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ORIGINAL ARTICLE

Body mass index does not influence the outcome of anti-incontinence surgery among women whereas menopausal status and ageing do: a randomised trial

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Abstract
Introduction and hypothesis A few series comparing the clinical efficacy of midurethral slings in obese and postmenopausal patients are available. The aim of the study was to assess clinical efficacy of suburethral tape operations for the surgical treatment of female stress urinary incontinence (SUI) stratified by obesity, menopause and ageing.
Methods Five hundred thirty-seven patients underwent either retropubic or transobturator sling procedure. Patients were randomly allocated into two study groups in a ratio of 1:1. After 18 months, 398 women were available for a follow-up efficacy evaluation.
Results The clinical effectiveness of surgical SUI treatment did not depend on patients' body mass index (BMI) and type of midurethral sling, but menopausal status and ageing significantly influenced the outcome of the surgery.
Conclusions We found that BMI does not influence the clinical effectiveness of SUI treatment, whereas both menopause and ageing had a detrimental influence on the final outcome of the surgery.

Keywords Ageing · Incontinence surgery · Menopause · Midurethral sling · Obesity · Stress urinary incontinence

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Introduction

Urinary incontinence affects, according to various epidemiological and clinical studies, from 10% to 40% of women and is associated with several risk factors or contributing variables [1]. According to Hunskaar et al., contributors responsible for urinary incontinence manifestation and severity are as follows: age, pregnancy, parity, obstetrical factors leading to pelvic organ prolapse, menopause, loss of ovarian hormones, hysterectomy, obesity, lower urinary tract abnormalities, functional impairment, cognitive impairment, smoking, family history and genetics [2]. Obesity is an increasing health problem all over the world and affects as much as 25% of the adult population in many countries in Europe, Australia and the USA [3]. Data from several studies indicate that urinary incontinence in women is associated with increased body mass index (BMI) [4, 5]. Data from the EPINCONT Study indicate that a stronger association exists between increasing BMI and stress incontinence (including mixed incontinence) than for urge incontinence and overactive bladder syndrome [6]. Moreover, in a group of 138 young morbidly obese women with a mean weight as high as 124 kg (BMI, 40–45), the prevalence of stress incontinence was found to be as high as 61% [7]. This extremely high prevalence rate of urinary incontinence among patients with a BMI over 40 was also reported in recently published study [8]. Additionally, a study analysing risk factors for stress and urge incontinence among 104 female former top athletes clearly revealed that only BMI was significantly associated with regular stress or urge incontinence symptoms [9].

Epidemiological data clearly show that rapid increase of all urogynecological disturbances parallels the occurrence of menopause and progress with further ageing [6]. The

Table 1 Demographic and urodynamic parameters of patients in both study groups (continuous parameters)

Parameter	Sling type	Mean	Median	SD	Lower quartile	Upper quartile	Min	Max	*Z*	*p*
Age (years)	Retropubic	55.56	54.0	10.19	49.0	62.0	26.0	82.0	−0.12	0.9
	Transobturator	55.75	54.0	11.29	48.0	64.0	31.0	83.0		
Parity (*n*)	Retropubic	2.63	2.0	1.19	2.0	3.0	0.0	7.0	0.12	0.9
	Transobturator	2.62	2.0	1.11	2.0	3.0	0.0	8.0		
PVR (ml)	Retropubic	13.32	6.0	22.87	3.0	15.0	0.0	181.0	0.05	0.96
	Transobturator	13.25	7.0	22.68	3.0	14.0	0.0	167.0		
MUCP (cm H_2O)	Retropubic	50.31	48.5	19.25	36.0	63.0	10.0	117.0	−0.84	0.4
	Transobturator	52.38	52.0	20.48	37.0	65.0	16.0	133.0		
FUL (mm)	Retropubic	23.91	24.0	5.19	20.0	27.0	12.0	48.0	0.7	0.48
	Transobturator	23.40	23.0	4.47	20.0	26.0	12.0	40.0		

PVR post-void residual volume, *MUCP* maximal urethral closure pressure, *FUL* functional urethral length

value of maximal urethral closure pressure is markedly decreased among menopausal women. Also, bladder capacity and detrusor pressure during micturition are significantly diminished in elderly population [10]. On the other hand, estrogen receptors have been identified throughout the pelvic floor, including the urethra, vagina, bladder trigone and uterosacral ligaments, and loss of estrogen after menopause very often paralleled urogenital atrophy associated with urinary symptoms [11]. However, according to recent data published by Tincello et al., ER are present in whole bladder, but only beta isoforms are translated into protein [12]. Although menopause has been shown to be associated with urinary incontinence, evidence for it being an independent factor in the prevalence of urinary incontinence is lacking [13]. Recently, it has even been shown that women currently using hormone replacement therapy had 1.39-fold increased odds of incident urinary incontinence, compared with women who never used hormone therapy [14].

