



# Influence of body mass index on short-term subjective improvement and risk of reoperation after mid-urethral sling surgery

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## Abstract

**Introduction and hypothesis** The objective was to evaluate the impact of body mass index (BMI) on the subjective improvement and risk of reoperation after first-time mid-urethral sling surgery.

**Methods** Data were retrieved from the national Danish Urogynaecological Database, including women with first-time surgery with mid-urethral polypropylene slings from 2011 to 2016. The subjective improvement was assessed by the difference in symptoms based on the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) completed pre- and 3 months postoperatively. A reoperation was defined as any new surgical procedure for stress urinary incontinence performed within the study period.

**Results** During the study period, 6,414 mid-urethral sling procedures were performed; 80.0% of these women filled out both pre- and post-surgical International Consultation on Incontinence Questionnaire (ICI-Q) forms. 42.4% had a BMI <25, 34.6% had BMI 25–30, 16.9% had BMI 30–35, and 6.0% BMI >35. The subjective improvement after surgery was high in all BMI categories and there were no differences between the categories. The overall cumulative hazard proportion at 2 years of follow-up was 1.9% (CI 95%: 1.6–2.3) and after 5 years 2.4% (CI 95%: 2.0–2.9). Adjusted for age, smoking, and use of alcohol, the cumulative hazard proportion after 2 years of follow-up was 3.2% (CI 95%: 1.6–6.2) for women with BMI >35 and after 5 years 4.0% (CI 95%: 2.0–7.7), which was the highest proportion of reoperation in the study. The crude hazard ratio was 1.84 (CI 95%: 0.89–3.83) women with BMI >35 and the adjusted hazard ratio was 1.94 (CI 95%: 0.92–4.09).

**Conclusions** We found high subjective improvement after the first-time surgery unrelated to BMI. Women with a BMI over 35 had the highest proportion of reoperations, although this was not statistically significant.

**Keywords** Urinary incontinence · Sling surgery · Body mass index · Patient reported outcomes · Subjective improvement · Reoperation · Mesh

## Abbreviations

BMI Body mass index  
DugaBase The National Danish Urogynaecological Database

ICI The International Consultation on Incontinence  
ICI-Q International Consultation on Incontinence Questionnaire  
ICIQ-SF International Consultation on Incontinence Questionnaire Short Form  
MUS Mid-urethral sling  
NPR Danish National Patient Registry  
PGI-I Patient Global Impression of Improvement  
PROM Patient Reported Outcome Measures  
PHA Public Health Notification  
SUI Stress urinary incontinence  
US FDA United States Food and Drug Administration  
VAS Visual analogue scales  
WHO World Health Organization

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## Introduction

The incidence of obesity in the western world is increasing. Estimations made by the World Health Organization suggest that more than one third (33.9%) of the adult American population is obese (body mass index [BMI] >30). Obesity is associated with numerous comorbidities [1]: increased risk of stress urinary incontinence (SUI), increased risk of cardiovascular diseases, diabetes, sleep apnea, osteoarthritis, etc. SUI can be a condition characterized by social inhibition and can limit the woman to a point where intervention is required. However, incontinence surgery should generally be considered as “quality of life-improving” surgery (as opposed to “life-saving” surgery), which requires a careful approach to decision-making concerning whether or not to perform surgical intervention. Each patient must be subjected to a critical risk and benefit assessment before being offered medical or surgical intervention to ensure that risks are exceeded by the benefits and to give the patient the possibility of providing informed consent.

The current surgical standard treatment for SUI in Denmark is the mid-urethral polypropylene sling. The retropubic sling was introduced in 1996 by Ulmsten et al. [2] and the trans-obturator sling by de Laval et al. in 2003 [3]. The mid-urethral sling (MUS) procedure is now considered safe and effective for treating obese women with SUI [4, 5].

Obesity is the reason for general concerns when considering surgical interventions with the risks of complications, technical challenges, and outcome. Positioning the patient for vaginal surgery, for example, can be challenging. Optimizing the view of the field and working position for the surgeon often requires the patient to be placed in Trendelenburg’s position, which increases the intra-abdominal and intrathoracic pressure, impairing the ventilation of the obese patient. The aims of this study were to evaluate the impact of BMI on the subjective improvement based on patient reported outcome measures (PROM) and the risk of reoperation within 5 years of a first-time MUS surgery.

