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ORIGINAL ARTICLE

A Danish national population-based cohort study of synthetic midurethral slings, 2007–2011

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Abstract

Introduction and hypothesis Synthetic midurethral slings (MUSs) have shown similar cure rates in several short- and medium-term follow-up studies. Recently, long-term follow-up studies have indicated that the cure rate is higher following the retropubic midurethral sling (RPMUS) compared with the transobturator midurethral sling (TOMUS) procedure.

The aim was to evaluate the efficacy of synthetic MUSs and to examine the influence of department and surgeon volume and patient-related factors on the cure rate of synthetic MUSs.

Methods A retrospective cohort study based on a national population over a 5-year period (2007–2011) using data from the Danish Urogynaecological Database (DugaBase).

Results A total of 4519 women with first-time MUS were registered in the DugaBase. Cure was achieved in 1242/1639 (75.78%) at a 3-month follow-up. RPMUSs were more frequently in use in high-volume departments compared with the other departments and more often implanted by high- than low-volume surgeons. Women treated by a medium- (adjusted OR 1.82; 95% CI 1.01–3.28, "frequency") or high-volume surgeon (1.98; 1.18–3.32, "frequency") had an increased probability of cure compared with women treated by a low-volume surgeon. The difference was only significant for women who received a TOMUS.

Conclusions This national population-based cohort study confirmed a high cure rate of synthetic MUSs at short-term follow-up. It is the largest study to indicate a learning curve for TOMUS. Patients were not actively involved in which synthetic MUS was to be performed as the choice of surgical option was made at the departmental level.

Keywords Midurethral slings · Retropubic midurethral sling · Transobturator midurethral sling · Surgeon volume · Department volume · Learning curve

Introduction

Synthetic midurethral slings (MUSs) are the current standard for surgical treatment of urinary incontinence (UI) in women [1, 2]. The synthetic MUSs [retropubic midurethral sling (RPMUSs) and transobturator midurethral sling (TOMUS)] have shown similar high objective and subjective cure rates in several short- and medium-term follow-up studies [1, 2].

At the long-term follow-up, recent literature, however, indicates that the objective cure rate is higher following RPMUS [3, 4] and consequently that the need for retreatment [5] and risk of reoperation are reduced [6].

In several countries there is consensus on using one or the other synthetic MUS [7]. The question is whether the patient is part of a shared decision-making or the choice rests with the surgeon or the department.

Previous studies have shown that both department and surgeon volume affect the objective and subjective outcomes of synthetic MUSs [8, 9]. The learning curve for RPMUS has in general been well documented [10], whereas this is poorly reported in the literature for TOMUS [11–14]. To date, no major studies have assessed the learning curve for TOMUS.

The Danish Urogynaecological DataBase (DugaBase) was established in 2006 to monitor the quality of urogynecological

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surgery [15]. It is mandatory by law to report to the clinical database, and it constitutes a unique source of information on women with synthetic MUSs as it allows a large population-based sample size representing several years to be obtained.

The aims of the present study were: (1) to evaluate the efficacy of synthetic MUSs on patient-reported outcome measures (PROMs) based on a national population over a 5-year period (2007–2011), (2) to describe the influence of department and surgeon volume on the use of either RPMUS or TOMUS, and (3) to examine the influence of department and surgeon volume and patient-related factors on the efficacy of synthetic MUSs.

Materials and methods

Study population and settings

The Danish healthcare system is tax financed and provides care free of charge for all residents. The study population included women 18 years or older residing in Denmark who had a first-time synthetic MUS from 2007 through 2011, as registered in the DugaBase. We included 2006 as a lag year on the assumption that a synthetic MUS was likely to be the woman's first-time MUS.

Only women who had completed the questionnaires pre- and postoperatively were included in the main analyses (Fig. 1). The guidelines for strengthening the Reporting of Observational Studies in Epidemiology (STROBE) were followed [16].

RPMUS was introduced in 1997 in Denmark and TOMUS (exclusively an inside-out method) in 2003. The synthetic MUSs in the period (2006–2011) consisted of macropore and were made of monofilaments (Table 6 in Appendix 1) [17].

In Denmark, approximately 1200 synthetic MUSs are performed annually, RPMUS and TOMUS being used equally [18]. The procedure is primarily performed in outpatient settings using a combination of local anesthetics and sedation. A minority of women (comorbid patients or patients with other concurrent procedures) have the procedure performed under general anesthesia and are hospitalized [18].

Data source

Data were retrieved from three Danish registers: the DugaBase, the Danish National Patient Registry [19], and the Danish National Prescription Registry [20]. All Danish residents have a unique personal identification number that indicates their date of birth and gender and is used for registration of each individual's contact (for purposes of consultation or treatment) with the national healthcare system, thus enabling linkage between all registries.

The DugaBase was established as a clinical database in 2006 and serves both clinical and scientific purposes [15, 18]. It comprises women residing in Denmark, who, at the age of 18 years or older, undergo surgical procedures for UI or pelvic organ prolapse (POP) according to the NOMESCO procedure codes [21].

It is mandatory by Danish law for all Danish hospital departments and private hospitals to report data to the DugaBase [15]. The database completeness of the DugaBase has increased from 33% in 2007 to 91% in 2011 using the Danish National Patient Registry as reference, whereas data completeness has been constantly lower than the reference during this period [18]. This is mainly due to the fact that follow-up after a UI procedure is not standardized. Some departments routinely follow up all patients, whereas others only follow up on patients with complications. The routine follow-up is usually scheduled for 3–6 months postoperatively.

