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

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1 **Serious complications and recurrences after retropubic versus**
2 **transobturator midurethral sling procedures for 2682 patients in the VIGI-**
3 **MESH register**
4

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70 **Conflict of interest:**

71 C.S is a consultant for the Coloplast company.
 72 M.C is consultant for AB Medica, Promedon, Syliva compagnies
 73 The remaining authors report non conflict of interest.

74

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81

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89

90 Word count for the text: 3737

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92 **Tweetable statement:** In a large French register, patients with midurethral slings placed by a
93 transobturator (vs retropubic) route had lower risks of serious complications but higher risks of
94 surgery for SUI recurrence. Both risks were low.

95

96 **Short Title:** Serious complications and recurrences after retropubic versus transobturator
97 midurethral sling procedures.

98

99

100 **AJOG at Glance:**

101 **A. Why was this study conducted?**

102 To compare serious complications and surgical revisions for recurrence after midurethral
103 sling procedures by the retropubic and transobturator routes for female stress urinary
104 incontinence.

105 **B. What are the key findings?**

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

110 **C. What does this study add to what is already known?**

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

115

116

117 **Abstract:**

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

121 Objective(s): To compare serious complications and reoperations for recurrence after
122 midurethral sling procedures by the retropubic and transobturator routes for female stress
123 urinary incontinence.

124 Study Design: This analysis covers patients included in the French multicenter VIGI-MESH
125 register since February 2017 who received a midurethral sling for female stress urinary
126 incontinence by the retropubic or transobturator route, excluding single-incision slings. Follow-
127 up continued to October 2021. Serious complications (Clavien-Dindo classification \geq Grade
128 III) imputable to the midurethral sling and reoperations for recurrence were compared by Cox
129 proportional hazard models including any associated surgery (hysterectomy or prolapse) and a
130 frailty term to consider the center effect. Baseline differences were balanced by propensity score
131 weighting. Analyses using the propensity score and Cox models were adjusted for baseline
132 differences, center effect, and associated surgery.

133 Results: 1830 participants received a retropubic sling and 852 a transobturator sling in 27
134 French centers, placed by 167 surgeons. The cumulative two-year estimate of serious
135 complications was 5.8% (95% CI 4.8%-7.0%) in the retropubic group and 2.9% (95% CI,
136 1.9%–4.3%) in the transobturator group, that is, after adjustment, half that of the retropubic
137 group (adjusted HR 0.41; 95% CI 0.3-0.6). The cumulative two-year estimate of reoperation
138 for recurrence of stress urinary incontinence was 2.7% (95% CI 2.0-3.6) in the retropubic group
139 and 2.8% (95% CI 1.7-4.2) in the transobturator group, with risk of revision for recurrence
140 higher in the transobturator group after adjustment (adjusted HR 1.9; 95% CI 1.2-2.9); this

141 surplus risk disappeared after exclusion of the patients with a previous surgery for stress urinary
142 incontinence.

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

147

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

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166 **Introduction**

167 Stress urinary incontinence (SUI) affects about two-thirds of middle-aged females and may
168 severely impair their quality of life.¹ After failure of conservative first-line treatment options,²
169 surgery proved effective decades ago.³ Ten to 15% of females will undergo surgery for SUI
170 during their lifetime.^{4,5}

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

175 MUS procedures can cause serious complications or sequelae: chronic pelvic pain, voiding
176 dysfunction, and mesh erosions.^{8,9} After issuing restrictions on the use of transvaginal meshes
177 for prolapse surgery in the United States and Europe, health authorities subsequently issued
178 warnings about the safety of MUS surgery. Some countries have proposed limitations on MUS
179 because of their uncertain risk-benefit ratio.¹⁰ In the United Kingdom, the National Institute for
180 Health and Care Excellence (NICE) guidelines do not recommend MUS as a first-line treatment
181 in SUI and state that the transobturator route should be avoided.¹¹ Canada and Australia have
182 also restricted the use of the transobturator sling.^{12,13} Recently, New Zealand has recommended
183 a temporary halt to mesh use for urinary incontinence.¹⁴

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

186 Registers enable monitoring of rare events in routine clinical practice among an unselected
187 population.^{16,17} The French VIGI-MESH register was thus designed to monitor prospectively
188 serious complications and recurrence of SUI or pelvic organ prolapse (POP) after pelvic floor
189 reconstructive surgery in participating centers.¹⁸ The register started in February 2017, and

190 participating centers have been enrolling cases continuously since then. This interval offers
191 adequate hindsight for studying medium-term outcomes.¹⁹