Therefore, the aim of our study was to assess if obesity, menopause and ageing are risk factors for clinical outcome of retropubic (IVS-02) and transobturator (IVS-04) mid-urethral slings.

Materials and methods

The trial was approved by the local ethics committee (KE-0254/47). The study was conducted in the Second Department of Gynecology, Medical University of Lublin from January 2003 to December 2005 on a group of 537 out of 611 incontinent women who underwent urodynamic work-up and surgical treatment of stress urinary incontinence (SUI), signed informed consent and fulfilled the criteria of our randomised trial. Detailed description of the study methods was presented previously [15]. Briefly, patients included into the study were not operated previously for any urogynecological condition and were free of any other gynecological diseases such as uterine fibroma, ovarian cyst or advanced uterine or vaginal prolapse. Only patients in grade 0 and grade 1 according to the pelvic organ prolapse quantification scale (POP-Q) were included in the study. Menopause was defined as the absence of menstruation for at least 6 months. At the time of surgery, the postmenopausal patients were not on systemic or topical estrogen supplementation, and they did not receive any hormonal treatment during the follow-up period. Urodynamic evaluation was performed according to the Interna-

Table 2 Demographic and urodynamic parameters of patients in both study groups (categorical parameters)

Parameter		IVS-02 (*n*)	IVS-04 (*n*)	
BMI (kg/m^2)	18.5–24.9	41 (21.6%)	43 (21.8%)	χ^2=0.33, p=0.85
	25.0–29.9	80 (39.8%)	81 (41.1%)	
	≥30	80 (39.8%)	73 (37.1%)	
Menopausal status	Premenopausal	82 (40.8%)	72 (36.5%)	χ^2=0.76, p=0.38
	Postmenopausal	119 (59.2%)	125 (63.5%)	
Valsalva maneuver	Negative Valsalva maneuver and VLPP>60 cmH_2O	156 (77.6%)	157 (79.7%)	χ^2=0.26, p=0.61
	VLPP≤60 cmH_2O	45 (22.4%)	40 (20.3%)	
Stamey incontinence score	I	34 (17.4%)	54 (27.4%)	χ^2=4.06, p=0.13
	II	99 (49.6%)	102 (51.8%)	
	III	48 (23.9%)	41 (20.8%)	

BMI body mass index

Table 3 Clinical effectiveness of retropubic (n=201) and transobturator (n=197) stratified by patients' body mass index

BMI			18.5–24.9	25.0–29.9	≥30	
Effect	Retropubic	Cured	80.5% (n=33)	80% (n=64)	67.5% (n=54)	χ^2=7.80, p=0.1
		Improved	14.6% (n=6)	13.7% (n=11)	21.2% (n=17)	
		Failure	4.9% (n=2)	6.2% (n=5)	11.2% (n=9)	
	Transobturator	Cured	86% (n=37)	71.6% (n=58)	69.9% (n=51)	χ^2=5.02, p=0.29
		Improved	9.3% (n=4)	13.6% (n=11)	17.8% (n=13)	
		Failure	4.65% (n=2)	14.8% (n=12)	12.3% (n=9)	

tional Continence Society standards and consisted of uroflowmetry, water cystometry and urethral profilometry. Leak-point pressures during Valsalva maneuver (VLPP) were measured. VLPP was determined at 180 ml of bladder filling. Post-void residual volume was measured after spontaneous micturition. The demographic characteristics of the patients and urodynamic parameters are given in Tables 1 and 2. Simple randomization was used from pseudorandom numbers generated by a computer to allocate patients into the retropubic group (n=269) or the transobturator group (n=268). Pseudorandom number means that the patients were operated on by the retropubic or the transobturator method in a ratio of 1:1. Investigators Jankiewicz and Futyma were not involved in the surgical procedures, but they were responsible for the randomization process. All patients who were operated with retropubic were checked for bladder injury with cystoscopy with a 70° lens. Cystoscopy is not routinely performed during transobturator tape placement due to our clinical experience. We routinely performed cystoscopy during our first 150 transobturator procedures, which were not included in this study, and we never encountered problems with bladder perforation; therefore, we discontinued this procedure, assuming that it was not necessary. The follow-up visits were scheduled for 1, 4, 6, 12 and 18 months after the surgery. The efficacy of both procedures in relation to BMI, menopausal status and ageing was assessed by gynecologic examination and cough test in the supine and standing positions with a comfortably full bladder. Patients were considered completely cured when they were free of all SUI symptoms and cough tests in the supine and standing positions were negative. Moreover, the completely cured patients reported that the use of hygienic pads was not necessary. The operation was considered as a failure if the patient still reported urine leakage during increases of intra-abdominal pressure, the cough test with a comfortably full bladder was positive or the woman had to use pads because of being wet during the day. In the improvement group, the cough test was negative, but patients still experienced stress urinary leakage (much less frequent than previously), and the pads were occasionally wet. Statistical analysis was performed using Statistica package version 7.1 (StatSoft, Poland). When comparing two independent groups, Mann–Whitney U test and Chi-square (χ^2) test were performed, and when comparing more than two groups, Kruskall–Wallis H test was used. Interrelation between age as a risk factor for failure of surgery outcome was assessed with a forward stepwise logistic regression analysis. p value <0.05 was considered as statistically significant.

