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The Comparison of Adjustable Single-incision Mini Sling and Transobturator Tape for the Treatment of Stress Urinary Incontinence

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ABSTRACT

Objective: The aim of the study was to compare the efficacy and complications of adjustable single-incision mini-sling (A-SIMS) with transobturator tape (TOT) in surgical management of female urinary incontinence.

Methods: The results of 54 patients performed A-SIMS and TOT were evaluated retrospectively. Inclusion criteria were stress urinary incontinence with valsava leak point pressure <60 cm H2O and at least one-year follow-up. Exclusion criteria were pelvic organ prolapsus, concominant or previous genitourinary surgery and patients without urodynamic assessment. Patients were enrolled into two groups as A-SIMS and TOT, each group included 27 patients. Results of the operations (postoperative hemoglobin decrease, operation time, perioperative complication, urinary retention, postoperative pain) and efficacy of the surgery (objective cure rate, subjective cure rate, failure rate) were compared.

Results: Both of the groups were similar according to the patients characteristics. The mean follow-up period was 21.5 and 17.7 months in TOT and A-SIMS groups, respectively. The difference between the two groups according to objective cure rate, subjective cure rate and failure rate was not statistically significant. Postoperative hemoglobin decrease and operation time in the A-SIMS group were significantly lower than in the TOT group. Five patients had postoperative pain in the TOT group. However, no pain was revealed in the A-SIMS group. Besides, no perioperative complication was revealed in both of the groups.

Conclusion: In short-term period, A-SIMS is as effective and safe as TOT in the surgical management of female urinary incontinence. However, A-SIMS may be superior as a simple procedure having shorter operation time.

Keywords: Mini-sling, tot, stress urinary incontinence

INTRODUCTION

Stress urinary incontinence (SUI) complaint is defined as involuntary urinary incontinence with exertion, exercise, sneezing or coughing (1-3). Urinary incontinence in women causes distress and negatively affects their daily lives. Urinary incontinence incidence varies between 10 and 40% (4,5). This problem affecting approximately 50% of incontinent women all over the world is primarily treated conservatively and medically (6). However, failed conservative treatments often make surgical treatment necessary. Surgical treatment is somewhat developed and aimed at correcting urethral hypermobility that causes SUI (7). Incontinence is more common in older women than in younger women (4). Obesity and childbirth are seen as general risk factors in SUI (8,9). Stress is the gold standard midurethral sling operation in the treatment of urinary incontinence and has a cure rate of 70-90% when considering the long-term results (10). Transobturator tape (TOT), tension-free vaginal tape (TVT) or adjustable single-incision mini-sling (A-SIMS) can be successfully applied according

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to the experience and choice of the surgeon who will apply them as surgical treatment options in SUI treatment (10-12). These surgical procedures can be performed with the approach from the rertopubic region or with the transobturator approach (13). Although sling operations are performed retrobupically and they are minimally invasive procedures, all of these surgical procedures involve complications in the intraoperative or postoperative period (14). During retropubic procedures, voiding dysfunction, bladder injury, and vascular injury can occur. In the transobturator approach, risks in reropubic processes can be avoided, while more pain arises (13).

SIMS are at the last point in the search for safe and effective minimally invasive surgery. In the first SIMS (MiniArc), the braid, which is shorter than the midurethral sling, is inserted through a single vaginal incision and bilaterally binded to the obturator muscle (such as Ajust, Altis, TFS). The latest developed Adjustible SIMS (A-SIMS) are designed without anchors (such as Contasure, Ophira). Because the SIMS are less invasive and easier to apply, while outpatient approach, short operation and recovery time and fewer perioperative complications are expected, its superiority to standard MUSs (TVT, TOT, TVT-O) in terms of efficacy and safety has not been clarified in the literature (11,15,16).

When the studies comparing TOT and mini sling operations are examined, it is seen that both methods are successful in preventing SUI, while less invasive procedure with mini-sling and therefore lower pain and complaints are reported in the postoperative period (9).

We also aimed to evaluate the efficacy and safety of contasure-needleness application, a new generation A-SIMS, in patients undergoing surgery for SUI, by comparing it with TOT application with the literature.

METHODS

Study Group

A total of 54 patients, including 27 patients who received TOT for SUI in the gynecology service of our hospital between March 2015 and April 2017 and 27 patients who underwent A-SIMS, were included in the study. Ethics committee approval was not obtained since the required data were obtained by retrospectively examining patient records.

