A randomized prospective comparison of the needleless mini-sling “hammock” and “U-shape” configurations for management of stress urinary incontinence: 60 month follow-up results

ozan dogan
alper basbug
Ecem Eren
drecemeren@gmail.com

Bakirkoy Dr Sadi Konuk Training and Research Hospital: Istanbul Bakirkoy Dr Sadi Konuk Egitim ve Arastirma Hastanesi https://orcid.org/0000-0001-5047-6961
murat yassa

Research Article

Keywords:

Posted Date: April 1st, 2024

DOI: https://doi.org/10.21203/rs.3.rs-3884273/v1

Version of Record: A version of this preprint was published at Archives of Gynecology and Obstetrics on March 19th, 2018. See the published version at https://doi.org/10.1007/s00404-018-4755-z.

Abstract

Objective: This study aimed to compare the efficacy of needleless mini-slings placed either retropubic (U-shape) or trans-obturator (hammock-shape) for treating stress urinary incontinence.

Setting: A total of 126 women were randomized in a 2:1 ratio to receive either hammock-shaped or U-shaped Contasure-NDL. A reassessment was conducted at the end of the 5th year with lost to follow-ups.

Methods: All surgical procedures were performed by an experienced senior surgeon specializing in anti-incontinence surgery with mesh. The objective outcome included a cough-stress test, while subjective outcomes involved the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), Patient Global Impression of Improvement (PGI-I), and a three-item Likert scale to measure satisfaction. Assessments were performed at the 60th month.

Results: At the end of 60 months, no significant differences were found in objective cure rate, subjective cure rate, mesh complications, or the need for reintervention due to incontinence between the U-shape and hammock-shaped groups . However, a significant decrease was observed in objective and subjective cure rates when comparing results at 18 and 60 months in both groups. In the hammock-shaped group, there was a significant difference in ICIQ-SF, Likert scale, and PGI-I scores between 18 and 60 months. In the U-shaped group, a significant difference was observed in ICIQ-SF and PGI-I scores, with no notable change in the Likert scale.

Conclusion: In conclusion, without a significant difference, it is challenging to assert the superiority of needleless mini-slings placed either retropubically (U-shape) or transobturatorly (hammock-shape) for treating stress urinary incontinence (SUI).

Introduction

Stress urinary incontinence (SUI) is characterized by the International Continence Society as the "expression of involuntary urine leakage during activities involving physical effort, including sports, as well as during sneezing or coughing (1). When conservative methods fail for uncomplicated stress urinary incontinence (SUI), surgery is the preferred option, typically with midurethral slings (MUS). Both retropubic and transobturator approaches for first and second-generation MUS are effective, but complications like bladder injury and groin/thigh pain led to the development of the third-generation single-incision slings or mini-slings (2).

Third-generation midurethral slings (MUS), known as single-incision mini-slings, were introduced for minimally invasive treatment of stress urinary incontinence (SUI), aiming to reduce postoperative pain and use less mesh (3).Unfortunately, TVT-SecurTM (ETHICON) and MiniArcTM (ASTORA), despite high scientific evidence, were withdrawn due to negative outcomes. TVT-Secur, allowing flexible placement in a "hammock" or "U" configuration, is no longer used clinically after disappointing one and five-year results, with trials primarily using the hammock position, not in the U shape (4)(5). Excluding TVT-Secur, there is

limited evidence in the literature comparing the effectiveness of transobturator and retropubic routes for the same mini-sling. This study aims to compare the outcomes of needleless mini-slings placed either retropubically (U-shape) or transobturatorly (hammock-shape) for treating stress urinary incontinence (SUI). We aimed to share the 60-month results of this study, where we previously presented the 18-month follow-up outcomes in 2018.

Materials and Method

Between August 3, 2015, and August 31, 2017, a randomized prospective study was conducted at the Department of Obstetrics and Gynecology, Duzce Public Hospital, Turkey. The study, approved by the Ethical Committee (approval number 0080/17), included participants who provided written informed consent. Inclusion criteria were patients aged 18 years or older with clinically proven stress urinary incontinence (SUI) that did not respond to conservative treatments. Exclusion criteria encompassed mixed or predominantly urge urinary incontinence, overactive bladder symptoms, intrinsic sphincter deficiency (ISD), urethral hypomobility, previous surgery for pelvic organ prolapse (POP) and urinary incontinence with or without mesh, concomitant POP (Stage II or greater), post-void residual volume exceeding 100 ml, known malignancy, recurrent urinary tract infection, chronic pelvic pain, and known neurologic or psychiatric disorders.Among 140 women with clinically proven SUI initially assessed, four were excluded primarily due to mixed or predominant urgency incontinence, two with clinically diagnosed ISD, three with a history of failed anti-incontinence surgeries, and two with pelvic organ prolapses greater than Stage II. Eligible patients were thoroughly counseled about the risk-to-benefit ratio of retropubic or transobturator approaches for mesh placement.Three patients withdrew consent, leaving 126 participants who agreed to randomization. In total, 11 in the U-shaped group and 12 in the hammock-shaped group were lost to follow-up during the 5 years because of invalid contact numbers or strong personal refusal to continue, as shown in Fig. 1.

