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## A Comparative Analysis of Different Types of Sling System for the Treatment of Female Stress Urinary Incontinence.

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### ABSTRACT

Objective was to compare comparison of the long-term results of using different options sling systems for the treatment of female stress urinary incontinence (SUI). The study included 698 women aged 42 to 68 years (median - 54 years) with SUI. We used 4 types of sling: TVT - in 167 women, TVT-O (Gynecare) – in 359 women, TVT-O (Monarch) - in 105 women, mini-sling system TVT-Secur – in 67 women. Time of follow-up of patients ranged from 12 to 108 months (median - 55 months). The results of treatment were assessed using questionnaires UDI-6 and IIQ-7, voiding diary, cough sample and 1-hour Pad-test. The efficacy and safety of modern sling systems for the treatment of female stress urinary incontinence does not depend on the type of sling system for centers with large experience in using these surgical procedures.

**Keywords:** female stress urinary incontinence, sling system.

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**INTRODUCTION**

Stress urinary incontinence (SUI) is common among women, and its prevalence in the female population ranges 12.8-81.9% [1-3]. This disease has a significant negative impact on quality of life, in particular, social, physical, psychological, professional and sexual life aspects [4-5]. In addition, the cost of medical treatment for female SUI is very high. For example, in the US the cost of the disease was 19.5 billion US dollars per year [6], and in the UK - 740 million pounds [7].

Currently sling system using synthetic loops occupy a leading position in the treatment of female SUI [8-11]. Many studies demonstrated sufficiently high efficiency and safety sling systems [12-15]. However, very few studies that have evaluated the long-term results sling systems for the treatment of female SUI. In addition, no studies comparing different types of sling systems based on the large experience of one center. These factors led to the relevance of this study to analyze a large experience in the use of different types of sling systems for the treatment of female SUI.

**MATERIALS AND METHODS**

The study included 698 women aged 42 to 68 years (median - 54 years) with SUI. Exclusion criteria were: detrusor overactivity; previous surgery on the wall of the vagina; low pressure urethra < 20 cm H<sub>2</sub>O. We used 4 types of sling: TVT - in 167 (23.9%) women, TVT-O (Gynecare) - 359 (51.4%) women, TVT-O (Monarch) - in 105 (15.0%) women, mini-sling system TVT-Secur - 67 (9.6%) women. Demographic parameters of patients are presented in Table 1.

**TABLE 1. Demographic parameters of patients**

Parameter	TVT (n=167)	TVT-O (Gynecare) (n=359)	TVT-O (Monarch) (n=105)	TVT-Secur (n=67)	p
	<b>Me [Q<sub>25%</sub>- Q<sub>75%</sub>]</b>				
Age (years)	53 [46-61]	54 [47-63]	55 [46-64]	53 [45-62]	0.564
BMI (kg/m <sup>2</sup> )	26.3 [23.6-30.3]	26.1 [23.1-30.1]	26.4 [23.7-30.6]	25.9 [22.8-30.2]	0.623
Parity (deliveries)	2 [1-3]	2 [1-3]	2 [1-3]	2 [1-3]	0.897
Incontinence period (years)	5.8 [3.6-7.1]	6.2 [4.1-7.6]	5.9 [3.8-7.2]	6.0 [4.0-7.5]	0.311
	<b>Number of patients (%)</b>				
Postmenopausal	115 (68.9%)	257 (71.6%)	76 (72.4%)	47 (70.1%)	0.098
Background chronic illness (diabetes mellitus, bronchial asthma, hypertension, venous insufficiency, and hypothyroidism)	56 (33.5%)	126 (35.1%)	38 (36.2%)	22 (32.8%)	0.201

Patients were assessed by questionnaires UDI-6 and IIQ-7, voiding diary, cough sample, and 1-hour Pad-test. Treatment outcome was considered as effective in the absence of leakage of urine as a sample with cough and Pad-test.

Evaluates the condition of the patients before surgery and at 1, 6, 12 months after the operation, then - 1 once a year. Time of follow-up of patients ranged from 12 to 108 months (median - 55 months).