## Materials and methods

In Denmark (population approximately 5.5 million), all citizens have free access to a tax-supported health care system and its uniform organization allowed us to use a population-based study design. This study is based on questionnaires completed by women aged 18 years or older undergoing a first-time surgery for SUI (synthetic MUS) in Denmark between 2011 and 2016, with a follow-up period on subjective improvement 3 months post-surgery and up to 5 years’ follow-up on reoperation.

## Data sources

The availability of nationwide Danish registries makes it possible to retrieve data from the National Patient Registry (NPR) on all patients discharged from Danish hospitals since 1977 and also on all outpatient visits since 1995 [6]. The NPR includes information about the patients’ civil registration number, hospital, departments, dates of admission and discharge, procedures performed, and up to 20 discharge diagnoses. The diagnoses have been based on the International Classification of Diseases (ICD) 10th revision since 1994 and before that, ICD 8. The ICD 9th revision has never been used in Denmark. Data on death and immigration were retrieved from the Danish Civil Registration System (CRS), which includes the entire Danish population. The CRS comprises all data on death and immigration since 1968 with a high accuracy [7]. For all Danish hospital departments and private hospitals/clinics performing SUI surgery (in women), it is compulsory by Danish law to report data to the DugaBase [8] and the data collection is based on a national web-based input module [9, 10].

The DugaBase was established in 2006 to monitor and improve the quality of urogynecological surgery in Denmark. The database has proved to be complete and reliable with data from more than 90% of all patients who underwent urogynecological procedures [10]. The DugaBase consists of five parts:

1. Referrals
2. A pre-operative self-administered patient questionnaire
3. A pre-operative questionnaire completed by the gynecologist including information on pre-operative examination
4. Information on surgical procedures
5. A post-surgery questionnaire similar to the self-administered questionnaires used before surgery

. Part 2 records baseline information on parity, mode of previous deliveries, previous urogynaecological surgery, previous hysterectomy, tobacco and alcohol consumption, height, weight, and other objective measures. The questionnaire is based on disease-specific questionnaires (International Consultation on Incontinence Questionnaire [ICI-Q]) [11, 12]. The ICI-Q is based on visual analogue scales (VAS) from 0 to 10, and two symptom-specific Likert scales, and the ICI-Q is the sum of a combination of scores. Satisfaction of improvement is the difference between pre- and post-surgery ICI-Q score [13]. The pre-surgery questionnaire is completed in connection with the preoperative examination. The post-surgery questionnaire is either sent to the patient 3 months after surgery or filled in by a nurse conducting a telephone interview with the patient. Cure is defined as one or less incontinence episode per week. A detailed description of the database [8] is available elsewhere [9, 10].

Information on surgery procedures was retrieved from the NPR and more detailed clinical information was not included in the NPR, such as ICI-Q scores, BMI, and possible confounders were collected from the DugaBase.

### BMI classification

We classified all women into BMI categories according to the WHO classification [14]. A BMI < 18.5 is classified as underweight, BMI 18.5–25 as normal weight, BMI 25–29.99 pre-obese, BMI 30–34.99 class I obese, BMI  $\geq$  35 class II + III obese.

### Identification of retropubic sling and transobturator sling surgeries

We included all women undergoing a first-time retropubic sling and transobturator sling surgeries (according to the Nordic Classification of Surgical Procedures KLEG10 and KLEG10A) registered in the DugaBase 1 January 2011 through 31 December 2016 or in the NPR. For this study cohort, we described the age, type of surgery, parity, mode of previous deliveries, previous urogynecological surgery, and current tobacco and alcohol consumption according to BMI classification. A reoperation following a retropubic sling or transobturator sling surgeries was defined as any urinary incontinence (UI) surgery (KLEG10; KLEG10A; KDV20; KDV22; KDG30; KDG00, and miscellaneous surgery procedures used for UI; see Appendix Table 4 for details).

### Statistical analysis

All results are reported using descriptive statistics in exact numbers and means with 95% confidence intervals (CI). To examine the subjective improvement, we analyzed the difference in the pre and post ICI-Q scores in the BMI categories.