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

196

197 **Materials and Methods**

198 This study is a subgroup analysis of the prospective VIGI-MESH register focused on MUS
199 surgery. The register was approved by the *Comité de Protection des Personnes Ouest III*
200 (Institutional Review Board) (IDRBC 2017-A000308-45), ClinicalTrials.gov (NCT03052985).
201 The *Agence Nationale de Sécurité du Médicament et des produits de santé* (National Medicines
202 Agency) provided funding for the VIGI-MESH register but has played no role in the data
203 collection or analysis, or the interpretation of the results. The study had no support from any
204 mesh manufacturer. The participating centers in the VIGI-MESH register were 27 volunteer
205 French centers (university teaching or general community hospitals) with a special interest in
206 urogynecologic surgery.¹⁸ Most of them had previously worked together on a randomized trial
207 of pelvic floor reconstructive surgery.²⁰ The updated annual activity (2017-2022) of the
208 participating centers ranges from 6 to 173 MUS per year. A quarter have fewer than 18 poses
209 per year (ie, low volume), a quarter more than 36 per year (ie, high volume), and half a medium-
210 volume activity.²¹

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

215 The participating centers prospectively collected all serious complications and reoperations for
216 recurrence during follow-up. Postoperative examinations were not standardized. Serious
217 complications were defined as those graded as III, IV, or V by the Clavien-Dindo
218 classification.²² An intraoperative injury (or other unexpected event) was considered a serious
219 complication only if it caused cancellation of the planned MUS (grade III) or a life-threatening
220 complication (grade IV).

221 The surgeon who operated on the patient for the complication or recurrence collected the
222 information on a specific form.¹⁸ Revision decisions were left to the surgeon, in accordance
223 with current practice, and no prior recommendations were given to the participating centers. To
224 check for exhaustivity we used two other sources: i) the French hospital discharge database
225 (PMSI) from each participating center, to cross-check the surgical procedure codes against the
226 procedures reported by surgeons; and ii) questionnaires sent annually to the participating
227 women.

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

238 The study period for the analyses presented here began in February 2017 and ended in October
239 2021. We included all patients who underwent MUS via the retropubic or transobturator route,
240 as primary or repeated treatment after previous SUI surgery. As the register was designed to
241 enable analysis of real-life surgery, the choice of MUS placement route was left to the surgeon
242 according to their individual current practice and current recommendations.²³ Adjustable MUS
243 were considered retropubic. Single-incision sling placements were excluded.

244 Follow-up continued until a first outcome of interest (if any), the patient's death, or the end of
245 the study period (here, October 25, 2021). Data were consolidated before extraction for

246 analysis. For the first occurrence of an outcome of interest, follow-up was censored at the time
247 of the event (complication or recurrence). The outcomes of interest, complications, and
248 recurrence were analyzed independently. If a complication occurred after a recurrence, the
249 decision to attribute the complication to the index surgery was based on all available
250 information.

251 The planned surgical group was considered for the analyses, that is, any complication requiring
252 cancellation of the procedure was imputed to the approach. Baseline comparisons of the two
253 surgical groups for patient's characteristics used Student's t-test or the Wilcoxon-Mann-
254 Whitney test for continuous variables and chi-square tests for categorical variables.

255 To balance the baseline differences between the two groups, we used a propensity score
256 approach with inverse probability of treatment weighting. A multinomial logistic regression
257 was constructed to estimate each patient's probability of receiving one of the two types of
258 surgeries, given her baseline covariates (i.e., the propensity score).^{24,25} The variables were
259 prespecified before any outcome analyses and included age, body mass index (BMI), smoking,
260 diabetes, previous hysterectomy, previous surgery for SUI or POP, physical status score (ASA),
261 and menopausal status. Stabilized weights were used to estimate the average treatment effect in
262 the entire population, and extreme weights were truncated. The balance between treatment
263 populations was evaluated by standardized differences of all baseline covariates, with a
264 threshold of 0.1 indicating imbalance.²⁶

265 Two Kaplan-Meier curves were constructed to graphically assess the incidence of serious
266 complications attributable to the MUS and the incidence of reoperation for SUI recurrence for
267 each of the two approaches. We calculated the cumulative event rate for each year of follow-
268 up for each outcome of interest. The numerators included all events up to the next follow-up
269 time point (year), and the denominators included events and patients censored during the
270 interval and those who had not previously experienced the event of interest. Two weighted Cox

271 models with frailty terms — one for serious complications, one for reoperations for SUI
272 recurrence — were used to compare the two groups. The models included a nonparametric
273 estimation of the baseline hazard, a gamma frailty term to account for unmeasured sources of
274 variation between centers in the model, and weights based on the propensity score.^{27,28} We also
275 included as a covariate any concomitant hysterectomy or prolapse surgery. Results are reported
276 as hazard ratios (HRs) with 95% confidence intervals (CIs) and *P* values. All statistical tests
277 were two-sided and a *P* value <.05 was considered significant. Missing data were handled with
278 a multiple imputation strategy for covariates (using the MICE package in R).²⁹ All analyses
279 were performed with R version 4.2.1 (www.R-project.org). Patients were not involved in the
280 development of the VIGI-MESH register or in these analyses.

281

282 **Results:**

283 Between February 2017 and October 2021, 3314 women agreed to participate in the register
284 and underwent surgery for SUI; after exclusion of single-incision slings, 2682 had MUS placed
285 (Figure 1). Among them, 1830 had retropubic slings and 852 transobturator slings, placed by
286 167 surgeons overall in the 27 participating centers. The median number of procedures at each
287 center was 34 [interquartile range (IQR): 17-105]. A detailed list of the tapes models is given
288 in the supplementary material (Supplementary table 1). Baseline characteristics of the patients
289 included are reported in Table 1. In the retropubic group, median operative time was
290 significantly higher and median blood loss significantly lower (Table 1).

