Risk Factors for 5-Year Complications after Midurethral Sling Surgery for Stress Urinary Incontinence: A Retrospective Cohort Study from Taiwan

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Abstract

Background: Midurethral sling surgery is the current gold standard worldwide for stress urinary incontinence (SUI) surgery. However, concerns surround mesh-related adverse events associated with the midurethral sling. The decision to use the midurethral sling for surgical treatment has become a challenging one for clinicians, surgeons and patients. Objectives: We sought to determine the factors for 5-year complications after midurethral sling surgery, to improve the clinical decision-making process. Study Design: Records were reviewed from a total of 1,961 female patients who underwent their first midurethral sling surgery for SUI between 2003 and 2018 at a single teaching hospital in Taiwan. A multivariable Cox proportional hazard model calculated the hazard ratios of risk factors for surgical complications, after adjusting for confounders. Results: Surgical complications (i.e., secondary surgery and urinary retention) occurred in 93 (4.7%) patients within 5 years following the index operations. These patients were more likely to be older, to have a history of menopausal syndrome within 1 year prior to the index operation,hormone replacement therapy (HRT), slower average flow rate, and longer voiding time compared with patients without surgical complications. In the multivariate analysis, menopausal syndrome or HRT (adjusted hazard ratio, 1.794; 95% confidence interval, 1.055–3.050, p=0.0390) was significantly associated with surgical complications at 5 years, after adjusting for age, gender, diabetes, average flow rate, and sling type. Conclusion: Our findings suggest that a history of menopausal syndrome within 1 year prior to surgery or a medication history of HRT may be risk factors associated with surgical complications

Introduction

Stress urinary incontinence (SUI), the involuntary loss of urine on effort or physical exertion (e.g., sporting activities) on sneezing or coughing is a critical public health issue.[1] According to the European Menopause and Andropause Society (EMAS) clinical guide, the prevalence of urinary incontinence and of other lower urinary tract symptoms increases after menopause and affects between 38% and 55% of women aged over 60 years.[2] A global review of epidemiological research on SUI that included studies published between January 1980 and October 2002 reported a median prevalence of female UI of 27.6%, most commonly caused by stress (50%).[3] Age plays an important part in SUI diagnosis, as the prevalence increases with age, with one large study in the United States reporting SUI in 28% of women aged between 30 and 39 years and 55% of women aged between 80 and 90 years.[4, 5] SUI impacts enormously on the patient's lifestyle and quality of life, at considerable financial cost for both patients and the health care system.[6-10]

International guidance recommends conservative therapies as the first-line management of women with SUI, such as lifestyle changes and behavioral therapies, weight loss, and supervised pelvic floor muscle training.[11, 12] For patients who do not experience improvement in physical symptoms and quality of life with

nonsurgical management or pharmacotherapy, surgery is the next step.[11, 12] The current gold standard for SUI surgery is the midurethral sling, with over 90% of surgeons worldwide using the midurethral sling for SUI between 2008 and 2018.[13, 14] The midurethral retropubic sling in particular has proven highly effective for the treatment of SUI, with high subjective and objective cure rates of between 80% and 90% after more than 11 years of follow-up.[15] The midurethral sling has replaced Burch culposuspension for the surgical correction of SUI,[16] because of the important advantages of being minimally invasive, shorter operative and recovery times, high continence rates and low complication rates.[17-19] Use of the midurethral sling in the surgical management of female SUI is supported by a joint position statement released by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU),[20] as well as a position statement by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG),[21] and the midurethral sling has become the surgical procedure of choice for female SUI in Australasia, Europe and the USA.[21]

Nonetheless, mesh-related adverse events are associated with the midurethral sling.[22, 23] In response to surgical complications involving the use of transvaginal mesh for pelvic organ prolapse, the United States Food and Drug Administration (US FDA) issued a safety communication in 2011[24] and, since April 16, 2019, has banned the production and sale of transvaginal mesh for pelvic organ prolapse.[25] By early 2015, over 70,000 women in the US had filed lawsuits alleging complications associated with transvaginal mesh used for both SUI and pelvic organ prolapse surgical procedures.[26] Litigation suits relating to financial costs and safety concerns surrounding these procedures have increased general awareness amongst the public and medical community of all synthetic mesh use in pelvic floor disorders, including SUI.[26] However, it is important to note that the US FDA publications did not refer to traditional midurethral slings as the subject of their safety communication; their 2019 advice stated that full-length midurethral slings are supported by 1-year follow-up safety and efficacy data from clinical trials and that longer-term follow-up data are also available, but are from a smaller pool of evidence.[11] Nevertheless, the decision to use the midurethral sling for surgical treatment has become a challenging one for clinicians, surgeons and patients. With this in mind, we sought to determine the risk factors for 5-year complications after midurethral sling surgery, to improve the clinical decision-making process.