Improvement in the ICI-Q score was reported as the median with 25th–75th percentiles. Figure 1 depicts a box-plot for ICI-Q score and illustrates the improvement at the individual level. Missing data on BMI were included in the analysis as a separate BMI group. Using BMI categories, we performed a Cox proportional hazard regression analysis and we adjusted for available and known confounders for BMI, including age, smoking, use of alcohol, and hospital, and we described the Nelson–Aalen cumulative hazard function graphically.

All calculations were performed using STATA Release 14.1.

### Approvals

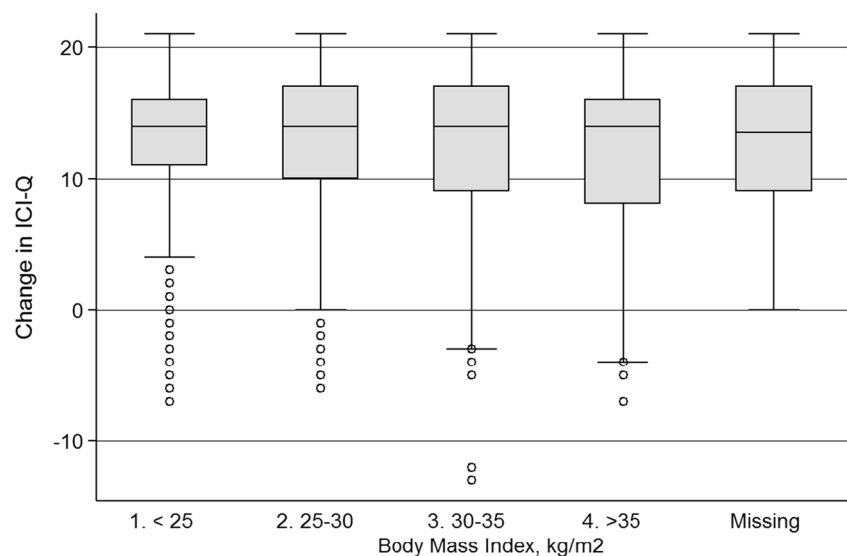
The DugaBase operates under the Danish law on data protection, with a license granted by the Danish Data Protection Agency and the Danish Health and Medicines Authority. This specific study has been approved by the Danish Data Protection Agency (Region Syddanmark: jr. nr. 15/38617). According to Danish law, ethical approval is not required for purely registry-based studies.

### Results

In the period from 2011 through 2016, we found 6,414 women who had undergone MUS surgery in Denmark, of which 61.1% were retropubic slings and 38.9% were transobturator slings.

A total of 5,130 women (80.0%) reported their BMI, 2,176 of whom had a BMI < 25 (normal weight) and 308 a BMI > 35 (class II + III obese). Only a small proportion of the women had a BMI < 18.5 ( $n = 40$ ) and >40 ( $n = 50$ ) and were therefore not reported separately, but included in the nearest BMI category, which results in the categories BMI < 25 and BMI > 35. We had no registration on BMI in 20.0% of the women.

**Fig. 1** Change in the International Consultation on Incontinence Questionnaire (ICI-Q) scores in 3,818 women who had completed both pre- and postoperative questionnaires according to the body mass index (BMI) in Denmark between 2011 and 2016



Further baseline characteristics are presented in Table 1. Eighty-one women were excluded, censored owing to death or migration.

### Subjective improvement

A total of 3,818 (59.3%) had fulfilled the patient questionnaires both pre- and postoperatively. 41.4% of these women ( $n = 1,581$ ) were of normal weight, 34.8% ( $n = 1,327$ ) were pre-obese, 16.3% ( $n = 623$ ) were class I obese, 5.9% ( $n = 225$ ) were class II + III obese, and 1.6% ( $n = 62$ ) of this subgroup had not registered their BMI. Figure 1 illustrates the improvement of ICI-Q score after surgery according to the BMI categories, showing high improvement in all categories. The median improvement was 14 (interquartile range 10–17; results not shown) and the improvement was at the same level among the BMI categories.

Of the 3,818 women who underwent MUS surgery, 48.1% ( $n = 3,082$ ) reported that they no longer experienced incontinence 3 months post-surgery and 11.6% ( $n = 741$ ) reported that they had experienced one or fewer episodes of incontinence per week.

