of the transobturator sling placement route.^{12,13} Recently, New Zealand has recommended a temporary halt to the use of mesh for urinary incontinence.¹⁴

Trials comparing the retropubic and transobturator approaches were not designed to identify the incidence of rare complications¹⁵ and may not reflect real-world evidence.

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AJOG at a Glance

Why was this study conducted?

This study aimed to compare serious complications and surgical revisions for recurrence after midurethral sling procedures when using the retropubic vs the transobturator route for female stress urinary incontinence.

Key findings

This analysis of a prospective, multicenter French register showed that the transobturator route for midurethral sling placement has a lower risk for serious complications but a higher risk for surgical reoperation for recurrence than the retropubic route. Despite the large number of surgeons involved, both these risks were low.

What does this add to what is known?

Both approaches remain useful. Women and surgeons need these data for shared decision-making before surgery for stress urinary incontinence based on individual risks for complications and recurrence. Our results are reassuring in a context where the use of midurethral slings is under scrutiny by health authorities.

and reoperations for recurrence during follow-up. Postoperative examinations were not standardized. Serious complications were defined as those graded as III, IV, or V according to the Clavien-Dindo classification.²² An intraoperative injury (or other unexpected event) was considered a serious complication only if it caused cancellation of the planned MUS (grade III) or a life-threatening complication (grade IV).

The surgeon who operated on the patient for the complication or recurrence collected the information on a specific form.¹⁸ Revision decisions were left to the surgeon, in accordance with existing practice, and no recommendations were given to the participating centers. To check for exhaustivity, we used 2 other sources, namely (1) the French hospital discharge database from each participating center to cross-check the surgical procedure codes against the procedures reported by surgeons and (2) questionnaires sent annually to the participating women.

Centralized analysis of each reported event by independent assessors was planned. Accordingly, the centers submitted the complication or recurrence form and medical reports; queries were sent when the information was considered insufficient. The independent assessors reviewed the records and reports of the index surgery and the subsequent procedures to assess the association between the MUS and the complications; they did not perform any physical examinations. They also reviewed the type of serious complication, including intraoperative wound, hemorrhage-related complication, bladder outlet obstruction (BOO), mesh exposure, infectious complication, pain complications, or overactive bladder. Isolated pain was defined as a pain symptom (spontaneous, provoked during physical examination or pain during intercourse) without any other diagnosis of complication regardless of the location.

The study period for the analyses presented here began in February 2017 and ended in October 2021. We included all patients who underwent MUS placement via the retropubic or the transobturator route as a primary or repeated

Registers enable the monitoring of rare events in routine clinical practice among an unselected population.^{16,17} The French VIGI-MESH register was thus designed to prospectively monitor serious complications and the recurrence of SUI or pelvic organ prolapse (POP) after pelvic floor reconstructive surgery in participating centers.¹⁸ The register started in February 2017, and participating centers have been enrolling cases continuously since then. This interval offers adequate hindsight for studying medium-term outcomes.¹⁹

We hypothesized that the incidence and type of serious complications and of reoperations for recurrence might differ by the type of initial surgical approach that was used.¹⁹ Our objective was to measure and compare the incidence of surgical revision for complications and SUI recurrence after MUS surgery by the retropubic vs the transobturator approaches in the VIGI-MESH register.

Materials and Methods

This study was a subgroup analysis of the prospective VIGI-MESH register focused on MUS surgery. The register was approved by the Comité de Protection des Personnes Ouest III (institutional review board) (IDRBC 2017-A000308-45) and registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (identifier, NCT03052985). The Agence

Nationale de Sécurité du Médicament et des produits de santé (National Medicines Agency) provided funding for the VIGI-MESH register but has played no role in the data collection or analysis or the interpretation of the results. This study had no support from any mesh manufacturer. The participating centers in the VIGI-MESH register were 27 volunteer French centers (university teaching or general community hospitals) with a special interest in urogynecologic surgery.¹⁸ Most of them had previously worked together on a randomized trial of pelvic floor reconstructive surgery.²⁰ The updated annual activity (2017–2022) of the participating centers ranged from 6 to 173 MUS per year. A quarter had fewer than 18 procedures per year (ie, low volume), a quarter had more than 36 per year (ie, high volume), and half had medium-volume activity.²¹

Each individual participant received information about the VIGI-MESH register and provided consent for inclusion. Surgeons described the operations on a specific case report form. Data collection was checked by comparing surgeons' reports with mesh deliveries from the hospital pharmacies and the surgical codes of eligible procedures recorded in the hospital database.

