

Tension-free Tape Ameliyatı Olan Hastalarda Yüksek Vücut Kitle İndeksinin Ameliyat Sonuçları Üzerine Etkisinin Değerlendirilmesi

The Evaluation of the Effect of High Body Mass Index on the Surgical Outcomes in Patients Undergoing Tension Free Tape Surgery

Hediye DAGDEVİREN¹, Huseyin CENGİZ¹, Sema SUZEN CAYPINAR², Sema BAGHAKI², Derya Ece ILIMAN², Murat EKİN²

¹ Istanbul Aydın University, Department of Obstetrics and Gynecology, Istanbul, Turkey

² University of Health Science, Bakirkoy Dr. Sadi Konuk Teaching and Research Hospital, Department of Gynecology and Obstetrics, Istanbul, Turkey

Özet

Amaç: Literatürde tension-free obturator tape (TOT) cerrahisinin kilolu ve obez kadınlardaki sonuçları ile ilgili çok az veri mevcuttur. Bu çalışmanın amacı vücut kitle indeksinin (VKİ) TOT cerrahi başarısına olan etkisini, hasta memnuniyetini ve cerrahi sonrası birinci yıldaki komplikasyonları değerlendirmektir.

Gereç ve Yöntemler: Bu çalışma prospektif kohort çalışması olup, stres üriner inkontinans (SUI) şikâyeti ile TOT ameliyatı olmuş 96 hasta çalışmaya dahil edildi. Ameliyat sonrası hastalar en az 1 yıl takip edildi. Hastalar VKİ ve Dünya Sağlık Örgütü (WHO) sınıflandırmasına göre üç gruba ayrıldı. Grup 1 (normal VKİ <25 kg/m²), Grup 2 (kilolu VKİ 25-30 kg/m²), ve Grup 3 (obez VKİ > 30 kg/m²). Subjektif ve objektif sonuçlar, komplikasyonlar ve hastaların yaşam kaliteleri doğrulanmış sorgu formları ile (UDI-6, IIQ-7) değerlendirildi. Sonuçlar gruplar arasında karşılaştırıldı.

Bulgular: Çalışmaya dahil edilen 96 hastanın 32'si normal kilolu, 32'si kilolu ve geri kalan 32'si ise obezdi. Komplikasyon oranları gruplar arasında istatistiksel olarak anlamlı bulunmadı (p>0.05). Tüm gruplarda hastaların UDI-6 ve IIQ-7 skorları bir yıllık takip sonrasında başlangıç değerine göre belirgin düşüş gösterdi. Tüm gruplarda bir saatlik ped testi ve öksürük testi (grup 1'de %71.8 ve grup 2 ve grup 3'de %84.3) sonuçlarına göre belirlenen toplam objektif kür oranının %80.2 (96 hastadan 77 tanesi) olduğu tespit edildi. Gruplar arasında istatistiksel olarak anlamlı fark yoktu.

Sonuç: TOT cerrahisi objektif ve subjektif başarı oranları tüm VKİ kategorilerinde benzer olarak izlendi. Artmış VKİ oranları ile komplikasyon oranları artmamaktadır.

Anahtar Kelimeler: Vücut kitle indeksi, Stres üriner inkontinans, Tension-free obturator tape.

Abstract

Objective: Only limited data are available on the outcome of tension-free obturator tape (TOT) procedures in overweight and obese women. This study aimed to assess the impact of body mass index (BMI) on TOT success rates, patient acceptability, and complications 1-year post-surgery.

Material and Methods: 96 women who suffered from stress urinary incontinence (SUI) underwent the TOT procedure were included to this prospective cohort study. Patients were followed for at least one year. Patients were divided into three different groups related to BMI according to the World Health Organization (WHO) classification; Group 1 (healthy BMI <25 kg/m²), Group 2 (overweight BMI 25-30 kg/m²), Group 3 (obese BMI > 30 kg/m²). The subjective and objective outcomes, complications, and quality of life were assessed by validated questionnaires (UDI-6, IIQ-7). The results were compared for each group.

Results: Of the 96 women, 32 were defined as having a healthy weight, 32 were overweight, and 32 were obese. The complication rate was not significantly different between the BMI groups (p>0.05). The UDI-6 and IIQ-7 scores at a one-year follow-up showed a significant reduction versus baseline in each group without significant differences between the BMI groups. The overall objective cure rate was 80.2% (77 out of 96) by 1-hour pad test and cough test (71.8% in group 1 and 84.3% in groups 2 and 3). There were no significant differences between the groups.