Materials and Methods

Study population

The China Medical University Hospital–Clinical Research Data Repository (CMUH–CRDR) was established by the Big Data Center of CMUH, which contains the medical records of 2,873,887 patients who sought care in CMUH between 2003 and 2018. The CMUH–CRDR has been described in greater detail in previous articles.[27-29] All patients enrolled in the CMUH–CRDR were followed up until December 31, 2018, or death, whichever occurred earlier. This study was approved with waived informed consent by the Big Data Center of CMUH and the Research Ethical Committee/Institutional Review Board of CMUH (CMUH105-REC3-068).

In this retrospective cohort study, we identified 2,789 patients from the CMUH–CRDR records who underwent 2,834 midurethral sling surgery procedures between 2003 and 2018. Next, we excluded operations without SUI diagnosis records during the index visit or within six months prior to the procedure date, patients whose surgical visits were not in the Department of Obstetrics and Gynecology, and patients who did not have any surgical records or who did not have sling type records on their surgical notes during the index visit (**Figure 1** ;**Supplementary Table 1**). The final study population consisted of 1,961 female patients with a SUI diagnosis who underwent their first midurethral sling surgery (index procedure) between 2003 and 2018 in the Department of Obstetrics and Gynecology of CMUH.

Definition of Risk Factors

Demographic information, comorbidities, medication histories, biochemical profiles, reports of urodynamic testing and surgical procedures were collected from the CMUH–CRDR. Comorbidities of diabetes mellitus, hypertension, cardiovascular diseases, psychosis, menopausal syndrome and constipation were defined by the International Classification of Diseases, 9th/10thRevisions, Clinical Modification (ICD-9-CM and ICD-10-

2

CM) codes, and medication histories for hypertension, diabetes, and hormone replacement therapy (HRT) were recorded within 1 year before the index midurethral sling surgery (**Supplementary Table 1**). Biochemical profiles of blood glucose, liver function, renal function, and complete blood count were obtained within 1 year prior to the index procedures. Reports of urodynamic testing, such as uroflowmetry information and urethra pressure profiles, were obtained within 3 years prior to the index procedures. Surgical information extracted from the operation database included length of operation, American Society of Anesthesiology (ASA) score, wound contamination classification, anesthesia type, and sling type.

Definition of Outcomes

The primary outcome of interest was surgical complications (including secondary surgery and urinary retention) within 5 years following the index procedures. Secondary surgery was defined as the patient undergoing the same operation within 5 years; urinary retention was defined by ICD-9-CM and ICD-10-CM codes (**Supplementary Table 1**).

Statistical Analysis

Continuous variables are presented as medians and interquartile ranges (IQRs); categorical variables are reported as frequencies and proportions (%). The associations between surgical complications and covariates were analyzed using the Wilcoxon rank-sum test (nonparametric) for continuous variables and the chi-square test for categorical variables.

We evaluated the associations of the risk factors with the risk of 5-year surgical complications by using separate multivariable Cox proportional hazards modeling. We adjusted for age, diabetes mellitus, duration of surgery, menopausal syndrome, HRT, average flow rate (AFR), voiding time and sling type. Subgroup analyses were performed for patients categorized by age groups and diabetes status.

All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). The 2-sided statistical significance level was $\alpha = 0.05$.

Results

We identified 1,961 women with SUI who underwent first-time midurethral sling surgery between 2003 and 2018 in CMUH, with a median age of 53.5 years (IQR, 46.4–64.0; **Table 1**). Surgical complications (i.e., secondary surgery and urinary retention) occurred in 93 (4.7%) patients within 5 years following the index operations.

Patients with surgical complications were more likely to be older (60.3 years vs 53.1 years), to have a history of menopausal syndrome within 1 year prior to the index operation (16.1% vs 9.6%), a medication history of oral antidiabetic drug (OAD; 8.6% vs 3.9%), HRT (32.3% vs 13.7%), slower AFR (8.0 ml/s vs 10.0 ml/s), and longer voiding time (45.4 s vs 33.0 s), compared with patients without 5-year surgical complications,.

We used multivariable Cox proportional hazard modeling to investigate the risk factors associated with 5-year surgical complications (**Table 2**). After including age, diabetes mellitus, duration of surgery, menopausal syndrome or HRT, AFR, and sling type in the full model, only menopausal syndrome or HRT (adjusted HR, 1.794; 95% CI, 1.055–3.050, p=0.0390) remained significantly associated with the risk of 5-year surgical complications.

