

## REOPERATION FOR URINARY INCONTINENCE: AN ENTIRE NATIONAL COHORT STUDY, 1998-2007

### Hypothesis / aims of study

The synthetic midurethral slings were introduced in the 1990'ies and rapidly became the gold standard due to the minimal invasive approach. It has been reported that TVT has an objective and subjective cure rate of 85 % at five years of follow up but only a few studies have used reoperation after TVT as an outcome at the long term follow up [1]. Existing literature specifies an overall life time rate of reoperation of 8-9% after an initial surgery for urinary incontinence (UI) [2]. There are, however, conflicting statements about the risk of reoperation after specific types of UI. The primary objective of this study was to describe the five year incidence of reoperation for UI based on an entire national population and secondarily to evaluate potential risk factors for reoperation.

### Study design, materials and methods

We used the Danish National Patient Registry (NPR), which provides information on diagnoses, minor procedures and operations in Danish hospitals. It has a high validity for procedure codes and it is mandatory for all Danish hospital departments and private hospitals to report to the NPR. The registry was used in this study to identify women who had first-time (UI) surgery from 1998 through 2007. The outcome was a reoperation within five years. Kaplan Meier survival curves were used to estimate the cumulative incidence of reoperation for six types of UI surgery (TVT, TOT, bulking agents, Burch colposuspension, pubovaginal slings and miscellaneous operations). Cox proportional hazard models were used to estimate the adjusted hazard ratio (HR) with 95% confidence intervals (CIs) for factors associated with reoperation.

### Results

A total of 8671 women (mean age 56.1y, SD 12.6) underwent surgical treatment for UI. Of these operations 5820 (67%) were synthetic midurethral slings at baseline. The cumulative incidence of reoperation after any surgery for UI was 10.2 %. Among women having the TVT procedure at baseline the incidence of reoperation was 6% and remained stable during the study period (1998-2007). The lowest cumulative incidence of reoperation observed was for Burch colposuspension and for pubovaginal slings. In a Cox proportional hazard model that adjusted for age, department volume, and calendar effect, TOT had a higher risk of reoperation compared to TVT (HR 2.1, CI 1.5-2.9) and bulking had a 12 fold-higher risk (11.5, CI 8.3-12.6).

### Interpretation of results

In this nationwide cohort study we found a cumulative incidence reoperation after all types of surgery for UI of 10.2% within a five year period. For TVT, the incidence of 6% remained stable during the study period (1998-2007) and was thus unlikely to be related to the initial learning curve. At present no studies based on an entire nation have reported reoperation after TVT as an outcome. A 6% rate of reoperation, however, seems acceptable as a single center study showed a similar rate (6%) and similarly a population-based study had a rate of reoperation after all sling surgery of 5% at five years of follow-up [1,2].

Bulking had as expected, the highest rate of reoperation.

In our study comprising 5820 women, the HR for reoperation after TOT compared to TVT (HR, 2.1, 95% CI, 1.5-2.9) was comparable to the result of a Cochrane-study (1.52, 95% CI 0.90 to 2.59) [3]. In contrast to our study the Cochrane- study only included 746 women and the follow-up period did not extend beyond 12 months.

### Concluding message

This cohort study based on an entire nation provides physicians with a representative evaluation on the rate of reoperations after different types of surgery for UI. Pubovaginal slings, Burch colposuspension and TVT had an almost similar risk of reoperation (6%). Our observation that women operated with TOT had significantly higher risk of reoperation compared to TVT, is novel in the literature. Future studies need to report not only efficiency and safety for a product but also long term outcomes, including the rate of reoperations.

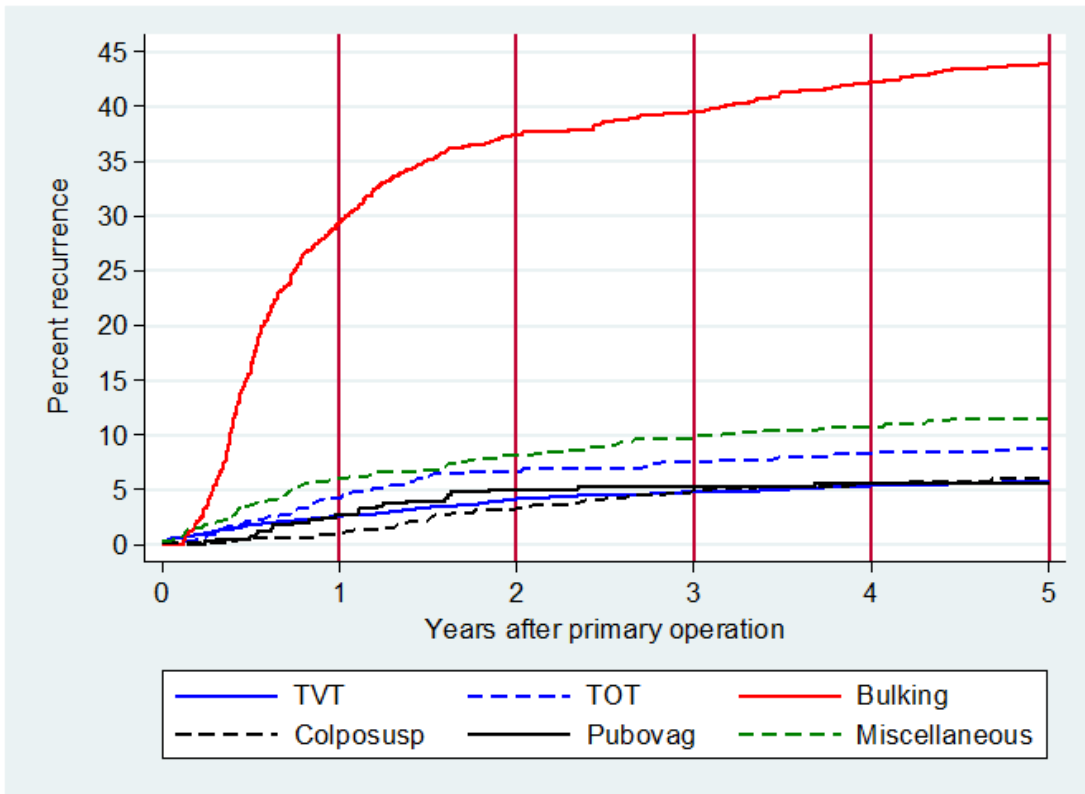


Fig 1: Cumulative incidence of reoperation after six types of surgery for urinary incontinence.

References

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Disclosures

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