291 Of the 12 covariates in the propensity score, 11 had weighted maximum standardized
292 differences below 10%, while one, history of SUI surgery, exceeded the threshold by 4%
293 (Figure 2).

294 The median follow-up was 26 [IQR:12-39] months with a maximum of 56 months.

295 Serious complications attributable to the MUS procedure occurred to 128 women, after a
296 median of 24 months [IQR: 10-38]: 103 with retropubic and 25 with transobturator slings (Table
297 2). All complications were Clavien-Dindo grade III except for one patient with a retropubic
298 sling who needed intensive care for a retropubic hematoma with anemia. No patient died.

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

306 BOO required revision for 71 patients: 58 in the retropubic group and 13 in the transobturator
307 group (Table 2). The sling was loosened for 41 patients, sectioned for 13, and removed for 15;
308 2 patients had other revision procedures. In this group, four patients complained of overactive
309 bladder.

310 Mesh exposure necessitated revision in 34 patients: 28 with retropubic and 6 with transobturator
311 slings. It was treated by sling removal for 31 and vaginal trimming without mesh excision for
312 3. Among this group, three patients complained of overactive bladder.

313 Severe pain required revision in eight patients. Two patients (one in each group) had
314 neuropathic pain in the obturator nerve area beginning immediately after surgery and were
315 treated with mesh removal. Six patients later required revision for pain: five in the retropubic
316 group (two for suprapubic pain, two for dyspareunia, and one for urethral pain), and one in the
317 transobturator group due to a painful vaginal polyp along the previous incision. They were
318 treated by mesh removal (three women), vaginal trimming without mesh excision (two patients
319 with de novo dyspareunia, with no apparent cause other than the tape itself), or removal of a
320 painful vaginal polyp by the vaginal route.

321 Mesh infections required revision for three patients in the retropubic group, two with infection
322 of the variotensor of the adjustable MUS. They were treated by removal of the mesh by the
323 vaginal route or the variotensor. The transobturator group had no mesh infections.

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

326 Fourteen patients had more than one surgery for complication (12 had 2 procedures and 2 had
327 3). Four of them had multiple partial ablations of the same tape for vaginal erosion.

328 The unadjusted two-year cumulative incidence of serious complications was 5.8% (95%CI,
329 4.8%-7.0%) in the retropubic group and 2.9% (95%CI, 1.9%–4.3%) in the transobturator group
330 (Figure 3a and supplementary Table 2) with a crude significant difference favoring the

331 transobturator route (Table 3). This difference persisted after application of the propensity score
332 and adjustment for the center effect and concomitant hysterectomy or prolapse surgery (Table
333 3). BOO and mesh exposure were both significantly less frequent in the transobturator group
334 (Table 3). Revision because of pain did not differ between groups (Table 3). A sensitivity
335 analysis excluding patients with a history of SUI surgery confirmed the lower risk of
336 complications in the transobturator group (Table 3).

337 SUI recurrence (Figure 3b and supplementary Table 2) required new surgery for 63 patients at
338 a median interval of 25 months [IQR: 11-39].

339 Forty-one patients had recurrence in the retropubic group: 14 patients received a new MUS (12
340 by retropubic route, one by transobturator route, and one by an unknown route), 7 received
341 bulking agent injections, 7 benefited from re-tensioning of the sling and 13 had adjustment of
342 an adjustable MUS. Eleven patients underwent reoperation for recurrence of SUI after
343 occurrence of a complication (four of them intraoperative cancellations of the procedure).

344 Twenty-two patients had recurrences in the transobturator group: eight patients received a new
345 MUS (seven by retropubic route and one by transobturator route), nine had the MUS re-
346 tensioned, and five bulking agent injections. Three patients underwent reoperation for SUI
347 recurrence after a complication (one a intraoperative cancellation of the procedure).

348 In the retropubic group, the unadjusted two-year cumulative incidence was 2.7%, 95%CI,
349 2.0%–3.6%; and 2.8%, 95%CI, 1.7%–4.2% in the transobturator group (Figure 3b and
350 supplementary Table 2): this difference was not significant (Table 3). Considering the center
351 effect and associated surgery (hysterectomy or prolapse), the weighted difference between
352 groups showed a significantly higher risk of recurrence for the transobturator route (adjusted
353 HR, 1.9; 95%CI 1.2-2.9) (Table 3). This difference disappeared after excluding women with a
354 history of SUI surgery in a sensitivity analysis (Table 3).

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

357

358 **Comment:**

359 **Principal Findings:**

360 This study provides real-world data from an unselected population of patients treated for SUI
361 by a large sample of surgeons that the risk of serious complications was higher after MUS
362 placement by the retropubic route. Rates of BOO (the most common complication) and of mesh
363 exposure requiring revision were higher in this group. Revisions for pain were rare and did not
364 differ between the groups. Finally, the reoperation rate for SUI recurrence was higher in the
365 transobturator group after adjustment for the unbalanced rate of previous incontinence surgery.