The participating centers prospectively collected all serious complications

treatment after a previous SUI surgery. Because the register was designed to enable analysis of real-life surgery, the choice of MUS placement route was left to the surgeon based on their individual existing practice and recommendations.²³ An adjustable MUS was considered retropubic. Single-incision sling placements were excluded.

Follow-up continued until a first outcome of interest (if any), the patient's death, or the end of the study period (October 25, 2021). Data were consolidated before extraction for analysis. For the first occurrence of an outcome of interest, follow-up was censored at the time of the event (complication or recurrence). The outcomes of interest, complications, and recurrence were analyzed independently. If a complication occurred after a recurrence, the decision to attribute the complication to the index surgery was based on all available information.

The planned surgical group was considered for the analyses, that is, any complication requiring cancellation of the procedure was attributed to the approach. Baseline comparisons between the 2 surgical groups for patient characteristics were conducted using the Student *t* test or Wilcoxon-Mann-Whitney test for continuous variables and the chi-square test for categorical variables.

To balance the baseline differences between the 2 groups, we used a propensity score approach with inverse probability of treatment weighting. A multinomial logistic regression was conducted to estimate each patient's probability of receiving 1 of the 2 types of surgeries based on baseline covariates (ie, the propensity score).^{24,25} The variables were prespecified before any outcome analyses and included age, body mass index, smoking, diabetes, previous hysterectomy, previous surgery for SUI or POP, physical status score, and menopausal status. Stabilized weights were used to estimate the average treatment effect in the entire population, and extreme weights were truncated. The balance between treatment populations was evaluated by standardized differences of all baseline

covariates with a threshold of 0.1 indicating imbalance.²⁶

Two Kaplan-Meier curves were constructed to graphically assess the incidence of serious complications attributable to the MUS and the incidence of reoperation for SUI recurrence for each of the 2 approaches. We calculated the cumulative event rate for each year of follow-up for each outcome of interest. The numerators included all events up to the next follow-up time point (year), and the denominators included events and patients censored during the interval and those who had not previously experienced the event of interest. Two weighted Cox models with frailty terms—1 for serious complications and 1 for reoperations for SUI recurrence—were used to compare the 2 groups. The models included a nonparametric estimation of the baseline hazard, a gamma frailty term to account for unmeasured sources of variation between centers in the model, and weights based on the propensity score.^{27,28} We also included as a covariate any concomitant hysterectomy or prolapse surgery. The results are reported as hazard ratios (HRs) with 95% confidence intervals (CIs) and *P* values. All statistical tests were 2-sided and a *P* value <.05 was considered significant. Missing data were handled with a multiple imputation strategy for covariates (using the MICE package in R).²⁹ All analyses were performed with R, version 4.2.1 (R Core Team, Vienna, Austria). Patients were not involved in the development of the VIGI-MESH register or in these analyses.

Results

Between February 2017 and October 2021, 3314 women agreed to be included in the register and underwent surgery for SUI; after the exclusion of single-incision slings, 2682 had an MUS placed (Figure 1). Among them, 1830 had retropubic slings and 852 had transobturator slings that were placed by 167 surgeons across the 27 participating centers. The median number of procedures at each center was 34 (interquartile range [IQR], 17–105). A detailed list of the tapes models is given in Supplemental Table 1. Baseline

characteristics of the patients included are reported in Table 1. In the retropubic group, the median operative time was significantly higher (30 min vs 27 min, *P* < .001) and the median blood loss was significantly lower (10 mL vs 20 mL, *P* < .001) (Table 1).

Of the 12 covariates in the propensity score, 11 had weighted maximum standardized differences <10%, whereas 1, history of SUI surgery, exceeded the threshold by 4% (Figure 2).

