

# PELVIPERINEOLOGY

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## EDITORIAL

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**Dear Reader;**

In the second issue of 2024, we are here with very high-quality scientific studies. We are happy that our readability rate is increasing every day. In this issue, we are here with 5 original article, 1 case report and 1 brief report.

I would like to express my gratitude to everyone who contributed and hope to see you again in the next issue.

**Prof. Dr. Ahmet Akın SIVASLIOĞLU**





# Body mass index, waist/hip ratio and sexual dysfunction

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## ABSTRACT

**Objectives:** Sexual functions are the result of multifactorial and complex processes. While the negative effects of weight gain in men are clearly known, this is not clearly known in women and also there are few studies on the subject. This study aims to determine the effects of body mass index (BMI) on sexual functions.

**Materials and Methods:** This study was designed as a cross-sectional and prospective research. Participants were divided into three groups according to their BMI data. The distribution of the participants to the groups is as follows: 80 normal weight (41.2%), 59 overweight (30.4%), and 55 obese (28.4%) participants. Female sexual function index (FSFI) was used to evaluate sexual dysfunctions.

**Results:** It was determined that 40.7% of the participants had sexual dysfunction. It was observed that there was no significant difference between BMI groups in terms of sexual dysfunction ( $p=0.336$ ). However, as a result of the evaluation of FSFI scores according to its domains, a statistically significant decrease was found in orgasm ( $r=-0.151$ ,  $p=0.036$ ) and FSFI total ( $r=-0.158$ ,  $p=0.028$ ) scores as WHR increased, and in orgasm ( $r=-0.205$ ,  $p=0.004$ ) scores as BMI increased.

**Conclusion:** It was observed that obesity is particularly associated with orgasm in women. The increase in the waist/hip ratio appears to be associated with sexual dysfunction.

**Keywords:** BMI; WHR; obesity; sexual dysfunction

## INTRODUCTION

Female sexuality has a multifactorial and complex nature. Many individual, social, and cultural factors effect sexuality. Female sexual dysfunctions (FSD) are classified as desire and arousal

disorders, dyspareunia, inhibited orgasm, and satisfaction.<sup>1</sup> FSD is a very common health problem that effects 22-93% of women and varies according to age.<sup>2,3</sup> Obesity and metabolic syndrome have now become a public health crisis and their prevalence continues to increase rapidly worldwide. Obesity is a risk factor

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for chronic diseases, particularly diabetes and cardiovascular diseases.<sup>4</sup> The effects of weight gain and obesity on overall health have been given more attention in the literature. However, it is seen that there are few studies evaluating the effects of weight gain and obesity on sexuality. The distinction between the terms overweight and obese is determined by using a formula called body mass index (BMI). BMI is calculated according to the person's weight and height.<sup>5</sup> When the literature is reviewed, it is seen that the effects of BMI on sexual functions are quite variable. Some studies suggest that an increase in BMI makes sex less satisfying due to negative body image perception, while others state that obesity does not lead to any sexual dysfunction.<sup>6,7</sup> This study was conducted to contribute to the literature on the subject by evaluating the effects of BMI and additionally waist/hip ratio on sexual functions.

## MATERIALS AND METHODS

This study was conducted as a prospective, cross-sectional research. The patient sample was selected from among the women who visited the obstetrics and gynecology outpatient clinic of our hospital between November 2021 and April 2022. Ethics committee approval was obtained from the Clinical Research Ethics Committee of Yozgat Bozok University Hospital before starting the study (2017-KAEK-189\_2022.12.29\_11). In addition, signed consent was obtained from all participants.

In this study, the National Heart, Lung, and Blood Institute's terminology was used with the categories of normal weight (BMI 18.5-<25), overweight (BMI 25-<30), and obesity (BMI ≥30). A total of 128 patients were included in the study. Women between the ages of 18-50, who had a regular heterosexual relationship for the last 6 months and had regular menstrual periods, participated in the study. Women with the following conditions were not included in the study: Pregnant or in the first 8 weeks postpartum, diabetes mellitus (fasting blood glucose >126 mg/dL) or impaired glucose tolerance (glucose levels 140-200 mg/dL after 2 hours from 75 g oral glucose load), uremia, multiple sclerosis, chronic alcoholism (≥500g/week intake), neoplasm, current moderate or severe depression, current or previous psychosis or dissociative symptoms, current substance abuse or dependency, bipolar disorder, cardiovascular disease, gynecological surgery, lower urinary tract symptoms, pelvic trauma, polycystic ovarian syndrome, abnormal thyroid function, and taking any medication.

Demographic characteristics of the participants including age, BMI, waist-hip ratio (WHR), parity, delivery method of the pregnancy, cigarettes and alcohol use, and economic level were recorded.

Body weight was measured with patients minimally clothed using a digital scale (Seca 707, Hanover, Md., USA) and rounded to the nearest 100 grams. Similarly, height was measured without shoes using a tape measure with shoulders in normal alignment. BMI was calculated by dividing weight in kilograms (kg) by the square of height (m<sup>2</sup>). Waist circumference was measured at the narrowest level between the costal margin and the iliac crest during normal breathing while the hip circumference was measured at the widest level on the hips. WHR was calculated.

The sexual function of women was assessed using Turkish version of female sexual function index (FSFI), which has been previously validated in Turkish by Turkish Society of Andrology.<sup>3,8</sup> FSFI has six domains including, (1<sup>th</sup>) Desire (questions 1 and 2); (2<sup>nd</sup>) Arousal (questions 3, 4, 5 and 6); (3<sup>rd</sup>) Lubrication (questions 7, 8, 9 and 10); (4<sup>th</sup>) Orgasm (questions 11, 12 and 13); (5<sup>th</sup>) Satisfaction (questions 14, 15 and 16); (6<sup>th</sup>) Pain (questions 17, 18 and 19). The total-scale score range was between 2 to 36. The cut-off value was 26.55. A value equal to or below this point was assumed as sexual dysfunction.

All blood samples were obtained in the morning between 8 AM and 9 AM, after overnight fasting and during the early follicular phase of a spontaneous or progesterone-induced menstrual cycle. Endocrine profile (including pituitary hormones, ovarian and adrenal steroids), serum lipids, fasting glucose and insulin levels were measured. Serum follicle-stimulating hormone, luteinizing hormone, estradiol, prolactin, insulin, and thyroid-stimulating hormone (0.38-5.33 mIU/mL), FT4, FT3, levels were determined by the chemiluminescent method. Fasting glucose, total cholesterol, high-density lipoprotein cholesterol and triglyceride levels were measured spectrophotometrically using an enzymatic colorimetric assay (Roche Integrated system, Mannheim, Germany). Low-density lipoprotein cholesterol was calculated using the Friedewald formula. Hematological parameters were measured in a standard complete blood count device. Insulin resistance was calculated using the homeostatic model assessment insulin resistance index (HOMA-IR). HOMA-IR formula: fasting plasma glucose (mg/dL) × fasting serum insulin (mU/mL)/405.

## Statistical Analysis

Statistical package program SPSS 20 (IBM Corp. released 2011. IBM SPSS Statistics for Windows, version 20.0, Armonk, NY: IBM Corp.) was used to evaluate the data. Data was expressed as mean ± standard deviation and in percentages. Continuous variables were investigated using analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk's test) to determine whether or not they are normally distributed. If the numerical data was non-parametric, the Kruskal-Wallis test was conducted, if it was parametric,

a One-Way ANOVA test was carried out and Bonferroni correction was used for the post-hoc assessment. For double comparison, The Mann-Whitney U test was utilized for the non-parametric numerical data while the Student t-test was adopted for the parametric numerical data. Relationships between categorical variables were analyzed by chi-square test. Bivariate correlations were investigated by Spearman's correlation analysis and  $p < 0.05$  was accepted as statistically significant.

## RESULTS

A total of 194 participants who met the inclusion criteria were included in the study. Participants were divided into three groups according to their BMI data (BMI 18.5-<25= normal weight, BMI 25-<30=, overweight, and BMI  $\geq 30$ = obesity). The distribution of the participants to the groups is as follows: 80 normal weight (41.2%), 59 overweight (30.4%), and 55 obese (28.4%) participants.

The demographic characteristics of the participants are shown in Table 1. The mean age of the participants is  $27.6 \pm 6.0$ , the mean BMI is  $26.8 \pm 5.4$ , the mean WHR is  $0.7 \pm 0.1$ , the mean gravidity is  $0.8 \pm 0.9$ . There was no significant difference between the groups in these values ( $p > 0.05$ ). In addition, no significant difference was found between the economic levels of the participants and the rates of smoking and alcohol use ( $p > 0.05$ ). In terms of the education levels of the participants, it was found that there was a statistically significant increase in the education level as the

BMI decreased ( $p = 0.005$ ). However, in terms of the relationship between education level and FSFI domains, no statistically significant relationship was found between education level and any of the FSFI domains ( $p > 0.05$ ) (data not shown). And also there was no statistically significant relationship between the groups in terms of the laboratory characteristics of the participants (Table 2).

Table 3 shows FSFI scores by BMI groups. It was found that 40.7% of the participants had sexual dysfunction. The rate of sexual dysfunction was found to be 45.8% in women with a BMI between 25-30 and 32.7% in women with a BMI of  $> 30$ . There was no significant difference between the groups in terms of sexual dysfunction ( $p = 0.336$ ). In terms of FSFI sub-scores, a statistically significant difference was found between the groups, with the FSFI orgasm domain being  $4.7 \pm 0.8$  in the normal group,  $4.2 \pm 0.8$  in the overweight group, and  $4.2 \pm 0.9$  in the obese group ( $p = 0.002$ ). On the other hand, no statistically significant difference was found between the groups formed according to BMI in other domains of FSFI ( $p > 0.05$ ).

As shown in Table 4, FSFI parameters and both WHR and BMI values were evaluated by correlation analysis. Accordingly, it was seen that there was a statistically significant decrease both in orgasm ( $r = -0.151$ ,  $p = 0.036$ ) and FSFI total scores ( $r = -0.158$ ,  $p = 0.028$ ) as WHR increased, and a statistically significant decrease in orgasm score ( $r = -0.205$ ,  $p = 0.004$ ) as BMI increased.

**Table 1. Demographic features**

		BMI group			p
		<25	25-30	>30	
Age (years)		26.7 $\pm$ 5.0	28.8 $\pm$ 6.5	27.5 $\pm$ 6.8	0.225
BMI (kg/m <sup>2</sup> )		22.6 $\pm$ 1.7	26.7 $\pm$ 2.1	33.1 $\pm$ 5.2	0.000
WHR		0.7 $\pm$ 0.1	0.7 $\pm$ 0.1	0.7 $\pm$ 0.1	0.032
Parity		0.5 $\pm$ 0.8	1 $\pm$ 1	0.8 $\pm$ 0.9	0.015
Type of birth	Nulliparity	51 (63.8%)	25 (42.4%)	30 (54.5%)	0.153
	Vaginal labor	4 (5.0%)	5 (8.5%)	5 (9.1%)	
	Cesarean section	25 (31.3%)	29 (49.2%)	20 (36.4%)	
Monthly income	0-3000 TL	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.468
	3000-5000 TL	22 (27.5%)	22 (37.3%)	17 (30.9%)	
	>5000 TL	58 (72.5%)	37 (62.7%)	38 (69.1%)	
Level of education	Primary school	0 (0.0%)	9 (15.3%)	6 (10.9%)	0.005
	Secondary school	34 (42.5%)	23 (39.0%)	28 (50.9%)	
	High school	46 (57.5%)	27 (45.8%)	21 (38.2%)	
Smoking	No	50 (62.5%)	29 (49.2%)	36 (65.5%)	0.156
	Yes	30 (37.5%)	30 (50.8%)	19 (34.5%)	
Alcohol use	No	77 (96.3%)	57 (96.6%)	55 (100.0%)	0.359
	Yes	3 (3.8%)	2 (3.4%)	0 (0.0%)	

BMI: Body mass index; WHR: Waist-hip ratio; TL: Turkish liras

**Table 2. Comparison of endocrine, biochemical, and metabolic characteristics among BMI groups**

	BMI group			p
	<25	25-30	>30	
HOMA-IR	2.2±1.2	2.4±1.5	2.2±1.3	0.758
Fasting glucose (mg/dL)	88.9±9.1	89±8	89.8±9.6	0.850
Insulin (µIU/mL)	9.8±5.2	10.9±6.4	9.7±5.3	0.715
FSH (mIU/mL)	8±17.5	6.8±7.5	12.4±29.5	0.854
LH (mIU/mL)	9.5±9.6	6.8±3.4	8.8±10.5	0.167
Estradiol (mIU/mL)	50.3±37.3	48±16.2	44.1±15.2	0.368
Progesterone (mIU/mL)	9.9±5.7	10.3±4.7	10.6±4.9	0.608
Prolaktin (mIU/mL)	13.2±8.6	14.5±8.8	15.7±9.8	0.175
TSH (mIU/mL)	2.1±1	2±0.8	2.2±1	0.344
T3 (mIU/mL)	0.3±0.2	0.5±0.7	0.4±0.3	0.586
T4 (mIU/mL)	1.3±0.2	1.2±0.2	1.3±0.2	0.105
HDL (mg/dL)	52.7±11.2	51.4±12.4	52.6±12.4	0.526
LDL (mg/dL)	93.5±23.4	88.2±27	96.5±26.8	0.378
HB (mg/dL)	13.3±0.9	13.3±1	13.3±0.9	0.924
WBC (K/mL)	7.2±2.1	7.6±2.5	7±2	0.395

BMI: Body mass index; HOMA-IR: Homeostatic model assessment insulin resistance index; HDL-C: HDL cholesterol; LDL-C: LDL cholesterol; FSH: Follicle-stimulating hormone; LH: Luteinizing hormone; TSH: Thyroid stimulating hormone

**Table 3. FSFI scores in all patients**

	BMI group			p
	<25	25-30	>30	
Desire	4.2±1	3.8±0.8	3.9±0.9	0.051
Arousal	4.3±0.8	4.1±0.6	4.4±0.6	0.315
Lubrication	4.9±0.8	4.8±0.7	4.8±0.7	0.567
Orgasm	4.7±0.8	4.2±0.8	4.2±0.9	0.002
Satisfaction	5.3±0.9	4.9±0.8	5.1±0.7	0.120
Pain	4.7±1.4	4.6±1.1	4.6±1.1	0.679
Total FSFI score	28.1±3.4	26.6±2.2	27±2.1	0.058
Sexual dysfunction	34 (42.5%)	27 (45.8%)	18 (32.7%)	0.336

BMI: Body mass index; FSFI: Female sexual function index

**Table 4. Correlation analysis between BMI and WHR and FSFI scores**

	BMI		WHR	
	r	p	r	p
Desire	-0.101	0.161	-0.029	0.692
Arousal	0.082	0.254	-0.018	0.806
Lubrication	-0.062	0.390	-0.064	0.375
Orgasm	-0.205	0.004	-0.151	0.036
Satisfaction	-0.059	0.413	-0.138	0.056
Pain	0.030	0.682	-0.124	0.085
Total FSFI score	-0.021	0.769	-0.158	0.028

BMI: Body mass index; WHR: Waist-hip ratio; FSFI: Female sexual function index

## DISCUSSION

It was found that 40.7% of the participants in the study had sexual dysfunction. It was determined that 45.8% of the overweight women and 32.7% of the obese women had sexual dysfunction. These results suggest that the increase in BMI is not associated with sexual dysfunction. On the other hand, as a result of the evaluation made according to FSFI domains, it is seen that increased BMI is associated with orgasmic disorder. A similar relationship is also seen in the increase in WHR. However, it was determined that the FSFI total scores decreased with the increase in WHR.