Conclusion: TOT procedure has similar objectives and subjective cure rates among all the BMI groups. Elevated BMI does not increase the complication rate.

Keywords: Body mass index, Stress urinary incontinence, Tension-free obturator tape.

Yazışma Adresi: Hediye DAGDEVİREN, İstanbul Aydın Üniversitesi Medikal Park Florya Hastanesi, İstanbul, Türkiye, Telefon: 05536161385,

Mail: hedyedagdeviren@gmail.com

ORCID No (Sırasıyla): 0000-0002-9384-4514, 0000-0001-6925-0989, 0000-0001-9482-5481, 0000-0003-3981-6069, 0000-0002-0409-4089, 0000-0002-4525-5125

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INTRODUCTION

Stress urinary incontinence (SUI) involves the involuntary loss of urine on effort or physical exertion (e.g., sporting activities) or sneezing or coughing (1, 2). Obesity is one of the critical risk factors for the development of urinary incontinence with age as well as pregnancy, childbirth, and reduced collagen turnover (2-4). Obesity is an increasing health problem, and some epidemiological studies have identified a positive association between obesity and an increased prevalence of SUI (5,6). Although weight loss may be beneficial to obese patients with SUI, definitive treatment may be best obtained through surgical intervention (6). Many techniques to correct SUI have been described over the years.

The Tension-free obturator tape (TOT) procedure launched by Delorme became a mainstay of SUI operations because of a high success rate and low risk of bladder perforation (7-9). However, there have been few studies to assess this procedure in overweight and obese women. The study aims to investigate the influence of Body Mass Index (BMI) on subjective and objective outcomes in patients with SUI who underwent the TOT surgery.

MATERIAL and METHODS

A total of 96 consecutive women with SUI who underwent TOT procedures were included in the study. Patient enrollment commenced in October 2010 and ended in December 2013. The study was planned according to the principles of the Helsinki Declaration. The Non-Invasive Human Research Ethics Committee and Local Health Ministry Authority approved the study (Approval number: 2015/125). All study participants provided written informed consent.

During diagnosis of the stress incontinence, we followed medical history, and performed a physical exam, which may include a rectal exam and a pelvic exam in women. To corroborate our first diagnosis, we benefit from laboratory tests to test for infection, traces of blood or other abnormalities. Also, we conducted a brief neurological exam to identify any pelvic nerve problems.

The follow-up period was at least one year. The patients were preoperatively evaluated through the review of their medical history, physical examinations, and urinalysis and urodynamic studies including post-void residual urine (PVR) determination, Valsalva leak point pressure (VLPP) and uroflowmetry. Patients were excluded if the PVR exceeded 100 ml. Turkish versions of Urogenital Distress Inventory (six-item, UDI-6) and Incontinence Impact Questionnaire (seven-item, IIQ-7) were administered and evaluated the baseline status of incontinence-related quality of life issues (Shumaker, Wyman, 1994, Uebersax, Wyman, 1995). Other patient characteristics and surgical details were extracted from the hospital charts. Postoperative follow-up was scheduled at one week after discharge as well as 1, 3, 6, and 12 months and yearly. At six months after surgery, the women underwent a full postoperative investigation including pelvic examination with a cough test, 1-h pad test, complete urod-

dynamic studies as well as the UDI-6 and IIQ-7. The same complete evaluation was then performed yearly thereafter.

The patient follow up was conducted 12 months after surgery. Women were invited to attend the clinic for review and to carry out a standardized pad test to evaluate the curative effects of SUI and to repeat the subjective outcome questionnaires for symptom experience and incontinence-related quality of life questionnaires. The objective cure rate was defined by a negative cough test and 1-h pad test <1 gram.

The operation was carried out with the I-STOP outside-in obturator tape (CL Medical Inc., Winchester, USA). The foley catheter was removed the next morning. The patients were classified into three groups according to the World Health Organization (WHO) and BMI: Group 1 (healthy BMI <25 kg/m²), Group 2 (overweight BMI 25-30 kg/m²), Group 3 (obese BMI > 30 kg/m²). Our Institutional Review Board approved the study.