Since their introduction, pre- and postoperative questionnaires have been collected systematically [15]. These include the Incontinence Questionnaire-Short Form (ICIQ-SF), which has been translated into and validated in Danish [22]. The main variables have been examined and 90–100% agreement was found when comparing information from the database with medical records [18].

The Danish National Patient Registry was established in 1977 and provides information on diagnoses, minor procedures, operations undergone by inpatients and outpatients, and emergency room attendance at Danish hospitals [19]. Studies of procedure codes registered in the Danish National Patient Registry have shown a high validity [19]. It is mandatory to report to the Danish National Patient Registry and hospitals are only reimbursed if they report to the registry [19].

The Danish National Prescription Registry was established in 1993 and retrieves information from Danish pharmacies on medicines prescribed. This means that drugs sold over the counter, dispensed at hospitals for outpatient treatment, or prescriptions that were not redeemed (primary non-compliance) are not registered [20].

Potential predictors

Potential variables associated with the outcome of synthetic MUSs were department and surgeon volume and patient-related factors.

Department and surgeon volume

We divided department volume into high-volume departments and the remaining departments. The five high-volume departments were equivalent to the largest departments in each region in Denmark. Two of those departments were highly specialized departments. A previous categorization into low, medium and high volume [6, 9] was obsolete, as surgical treatment for female UI underwent centralization during the study

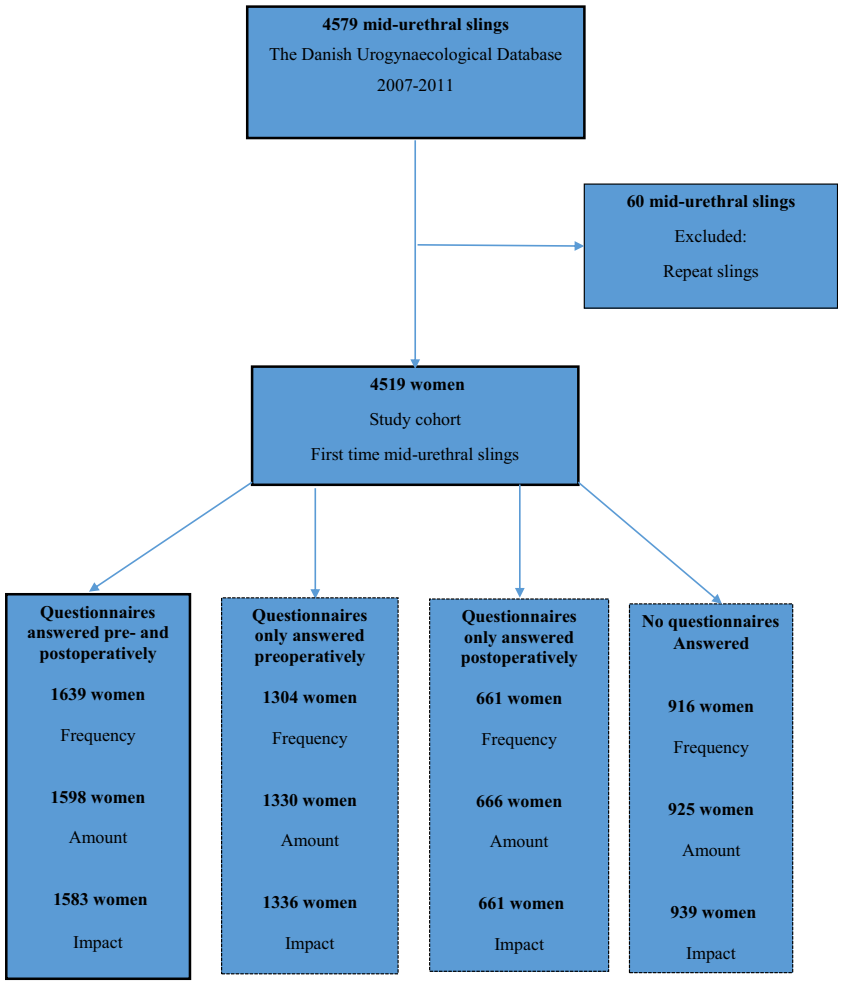

Fig. 1 Description of the study cohort

period in Denmark and the majority of the low-volume departments were closed.

Surgeon volume, as registered in the DugaBase for each synthetic MUS, was categorized into three groups (number of procedures performed during career as a surgeon): low (≤ 25), medium (26–75), and high volume (>75).

Patient-related factors

Patient-related factors included a medical history as registered in the DugaBase [age, body mass index (BMI), American Society of Anesthesiologist's (ASA) Classification, previous hysterectomy, UI, or POP surgery, and severity of UI preoperatively using the ICIQ-SF]. Information on preoperative use of medication related to UI was retrieved from the Danish National Prescription Registry [diuretics (ATC C03) antimuscarinic drugs (ATC G04BD), estrogens (ATC G03C) and a group of less frequently used drugs (desmopressin ATC H01BA02, imipramine ATC N06AA02 and duloxetine ATC N06AX21)].