### Reoperation

The overall cumulative hazard proportion at 2 years of follow-up was 1.9% (CI 95%: 1.6–2.3) and after 5 years 2.4% (CI 95%: 2.0–2.9; results not shown). Adjusted for age, smoking, and use of alcohol, the cumulative hazard proportion after 2 years of follow-up was 3.2% (CI 95%: 1.6–6.2) for class II + III obese women and after 5 years 4.0% (CI 95%: 2.0–7.7; Fig. 2). The crude hazard ratio was 1.84 (CI 95%: 0.89–3.83) class II + III obese women and the adjusted hazard ratio was 1.94 (CI 95%: 0.92–4.09; Table 2). Normal weight women who had undergone re-operation had the highest proportion of re-MUS (69%). The type of reoperation according to BMI is shown in Table 3.

### Discussion

To our knowledge, this is the largest study of its kind and contributes to the body of information on the subjective improvement of urinary incontinence symptoms in women who undergo MUS treatment and how BMI influences the

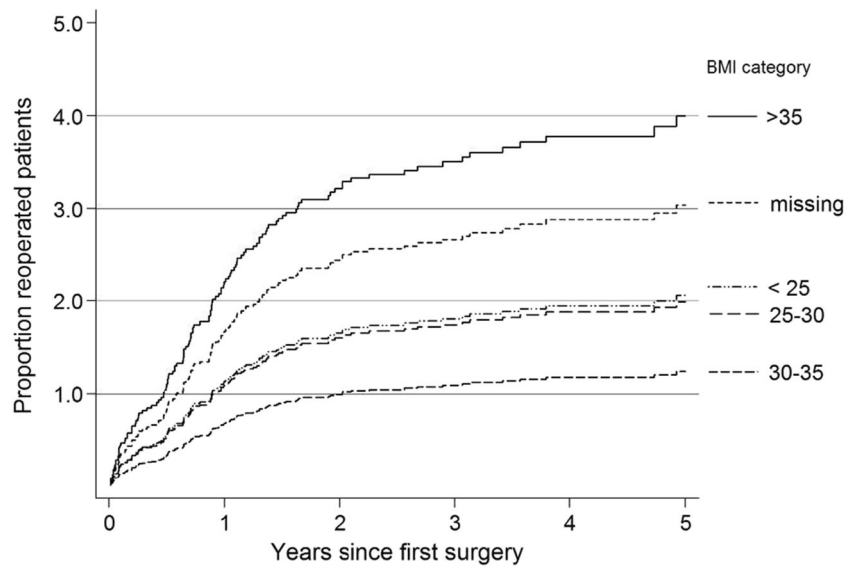
**Table 1** Baseline patient characteristics of women undergoing mid-urethral sling surgery for urinary incontinence according to body mass index, Denmark 2011–2016

	Total	BMI < 25	BMI 25–30	BMI 30–35	BMI > 35	Missing BMI
All	6,414	2,176	1,776	870	308	1,284
Mean age (SD)	51.7 (11.8)	50.1 (11.6)	53.3 (11.9)	52.7 (11.6)	51.6 (11.1)	51.7 (12.0)
Age < 50 (%)	3,007 (46.9)	867 (39.8)	929 (52.3)	448 (51.5)	158 (51.3)	605 (47.1)
Age 50–75 (%)	3,200 (49.9)	1,244 (57.2)	781 (44.0)	392 (45.1)	144 (46.8)	639 (49.8)
Age > 75 (%)	207 (3.2)	65 (3.0)	66 (3.7)	30 (3.4)	6 (1.9)	40 (3.1)
Surgery						
Retropubic sling (%)	3,920 (61.1)	1,392 (64.0)	1,116 (62.8)	533 (61.3)	189 (61.4)	690 (53.7)
Transobturator sling (%)	2,494 (38.9)	784 (36.0)	660 (37.2)	337 (38.7)	119 (38.6)	594 (46.3)
Smoking: yes (%)	1,003 (15.6)	330 (15.2)	351 (19.8)	201 (23.1)	82 (26.6)	–
Alcohol: yes (%)	2,593 (40.4)	1,216 (55.9)	840 (47.3)	361 (41.5)	104 (33.8)	–
Alcohol: ≤ 1 daily (%) <sup>a</sup>	2,221 (34.6)	1,047 (48.1)	689 (38.8)	323 (37.1)	94 (30.5)	–
Alcohol: > 1 daily (%) <sup>a</sup>	372 (5.8)	169 (7.8)	151 (8.5)	38 (4.4)	10 (3.3)	–
Previous						
Parity mean (SD) <sup>a</sup>	2.4 (1.0)	2.3 (0.9)	2.4 (1.0)	2.4 (1.1)	2.4 (1.1)	–
Cesarean section: yes (%) <sup>a</sup>	13.9	12.8	14.3	14.2	17.9	–
Hysterectomy: yes (%) <sup>a</sup>	15.9	11.5	18.6	20.0	19.5	–
POP surgery: yes (%)	7.8	8.2	11.0	10.0	7.5	–
Preoperative ASA score (%)						
1	50.5	69.8	53.5	44.3	31.8	–
2	28.4	21.3	35.4	45.1	52.9	–
3	2.3	1.4	2.5	3.3	6.8	–
4	0.1	0.1	0.1	0.1	0.0	–