Rates of sexual dysfunction in women vary by years and countries. In 2017, this rate was found to be quite high as 91.5% by Rabiepoor et al.<sup>5</sup> likewise the results of the study of Martins e Silva et al.<sup>9</sup> from Brazil. On the other hand, in a study conducted in Iran, sexual dysfunction was found in 27.3% of women of reproductive age.<sup>10</sup> In another study conducted with 1749 women between the ages of 18-59 in the USA, this rate was found to be 43%. In a study from our country, this rate was found to be 53%.<sup>11,12</sup> Although it varies from society to society, it is seen that this rate is between 17-55% in the general evaluation and it was determined as 40.7% in this study.

In the evaluation of sexual dysfunction rates in obese and overweight women, Rabiepoor et al.<sup>5</sup> found high rates such as 91.3% and 91.8%. Similarly, Yaylali et al.<sup>13</sup> reported a rate of 86%, which is quite high. On the other hand, in a few studies in which normal weight women were also evaluated, as in this study, no statistically significant difference was found between sexual dysfunction and BMI.<sup>14,15</sup> However, weight gain and obesity seem to cause some sexual problems. While Kolocin draws attention to low sexual desire and sexual interest disorders<sup>16</sup>, Larsen et al.<sup>17</sup> state that obese individuals experience difficulty in orgasm and have satisfaction problems.<sup>16</sup> Sexuality is a multifactorial experience; thus it is very difficult to evaluate the effects of obesity alone. Assimakopoulos et al.<sup>18</sup> explain the effect of obesity with 3 possible mechanisms: (a) insulin resistance and related hormonal changes; (b) dyslipidemia and related drugs; and (c) psychological problems. However, there are insufficient data to verify these possible effects. When clinical studies were examined, Esposito et al.<sup>19</sup> stated that total fat amount was more important than fat distribution in the evaluation of sexual dysfunction according to WHR and BMI values, and they did not find a relationship with WHR. According to Esposito's study, BMI has a positive but non-significant relationship with sexual desire and does not effect pain, but effects arousal, lubrication, satisfaction, and orgasm. In our study, we found a relationship between increased WHR and difficulty in orgasm. As Esposito stated, some biochemical processes related to the total amount of fat can cause events that will effect sexual functions. However, as seen in our study, the variability in fat distribution can create problems related to different processes. The fact that the increase in waist circumference creates metabolic and cardiac problems indicates that fat distribution may be related to many processes. Of course, it's not just about fat distribution. Sexual activity is also closely related to WHR.

Studies show that the male population prefers women with narrow waists and wide hips. Although men's lust for a woman varies according to ethnic and cultural factors, the "hourglass" appearance is a feature that is accepted and especially

emphasized in Latin culture. WHR =0.8 is generally considered the most attractive appearance.<sup>20</sup> In addition to all these, increase in WHR and short height are stated as causes of sexual dysfunction, particularly in studies from Brazil.<sup>18</sup> The review of studies evaluating the effects of obesity on sexual functions with psychological scales reveals different dimensions of the issue. It is seen that comorbid conditions in obese individuals cause anxiety and depression, and also cause problems with self-esteem and body image.<sup>21,22</sup> These problems and negative perception of obesity cause lower sexual satisfaction in obese women.<sup>7</sup> Arguete et al.<sup>23</sup> define this condition as "the presence of a silhouette that is assumed to be ideal for sufficient sexual attractiveness". Despite all these negative results, there are also studies in the literature stating that overweight and obese women enjoy excessive pleasure. Individuals may not be satisfied with their body image perceptions, however the interaction and relationship dynamics of the couples cause variable results.

### Study Limitations

The fact that there are few studies on the subject is a clear indication of the importance of our study. However, the most important limitation of this study is that the pathophysiological processes that can define the current results and the sexual functions of the partner could not be evaluated.

### CONCLUSION

The effects of obesity in sexuality are complex. Our results reveal that obesity specifically refers to problems with orgasm. Excessive fat distribution in the waist causes sexual dysfunction. However, randomized controlled studies with different designs are needed to explain the effects.

### ETHICS

**Ethics Committee Approval:** Ethics committee approval was obtained from the Clinical Research Ethics Committee of Yozgat Bozok University Hospital before starting the study (2017-KAEK-189\_2022.12.29\_11).

**Informed Consent:** Signed consent was obtained from all participants.

### Contributions

Concept: D.A.K. A.C.K.; Design: E.B.; Data Collection or Processing: E.B., N.S.Ş., D.A.K.; Analysis or Interpretation: E.B.; Literature Search: A.C.K., D.A.K.; Writing: D.A.K., E.B.

### DISCLOSURES

**Conflict of Interest:** No conflict of interest was declared by the authors.

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# Evaluation of the results of loop electrosurgical excision procedure surgical margin positivity and recurrence

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## ABSTRACT

**Objectives:** Loop electrosurgical excision procedure (LEEP), which is effectively used in the diagnosis and treatment of cervical intraepithelial neoplasia (CIN), can be performed under general and local anesthesia. The aim of this study is to retrospectively examine whether the chosen anesthesia method affects the surgical margin and the factors affecting the surgical margin.

**Materials and Methods:** Data of 122 patients who met the inclusion criteria and underwent LEEP between 2016 and 2021 were retrospectively analyzed. Demographic data (age, body mass index, alcohol and smoking); gynecological anamnesis: Gravida, parity, number of living children, number of abortions, menopausal status, type of contraceptive method and presence of additional metabolic diseases (hypertension, diabetes, coronary artery disease) were recorded from the patients' files and epicrisis. LEEP indications and pre-LEEP HPV information were recorded. LEEP procedure data: Anesthesia method used; general or local anesthesia, positive surgical margin rate (for example, the presence of CIN II/III at the ectocervical and/or endocervical resection margins was considered positive), size of the removed piece (anteroposterior length, transverse length and height, volume), pathology results were recorded and factors affecting margin positivity were examined.

**Results:** It was determined that the type of anesthesia administered (general or local), patient age older than 40 years, patient being in menopause, and the size and volume of the sample taken during LEEP had no effect on margin positivity, whereas high-grade cervical cytology before LEEP, the presence of endocervical gland involvement, and the number of multiple passes in the excision were shown to increase the risk for margin positivity.

**Conclusion:** We found that high-grade cervical cytology before LEEP, the presence of endocervical gland involvement, and multiple passes in excision were risk factors predicting a positive surgical margin; however, the type of anesthesia did not affect the surgical margin.

**Keywords:** HPV; LEEP; cervical intraepithelial neoplasia

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## INTRODUCTION

Cervical cancer is among the preventable cancers with screening methods. Cervical cancer precursor lesions are defined as cervical intraepithelial neoplasia (CIN). CINs can be detected by smear and colposcopic biopsy and can be treated with conization methods [cold conization, loop electrosurgical excision procedure (LEEP)] without the need for advanced surgical operations.

Conization is the surgical removal of the lesioned part of the cervix in the shape of a cone. The application of this procedure using a scalpel is called cold conization, and the application of this procedure using a “U” shaped cautery tip is called the LEEP procedure. The presence of a lesion on the surgical margins of the piece taken as a result of post-procedure pathology is considered a positive surgical margin/positive margin, and in this case, the patient may require reconization or further surgery (trachelectomy) or hysterectomy. LEEP can be performed under local anesthesia (LA) or general anesthesia (GA), depending on patient preference, surgeon experience, and clinical parameters such as cervical anatomy, prolapse of the vaginal side walls, and pain during colposcopy.<sup>1</sup> The advantages of LEEP performed under LA include avoiding the risks associated with GA, eliminating the need for an operating theater, and, consequently, being more available and lower in cost. However, LEEP under LA can be more difficult to perform and can potentially lead to a smaller sample size and higher recurrence rates.<sup>2</sup> Data on positive surgical margin rates, the risk of recurrence of the cervical lesion, and the need for reconization are sparse and inconsistent in the literature. Some studies suggest that a positive margin after LEEP is an important factor in recurrence and an indicator of the quality of clinical practice.<sup>3</sup> A meta-analysis has shown that positive surgical margins have an increased risk of residual or recurrence compared to negative surgical margins.<sup>4</sup> Previous studies have also found a fivefold increase in the risk of treatment failure with positive margins. However, it is not yet clear which factors influence positive margins after LEEP surgery. Studies evaluating LEEP procedures performed under GA and LA have found that patient satisfaction, pain, and procedure related complications rates are comparable between the two approaches. However, data on the rate of positive surgical margin detection after LEEP procedures performed under GA and LA and the need for reconization procedures are insufficient in the current literature.

In this retrospective study, we compared the rate of positive surgical margins, the need for reconization and post LEEP findings in patients who underwent LEEP under GA and LA.

## MATERIALS AND METHODS

This retrospective study was carried out by retrospectively analyzing the cases treated with LEEP procedures and followed up between January 1, 2016 and December 31, 2021 in the Gynecological Oncology Clinic of Muğla Sıtkı Koçman University Training and Research Hospital. The study was approved by the Clinical Research Ethics Committee of Muğla Sıtkı Koçman University (E-72855364-050.01.04-608052).

Demographic data [age, body mass index (BMI), smoking]; gynecological anamnesis: Gravida, parity, number of living children, number of abortions, menopausal status, type of contraceptive method, and presence of additional metabolic diseases (hypertension, diabetes, coronary artery disease) were recorded from the patients' files and epicrisis. LEEP indications and pre-LEEP HPV information were recorded. LEEP procedure data: Method of anesthesia used; general or LA; positive surgical margin rate (for example, the presence of CIN II/III at the ectocervical and/or endocervical resection margins was considered positive); size of the removed piece (anteroposterior length, transverse length, and height); pathology results were recorded.

The LEEP procedure was performed by a single gynecology oncology specialist with knowledge and experience in the field.

Digene HC2 HPV DNA test (Qiagen Germantown, Inc., MD, USA) was used for HPV typing in our hospital. This kit can detect 13 types of high-risk HPV (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) and 5 types of low-risk HPV (6, 11, 42, 43, 44).

SurePath liquid-based cytology preparations available in our hospital were used as smear method.

In the LEEP procedure performed under LA, patients were prepared in the dorsal lithotomy position in the local procedure room in the outpatient clinic. A sterile speculum was inserted into the vagina, and 8 cc prilocaine was applied to the four quadrants of the cervix at 2, 4, 7, and 11 o'clock. After waiting for 60 seconds to ensure adequate anesthesia, cervical excision was performed using a LEEP tip suitable for the size of the cervix. The hemorrhages occurring in the cervix were coagulated with a 50W knob-tipped cautery.

In the patient group who underwent GA, standard monitoring was performed according to ASA recommendations after the patients were taken to the operating room. All patients received 1.5 mg/kg propofol, 1 mcg/kg fentanyl, and a laryngeal mask suitable for the patient' body weight under standard anesthetic management. For maintenance of anesthesia, 1 MAC desflurane and a 0.4/0.6 oxygen/air mixture were administered. After the anesthesiologist gave approval to start the procedure, a sterile



speculum was inserted into the vagina, and cervical excision was performed using a LEEP tip in accordance with the size of the cervix. The hemorrhages occurring in the cervix were coagulated with a 50W knob-tipped cautery.

In both procedures, the samples were taken to the pathology laboratory in a formaldehyde solution.

Age, smoking status, presence of chronic diseases, BMI, number of pregnancies and births, presence of menopause, whether they used a hormonal contraceptive method, smear result, HPV positivity status, cervical biopsy result (if any), under which anesthesia method the LEEP procedure was performed (general or local), size of the piece taken after the LEEP procedure, pathology result reports, presence of a positive surgical margin, and presence of endocervical gland involvement were recorded as data.

### Population and Sample of the Study

**Criteria for inclusion in the study:** Patients who were found to be HPV 16-18 positive, had intraepithelial lesions as a result of smear, and underwent LEEP due to HGSIL (CIN II-III) as a result of colposcopic biopsy at the Gynecological Oncology Clinic of Muğla Sıtkı Koçman University Training and Research Hospital were included in the study.

**Exclusion criteria for the study:** Patients who did not attend routine check-ups and were lost to follow-up within the first year after the procedure were not included in the study.

### Statistical Analysis

Statistical analyses were performed in the Statistical Package for Social Sciences (SPSS) version 18.0 package program. The descriptive statistics of the data were given in tables. The suitability of the numerically measured data for a normal distribution was analyzed by the Shapiro-Wilk test. Parametric tests were used for normally distributed variables, and non-

parametric tests were used for non-normally distributed variables. Student’s independent, Mann-Whitney U, and chi-square (Pearson chi-square, Monte Carlo chi-square) tests were used to compare independent groups with each other. A probability value of  $p < 0.05$  was considered significant.

### RESULTS

A total of 122 patients who were found to be HPV 16-18 positive in screening, who had intraepithelial lesions on smear, who underwent LEEP after colposcopic biopsy revealed HGSIL (CIN II-III), and including 61 patients who were margin-positive and 61 patients who were margin-negative according to pathology results were included in our study. When the groups were evaluated in terms of demographic data, it was observed that they were homogenous (Table 1).

There was no statistically significant difference between margin positive and negative patients in terms of age older than 40 years ( $p = 0.415$ ). The mean age of margin-positive patients was  $34.8 \pm 8.81$  years, and the mean age of margin-negative patients was  $37.8 \pm 11.39$  years. It was found that body mass index and intrauterine device use did not make a statistically significant difference in margin positivity ( $p = 0.887$ ,  $p = 1.000$ ). It was observed that 29.50% ( $n = 18$ ) of the margin-positive women had alcohol consumption, and alcohol consumption did not make a difference in margin positivity or negativity when compared with non-users ( $p = 0.840$ ). Similarly, for smoking, 41.00% ( $n = 25$ ) of the patients with margin positivity were found to be smokers, and smoking did not make a difference ( $p = 1.000$ ).

According to margin positivity and the presence of menopause, margin groups were divided as positive and negative. The menopause classification was grouped by the presence or absence of menopause. In the statistical analysis, margin-positive patients who were in menopause at the same time constituted

**Table 1. The effect of demographic characteristics on margin positivity**

Variables	Group 1 Margin positive (n=61)	Group 2 Margin negative (n=61)	p-value
Age>40 <sup>a</sup>	14 (23.00)	19 (31.10)	0.415
Body mass index (kg/m <sup>2</sup> <sup>b</sup> )	25.80±4.17	26.09±4.22	0.887
Menopause <sup>a</sup>	8 (13.10)	18 (29.50)	0.045
Vaginal delivery <sup>a</sup> 1	11 (36.70)	14 (42.40)	0.797
≥2	19 (63.30)	19 (57.60)	
Alcohol consumption <sup>a</sup>	18 (29.50)	16 (26.20)	0.840
Smoking <sup>a</sup>	25 (41.00)	25 (41.00)	1.000
Use of intrauterine device <sup>a</sup>	7 (11.5)	7 (11.5)	1.000

<sup>a</sup>: Frequency values (percentage rates); <sup>b</sup>: Mean values ± standard deviation

13.10% (n=8), while those who were not in menopause constituted 86.90% (n=53) of the group. Margin-negative patients who were in menopause at the same time constituted 29.50% (n=18) of the group, while those who were not in menopause constituted 70.50% (n=43). There was a significant difference between the margin groups and the presence or absence of menopause ( $p=0.045$ ), and this difference was caused by the non-menopausal group.

Similarly, in the comparison of vaginal deliveries (1 or  $\geq 2$ ) according to margin positivity and negativity, margin positivity was observed in 36.7% (n=11) and negativity in 42.40% (n=14) of vaginal deliveries. In those who had two or more vaginal deliveries, margin positivity was 63.30% (n=19) and negativity was 57.60% (n=19). In the analysis between the margin groups and vaginal delivery groups, it was observed that there was no difference between these groups ( $p=0.797$ ) (Table 1).

