

ICS 2019 Complications one year after Mid Urethral Slings in Sweden

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Abstract

Hypothesis/aims of study

The use of mid-urethral slings (MUS), has been the subject of almost 2000 published articles and has come to dominate the treatment of female Stress Urinary Incontinence for almost 20 years (1). Long-term effects are good, and complications have been considered rare. Because of this, individual surgeons have seen only a handful of women with complications and may thus underestimate the impact of possible adverse outcomes. However, as more women are treated, rare but serious side effects accumulate (2). Affected women all over the world have come together in support groups with the aid of social media. The UK Department of Health and Social Care put a pause in the use of MUS in the summer of 2018. A set of terms for surgeons were determined and needed to be fulfilled by clinics to allow for further MUS use.

One of the terms set up by the UK Government was that Stress Urinary Incontinence (SUI) surgery should be monitored in a register. In Sweden this has been done since 2007. From that dataset, we have access to women's own words to gain more information about what they are experiencing. In a first study it is highlighted what the women write when they give their doctor their opinion about the surgery. In this follow-up the women's answers are categorized as minor or severe complications according to the GynOp criteria. The aim of the study is to give a quantitative description of long-term complications at the one-year follow-up for mid urethral slings in Sweden.

Study design, materials and methods

The Swedish National Registry for Gynecologic Surgery (GynOp) is a nationwide register with patient reported function and outcome measures before, 8 weeks and 1 year after surgery as well as perioperative data. The surgeon performing the surgery receives and takes the appropriate action regarding the women's questionnaire answers at these three points of time. The follow-up answers are classified as no, mild, or serious complication using pre-set criteria established in national consensus group.

All women having undergone incontinence operations registered in GynOp with one of the three MUS methods TVT, TVT-O or TOT during the year 2017 comprised the original dataset. With combined operations excluded, 4160 operations were registered. The women's answers were categorized according to GynOp criteria for complications. Most clinics use register excerpts as their documentation, so medical records have not been checked for validity. Over 80% of the women reply to the questionnaires, that are either postal or web-based according to their preference. 3% were regarded not able to answer the questionnaires and 17% were missing.



The patient reported complications are categorized in the questionnaire as urinating problems, persisting pain, infection, organ damage or other and analyzed quantitatively. The women's subjective, unedited description has been categorized separately. Uncertain cases are discussed by the authors.

Results

In the one-year questionnaire, 681/4160 women (16%) responded that they either considered themselves exposed to a complication, that they were worse off in their incontinence than before or/and that they were unhappy with the result. The open-ended questions in the questionnaires were used by 578/681 (84%) of these patients to describe their problems further.

The 578 (14%) women who described complications at one-year follow up after MUS operations is greater than expected (3). 61,8% of the women were operated with TVT technique, 20,4% with the TOT and 17,8% with TVT-O which corresponds to the distribution as in the whole group of operated patients.

Of the women describing their complication in free text, 83% rate their complication as minor and 17% as major. However, only in 14% of the women reporting serious complications, the surgeon had rated the described problem as a serious complication. In 60% of cases the surgeon rates that no complication occurred at all and in 12,7% of cases the surgeon has failed to classify the patient reported data at all. Following the GynOp criteria for complications 12% of the cases are physician-rated as serious complication and 3 % of cases as both serious and minor. Thus, there is a large gap between the women's judgement and the operating surgeons. In contrast, our opinion and the women's concur in most cases. The discrepancy might mainly lie in that the GynOp criteria classify persisting negative influence on quality of life as a major complication.

Two women described life threatening conditions leading to laparotomy – one intraabdominal bleeding and one case with free gas in the abdomen. One woman had a six-day hospital stay at a stroke unit because of a TIA and one woman received a six-day antibiotic treatment due to infection.

63% of the women describe persisting problems at one year follow up. The most common main problems (each woman will end in one of these groups only) are urinating problems, pain, infection and rupture of the suture/erosion of the tape in the vagina. Classic surgical complications like organ damage and bleeding are very rare.

Voiding problems were reported by 42% of the women with complications. Among these, de novo urge (30%), voiding difficulty (27%), increased urinary leakage (23%) and urinary retention (18%) are the most common problems. 3% of patients with complications have serious pain at intercourse, 7% suffer from persisting groin pain whereas abdominal pain and voiding pain are very rare. Reduced clitoral sensation was reported by some patients and one woman even experienced a six months period of repeated spontaneous orgasms while sleeping.



Among the women who describe complications after MUS 20% are dissatisfied or very dissatisfied with the result of the operation. Even with complications, many patients value the result of the operation - not leaking urine - higher than the new problems. 77% consider themselves better off than before and 14% feel worse.

Interpretation of results

Though effective for most women, incontinence surgery can lead to a wide range of different complications. Although most complications are minor and have disappeared at the one-year follow-up, there are women experiencing serious persistent negative effects on their quality of life. The finding that some surgeons do not read or even disregard women's opinion about complications severely afflicting their quality of life is troublesome. The reasons for this remain to be studied.

Concluding message

Mid-urethral sling complications at one-year follow-up are more common than generally anticipated. Most complications are minor, but some have a severe impact on the women's quality of life. Before deciding to go through incontinence surgery, women need to have access to complete information about possible results as well as complications, both common and rare.

The Swedish National Register for Gynecologic Surgery (GynOp) is unique in giving the affected women a chance to be heard. Surgeons should not miss the opportunity to learn from their answers.

References

1. Fusco F, Abdel-Fattah M, Chapple CR, Creta M, La Falce S, Waltregny D, et al. Updated Systematic Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. *Eur Urol.* 2017;72(4):567-91.
2. Gurol-Urganci I, Geary RS, Mamza JB, Duckett J, El-Hamamsy D, Dolan L, et al. Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women With Stress Urinary Incontinence. *JAMA.* 2018;320(16):1659-69.
3. Kim Keltie, Sohier Elneil, Ashwani Monga, Hanah Patrick, John Powell, Bruce Campbell & Andrew J. Sims. Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92246 women. *Scientific Reports* 7, Article number 12015 (2017)