366 **Results in the Context of What is Known:**

367 Our study highlights a low rate of medium-term serious complications and reoperations for
368 recurrence with both approaches.¹⁹ This is consistent with several retrospective studies that used
369 large databases of routinely collected data to estimate the rate of mesh revision or removal at 4
370 years at 2 to 3% and the rate of reoperation for recurrent SUI at 3 to 4%.³⁰⁻³³ In the context of
371 the warnings and use restrictions issued by health authorities in North America, Europe, and
372 Australia, these results show that MUS surgery remains a useful and fairly safe procedure with
373 a favorable risk-benefit ratio.

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

379 **Clinical implications and research implications:**

380 More than half the complications requiring revision in our study were related to BOO, and they
381 were three time more frequent in the retropubic group, in line with previous randomized
382 trials.^{15,19,34-36} A randomized study with 5-year follow-up³⁷ reported a cumulative incidence

383 rate of BOO requiring surgery of 6% by the retropubic and 4% by the transobturator route,
384 similar to our results. Recent knowledge about the management of such obstruction after MUS
385 placement stresses the need for early recognition and early MUS mobilization to enable high
386 resolution rates for voiding dysfunction and reduce the risk of recurrent or persistent SUI.^{38,39}
387 Revisions in this study occurred mostly in the first two months after the index surgery. Efforts
388 should be made to optimize the tape placement during the TVT procedure. Proper adjustment
389 of the amount of tension applied to the sling can significantly reduce the BOO risk.⁴⁰
390 Our study showed an unanticipated higher risk of revision for mesh exposure after retropubic
391 sling procedures. Multiple RCTs have shown no difference in mesh exposure rates between
392 these two approaches.^{35,37,41-45} Most of these studies included in their outcome assessment a
393 systematic physical examination enabling the diagnosis of asymptomatic exposure, whereas our
394 register considers only severe symptomatic mesh exposure requiring revision. We can
395 hypothesize that the exposure site and symptoms differ according to the route used. Indeed, a
396 multicenter, randomized equivalence trial comparing outcomes with retropubic and
397 transobturator slings reported a higher mesh exposure rate in the retropubic group when erosion
398 was defined by mesh visualized in the vagina through a prior incision.³⁵
399 The Québec *Collège des Médecins* recently called attention to severe pain complications after
400 transobturator sling placement.¹² Its expert opinions relied on clinical cases of 400 women
401 undergoing MUS procedures and describing sling-related side effect. The Collège
402 recommended a moratorium on transobturator slings due to the high risk of debilitating chronic
403 pain. Results from our study (based on a comparative quantitative study design) provide some
404 reassurance: pain symptoms were the indication for only 21% of the revisions. The medium-
405 term incidence rate of revision for pain was reassuringly low and similar for both approaches.
406 Some randomized controlled trials have shown higher rates of groin pain after the transobturator
407 route,^{35,46} but most resolved within 6 months.¹⁹ Moreover, randomized controlled trials with

408 follow-ups longer than 5 years have not reported this result.^{37,41–45} When patients report lower
409 limb or groin pain immediately after surgery, injury to the obturator or pudendal nerve is often
410 suspected, and mesh removal most often cures the pain. When isolated pain occurs later on after
411 MUS insertion, the first-line treatment is often medical treatment.⁴⁷ Mesh removal is then
412 considered if these first-line treatments fail.⁸ Our study did not include patients with pain that
413 required only medical treatment. Moreover, we suppose that mesh removal for pain is more
414 likely to be observed over a longer follow-up period. Further studies based on the national
415 health data system might enable a comprehensive inventory of pain as an adverse event.

416 Previous RCTs have not shown any clear-cut difference in efficacy between the two
417 approaches,^{15,19,34–36} as we did. Most excluded patients with histories of SUI surgery.^{37,43,46,48}
418 Because these patients were more frequent in the retropubic group, the difference between the
419 approaches only appeared after correcting the imbalance for previous surgery. Differences in
420 intrinsic sphincter deficiency between the groups may explain these results. One trial designed
421 for patients with intrinsic sphincter deficiency showed an advantage for the retropubic approach
422 in short- and medium-term cure rates.⁴⁹ It was confirmed by a meta-analysis of studies reporting
423 subgroup analyses among patients with sphincter deficiency.⁵⁰

424 Strengths and limitations:

425 The strengths of our study are its large, prospective, multicenter register operating in real-life
426 conditions, which enables an assessment of the benefit rate ratio of the MUS procedure that,
427 unlike a randomized trial, includes uncommon events. Furthermore, a high proportion of our
428 population would have been excluded from a randomized trial, because of their complex clinical
429 situations, i.e., recurrence after previous SUI surgery or concomitant surgical procedures.
430 Furthermore, in contrast to database studies that are based on routinely collected data,^{30–33}
431 prospective data collection was performed using specific case report forms that allow for

432 precise and structured information and therefore enable specific events of interest to be
433 monitored.^{12,13}

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

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

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

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

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Conclusions:

Analysis of the mid-term results of our register show a lower risk of complications with surgical repair of SUI by the transobturator compared to the retropubic route. The difference is mainly related to voiding dysfunction but also to the risk of erosion. The risk of revision for pain was low and did not differ between the groups. On the other hand, the transobturator approach was associated with a higher rate of recurrence than the retropubic approach.