Statistical analysis

Statistical analysis was performed using one-way ANOVA and Mann-Whitney U-test for continuous variables and the Chi-square or Fisher's exact test for categorical variables. A P value of <0.05 was considered statistically significant. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) 22.0 for Windows (SPSS, Chicago, IL, USA).

RESULTS

Of the 96 women, n=32 were defined as normal weight (group 1), 32 were overweight (group 2), and 32 were obese (group 3) according to the World Health Organization BMI classification.

Kruskal-Wallis / chi-square test

The mean age was 50.0±8.4 years in group 1, 50.7±9.3 in group 2 and 50.7±6.8 in group 3. The demographic and clinical characteristics of the patients are shown in **Table 1**, and no statistically significant differences were seen between groups other than for BMI.

The median BMI was 23 kg/m² (19-25) in Group 1, 29 kg/m² (25-30) in Group 2 and 35 kg/m² (32-45) in Group 3. Concomitant surgery with anterior or/and posterior colporrhaphy was performed during the TOT procedure to 11 women in group 1 and 14 women in group 2 and group 3. The average operation time including the cases with concomitant surgery was 64.5 minutes with no significant differences between the groups.

The initial urodynamic parameters, including post-void residual volume, maximum flow rate and maximal cystometric capacity, were not statistically different, while mean preoperative Valsalva leak point pressure (VLPP) were significantly lower in group 2 (48.7 ±38.7) than group 1 (72.0±38.4) and group 3 (79.7±44.7) (p<0.05).

Intraoperative and postoperative complications are summarized in **Table 2**. Postoperative de novo urge incontinen-

Table 1. Characteristics of patients undergoing the TOT procedure according to BMI groups.

				Group 1				Group 2				Group 3				P
Age (years)		aver.±s.d		50.0 ±	8.4			50.7 ±	9.3			50.7 ±	6.8			0.722
Med(Min-Max)		49	36	-	68		50	36	-	71		50	34	-	70	
BMI(kg/m)		aver.±s.d.		22.8 ±	1.8			28.3 ±	1.4			35.5 ±	2.9			0.001
Med(Min-Max)		23	19	-	25		29	25	-	30		35	32	-	45	
Occupation	Housewife	n-%		30	94%			30	94%			31	97%			0.810
	Working	n-%		2	6%			2	6%			1	3%			
Education	No	n-%		4	13%			6	19%			12	38%			p 0.05
	Primary	n-%		27	84%			25	78%			18	56%			
	High school	n-%		1	3%			0	0%			2	6%			
	University	n-%		0	0%			1	3%			0	0%			
Duration of the symptom(years)		aver.±s.d.		3.2 ±	2.2			5.8 ±	5.5			5.4 ±	5.3			0.210
	Med(Min-Max)		3	1	-	10		4	1	-	20		4	1	-	
Gravida		aver.±s.d.		4.6 ±	2.1			4.9 ±	2.9			4.8 ±	1.8			0.746
	Med(Min-Max)		4	2	-	13		4	1	-	12		5	2	-	
Parity		aver.±s.d.		3.8 ±	2.1			3.8 ±	2.2			4.1 ±	1.7			0.383
	Med(Min-Max)		3	1	-	12		3	1	-	11		4	2	-	
Menopausal status	No	n-%		15	47%			17	53%			21	66%			0.307
	Yes	n-%		17	53%			15	47%			11	34%			
Concomitant surgery with anterior or/ and posterior colporrhaphy	No	n-%		18	56%			21	66%			18	56%			0.678
	Yes	n-%		14	44%			11	34%			14	44%			
Operation time (min)		aver.±s.d.		68.0 ±	38.3			62.3 ±	40.6			63.3 ±	35.7			0.616
	Med(Min-Max)		55	25	-	165		45	25	-	195		50	25	-	
Follow up (months)		aver.±s.d.		44.3 ±	20.7			48.0 ±	18.8			41.3 ±	22.4			0.451
	Med(Min-Max)		49	12	-	74		49	12	-	77		44	12	-	

ce was the main postoperative complication (n=10, 10.4%). Bladder and urethral injury during needle passage or dissection occurred in 4 women (4.1%). There was no significant bleeding that required transfusion. Wound infection and mesh erosion were the other postoperative complications. The incidence of each complication was not significantly different between the BMI groups (p>0.05). Subjective outcomes at 12 months after surgery are reported in **Table 3**. Scores on the short forms of UDI-6 and IIQ-7 were compared preoperatively and postoperatively between groups.

