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Association between body mass index and pain following transobturator sling

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Abstract

We aimed to prospectively evaluate the association between body mass index (BMI) and development of postoperative-onset pain in women undergoing transobturator midurethral sling procedures. We conducted a prospective, observational cohort study of women undergoing inside-to-out transobturator midurethral sling. At preoperative visit, height, weight, self-reported activity level and baseline pain were documented. At postoperative visits, patients indicated pain location and severity, procedure success, and satisfaction. We used log binomial regression to calculate risk ratios, controlling for potential confounders. For the 129 women included, median age was 50.0 years and BMI was 27.2 kg/m². Adjusting for age and activity level, overweight and obese women had significantly increased risk of postoperative-onset pain compared to normal BMI women. Overweight women were at 1.70 (95%CI 1.05–2.75) times the risk compared to leaner counterparts, whereas obese women were at 1.76 times the risk (95%CI 1.04–2.89). Neither success nor satisfaction was associated with BMI.

Keywords

Body mass index; obesity; pain; postoperative; stress urinary incontinence; transobturator midurethral sling

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Disclosure statement

Dr. Cadish's and Dr. Dessie's affiliations reflect those at the time of the study's inception. Dr. Cadish currently serves as Urogynaecologist at Providence Saint John's Health Centre in Santa Monica, CA and as Volunteer Assistant Clinical Professor at University of California, Irvine Medical Centre in Orange, CA. Dr. Dessie currently serves as Urogynaecologist at the Mid-Atlantic Permanente Medical Group.

Introduction

Urinary incontinence is among the many conditions adversely affected by obesity. In the case of stress urinary incontinence in particular, obesity leads to increase in intra-abdominal pressure that may weaken the pelvic floor (Osborn et al. 2013). When conservative measures fail, women and their physicians often turn to a midurethral sling procedure, now considered the standard of care (Nager et al. 2014). While the lifetime risk of undergoing an anti-incontinence procedure is 13% for American women overall, this risk may be higher for obese women, who are at 2.3 times the risk of stress urinary incontinence (Subak et al. 2009; Wu et al. 2014).

While reassuring, the evidence suggesting equivalent effectiveness of midurethral sling procedures in obese and lean women does not address potential differences in morbidity and recovery (Killingsworth et al. 2009; Liu et al. 2011; Frohme et al. 2014). Several factors may be considered when choosing an approach in a patient planning midurethral sling for the treatment of stress urinary incontinence. With comparable efficacy between retropubic and transobturator approaches amongst women with normal urethral function, the decision is often based on differing complication rates and surgeon preference (Richter et al. 2010; Schimpf et al. 2014). While the transobturator approach is notable for decreased risks of urinary tract injury, voiding dysfunction and blood loss, the presence of postoperative pain is of concern. This rate has been estimated at 16%, with a smaller 2% having pain extending beyond the sixth postoperative week (Laurikainen et al. 2007; Richter et al. 2010).

We designed this prospective study with the primary objective of evaluating for a possible association between body mass index (BMI) and pain in women undergoing transobturator midurethral sling. A secondary analysis of this study population examining location and severity of pain following transobturator sling has been previously published (Cadish et al. 2014).

Materials and methods

We conducted a prospective, observational cohort study of women undergoing inside-to-out transobturator midurethral sling procedures at Mount Auburn Hospital from March 2011 to February 2013. The Mount Auburn Hospital Institutional Review Board approved the study. Adult women with either symptomatic or occult stress urinary incontinence, as determined by urodynamic studies, and in whom a transobturator midurethral sling was planned were eligible and informed consent was obtained at the preoperative visit. Patients were counselled fully regarding the risks and benefits of the procedure itself, and were counselled separately regarding the option to participate in a study following their outcomes postoperatively. There were no exclusion criteria. The same transobturator midurethral sling is the primary sling of choice for each surgeon in the group. Baseline height and weight were recorded, and preoperative pain location and severity were noted on a standardised diagram and pain scale. The diagram included views of a woman anteriorly, posteriorly and in lithotomy, and the pain scale was calibrated with 0 representing no pain and 10 representing the 'worst imaginable' pain. Participants self-reported their activity level on a

1–10 scale, with 1 being sedentary and 10 being very active. BMI was categorised as normal (18.5–24.9 kg/m²), overweight (25.0–29.9 kg/m²) or obese (≥ 30.0 kg/m²).