Despite the large number of surgeons participating in the register, the rate of serious complications and the risk of 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 of complications with the transobturator approach must be balanced against the lower risk of 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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747 **Table 1.** Patients' baseline characteristics at the index surgery to place a midurethral sling for
 748 stress urinary incontinence and intraoperative characteristics (n = 2682).
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	Retropubic (n=1830)	Transobturator (n=852)	P Value
Age, mean (SD), years	56.9 (13.0)	58.8 (12.6)	<.001
BMI, mean (SD) [N], kg/m²	26.2 (5.0) [1810]	26.8 (5.2) [837]	.010
Menopausal, No./N (%)	1013/1763 (55)	526/834 (62)	.006
Smoking, No./N (%)	211/1792 (12)	106/828 (12)	.47
Diabetes, No./N (%)	101/1768 (6)	54/819 (6)	.38
Physical status (ASA), No./N (%)			
1	730/1716 (40)	314/819 (37)	
2	843/1716 (46)	420/819 (49)	.24
3	140/1716 (8)	69/819 (8)	
4	3/1716 (0,2)	0/819 (0)	
Surgical history			
Previous ysterectomy (Subtotal, total), No./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
Concomitant hysterectomy, No. (%)			
Subtotal hysterectomy	28 (2)	43 (5)	
Total hysterectomy	25 (1)	50 (6)	<.001
No	1777 (97)	759 (89)	
Concomitant POP surgery, No. (%)	234 (13)	244 (29)	<.001
Operative length, median [IQR], min	30 [20]	27 [57]	<.001
Blood loss, median [IQR], mL	10 [50]	20 [40]	<.001
Blood transfusion, No.	1	2	.19

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751 Abbreviations: ASA, physical status score; BMI, body mass index; SUI, stress urinary
 752 Incontinence; POP, pelvic organ prolapse.

753 In case of missing value, No/N or [N] indicate the number with available data

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756 **Table 2.** Description of serious complications (Clavien–Dindo grade III or higher) by time to
 757 revision after MUS surgery. Each patient could have one or more indications for revision.
 758

	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)
<i>Bleeding</i>	5	0
Intraoperative bleeding	3	0
Postoperative hematomas	2	0
<i>Intraoperative wound^b</i>	8	3
Vaginal wounds	0	2
Urethral wounds	3	1
Vascular wounds	1	0
Vesical wounds	4	0
<i>Bladder outlet obstruction</i>	13	1
<i>Pain</i>	4	1
Isolated pain	1	1
Between 2 days and 2 months postoperative	39 (38)	9 (36)
<i>Bladder outlet obstruction</i>	34	8
<i>Vaginal exposures</i>	3	0
<i>Infections</i>	5	1
Abscesses	2	1
Variotensor infections	1	0
Urinary tract infections	2	1
<i>Bleeding</i>	0	3
Postoperative hematomas	0	2
External bleeding	0	1
<i>Pain</i>	4	2
Isolated pain	0	0
<i>Vaginal discharge</i>	1	0
Between 2 and 12 months postoperative	31 (30)	6 (24)
<i>Bladder outlet obstruction</i>	8	1
<i>Mesh exposure</i>	23	4
Vaginal exposure	20	4
Urethral exposure	2	0
Unknown exposure	1	
<i>Urinary tract infections</i>	4	1
<i>Pain</i>	9	3
Isolated pain	3	0
<i>Vaginal discharge</i>	1	0
<i>Overactive bladder</i>	4	1
After 12 months postoperative	8 (8)	5 (20)
<i>Bladder outlet obstruction</i>	4	2

<i>Mesh exposure</i>	2	1
Vaginal exposure	2	1
Urethral exposure	0	0
<i>Urinary tract infections</i>	3	0
<i>Pain</i>	2	3
Isolated pain	1	2
<i>Overactive bladder</i>	1	1

759

760 ^a Standardized grading system of surgical complications with four grades of increasing
761 severity: Grade III is defined as surgical complications requiring surgical, endoscopic, or
762 radiological intervention (classified into grade IIIa and IIIb when performed respectively
763 without and with general anesthesia). Grade IV is defined as a life-threatening complication.

764 ^b During surgery, intraoperative injuries (mostly bladder and vaginal wounds) occurred to 121
765 women in the retropubic group and 27 in the transobturator group but only those resulting in
766 abandoning or changing the procedure were considered serious complications.