Significant differences in preoperative scores were not observed between groups 1, 2 and 3. The UDI-6 and IIQ-7 scores at 12 months showed a significant reduction versus baseline in every group without significant differences between the BMI groups. Preop / postop UDI-6 and IIQ-7 change did not differ significantly among the three groups.

Objective measurement of SUI cure at 12 months following surgery was standardized by the 1-hour pad test (**Table 4**). Preoperative median test results were 10 (5-24 g) in group 1, 12 (4-24 g) in group 2, and 9 (4-28 g) in group 3; significant differences were not observed between groups.

Six- and 12-months post-operation pad test results showed a statistically significant decrease in all three groups (p<0.05) versus baseline. Preop/postop at six and 12 months differ significantly among the three groups. The overall objective cure rate was 80.2% (77 out of 96) by the 1-hour pad test and cough test including 71.8% in group 1 and 84.3% in groups 2 and 3. No significant differences were seen between the groups.

DISCUSSION

SUI is one of the most common indications for surgery in women; approximately 4% of women will undergo surgery for SUI during their lifetime (10-13). Although obesity is a well-established risk factor for the development of SUI and could impact the voiding pattern, the exact mechanism remains unclear. Higher intra-abdominal pressures have been observed in patients with greater BMI, and this may stress the pelvic floor secondary to a chronic state of increased pressure (14). Increased intra-abdominal pressure elevates pressure to maximum cystometric capacity. This decreases cough pressure transmission from the bladder to the urethra as well as decreasing VLPP. This may contribute to the deve-

Table 2. Intraoperative and postoperative complications according to the BMI groups.

		Group 1		Group 2		Group 3		P
Intraoperative								
Bladder injury	n-%	1	3%	1	3%	0	0%	1.000
Urethral injury	n-%	0	0%	1	3%	1	3%	0.760
Postoperative								
Wound infection	n-%	1	3%	0	0%	0	0%	0.590
Mesh erosion	n-%	1	3%	1	3%	1	0%	0.200
Voiding difficulty	n-%	1	3%	3	9%	0	0%	0.360
Denovo urgency	n-%	3	9%	3	9%	4	13%	0.894
Recurrent stress	n-%	4	13%	2	6%	3	9%	0.692
Kruskal-Wallis / chi-square test								

Table 3. Subjective outcomes with UDI-6 and IIQ-7 scores at 12 months after surgery.

		Group 1				Group 2				Group 3				P	
UDI	Preop	aver.±s.d.		11.1	±	3.6		10.6	±	4.6		10.6	±	4.4	0.915
		Med(Min-Max)	12	4	-	18	11	2	-	18	11	2	-	18	
	Postop	aver.±s.d.		8.2	±	3.6		7.3	±	3.5		6.9	±	2.9	0.361
		Med(Min-Max)	7	3	-	18	7	2	-	14	6	2	-	12	
Preop/Postop change		aver.±s.d.		-2.9	±	2.7		-3.3	±	2.8		-3.7	±	3.2	0.801
		Med(Min-Max)	-3	-8	-	2	-3	-10	-	0	-3	-10	-	0	
IIQ	Preop	aver.±s.d.		10.8	±	5.4		9.8	±	4.7		9.9	±	5.2	0.711
		Med(Min-Max)	11	2	-	21	9	2	-	21	10	1	-	21	
	Postop	aver.±s.d.		7.4	±	4.0		7.2	±	3.0		7.0	±	4.2	0.846
		Med(Min-Max)	7	2	-	18	7	2	-	13	6	1	-	20	
Preop/Postop change		aver.±s.d.		-3.4	±	3.1		-2.6	±	2.4		-2.9	±	3.3	0.631
		Med(Min-Max)	-3	-10	-	0	-2	-9	-	0	-2	-14	-	0	
Kruskal-Wallis / Wilcoxon test															

lopment of SUI in obese patients (15). However, much less is known about the influence of obesity on the effectiveness of SUI surgical treatment.