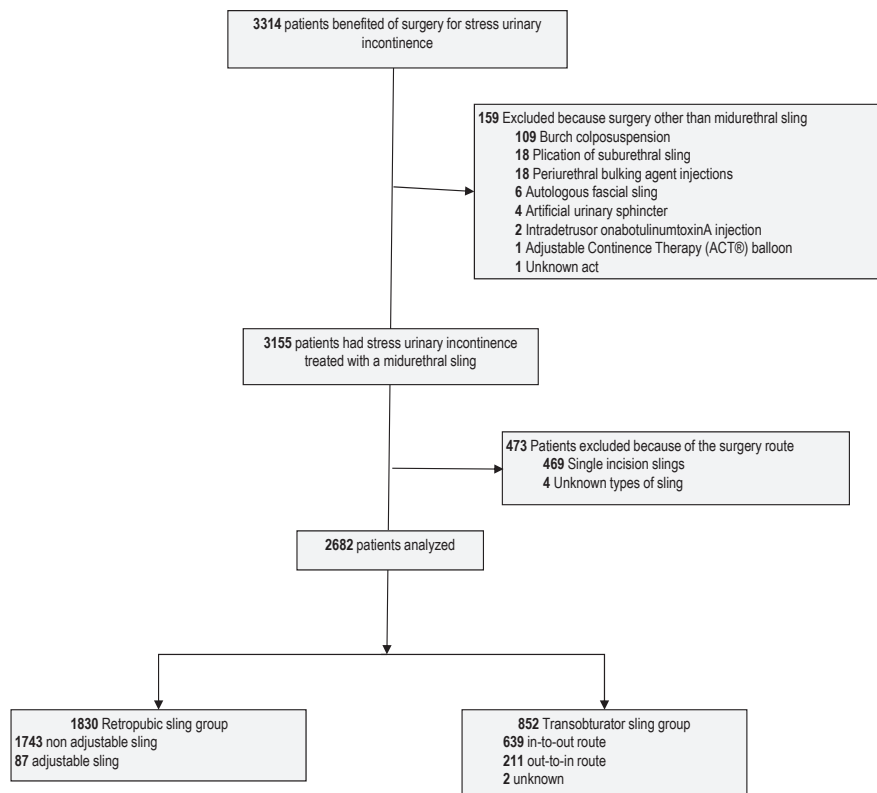
The median follow-up was 26 (IQR, 12–39) months with a maximum of 56 months.

Serious complications attributable to the MUS procedure occurred in 128 women after a median of 24 months (IQR, 10–38); 103 occurred among those with a retropubic sling and 25 among those with a transobturator sling (Table 2). All complications were Clavien-Dindo grade III except for 1 patient with a retropubic sling who needed intensive care for a retropubic hematoma with anemia. No patient died.

Eight patients had serious hemorrhage-related complications. In the retropubic group, we observed 3 intraoperative hemorrhages (including 2 from an intraoperative wound) and 2 postoperative hematomas that were resolved by laparoscopic or laparotomic drainage within 2 days after surgery. In the transobturator group, 1 patient needed a laparotomy for an infected hematoma of the Retzius space 9 days after surgery; another returned to the operating room to evacuate a suburethral thrombus that obstructed micturition 13 days after surgery, and a third patient developed hematuria during self-catheterization.

BOO requiring revision occurred in 71 patients; 58 of those were in the retropubic group and 13 were in the transobturator group (Table 2). The sling was loosened for 41 patients, sectioned for 13, and removed for 15; 2 patients had other revision procedures. In this group, 4 patients complained of an overactive bladder.

Mesh exposure necessitated revision in 34 patients; 28 had retropubic slings and 6 had transobturator slings. It was treated by sling removal in 31 and by

FIGURE 1
Study flowcharts

Armengaud. Serious complications and recurrence after retropubic vs transobturator midurethral sling procedures. *Am J Obstet Gynecol* 2023.

vaginal trimming without mesh excision in 3. Among this group, 3 patients complained of an overactive bladder.

Isolated pain requiring revision occurred in 8 patients. Two patients (1 in each group) had neuropathic pain in the obturator nerve area beginning immediately after surgery and were treated with mesh removal. Six patients later required revision for pain; 5 were in the retropubic group (2 for suprapubic pain, 2 for dyspareunia, and 1 for urethral pain) and 1 was in the transobturator group owing to a painful vaginal polyp along the previous incision. They were treated by mesh removal (3 women), vaginal trimming without mesh excision (2 patients with de novo dyspareunia with no apparent cause other than the tape itself), or removal of a painful vaginal polyp using the vaginal route.

Mesh infections requiring revision occurred in 3 patients in the retropubic group, 2 with infection of the

variator of the adjustable MUS. They were treated by removal of the mesh or the variator using the vaginal route. The transobturator group had no mesh infections.

In the transobturator group, 1 patient with an overactive bladder required an intradetrusor injection of onabotulinumtoxin A in the operating room.

Fourteen patients had more than 1 surgery for complications (12 had 2 procedures and 2 had 3 procedures). Four of them had multiple partial ablations of the tape for vaginal erosion.

The unadjusted 2-year cumulative incidence of serious complications was 5.8% (95% CI, 4.8–7.0) in the retropubic group and 2.9% (95% CI, 1.9–4.3) in the transobturator group (Figure 3, A and Supplemental Table 2) with a crude significant difference favoring the transobturator route (Table 3). This difference persisted after application of the propensity score and

adjustment for the center effect and concomitant hysterectomy or prolapse surgery (Table 3). BOO and mesh exposure were both significantly less frequent in the transobturator group (Table 3). Revision because of pain did not differ between groups (Table 3). A sensitivity analysis in which patients with a history of SUI surgery were excluded confirmed the lower risk for complications in the transobturator group (Table 3).