ASA American Society of Anesthesiologists physical status classification system, BMI body mass index, POP pelvic organ prolapse, SD standard deviation

<sup>a</sup> Missing: smoking: 1,274 (19.9%), alcohol: 1,383 (22.6%)

**Fig. 2** Cumulative hazard function of proportion of reoperation according to the BMI following first-time mid-urethral sling surgery for urinary incontinence in women, Denmark 2011–2016, adjusted for age, smoking, and use of alcohol



outcome and risk of re-operations. Owing to the number of women included in this study, we have been able to divide the women into subgroups according to WHO sub-classifications.

This study included data on the subjective improvement of 3,818 women and data on reoperation after MUS surgery from 6,414 women over a 5-year period. We found a high subjective improvement of SUI symptoms after the first-time MUS surgery using short-term PROM data. The subjective improvement was unrelated to BMI, as we found similar subjective improvement in all BMI subgroups. Furthermore, we found a small proportion of reoperation within 5 years. Class II + III obese women had the highest proportion of reoperation

after first-time MUS surgery. We adjusted for age, smoking, and use of alcohol and our result appears to be confounded by these factors. Lifestyle factors such as smoking and use of alcohol seemed to lower the risk of reoperation. This may be due to confounding as regards the surgeons' considerations regarding lifestyle factors. This may also apply to being overweight.

Comparison of our results with similar studies is impeded by the heterogeneity of the studies; the use of different designs regarding sample size, time to follow-up, subjective or objective outcome, prospective or retrospective designs, chart review, interviews or PROMS. However, we consider our results to be supported by a number of studies [15–18] where similar subjective cure rates across BMI subgroups were found. In a few studies [19–21], BMI > 30 was one of the most significant predictors of subjective failure.

In a nationwide population-based study by Hansen et al. [22] including 5,820 patients during a 10-year period, the cumulative incidence of reoperation was found to be 6% within 5 years of having a synthetic MUS. We found a significantly lower incidence of reoperation after 5 years. The

**Table 2** Crude and adjusted hazard ratios for re-operations, with 95% confidence interval (CI), for age, smoking, and alcohol

	Crude hazard ratio	Adjusted hazard ratio
<b>BMI</b>		
<25	1	1
26–30	0.96 (0.58–1.58)	0.97 (0.58–1.61)
31–35	0.57 (0.27–1.23)	0.60 (0.28–1.31)
> 35	1.84 (0.89–3.83)	1.94 (0.92–4.09)
Missing	2.14 (1.37–3.34)	1.47 (0.64–3.36)
<b>Age</b>		
<50	1	1
50–75	0.70 (0.48–1.01)	0.69 (0.47–1.00)
> 75	0.63 (0.20–2.01)	0.61 (0.19–1.94)
<b>Smoking (yes)</b>		
Missing	2.13 (1.45–3.13)	1.46 (0.56–3.78)
<b>Alcohol (yes)</b>		
> 1 daily	1.04 (0.47–2.32)	1.22 (0.54–2.78)
Missing	1.88 (1.23–2.89)	1.01 (0.41–2.47)