Outcome measures

The primary outcome was based on the ICIQ-SF, completed at 3 months' follow-up after the primary synthetic MUS. The ICIQ-SF consists of three questions (frequency of UI, amount of leakage, and impact of UI on daily life) and a total score based on these questions (total ICIQ-SF). Within each of the three questions, "cure" was based on a dichotomization in accordance with previously reported criteria [23]. The steering committee of the DugaBase has defined cure (a successful outcome) as leakage once a week or less often, and we focused in particular on this outcome [15]. The secondary outcome was "Change" evaluated as the difference on the total ICIQ-SF, pre- and postoperatively.

Statistical analysis

The analytical unit was the first-time MUS. Descriptive statistics were used to evaluate baseline characteristics. To evaluate baseline characteristics between patients treated by a low-, medium-, or high-volume surgeon, we used the χ^2 test (categorical variables) and one-way analysis of variance (ANOVA)

(continuous variables) and for department volume the χ^2 test (categorical variables) and Student's t-test (continuous variables). Any change from baseline in the ICIQ-SF scores was analyzed by means of the Wilcoxon signed-rank test.

Initially, we performed all analyses year by year, but as we found no essential differences between years we merged all results (data not shown).

At logistic regression the cure rate for the ICIQ-SF postoperatively was dichotomized for all three questionnaires and adjusted for the preoperative ICIQ-SF score ("severity").We analyzed the impact of patient-related factors believed to be clinically relevant and the influence of surgeon and department volume on cure by uni- and multivariate logistic regression. The Hosmer Lemeshow goodness-of-fit test was performed to assess the fit of the models.

Furthermore, we analyzed the impact of patient-related factors, surgeon and department volume on the cure rate for RPMUS and TOMUS, individually.

In additional analyses, we compared potential predictors prior to surgery between women who had completed both questionnaires pre- and postoperatively with women who had not completed the questionnaires (pre- and/or postoperatively).

$p < 0.05$ was considered statistically significant.

Data analysis was performed using STATA version 14.0 (StataCorp, College Station, TX, USA).

Approval

The study was approved by the Danish Data Protection Agency (J.no. 2013–41-0414). As the study did not include patient contact, it was not necessary to obtain approval from the Health Research Ethics Committee.

Results

Descriptive

Between 1 January 2007 and 31 December 2011, a total of 4519 women with first-time synthetic MUSs were registered in the DugaBase; 2331 (51.58%) had a RPMUS and 2188 (48.42%) a TOMUS. The mean age was 52.86 years, the mean BMI 26.59, and 49.32% had pure stress UI (SUI) and 47.90% mixed UI (MUI) (Table 1). There were only minor differences in the baseline characteristics between women assigned to RPMUS or TOMUS (Table 7 in Appendix 2).

Among the 1639 women who pre- and postoperatively had answered both questionnaires, 1242 (75.78%) were cured and 852 (51.98%) had achieved no leakage at all at the 3-month follow-up. There was a statistically significant improvement on all three ICIQ-SF scores (Table 2). The mean total ICIQ-SF score was 15.70 (SD 3.31) preoperatively and 3.94 (SD 5.86) ($p < 0.001$) postoperatively.

Table 1 Patient characteristics for women with first-time midurethral slings, 2007–2011, Denmark

Variables	All[1]
Age, years, mean (SD)	52.86 (11.91)
BMI, mean (SD)	26.59 (4.65) [2]
Type of UI (%)	
Stress	1488/3017 (49.32)
Urgency	30/3017 (1.00)
Mixed	1445/3017(47.90)
Not specified	54/3017 (1.79)
Smoking (%)	751/3119 (24.08)
Alcohol units per week, mean (SD)	3.07 (4.36)[3]
ASA (%)	
1–2	3059/3228 (94.76)
3–5	169/3228 (5.24)
Parity (%)	
0	70/3370 (2.08)
1–2	2057/3370 (61.04)
≥3	1243/3370 (36.88)
Previous surgery (%)	
Hysterectomy	629/3355 (18.75)
UI surgery	191/3358 (5.69)
POP surgery	326/3330 (9.79)
Use of preoperative medication (%)	
Estrogen	1597/3419 (46.71)
Antimuscarinic drugs	426/3419 (12.46)
Diuretics	792/3419 (23.16)
Other drugs	106/3419 (3.10)

[1] $n = 4519$, unless stated otherwise

[2] $n = 3487$

[3] $n = 2839$

BMI body mass index, *ASA* American Society of Anesthesiologist's Classification, *UI* Urinary incontinence *POP* Pelvic organ prolapse. Other drugs: desmopressin, imipramine, or duloxetine

The synthetic MUSs were performed at 35 departments, of which 16 exclusively implanted RPMUSs, 15 only TOMUSs, and 4 both sling types to the same extent.

At high-volume departments, RPMUSs were more frequently used (74.59%) than in other departments (33.38%) ($p < 0.001$, Table 3).

RPMUSss were more often implanted by high-volume surgeons, 1699 (58.20%) compared with low (34.78%) and medium (37.04%) volume surgeons (Table 4).

There were more high-volume surgeons at high-volume departments (71.50%) than at the other departments (64.20%) (data not shown, $p < 0.001$).