**Table 2. Effect of pathology material on margin positivity**

	Group 1 Margin positive (n=61)	Group 2 Margin negative (n=61)	p-value
LEEP material <sup>a</sup>			
Length (mm)	23.88±5.89	24.6±5.87	0.873
Width (mm)	11.01±2.36	10.83±2.48	0.885
Height (mm)	17.6±3.67	17.8±3.56	0.820
Volume (cm <sup>3</sup> )	1.62±0.84	1.67±0.89	0.709
Pathology result <sup>b</sup>			
CIN II	23 (37.70)	43 (70.50)	0.001
CIN III	38 (62.30)	18 (29.50)	0.001
Endocervical <sup>b</sup>			
Positivity	15 (24.60)	3 (4.90)	0.004
Negativity	46 (75.40)	58 (95.10)	0.004

<sup>a</sup>: Mean values ± standard deviation; <sup>b</sup>: Frequency values (percentage rates)

Those with endocervical positivity were margin-positive with 24.60% (n=15) and margin-negative with 4.90% (n=3). Those with endocervical negativity were margin-positive with 75.40% (n=46) and margin-negative with 95.10% (n=58). In the analysis performed according to the margin positivity and negativity of endocervical positive and negative patients, a significant difference was found, and this difference was observed in both endocervical negative and margin negative groups ( $p=0.004$ ) (Table 2).

In the analysis performed between the groups with CIN II and CIN III in LEEP pathology results and those with positive and negative margin, it was observed that the margin-negative groups of those with CIN II (70.50%) (n=43) in LEEP pathology results made a significant difference, whereas in those with CIN III (62.30%) (n=38), this difference was due to the margin-positive group ( $p=0.001$ ) (Table 2).

In the LEEP materials taken, the mean length of the sample of those with positive margins was 23.88±5.89 mm, the mean height was 17.67±3.67 mm, the mean width was 11.01±2.36 mm, and the mean volume was 1.62±0.84 cm<sup>3</sup>; negative ones were found to be 24.63±5.87 mm, 17.67±3.67 mm, 11.01±2.36 mm, 1.67±0.89 cm<sup>3</sup>, respectively. The analysis of length, width, height and volume values on margin positivity and negativity showed no significant differences ( $p=0.873$ ,  $p=0.820$ ,  $p=0.885$ ,  $p=0.709$ , respectively) (Table 2).

In the multivariate analysis of variance, it was seen that the margin positivity rate of patients with CIN III detected in the LEEP pathology result made a significant difference ( $p=0.001$ ). Similarly, there was a significant difference in the number of multiple passes in the way the LEEP material was obtained with the margin positivity rate ( $p=0.045$ ). Endocervical positivity was found to make a significant difference in margin positivity ( $p=0.011$ ) (Table 3).

**Table 3. Evaluation of age, anesthesia type, endocervical positivity, menopausal status, transformation zone type and pathology results on margin positivity according to single and multiple analysis of variance**

Variables	Univariate analysis			Multivariate analysis		
	Hazard rate	95% CI	p-value	Hazard rate	95% CI	p-value
Age ( $\leq 40y$ or $>40y$ )	1.51	0.67-3.39	0.310	1.12	0.27-4.58	0.870
Anesthesia type (general or local)	1.46	0.67-3.14	0.330	1.29	0.53-3.16	0.560
Endocervical positivity (present or not)	0.15	0.04-0.58	0.005	0.168	0.04-0.67	0.011
Menopausal status (present or not)	1.97	0.76-5.11	0.160	1.12	0.21-5.99	0.890
Number of transitions	0.35	0.15-0.77	0.009	0.41	0.17-0.98	0.040
Transformation zone type	1.31	0.68-2.52	0.410	1.14	0.51-2.53	0.730
Pathology	0.23	0.11-0.50	0.0002	0.24	0.10-0.59	0.001

CI: Confidence interval

The type of anesthesia (general or local) had no effect on margin positivity ( $p=0.560$ ) (Table 3).

## DISCUSSION

Cervical cancer is an important disease in terms of public health today, and this situation is expected to continue in the near future. The slow course of cervical cancer pathogenesis compared to other malignancies distinguishes it from other malignant diseases. Therefore, the importance of screening, identification, and treatment of preinvasive lesions is increasing. As a result, it is aimed at improving the treatments used in current management, increasing patient satisfaction and comfort, and reducing disease progression.<sup>5</sup>

LEEP surgery is frequently used in the treatment of cervical preinvasive lesions compared to all other methods and is offered as the primary option in developed countries. Another reason for preference is that it provides diagnosis and treatment at the same time in the indicated patient population. In addition, perioperative and postoperative complication rates are lower compared to other treatment modalities.<sup>6</sup>

A positive surgical margin is one of the most important predictors of recurrence.<sup>4</sup> Therefore, gynecologists should know how to avoid a positive surgical margin when performing LEEP and should make every effort to prevent inadequate excision.<sup>7</sup>

LEEP is a method that can be performed under GA or LA. Our Ministry of Health and national associations have made no additional recommendations for the selection of anesthesia. Likewise, while international associations and organizations such as World Health Organization, ASCCP and ACOG do not make a standard recommendation on the selection of anesthesia for excision procedures, the United Kingdom National Health Service Guide recommends that excision procedures for cervical preinvasive lesions be performed under LA.<sup>8-11</sup>

There are a limited number of studies in the literature comparing anesthetic methods for LEEP. Tzur et al.<sup>2</sup> examined the effect of general and LA on recurrence in 146 patients undergoing LEEP. Under GA compared with LA, the proportion of positive sample margins was similar for both the endocervical margin [16/71 (22.5%) and 16/75 (21.3%), respectively;  $p=0.861$ ] and the ectocervical margin [14/71 (19.7%) and 11/75 (14.7%), respectively;  $p=0.418$ ]. The type of anesthesia was not shown to make a difference for margin positivity.<sup>12</sup> Güngördük et al.<sup>13</sup> evaluated a total of 244 patients who underwent LEEP (123 under LA and 121 under GA) and found margin positivity in 14 (11.3%) patients in the LA group and 11 (9.9%) patients in the GA group and found that the type of anesthesia did not make a statistically significant difference on margin positivity. Our

study demonstrated that the type of anesthesia preferred during LEEP had no effect on margin positivity, supporting the existing literature. It is obvious that margin positivity is a risk factor for recurrent disease.<sup>14</sup> Considering that the type of anesthesia to be chosen has no effect on margin positivity, LA seems to be more practical and applicable in terms of being simpler, shorter hospital stay, and less costly compared to GA.

In their retrospective study including 1.359 patients, in which they evaluated the involvement of margin, disease recurrence and incidence of complications, Xiang et al.<sup>15</sup> found that the rate of premenopausal patients with positive margins in the LEEP materials was 6.9%, while the rate of postmenopausal patients was 16.9%. Xiang et al.<sup>15</sup> showed that menopause is a risk factor for positive surgical margins (95% confidence interval: 1.6-5.9,  $p<0.01$ ). In our study, it was found that menopause was not a risk factor for margin positivity. A higher rate of margin positivity was found in the premenopausal patient group. In the menopausal period, the size of the cervix atrophies compared to the premenopausal period.<sup>16</sup> There as on why we obtained different results from the existing literature may be due to the higher rate of specimen removal with multiple passes during the LEEP procedure and the higher number of premenopausal patients.

Kanjanasirirut et al.<sup>17</sup> analyzed 547 patients who underwent LEEP in a study on the factors affecting margin positivity and showed that 74.1% ( $n=405$ ) of these patients were multiparous, 25.9% ( $n=142$ ) were nulliparous, 39.0% ( $n=158$ ) of multiparous patients, and 6.3% ( $n=9$ ) of nulliparous patients were margin positive. The Kanjanasirirut et al.<sup>17</sup> study revealed that multiparity was an important factor for a positive surgical margin after LEEP. Durmuş et al.<sup>18</sup> found margin positivity in 30.6% ( $n=82$ ) and margin negativity in 69.4% ( $n=186$ ) of 268 patients who underwent conization. Margin positivity was found in 9.5% ( $n=2$ ) of 7.8% ( $n=21$ ) nulliparous patients in the study. Durmuş et al.<sup>18</sup> reported a significantly lower surgical margin positivity rate in nulliparous patients.<sup>18</sup> In our study, unlike the current literature, no significant difference was found between the number of vaginal deliveries and margin positivity. While the margin positivity rate of patients who delivered vaginally was compared in our study, no distinction was made in terms of mode of delivery in the other studies analyzed. Larger-scale studies should be conducted to reach a meaningful and clear conclusion in the study design in which similar subgroups will be compared in terms of mode of delivery.

Kanjanasirirut et al.<sup>17</sup> found that 54.5% ( $n=145$ ) of 266 patients with endocervical gland involvement were margin-positive. In our study, we found that the risk of margin positivity increased

in the presence of endocervical gland involvement, supporting the current literature.

Papoutsis et al.<sup>19</sup> reported that a conization height of more than 10 mm resulted in significantly less residual disease. In the subgroups with conization depth <10 mm and >10 mm, the number of lesions not completely removed was 64/222 (28.0%) and 28/139 (20.0%), respectively ( $p=0.013$ ). Beyer et al. reported 100% negative margin cones with a cone height of 20 mm. Resection height values between 10 and 19.9 mm resulted in 73% negative margin cones.<sup>20</sup> Öz et al.<sup>21</sup> found that cone volume, cone length, and cone height of conization samples were not related to the margin status of conization samples, but the mean cone height was significantly different between margin-positive and margin-negative patients. The cone heights of patients with positive margins were smaller than those of patients with negative margins (13.7 mm and 15.1 mm, respectively  $p\leq 0.05$ ).<sup>21</sup> In our study, we found that length, width, height, and volume values did not produce significant differences in the analysis of margin positivity and negativity. Thereas on why we did not find statistically similar results with the existing studies may be that the mean height of the LEEP materials taken in our study was higher than the risk limit specified in the studies examined.

In the study of Fan et al.<sup>22</sup> 94.7% (n=54) of the margin-positive cases were HSIL. In a study of 135 patients, 57.8% (n=78) were margin negative and 42.2% (n=57) were margin positive. Univariate analysis in the study by Sun et al.<sup>23</sup> showed that parity, cytological grade, multiple quadrants of CIN III by punch biopsy, gland involvement, as well as depth of conization, were significant factors associated with a positive margin ( $p=0.05$ ). Multivariate analysis revealed that the cytological grade of CIN III (odds ratio=1.92) was the significant determinant increasing the risk of positive margin.<sup>23</sup> In our study, we determined that the risk of a positive margin increased as the grade of HSIL increased, supporting the literature.

### Study Limitations

The fact that our study design was retrospective, there was no randomization, and the low number of patients can be considered weaknesses. However, the strength of our study is that LEEP procedures were performed by the same surgeon in a single center, and a more homogeneous group was formed by including only patients with HPV 16-18 positivity by excluding patients with invasive cancer and carcinoma *in situ* on cervicalcytology before conization and similarly excluding patients with invasive cancer and carcinoma *in situ* on final pathology.

## CONCLUSION

High-grade cervical pathology before LEEP, the presence of endocervical gland involvement, and multiple passes in excision are risk factors predicting a positive surgical margin. The type of anesthesia applied does not affect the surgical margin.

## ETHICS

**Ethics Committee Approval:** The study was approved by the Clinical Research Ethics Committee of Muğla Sıtkı Koçman University (E-72855364-050.01.04-608052).

**Informed Consent:** Retrospective study.

## Contributions

Surgical and Medical Practices: H.E.T., K.G.; Concept: H.E.T.; Design: H.E.T.; Data Collection or Processing: H.E.T., K.G.; Analysis or Interpretation: H.E.T., B.S.; Literature Search: B.S.; Writing: H.E.T.

## DISCLOSURES

**Conflict of Interest:** No conflict of interest was declared by the authors.

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# The short-term efficacy of trans-obturator tape procedure and its effect on the quality of life in women with stress urinary incontinence

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## ABSTRACT

**Objectives:** Demonstrating the efficacy of trans-obturator tape (TOT) procedure for treatment of stress urinary incontinence (SUI) and its effects on patient's quality of life.

**Materials and Methods:** We analyzed the data of 108 patients (63 SUI; 45 MUI) who underwent the TOT procedure between January 2006 and January 2009. Preoperative and postoperative evaluations included physical examination, Q-tip test, stress test, pad use, bladder capacity, PVR, POP-Q score and QoL questionnaires (IIQ-7 and UDI-6). Three different tapes were used and two different approaches (68 outside-in, 40 inside-out) were performed.

**Results:** Patients were between 30 and 81 years old. One-year minimum follow-up (median, 22 months) was available for all patients. Postoperative Q-tip test results, pad use, number of voiding during the day and night, and QoL-Q scores were significantly lower ( $p < 0.01$ ). There was no significant difference in between groups regarding device or approach related complications ( $p > 0.05$ ). The device type, the technique performed, BMI, concomitant surgery did not significantly affect the success rates ( $p > 0.05$ ). The overall success rate of the TOT procedure was 87.9% after one year.

**Conclusion:** TOT is an easy procedure with compatible effectiveness in short and medium term relative to other treatments in the literature, and could substantially eliminate the great vessel, bladder, and bowel injuries. It seems to be effective for both SUI and MUI patients, and could be useful at obese cases, as well. Both trans-obturator access routes are equally safe. Concomitant pelvic surgery does not seem to have an impact on success rates.

**Keywords:** Mid-urethral slings; trans-obturator tape; urinary stress incontinence

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## INTRODUCTION

Urinary incontinence (UI) is a common condition that causes a significant decline in the physical activity, sexual function, and psychological well-being of women.<sup>1</sup> The prevalence of UI in women is reported at 13.1%, with stress urinary incontinence (SUI) (6.4%) as the most common type (48.9%).<sup>2</sup> SUI is the involuntary leakage of urine arising with effort or physical exertion, or on sneezing or coughing.<sup>3</sup> Loss of support of the urethra and bladder neck, and deficiency of intrinsic urethral sphincter are the two recognized pathophysiologic mechanisms of the condition.<sup>4-6</sup> First described retropubically by Petros and Ulmsten,<sup>6</sup> tension-free mid-urethral slings became the mainstream surgical treatment of SUI. Mid-urethral tapes seem to provide urethral support or closure during increases in abdominal pressure.<sup>7,8</sup> In the early 2000's Delorme<sup>9</sup> and de Leval<sup>10</sup> developed the transobturator route which is pronounced as an easier and safer technique that does virtually not require cystoscopy.

This study aimed to evaluate the short and medium-term effectiveness, complications, and effects on the quality of life of the transobturator route.

## MATERIALS AND METHODS

This was a retrospective study based on the UI evaluation forms of 130 patients who underwent TOT between January 2006 and January 2009 in our Clinic within the Department of Obstetrics and Gynecology of Göztepe Training and Research Hospital. The hospital's ethics committee approved the study, and all the patients were given written informed consent. The manufacturers of the meshes used in the trial did not give any funding for the research or did not provide the products.

Surgical indications in our series consisted of SUI and stress-predominant MUI. The diagnosis of SUI was confirmed with a provocative stress test assessed under lithotomy position with a full bladder. A Q-tip test was used to evaluate the bladder neck mobility. Bladder neck mobility was considered positive when the angle change of the cotton swab placed in the internal urethral meatus was greater than 30° between straining and resting, and there was 200 mL of urine in the bladder. Pad use, urethral mobility, bladder capacity, residual urine, and POP-Q score were the other components of the preoperative evaluation after relevant history and gynecologic examination. Preoperative and postoperative filling cystometry tests were performed after full urinalysis and urine culture tests' results were seen as normal. In the presence of infection, cystometry was postponed until after treatment. Bladder sensation parameters (first desire to void, normal desire to void, and maximum cystometric capacity)

were recorded. Preoperative urodynamics was not required in cases where typical pure SUI was considered. Urodynamics was requested in patients with complex complaints, or previous incontinence/pelvic floor surgery. In the evaluation of patients' symptoms, the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) tests, validated for Turkish-speaking societies, were used.