**Table 3** Numbers of re-operations after mid-urethral sling (MUS) distributed according to BMI groups

BMI	Re-operation MUS (%)	Re-operation others (%)
<25	24 (69)	11 (31)
26–30	12 (46)	14 (54)
31–35	2 (25)	6 (75)
>35	4 (44)	5 (56)
Missing	30 (68)	14 (32)



considerable difference could be explained by a range of explanations. Our data are more recent (2011–2016) than the study by Hansen et al. (1998–2007). Since the introduction of the MUS procedures, we may have become more restrictive in our selection of patients whom we find eligible for MUS surgery; the surgical treatment has been centralized and the surgeons have become more highly trained in the MUS technique. Most important may be a more restrictive approach when considering a second MUS in the case of recurrent incontinence after the first MUS. The fact that we, in this study, found a higher proportion of retropubic slings compared with transobturator slings may also contribute to a lower overall reoperation rate, which is in line with that previously found by Hansen et al. [22]. They found a higher reoperation rate after transobturator slings than after transvaginal slings.

A Public Health Notification (PHN) was issued in 2008 [23] by the United States Food and Drug Administration (FDA) to provide information about adverse events related to the urogynecological use of a surgical mesh and recommendations. Following the PHN, the FDA continued to monitor the outcomes and adverse events of the use of surgical mesh for both surgical treatment for SUI and for pelvic organ prolapse (POP) surgery. A result of this monitoring and a systematic review of the scientific literature was that serious adverse events are not rare and that the transvaginal use of mesh does not improve the clinical outcome of POP repair. This statement raised awareness and may have reduced the use of mesh in urogynecological surgery.

### Strengths of the study

This is to our knowledge the largest series of data conducted on the subject, including 5,130 women who contributed with data on BMI and 3,818 subjective improvements after MUS surgery for SUI and 6,414 women contributing with data regarding the risk of re-operations after MUS. Data were retrieved from an unselected nationwide database and data are shown to be valid and with complete follow-up [9].

### Limitations of the study

The DugaBase does not contain registration of indication for operations, and post-operative follow-up is limited to 3 months. Only women who undergo surgical intervention are registered in the DugaBase. Women who are diagnosed with SUI, but, for any reason (based on either her decision or the surgeon's decision) are not operated, will not be presented in the database, i.e., women who have extensive comorbidities that increase their risks for peri-operative complications will not receive surgical intervention and will thereby not be represented in the DugaBase. This goes for all the BMI subgroups; however, we are not able to detect those who were not offered surgical intervention. We can only retrieve the data

of those who did undergo surgical intervention. When the surgeon carries out the risk and benefit assessment on whether to offer MUS treatment for SUI, there could be some bias in knowing the patients' BMI. We would have liked to investigate whether the BMI influences the rate of peri-operative complications, but at this point, the DugaBase has its limitations as not all complications are being registered and the data are inadequate, either because it is not possible to report certain diagnoses or simply because patients forget to give information about complications treated somewhere other than their primary hospital (e.g., different hospital, different ward, or by their physician).

### Conclusions

In this large study we found a high subjective improvement on the ICI-Q and a very low proportion of reoperation after first-time surgery for urinary incontinence. Furthermore, we found no influence of the BMI on the subjective improvement. Women with a BMI over 35 had the highest proportion of reoperations, although this was not statistically significant.

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### Compliance with ethical standards

**Conflicts of interest** Dr Weltz had travel expenses paid for by Astellas for EUGA Congress 2016. Dr Guldberg has accepted grants from Astellas and Pierre Fabre, Dr Lose has accepted payment for research from Astellas and worked as a consultant for Contura. The remaining authors claim that they have no conflicts of interest.

### Appendix

**Table 4** Surgical procedures according to the Danish Nordic Medico-Statistical Committee (NOMESCO)

Number	Procedure
KLEG10	Vaginal urethrocystopexy with use of sling
KLEG10A	Vaginal urethrocystopexy with use of sling through the obturator foramen
KDV20	Submucosal urethral injection
KDV22	Transluminal endoscopic submucosal urethral injection
KDG30	Suprapubic sling urethrocystopexy
KDG00	Retropubic suspension of the urethra

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