Table 2 Frequency, amount, impact, and total score before and after treatment, evaluated by ICIQ-SF

ICIQ-SF Questionnaires	Before, (mean ± SD)	After, (± mean SD)	Change, (± mean SD)	*p* value[1]
Frequency[2]	3.68 (0.94)	0.99 (1.36)	2.68 (1.48)	< 0.001
Amount[3]	3.72 (1.46)	1.23 (1.53)	2.49 (2.01)	< 0.001
Impact[4]	8.28 (1.91)	1.65 (2.74)	6.62 (3.23)	< 0.001
Total score[5]	15.70 (3.31)	3.94 (5.86)	11.75 (5.86)	< 0.001

[1] Wilcoxon sign-ranked test

[2] $n = 1639$

[3] $n = 1598$

[4] $n = 1583$

[5] $n = 1508$

ICIQ-SF The International Consultation on Incontinence Questionnaire Short Form

Department and surgeon volume in logistic regression analyses

Based on the ICIQ-SF scores (Table 5), there was no influence of department volume on cure. Women treated by a medium-volume surgeon (adjusted OR 1.82; 95% CI 1.01–3.28, "frequency") and a high-volume surgeon (adjusted OR 1.98; 95% CI 1.18–3.32, "frequency") had an increased chance of cure compared with women treated by a low-volume surgeon. This difference was only relevant for women who underwent a TOMUS procedure: medium-volume surgeon (adjusted OR 2.27; 95% CI 1.04–4.97, "frequency") and high-volume surgeon (adjusted OR 2.07; 95% CI 1.00–4.27, "frequency") (data not shown).

Patient-related factors in logistic regression analyses

The most severe form of UI preoperatively decreased the likelihood of cure significantly in all ICIQ-SF scores (data not shown).

The cure rate for women with a high BMI (kg/m^2) was lower (adjusted OR 0.95; 95% CI 0.92–0.99, "frequency"; adjusted OR 0.92; 95% CI 0.88–0.97, "impact") (Table 5).

Table 3 Department volume and synthetic midurethral slings, 2007–2011, Denmark

Department volume	High-volume departments	Other departments	*p* value
RPMUS(%)	1485 (74.59)	844 (33.38)	< 0.001
TOMUS (%)	506 (25.41)	1684 (66.61)	
Total (%)	1991 (100)	2528 (100)	

[1] Chi-squared test

Table 4 Surgeon volume and synthetic midurethral slings, 2007–2011, Denmark

Surgeon volume[1]	Low	Medium	High	*p* value[2]
RPMUS (%)	168 (34.78)	346 (37.04)	1699 (58.20)	< 0.001
TOMUS (%)	315 (65.21)	588 (63.06)	1220 (41.80)	
Total (%)	438 (100)	934 (100)	2919 (100)	

[1] Number of procedures during career as a surgeon; low (≤25), medium (26–75), and high (> 75)

[2] Chi-squared test

Similarly, women with MUI had a lower chance of cure (adjusted OR 0.58; 95% CI 0.41–0.82, "frequency"; adjusted OR 0.61; 95% CI; 0.39–0.98 "amount"). This difference was only relevant for women who received an RPMUS implant (adjusted OR 0.11; 95% CI 0.06–0.19, "frequency"; adjusted OR 0.14; 95% CI; 0.08–0.27 "amount").

Women who took antimuscarinic drugs preoperatively had a decreased likelihood of cure according to all ICIQ-SF scores [0.14 (0.09–0.23) "frequency"; adjusted OR 0.14; 95% CI 0.09–0.23, "amount"; adjusted OR 0.15; 95% CI 0.09–0.24 "impact"].

Likewise, women who were prescribed other drugs (desmopressin, imipramine, or duloxetine) displayed a lower cure rate (adjusted OR 0.42; 95% CI 0.17–1.01 "frequency"; adjusted OR 0.25; 95% CI 0.09–0.66 "impact").

Additional analyses

At baseline, there were a few differences in potential predictors between women who completed the total ICIQ-SF both pre- and postoperatively and women who did not complete it at all: age (52.74 vs. 53.79, $p = 0.03$), antimuscarinic drugs (11.53% vs. 16.40%, $p = 0.002$), other drugs (2.96% vs. 4.93%, $p = 0.03$), ASA 1–2 (4.83% vs. 7.65%, $p = 0.03$), and department volume (high: 47.19% vs. 34.83%, $p < 0.001$).

Similarly, there were differences in predictors between women who had completed both questionnaires and women who had only completed the questionnaire preoperatively: age (52.74 vs.51.49, $p = 0.01$), smoking (21.89% vs. 26.23%, $p < 0.001$), estrogen (49.56 vs. 40.62%, $p = 0.001$), antimuscarinic drug (11.53% vs. 8.27%, $p = 0.01$), department volume (high 47.19% vs. 54.60%, other departments 52.81% vs. 45.40%, $p < 0.001$).

Differences were observed between women who had filled in both questionnaires and women who had only answered the questionnaires postoperatively: age (52.73 vs. 54.61, $p = 0.006$), BMI (26.51 vs. 27.20, $p = 0.02$), smoking (21.89% vs. 28.34%, $p = 0.05$), antimuscarinic drugs (11.33% vs.