Surgical interventions were performed based on the techniques described by Emmanuel Delorme (outside-in) and Jean de Leval (inside-out) depending on the tool used. All surgeons were experienced in TVT and vaginal surgery. Three different instruments and tapes were used in the study, including two different transobturator approaches (outside-in, inside-out). Obturator IVS Tunneller (IVS04™) and I-STOP devices were applied outside-in, and Gynecare TVT™ Obturator System (TVT-O) was applied inside-out. All three meshes had a monofilament and macropore structure. Cystoscopy has rarely been performed. The duration of hospitalization, the period of urinary catheterization, and the method of anesthesia varied depending on the surgeons' preference. Women were excluded if they had residual urine volume equal to or greater than 100 mL, previous pelvic irradiation, neurological conditions such as multiple sclerosis, and a history of genital or abdominal cancer or a pelvic mass.

Perioperative complications (vaginal injuries, bladder injury, bleeding requiring transfusion, hematoma), early postoperative complications (leg pain, fever, urinary retention, vaginitis, urinary tract infection), and late complications (*de novo* urge, mesh erosion, straining to urinate, dyspareunia) were recorded. Early postoperative complications were defined and recorded as complications in the first 15 days, and late complications were defined as complications after the 15<sup>th</sup> postoperative day. Patients were discharged when the postoperative residual urine was below 100 mL. Postoperative follow-up information was recorded after 1 year and 3 years.

The effectiveness of the TOT procedure was defined as follows: Those who had a negative post-operative stress test, residual urine less than 100 mL, and those who described full continence were considered "cured". Those whose incontinence frequency decreased but still described leakage were decided "partial recovery". Patients who reported no change after the operation, whose incontinence worsened, or who underwent reoperation in the first year due to incontinence were judged as "failure".

## Statistical Analysis

For the assessment of the findings obtained in this research, the NCSS 2007 & PASS 2008 Statistical Software (Utah, USA) program



was used for statistical analysis. In addition to descriptive statistical methods (mean, standard deviation), Student's t-test was used to compare the parameters with normal distribution between two groups to check quantitative data. A paired Samples t-test was used for preoperative/postoperative comparisons of parameters showing normal distribution, and the Wilcoxon signed-rank test was used in the comparisons with parameters showing abnormal distribution. The chi-square test and McNemar's test were used to compare qualitative data. The results were presented using a 95% confidence interval, and a  $p$ -value  $<0.05$  was described as statistically significant.

## RESULTS

The study was conducted retrospectively on the data of 130 patients who underwent the TOT procedure between January 2006 and January 2009. Ten patients who did not reach the first year of surgery and 12 patients who were lost to follow-up were not evaluated. The remaining 108 women whose data was analyzed had a mean age of  $48.81 \pm 8.45$ . The mean follow-up time was  $22.62 \pm 7.67$  months (range 12-39 months). The baseline data of the patients is presented in Table 1. Among 108 women 48 had descensus uteri ( $n=40$ , 30.7% POP-Q Stage I;  $n=8$ , 7.4% POP-Q Stage II), 80 had cystocele ( $n=45$ , 41.7% POP-Q Stage I;  $n=30$ , 27.8% POP-Q Stage II;  $n=5$ , 4.6% POP-Q Stage III), and 67 had rectocele ( $n=44$ , 40.7% POP-Q Stage I;  $n=19$ , 17.6% POP-Q Stage II;  $n=4$  3.7% POP-Q Stage III).

Most of the women ( $n=63$ , 58.3%) were operated on with a diagnosis of pure SUI, while the rest ( $n=45$ , 41.7%) had an indication of MUI. Obturator IVS Tunneller (IVS04™) was used in 40.7%, Gynecare TVT Obturator (TVT-O) in 37.0% and I-STOP in 22.2% of the patients. Mean operation time was  $25.08 \pm 9.021$  minutes (range 10-60 minutes). 69.4% of the patients received general anesthesia, and regional anesthesia was applied to 30.6%. In 80.5% of the patients, no intervention other than TOT was needed. Concomitant surgeries were performed in 21 (19.4%) patients: 8 (7.4%) had a colporrhaphy anterior, 8 (7.4%) had a colporrhaphy posterior, 4 (3.7%) patients had colporrhaphy anteroposterior, and one patient had sacrospinous fixation. The mean duration of urinary catheter maintenance and postoperative stay at the hospital was  $1.08 \pm 0.939$  days (range 0-6 days) and  $2.14 \pm 1.363$  days (range 1-7 days), respectively.

Q-tip test was used as an objective test to evaluate patients before and after the procedure. Compared to the Q-tip test result in the preoperative period (mean=60.23), the decrease seen in the postoperative period (mean=26.90) is statistically highly significant ( $p<0.001$ ). The percentage of patients using pads decreased from preoperative ( $n=74$ ) 68.5% to ( $n=19$ ) 17.6%

postoperatively ( $p<0.001$ ). There was a statistically significant relationship between the Q-tip test results measured in the clinic and the pad use reported by the patients.

The frequency of urination during the day and night was compared before and after the surgery.

The decreases observed in daytime and nocturnal urine counts during the postoperative period compared to the preoperative period were statistically highly significant ( $p<0.01$ ).

The mean value of post-void residue was  $19.31 \pm 26.52$  mL preoperatively, and  $20.98 \pm 18.02$  mL postoperatively. The mean value of bladder capacity was  $453.65 \pm 90.50$  mL preoperatively and  $455.70 \pm 94.33$  mL postoperatively. There was no statistical significance between preoperative and postoperative values for both measurements.

Comparisons regarding quality of life are presented in Table 2 and Table 3. All results showed that the quality of life increased significantly in the postoperative period.

According to the UDI-6 test, the decrease seen in the score obtained during the postoperative period from the first 2

**Table 1. Descriptive characteristics of 108 patients at baseline.**

	n=108	%
Age (years), mean $\pm$ SD (range)	48/81 $\pm$ 8.8 (30-81)	
BMI (kg/m <sup>2</sup> )		
<25	25	23.1%
25-30	44	40.7%
30-35	26	24.1%
>35	13	12.0%
Gravidity, median (range)	5.0 (1-15)	
Parity, median (range)	3.0 (1-10)	
Postmenopausal	53	49.1%
Diabetes		
Yes	15	13.8%
No	93	86.1%
Previous surgery		
Abdominal hysterectomy	10	9.25%
Vaginal hysterectomy + kelly plication	4	3.70%
Vaginal hysterectomy + TOT	1	0.92%
Hysteropexy	1	0.92%
Medication, n (%)		
Diuretics	10	9.25%
Ca <sup>2+</sup> channel blockers	8	7.40%
Alpha adrenergic blocker	1	0.92%
Beta adrenergic agonist	2	1.85%
Corticosteroids	4	3.70%
Stress urinary incontinence	63	58.3%
Mixed urinary incontinence	45	41.7%

questions investigating the urge component, from 3<sup>rd</sup> and 4<sup>th</sup> questions which investigate the stress component, and from the 5<sup>th</sup> and 6<sup>th</sup> questions which investigate the obstructive component was highly statistically significant compared to the preoperative period ( $p < 0.01$ ). Compared to the preoperative period, the decrease observed in IIQ-7 questionnaire scores in the postoperative period was statistically highly significant ( $p < 0.01$ ).

No serious complications occurred during the operations (Table 4). All 8 vaginal perforations occurred with the outside-in technique. Seventeen women had leg pain in the early postoperative period, and the complaints disappeared completely in the short-term follow-up. Nine of these 17 women were operated with the outside-in technique, and the rest with the inside-out technique. Patients' hemoglobin levels dropped significantly after the procedures ( $p < 0.01$ ).

All vaginal tape erosions ( $n=6$ ) were noticed between 6<sup>th</sup> and 10<sup>th</sup> month after the procedures. Vaginal perforation or erosion was not observed in patients who had previously undergone cystocele surgery, Kelly plication, or TOT. While two of the patients with vaginal erosion had no complaints, three had foul-smelling vaginal discharge, and one had a complaint of "dryness" during sexual intercourse. Three women with vaginal erosion had type 2 diabetes mellitus. Three women who had vaginal perforation during the operation also presented with erosion at follow-up. These patients were treated by resecting the band in the erosion area, and by secondary mucosal repair. No abscess was seen. The entire mesh did not need to be removed. Continence was preserved in all patients after resection of the tape. Dyspareunia and straining to urinate occurred in one patient after resection of the tape and secondary vaginal suturing. No erosion was observed in the 3 patients who described dyspareunia. Finally, one patient who was operated on with an indication of MUI was considered a failure at the 3<sup>rd</sup> month postoperative examination, and TVT was applied.

Complication rates showed no statistically significant difference between the techniques and the devices applied ( $p > 0.05$ ) (Table 5). There is no statistically significant difference demonstrated in the success rates depending on the technique, the device applied, body mass index, and concomitant surgery ( $p > 0.05$ ) (Table 6). The success rate of operations in which IVS-O devices were used showed no statistically significant difference between incontinence types (SUI vs. MUI) ( $p > 0.05$ ). There is a statistically significant difference in the success rates of operations using TVT-O device according to the type of incontinence ( $p < 0.05$ ). After the operations performed with TVT-O devices, the cure rate in women with SUI (80%) was significantly higher than the cure rate in women with MUI (40%) (Table 7). The success rate

after procedures with I-Stop devices also showed no statistically significant difference between SUI and MUI patients ( $p > 0.05$ ).

## DISCUSSION

In the joint report on the terminology for female pelvic floor dysfunction, SUI is defined as an involuntary loss of urine on effort or physical exertion, or on sneezing or coughing, and it was emphasized to base the diagnosis on the correlation between a woman's symptoms, signs, and any relevant investigations.<sup>3</sup>

**Table 2. Preoperative and postoperative UDI-6 evaluation**

		Mean ± SD	Median	p
UDI-6 (Q1-Q2)	Preop	3.44±1.65	4	0.001**
	Postop	1.48±1.58	1	
UDI-6 (Q1-Q2)	Preop	3.44±2.00	3	0.001**
	Postop	0.56±1.22	0	
UDI-6 (Q1-Q2)	Preop	1.26±1.52	1	0.001**
	Postop	0.60±0.97	0	

\*\* : Wilcoxon sign test was used  $p < 0.01$ ; SD: Standard deviation; UDI-6: Urogenital distress inventory

**Table 3. Preoperative and postoperative IIQ-7 and UDI-6 evaluations**

		Mean ± SD	Median	p
IIQ-7	Preop	9.46±4.80	9	0.001**
	Postop	2.20±3.67	1	
UDI-6	Preop	8.47±3.62	8	0.001**
	Postop	2.55±2.89	2	

\*\* : Wilcoxon sign test was used  $p < 0.01$ ; UDI-6: Urogenital distress inventory; SD: Standard deviation; IIQ-7: Incontinence impact questionnaire

**Table 4. Rates of complications**

	n (%)	
Perioperative complications	Bladder injury	-
	Vaginal perforation	8 (7.4%)
	Hematoma	-
	Hemorrhage	-
Early postoperative complications	Urinary tract infections	3 (2.7%)
	Urinary retention	2 (1.8%)
	Vaginitis	-
	Leg pain	17 (15.7%)
	Fever	1 (0.9%)
Late postoperative complications	de novo urge	3 (2.8%)
	Dyspareunia	3 (2.8%)
	Vaginal erosion	6 (5.6%)
	Straining to urinate	5 (4.6%)
	Fever	1 (0.9%)

In addition to being a general health problem, SUI could be considered a social problem that causes a decrease in quality of life as a result of depression, bone fractures, and sexual dysfunction.<sup>11</sup> Increasing life expectancy in the last century brings the desire to improve women's physical, emotional, and social well-being. Towards this expectation, surgeons have introduced more than 200 different procedures for the permanent treatment of SUI, but very few have high effectiveness.

Sling procedures are one of the effective solutions. Most of them can be performed under local/regional anesthesia, in shorter operation times, with minimal dissection, and do not even require hospitalization. Retropubic TVT which was first introduced and widely accepted due to its simplicity, is comparable in long-term effectiveness with the gold standard Burch colposuspension.<sup>12,13</sup>

**Table 5. Postoperative complication rates of different devices and techniques**

		Complication		p
		Yes	No	
		n (%)	n (%)	
Device	IVS-O	8 (18.2%)	36 (81.8%)	0.926
	TVT-O	6 (15.0%)	34 (85.0%)	
	I-stop	4 (16.7%)	20 (83.3%)	
Technique	Outside-in	12 (17.6%)	56 (82.4%)	0.722
	Inside-out	6 (15.0%)	34 (85.0%)	

chi-squared test was used

**Table 6. Rates of success**

		Success				p
		Cure	Improvement	Failure	Recurrence	
		n (%)				
Device	IVS-O	30 (68.2%)	10 (22.7%)	4 (9.1%)	-	0.306
	TVT-O	24 (60.0%)	8 (20.0%)	5 (12.5%)	3 (7.5%)	
	I-stop	19 (79.2%)	4 (16.7%)	-	1 (4.2%)	
Technique	Outside-in	49 (72.1%)	14 (20.6%)	4 (5.9%)	56 (82.4%)	0.227
	Inside-out	24 (60.0%)	8 (20.0%)	5 (12.5%)	34 (85.0%)	
BMI	<25	16 (64.0%)	8 (20.0%)	5 (12.5%)	3 (7.5%)	0.729
	25-30	32 (72.7%)	4 (16.7%)	-	1 (4.2%)	
	30-35	17 (65.4%)	6 (23.1%)	1 (3.8%)	2 (7.7%)	
	>35	8 (61.5%)	3 (23.1%)	1 (7.7%)	1 (7.7%)	
Concomitant surgery	Yes	13 (61.9%)	6 (28.6%)	1 (4.8%)	1 (4.8%)	0.691
	No	60 (69.0%)	16 (18.4%)	8 (9.2%)	3 (3.4%)	

chi-squared test was used; BMI: Body mass index

**Table 7. Rates of success according to incontinence types**

Device	Type of incontinence	Success				p
		Cure	Improvement	Failure	Recurrence	
		n (%)				
IVS-O	Stress UI	21 (72.4%)	6 (20.7%)	2 (6.9%)	-	0.661
	Mixed UI	9 (60.0%)	4 (26.7%)	2 (13.3%)	-	
TVT-O	Stress UI	16 (80.0%)	3 (15.0%)	-	1 (5.0%)	0.037*
	Mixed UI	8 (40.0%)	5 (25.0%)	5 (25.5%)	2 (10.0%)	
I-Stop	Stress UI	13 (92.9%)	1 (7.1%)	-	-	0.134
	Mixed UI	6 (60.0%)	3 (30.0%)	-	1 (10.0%)	

\*: chi-squared test was used  $p < 0.05$

The transobturator route, developed by Delorme to reduce the accompanying morbidity of the retropubic route, enabled anti-incontinence surgery to become widespread. The transobturator approach has two important advantages: Avoiding the Retzius area and working in limited proximity to the peritoneal cavity. Although vaginal meshes have serious complications such as erosion of the vagina, urethra, or bladder, injuries of the bladder, bowel, and vessels, infection, hematoma, and nerve damage, they appeared to be rare or identified in the literature rarely.<sup>1,14,15</sup> As a result, mid-urethral slings soon approved superior, the new gold standard.<sup>16</sup>

A Cochrane review in 2017 assessing mid-urethral slings revealed that the transobturator route has a lower risk of complications.<sup>1</sup> In this study, the most common complication was groin pain (1.6%). Bladder perforation and pelvic hematoma rates were 0.4% and 0.5% respectively. Both complications were not observed in our study. In our opinion bladder and urethra injuries, previously reported as more common in the outside-in approach, can be minimized with the controlled guidance of the index finger that meets the device in the vaginal incision.<sup>17,18</sup> On the other hand, the rate of perioperative vaginal perforation (7.4%) in our study was nearly the same as reported in the literature (7.39%).<sup>1</sup> Vaginal perforation was reported to happen less with the inside-out technique. All the cases in our research were observed in surgeries performed with the outside-in approach in the first year. This could be primarily attributed to the learning curve of the technique and the effort to stay away from the bladder and urethra.