VLPP currently offers a reliable way of assessing the function of the bladder neck and proximal urethra. However, several technical factors may influence the performance of the VLPP and should be recognized by all clinicians using the test. In our clinic, 3 different clinicians perform the urodynamic test therefore VLLP points may vary. Additionally; the VLPP is an evolving test and is not fully standardized (16).

Obesity has long been considered a significant risk factor for the failure of incontinence surgery. Increased failure rates are reported in obese women undergoing needle suspension or retropubic procedures (17). Mid-urethral slings have gained in popularity since their introduction into clinical practice. They are now the “standard” treatment in the surgical management of SUI. Conflicting data exist about the success rate of MUS when used in obese patients. Most published studies report on retropubic TVT procedures, and there is limited data regarding the TOT procedure. A study by Gillon *et al.* clearly shows that the results of Marshall–Marchetti–

Table 4. Objective outcomes at 6 and 12 months after surgery

		Group 1			Group 2			Group 3			P		
Pad Test	Preop	mean.±s.d.	10.6	±	4.2	11.5	±	5.2	10.5	±	6.1	0.479	
		Med(Min-Max)	10	5	-	24	12	4	-	24	9		4
	Postop 6 months	mean.±s.d.	2.0 _a	±	3.1	2.0 _{a,b}	±	4.7	1.6 _b	±	4.4	0.000	
		Med(Min-Max)	1	0	-	12	0	0	-	16	0		0
	Postop 12 months	mean.±s.d.	1.7 _a	±	2.8	1.7 _{a,b}	±	4.2	1.8 _b	±	4.9	0.028	
		Med(Min-Max)	1	0	-	10	0	0	-	14	0		0
Preop/Postop 6 months change	mean.±s.d.	-8.6	±	5.4	-9.6	±	5.8	-8.9	±	6.1	0.789		
	Med(Min-Max)	-8	-24	-	2	-8	-24	-	2	-8		-24	-
Preop/Postop 12 months change	mean.±s.d.	-9.0	±	5.1	-9.8	±	5.5	-8.7	±	6.4	0.708		
	Med(Min-Max)	-8	-24	-	1	-8	-24	-	-2	-7		-24	-
Kruskal-Wallis (Mann-Whitney u test) / Wilcoxon test													

Krantz vesicourethropexy and Burch colposuspension do not depend on the BMI of the treated patients (18). Cummings et al. reported that the suburethral sling might be used with a high success rate even in morbidly obese patients (19). Skriapas et al. (20) compared 31 morbidly obese patients with BMI > 40 kg/m² and 52 patients with a BMI of <30 kg/m² with a mean follow-up of 18.5 months. The objective cure rate in the control group was 92.3% and 86.9% for the morbidly obese group—there were no significant differences (20). In contrast, responses to a mailed questionnaire by 970 women who underwent TVT indicated a markedly unfavorable outcome in 61 very obese women (BMI > 35 kg/m²). The overall cure rate in 291 women of healthy weight was 81.2% versus 52.1% in the 61 very obese (21).

In this study, we showed that the TOT procedure was equally safe and effective for treating SUI regardless of BMI. The postoperative quality of life was similarly improved for women in each weight group. There were no significant differences in the complication rate. Besides, two studies using the Tension-free obturator tape procedures showed no significant association between BMI and surgical outcomes. Even if the cure was defined differently in these two studies, the results are in line with our findings after a follow up for nearly two years (22,23). Liapis et al. reported an objective cure rate of 82.4% in 115 subjects after TOT based on the pad test 4 years after treatment. There was a slightly lower objective success rate at 24 months of follow-up (24).

Yonguc and colleagues showed that the objective cure, subjective cure and patient satisfaction rates of 126 women at one year after TOT were 89.6, 86.5 and 92% respectively. During a 5-year follow-up, the objective cure rate was stable

at 87.3%, whereas the subjective cure and patient satisfaction rates were only 65.9 and 73% respectively (25).

Differences between the results are due to different lengths of follow-up, different cure definitions, and variations in the type of continence surgery. Therefore, comparisons are difficult. The main limitation of our study was the short duration of follow up, the small sample size and the fact that we limited our cohort to the woman with isolated SUI.

We believe that BMI does not influence the short-term outcome and safety of TOT in the treatment of female SUI. Patient selection with preoperative urodynamics may improve the outcome independent from BMI, but BMI may have an overall negative effect on long-term cure rates.

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