Table 5 Uni- and multivariate analyses of potential predictors for cure, ICIQ-SF (frequency, amount, and impact)

Variables	Frequency		Amount		Impact	
	Univariate analysis	Multivariate analysis	Univariate analysis	Multivariate analysis	Univariate analysis	Multivariate analysis
			Age, years			
20–39	Reference	Reference	Reference	Reference	Reference	Reference
40–69	0.74 (0.50–1.10)1	1.05 (0.57–1.93)	0.83 (0.49–1.43)	0.94 (0.41–2.15)	1.06 (0.65–1.72)	1.88 (0.90–3.90)
70–89	**0.39 (0.24–0.65)**	0.9 (0.41–1.96)	**0.34 (0.18–0.63)**	0.61 (0.22–1.63)	0.55 (0.30–1.02)	2.43 (0.92–6.45)
BMI, kg/m^2	**0.93 (0.91–0.96)**	**0.95 (0.92–0.99)**	**0.95 (0.92–0.98)**	1.00 (0.95–1.04)	**0.90 (0.87–0.93)**	**0.92 (0.88–0.97)**
			Type of UI			
Stress	Reference	Reference	Reference	Reference	Reference	Reference
Urgency	**0.21 (0.08–0.58)**	0.42 (0.10–1.66)	**0.17 (0.06–0.45)**	0.43 (0.09–2.06)	**0.20 (0.07–0.58)**	0.58 (0.11–3.08)
Mixed	**0.50 (0.39–0.65)**	**0.58 (0.41–0.82)**	**0.39 (0.28–0.58)**	**0.61 (0.39–0.98)**	**0.51 (0.36–0.73)**	0.73 (0.46–1.19)
Not specified	**0.50 (0.24–1.05)**	0.96 (0.37–2.52)	**0.24 (0.1–0.55)**	0.85 (0.28–2.62)	**0.21 (0.09–0.47)**	0.43 (0.15–1.26)
			ASA			
1–2	Reference	Reference	Reference	Reference	Reference	Reference
3–5	**0.51 (0.31–0.84)**	0.88 (0.44–1.73)	**0.49 (0.27–0.91)**	0.71 (0.32–1.59)	0.69 (0.35–1.36)	2.23 (0.71–6.95)
			Parity			
0	Reference	Reference	Reference	Reference	Reference	Reference
1–2	1.05 (0.48–2.29)	0.45 (0.14–1.44)	1.88 (0.75–4.68)	1.19 (0.35–4.06)	2.04 (0.81–5.09)	0.83 (0.20–3.32)
≥3	0.76 (0.34–1.66)	0.34 (0.10–1.08)	1.44 (0.58–3.62)	1.08 (0.31–3.75)	1.20 (0.48–3.01)	0.53 (0.13–2.17)
			Previous surgery			
Hysterectomy	**0.59 (0.45–0.79)**	0.71 (0.47–1.04)	**0.49 (0.34–0.70)**	**0.6 (0.36–0.97)**	**0.49 (0.33–0.70)**	0.61 (0.37–1.02)
UI surgery	1.23 (0.75–2.02)	1.58 (0.77–3.25)	**1.87 (1.04–3.34)**	1.37 (0.56–3.33)	1.50 (0.80–2.81)	1.50 (0.58–3.87)
POP surgery	0.83 (0.57–1.20)	1.25 (0.75–2.1)	**0.55 (0.35–0.85)**	0.98 (0.52–1.87)	0.67 (0.42–1.07)	0.89 (0.45–1.74)
			Preoperative medication			
Estrogen	**0.62 (0.48–0.81)**	0.79 (0.56–1.11)	**0.57 (0.41–0.81)**	0.99 (0.63–1.55)	**0.61 (0.43–0.86)**	0.95 (0.6–1.52)
Antimuscarinic drugs	**0.09 (0.06–0.13)**	0.14 (0.09–0.23)	**0.15 (0.10–0.22)**	**0.14 (0.09–0.23)**	**0.13 (0.09–0.20)**	**0.15 (0.09–0.24)**
Diuretics	**0.70 (0.52–0.94)**	0.87 (0.59–1.29)	**0.58 (0.40–0.85)**	**0.59 (0.37–0.95)**	**0.66 (0.44–0.96)**	0.71(0.43–1.17)
Other drugs	**0.41 (0.21–0.80)**	**0.42 (0.17–1.01)**	**0.31 (0.14–0.66)**	0.45 (0.17–1.21)	**0.24(0.12–0.50)**	**0.25 (0.09–0.66)**
			Department volume			
Other	Reference	Reference	Reference	Reference	Reference	Reference
High volume	0.84 (0.67–1.07)	0.97 (0.70–1.35)	**0.62 (0.45–0.86)**	0.83 (0.54–1.28)	**0.72 (0.53–0.99)**	0.83 (0.54–1.27)
Surgeon volume						
Low	Reference	Reference	Reference	Reference	Reference	Reference
Medium	1.24 (0.79–1.95)	**1.82 (1.01–3.28)**	0.75 (0.39–1.44)	0.77 (0.73–2.76)	0.88 (0.44–1.74)	0.79 (0.33–1.9)
High	1.08 (0.73–1.60)	**1.98 (1.18–3.32)**	0.73 (0.41–1.31)	0.90 (0.43–1.88)	0.73(0.40–1.34)	0.77 (0.35–1.67)

[1] Odds ratio (95% CI)

Cure was dichotomized and throughout all analyses, adjusted by the preoperative ICIQ-SF score ("severity")

ICIQ-SF The International Consultation on Incontinence Questionnaire Short Form

BMI body mass index, *ASA* American Society of Anesthesiologist's Classification, *UI* Urinary incontinence, *POP* Pelvic organ prolapse.