SUI recurrence (Figure 3, B and Supplemental Table 2) required new surgery in 63 patients at a median interval of 25 months (IQR, 11–39).

In the retropubic group, 41 patients had recurrence; 14 patients received a new MUS (12 through the retropubic route, 1 through the transobturator route, and 1 through an unknown route), 7 received bulking agent injections, 7 benefited from re-tensioning of the sling, and 13 had adjustment of an adjustable MUS. Eleven patients underwent reoperation for recurrence of SUI after occurrence of a complication (4 of them had intraoperative cancellations of the procedure).

In the transobturator group, 21 patients had recurrences; 8 patients received a new MUS (7 through the retropubic route and 1 through the transobturator route), 9 had the MUS re-tensioned, and 5 received bulking agent injections. Three patients underwent reoperation for SUI recurrence after a complication (1 had intraoperative cancellation of the procedure).

In the retropubic group, the unadjusted 2-year cumulative incidence was 2.7% (95% CI, 2.0–3.6), and it was 2.8% (95% CI, 1.7–4.2) in the transobturator group (Figure 3, B and Supplemental Table 2)—this difference was not significant (Table 3). Considering the center effect and the associated surgery (hysterectomy or prolapse), the weighted difference between the groups showed a significantly higher risk for recurrence among those in the transobturator route (adjusted HR, 1.9; 95% CI, 1.2–2.9) (Table 3). This difference disappeared after excluding women with a history of SUI surgery in a sensitivity analysis (Table 3).

TABLE 1

The baseline characteristics of patients at the index surgery to place a midurethral sling for stress urinary incontinence and intraoperative characteristics

Characteristic	Retropubic (n=1830)	Transobturator (n=852)	P value
Age (y), mean (SD)	56.9 (13.0)	58.8 (12.6)	<.001
BMI (kg/m ²), mean (SD) [n]	26.2 (5.0) [1810]	26.8 (5.2) [837]	.010
Menopausal, n/N (%)	1013/1763 (55)	526/834 (62)	.006
Smoking, n/N (%)	211/1792 (12)	106/828 (12)	.47
Diabetes, n/N (%)	101/1768 (6)	54/819 (6)	.38
Physical status (ASA), n/N (%)			
1	730/1716 (40)	314/819 (37)	.24
2	843/1716 (46)	420/819 (49)	
3	140/1716 (8)	69/819 (8)	
4	3/1716 (0.2)	0/819 (0)	
Surgical history			
Previous hysterectomy n/N (%)	271/1757 (15)	128/803 (16)	>.99
Previous SUI surgery, n (%)	241 (13)	27 (3)	<.001
Previous POP surgery, n (%)	234 (13)	244 (29)	.06
Index surgery			
Concomitant hysterectomy, n (%)			
Subtotal hysterectomy	28 (2)	43 (5)	<.001
Total hysterectomy	25 (1)	50 (6)	
No	1777 (97)	759 (89)	
Concomitant POP surgery, n (%)	234 (13)	244 (29)	<.001
Operative length (min), median [IQR]	30 [20]	27 [57]	<.001
Blood loss (mL), median [IQR]	10 [50]	20 [40]	<.001
Blood transfusion, n	1	2	.19

The data for n=2682 participants are presented. In case of missing values, n/N or [n] indicate the number of participants with available data.

ASA, physical status score; BMI, body mass index; IQR, interquartile range; POP, pelvic organ prolapse; SD, standard deviation; SUI, stress urinary incontinence.

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The results remained unchanged after excluding the 87 patients who were treated with adjustable slings via the retropubic route.

Comment

Principal findings

This study provides real-world data from an unselected population of patients who were treated for SUI by a large sample of surgeons that the risk for serious complications was higher after MUS placement via the retropubic route. Rates of BOO (the

most common complication) and of mesh exposure requiring revision were higher in this group. Revisions for pain were rare and did not differ between the groups. Finally, the reoperation rate for SUI recurrence was higher in the transobturator group after adjustment for the unbalanced rate of previous incontinence surgeries.

Results in the context of what is known

Our study highlights that there is a low rate of serious medium-term complications

and reoperations for recurrence with either of the approaches.¹⁹ This is consistent with several retrospective studies that used large databases of routinely collected data to estimate the rate of mesh revision or removal at 4 years, which was determined to be 2% to 3%, and the rate of reoperation for recurrent SUI, which was 3% to 4%.^{30–33} In the context of the warnings and use restrictions issued by health authorities in North America, Europe, and Australia, these results show that MUS surgery remains a useful and fairly safe procedure with a favorable risk-benefit ratio.

