The Effect of Patient Position during Mid-Urethral Sling Operations on the Postoperative Outcomes of Sling Success: A Randomized Clinical Study

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Abstract

Aims: To determine and compare the effectiveness, peri- and postoperative outcomes of mid-urethral sling (MUS) operations for urinary incontinence, using 2 different patient positions during surgery. Methods: In this study, 146 patients underwent MUS surgery in a urogynecology clinic. Of them, 72 patients underwent the intraoperative surgical procedure of reverse trendelenburg patient positioning for tape adjustment (group 1) and the remaining 74 patients had the routine surgical procedure of MUS surgery (group 2). The primary outcome was the evaluation of postoperative urine leaks, using the stress test, and secondary outcomes were quality of life, using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF, Turkish version) and complication rates. Results: There were no significant differences in demographic variables between the 2 groups. The overall cure rates for incontinence in the lithotomy position was 97.22 and 85.13\% for groups 1 and 2, respectively, in which group 1 had a statistically significant decrease in urine leak postoperatively (p < 0.05; OR 3.08, 95% CI 2.78–22.14). The postoperative ICQ-SF scores showed no significant difference between the 2 groups (p = 0.19). Conclusion: Applying a 45-degree reverse trendelenburg position for tape adjusting during MUS operation results in a greater objective cure rate compared with the typical dorsolitthotomy position; however, there was no difference in the subjective outcome.

Key Words

Urinary incontinence · Tension-free vaginal tape adjustment · Surgery · Dorsolithotomy position · Trendelenburg position

Introduction

It is shown that patient position has an important effect on the mobility of the urethrovessical junction, in that the female urethra is more mobile in the supine position than when standing; so the surgical option may change according to the presence or absence of urethral hypermobility [1]. Stress urinary incontinence (SUI) can be treated with
conservative treatments, including lifestyle changes, pelvic floor muscle training and functional electrical stimulation, and if conservative treatment fails, surgery can be the next option [2, 3]. The mid-urethral sling (MUS) operations represent the new gold standard for female SUI. The success rate of the MUS operation varies from 84 to 90%.

The main objective of the suburethral sling operation is to prevent urinary leakage by increasing the pressure transmission to the mid-urethra and maintaining the urethral mobility during any increases in intra-abdominal pressure [4]. In the classical MUS operation, we perform the suburethral mesh in a tension-free manner using the lithotomy position while the bladder is empty, and we expect the same success rate in all patients. Here, the important point is that the bladder neck mobility is not the same in all patients. This creates inadequate urethral coaptation in patients with low bladder neck mobility and leads to difficulty in micturition for patients with high bladder neck mobility. Therefore, we aimed at using a different technical step when performing the MUS, so as to minimize differences in the bladder neck mobility between patients and to improve the success rate of the operation.

The aim of this study was to improve the efficacy of the MUS procedure by using the reverse trendelenburg position during the adjustment of the mesh tension, based on the theory of Handa et al. [1] of excessive bladder neck mobility in incontinent patients in the supine position. This study was conducted as a preliminary randomized study that aimed at evaluating the effect of the 45-degree reverse trendelenburg position during mesh placement, in an MUS operation on postoperative sling success, for urinary incontinence.

Materials and Methods

Patients with SUI and/or mixed urinary incontinence (MUI) were enrolled for this study. The patients who underwent MUS operations for the treatment of urinary incontinence were included in the study. They were randomly allocated into 2 groups by a predetermined computer-generated randomization code, to the reverse trendelenburg group or routine classical surgery group and were prospectively followed for at least 6 months. The exclusion criteria were reoperation for SUI and patients who had undergone a prophylactic MUS operation with a total uterine prolapse and negative stress incontinence test and patients who refused to attend follow-ups.

Subject Population

Between April 2012 and October 2013, 146 patients approached the final for this study at Istanbul Kanuni Sultan Süleyman Research and Teaching Hospital. Written informed consent was obtained from each subject, following a detailed explanation of the objectives, protocol of the study and follow-up examinations, which was conducted in accordance with the ethical principles stated in the Declaration of Helsinki. The study was approved and registered by the Hospital Institutional Review Board.

The diagnosis of SUI was made by a positive stress test during coughing in the absence of simultaneous detrusor contraction and the diagnosis of MUI was made with a positive stress test with the simultaneous detrusor contraction during urodynamic examination or urgency symptoms without detrusor overactivity. All of the patients with MUI had stress-predominant urinary incontinence. The stress test was performed during moderate coughing in lithotomy when the bladder volume measured 300–350 ml, in 3 dimensions using ultrasound. All the patients underwent urodynamic investigations, including uroflowmetry, filling cystometry, valsalva leak point pressure (VLPP), and post-voiding residual urine determination. The stress test was applied to all patients postoperatively to investigate the success of sling operation.

Surgical Procedures

A non-elastic polypropylene monofilament tape was used in the MUS procedure (Betamix vaginal sling, Betatech laboratories, Turkey). The MUS procedures were performed by an experienced surgeon, using standard techniques, as detailed by Ulmsten et al. [7].