Other drugs: desmopressin, imipramine, or duloxetine

Adjustment was made for age, years 20–39 (ref), 40–69, and 70–89; BMI; stress (ref), urgency, mixed, not specified; ASA 1–2, 3–5; parity 0 (ref), 1–2, ≥ 3; previous surgery, hysterectomy (ref), UI surgery, POP surgery; preoperative medication, estrogen (ref), antimuscarinic drugs, diuretics; department volume, other (ref), high volume, high surgeon volume, low (ref), medium, high

Significant odds ratios are emphasized with bold

16.91%, $p = 0.002$), diuretics (21.62% vs. 27.32%, $p = 0.009$), ASA (4.83% vs. 8.66%, $p = 0.012$), and department volume (high 47.19% vs. 28.29%, other departments 52.80% vs. 71.71%, $p < 0.001$).

Discussion

This national population cohort study is to the best of our knowledge the largest study to indicate a learning curve for TOMUS. Due to the cross-sectional design of the study, we cannot exclude that surgeons with poorer outcomes had disappeared from the specialty. However, three longitudinal studies support the finding of a learning curve for TOMUS [13, 14] in that, like the present study, they found that a standard minimum of 10–20 procedures was necessary to achieve better outcomes, as indicated by ICIQ-SF scores [13], but also found a lowered risk of groin pain [13] and reduction of operative time [12–14]. One study did not find any impact of the learning curve, but this was probably attributable to the study's small sample size[11].

A high subjective cure rate for synthetic MUSs was demonstrated nationally, which is in agreement with previous studies [1, 2]. It is generally accepted in short- and medium-term follow-up studies that the safety and efficacy ratings are similar for both types of slings [1, 2], although recent literature indicates that in the long term RPMUS is considered superior to TOMUS [2, 6, 24], and in one country, Scotland, the usee of TOMUS is no longer recommended [25].

Shared decision-making with the patient regarding which synthetic MUS is to be implanted should be mandatory and should include preoperative counselling for the patient, balancing the efficiency and surgical profile for each method [7]. However, the present study showed that patients were not actively involved in the decision as to which sling to implant, as the majority of departments implanted either RPMUS or TOMUS.

The preference for RPMUS at high-volume departments has previously been reported in Denmark and Norway [4, 9]. Originally, TOMUS was introduced because of its time-saving effect, as no cystoscopy was necessary postoperatively, and this advantage might have been more appealing to smaller departments [11].

Among several patient-related factors addressed in the present study, the use of antimuscarinic drugs preoperatively was found to negatively impact PROMs in all ICIQ-SF scores. This corresponds to the literature [26], and it is likely that antimuscarinic drugs may be considered a proxy for overactive bladder syndrome or severe MUI or severe UI, as all groups in the present study also showed a lower cure rate, their conditions being predictors of a lower cure rate from synthetic MUSs [26, 27].

Women with a higher BMI showed a significantly poorer outcome in ICIQ-SF scores. This is contrary to small-scale studies ($n = 35$–195) with follow-up, up to 1 year [28, 29], whereas two large-scale studies ($n = 310$–760) similar to the present one found lower subjective cure rates among overweight women [30, 31].

The major strength of the present study derives from its national population-based design, as it reflects an everyday life setting covering a broad spectrum of women and surgeons. Second, the synthetic MUS procedures undertaken during this period were mainly of the same type and using the same anesthetic techniques. Third, we were able to include several potential confounders. Fourth, the study was strengthened by the use of validated patient-reported outcome measures.

The limitations of the study relate to its retrospective design and short duration of follow-up. The study confirmed the axiom that practice makes perfect, but we had no information on which area would benefit from further practice or the number of procedures needed to maintain a high level of surgical expertise. Furthermore, we cannot exclude some selection bias related to patient characteristics, as some departments only follow-up on patients with a poor outcome, meaning that had all patients been followed up, the cure rate might have been higher.

Conclusion

This national population-based cohort study confirmed a high cure rate at short-term follow-up for the two types of synthetic midurethral slings (MUS) currently in use. It is to the best of our knowledge the largest study to indicate a learning curve for TOT. The patients were not actively involved in the decision as to which synthetic MUS procedure to perform, as the choice of surgical option was rather made at the departmental level.

Compliance with ethical standards

Conflicts of interest None.

Appendix

Table 6 Information on material of synthetic midurethral slings used in Denmark 2006–2011

Synthetic midurethral slings[1]	RPMUS n (%)	TOMUS n (%)
J&J TVT	1402 (55.92)	463 (20.08)
J&J Prolift	9 (0.35)	39 (1.69)
Boston S. Advantage	319 (12.72)	23 (1.00)
Boston S. Obtryx 38	38 (1.51)	837 (36.29)
Monarch	2 (0.08)	151 (6.54)
Miscellaneous, *e.g.,* Cousin, J&J TVT-O	322 (12.84)	347 (15.04)
No information	415 (16.55)	446 (19.34)
Total	2507 (100.00)	2306 (100.00)

[1] All synthetic MUSs consist of makropore, monofilament

Table 7 Patient characteristics for women with tension-free vaginal tape and transobturator tape, 2007–2011, Denmark