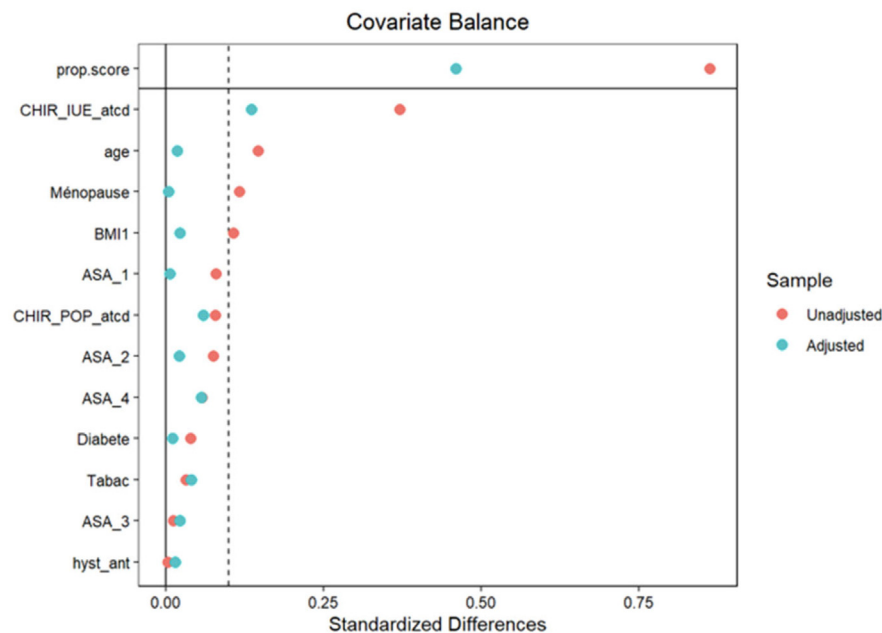
The fear of severe intraoperative injuries and urinary sequelae associated with the retropubic approach fueled the development of the transobturator approach. Previous meta-analyses of clinical trials have reported conflicting results about the relative advantages in terms of safety.^{15,34} Our study, consistent with the latest meta-analysis,¹⁹ highlights a robust difference between them that favors the transobturator route.

Clinical implications and research implications

More than half of the complications requiring revision in our study were related to BOO, and they were 3 times more frequent in the retropubic group, in line with previous randomized trials.^{15,19,34–36} A randomized study with a 5-year follow-up period³⁷ reported a cumulative incidence rate of BOO requiring surgery of 6% when using the retropubic route and 4% when using the transobturator route, which is similar to our results. Recent knowledge about the management of such obstruction after MUS placement stresses the need for early recognition and early MUS mobilization to enable high resolution rates for voiding dysfunction and to reduce the risk for recurrent or persistent SUI.^{38,39} Revisions in this study occurred mostly in the first 2 months after the index surgery. Efforts should be made to optimize the tape placement during the TVT procedure. Proper adjustment of the amount of tension applied to the sling can significantly reduce the BOO risk.⁴⁰

FIGURE 2

Baseline differences and weighted differences between the 2 surgical groups



ASA, physical status score; BMI, body mass index; CHIR_IUE_atcd, previous stress incontinence surgery; CHIR_POP_atcd, previous pelvic organ prolapse surgery; hyst_ant, previous hysterectomy; Tabac, smoker.

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Our study showed an unanticipated higher risk for revision for mesh exposure after retropubic sling procedures. Multiple randomized controlled trials have shown no difference in the mesh exposure rates between these 2 approaches.^{35,37,41–45} Most of these studies included a systematic physical examination in their outcome assessment, thereby enabling the diagnosis of asymptomatic exposure, whereas our register considered only severe symptomatic mesh exposure requiring revision. We can hypothesize that the exposure site and symptoms differ according to the route used. Indeed, a multicenter, randomized equivalence trial comparing outcomes between retropubic and transobturator slings reported a higher mesh exposure rate in the retropubic group when erosion was defined by mesh visualized in the vagina through a previous incision.³⁵

The Québec Collège des Médecins recently called attention to severe pain complications after transobturator sling

placement.¹² Its expert opinions relied on clinical cases of 400 women who underwent MUS procedures and described sling-related side effect. The Collège recommended a moratorium on transobturator slings because of the high risk for debilitating chronic pain. Results from our study (based on a comparative quantitative study design) provide some reassurance; pain symptoms were the indication for only 21% of the revisions. The medium-term incidence rate of revision for pain was reassuringly low and similar for both approaches. Some randomized controlled trials have shown higher rates of groin pain after the transobturator route,^{35,46} but most resolved within 6 months.¹⁹ Moreover, randomized controlled trials with follow-up periods of longer than 5 years have not reported this result.^{37,41–45} When patients reported lower limb or groin pain immediately after surgery, injury to the obturator or pudendal nerve was often suspected, and mesh removal most often cured the pain.