Subgroup analyses of patients characterized by age ([?]65 years, >65 years) and diabetes status showed that menopausal syndrome or HRT remained associated with adverse outcomes in patients aged [?]65 years (aHR, 2.164; 95% CI, 1.333-4.136; p for interaction = 0.3750) and in patients without diabetes (aHR, 2.302; 95% CI, 1.303-4.066; p for interaction = 0.0534) (**Table 3**).

Discussion

The overall 5-year rate of surgical complications after midurethral sling surgery was 4.7% in our study. The univariable analyses identified several factors that potentially place patients at risk of experiencing surgical complications after midurethral sling surgery, including older age, menopausal syndrome, OAD

3

medication, HRT, slower AFR and longer voiding time. In the multivariable Cox proportional hazards analyses, menopausal syndrome or HRT was significantly associated with an almost two-fold increased risk of 5-year surgical complications (i.e., urinary retention or secondary surgery) after midurethral sling surgery. The association between menopausal syndrome or HRT remained significant in the subgroup of patients aged [?]65 years.

Surgical Complications Following Midurethral Sling Surgery

A global review of epidemiological research on SUI that included studies published between January 1980 and October 2002 reported a median prevalence of female UI of 27.6%, most commonly caused by stress (50%).[3] Population-based prevalence rates of SUI among Chinese women range from 6.7% to 44%,[30] while one Taiwanese study has reported a prevalence of 18.0% based on patients' perceptions.[31]

Midurethral sling surgery is the current gold standard worldwide for SUI surgery; however, concerns surround mesh-related adverse events associated with the midurethral sling. One retrospective cohort study that identified 188,454 eligible women who underwent an index sling surgery showed that the 9-year risk of sling revision/removal was relatively low at 3.7%, with a 9-year risk of 1.3% (95% CI, 1.2–1.4) for urinary retention and the majority occurred within 4 years after the surgery.[32] Similarly, in our study, a relatively low proportion of patients (4.7%) developed surgical complications within 5 years of undergoing midurethral surgery.

Risk Factors Associated with Surgical Complications

We identified factors that potentially place patients at risk of experiencing surgical complications after midurethral sling surgery: older age, menopausal syndrome, HRT, slower AFR and longer voiding time.

Age

In a retrospective analysis of 188,454 women aged [?]18 years who underwent an index sling between 2001 and 2010, the youngest age group (18–29 years) was most likely to undergo repeat surgery, while older-aged individuals were more likely to suffer from impaired detrusor contractility and a higher risk of urinary retention after sling surgery.[32] In contrast, in our study, the average age of patients with 5-year surgical complications was higher than those without complications (60.3 vs 53.1 years, p<0.0001) and, furthermore, 40.9% of patients with 5-year surgical complications were aged over 65 years. It is worth mentioning that the study authors of that retrospective analysis speculated that the strong effect of age upon the risk of sling revision/removal for mesh erosion may be because younger women are more sexually active and because sexual activity could be a risk factor for mesh erosion.[32] The study authors also suggested that younger women who are sexually active may be more likely to detect mesh erosion and request surgical management.[32]

Menopausal Syndrome

A 2012 review of the literature on the epidemiology of UI in women and the effects of HRT on urinary leakage found that UI was a common symptom during menopause.[33] Decreased estrogen concentrations associated with menopause have been considered to be responsible for the increasing prevalence of SUI in aging women, possibly because vaginal tissue is weaker in postmenopausal women than in premenopausal women and thus becomes a risk factor for the deterioration of continence mechanisms and consequently the efficacy of anti-incontinence surgery.[34, 35] Although menopausal syndrome is a recognized risk factor for SUI, scant study evidence describes the effects of menopausal syndrome on surgical outcomes. A retrospective study from Turkey that investigated mesh erosion after tension free vaginal tape (TVT) and transobturator tape (TOT) found that menopausal status was a statistically significant factor in patients with mesh erosion, but was no longer a significant independent risk factor after multivariate analysis.[36] In contrast, our study found that patients who had a history of menopausal syndrome within 1 year prior to the index operation were more likely to develop surgical complications. Moreover, menopausal syndrome or HRT were significantly associated with the risk of 5-year surgical complications (aHR, 1.794; p=0.0390), although the association was not significant in patients aged [?]65 years (aHR, 2.164; p for interaction=0.3750). Estrogen increases

4

angiogenesis, which is important for nourishing vaginal tissue. However, a negative correlation has been observed between angiogenic activity and mesh-induced inflammation in mice implanted with steroid-coated polyvinylidenfluoride (PVDF) meshes.[37] At menopause, decreased estrogen levels lead to a reduction in angiogenesis and therefore poor nourishment of vaginal tissue, which would increase the possibility of surgical complications.