Variables	Retropubic midurethral sling	Transobturator midurethral sling	*p* value
Age, years, mean (SD)	52.75 (11.89) [1]	52.92 (11.92) [2]	0.48 [3]
BMI, mean (SD)	26.68 (4.66) [4]	26.48 (4.63) [5]	0.78 [6]
Type of UI (%)			
Stress	833/1813 (45.94)	651/1203 (54.11)	< 0.001 [7]
Urgency	20/1813 (1.10)	10/1203 (0.83)	
Mixed	928/1813 (51.19)	518/1203 (43.06)	
Not specified	31/1813 (1.70)	24/1203 (2.00)	
Smoking (SD)	411/1799 (22.84) [8]	343/1320 (26.00) [9]	0.04 [10]
Alcohol units per week, mean (SD)	3.11 (4.31) [11]	3.03 (4.43) [12]	0.29 [13]
ASA (%)			
1–2	1789/1844 (97.02)	1269/1382 (91.82)	< 0.001 [14]
3–5	55/1844 (2.98)	113/1382 (8.18)	
Parity (%)			
0	45/1906 (2.36)	25/1464 (1.70)	0.41[15]
1–2	1157/1906 (60.70)	900/1464 (61.48)	
≥3	704/1906 (36.93)	539/1464 (36.81)	
Previous surgery (%)			
Hysterectomy	338/1896 (17.83)	219/1458 (19.96)	0.12 [16]
UI surgery	126/1902 (6.62)	67/1455 (4.60)	0.01 [17]
POP surgery	166/1875 (8.85)	162/1453 (11.15)	0.02 [18]
Use of preoperative medication(%)			
Estrogen	778/1725 (45.10)	822/1694 (48.52)	0.05 [19]
Antimuscarinic drugs	194/1725 (11.25)	232/1694 (13.70)	0.03 [20]
Diuretics	402/1725 (23.30)	390/1694 (23.00)	0.84 [21]
Other drugs	52/1725 (3.01)	53/1694 (3.13)	0.85 [22]

[1] $n = 2329$, [2] $n = 2190$, [4] $n = 1951$, [5] $n = 1535$, [8] $n = 1799$, [9] $n = 1320$, [11] $n = 1662$, [12] $n = 1174$,

[3, 6, 13] Student's t-test

[7, 10, 14-22] Chi-squared test

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. https://doi.org/10.1016/j.eururo.2017.04.026.
2. Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev (Online). 2015;7:CD006375. https://doi.org/10.1002/14651858.CD006375.pub3.
3. Brubaker L, Norton PA, Albo ME, Chai TC, Dandreo KJ, Lloyd KL, et al. Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study. Am J Obstet Gynecol. 2011;205(5):498.e491–6. https://doi.org/10.1016/j.ajog.2011.07.011.
4. Dyrkorn OA, Kulseng-Hanssen S, Sandvik L. TVT compared with TVT-O and TOT: results from the Norwegian National Incontinence Registry. Int Urogynecol J. 2010;21(11):1321–6. https://doi.org/10.1007/s00192-010-1195-0.
5. Kenton K, Stoddard AM, Zyczynski H, Albo M, Rickey L, Norton P, et al. 5-year longitudinal followup after retropubic and transobturator mid urethral slings. J Urol. 2015;193(1):203–10. https://doi.org/10.1016/j.juro.2014.08.089.
6. Foss Hansen M, Lose G, Kesmodel US, Gradel KO. Reoperation for urinary incontinence: a nationwide cohort study, 1998-2007. Am J Obstet Gynecol. 2016;214(2):263.e261–8. https://doi.org/10.1016/j.ajog.2015.08.069.
7. Kirby AC, Tan-Kim J, Nager CW. Midurethral slings: which should I choose and what is the evidence for use? Curr Opin Obstet Gynecol. 2015;27(5):359–65. https://doi.org/10.1097/gco.0000000000000202.
8. Ammendrup AC, Jorgensen A, Sander P, Ottesen B, Lose G. A Danish national survey of women operated with mid-urethral slings in 2001. Acta Obstet Gynecol Scand. 2009;88(11):1227–33. https://doi.org/10.3109/00016340903295600.
9. Hansen MF, Lose G, Kesmodel US, Gradel KO. Repeat surgery after failed midurethral slings: a nationwide cohort study, 1998-2007. Int Urogynecol J. 2016;27(7):1013–9. https://doi.org/10.1007/s00192-015-2925-0.
10. Maguire T, Mayne CJ, Terry T, Tincello DG. Analysis of the surgical learning curve using the cumulative sum (CUSUM) method. Neurourol Urodyn. 2013;32(7):964–7. https://doi.org/10.1002/nau.22375.
11. Ito H, Yamanaka H, Hagiwara M, Furuuchi T, Matsumoto K, Kanai K, et al. Efficacy of tension-free vaginal tape compared with