Not reported in de Leval's<sup>10</sup> series, the vaginal tape erosion rate was published between 0.4% and 4.5%.<sup>19,20</sup> In our research, tape erosion was observed in 6 (5.6%) women. Outside-in route was performed in 5 of these patients. In a study conducted in our country with a 4-year follow-up, surgical technique and multifilament mesh erosion were compared, and it was determined that erosion was more frequently encountered in cases where the pubocervicovaginal fascia was not closed properly.<sup>21</sup> Kroon and Smith<sup>22</sup> stated that the material from which the mesh was made, as well as the weave type, could be one of the factors affecting success. In our series, vaginal erosion was observed more frequently in cases performed with the outside-in technique. This might be associated with the wider opening of the vaginal incision to manipulate the index finger employed in this technique.

Another issue that is particularly emphasized in the literature is the relationship between mesh erosion and diabetes mellitus. It has been found that diabetes increases the risk of erosion by 8.3 times.<sup>23</sup> Similarly, half of our cases in which erosion developed

had diabetes mellitus. Since many factors play a role in the formation of mesh erosion, clearly stating the risks to all patients especially if they are diabetic is important, and will be protective for both sides.

Leg pain is significantly a more common complaint in women who underwent TOT than TVT.<sup>1</sup> It is assumed that there were 163 more cases per 1000 in the TOT group. The median duration was 8 weeks showing most groin pain resolves in a short period with anti-inflammatory treatment.<sup>18,24,25</sup> In rare cases that do not resolve, steroids and local anesthetics were shown to be useful after excluding mesh erosion and abscess.<sup>26</sup> In all the cases with leg pain in our study, the complaints were observed to regress in the short-term follow-up.

Women with *de novo* urgency observed in the TOT series showed a rate of approximately 8%, and there was no statistically significant difference compared to TVT in both short and long-term data.<sup>1,27</sup> It is stated that *de novo* complaints decrease to a minimum in one year.<sup>19,24</sup> The lower rate in the transobturator route might be associated with the horizontal placement of the tape between the ischiopubic rami and urethra, as well as the possibility leaving it under less tension compared to TVT. In the operations during the tape placement, we used Mayo scissors between the tape and urethra to ensure a tension-free installation. However, the rate of *de novo* urgency (2.8%) in our study was quite low compared to the literature.

Transient urinary retention and straining to urinate, the other two complications of voiding dysfunction, were detected at a rate of 1.8% and 4.6%, respectively. The amount of the post-void residual urine of these patients was measured under 100 mL. No patient required long-term indwelling catheterization or readjustment of the mesh. These results are similar to the data demonstrating a long-term follow-up after the TOT procedure.<sup>27</sup> The success of the conservative management of complications can be attributed to the appropriate indication given in line with residue measurement at the preoperative period and urodynamic confirmation of patients with complicated symptoms.

In our study, we found no statistical difference in complication rates between all three devices and two techniques. In his research comparing outside-in and inside-out techniques, DeBodinance<sup>18</sup> declared that both methods are equally safe and that trying to make one technique superior to the other would be short-sighted. Petri et al.<sup>28</sup> stated that the most common cause of complications was inadequate surgical technique, and pointed out that appropriate training and performing a sufficient number of procedures would help to reduce complication rates significantly.

The main goal of our study was to demonstrate TOT effectiveness and its effect on quality of life. Although objective methods



such as stress tests, pad tests, and urodynamics can be used to evaluate the effectiveness of UI, the primary goal of the clinician should be the patient's satisfaction. In this context, classification as dry or wet - partial recovery/failure -, presence of preoperative and postoperative pad use, and QoL questionnaires are the most frequently used subjective parameters. When compared to the data of QoL questionnaires, stress test data may overestimate the results in studies. On the other hand, the diversity of subjective measures proposed in the studies and the lack of standardized parameters used in defining success make it difficult to evaluate the related data in the literature.<sup>29</sup>

In our study, we considered stress test and pad use as objective criteria, and the patient's descriptions of healing, partial recovery, and failure with the QoL questionnaires (IIQ-7 and UDI-6) as subjective criteria. Urodynamic examinations were not included in these criteria because they were only requested for specific indications. Highly significant results were found in favor of the TOT procedure in all effectiveness measurements in our analysis. Again, there was a statistically significant relationship between the improvement in Q-tip test results and the decrease in the need for pad use. In our research, cure, partial recovery, failure, and recurrence rates at the end of one year were 67.5%, 20.3%, 8.3%, and 3.7%, respectively. When partial recovery is included in the definition of success, the efficiency of TOT can be stated as 87.9%. These rates are similar in many studies and are equal to TVT in the short term.<sup>17-19,24</sup> There was no significant difference in success rates between all three instruments and two techniques.

Another factor that should be considered is the concomitant pelvic floor surgery. Incontinence operations are often expected to be accompanied by prolapse surgeries, and their proportion in the study population should be specified. While this rate was 56% in Tamussino et al.'s<sup>17</sup> series of 2543 cases, Krauth et al.<sup>24</sup> stated it as 8.3%. In our study, additional prolapse surgery was observed at a rate of 19.4%, and it did not change the effectiveness of TOT.

Formerly publications emphasized the negative impact of obesity which is thought to play a role in the etiology of mid-urethral sling success. However, recent literature showed no change in cure rates, especially in the subjective success rates of overweight or obese women.<sup>30</sup> Our research found that the efficiency of TOT did not change among women of a different body-mass index.

When the effectiveness rates were compared for SUI and MUI according to the device type, a statistical difference was found between the results obtained with TVT-O applied with the

inside-out technique. It was observed that the success rates in patients who underwent TVT-O with SUI indication decreased significantly in the patient group in which the UUI component was added. However, some publications in the literature report that the TOT procedure is also very effective on lower urinary tract symptoms.<sup>18,31</sup> In our study this decrease specific to TVT-O unlike other devices and techniques was not considered remarkable due to the abundance of variables that could affect the results.

In the literature, in the prospective 3-year follow-up of 91 patients who underwent TVT-O with a clinical and urodynamic diagnosis of SUI, cure and partial recovery rates were reported as 88.4% and 9.3%, respectively, and these rates were similar to those in the first year.<sup>19</sup> Finally, in our series, 8 patients completed the 3-year follow-up period, and it was observed that the success rates of these patients did not change compared to the 1st year.

The data come from a heterogeneous study group, its retrospective design and the number of patients lost to follow-up are the potential weaknesses of our study. Besides, the individual practice of the surgeon determined the type of anesthesia, duration of hospitalization, and duration of the urinary catheter. The series also includes each surgeon's learning curve. However, this situation further increases the value of the results regarding the easy and safe applicability of the transobturator technique.

## CONCLUSION

The transobturator approach through mid-urethral slings stands out as a minimally invasive procedure that is equally effective as other methods in the literature in the short and medium term, and can eliminate vascular, bladder, and bowel injuries. It is easy to learn with a short operating time and does not require cystoscopy. Inside-out and outside-out techniques have no advantage over each other. The presence of additional surgery does not affect the results. Women experience a significant improvement in the quality of life after surgery indicated by either SUI or MUI. The finding that the effectiveness is independent of body-mass index draws attention to the fact that it may also benefit obese patients. Nevertheless, it requires more research to publish the data of longer follow-up time to determine the effectiveness in time and to identify the long-term adverse events. Good quality trials with standardized subjective and objective outcome measures are essential to provide robust evidence.

## ETHICS

**Ethics Committee Approval:** The study was approved by the Ethics Committee of the Göztepe Training and Research Hospital.

**Informed Consent:** All the patients were given written informed consent.

## Contributions

Surgical and Medical Practices: N.Y., T.A.; Concept: N.Y., G.G.; Design: G.G.; Data Collection or Processing: T.A.; Analysis or Interpretation: T.A.; Literature Search: T.A.; Writing: T.A.

## DISCLOSURES

**Conflict of Interest:** No conflict of interest was declared by the authors.

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# What are the reasons for our lack of success in treating vaginitis despite our various empirical treatment approaches? Where are we going wrong?

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## ABSTRACT

**Objectives:** Vaginitis poses a significant challenge for women of all ages, impacting their quality of life. Clinicians struggle with diagnosis and management, facing treatment resistance and patient hygiene habits. We aimed to compare the effectiveness of vaginal and combined empirical treatments for vaginitis and identify factors contributing to treatment failure.

**Materials and Methods:** A retrospective cross-sectional study, incorporating both quantitative and qualitative approaches, was conducted on 369 patients who sought care at the gynecology outpatient clinic between 2021 and 2023 with complaints of vaginal infection. Empirical treatment was initiated after obtaining vaginal culture samples, and the diagnosis of vaginal candidiasis was confirmed through culture results. The specimens were collected at the gynecology outpatient clinic of Kafkas University Hospital. Comprehensive demographic information was gathered from all patients presenting with complaints of vaginal infection. The “daily hygienic behaviors questionnaire” was also administered, evaluated, and documented for each patient. The treatment responses of patients who presented to the clinic and were treated with two different empirical treatments, determined randomly by the attending clinician’s preference, were evaluated. In our clinic, empirical treatment involved either vaginal treatment with 750 mg metronidazole + 200 mg miconazole nitrate or a combination of vaginal 750 mg metronidazole + 200 mg miconazole nitrate and oral 150 mg fluconazole, administered based on the clinician’s choice.

**Results:** There was no statistically significant difference in the results of the two empirical treatments administered to the patients. There was no significant difference in demographic characteristics in the two treatment groups. Previous antibiotic use was significantly higher in the vaginal treatment group ( $p<0.05$ ). When the questionnaires questioning the personal hygiene habits of the patients with treatment failure were evaluated, erroneous habits that could explain this failure in treatment were revealed.

**Conclusion:** Candida infections, especially fluconazole-resistant strains, pose challenges. Access to microbiological testing and detailed medical histories is crucial. Patient education on culture-based treatment is essential. Addressing these challenges requires a sustainable solution.

**Keywords:** Antifungal treatment; *Candida albicans*; fluconazole; genital hygiene; pelvic infections; preventive medicine; sexually transmitted infections; vaginal discharge syndrome; vulvovaginal candidiasis; women’s health

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## INTRODUCTION

Issues pertaining to the vagina represent a frequent cause for patients to consult with obstetrician-gynecologists. These symptoms carry notable consequences, resulting in discomfort, pain, absenteeism from school or work, disturbances in sexual functioning, and impacts on self-image.<sup>1</sup>

The vaginal microbiome is complex and unique in comparison to that of anywhere else.<sup>2</sup> The vaginal microbiome experiences temporary changes due to menstruation, sexual activity, pregnancy, antimicrobial usage, hormonal therapies, perimenopause, and menopause.<sup>2,3</sup> It is predominantly characterized by *Lactobacillus*, an aerobic, Gram-positive rod.<sup>4</sup> *Lactobacilli* play a role in lactic acid and hydrogen peroxide production and help maintain a low vaginal pH. This acidic environment serves to reduce pro-inflammatory cytokines in the vagina and inhibit bacterial overgrowth.<sup>5</sup>

*Candida* is normally present in the genitourinary tract at colonization rates of 11.6-17%. *Candida* is a typically commensal microorganism in the genitourinary tract, with colonization rates ranging from 11.6% to 17%.<sup>6</sup> *Candida albicans* is responsible for over 70% of vulvovaginal candidiasis (VVC) cases affecting both the vulva and vaginal wall, followed by *Candida glabrata*, *Candida tropicalis*, *Candida parapsilosis*, and *Candida krusei*.<sup>6-8</sup>

When local host defense mechanisms are compromised, candida can proliferate and cause a non-invasive infection known as VVC.<sup>6</sup> Frequent symptoms of *Candida* overgrowth in the vaginal area include an atypical odor, soreness, dysuria, dyspareunia, irritation, burning, itching, or changes in vaginal discharge.<sup>9,10</sup>

In Europe, VVC is a common cause of vaginitis, and in the United States, it ranks as the second most prevalent infection after bacterial vaginosis.<sup>6</sup> Epidemiological studies indicate that around 75% of women experience at least one VVC episode during their lifetime, with 40-45% having a second episode,<sup>8</sup> while 7-8% will develop recurrent VVC (RVVC), characterized by at least four confirmed episodes per year.<sup>6</sup>

Risk factors include diabetes mellitus, use of broad-spectrum antibiotics, factors like pregnancy or oral contraceptives, which will lead to increased estrogen levels causing an increase in glycogen content in vaginal secretion, immunosuppression, use of contraceptive device use (barrier methods), poor and wrong hygienic habits, certain sexual and clothing habits.<sup>6,11-14</sup>

Identifying *Candida* species and their susceptibility to antifungal agents is essential for effective therapy, especially since azoles are the most frequently prescribed class of antifungal drugs.<sup>6</sup> The main synthetic azole antifungal agents for VVC treatment are miconazole and fluconazole. These agents target the

lanosterol 14a-demethylase enzyme, which is critical for converting lanosterol to ergosterol, which is essential for *Candida* membrane integrity.

Insufficient treatment for vaginal *Candida* infection, along with antifungal drug resistance and patients' poor or incorrect hygiene practices, can lead to treatment failure. Our objective was to assess whether vaginal treatment alone or combined treatment methods, commonly used empirically for vaginitis in outpatient settings, exhibit superiority over one another and to identify factors contributing to treatment failure. The primary focus of this study was to pinpoint the factors responsible for treatment resistance in cases of VVC, even in situations where empirical treatment is administered.

## MATERIALS AND METHODS

A retrospective cross-sectional study, both quantitative and qualitative, was undertaken utilizing 369 vaginal swab samples obtained from female patients aged over 18 years experiencing signs and symptoms suggestive of vulvovaginitis during 2021 and 2023. The samples were collected at the Gynecology Outpatient Clinic of Kafkas University Hospital. Detailed demographic information was gathered, and the "Daily hygienic behaviors questionnaire results" from patients' records were assessed and subsequently performed. All participants signed informed written consent before being enrolled in the study. The study was reviewed and approved by the ethics committee of Kafkas University Faculty of Medicine, Ethics Committee of Clinical Trials (ethics approval reference number: 80576354-050-99/250). All procedures were performed according to the Declaration of Helsinki.

### Sample Collection

Participants were positioned in lithotomy for vaginal examination. A sterile swab stick was used to collect vaginal samples from the posterior fornix and vaginal walls after opening the labia with a speculum. Samples were transported to the lab in Amies medium for analysis and promptly transferred to the microbiology laboratory for further processing.

### Treatment and Follow-ups

The data were collected by reviewing patient files from clinicians who consistently follow similar monitoring procedures but employ different VVC treatment methods in their routine practice. These clinicians employed a random assignment method to allocate their patients to receive either exclusive vaginal treatment (750 mg metronidazole + 200 mg miconazole nitrate) or a combination of both vaginal and oral treatment (oral 150 mg fluconazole and vaginal 750 mg metronidazole

+ 200 mg miconazole nitrate). The data underwent analysis to evaluate treatment failure rates, make a comparison between the effectiveness of distinct treatments, and identify the variables associated with treatment failure during the 4-week follow-up assessments for patients who were administered either vaginal or combined (vaginal-systemic) treatment protocols following the clinicians' typical practice for VVC.