Results

Investigated groups did not differ significantly in terms of demographic and urodynamic parameters (Tables 1 and 2). Clinical effectiveness of both types of midurethral slings

Table 4 Efficacy of retropubic (n=201), transobturator (n=197) and both slings (n=398) stratified by patients' menopausal status (postmenopausal ≥6 months after last menstrual period)

Menopausal status			Premenopausal	Postmenopausal		
Effect	Retropubic	Cured	34.8% (n=70)	40.3% (n=81)	75.2%	χ^2=9.06, p=0.01
		Improved	5.0% (n=10)	11.9% (n=24)	16.9%	
		Failure	1.0% (n=2)	6.9% (n=14)	7.9%	
	Transobturator	Cured	29.0% (n=57)	45.2% (n=89)	74.2%	χ^2=2.57, p=0.28
		Improved	5.1% (n=10)	9.1% (n=18)	14.2%	
		Failure	2.5% (n=5)	9.1% (n=18)	11.6%	
	Retropubic and transobturator	Cured	31.9% (n=127)	42.7% (n=170)	74.6%	χ^2=10.23, p=0.006
		Improved	5.0% (n=20)	10.6% (n=42)	15.6%	
		Failure	1.8% (n=7)	8.0% (n=32)	9.8%	

stratified by BMI (Table 3) and menopausal status of patients (Table 4) was estimated in subjective cure rate scale as described. Surprisingly, clinical effectiveness of surgical SUI treatment did not depend on patients' BMI and type of midurethral sling, whereas menopausal status and ageing significantly influenced the outcome of anti-incontinence surgery. To evaluate correlation between age and clinical efficacy, we compared all patients aged <50 with consecutive age groups separately. Tables 5, 6 and 7 show the results of sling efficacy stratified by age groups. Stepwise logistic regression analysis clearly revealed that increasing age (per decade) is an independent risk factor for failure of sling procedure: OR=4.26 (95% CI, 2.25–8.09), $p<0.0001$ for retropubic surgery, OR=1.64 (95% CI, 1.10–2.46), $p=0.016$ for transobturator surgery, and OR=1.96 (95% CI, 1.96–2.84), $p=0.0006$ for both procedures.

Discussion

SUI represents one of the most common indications for surgery in women since approximately 4% of women will undergo surgery for SUI during their lifetime [16]. Obesity is a well-established risk factor for the development of SUI. Excessive weight affects pelvic floor structures by increase in intra-abdominal pressure and possibly by neurophysiological mechanisms. However, much less is known about the influence of obesity on the effectiveness of the SUI surgical treatment. Clinical data clearly show that the results of Marshall–Marchetti–Krantz vesicourethropexy and Burch colposuspension do not depend on BMI of treated patients [17]. A study done by Cummings et al. proved that suburethral sling may be used with high success rate even in morbidly obese patients [18]. The Korean study also showed that BMI did not have an influence on the midurethral sling success rates [19]. By contrast, Hellberg et al. found increased failure rates in obese (BMI, 30–34) and morbidly obese (BMI≥35) groups treated with tension-free vaginal tape (TVT) procedure [20]. They noted a dramatic decrease of the cure rates from 81.2% in normal weight woman to 52.1% in the obese group. Our data are consistent with those previously published by Rafii et al. concerning the effectiveness of TVT in overweight and obese women [21]. After 27 months follow-up, they did not find a difference in cure rate between the groups. This was also confirmed by Skriapas et al. [22]. They assessed the efficacy of TVT in 31 patients with BMI>40 and 52 patients with BMI<30. The cure rate after 18 months was 87% (BMI>40) and 92% (BMI<30), respectively. Similar to that, Lovatsis et al. also did not find differences in success rates between the normal weight and obese groups that underwent TVT procedure [23]. We can imagine that the positioning of the TVT in retropubic space provides good anchoring to adjacent tissues and possibly a low likelihood of tape displacement during sudden increase in intra-abdominal pressure. The question arises whether it is also true for transobturator tape. Our study did not show statistically significant differences in the efficacy of transobturator and retropubic procedures with regard to BMI. Based on these results, we can conclude that sling procedure success rates are acceptable and high enough to be a method of choice in the SUI treatment also in the overweight population. We noted, however, the trend toward worse treatment results in overweight patients. Due to relatively few patients with BMI≥35 in our study, it is possible that the adverse influence of morbid obesity on the efficacy of transobturator procedure was not revealed. Ageing and menopause are definite risk factors for anatomical as well as functional disorders of the female pelvic floor. As yet, there is no consensus whether deterioration of pelvic floor support after menopause is caused by: normative ageing itself, falling of circulating estrogen levels (menopausal ovarian failure) or a combination of both factors. A decrease in estrogen concentra-