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768

769 **Table 3.** Risk of serious complication and reoperation for recurrence after MUS surgery
 770 according to the approach used. Hazard ratio estimated with Cox proportional hazard model
 771 including a frailty term with center as a random effect (N= 2682)
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Outcome		No. with the event	Crude HR (95% CI)	Weighted ^a and adjusted ^b HR (95% CI)
	<i>Overall population (N = 2682)</i>			
Serious complication (any)	Retropubic route	103	1	1
	Transobturator route	25	0.50 (0.32 to 0.77)	0.41 (0.29 to 0.56)
Bladder outlet obstruction	Retropubic route	58	1	1
	Transobturator route	13	0.46 (0.25 to 0.85)	0.35 (0.22 to 0.53)
Erosion	Retropubic route	27	1	1
	Transobturator route	5	0.37 (0.14 to 0.97)	0.28 (0.15 to 0.52)
Pain	Retropubic route	20	1	1
	Transobturator route	7	0.72 (0.30 to 1.70)	0.58 (0.31 to 1.1)
Recurrence	Retropubic route	41	1	1
	Transobturator route	22	1.0 (0.59 to 1.8)	1.9 (1.2 to 2.9)
	<i>History of SUI surgery excluded (N = 2414)</i>			
Serious complication (any)	Retropubic route	93	1	1
	Transobturator route	25	0.49 (0.31 to 0.76)	0.4 (0.3 to 0.6)
Recurrence	Retropubic route	35	1	1
	Transobturator route	20	1.0 (0.59 to 1.8)	1.2 (0.7 to 1.9)

774

775 Abbreviations: HR, hazard ratio; CI, confidence interval; SUI, stress urinary incontinence

776 a. Weights based on the propensity score; these included age, body mass index, smoking,

777 diabetes, surgical history (previous hysterectomy, or previous surgery for stress urinary

778 incontinence or previous pelvic organ prolapse), physical status score (ASA), menopausal

779 status.

780 b. Concomitant hysterectomy or prolapse surgery, if any.

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783

784 **Figure legends:**

785 Figure 1. Study flowcharts

786 Figure 2: Baseline differences and weighted differences between the two surgical
787 groups.

788 Figure 3: Kaplan-Meier curves for serious complications and SUI recurrence

789 Figure 3a: Cumulated incidence of serious complication (Clavien-Dindo grade III
790 or more)

791 Figure 3b: Cumulated incidence of reoperation for SUI recurrence

792 Abbreviations: Propensity score, Previous SUI surgery, Age, Menopause Body
793 Mass Index, physical status score (ASA), Previous POP surgery, Diabetes,
794 Smoker, Previous hysterectomy