The study was conducted at the gynecology outpatient clinic, where patients receiving treatment for vaginitis were assessed through face-to-face questionnaires during their outpatient clinic visits. The questionnaires focused on the patients' genital hygiene habits as part of their daily routines. The primary objectives were to evaluate potential variances between two distinct empirical treatments for VVC commonly chosen by clinicians and to investigate the reasons for treatment failure in some patients, including potential factors like sexual behavior history, medical background, hygiene habits, or antibiotic resistance.

The demographic characteristics reported in the study included age, gravida, parity, education status, employment status, frequency of sexual intercourse, contraceptive methods, systemic disease, previous antibiotic use, and recurrent VVC and symptoms (Table 1). The patients were given a questionnaire to inquire about their genital hygiene habits.

### Statistical Analysis

Demographic information, including educational status, treatment, control culture results, and systemic diseases, was presented using numbers (n) and percentages (%). Cross-tabulations were employed, along with numbers (n), percentages (%), and the chi-square ( $\chi^2$ ) test statistics, to compare control culture results based on treatment status. Similarly, cross-tabulations were generated, and numbers (n), percentages (%), and chi-square ( $\chi^2$ ) test statistics were provided to compare categorical variables concerning control culture results.

IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) and MS-Excel 2007 software were utilized for statistical analysis. A significance level of  $p < 0.05$  was considered statistically significant.

### RESULTS

Three hundred and sixty nine patients who sought care at the gynecology outpatient clinic with complaints of vaginal infection. The study included individuals with a mean age of  $31.86 \pm 17.80$  years. Among the participants, 58.9% had basic education, and 4.3% had no formal education. Furthermore, 82.4% (n=304)

Table 1. Demographic data	
	<b>All patients (n=369)</b>
Age (year) mean $\pm$ standard deviation	31.86 $\pm$ 17.80
Gravida mean (min-max)	3.0 (0-11)
Parity mean (min-max)	2.0 (0-11)
Education status, n (%)	
None	16 (4.3)
Primary	146 (39.6)
Middle	71 (19.3)
High	95 (25.7)
University	41 (11.1)
Employment, n (%)	
Not employed	304 (82.4)
Employed	65 (17.6)
*Symptoms, n (%)	
Discharge	339 (91.9)
Itching	236 (64.0)
Irritation & burning sensation	227 (61.5)
Dyspareunia	153 (41.5)
Bad odor	195 (52.8)
Vaginal discharge, n (%)	
Normal	63 (17.1)
Thin, grey	115 (31.4)
White, thick	189 (51.5)
Treatment, n (%)	
Vaginal	214 (58.0)
Orally + local	155 (42.0)
Control vaginal culture, n (%)	
Negative culture	292 (79.1)
Positive culture	77 (20.9)
Previous similar complaints, n (%)	
None	151 (40.9)
Exist	218 (59.1)
Sexual intercourse frequency, n (%)	
1-2 times a week	209 (56.6)
3-4 times a week	141 (38.2)
5 times or more a week	19 (5.1)
Contraception, n (%)	
OC	23 (6.5)
IUD	54 (15.2)
Monthly depot progestins	11 (3.1)
Calendar method	13 (3.7)
Condom	49 (13.8)
Withdrawal	45 (12.7)
BTL	14 (4.0)
None	145 (41.0)
Systemic disease, n (%)	
None	272 (73.7)
Exist	97 (26.3)
Complaints in the partner, n (%)	
None	273 (74.0)
Exist	96 (26.0)

were unemployed, while 17.6% (n=65) were employed. Vaginal discharge was the primary complaint in 82.3% of the patients who visited the outpatient clinic (Table 1).

The highest incidence of Candida isolation was noted among patients aged 20 to 29, whereas the lowest incidence was observed in patients aged 50 and above. According to the control culture results, no statistically significant difference was found in age groups ( $\chi^2=1.354$ ,  $p=0.716$ ) (Table 2).

Based on the results of the control culture, no statistically significant difference was found in terms of educational status ( $\chi^2=3.683$ ,  $p=0.451$ ) (Table 3).

According to the scanned data, it was observed that 155 patients received combined treatment (systemic and local), and 214 patients received vaginal treatment only in the outpatient clinic. Among individuals receiving vaginal treatment, 81.3% (n=174) showed no signs of growth in control vaginal cultures, while 18.7% (n=40) had. In contrast, among those who received a combined treatment, 76.1% (n=118) showed no growth in control vaginal cultures, while 23.9% (n=37) had. The study did not identify any statistically significant difference in control

culture results based on the two treatment methods received ( $\chi^2=1.460$ ,  $p=0.227$ ) (Table 4).

Analysis of questionnaires investigating the genital hygiene routines of women who did not have a chronic disease predisposing them to infection, such as immunodeficiency or DM, and yet experienced treatment failure, revealed statistically significant correlations with daily pad use, vaginal douching practices, preference for synthetic underwear and ironing habits (Table 5).

In the analysis of patients who received only vaginal treatment and did not achieve improvement in their follow-up clinic visits, it was determined that 3 women had a history of antibiotic treatment in the last 4 weeks, none of the women had a history of diabetes in their medical history, and rest of the women had incorrect hygienic practices as 31 of them used daily sanitary pads, 33 of them had vaginal douche habit, 15 of them preferred synthetic underwear usage, 9 of them described a habit of back to front bidet and all the women described a routine of pubic hair removal.

On the other hand, among the 40 patients who received combined treatment and did not achieve treatment success in their follow-up appointments, it was found that two of them had a history of antibiotic use in the last 4 weeks. Seven of the patients had a history of diabetes in their medical history. The rest of the women had incorrect hygienic practices as 22 of them used daily sanitary pads, 24 of them had vaginal douche habits, 16 of them preferred synthetic underwear usage, 8 of them described a habit of back to the front bidets and 28 of them women described a routine of pubic hair removal.

There has been a statistically significant difference in the use of vaginal douching according to educational status ( $\chi^2=10.532$ ,  $p=0.032$ ). Additionally, a statistically significant difference in pubic hair grooming has been identified based on educational status ( $\chi^2=37.882$ ,  $p=0.036$ ).

Furthermore, a statistically significant difference in daily pad usage has been detected based on age grouping ( $\chi^2=19.913$ ,  $p<0.001$ ).

Table 2. Comparison of age groups based on culture results					
	Growth in control culture			Test statistics	
	No growth (n=292)	Present (n=77)	$\chi^2$	p	
	n (%)	n (%)			
Age groups					
29 years and under	154 (52.7)	42 (54.5)	=1.354	0.716	
30-39 year	78 (26.8)	22 (28.6)			
40-49 year	43 (14.7)	11 (14.3)			
50 years and over	17 (5.8)	2 (2.6)			
$\chi^2$ : chi-square test statistics					

Table 3. Comparison of educational status based on culture results					
	Growth in control culture			Test statistics	
	No growth (n=292)	Present (n=77)	$\chi^2$	p	
	n (%)	n (%)			
Education status					
Illiterate	14 (4.8)	2 (2.6)	=3.683	0.451	
Primary	109 (37.3)	37 (48.1)			
Middle	57 (19.5)	14 (18.1)			
High	77 (26.4)	18 (23.4)			
University	35 (12.0)	6 (7.8)			
$\chi^2$ : chi-square test statistics					

Table 4. Post-treatment vaginal culture results				
	Treatment		Test statistic	
	Vaginal treatment (n=214)	Combined treatment (n=155)	$\chi^2$	p
	n (%)	n (%)		
Control culture				
No growth	174 (81.3)	118 (76.1)	=1.460	0.227
Growth exist	40 (18.7)	37 (23.9)		

**Table 5. Evaluation of genital hygiene questionnaire results together with control culture results**

	Control culture		Test statistic	
	No growth (n=292)	Growth exist (n=77)	$\chi^2$	p
	n (%)	n (%)		
Daily sanitary pads				
None	161 (55.1)	17 (22.1)	=26.670	<0.001
Exist	131 (44.9)	60 (77.9)		
Vaginal douche				
None	94 (32.2)	13 (16.9)	=6.936	0.008
Exist	198 (67.8)	64 (83.1)		
Underwear preference				
Cotton	165 (56.5)	42 (54.5)	=6.383	0.041
Synthetic	26 (8.9)	1 (1.3)		
Both	101 (34.6)	34 (44.2)		
Frequency of use of synthetic linen				
None	163 (55.8)	42 (54.5)	=15.849	0.001
1-2 times a week	45 (15.4)	23 (29.9)		
3-4 times a week	35 (12.0)	10 (13.0)		
More than 5 times a week	49 (16.8)	2 (2.6)		
Ironing lingerie				
Never	181 (62.8)	58 (75.3)	=7.087	0.029
Sometimes	59 (20.5)	15 (19.5)		
Always	48 (16.7)	4 (5.2)		
Pubic hair				
Do not interfere	6 (2.1)	0 (0.0)	=13.796	0.032
Waxing	116 (39.8)	34 (44.2)		
Shaving	133 (45.5)	40 (51.9)		
Trimming	1 (0.3)	1 (1.3)		
Laser	22 (7.5)	2 (2.6)		
Hair removal cream	12 (4.1)	0 (0.0)		
Waxing + trimming	2 (0.7)	0 (0.0)		

## DISCUSSION

VVC is a prevalent infection that affects millions of women each year, exerting a substantial adverse influence on the quality of their social and sexual well-being and is linked to noteworthy direct and indirect expenses.<sup>15</sup>

Limited data on the prevalence of VVC are accessible because the disease is not mandatory for reporting and is frequently self-

diagnosed without clinical and laboratory verification.<sup>1,16</sup> While vulvovaginal candida is not classified as a sexually transmitted infection, there is a higher likelihood that male partners may harbor the same Candida strain.<sup>1,16</sup> VVC seems to be more linked with orogenital rather than anogenital sexual activity.<sup>1,16</sup>

Complex infections are correlated with severe symptoms, the recurrence of non-albicans species more than three times annually in women dealing with uncontrolled diabetes, undergoing immunosuppressive therapy, compromised immunity or HIV, or during pregnancy.<sup>1,16</sup>

This study is important since diagnosis and treatment of VVC in low-to-middle-income countries are mostly done based on clinical presentations, without any laboratory diagnosis. The mean age of the study participants was  $31.86 \pm 17.80$  years, which correlates with the mean age of 31.5 years reported by Sasikala et al.<sup>17,18</sup> On the contrary, Amar et al.<sup>19</sup> reported a higher mean age of 37.3 years. Similar to Waikhom et al.'s<sup>18</sup> and other previous studies,<sup>17,19</sup> our research observed that the mean age of women comprising the patient population seeking treatment for vaginitis in our clinic was highest in the 20-29 age group followed by women aged 30-39. However, there was no statistically significant difference in age groups based on control culture results ( $\chi^2=1.354$ ,  $p=0.716$ ).

Similar to Bitew and Abebaw's<sup>20</sup> study, our research also found that most of the patient population consisted of women with only basic education who were not employed. A lower level of education and economic status may be linked to inadequate personal hygiene, potentially predisposing women to VVC. However, for the subset of women who received empirical treatment for vaginitis but did not experience its benefits, age, educational status, and economic status were not statistically significant.<sup>20</sup>

When post-treatment culture results were evaluated, candida was detected in 77 patients (20.86%) from both treatment groups. No statistically significant difference was observed between the treatment groups ( $p=0.22$ ). In this study, we observed similar efficacy of vaginal miconazole and combined vaginal miconazole plus oral fluconazole, which are preferred for empirical treatment of vaginitis. It was observed that fluconazole treatment was ineffective in 20.86% of our patients. The re-growth of *C. albicans* suggests that either resistance to the drug, misuse of the drug, or continuation of improper hygiene practices are possible. Although fluconazole has been used as a first-line empirical antimycotic drug for many years,<sup>18</sup> the failure to cure the infection in 20% of patients may be due to resistance to the drug, misuse, or poor personal hygienic habits. Whatever the reason, this is a very high percentage of treatment failure.



Therefore, the necessity of avoiding empirical treatment without waiting for culture results should be explained to patients with justification, and the patient's compliance with treatment should be increased.

### Study Limitations

The major limitation of our study is the small patient sample size and the retrospective nature of data collection. Redesigning the same study as a randomized controlled trial (RCT) would provide stronger support for the points the study aims to highlight. However, due to the unavailability of RCT ethics approval at our affiliated university, our study was designed retrospectively.

Although the number of patients in our study may not seem sufficient to generalize the results, all gynecologists working in the field, especially those dealing with recurrent vaginitis, will agree that our study primarily emphasizes the significant impact of daily lifestyle habits on the failures of medical treatment. In this area where preventive medicine is paramount, although our highlighted findings may need further support from additional studies, it is well-known to clinicians that it is crucial to make a difference by offering simple suggestions to patients and facilitating lifestyle changes.

### CONCLUSION

The management of vaginitis remains a complex issue for both women and clinicians. Vaginal and combination therapies, commonly chosen as empirical treatments, do not exhibit superiority in terms of efficacy. Clinically validated, effective treatments are now accessible through advancements in vaginal microbiome research and innovative therapeutic approaches. Women experiencing recurrent or complicated vaginitis must consult clinicians with specialized expertise in vaginitis rather than opting for empirical treatment. Emphasizing the significance of avoiding behaviors that may disturb vaginal flora is essential. To counteract the rise of drug resistance, we endorse the broad implementation of treatment strategies guided by culture antibiogram results instead of relying on empirical methods. Urgent measures are needed to heighten public awareness and restrict self-medication practices to tackle this issue effectively.

### ETHICS

**Ethics Committee Approval:** The study was reviewed and approved by the ethics committee of Kafkas University Faculty of Medicine, Ethics Committee of Clinical Trials (ethics approval reference number: 80576354-050-99/250). All procedures were performed according to the Declaration of Helsinki.

**Informed Consent:** All participants signed informed written consent before being enrolled in the study.

### Contributions

Surgical and Medical Practices: A.Y., M.C.; Concept: M.C.; Design: M.C.; Data Collection or Processing: A.Y., M.C.; Analysis or Interpretation: A.Y.; Literature Search: A.Y., M.C.; Writing: A.Y., M.C.

### DISCLOSURES

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# Positive effect of labiaplasty on sexual satisfaction and self confidence

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## ABSTRACT

**Objectives:** This study aimed to compare women's body image, positive effect on sexual functions and aesthetic appearance satisfaction after gynecologic cosmetic surgery especially labiaplasty.

**Materials and Methods:** This was a retrospective study. A sample of 42 women attending the private gynecology clinic in Mersin was entered into the study. Surgeries included labiaplasty plus vaginoplasty, clitoral hoodoplasty, perinoplasty, augmentation of labia majora by filler or autolog fat transfer. Women were assessed for the female sexual function inventory at two points in time: 1 and 2 months after surgery.

**Results:** The results showed that women's body image, sexual function and couples' sexual satisfaction improved significantly after labiaplasty.

**Conclusion:** The findings suggest that female genital cosmetic surgery especially labiaplasty improved the body image and sexual function of women and sexual satisfaction in couples.

**Keywords:** Labiaplasty; female cosmetic genital surgery; self confidence; sexual satisfaction, clitoris, perinoplasty, vaginoplasty

## INTRODUCTION

The most frequently applied procedure among female genital cosmetic surgeries (FGCS) is labiaplasty. The reason for this is that the labium minus is the place that is most affected by the anatomical diversity that women encounter in the external genitalia; including the post-adolescent, reproductive age and menopause period, as well as the changes related to age and childbirth. For this reason, it is inevitable to apply it in combination with other procedures in female genital cosmetic surgeries.

Labiaplasty surgery often describes a surgical procedure that involves removing excess skin from the labium minus.

The main purpose of this surgery is not only to get rid of the excess skin in the labium minus, but also to correct the end parts of them that do not look esthetic in their dark and fluffy state, unlike the pink and flat-appearing tissue of the mucosa.