Data analysis was performed with the program «Statistica version 17.0» (StatSoft, USA). Data are presented in the form of descriptive statistics. Categorical variables are depicted by a count and percentage, and continuous

variables are represented by the median (Me) and interquartile range (Q<sub>25%</sub>-Q<sub>75%</sub>). Changes occurred after surgery was evaluated using Wilcoxon method, comparison types sling systems performed using test  $\chi^2$ . It was considered significant difference between the parameters at the level of statistical significance of  $p < 0.05$ .

### RESULTS

Evaluated following perioperative parameters: operative time, type of anesthesia, blood loss, bladder drainage duration, postoperative period of hospital treatment, postoperative pain, overall intraoperative and early postoperative complication rate. Postoperative pain was evaluated using a visual analog scale (VAS). Perioperative results are included in Table 2. For all the perioperative parameters, except for duration of surgery, compared types of sling systems had no significant differences. TVT-O (Gynecare), TVT-O (Monarch) and TVT-Secur had no significant differences between the duration of surgery, but between them all and TVT had a difference on this parameter.

**TABLE 2. Perioperative results**

Parameter	TVT (n=167)	TVT-O (Gynecare) (n=359)	TVT-O (Monarch) (n=105)	TVT-Secur (n=67)	p
	Me [Q <sub>25%</sub> -Q <sub>75%</sub> ]				
Operative time (min)	26 [22-30]	16 [14-19]	18 [15-20]	14 [12-17]	0.025
Blood loss (ml)	40 [34-48]	45 [35-50]	42 [35-48]	38 [33-45]	0.085
Bladder drainage duration (hour)	11 [10-12]	11 [10-12]	11 [10-12]	11 [10-12]	0.985
Postoperative period of hospital treatment (day)	1 [1-2]	1 [1-2]	1 [1-2]	1 [1-2]	0.987
Postoperative pain (VAS score)	3 [2-4]	2 [1-3]	3 [2-4]	2 [1-3]	0.836
	Number of patients (%)				
Local anesthesia	154 (92.2%)	335 (93.3%)	99 (94.3%)	64 (95.5%)	0.790
General anesthesia	13 (7.8%)	24 (6.7%)	6 (5.7%)	3 (4.5%)	0.603
Overall intraoperative and early postoperative complications	13 (7.8%)	25 (6.9%)	8 (7.6%)	5 (7.5%)	0.757

Types of intraoperative and early postoperative complications are presented in Table 3. A comparison of complications types are not met, since there was no difference between the types of slings on the overall complication rate.

**TABLE 3. Types of intraoperative and early postoperative complications**

Complications	Number of patients (%)			
	TVT (n=167)	TVT-O (Gynecare) (n=359)	TVT-O (Monarch) (n=105)	TVT-Secur (n=67)
Perforation of the bladder	1 (0.6%)	3 (0.8%)	1 (1.0%)	0
Perforation of the vagina	1 (0.6%)	1 (0.3%)	1 (1.0%)	1 (1.5%)
Retropubic or perineal hematoma	2 (1.2%)	3 (0.8%)	2 (1.9%)	1 (1.5%)
Wound infection	1 (0.6%)	1 (0.3%)	0	0

Postoperative fever, urinary tract infection	3 (1.8%)	6 (1.7%)	1 (1.0%)	2 (3.0%)
Haematuria	1 (0.6%)	3 (0.8%)	0	0
Irritative and obstructive symptoms without acute urinary retention	2 (1.2%)	5 (1.4%)	2 (1.9%)	1 (1.5%)
Acute urinary retention	1 (0.6%)	2 (0.6%)	1 (1.0%)	0
Neuropathy	0	1 (0.3%)	0	0
Exposure of synthetic tape	1 (0.6%)	0	0	0

Changes in urinary diary during the first year after surgery compared with preoperative data presented in Table 4.