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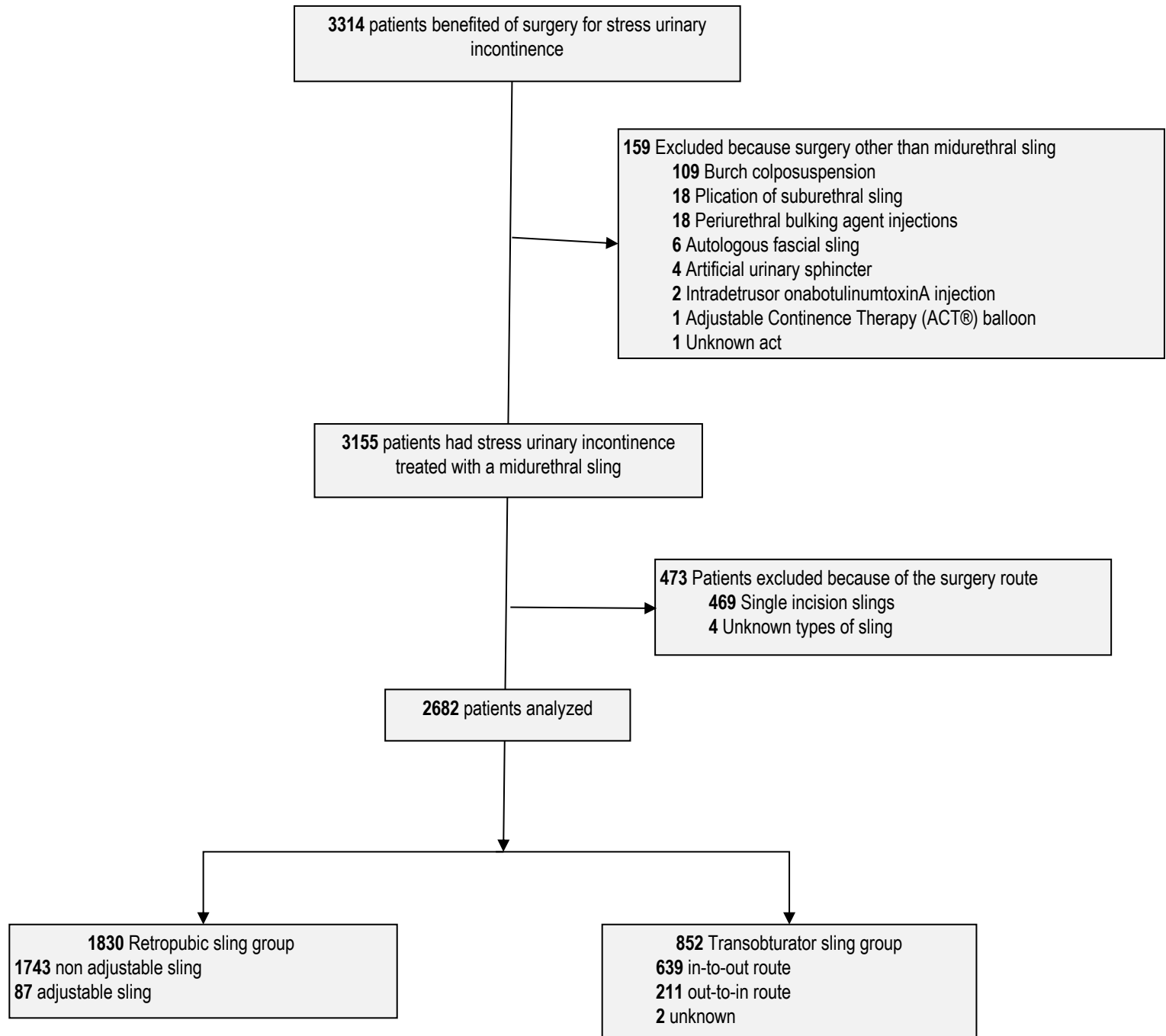
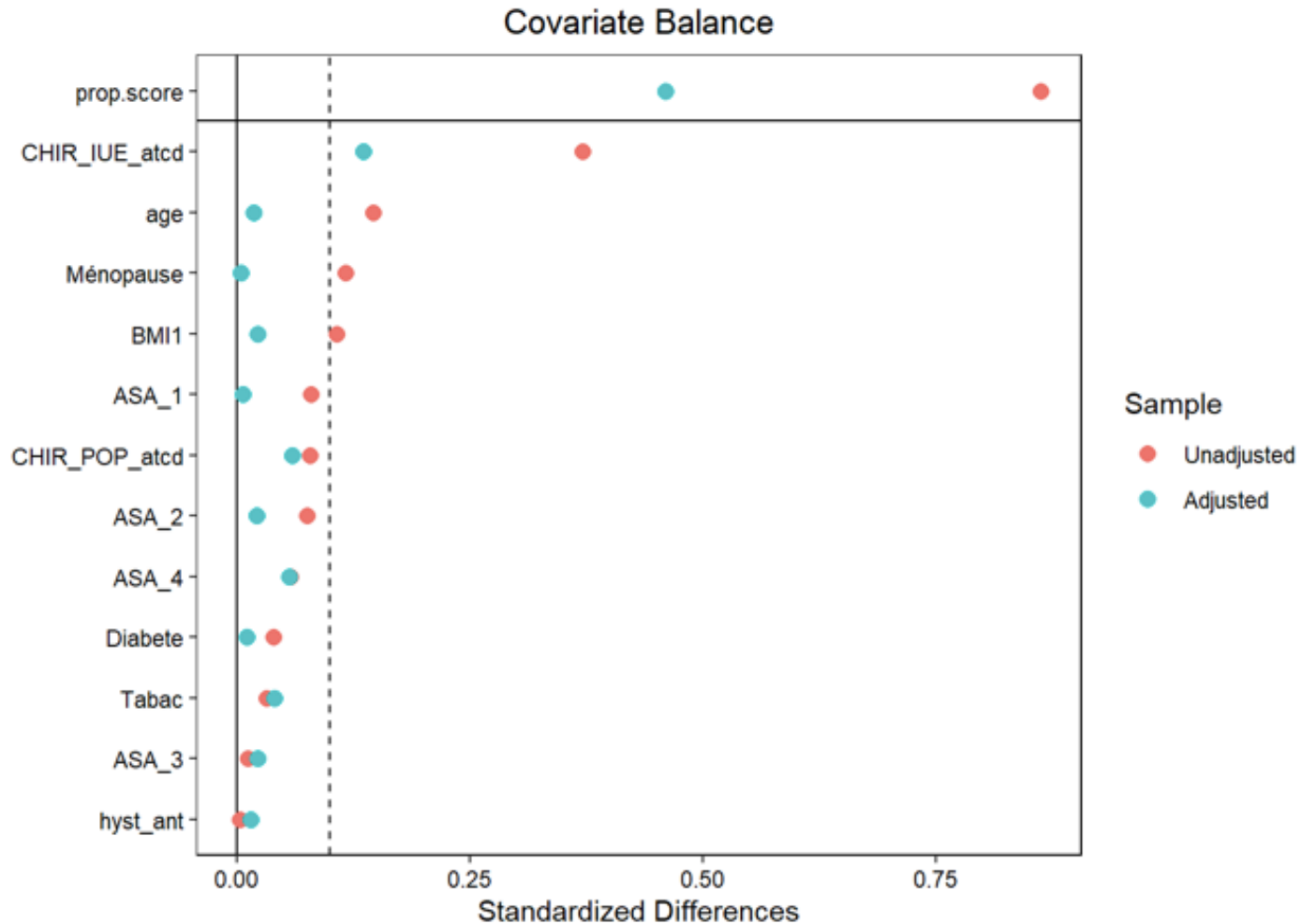