Several labiaplasty techniques have been described including linear excision, deepithelialization, wedge resection, and composite reduction. Linear excision is a straightforward

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approach to volume reduction.<sup>1</sup> Deepithelialization removes a small amount of tissue while preserving the labial contour. It is best suited for patients with minimal hypertrophy.<sup>2</sup> Wedge resection accomplishes a comparable volume reduction with direct excision while preserving the native labial contour.<sup>2</sup> Composite reduction labiaplasty aims to correct clitoral protrusion and hooding in addition to labial reduction. Additional procedures such as W-shaped resection, Z-plasty, and laser labiaplasty have been described in a small number of patients.<sup>3</sup> The linear excision also known as trimming and amputation labiaplasty, is a technique commonly used. Complications associated with a linear labiaplasty include overresection and scalloped labia edges.<sup>4</sup>

## MATERIALS AND METHODS

In this study, we retrospectively analyzed 42 patients who underwent linear labiaplasty combined or not combined with other FGCS (such as vaginoplasty, clitoral hoodoplasty, perinoplasty, augmentation of labia majora by filler or autolog fat transfer) between the years 2019-2022 in terms of the postoperative recovery process, its effect on sexual functions and aesthetic appearance satisfaction.

Inclusion criteria for the study; not having undergone any previous vaginal aesthetic operation, not having a history of genital cancer, not having a sexually transmitted disease, not having any systemic disease that impairs wound healing (diabetes, cardiac diseases, immune deficiency, etc.) and being past adolescence.

This study was approved by the ethics board and conformed to the guidelines of the Declaration of Helsinki. All patients provided informed consent for the use of their clinical data and photographs of their genitals.

### Statistical Analysis

All statistical analyses were performed using SPSS version 24 software (SPSS Inc., Chicago, IL, USA). Quantitative data are reported as mean  $\pm$  standard deviation. The paired samples t-test was used to compare normally distributed data.

## RESULTS

The mean age of our patients was 18-55. All of our patients were examined at least twice before the operation and prepared for the operation by filling out detailed information and consent forms. All of our patients were not satisfied with the appearance of the labium minus, 88% (37 patients) had difficulty in achieving sexual satisfaction, 76% (32 patients) were afraid and embarrassed to wear tight and stretchy clothes in their daily lives

and while doing sports, 55% (23 patients) had self-confidence problems.

All FCGSs were performed by the same senior surgeon (S.S.O.), who has been practicing for 12 years.

All patients underwent linear labiaplasty, and 16% (7 patients) underwent only labiaplasty without additional procedures. In addition different procedures were performed, including clitoral hoodoplasty in 26% (11 patients), vaginoplasty in 26% (11 patients), augmentation of labia majora by filler in 7% (3 patients), perinoplasty in 30% (13 patients), cystocele repair in 11% (5 patients) and liposuction plus fat transfer in 11% (5 patients) of the women.

Only 36% (16 patients) of patients stayed in the hospital the first night after surgery. The remaining 26 patients were discharged on the same day.

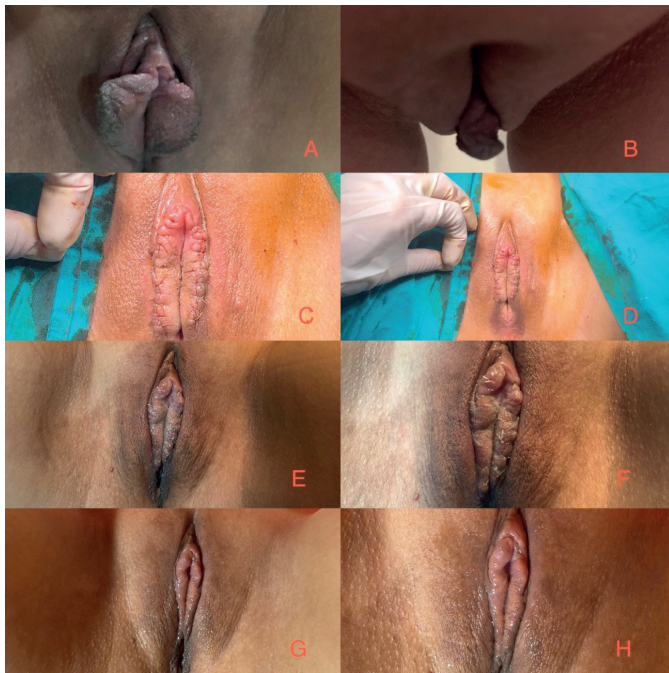
In the first week of postoperative care, 3<sup>rd</sup> generation cephalosporins, analgesics and antiseptic washing solutions for wound care were administered. They were instructed to keep the wound area clean and dry; to wear comfortable, loose and cotton clothes. It was explained that for pain and edema, they could apply ice for 15 minutes every hour until they went to bed on the 1<sup>st</sup> day.

Locally effective epithelializing creams were recommended to patients with itching and slow healing at the wound site during the 1<sup>st</sup> week postoperative control. Only one patient had a single point of dehiscence at the wound site. In the remaining 41 patients, the wound site was observed to be clean.

When the patients were called for postoperative 1<sup>st</sup> month follow-up, all wound healing was complete. Patients with an active sexual life were recommended to stop their sexual diet after the wound healing was completed. The images of a patient who underwent only labiaplasty were shown in the Figure 1.

The patients were called for a 2<sup>nd</sup> month follow-up in terms of post-operative sexual performance, self-confidence, and evaluation of daily life. Forty-one of forty-two patients were quite satisfied with their appearance. Post-secondary suture evaluation of the patient with wound dehiscence was also performed.

All patients also said that they could wear tight and stretchy clothes in their daily lives, that they did not have any difficulties while doing sports and exercise, and their sexual self-confidence was restored. Only 1 of 42 patients was a virgin. The other 41 patients said that they were no longer ashamed to have sex with their spouse or partners, and their partners were more satisfied after the operation. The Figure 2 shows the patient who had the procedure including labiaplasty, vaginoplasty and



**Figure 1.** A, B, Preoperative images; C, D, Just after operation; E, F, 7 days after surgery; G, H, First month follow-up

perinoplasty.

All of our patients stated that they returned to their daily lives in a very short time after the operation, and they did not experience any problems other than mild itching on the labiaplasty sutures.

## DISCUSSION

FCGS aims for better aesthetic genital appearance and improved functional aspects. Although numerous procedures fall under FCGS, one of the most common FCGS is labiaplasty.<sup>5,6</sup>

After the first publication on this subject in 1976, the increase in publications on labiaplasty and other female genital plastic surgeries, especially in the last 2 years, is a proof of the need for female genital aesthetics.

Women frequently give nonaesthetic reasons for seeking surgery to correct hypertrophy of the labia minora. This condition is associated with pain during intercourse, discomfort when exercising or wearing tight clothing, and concerns about hygiene.<sup>7</sup> In a multicenter study by Goodman et al.<sup>8</sup> functional issues were the most common reason for considering labiaplasty (75% of 258 patients), followed by aesthetic concerns and low self-esteem

Apart from the improvement in quality of life, there are many studies on improvement in sexual functions, increase in sexual pleasure, and increase in self-confidence after genital aesthetics. In a retrospective study that involved 48 women who had undergone a labiaplasty procedure, they found women very



**Figure 2.** A, B, Preoperative images; C, D, just after surgery; E, F: First month follow-up

satisfied with the results of their labiaplasty and they also seem to experience improvements in their sexual satisfaction and psychological well-being and physical/functional motivations for undergoing labiaplasty are associated with greater satisfaction with outcomes.<sup>9</sup>

In our retrospective study, we observed a significant improvement in the quality of life and a satisfactory improvement in their sexual lives both in our patients who underwent labiaplasty alone and in our patients who had additional female genital aesthetic operations in addition to labiaplasty.

Although the postoperative complication rate reported in the literature is 7%, in our study, we observed wound dehiscence at one point on the labiaplasty incision in one of our patients. We could say that female genital aesthetic operations are safe with the planning of the operation according to the patient and with strict postoperative follow-up.

## Study Limitations

There are some limitations of our study. Most importantly, the number of samples is small. Another limitation is that we have not compared linear labiaplasty with other labiaplasty techniques. But our study also has strengths. The first is the low complication rate. Another was that patients who underwent only linear labiaplasty gave positive responses in terms of quality of life, improvement in sexual life and increased self-confidence, as did patients who underwent combined surgery with labiaplasty.

## CONCLUSION

According to our findings, we could say that linear labiaplasty provides improvement in sexual functions together with its positive effect on quality of life in patients who want labium minus aesthetics.

## ETHICS

**Ethics Committee Approval:** Human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed Consent:** All patients provided informed consent for the use of their clinical data and photographs of their genitals.

## Contributions

Surgical and Medical Practices: S.Ö.; Concept: S.Ö., A.A.S.; Design: S.Ö., A.A.S.; Data Collection or Processing: S.Ö.; Analysis or Interpretation: S.Ö.; Literature Search: S.Ö.; Writing: S.Ö.

## DISCLOSURES

**Conflict of Interest:** No conflict of interest was declared by the authors.

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# A case report: Sepsis related to vulvar abscess

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## ABSTRACT

Vulvar abscesses are mass-forming and infectious lesions that occur in the external genital organs of women. The abscess may affect larger areas and progress to more complicated stages due to factors such as the patient's hygiene, immunosuppressive reasons, and additional medical conditions. Management of vulvar area abscesses typically requires a multidisciplinary approach, primarily involving gynecology. In this case presentation, we aim to present a case of sepsis secondary to vulvar abscess in 62-year-old morbidly obese patient with additional medical conditions, who was deemed inoperable.

**Keywords:** Sepsis; vulvar abscess; antibiotherapy

## INTRODUCTION

Vulvar abscesses are massive and infectious lesions of the female external genitalia characterized by abscess formation. Abscess formation occurs most commonly in the Bartholin gland, but abscesses involving the labium majus and minus are also encountered.<sup>1</sup> Abscesses may affect larger areas and have a more complicated course due to the patient's hygiene, immunosuppressive causes and comorbidities. The presence of necrotic tissues with abscess in the genital region suggests Fournier gangrene. Vulvar abscesses require a multidisciplinary approach, especially gynecology.

## CASE REPORT

A 62-year-old patient with morbid obesity (body mass index 54.11 kg/m<sup>2</sup>) and associated mobility limitation, known diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), heart failure, coronary artery disease (CAD) and hypertension was admitted to the emergency room with general condition disorder, fever and confusion. After the initial evaluation of the patient, the patient was followed up in the intensive care unit due to sepsis. On admission, fever was 38.1 °C, arterial blood pressure was 100/60 mm/hg, and pulse rate was 120 beats/min. On admission, blood glucose was 543 mg/dL, serum creatinine

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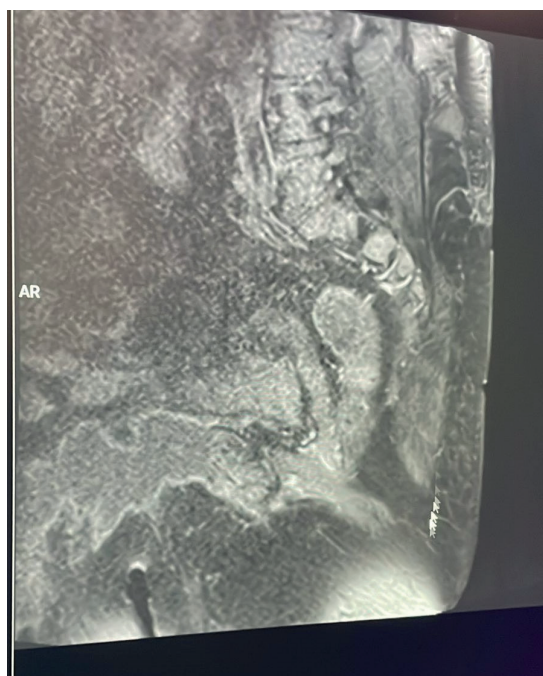
2.9 mg/dL, white blood cell 38600/ $\mu$ L, hemoglobin 9.5 g/dL, C-reactive protein >200 mg/L and procalcitonin 4.5 ng/mL.

The patient was evaluated by a gynecologist and obstetrician after a necrotic, purulent discharge lesion of approximately 6 cm on the left labium majus (Figure 1) was detected on physical examination. The patient was evaluated by cardiology, internal medicine, pulmonology, infectious diseases and obstetrics and gynecology, and it was determined that the focus of sepsis was the lesion on the vulva. It was learned that the patient underwent hysterectomy and bilateral salpingoophorectomy operation for myoma uteri approximately 20 years ago. After physical examination findings and follow-up of the lesion, it was determined that the patient did not have fornier's gangrene and emergency surgery was not considered due to comorbidities. In addition to symptomatic treatment, intravenous (IV) clindamycin 3x600 mg and ceftriaxone 3x2 gr antibiotherapy was started with the recommendation of infectious diseases. Methicillin-resistant staphylococcus epidermidis was grown in blood cultures. Meropenem 3x1 gr treatment was started on the 5<sup>th</sup> day of hospitalization. The abscess content was tried to be drained with daily dressing and local debridement. The patient was followed up in the intensive care unit for 9 days and was followed up in the gynecology and obstetrics ward after her sepsis picture improved, her laboratory values showed white blood cell 31000/ $\mu$ L, serum creatinine 0.85 mg/dL, hemoglobin 9.1 g/dL, C-reactive protein 135 mg/L and procalcitonin 2.4 ng/mL and her general condition improved. Her laboratory values



**Figure 1.** Infected appearance of the left labium majus on admission

(hemogram, biochemistry, C-reactive protein) were monitored daily. The patient was not operated because of her comorbidities and anesthesia risk. Contrast-enhanced magnetic resonance imaging was performed to investigate the depth of the vulvar lesion and possible intraabdominal mass-malignancy-fistula. Because of the appearance compatible with an approximately 18 cm abscess extending to the vulva on the rectus (Figure 2), a catheter was inserted for percutaneous abscess drainage from the suprapubic region by interventional radiology. Approximately 2500 cc purulent abscess content was drained on the first day. The patient was followed up daily by flushing the abscess contents with metronidazole and ceftriaxone through a catheter. There was no growth in control blood, urine, wound and urine cultures after catheterization. IV antibiotic treatment, blood glucose regulation and monitoring of her intake brought the signs of overload under control. The patient was dressed 3 times a day with local antibiotics (nitrofurazone and mupirocin) and epithelizing cream (hamamelis Virginia and triticum vulgare) for the vulvar area. After 25 days of catheterized follow-up, a control computed tomography was performed and the catheter was withdrawn when it was observed that the abscess content had drained. On the 52<sup>nd</sup> day of hospitalization, the patient was discharged with a white blood cell count of 5700/ $\mu$ L, hemoglobin 9.7 g/dL, C-reactive protein 4.9 mg/L, negative procalcitonin value, sedim 53 and the infectious picture and necrotic appearance in the vulvar region were completely corrected (Figure 3).