All participants underwent an inside-to-out transobturator midurethral sling (TVT-O, Ethicon, Inc; Somerville, NJ). Given that concomitant surgery is common in women planning midurethral sling, inclusion criteria allowed for enrolment of women with and without planned concomitant surgery to improve generalisability. All procedures were performed in a standardised fashion by one of four fellowship-trained urogynaecologists, with the participation of fellows and/or senior residents as appropriate. All patients were positioned in lithotomy position using Yellofin stirrups (Allen Medical; Acton, MA). Participants undergoing another type of sling procedure or who did not undergo midurethral sling were subsequently excluded from the analysis.

Postoperatively, data were collected at two- and six-week visits, and at later visits if additional postoperative care was clinically indicated. At each postoperative visit, participants indicated pain location and severity using the same tools as at the preoperative visit. Postoperative-onset pain was defined as pain at any postoperative visit not present in that location and laterality preoperatively. Participants were asked at each visit if they were 'satisfied with the outcome of the surgery', and, if not, the reason was noted on the data collection sheet. Those patients reporting no stress-related leakage episodes postoperatively were considered cured, whereas those with at least one episode but reporting less stress leakage than preoperatively were deemed improved. Those with either improvement or cure met our definition of a successful sling procedure. A secondary analysis restricted the definition of success only to those cured. The Mount Auburn Hospital Institutional Review Board approved this study.

We performed an *a priori* power calculation, estimating a 10% incidence of postoperative pain in obese women based on previous retrospective data. In order to have 80% power to detect a risk ratio of 2.5 among women of normal weight compared with women in the obese group at a significance level of 0.05, we estimated that 100 participants would be required in each group.

Data were collected and managed using the Research Electronic Data Capture tool (Harris et al. 2009). Data are presented as median (interquartile range) or proportion. Categorical variables were compared using a Chi-square or Fisher's exact test and continuous variables were compared using the Wilcoxon rank-sum test. We used log binomial regression to estimate risk ratios (RR) and 95% confidence intervals (CI) for postoperative-onset pain. We also evaluated the potential confounding effects of variables that we believed could be associated with both BMI and the risk of postoperative-onset pain, including age at surgery, activity level, concomitant surgery, postoperative satisfaction, and procedure success. Those variables that made an appreciable difference were retained in the multivariate model. All statistical tests were performed using SAS 9.3 (SAS Institute Inc., Cary, NC). All tests were two-sided and *p* values < .05 were considered statistically significant.

Results

Of the 137 women who consented at the time of their preoperative visit, 129 (94.2%) were included in the analysis. Those who were excluded included two women who cancelled their surgery, three who underwent retropubic midurethral sling, one who was underweight and two with incomplete records. With slowing enrolment and limited resources, the decision was made to conclude the study after two years although the target sample size had not been reached. The participants' median age was 50.0 years (44.0–62.0) and median BMI was 27.2 kg/m² (23.8–31.3), with a range of 18.9–50.6. Forty-seven women were of normal BMI (36.4%), 41 were overweight (31.8%) and 41 were obese (31.8%). Leaner women were significantly more likely to assess themselves as being more active ($p < .001$, Table 1) compared to obese women. The proportion of women undergoing concomitant surgery was similar among BMI groups ($p = .94$). Nearly half (44.6%) of the participants endorsed pain at the time of their preoperative visit.

While 45.0% of the participants reported postoperative-onset pain at one or more postoperative visits, 6.7% endorsed pain at the six-week visit. Location and severity of pain have been previously reported (Cadish et al. 2014).