transobturator tape in the treatment of stress urinary incontinence in women: analysis of learning curve, perioperative changes of voiding function. BMC Urol. 2011;11:13. https://doi.org/10.1186/1471-2490-11-13.
12. Sivaslioglu AA, Demir B, Dolen Y, Gelisen O, Haberal A. Residents performance in transobturator tape procedures for stress urinary incontinence. Eur J Obstet Gynecol Reprod Biol. 2007;134(2):259–61. https://doi.org/10.1016/j.ejogrb.2006.12.011.
13. Serati M, Bogani G, Braga A, Sorice P, Salvatore S, Uccella S, et al. Is there a learning curve for the TVT-O procedure? A prospective single-surgeon study of 372 consecutive cases. Eur J Obstet Gynecol Reprod Biol. 2015;186:85–90. https://doi.org/10.1016/j.ejogrb.2015.01.008.
14. Montera R, Plotti F, Ricciardi R, Miranda A, Venturella R, Zullo F, et al. Learning curves of a resident surgeon performing transobturator tape procedures for stress urinary incontinence. Int J Gynaecol Obstet Off Organ Int Fed Gynaecol Obstet. 2016;134(3):345–9. https://doi.org/10.1016/j.ijgo.2016.02.017.
15. Guldberg R, Brostrom S, Hansen JK, Kaerlev L, Gradel KO, Norgard BM, et al. The Danish Urogynaecological Database: establishment, completeness and validity. Int Urogynecol J. 2012;6(24):983–90. https://doi.org/10.1007/s00192-012-1968-8.
16. STROBE (2016) Strengthening the Reporting of Observational Studies in Epidemiology (STROBE). http://www.strobe-statement.org/index.php?id=available-checklists. Accessed 26.01.2018
17. Kirurgisk behandling af urininkontinens [Surgical treatment of urinary incontinence]. 2012. http://gynobsguideline.dk/hindsgavl/Kir%20SUI-endelig.pdf. Accessed 22.03.2018
18. Guldberg R, Kesmodel US, Hansen JK, Gradel KO, Brostrom S, Kaerlev L, et al. Patient reported outcome measures in women undergoing surgery for urinary incontinence and pelvic organ prolapse in Denmark, 2006-2011. Int Urogynecol J. 2013;24(7):1127–34. https://doi.org/10.1007/s00192-012-1979-5.
19. Schmidt M, Schmidt SA, Sandegaard JL, Ehrenstein V, Pedersen L, Sorensen HT. The Danish National Patient Registry: a review of content, data quality, and research potential. Clin Epidemiol. 2015;7:449–90. https://doi.org/10.2147/clep.s91125.
20. Kildemoes HW, Sorensen HT, Hallas J. The Danish National Prescription Registry. Scand J Public Health. 2011;39(7 Suppl):38–41. https://doi.org/10.1177/1403494810394717.
21. Schiøler G, Larsen OBF, Sundhedsstyrelsen. Klassifikation af operationer [Classification of operations]. 2 edn. Munksgaard Danmark, Kbh; 2005.
22. Hansen BB, Svare J, Viktrup L, Jorgensen T, Lose G. Urinary incontinence during pregnancy and 1 year after delivery in primiparous women compared with a control group of nulliparous women. Neurourol Urodyn. 2012;31(4):475–80. https://doi.org/10.1002/nau.21221.
23. Hansen MF, Lose G, Kesmodel US, Gradel KO. A national population-based cohort study of urethral injection therapy for female stress and mixed urinary incontinence: the Danish Urogynaecological Database, 2007-2011. Int Urogynecol J. 2017. https://doi.org/10.1007/s00192-017-3265-z.
24. Lose G, Klarskov N. Retropubic versus transobturator MUS: time to revisit? Int Urogynecol J. 2017;28(8):1113–4. https://doi.org/10.1007/s00192-017-3403-7.
25. Wilkey L (2017) Scottish Independent Review of the use , safety and effcicacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women. Final Report March 2017. http://www.gov.scot/Publications/2015/10/8485/downloads (26.01.2018)
26. Barber MD, Kleeman S, Karram MM, Paraiso MF, Ellerkmann M, Vasavada S, et al. Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings. Am J Obstet Gynecol. 2008;199(6):666.e661–7. https://doi.org/10.1016/j.ajog.2008.07.050.
27. Stav K, Dwyer PL, Rosamilia A, Schierlitz L, Lim YN, Lee J. Risk factors of treatment failure of midurethral sling procedures for women with urinary stress incontinence. Int Urogynecol J. 2010;21(2):149–55. https://doi.org/10.1007/s00192-009-1020-9.
28. Lovatsis D, Gupta C, Dean E, Lee F. Tension-free vaginal tape procedure is an ideal treatment for obese patients. Am J Obstet Gynecol. 2003;189(6):1601–4; discussion 1604-1605. https://doi.org/10.1016/j.ajog.2003.09.041.
29. Killingsworth LB, Wheeler TL 2nd, Burgio KL, Martirosian TE, Redden DT, Richter HE. One-year outcomes of tension-free vaginal tape (TVT) mid-urethral slings in overweight and obese women. Int Urogynecol J Pelvic Floor Dysfunct. 2009;20(9):1103–8. https://doi.org/10.1007/s00192-009-0909-7.
30. Hellberg D, Holmgren C, Lanner L, Nilsson S. The very obese woman and the very old woman: tension-free vaginal tape for the treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(4):423–9. https://doi.org/10.1007/s00192-006-0162-2.
31. Abdel-Fattah M, Familusi A, Ramsay I, Ayansina D, Mostafa A. Preoperative determinants for failure of transobturator tapes in the management of female urodynamic stress incontinence. Int J Gynaecol Obstet: Off Organ Int Fed Gynaecol Obstet. 2010;110(1):18–22. https://doi.org/10.1016/j.ijgo.2010.02.016.