Table 5 Efficacy of retropubic slings stratified by patients' age (n=201)

Age group (no.)	Cured	Improved	Failures	χ^2; p value
<50 (n=70)	88.6% (n=62)	10.0% (n=7)	1.4% (n=1)	
51–60 (n=74)	85.1% (n=63)	12.2% (n=9)	2.7% (n=2)	0.16; 0.68
61–70 (n=32)	65.6% (n=21)	25% (n=8)	9.4% (n=3)	3.68; 0.055
71–80+ (n=25)	20% (n=5)	40% (n=10)	40% (n=10)	26.77; <0.001

Table 6 Efficacy of transobturator slings stratified by patients' age (n=197)

Age group (no.)	Cured	Improved	Failures	χ^2; p value
<50 (n=64)	79.7% (n=51)	12.5% (n=8)	7.8% (n=5)	
51–60 (n=70)	78.6% (n=55)	14.3% (n=10)	7.1% (n=5)	0.02; 0.88
61–70 (n=36)	69.5% (n=25)	11.1% (n=4)	19.4% (n=7)	2.95; 0.085
71–80+ (n=27)	55.6% (n=15)	22.2% (n=6)	22.2% (n=6)	3.71; 0.054

Table 7 Efficacy of retropubic and transobturator slings stratified by patients' age (n=398)

Age group (no.)	Cured	Improved	Failures	χ^2; p value
<50 (n=134)	95.8% (n=113)	4.2% (n=15)	0% (n=6)	
51–60 (n=144)	81.9% (n=118)	13.2% (n=19)	4.9% (n=7)	0.2; 0.88
61–70 (n=68)	67.6% (n=46)	17.6% (n=12)	14.8% (n=10)	6.47; 0.01
71–80+ (n=52)	38.4% (n=20)	30.8% (n=16)	30.8% (n=16)	24.83; <0.001

tion associated with menopause has been considered as a factor responsible for the increasing urinary incontinence prevalence in ageing women. Ageing itself is definitely a risk factor for POP and functional disturbances of pelvic organs, but menopause in a natural way is a consequence of ageing, and therefore both these risk factors for pelvic disorders should be analysed simultaneously. Biomarkers of the ageing of female pelvic floor, which could not be reversed in elderly women by estrogen supplementation, are as follows: decreased number of vascular plexuses in the submucosa of the urethra and anal canal, and decrease in collagen type I/III ratio in the submucosa of the urethra and anal canal. They are accompanied by changes in the striated pelvic floor muscles such as: increased expression of cytoplasm p27kip1 protein associated with muscle shrinking, a higher proportion of isomyosin or myosin heavy chain type I/type II and ultrastructural changes in satellite cell number which are precursors of the myofibers and their number represents capacity for repair and regeneration of striated muscles including pelvic floor muscles [24]. Moreover, in postmenopausal vaginal tissue, a significantly higher elastic Young's modulus when compared to premenopausal was observed, which indicates that this tissue was stiffer. This finding signifies that postmenopausal tissue could be weaker than the premenopausal counterparts [25]. It is obvious that surgery itself could not correct biomarkers of pelvic floor ageing, and therefore, it seems that ageing itself is definitely a risk factor for the deterioration of continence mechanisms and consequently also for the efficacy of anti-incontinence surgery. This was also the case in our study where age at the time of operation was definitely a risk factor for diminished treatment efficacy. On the other hand, estrogens have a neuromodulation function, increasing sympathetic nerve density (which physiologically promote urine storage) in the pelvis and regulating neurotrophins; however, how this may affect continence is still unknown [26]. Moreover, taking into account messages from the WHI study that there was no significant increase in urinary incontinence in women aged <60 years while on hormone treatment it is reasonable to speculate that starting estrogen replacement soon after menopause ("therapeutic window") may be effective in preventing, or at least delaying, the onset of SUI.

To conclude, BMI does not influence the clinical effectiveness of either retropubic or transobturator suburethral slings in the treatment of female SUI, whereas both menopause and ageing had a detrimental influence on the final outcome of incontinence surgery.

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Conflicts of interest None.

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