**TABLE 4. Changes of voiding diary parameters (Me)**

Parameter	TVT (n=167)	TVT-O (Gynecare) (n=359)	TVT-O (Monarch) (n=105)	TVT-Secur (n=67)	p**
<b>The frequency of urination/24 h</b>					
preoperative	10	11	10	10	0.875
after 1 months after surgery	9	9	9	9	0.956
<b>p*</b>	0.034	0.011	0.035	0.032	
after 6 months after surgery	8	8	8	8	0.981
<b>p*</b>	0.030	0.031	0.029	0.028	
after 12 months after surgery	8	8	8	7	0.834
<b>p*</b>	0.912	0.923	0.918	0.036	
<b>The frequency of nighttime urination/24 h</b>					
preoperative	1	1	1	1	0.963
after 1 months after surgery	1	1	1	1	0.956
<b>p*</b>	0.948	0.956	0.960	0.963	
after 6 months after surgery	0	0	0	0	0.981
<b>p*</b>	<0.001	<0.001	<0.001	<0.001	
after 12 months after surgery	0	0	0	0	0.970
<b>p*</b>	0.970	0.959	0.961	0.965	
<b>Urgency episodes/24 h</b>					
preoperative	2	2	2	2	0.947
after 1 months after surgery	1	1	1	1	0.953
<b>p*</b>	0.001	0.001	0.001	0.001	
after 6 months after surgery	0	0	0	0	0.971
<b>p*</b>	<0.001	<0.001	<0.001	<0.001	
after 12 months after surgery	0	0	0	0	0.961
<b>p*</b>	0.954	0.959	0.968	0.964	
<b>Urgency urinary incontinence episodes/24 h</b>					
preoperative	1	1	1	1	0.982
after 1 months after surgery	0	0	0	0	0.976
<b>p*</b>	<0.001	<0.001	<0.001	<0.001	
after 6 months after surgery	0	0	0	0	0.977
<b>p*</b>	0.971	0.962	0.967	0.970	
after 12 months after surgery	0	0	0	0	0.979

$p^*$	0.968	0.965	0.961	0.969	
<b>Average volume of urination (ml)</b>					
preoperative	165	170	160	175	0.589
after 1 months after surgery	180	190	185	190	0.611
$p^*$	0.039	0.035	0.022	0.041	
after 6 months after surgery	195	200	200	205	0.626
$p^*$	0.045	0.029	0.032	0.034	
after 12 months after surgery	200	205	200	205	0.671
$p^*$	0.902	0.913	0.963	0.956	
<b>Average volume of nighttime urination (ml)</b>					
preoperative	150	155	145	150	0.520
after 1 months after surgery	145	150	150	150	0.601
$p^*$	0.911	0.914	0.912	0.966	
after 6 months after surgery	0	0	0	0	0.973
$p^*$	<0.001	<0.001	<0.001	<0.001	
after 12 months after surgery	0	0	0	0	0.968
$p^*$	0.936	0.948	0.940	0.944	

$p^*$  - Wilcoxon test;  $p^{**}$  -  $\chi^2$  test.

As a result of these positive changes in all parameters correspond to normal voiding diary criteria at 6 months after surgery. After 12 months in all types of sling systems were not deteriorating any parameter voiding diary, reached after 12 months.

Revealed similar changes in the values of the questionnaires UDI-6 and IIS-7. A moderate improvement was 1 month after surgery and a significant improvement after 6 months without further deterioration during the observation period. There were no differences between the types of slings according to criteria (Table 5).

**TABLE 5. Changes of UDI-6 and IIQ-7 scores (Me)**

Parameter	TVT (n=167)	TVT-O (Gynecare) (n=359)	TVT-O (Monarch) (n=105)	TVT-Secur (n=67)	$p^{**}$
<b>UDI-6 scores</b>					
preoperative	12.8	13.2	12.9	13.0	0.834
after 1 months after surgery	4.3	4.5	4.2	4.4	0.793
$p^*$	0.001	0.001	0.001	0.001	
after 6 months after surgery	1.1	1.2	1.0	1.1	0.781
$p^*$	0.001	0.001	0.001	0.001	
after 12 months after surgery	0.9	1.0	0.8	0.9	0.801
$p^*$	0.787	0.788	0.771	0.785	
after > 12 months after surgery	1.0	1.0	0.9	0.8	0.767
$p^*$	0.820	0.912	0.805	0.810	
<b>IIQ-7 scores</b>					
preoperative	17.8	18.1	18.0	17.9	0.856
after 1 months after surgery	4.8	4.9	5.0	4.7	0.812
$p^*$	0.001	0.001	0.001	0.001	
after 6 months after surgery	1.2	1.3	1.3	1.1	0.798
$p^*$	0.001	0.001	0.001	0.001	