Two different modifications of the surgical techniques were performed in these 146 patients for the MUS procedure. In group 1 (n = 72, 49.3%), after the placement of the mesh under the midurethra, 300 ml normal saline was infused into the bladder, the operation table was moved by 45-degree reverse trendelenburg position in lithotomy, and the sling was adjusted so that it is tension free. No spacer was used on sling adjustment in group 1. In group 2 (n = 74, 50.7%), the mesh was suited, as a pair of scissors could be easily moved between the urethra and the mesh in the dorsal lithotomy position.

The primary outcome assessed was per-protocol analysis, and all randomized subjects included in the analysis. The primary outcome time-point was planned to occur at 3 months. All the patients completed the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF, Turkish version) preoperatively and postoperatively. ICIQ-SF is a self-administered questionnaire that qualifies the symptoms and quality of life in adult patients with urinary incontinence.

Demographic data, body mass index (BMI), parity, menopausal state, medical history, physical examination findings (POP-Q stage), preoperative urodynamic examination and ICIQ-SF results and complications were compared between the 2 groups.

The required sample size was estimated by prior analysis, using MedCalc statistical software (version 10.3.0.0). Sample size calculations assumed an 80% success in the midurethral sling group in which the typical dorsolithotomy position was used. To detect a difference of approximately 15% between the 2 groups, assuming 80% power and a 2-sided significance level of 0.05, a sample of 72 patients per group would be required. Statistical analyses were performed using SPSS (version 16.0). The t test, Mann–Whitney U test and χ² tests were used for analysis of data between the 2 groups. Within-group comparisons were analyzed using the Wilcoxon signed rank test for continuous variables, and the McNemar’s test for categorical variables. A difference was considered statistically significant when p < 0.05.
Results

During the study period, 158 patients were assessed for eligibility, although 8 patients declined to take part and 4 cases were lost during follow-up and ultimately 146 patients completed the study: 72 patients in group 1 and 74 patients in group 2 (fig. 1). The mean age of the patients in groups 1 and 2 was 53.6 ± 11.3 and 50.5 ± 8.8, respectively (p = 0.07). Parity, BMI, menopausal state, and history of hysterectomy were shown to have no significant difference between the 2 groups (table 1). The preoperative VLPP was ≤60 cm/water in 17 (23.6%) and 14 (18.9%) patients in groups 1 and 2 respectively and was >60 cm/water in 55 (76.4%) and 60 (81.1%) in groups 1 and 2 respectively and showed no significant difference between the 2 groups (table 1). The type of incontinence was SUI in 47 (65.3%) and 54 (73%) patients and MUI in 25 (34.7%) and 20 (27%) in groups 1 and 2 respectively, and there were no significant differences between the 2 groups (table 1).

Several concomitant procedures were performed in addition to the MUS procedures in both groups. All of the patients with MUI had stress-predominant urinary incontinence. Anterior repair was performed in all patients in groups 1 and 2. Vaginal hysterectomy, posterior repair, culdoplasty, sacrospinous fixation, tubal ligation and salpingo-oopherectomy were performed as other additional procedures to MUS in both groups and there were no significant differences between the 2 groups (table 1).

Postoperatively blood loss over 500 ml was recorded in 4 (5.5%) and 1 (1.3%) in groups 1 and 2 respectively (p = 0.2). Bladder injury was recorded in 2 (2.7%) patients in group 2. Postoperative recorded complications were urinary retention, hematoma, de novo urge incontinence, and groin pain. These postoperative complication rates were not statistically different between the 2 groups (table 2). The median follow-up period for the first and second group patients was 9 months (range 6–11, mean ± SD 8.62 ± 1.7) and 8 months (range 6–11, mean ± SD 8.44 ± 1.8), respectively.

The primary outcome of the study as postoperative urine leakage on stress test was positive in 2 (2.8%) patients in group 1 and 11 (14.9%) of the patients in group 2, which was statistically and significantly different (p = 0.023, OR 3.08 and 95% CI 2.78–22.14). In group 1, urine leak significantly decreased in the lithotomy position postoperatively when evaluated by the stress test (p < 0.05). With regard to the postoperative secondary subjective outcome, evaluated by ICIQ-SF scores, the pre- and postoperative ICIQ-SF scores were not statistically different between the 2 groups (p = 0.19). Both groups showed no difference in the preoperative results of the stress test (table 3).

Both groups investigated ICIQ-SF scores, urine leak in stress test preoperatively and postoperatively and it is found that all parameters significantly decreased postoperatively (p < 0.05; table 3).

Discussion

Our study findings showed that applying a 45-degree reverse trendelenburg position for tape adjustment during MUS operation results in greater objective cure rate, as evaluated by the postoperative stress test, when com-
pared with the typical dorsolithotomy position, however with no difference in subjective outcome in ICQ-SF scores.