In the urodynamic evaluation of all operated patients, valsava leak point pressure <60 cm H_2O and at least 1-year postoperative follow-up were determined as inclusion criteria. Informed consent was ontained. Genital prolapse, concomitant or previous genitourinary surgery, and the absence of preoperative urodynamic evaluation were accepted as exclusion criteria.

Age, parity, body mass index (BMI), type and number of births, if any, smoking and menopausal status of all patients were evaluated as patient characteristics.

Hemoglobin levels before and after the operation, operation and hospitalization times, perioperative complications, urinary retention after operation, and postoperative pain information were evaluated as the results of the application.

In order to evaluate the effectiveness of the application, the objective treatment, subjective treatment, and inadequate treatment criteria recorded in the patients' most recent controls (16-30 months) were used. Objective therapy was defined as the negative cough stress pad test (CSPT) and bladder volume of 150 cc and above, and subjective treatment was defined as CSPT positive and bladder volume less than 150 cc. Continuation of incontinence was accepted as inadequate treatment.

The authors declared that the study was conducted in accordance with the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects" (amended in October 2013).

Surgical Technique

All operations were performed under spinal anesthesia and by two different surgeons. In TOT application, with Supro SUI (Klas Medikal, Turkey), one side of the groin was inserted with the aid of a 1.2 cm wide monoflament polypropylene knitting needle, using standard outward-inward technique. The obturator foramen was passed and it was placed in the periurethral area prepared previously. The other end of the knitting was taken out of the other groin in the same way. The knitting ends were cut under the skin to allow tension-free application. A-SIMS application was performed as described by Petros and Richardson (17). In A-SIMS, the knitting is the same type but shorter and is applied through a single vaginal incision. The contasure-needleness (Neomedic Int., Spain) sling used in this study has no anchor and has facial pockets on both ends that provide post-insertion stabilization.

Statistical Analysis

SPSS v. 16.0 package program (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis of the data. The normal distribution of data in both groups was evaluated with the Kolmogorov-Simirnov test. Comparison of numerical data with normal distribution between groups was performed with the Student's t-test and comparison of non-normally distributed numerical data was performed by using the Mann-Witney U test. The chi-square test was used for categorical variables. Average and standard deviation values of both groups were calculated separately. Values of $p<0.05$ were considered statistically significant.

RESULTS

Demographic data of 54 patients included in the study are shown in Table 1. There was no significant difference between the groups in terms of age, BMI, parity, menopausal status and smoking. When we evaluated the ages of the patients, the mean age of the A-SIMS group was 47.41±10.89 years, while the mean age of the TOT group was 52.22±10.98 years. While the mean age was higher in the TOT group, the difference between the groups was not found to be statistically significant (p=0.112). When the parity numbers of the patients were analyzed, it was 3.26±1.99

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in the mini-sling group and 2.74±2.29 in the TOT group. In both groups, the number of births of the patients was more than 2, but the difference between the groups was found to be statistically insignificant after comparing the groups (p=0.380). Vaginal delivery in the TOT group was higher than in the A-SIMS group. In the A-SIMS group, cesarean delivery was higher than in the TOT group.

When the operation results were evaluated in both groups, the operation time was found to be significantly shorter in the SIMS group (p<0.001). Similarly, the decrease in postoperative hemoglobin was found to be significantly higher in the A-SIMS group (p<0.007). In the TOT group, 3 patients had urinary retention and 5 patients developed early postoperative groin pain. No other perioperative complications developed in both groups. No significant difference was found between the groups in terms of length of stay (Table 2).

The effectiveness of the treatments applied was evaluated by the examination performed at the last control of the patients. The shortest follow-up was 16 months, and the longest was 30 months. The mean follow-up time was 21.5 months in the TOT group and 17.7 months in the A-SIMS group. When we evaluated the objective treatment, subjective treatment, and inadequate treatment rates, it was found that there was no significant difference between the two groups (Table 3).