When isolated pain occurs later on after MUS insertion, the first-line treatment is often medical treatment.⁴⁷ Mesh removal is then considered if these first-line treatments fail.⁸ Our study did not include patients with pain that required only medical treatment. Moreover, we suspect that mesh removal for pain is more likely to be observed over a longer follow-up period. Further studies based on the national health data system might enable a comprehensive inventory of pain as an adverse event.

Previous randomized controlled trials have not shown any clear-cut differences in efficacy between the 2 approaches^{15,19,34–36} like we did. Most excluded patients with a history of SUI surgery.^{37,43,46,48} Because these patients were more frequent in the retropubic group, the difference between the approaches only appeared after correcting the imbalance for previous surgery. Differences in intrinsic sphincter deficiency between the groups may explain these results. One trial designed for patients with intrinsic sphincter deficiency showed an advantage for the retropubic approach in short- and medium-term cure rates.⁴⁹ It was confirmed by a meta-analysis of studies that reported subgroup analyses among patients with sphincter deficiency.⁵⁰

Strengths and limitations

The strength of our study is its use of a large, prospective, multicenter register operating in real-life conditions, which enabled an assessment of the benefit rate ratio of the MUS procedure that, unlike a randomized trial, includes uncommon events. Furthermore, a high proportion of our population would have been excluded from a randomized trial, because of their complex clinical situations, that is, recurrence after a previous SUI surgery or concomitant surgical procedures. Furthermore, in contrast with database studies that are based on routinely collected data,^{30–33} prospective data collection was performed using specific case report forms that allowed for precise and structured information and therefore enabled specific events of interest to be monitored.^{12,13}

TABLE 2

Description of serious complications (Clavien–Dindo grade III or higher) by time to revision after MUS surgery

Complication	Retropubic: 103/1830	Transobturator: 25/852
	No. (%)	No. (%)
Clavien-Dindo classification ^a		
III	102 (99)	25 (100)
IV	1 (1)	0
During surgery to day 2 postoperative	25 (24)	5 (20)
Bleeding	5	0
Intraoperative bleeding	3	0
Postoperative hematomas	2	0
Intraoperative wound ^b	8	3
Vaginal wounds	0	2
Urethral wounds	3	1
Vascular wounds	1	0
Vesical wounds	4	0
Bladder outlet obstruction	13	1
Pain	4	1
Isolated pain	1	1
Between 2 d and 2 mo postoperative	39 (38)	9 (36)
Bladder outlet obstruction	34	8
Vaginal exposures	3	0
Infections	5	1
Abscesses	2	1
Variotensor infections	1	0
Urinary tract infections	2	1
Bleeding	0	3
Postoperative hematomas	0	2
External bleeding	0	1
Pain	4	2
Isolated pain	0	0
Vaginal discharge	1	0
Between 2 and 12 mo postoperative	31 (30)	6 (24)
Bladder outlet obstruction	8	1
Mesh exposure	23	4
Vaginal exposure	20	4
Urethral exposure	2	0
Unknown exposure	1	
Urinary tract infections	4	1
Pain	9	3
Isolated pain	3	0

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(continued)

Some limitations must be mentioned. First, because the outcomes of interest were based on the participating surgeons' reports and hospital databases, some reoperations by different surgeons at different hospitals might have been missed. Nonetheless, the regular and routine verification of the follow-up information from hospital databases and participants¹⁸ and the annual questionnaire sent to patients (which included specific questions about new surgeries) make us confident in our ability to detect events at different postoperative points and to minimize the risk for unreported reinterventions.

Second, our study only recorded serious complications involving inpatient procedures and recurrences requiring revision (Dindo-Clavien grades III–V), although grade I and II complications can also impair quality of life. This definition of serious complication may not correspond to the patient's perception of the complication.⁵¹ Nonetheless, persistent pain after first-line medical treatment often leads to partial or total removal of the MUS—reflecting the emerging part of this risk.