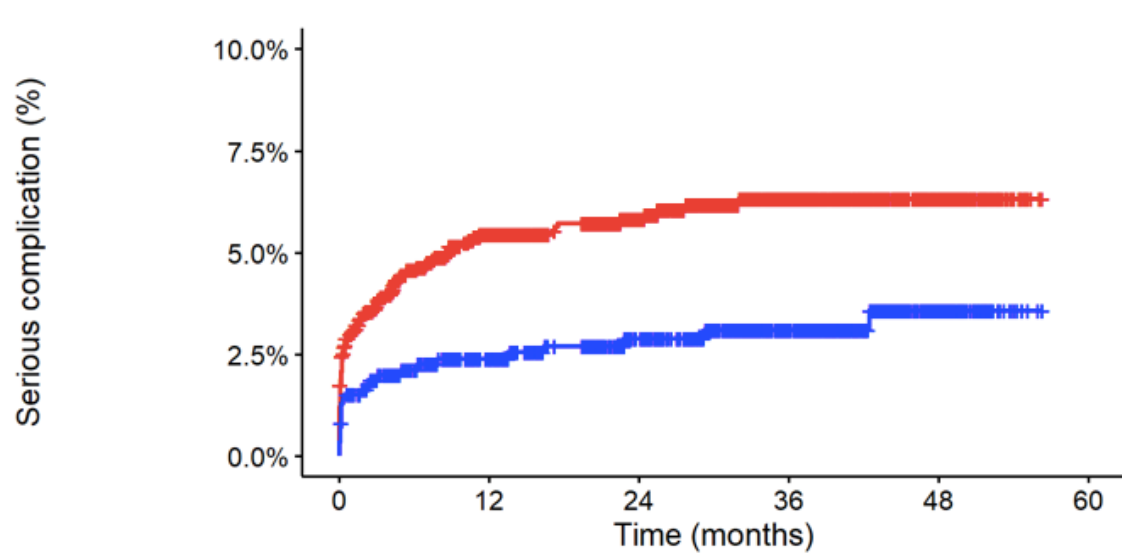
Figure 1. Study flowcharts

Figure 2: Baseline differences and weighted differences between the two surgical groups



Abbreviations: Propensity score, Previous SUI surgery, Age, Menopause Body Mass Index, physical status score (ASA), Previous POP surgery, Diabetes, Smoker, Previous hysterectomy

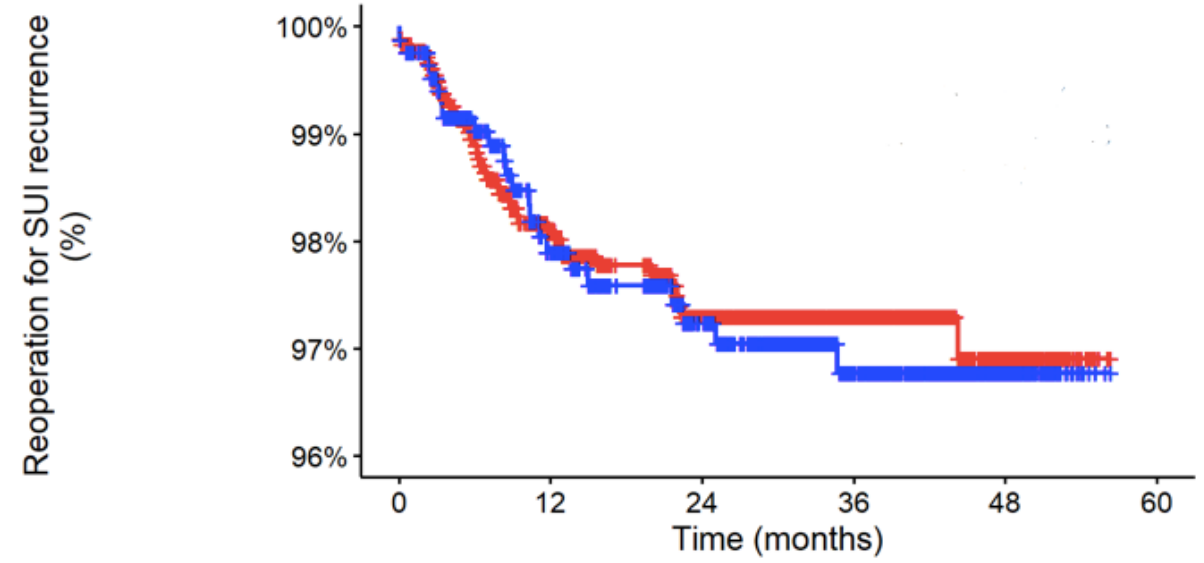
Figure 3: Kaplan-Meier curves for serious complications and SUI recurrence



Number at risk

Retropubic sling	1830	1263	865	485	131	0
Transobturator sling	852	659	529	324	82	0

—+ Retropubic sling —+ Transobturator sling



Number at risk

Retropubic sling	1830	1317	901	511	139	0
Transobturator sling	852	663	531	325	84	0

—+ Retropubic sling —+ Transobturator sling

Figure 3a: Cumulated incidence of serious complication (Clavien-Dindo grade III or more)

Figure 3b: Cumulated incidence of reoperation for SUI recurrence