Table 1. Demographic data of patients

	A-SIMS** (n=27)	TOT*** (n=27)	p
Age	47.41±10.89	52.22±10.98	0.112
BMI****	30.00±4.53	28.92±6.03	0.461
Parity	3.26±1.99	2.74±2.29	0.380
Vaginal delivery	21 (77.8%)	26 (96.3%)	**0.043***
Caesarean	6 (22.2%)	1 (3.7%)	**0.043***
Post menopause	13 (48%)	16 (59.3%)	0.115
Smoking	12 (54.5%)	10 (45.5%)	0.413

*p<0,05, **A-SIMS: adjustable single-incision mini-sling, ***TOT: transobturator tape, ****BMI: body mass index

Table 2. Operative results

	A-SIMS** (n=27)	TOT*** (n=27)	p
Duration of operation (minutes)	15,81±3,58	25.41±6.82	<0.001*
Length of hospitalization (day)	2,85±0,90	3.52±1.52	0.057
Perioperative complication	0	0	-
Decreased postoperative hemoglobin level (g/dL)	1,31±0,60	1.78±0.61	0.007*
Urinary retention	0	3 (11.1%)	0.075
Postoperative pain	0	5 (18.5)	0.019

*p<0,05, **A-SIMS: adjustable single-incision mini-sling, ***TOT: transobturator tape

DISCUSSION

In our study, TOT and A-SIMS procedures applied to patients with urinary incontinence due to SUI were evaluated. When the data of our study were evaluated, the superiority of both methods to each other could not be determined statistically in the comparison of the A-SIMS procedure and the TOT procedure. In the literature, many studies evaluating patients undergoing anti-incontinence surgery due to SUI have been conducted (18,19). In a study by Pascom et al. (2), 130 women undergoing mini-sling (SIMS) and TOT operations from a single incision were followed up for 36 months. In the study, they determined that both surgical procedures had a similar effect in improving the quality of life. In the study, they also determined that the mini-sling operation required more revision procedures compared to the TOT operation. In addition, after 3-year follow-up in the group of patients who underwent TOT, they determined less persistence in SUI. As a result, they reported that although both groups had similar satisfaction rates for surgery in the postoperative 36-month follow-up, TOT operation had higher treatment rates in SUI compared to A-SIMS operation.

In our study, TOT and A-SIMS were applied to patients with similar characteristics (age, BMI, number of vaginal births) as SUI surgery, the results of the patients were evaluated, and no statistically significant difference was found regarding the results of both groups.

In a study by Schellart et al. (14), 225 patients who underwent mini-sling and TOT were followed for 24 months and the results of the patients were compared with each other at the end of the study. The study was started with 225 patients, and 32 patients refused to participate in the study and the study continued with 193 patients. 20 patients after the first year follow-up and 32 patients after the second year of follow-up were excluded. The study ended with 141 patients. The age, BMI, parity and postmenopausal status of the patients were evaluated and no difference was found between the groups. In the study, the treatment rates of TOT and mini-sling patients were similar in the first and second years, and the side effects were similar. In the study, the superiority of TOT or mini-sling to each other could not be determined after 2 years. In our study, we could not determine the superiority of both methods to each other.

In a meta-analysis by Zhang et al. (9), they compared mini-sling and TOT surgery in female SUI surgery. In the study, 154 studies were evaluated and meta-analysis was completed with 5 randomized controlled studies. As a result of the study, they found that the mini-sling operation was safe and effective in SUI in women. In

Table 3. Effectiveness of treatment

	A-SIMS* (n=27)	TOT** (n=27)	p
Objective therapy	25 (92.6%)	23 (85.2%)	0.386
Subjective therapy	3 (11.1%)	2 (7.4%)	0.639
Inadequate therapy	1 (3.7%)	1 (3.7%)	0.755

*A-SIMS: Adjustable single-incision mini-sling, **TOT: transobturator tape

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comparison with TOT and TVT, they stated that they had the same rate of treatment effects and that there were few perioperative complications. In addition, although they reported that mini-sling operations caused shorter operation time and less pain in meta-analysis, they reported that the studies had short follow-up time and the results should be examined again by having a longer follow-up time. Our study also showed that there was no difference between A-SIMS and TOT procedures in women operated for SUI, as in meta-analysis by Zhang et al. (9).

In the review of Nambiar et al. (20), which included 3290 women and 31 studies, they compared A-SIMS and transobturator or retropubic sling operation. They reported in the review that there was not enough evidence to show that both operations were better than each other, and studies involving longer periods should be done. They also stated clearly that the difference in fixation mechanisms desired to be achieved by operation might affect success. Our study also shows similar results.