Third, in real-life conditions, surgeons select the route based on their own experience and the technique they were taught. Thus, not all surgeons may be appropriately trained to offer both routes and select the one best suited to the patient's risk factors. Likewise, the indications for revision for complications or recurrence were not standardized. To limit these biases, our analyses were adjusted for the center effect to take the variability between centers into account, and we used propensity score methodology to adjust for baseline differences between the surgical groups.²⁴

Finally, the inclusion of patients who received adjustable slings in the analyses is arguable because of the specific complications and possible reoperation to adjust the sling. However, the results remained unchanged after exclusion of these patients.

Conclusion

Analysis of the mid-term results of the patients included in the register shows a lower risk for complications when

TABLE 2

Description of serious complications (Clavien–Dindo grade III or higher) by time to revision after MUS surgery (continued)

Complication	Retropubic: 103/1830	Transobturator: 25/852
	No. (%)	No. (%)
Vaginal discharge	1	0
Overactive bladder	4	1
After 12 mo postoperative	8 (8)	5 (20)
Bladder outlet obstruction	4	2
Mesh exposure	2	1
Vaginal exposure	2	1
Urethral exposure	0	0
Urinary tract infections	3	0
Pain	2	3
Isolated pain	1	2
Overactive bladder	1	1

Each patient could have one or more indications for revision.

^a Standardized grading system of surgical complications with 4 grades of increasing severity. Grade III is defined as surgical complications requiring surgical, endoscopic, or radiological intervention (classified into grade IIIa and IIIb when performed respectively without and with general anesthesia). Grade IV is defined as a life-threatening complication; ^b During surgery, intraoperative injuries (mostly bladder and vaginal wounds) occurred in 121 women in the retropubic group and in 27 in the transobturator group but only those leading to cancellation or changing of the procedure were considered serious complications.

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surgical repair of SUI is performed via the transobturator route than via the retropubic route. The difference is mainly related to voiding dysfunction but also to the risk of erosion. The risk for revision for pain was low and did not

differ between the groups. In contrast, the transobturator approach was associated with a higher rate for recurrence than the retropubic approach.

Despite the large number of surgeons who performed procedures for patients recorded in the register, the rate of serious complications and the risk for surgical reoperation for recurrence were found to be low. These data are thus reassuring in a context in which health authorities question the use of MUS procedures.

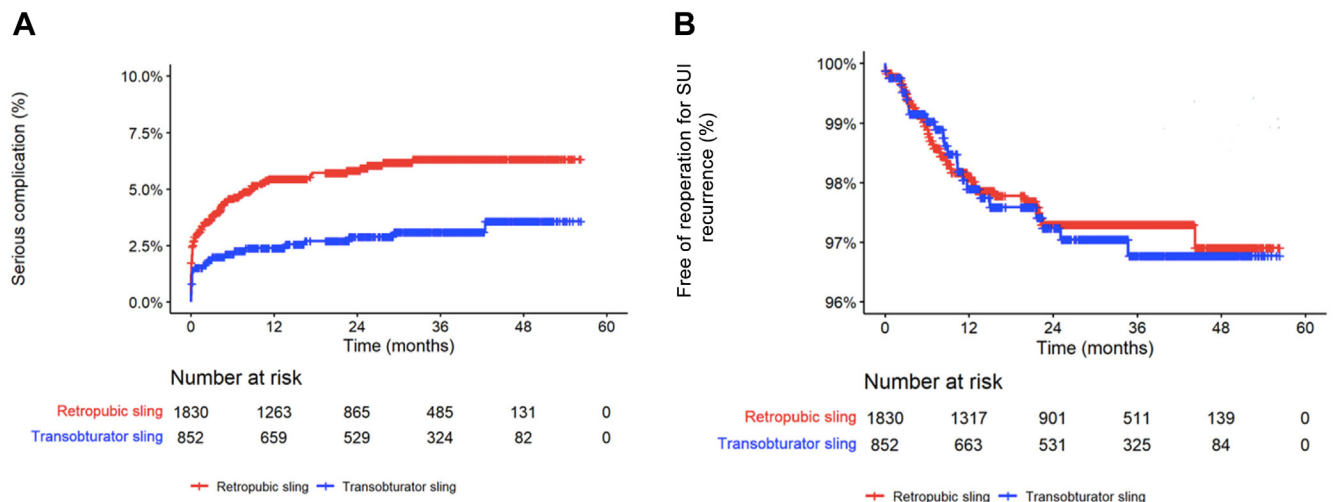
Both approaches remain useful. The lower risk for complications with the transobturator approach must be balanced against the lower risk for recurrence with the retropubic approach—the latter only in women with a history of SUI surgery. Women and surgeons need these data for shared decision-making before surgery for stress urinary incontinence.