after 12 months after surgery	1.1	1.2	1.2	1.2	0.790
$p^*$	0.837	0.844	0.848	0.840	
after > 12 months after surgery	1.2	1.1	1.3	1.1	0.795
$p^*$	0.843	0.841	0.853	0.846	

$p^*$  - Wilcoxon test;  $p^{**}$  -  $\chi^2$  test.

Cough sample and 1-hour Pad-test used in the median 59, 56, 54 and 49 months after TVT, TVT-O (Gynecare), TVT-O (Monarch) and TVT-Secur respectively. The results are included in Table 6.

**TABLE 6. Long-term results of surgical treatment of women with SUI**

Cough sample + 1-hour Pad-test result	Number of patients (%)				$p$
	TVT (n=167)	TVT-O (Gynecare) (n=359)	TVT-O (Monarch) (n=105)	TVT-Secur (n=67)	
Lack of urinary incontinence	154 (92.2%)	335 (93.3%)	96 (91.4%)	62 (92.5%)	0.681
The presence of urinary incontinence	13 (7.8%)	24 (6.7%)	9 (8.6%)	5 (7.5%)	0.439

The frequency of late complications was 9.6% (16/167), 8.9% (32/359), 10.5% (11/105) and 9.0% (6/67) after TVT, TVT-O (Gynecare), TVT-O (Monarch) and TVT-Secur respectively. There were no differences between the types of sling systems in this parameter ( $p = 0,498$ ). Data on late postoperative complications in this time of observation are shown in Table 7. Not done comparing sling type systems species late postoperative complications, so they were represented by a small number of cases.

**TABLE 7. Late postoperative complications**

Вид осложнения	Number of patients (%)			
	TVT (n=167)	TVT-O (Gynecare) (n=359)	TVT-O (Monarch) (n=105)	TVT-Secur (n=67)
Tape protrusion into the vagina	1 (0.6%)	2 (0.6%)	1 (1.0%)	1 (1.5%)
Bladder outlet obstruction, which required tape dissection	2 (1.2%)	2 (0.6%)	1 (1.0%)	0
Recurrence of SUI	6 (3.6%)	12 (3.3%)	5 (4.8%)	2 (3.0%)
Imperative incontinence <i>de novo</i>	2 (1.2%)	4 (1.1%)	2 (1.9%)	0
Overactive bladder <i>de novo</i>	1 (0.6%)	4 (1.1%)	1 (1.0%)	1 (1.5%)
Dyspareunia	2 (1.2%)	5 (1.4%)	0	1 (1.5%)
Chronic pelvic pain syndrome	2 (1.2%)	3 (0.8%)	1 (1.0%)	1 (1.5%)

**CONCLUSION**

Data were obtained on the basis of long-term postoperative observations, a large number of patients and the use of any type of sling systems in a single center. The effectiveness of surgical treatment of stress urinary incontinence using the sling systems can achieve more than 90% irrespective of the type sling procedure. This efficacy of the treatment, as well as high safety and low morbidity are the main advantages of sling procedures prior to the classical approach to the surgical treatment of urinary incontinence. The study showed that compared sling techniques had no significant differences in objective and subjective criteria for the effectiveness of treatment. Based on these data it can be argued that the success of surgical treatment does not depend on the type of sling surgery for a large surgical experience. Therefore the choice of the type

of sling techniques should be based primarily on the experience of the surgeon and the cost of the procedure. Our data are consistent with the results of the largest studies in recent years [16-20].

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