When adjusting for age at surgery and activity level, both overweight and obese women were at significantly increased risk of developing postoperative pain as compared to women of normal BMI (Table 2). Whether a participant underwent concomitant surgery was not found to make an appreciable difference in the risk of postoperative pain. Overweight women were at 1.70 (95%CI 1.05–2.75) times the risk as compared to their leaner counterparts, whereas obese women were at 1.76 times the risk (95%CI 1.04–2.89) of those with normal BMI. For each 5-unit increase in BMI, the risk of postoperative-onset pain was found to increase by 15%.

Neither success nor satisfaction was associated with BMI (Table 2). High levels of success – 87% or higher – were reported from all BMI groups. The lack of association between success and BMI persisted even when restricting the definition of success to include only patients who reported a cure. Overall patient satisfaction with the procedure was high. While the obese BMI group reported slightly higher satisfaction with the procedure than the normal and overweight groups, the differences did not reach statistical significance.

Discussion

The finding that overweight and obese women have a significantly higher likelihood of developing postoperative-onset pain following inside-out transobturator midurethral sling, despite similar rates of continence and satisfaction, is surprising and informative. The incidence of postoperative pain among our participants was higher than anticipated; thus, we were able to demonstrate statistically significant differences despite not reaching our *a priori* enrolment goal.

Data have been largely lacking regarding the association between BMI and pain following transobturator midurethral sling procedures. We previously published a retrospective analysis suggesting a decreased risk of postoperative pain in obese women, although these

findings are limited by the study design (Cadish et al. 2010). Moore and colleagues noted increased pain of short duration among obese women undergoing single-incision sling; however, it is doubtful that single-incision sling data is generalisable to the more robust transobturator sling population (Moore and Goldman 2013). Our findings agree in part with those of Heinonen and colleagues, who found that women with BMI greater than 30 reported significantly higher pain levels on a visual analogue scale in long-term follow up of outside-in transobturator sling (Heinonen et al. 2013).

Neither Heinonen's study nor ours fully explain why those with higher BMI suffer greater levels of postoperative pain. Cadaver studies indicate a great deal of variation in the obturator nerve and its subdivisions (Anagnostopoulou et al. 2009). It is possible that higher BMI participants in both studies had anatomic variations of the obturator nerve predisposing them to postoperative pain. Whether such disadvantageous anatomic variations exist, and if so, could be more commonly found in higher BMI women, is unknown.

Our study benefits from its prospective nature, evaluation of pain that is specifically of postoperative onset, use of standardised pain scales and diagrams and consideration of activity level as a potential confounder. Leaner women with higher activity levels are likely to be more active following surgery and therefore may experience proportionally more pain. We believe that retrospective data identifying a possible protective effect of obesity were biased. A likely explanation is that leaner, more active women were more likely to have resumed activity by the time of a two- or six-week postoperative visit, and were more likely to report it to their clinicians. Further, retrospective studies are often plagued by non-standardised and incomplete data collection in patient charts.

There are a number of limitations in our study. The procedure evaluated in our study was specifically the Ethicon inside-out TVT-O, and therefore data may not be generalisable to other transobturator slings. Our limited numbers, while sufficient to demonstrate a difference between groups, precluded the possibility of meaningful subgroup analyses, particularly with regards to assessing the association between BMI and pain among women without concomitant surgery. In addition, while the 0–10 pain scale we used has been validated, the activity level scale and diagram we used have not been validated. Finally, our postoperative data collection did not include quantification of the nonsteroidal or narcotic medication used by patients, which would have given more objective data regarding postoperative pain. Given that pain following transobturator sling has been previously characterised as typically self-limited and of short duration following surgery, we considered short-term follow up adequate to answer our study question (Trabuco et al. 2014).

As both stress urinary incontinence and obesity increase in our population, considerations of surgical optimisation for higher BMI patients become ubiquitous. These data may better inform preoperative counselling and proper patient selection.