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FIGURE 3

Kaplan-Meier curves for serious complications and SUI recurrence



A, Cumulated incidence of serious complication (Clavien-Dindo grade III or more). **B**, Cumulated incidence of reoperation for SUI recurrence.

SUI, stress urinary incontinence.

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TABLE 3

Risk of serious complication and reoperation for recurrence after MUS surgery according to the approach used

Outcome	Overall population (N=2682)	No. of events	Crude	Weighted ^a and adjusted ^b
			HR (95% CI)	HR (95% CI)
Serious complication (any)	Retropubic route	103	1	1
	Transobturator route	25	0.50 (0.32–0.77)	0.41 (0.29–0.56)
Bladder outlet obstruction	Retropubic route	58	1	1
	Transobturator route	13	0.46 (0.25–0.85)	0.35 (0.22–0.53)
Exposure	Retropubic route	27	1	1
	Transobturator route	5	0.37 (0.14–0.97)	0.28 (0.15–0.52)
Pain	Retropubic route	20	1	1
	Transobturator route	7	0.72 (0.30–1.70)	0.58 (0.31–1.1)
Recurrence	Retropubic route	41	1	1
	Transobturator route	22	1.0 (0.59–1.8)	1.9 (1.2–2.9)
History of SUI surgery excluded (n=2414)				
Serious complication (any)	Retropubic route	93	1	1
	Transobturator route	25	0.49 (0.31–0.76)	0.4 (0.3–0.6)
Recurrence	Retropubic route	35	1	1
	Transobturator route	20	1.0 (0.59–1.8)	1.2 (0.7–1.9)

Hazard ratio estimated with Cox proportional hazard model including a frailty term with center as a random effect (N=2682).

CI, confidence interval; HR, hazard ratio; SUI, stress urinary incontinence.

^a Weights based on the propensity score; these included age, body mass index, smoking, diabetes, surgical history (previous hysterectomy or previous surgery for stress urinary incontinence or previous pelvic organ prolapse), physical status score (ASA), and menopausal status; ^b Concomitant hysterectomy or prolapse surgery, if any.

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SUPPLEMENTAL TABLE 1

Type of mesh and manufactures used in the registry

Retropubic MUS	Transobturator MUS
AMI: Sensi TVT	AMI: Sensi TVT
Boston Scientific: Advantage Fit Blue System, Advantage Fit System, Advantage Blue, system, Advantage System	Boston Scientific: Obtryx II System Halo and curved
Ethicon: Gynecare TVT Exact, Gynecare TVT Sling	Coloplast: Aris
Microval: Safire	Ethicon: Gynecare TVT ABBREVO, Gynecare TVT Obturator System
Neomedic: Remeex	Microval: Safire
SURGYNAL: Glutea	THT BIO-SCIENCES: Swing-Band SB3, Swing-Band SB4
THT BIO-SCIENCES: Swing-Band SB4	

MUS, midurethral sling.

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SUPPLEMENTAL TABLE 2

Cumulative incidence rate of serious complication and reoperation for recurrence after MUS surgery by years of follow-up

Outcome	Year	Strata	No. of patients at the beginning of follow-up	Censored	With event	Cumulative incidence (95% CI)
Serious complication						
	1	Retropubic route	1830	472	95	5.5 (4.5–6.6)
	1	Transobturator route	852	173	20	2.4 (1.5–3.6)
	2	Retropubic route	1263	394	4	5.8 (4.8–7)
	2	Transobturator route	659	127	3	2.9 (1.9–4.3)
	3	Retropubic route	865	376	4	6.3 (5.2–7.6)
	3	Transobturator route	529	204	1	3.1 (2–4.5)
	4	Retropubic route	485	356	0	6.3 (5.2–7.6)
	4	Transobturator route	324	241	1	3.6 (2.3–5.4)
Reoperation for recurrence						
	1	Retropubic route	1830	482	31	1.9 (1.3–2.7)
	1	Transobturator	852	173	16	2.1 (1.2–3.3)
	2	Retropubic route	1317	407	9	2.7 (2–3.6)
	2	Transobturator	663	128	4	2.8 (1.7–4.2)
	3	Retropubic route	901	390	0	2.7 (2–3.6)
	3	Transobturator	531	204	2	3.2 (2.1–4.8)
	4	Retropubic route	511	373	1	3.1 (2.1–4.4)
	4	Transobturator	325	241	0	3.2 (2.1–4.8)

CI, confidence interval; MUS, midurethral sling.

Armengaud. Serious complications and recurrence after retropubic vs transobturator midurethral sling procedures. *Am J Obstet Gynecol* 2023.