In our study, patients with BMI 30 and below were evaluated. There are also studies in the literature evaluating anti-incontinence surgeries applied to obese patients (BMI >30) with SUI. In a study conducted by Kokanalı et al. (21), TOT and TVT performed for SUI were divided into two groups as obese and non-obese and the results of the surgery were compared. TOT was applied to 69 obese (31 patients) and non-obese (38) patients in the study; TVT was applied to 120 obese (62 patients) and non-obese (58 patients) patients. As a result of the study, successful results were obtained in both obese and non-obese women with TOT and TVT procedures. Considering the short term results, they determined that they were successful in obese women with SUI. They reported that they achieved similar and successful results in obese and non-obese groups although voiding dysfunction and bladder injury were slightly observed as a complication, but a little more in the TVT group.

There are also studies evaluating pain after TOT and mini-sling operations. In a study by Thomas et al. (13), data from 597 patients were evaluated and the timing of pain and resolution after the transobturator and retropubic sling operation were evaluated. They determined that suprapubic pain was more frequent in transoburator operations, and groin pain was higher in retropubic operations, but they did not find a difference among pain caused by surgery, pain intensity, and drug use for pain.

In the literature, there are also studies involving surgical application and results for SUI, which occurred during pregnancy and continued in the postpartum period. Twelve female patients were evaluated in a study conducted by Cavkaytar et al. (4) As a result of the study, they stated that the SUI with ongoing postpartum was independent of the way of delivery. They reported that patients with urinary incontinence during pregnancy might be a risk factor for incontinence seen after delivery.

In recent studies, successful results have been obtained by applying TOT or TVT procedure in cases where medical treatment fails in women with mixed urinary incontinence other than SUI (22).

In our study, after 1-year follow-up of the patients, the objective and subjective treatment rates in the A-SIMS group were higher than the TOT group (92.6%-11.1% versus 85%-7.4%), but there was no statistically significant difference between the two groups. Our results are similar to the study done by Sivaslıoglu et al. (15) In this study, the objective treatment rates obtained at the end of the 3-year follow-up in the TOT and A-SIMS (TFS) groups were reported as 90% and 84%, respectively, and no statistically significant difference was found.

In the first studies comparing SIMS and traditional MUSs, SIMSs were found to be lower according to objective treatment rates (11). However, these studies included third generation MUSs, called TVT-secure, that were withdrawn from the market in 2013 due to poor clinical results. After that, promising results were obtained in studies that excluded TVT-secure (16,23). In two separate meta-analyzes (6.9) that included five randomized controlled trials comparing A-SIMS and MUSs in 2015 and eight studies in 2018, A-SIMS was reported to be as effective as MUS when considering short-term results (12 months).

This result may be due to the fact that both techniques were developed with the same surgical principle. However, it has been reported that SIMS application does not show perioperative complications in standard MUS applications and its operation time is shorter because it is less invasive and easy (9).

In our study, shorter operation times ($p<0.001$) and higher postoperative hemoglobin decrease ($p=0.007$) were found statistically significant in the A-SIMS group. Although the duration of hospitalization in the A-SIMS group was shorter, there was no statistically significant difference in terms of length of stay between the two groups ($p=0.057$). Perioperative complications did not develop in both groups.

In TOT application, bladder, obturator nerve and vessels can be injured during the transition from obturator foramen. Similarly, passage through the adductor tendons and skin is thought to cause postoperative groin and thigh pain (13). In the literature, it has been reported that postoperative pain formation with SIMS is much less than transobturator slings (14). The absence of transition from the obturator foramen and exit from the skin in SIMS application prevents these complications and reduces the possibility of postoperative pain.

In our study, postoperative groin pain was observed in 5 patients (18.5%) in the TOT group. In addition, although 3 patients (11.1%) developed postoperative urinary retention, pain and urinary retention were not observed in the A-SIMS group.

Considering the limitations of our study, it is remarkable that it is retrospective and the number of cases is not very high. However, the fact that the data of the study are single-centered and that surgical procedures are performed by the same surgeons are among the advantages of our study.

CONCLUSION

A-SIMS or TOT procedures applied in the treatment of SUI are successful and have not been proven to be superior to each other.

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Although advantages such as the mini-sling procedure's being less invasive and short length of hospital stay are short, we are of the opinion that patient-related risks should be discussed before decision-making for the selection of surgical procedure and type in addition to the experience of surgeon.

Ethics Committee Approval: Ethics committee approval was not obtained since the required data were obtained by retrospectively examining patient records.

Informed Consent: It was obtained.

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