**Figure 2.** Image of abscess extending to the anterior abdominal wall



Figure 3. Labium majus healed with wound care

## DISCUSSION

Vulvar abscess is an important gynecologic problem that is common in genital tract infections and can lead to serious problems. It usually starts as a simple superficial infection and forms an abscess by affecting the vulvar skin and subcutaneous tissues due to reasons such as the strength of the immune system and personal hygiene. The loose areolar structure of the subcutaneous layer of the vulvar region and its fascial connection with the groin and anterior abdominal wall facilitate the distribution and deepening of the abscess.<sup>2</sup> MRSA, enteric gram-negative cocci and anaerobes of the female genital tract are mainly implicated.<sup>3</sup> For vulvar abscesses requiring surgery, MRSA is the most common organism isolated.<sup>4</sup> In addition, in conditions such as uncontrolled diabetes mellitus, the size of the abscess is larger and more complicated pictures are seen.<sup>2</sup> There are studies showing that skin and soft tissue infections increase in conditions with impaired lymphovascular circulation such as obesity.<sup>5</sup> In addition, restricted mobility and obesity negatively affect vulvar hygiene and predispose to infectious conditions.<sup>6</sup>

The principles of treatment of vulvar abscesses vary according to the appearance of the abscess, the cavitory lesion it forms and whether there is a rapidly progressive lesion such as necrotizing fasciitis and systemic status. In the presence of a purulent and superficial infection, antibiotic therapy and strict surveillance after drainage may be recommended.<sup>7</sup> Community-acquired vulvar MRSA infections can be treated as outpatients but usually require hospitalization.<sup>8,9</sup> Furthermore, the relationship between vulvar abscesses and conditions such as Bartholin's gland cysts should be considered, especially in cases at risk of complications such as septic shock.<sup>3</sup> For the healing of chronic and ulcerated vulvar lesions, interventions that provide cell regeneration are

needed.<sup>10</sup> Antibiotherapy, surgical incision and abscess drainage are applied in the treatment of vulvar abscesses and appropriate antibiotic treatment is recommended for polymicrobial agents.<sup>11</sup> In addition, the effectiveness of antibiotherapy is decreased in abscess formations larger than 5 cm and surgery is required.<sup>11</sup>

In this case report, methicillin-resistant *Staphylococcus aureus* was isolated from a patient with COPD, CAD, DM, morbid obesity and accompanying circulatory disorders who developed sepsis due to abscess in the vulvar region. Due to comorbidities, the patient could not be operated and was treated with drainage and antibiotherapy. Close follow-up by pulmonology, cardiology, infectious diseases, gynecology, obstetrics and gynecology and interventional radiology led to a cure. Giant abscess formation on the rectus due to vulvar abscess and associated sepsis is a rare presentation. Recently, there has been an increase in the frequency of MRSA-caused vulvar abscesses in the literature. The hospitalization requirement is more common in patients with medical problems due to more widespread infection and larger abscesses.

## ETHICS

**Informed Consent:** Consent was obtained or waived by all participants in this study.

## DISCLOSURES

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# A hypothesis explaining weight loss cure of obesity-linked female urinary incontinence

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## ABSTRACT

**Objectives:** The vagina has an important role in transmission of 3 opposite striated pelvic muscle forces acting against pelvic ligaments to close urethra distally and at bladder neck. The same muscle forces stretch vagina to support the urothelial stretch receptors to prevent them activating the micturition reflex at low bladder volumes, and to open the urethra prior to micturition. Striated muscles have a limited contractile force. The hypothesis the weight of the intraabdominal contents on the vaginal membrane adds additional weight for the striated pelvic muscles to move when they tension the vagina to close the urethra for continence, open it for evacuation and prevent urothelial stretch receptors from activating micturition prematurely (interpreted as urgency).

**Materials and Methods:** To test if a binary musculo-elastic model of bladder control can explain significant cure/improvement of lower urinary tract symptoms following weight loss after bariatric surgery.

**Results:** The results for improvement of stress urinary incontinence (SUI), overactive bladder syndrome (OAB) and mixed symptoms were consistent with the concept of an extra intraabdominal intestinal load on the vagina membrane which prevented the 3 opposite striated muscle forces stretching the vagina sufficiently to close the urethra (SUI) and/or prevent excessive afferent impulses from the urothelial stretch receptors activating micturition prematurely (OAB).

**Conclusion:** Removing the burden of intestinal contents on the vagina restored several different areas of incontinence, SUI, mixed incontinence, urgency (OAB) seemingly validates the hypothesis.

**Keywords:** Urinary incontinence; integral theory; weight loss; obesity; bariatric surgery, damaged ligaments

## INTRODUCTION

In 2006, O'Boyle et al.<sup>1</sup> tracked urinary symptoms in 240 female patients who lost weight following bariatric surgery. The results were quite remarkable, and are quoted directly:<sup>1</sup> "The prevalence

of urinary incontinence preoperatively was 45% (108). Eighty-two (76%) completed urinary function questionnaires pre-operatively and post-operatively. Fifty-seven (70%) underwent laparoscopic gastric bypass, twenty-four (29%) underwent sleeve

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gastrectomy and one underwent a banding procedure. Thirty-one (38%) reported leaking on sneezing or coughing-stress urinary incontinence (SUI). Thirteen (16%) complained of leaking before reaching the toilet-overactive bladder syndrome (OAB). The remaining thirty-eight (46%) reported mixed symptoms. The mean pre-operative weight and body mass index (BMI) were 133 (18) kg and 50 [standard deviation (SD) =6.2] kg/m respectively. The mean post-operative BMI drop was 16 (SD =5.2) kg/m<sup>2</sup>. Preoperatively, 61 (75%) reported moderate to very severe urinary incontinence compared to 30 (37%) post-operatively. Twenty-seven (33%) patients reported complete resolution of their urinary incontinence. Fifty-one (62%) patients required incontinence pads on a daily basis pre-operatively, compared to 35 (43%) post-operatively. The mean international consultation on incontinence questionnaire-urinary incontinence short form (ICIQ-UI SF) score was 9.3 (SD =4.4) pre-operatively compared to 4.9 (SD =5.3) post-operatively ( $t=7.2, p=0.000$ ). The improvement score post-operatively was 8 (SD =3). A significant difference in the ICIQ-UI SF was identified between OAB and SUI groups when adjusting for age, number of children, type of delivery and pre-op BMI.”

### Hypothesis for Obesity Causation of Incontinence and Cure by Weight Loss

With reference to Figure 1, the increased weight of the organs pressing on the bladder and vagina is an additional load for the opposite muscle forces which stretch the vagina to perform their natural reflex functions of urethral closure during effort; to support the stretch receptors “N” to control urgency; to externally open the urethra prior to micturition by lowering resistance, thus facilitating urine flow. The hypothesis is based on the Integral Theory of Female Urinary Incontinence (IT), which states that control of bladder function is binary, and not from the bladder itself, but from structures outside it, the vagina, its supporting ligaments, and pelvic muscles.<sup>2</sup>

## MATERIALS AND METHODS

To test if a binary musculo-elastic model of bladder control, Figure 1, can explain cure/improvement of lower urinary tract symptoms following bariatric surgery.

### Normal Binary Control of the Bladder

The vagina has an essential role in all bladder functions.<sup>2</sup> With reference to Figure 1, under reflex binary cortical control, the 3 directional muscle forces (large arrows) contract against the pubourethral ligaments anteriorly and the uterosacral ligaments (USL) posteriorly to stretch the vagina to enact 3 functions: To close the urethra during effort; to stretch the vagina in opposite

directions to prevent activation of the micturition reflex at low volume (OAB);<sup>2,3</sup> to open it prior to micturition.

### A Hypothesized Anatomical Pathway for Obesity-induced Incontinence

The pathway is graphically indicated in Figure 1. Essential to explaining the hypothesis, is the well-known fact that striated muscles (large arrows, Figure 1) have a finite contractile force.<sup>4</sup> The additional intraabdominal weight of fat-laden organs is an extra weight added to the contractile force required for the opposite muscle forces pubococcygeus muscle, levator plate/conjoint longitudinal muscle of the anus to stretch the vagina to perform the 3 functions of the musculo-elastic control complex. In consequence, all 3 functions of the musculo-elastic control complex, Figure 1, weaken, and can be expressed clinically as described, stress urinary incontinence (SUI), “mixed incontinence”, OAB (1). According to hypothesis predictions, these same patients<sup>1</sup> would have symptoms of inability to empty adequately “UAB” (“underactive bladder”), Figure 1.

## DISCUSSION

The pre-operative and post-operative results<sup>1</sup> are consistent with the predictions of the hypothesis, that weight loss would relieve some of the burden on the contractile force of the striated pelvic muscles, thus allowing them to perform their natural control functions unhindered. Pre-operatively, the symptom incidence was: SUI (38%), OAB (16%), mixed symptoms (46%). Post-operatively 33% of these patients reported complete resolution of their urinary incontinence, and daily pad use reduced from 62% to 43%. With reference to Figure 1, the anatomical pathway to the described cure,<sup>1</sup> is the reduction of the added load on the striated muscles, allows the muscles to close and open the urethra normally.

Urinary incontinence is one of many co-morbidities associated with the intraabdominal pressure (IAP) from obesity. Sugerman<sup>5</sup> reported increased IAP increases pleural pressure, cardiac filling pressures, femoral venous pressure, renal venous pressure, systemic blood pressure, and vascular resistance, renin and aldosterone levels, and intracranial pressure. Varela et al.<sup>6</sup> reported systemic hypertension, type 2 diabetes mellitus, gastroesophageal reflux disease, urinary stress incontinence, lower extremity edema, obstructive sleep apnea, and abdominal wall hernia. Jordan and Tincello<sup>7</sup> stated that weight loss has a profound effect upon urinary, anal, and prolapse symptoms: achieving a target weight loss of 5-10% of baseline body weight is associated with 30-70% cure of urinary leakage, around 65% improvement of anal symptoms, and 75% resolution of prolapse symptoms. They recommended that weight loss should

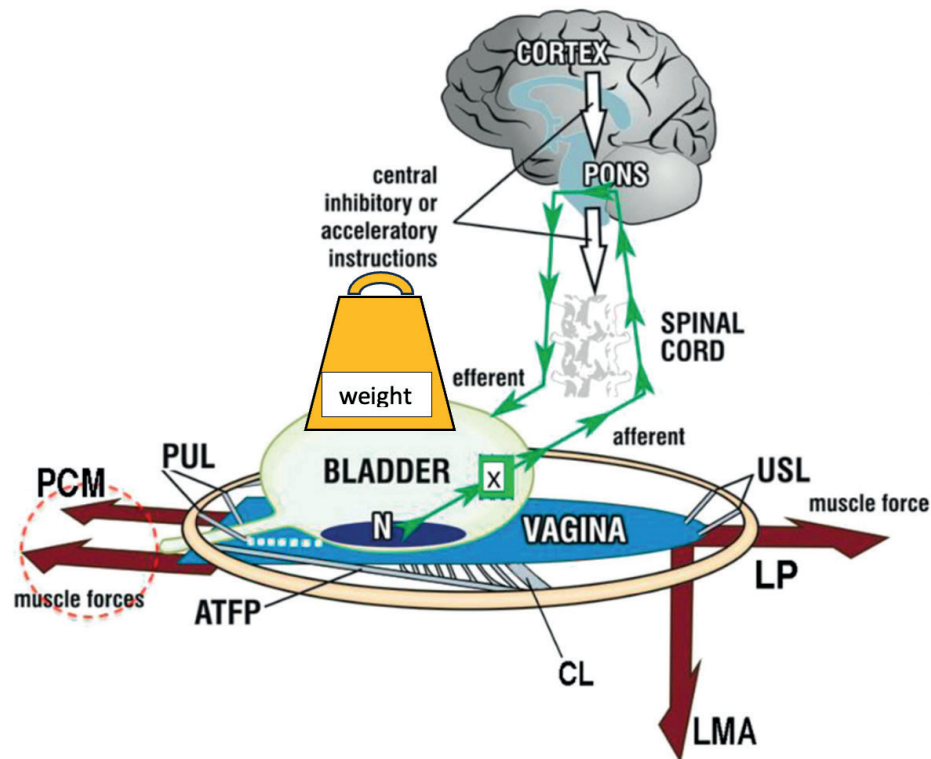


be recommended as first-line intervention for obese incontinent women. Surgery for incontinence carries a slightly lower cure rate in obese women but no higher risk of complications.

### The Hypothesis and the Integral Theory

This is the first time the IT has been able to explain how restoration of the muscle forces themselves can restore normal bladder function, and therefore continence.

The hypothesis itself, and the anatomical analysis, both flow from the IT which is summarized by Figure 1. The anatomical analysis is an example of Karl Popper's dictum, that a universal theory (for example, the IT), must be simply stated, falsifiable and predictive.<sup>8</sup> In all surgical studies to date, surgical cure has been based on native ligament repair<sup>9</sup> or harnessing the wound reaction of a precisely implanted tape to create new collagen to repair weak collagen-deficient ligaments<sup>10</sup> against which the



**Figure 1.** Binary model for bladder control by 2 opposing reflexes, EITHER closure OR micturition. Schematic 3D sagittal view, System in normal closed mode. PCM=pubococcygeus muscle; LP=levator plate; LMA=conjoint longitudinal muscle of the anus; PUL=pubourethral ligaments; USL=uterosacral ligaments; N=urothelial stretch receptors; CX=cervix; CL=cardinal ligament; ATFP=arcus tendineus fascia pelvis.

**Control of SUI:** PCM stretches distal vagina forwards to close distal urethra from behind; LP/LMA stretch proximal vagina and bladder base back and around PUL to close bladder neck.

**Cortical control of OAB:** Afferent impulses "X" from stretch receptors "N" are reflexly suppressed cortically (white arrows). Efferent impulses prevent coalescence of micromotions which are necessary for smooth muscle contraction during micturition.

**Peripheral control of OAB:** Is by a musculo-elastic mechanism which responds to cortical efferents (small arrows) to stretch vagina in opposite directions to support "N" and decrease afferent impulses "X". The three directional muscles (large arrows), forward, (PCM), backward (LP), and downward, (LMA) contract against the supporting ligaments, PUL and USL, to stretch vagina tightly, much like the membrane of a drum. The stretched vagina supports the urine column, preventing activation of the stretch receptors "N", decreasing afferent impulses to the cortex.

**Micturition:** The closure reflex is shut down and the micturition reflex is activated. Central control (white arrows) relaxes, as does PCM (broken circle); PCM relaxation allows the posterior muscles LP and LMA to unrestrictedly open out the posterior wall of urethra (white broken lines below urethra) just before bladder evacuation by detrusor contraction.

**Dysfunction:** PCM, LP, LMA contract against PUL and USL. As they are striated muscles, they require a firm anchoring point to contract against. If the ligament is weak, the contractile force of the muscles weakens, and inhibits their function (4): the muscles cannot mechanically close urethra (causing stress incontinence), cannot open it (causing obstructed micturition) or they cannot stretch the vagina sufficiently to support the urothelial stretch receptors "N"; these may fire off excess afferent impulses to activate the micturition reflex, experienced as "urge to go" ("OAB").

**Obesity:** The extra weight of the abdominal organs weighs down on the bladder and vagina. The opposite forces are not sufficiently strong to stretch the vagina to close the urethra or to support "N", so control of all the above functions, SUI, urge, emptying is weakened. Improvement in all the foregoing parameters following bariatric surgery (1) provides support for this anatomical explanation

pelvic muscles (large arrows, Figure 1) contracted. However, as is evident from,<sup>11</sup> no surgery was performed on the ligaments, so only restoration of contractile strength to the muscles could prevent the symptom cure reported.<sup>1</sup> Removing the burden of intestinal contents on the vagina restored several different areas of incontinence, SUI, mixed incontinence, urgency (OAB) seemingly validates the hypothesis, and the underlying Integral Theory itself.

## CONCLUSION

Loss of weight, either by diet or by bariatric surgery to lower caloric intake is a well documented treatment for urinary and even bowel incontinence. The vagina has an important role in closure and opening of the urethra by the pelvic muscles. The hypothesis of additional weight of the intrabdominal contents imposing an additional contractile force to stretch the vagina seems to explain the relief of SUI and urge reported by several investigators. It also supports the statement that control of the bladder is from outside the bladder from the vagina, muscles and ligaments.<sup>2</sup> The hypothesis predicts significant cure of emptying symptoms also, which would be a further test of the hypothesis.

## DISCLOSURES

**Financial Disclosure:** The author declared that this study received no financial support.

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