

## INCIDENCE AND RISK FACTORS FOR REOPERATION AFTER SURGICALLY MANAGED URINARY INCONTINENCE: A NESTED CASE CONTROL STUDY.

### Hypothesis / aims of study

The incidence and the risk factors of reoperation for recurrent urinary incontinence are poorly described. Data arise from few studies with limited follow-up. We found one study describing a reoperation rate for urinary incontinence of 8.6% at 8 years [1]. Few risk factors were identified. The objective of this study was to estimate the incidence and identify the risk factors of reoperation for urinary incontinence after surgically managed urinary incontinence.

### Study design, materials and methods

We conducted a case-control study among a cohort of 1132 women who underwent consecutive stress urinary incontinence (SUI) surgery from January 1988 to June 2007 in our gynecology clinic. Cases (n=35) were women who required reoperation for recurrence of SUI following the first intervention through December 2008. Controls (n=89) were women, randomly selected from the same cohort, who did not require recurrent SUI surgery during the same period. Each woman had a standardized preoperative assessment including urodynamics in most cases. We performed a univariable and a multivariable analysis among 35 cases and 89 controls to identify the variables associated with SUI reoperation after index surgery. We calculated that a sample size of 102 women with 34 cases and 68 controls had a power of 80% with a two-tailed alpha of 0.05 to show odds ratio of 4 in a plausible range of probability of exposure to a risk factor of 50 % among controls. To increase power, we increased the number of controls.

### Results

The cumulative incidence of SUI reoperation was 3.1% in our cohort. The mean interval between operations was 4.1 years (range 0.2 to 17.4) in the case group and the mean follow up was 10.9 years (range 1.7 to 21.0) in controls. The mean age and the mean body mass index were similar between groups. In univariable analysis, multiparity, menopause, diabetes, constipation, sexual activity, pulmonary disease, and associated pelvic organ prolapse (POP) were not associated with a higher risk of reoperation. History of two or more vaginal deliveries was associated with a significant increased risk of reoperation (odds ratio (OR) 3.55; 95% confidence interval (CI) 1.15-11.05; P=0.02). History of POP repair (OR 5.33; 95% CI 0.47-60.80; P=0.19), the presence of intrinsic sphincter deficiency (urethral closure pressure  $\leq$  20 cm H<sub>2</sub>O or Valsalva leak point pressure  $\leq$  60 cm H<sub>2</sub>O) at urodynamics, (OR 7.07; 95% CI 0.71-70.60; P=0.09), and associated hysterectomy (OR 1.76; 95% CI 0.79-3.89; P=0.23) were all associated with an increased risk of reoperation, but statistically non significant. Statistically significant risk factors included Burch colposuspension (OR 6.06; 95% CI 2.47-14.90; P<0.001), the use of fascial slings (OR 7.17; 95% CI 1.73-29.59; P=0.005) and periurethral bulking agent (P=0.006). The use of synthetic slings (transobturator or retropubic) was a protective factor (OR 0.10, 95% CI 0.02-0.44; P<0.001). In multivariable analysis, when all statistically significant variables were taken into account, synthetic slings remained a protective factor (OR 0.05; 95%CI 0.01-0.25; P<0.001) compared to Burch colposuspension. History of two or more vaginal deliveries still increased the risk of reoperation for SUI (OR 4.63; 95% CI 0.71-30.29; P=0.11) although not statistically significant.

### Interpretation of results

The incidence of reoperation for SUI after previous SUI surgery is low in our setting. The incidence could be underestimated, if women who had undergone SUI surgery in our institution had been treated for recurrence elsewhere. However, that number is probably low, because our clinic is the only public institution in our area, and women followed in public hospitals rarely go to private clinics due to their lack of private health insurance coverage. Moreover our health insurance system only exceptionally accept that a patient be referred to another area or country to be operated. We chose to evaluate surgically treated recurrent SUI, as it represents the severe end of the clinical spectrum. The incidence of SUI recurrence is probably higher, but most women find it tolerable and do not seek surgery. Our study suggests that SUI reoperation is associated with the history of two or more vaginal deliveries. We hypothesize that each vaginal delivery increases the risk of denervation and consecutively the lack of pelvic support, as well as intrinsic sphincter deficiency. This could explain the failure of the surgical procedures which do not restore solid and long-lasting suburethral support. To limit the risk of reoperation, it might be important to use synthetic suburethral slings rather than fascial slings or Burch colposuspension, especially in case of multiple vaginal deliveries or intrinsic sphincter deficiency.

### Concluding message

The risk of reoperation after SUI is low. Risk factors and protective factors described in this study might help choosing the optimal surgical technique.

### References

1. Michael Fialkow et al. Reoperation for urinary incontinence. Am J Obstet Gynecol 2008;199:546.e1-546.e8

<b>Specify source of funding or grant</b>	<b>NONE</b>
<b>Is this a clinical trial?</b>	<b>Yes</b>
<b>Is this study registered in a public clinical trials registry?</b>	<b>No</b>
<b>Is this a Randomised Controlled Trial (RCT)?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>Institutional Ethics Committee of the Geneva University</b>

---

	Hospitals
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No

---