Hormone Replacement Therapy

International guidance recommends conservative therapies as the first-line management of women with SUI, such as lifestyle changes and behavioral therapies, weight loss, and supervised pelvic floor muscle training.[11, 12] Estrogens are believed to be beneficial in the treatment of SUI; starting estrogen replacement soon after menopause may be effective in preventing or delaying the onset of SUI.[35, 38]

HRT is a common medical treatment used to supplement women with hormones that are lost during the menopausal transition. Conventional HRT includes an estrogen and progesterone component to relieve the menopausal syndrome.[39] In our study, patients with diagnosed menopausal syndrome who used HRT within a year prior to midurethral sling surgery had a significantly higher risk of surgical complications at 5 years following midurethral sling surgery for SUI compared with their counterparts who did not have these risk factors. As patients diagnosed with menopausal syndrome commonly receive HRT to relieve their symptoms, it is difficult to distinguish between the effects of HRT and aging-related menopausal syndrome upon the risk of surgical complications associated with midurethral sling surgery. Although vaginal estrogen may be effective in preventing or delaying SUI, no evidence has shown that oral estrogen has benefits in SUI patients. A retrospective study in 2018 had found that the use of systemic estrogen may increase the SUI risk.[40]Estrogens are known to stimulate collagenase activity, which may lead to degradation of total collagen, especially the most supportive type I collagen, which may be replaced by weaker immature collagen.[40] The lack of mature collagen might lead to inadequate support of the vaginal and pelvic structure, especially postoperatively, increasing the possibility of surgical complications such as urine retention.

AFR and Voiding Time

According to our study findings, AFR and voiding times from the urodynamic exam were worse in patients with surgical complications. Preoperative urodynamic evaluations may predict the risk of voiding dysfunction in women with SUI undergoing midurethral sling surgery,[41] although other research has failed to support such evaluations.[42] Another study from Taiwan has found that an abnormal preoperative uroflowmetry pattern and preoperative peak flow <15 ml/s are risk factors contributing to voiding dysfunction following midurethral sling surgery,[43] and a low flow rate is reported by other researchers to be a risk factor for early voiding dysfunction postoperatively.[44] In our study, all of our patients (with and without surgical complications) had much lower AFR values (8.0 vs 10.0 ml/s, respectively) than the studies mentioned above. The discrepant outcomes may depend upon different criteria used by the various studies to determine low flow rates, as well as the differing severity of SUI in the various study populations.

Study Strengths and Limitations

The strengths of this study include the careful efforts made to verify the study population to avoid selection bias. Because the sling type data were recorded only in unstructured text and could not be easily identified, an Obstetrics and Gynecology (OBGYN) physician (TFC) reviewed the operation records of all eligible patients to verify that these patients indeed received midurethral sling surgery. Another strength is that this study was able to examine the association between urodynamic parameters and surgical outcomes, as OBGYN physicians in CMUH regularly perform detailed urodynamic evaluations prior to surgery. Interestingly, a Cochrane review has concluded that urodynamic studies may change clinical decision making, but scant evidence shows that these evaluations improve clinical outcomes.[45-47] In our unadjusted analysis, we identified that lower average flow rate and longer voiding time were associated with surgical complications, which, if validated in another study, may serve as quantitative indicators for a high risk of surgical complications.

This study has several limitations. First, residual and unmeasured confounders could not be entirely ex-

5

cluded. For example, we may have misclassified patients with menopausal syndrome as being without menopausal syndrome, because we were reliant on ICD records from different doctors and from a retrospective single center database. Therefore, the effects of potential risk factors (such as patient lifestyle factors, physician bias and experience with recording menopausal symptoms) may have been slightly overestimated due to the underestimation of these positive confounders. Second, the standard protocol for follow-up is usually 6 months following surgery; we may have misclassified patients with surgical complications as instead belonging to the group without complications, because these patients may not come back to our hospital for care so were lost to follow-up. Third, the associations found in our study do not guarantee causality. Our findings were not verified in other populations under different healthcare systems and the results should be externally validated to prove generalizability.

Conclusion

Our study found that a history of menopausal syndrome within 1 year prior to surgery or a medication history of HRT were risk factors for 5-year complications in women undergoing midurethral sling surgery for SUI. If this association is validated in future studies, it could provide guidance for surgeons, clinicians and patients assessing the risk of surgical complications when considering midurethral sling surgical treatment for SUI.

Conflict of Interest Statement

None of the authors has any financial or personal relationships with other people or organizations that could inappropriately influence this work.

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