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IMPACT STATEMENT

- Over three million midurethral slings have been placed worldwide for the treatment or prevention of stress urinary incontinence. The procedure has been studied in lean, overweight and obese populations, and found to have similar efficacy regardless of BMI. Similarly, the risks of midurethral sling have been well-documented, including the risk of pain after transobturator sling. Little attention has been given to whether this risk of postoperative pain varies based on patient BMI. Our previous work suggesting that leaner patients might be at increased risk of postoperative pain following transobturator sling was limited by the shortcomings of a retrospective study design.
- In this prospective study, we were able to adjust for age and activity level, finding that higher BMI women were at increased risk of postoperative pain, while reporting similar levels of satisfaction with the procedure. Future research is needed to find what differences in anatomy or physiology can explain this finding. From a clinical standpoint, thorough counselling of all patients but particularly those with elevated BMI, is required so that appropriate expectations regarding recovery can be set preoperatively.

Table 1

Preoperative and operative characteristics by BMI category.

Characteristic	Normal BMI (18.5–24.9 kg/m ²) N = 47	Overweight (25.0–29.9 kg/m ²) N = 41	Obese (≥ 30.0 kg/m ²) N = 41	<i>p</i> ^a	<i>p</i> ^b
Age at surgery (years)	49.0 (42.0–59.0)	54.0 (46.0–67.0)	54.0 (47.0–62.0)	.04	.12
Type of stress incontinence				.74	.28
Current	40 (85.1)	37 (90.2)	37 (90.2)		
Occult	6 (12.8)	4 (9.8)	2 (4.9)		
Unknown	1 (2.1)	0 (0.0)	2 (4.9)		
Activity level				.21	<.001
Low	3 (6.4)	2 (4.9)	7 (17.1)		
Moderate	15 (31.9)	20 (48.8)	25 (61.0)		
High	29 (61.7)	18 (43.9)	9 (22.0)		
Missing	0 (0.0)	1 (2.4)	0 (0.0)		
Concomitant surgery	26 (55.3)	19 (46.3)	23 (56.1)	.40	.94
Laparoscopic ^c	12 (46.2)	8 (42.1)	8 (30.8)		
Robotic ^c	8 (30.8)	1 (5.3)	1 (4.3)		
Abdominal ^c	1 (3.8)	0 (0.0)	1 (4.3)		
Vaginal ^c	14 (53.8)	15 (78.9)	20 (87.0)		

Data are presented as median (interquartile range) or n (%).

^aCompares overweight vs. normal BMI.^bCompares obese vs. normal BMI.^cWomen could have multiple modes of surgery; therefore, the proportions sum to more than 100% and a *p*-value was not calculated for each mode of surgery.

Table 2

Relative risk of postoperative-onset pain, sling satisfaction, and success by BMI category.

Body mass index category	N (%)	Risk ratio crude (95%CI)	Risk ratio adjusted (95%CI)
Postoperative-onset pain			
Normal	16 (34.0)	Reference	Reference
Overweight	21 (51.2)	1.50 (0.91–2.47)	1.70 (1.05–2.75) ^a
Obese	21 (51.2)	1.50 (0.91–2.47)	1.76 (1.04–2.89) ^a
Postoperative-onset pain			
BMI (5-unit increase)	58 (45.0)	1.18 (1.0–1.38)	1.15 (0.99–1.34) ^a
Sling success ^b			
Normal	44 (93.6)	Reference ^c	
Overweight	36 (87.8)	0.94 (0.82–1.07)	
Obese	39 (95.1)	1.02 (0.92–1.13)	
Satisfaction			
Normal	40 (85.1)	Reference	Reference ^d
Overweight	36 (87.8)	1.03 (0.87–1.22)	1.02 (0.86–1.21)
Obese	37 (90.2)	1.06 (0.91–1.24)	1.14 (0.86–1.50)

^a Adjusted for age at surgery and activity level.^b Success is defined as improvement or cure.^c Adjustment did not affect risk ratio.^d Adjusted for activity level.