Sarlos et al. [5] reported that 2 points seem to be important for the functioning of the tension-free vaginal tape: a dynamic kinking of the urethra during stress, and the movement of the tape against the symphysis, compressing the tissue between the tape and the symphysis. Dietz et al. [6] reported that the curative effect of the MUS on stress incontinence is likely to be due to the mecha-
In our study, we aimed at adjusting the tension of the vaginal tape using a 45-degree reverse trendelenburg position, to increase the efficacy of the MUS procedure, bearing in mind that each patient had different urethral mobility. For improving the surgical results of an MUS, Ulmsten et al. [7] recommended using the intraoperative cough test [12]. Kang et al. [8] reported that by adjusting the tape stress in accordance with the cough test during the MUS can increase the possibility of urinary retention or difficulty of urination following the operation. In this study, we aimed at evaluating the success rate and postoperative results of an MUS procedure, by using the reverse trendelenburg position during mesh tension adjustment, so as to improve the surgical outcomes.

In our study, it can be seen from the stress tests that postoperative urine leaks are significantly decreased in group 1 patients. In our opinion, the explanation for this may be that urethrovesical junction mobility is significantly affected by patient position because the female urethra is more mobile in the supine position than when standing [1]. Therefore, before adjusting the tension of the tape, the bladder was filled with 300 ml of normal saline solution and the patients placed in a 45-degree reverse trendelenburg position; so, a natural micturition environment was generated and the mesh and the urethra were regulated within this context. The reverse trendelenburg position used for patients during tape adjustment decreased the possibility of creating over tense or loose tapes in adjustment, so that they may have an effect in improving the efficacy and success rate of the procedure.

Urinary retention is one of the most common complications after an MUS operation. Voiding dysfunction, following an MUS procedure, has been reported to be between 4 and 10%, and for urinary retention it was 2 and 43%. Since tape adjustment during a MUS operation may influence the rate of urinary retention, Ulmsten et al. [7] recommended the use of an intra-operative cough test. However, Kang et al. [8] and Low et al. [9] reported no benefit from the intra-operative cough test in reducing the rate of postoperative urinary retention and dysuria. When examining our data, postoperative urinary retention was seen only in 1 patient in each of the groups, and as a result, we think that intraoperative tape adjustment using the 45-degree reverse trendelenburg position has no benefit for urinary retention as consistent with earlier data.

Sola et al. [10] reported that the intraoperative complication rate of MUS procedure is 6.6%, and complications were bladder perforation in 3 cases and parietal peritoneum in 1 case. In our case series, bladder perforation was seen only in 2 patients, in group 2. When comparing postoperative complications, in our experience, it was low in both procedures, and the difference between both techniques was not remarkable. In the literature, many authors believe that the MUS procedure should be considered as gold standard for treatment of SUI because of the fact that its efficacy, of over 81%, offers complete recovery [11, 12]. In our study, we have observed that with all the parameters of ICIQ-SF scores, urine leak in the lithotomy position decreased significantly postoperatively in both groups using the MUS procedure. The success rate of the MUS procedure for urinary incontinence in the lithotomy position was 97.22 and 85.13% for groups 1 and 2 respectively, in which group 1 had statistically significant decrease in postoperative urine leak (p < 0.005). We think that this may be due to the fact that when applying the stress test in an upright position, urethra contact creates more pressure on the inserted mesh, thus resulting in more urethral coaptation, so the differences between the 2 techniques were minimized. However, in order to establish data regarding the use of this reverse trendelenburg patient position during MUS operation, it is obvious that we should observe the longer-term follow-up and outcomes of these patients.

The main limitation of our study may be that there was no measurement of urethral rotational mobility in the 2 groups, which may be a confounding variable on the success rate of MUS operations. Another important limitation may be the short follow-up period (approximately 8 months). The high order of concomitant surgery undertaken for pelvic organ prolapse is another limitation of our study that creates a different interaction of the results. And also, among these concomitant procedures, the sacrospinous fixation procedure creates a certain tension on the anterior wall and this may affect the outcomes of the study. However, the randomization, postoperative objective assessment with the stress test, and subjective outcomes with a validated questionnaire form (ICIQ-SF), are the main strengths of our study.

Based on data obtained from our study, the relevance and influence of tape adjustment in MUS procedure on patient outcomes seem to be effective in postoperative urinary incontinence. In this study, group 1 patients had a higher success rate than group 2 patients. The group 1 patients had a significantly less objective SUI rate com-

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pared with group 2, and no difference in postoperative ICIQ scores between the groups was noted. However, each group had a significant reduction in ICIQ scores and SUI rates, postoperatively. Our preliminary results have shown that applying a 45-degree reverse trendelenburg position for tape adjusting during MUS operation results in greater objective cure rate compared with the typical dorsolithotomy position. Also, it is obvious that more randomized clinical studies with longer-term follow-up and outcomes are needed to make a final decision.

Authorship Contributions

E. Karaman: manuscript writing/editing, data collection, project development. I. Alkış: project development, data collection, manuscript writing. A. Han: data collection, project development, manuscript writing. H.C. Ark: data collection, project development. A. Akça: data collection. C. Numanoğlu: data collection, manuscript writing. B.B. Alptekin: data collection. A.F. Tunca: data collection.

Disclosure Statement

The authors declare that they have no conflict of interest.

References