The design of this randomized controlled trial (RCT) did not allow for a formal a priori power analysis due to the lack of robust evidence supporting the clinical efficacy of the U-shaped application of the needleless SIMS. The only mini-sling that could be used in both "U" and "hammock" configurations, TVT-Secur, was withdrawn from the market with conflicting results. Another mini-sling, TFS, designed for "U" (retropubic) insertion, cannot be used in a "hammock" configuration. Using a study comparing a retropubic mini-sling with a transobturator mini-sling to estimate the sample size was not preferred because each mini-sling exhibits distinct biomechanics (6) (7). To determine the achieved power of the current study and guide a future clinical trial, effect sizes and post hoc power were calculated. The post-power design allowed for the discontinuation of participant inclusion once optimal power (minimum 80%) was attained.Participants underwent randomization using a computer-generated block sequence, as we described at our previous article (8). All patients underwent a comprehensive assessment and all surgical procedures were performed by one senior surgeon experienced in anti-incontinence surgery with mesh as we described in detail at the same article. Postoperative complaints were categorized by the examining surgeon using the ICS/IUGA Complication Classification Code guidelines, employing a code that specified category, time, site, and pain (9). Exposure was defined as the visualization of vaginal

mesh through separated epithelium, while mesh extrusion referred to the gradual passage of mesh out of the body structure or tissue.Patients evaluated their overall satisfaction using a three-item Likert scale (3: Cured, continent/dry, very satisfied; 2: Improved, very small leakage, satisfied; 1: No change from preoperative status or worsened, not satisfied) and the Patient Global Impression of Improvement (PGI-I), which measured perceived improvement on a seven-option single-item scale ranging from very much better to very much worse (10). Primary outcome was to measure rates of objective and subjective cures after the surgery. Objective cure was defined as the absence of SUI and nega- tive cough-stress test with regarding to clinician's observations at postoperative 18th and 60th month. Subjective cure was defined as no leakage of urine after surgery if the response to ICIQ-SF question no. 6 ("When does urine leak?") was "Never/Urine does not leak". ICIQ-SF was assessed preoperatively and at postoperative 18th and 60th month. Failure of the surgery was defined as the need of re-operation due to persistent symptomatic SUI or an unsuccessful management of a complication leading to total removal of the initial mesh. The data in the study were analyzed using IBM SPSS Statistics for Windows v 21.0 (IBM Corp, Armonk, NY). In the tables, the quantitative data are presented as the mean ± IQR, and the categorical data as number (n) and percentage (%).Statistical analyses were performed using the Chi- squared, Fisher's exact or wilcoxon signed rank test when appropriate. Data were determined at the 95% confidence level and p value; 0.05 was accepted as statistically significant.

Results

At the end of 60 months, there were no significant differences in terms of objective cure rate, subjective cure rate, mesh complications, and the need for reintervention due to incontinence between the U-shape and hammock-shaped groups (Table 1). However, when comparing the results at 18 and 60 months in both groups, a significant decrease was observed in objective and subjective cure rates (Table 2). In the hammock-shaped group, a significant difference was observed in ICIQ-SF, Likert scale, and PGI-I scores when comparing results at 18 and 60 months. In the U-shaped group, while a significant difference was observed in ICIQ-SF and PGI-I scores, no significant difference was noted in the Likert scale (Table 3, Fig. 2,3,4).

Table 1. Objective and subjective results on incontinence in the trans obdurator and retropubic groups

	Hammock-shaped (n=72)	U-shaped (n=30)	p values
Objective cure rates	56 (77.8%)	21(70.0 %)	0.453
Subjective cure rates (dry)	53 (73.6%)	19 (63.3%)	0.344
Mesh complication over 18 months	2 (2.8%)	1 (3.3%)	0.653
Reintervation for SUI	9(12.5%)	6 (20.0%)	0.365

Pearson χ2 test /Fisher exact test

Table 2
Objective and subjective cure rates 18 vs 60 months

	Hammock-shaped		p values	U-shaped		p values
	18 months	60 months		18 months	60 months	
objective cure	69(95.8%)	56 (77.7%)	0.001	26 (86.6%)	21 (70.0%)	0.028
subjective cure	78 (97.2%)	57 (73.6%)	0.001	30 (100%)	19 (63.3%)	0.001
Pearson χ2 test						

Table 3
Total ICIQ-SF scores, Likert scale, PGI-I scores 18 vs 60 months

	Hammock-shaped		p values	U-shaped		p values
	18 months	60 months		18 months	60 months	
	Median ± IQR			Median ± IQR		
ICIQ-SF scores	0.0 ± 3.00	2.00 ± 4.00	0.001	4.50 ± 5.00	4.50 ± 3.00	0.014
Likert scale	3.00 ± 0.00	3.00 ± 0.00	0.006	2.50 ± 1.00	2.00 ± 1.25	0.083
PGI-I scores	1.00 ± 1.00	2.00 ± 2.00	0.001	2.00 ± 2.00	3.00 ± 1.00	0.018

Discussion

This randomized trial evaluated the effectiveness of needleless single-incision mini-slings (SIMS) with tape positioned in "U" or "hammock" shapes for treating stress urinary incontinence (SUI). It is the first study providing evidence for needleless SIMSs in a U-shaped configuration.Objective and subjective cure rates were comparable at the 18th postoperative month in both groups. While there was a statistical difference in objective cure rates favoring the hammock group at the 6th and 12th months in our previous article, no such difference was observed at the 18th month. When we reached end of 60 months, there were no significant differences in terms of objective cure rate, subjective cure rate, mesh complications, and the need for reintervention due to incontinence between the U-shape and hammock-shaped groups. Liapis et al. explored the effectiveness of TVT-Secur in both hammock- and U-shaped placements (11). After 1 year of follow-up, both groups exhibited similarly disappointing overall objective and subjective cure rates. In contrast, Lee et al. reported comparable objective and subjective rates for U- and hammock-shaped positioning of TVT-Secur after 1 year of follow-up (12). At 60 months, there were no significant differences in terms of objective cure rate and subjective cure rate. Petros et al. reported an 86.5% overall cure of SUI on an intention-to-treat basis three years after the surgery. Sivaslioglu et al. found a significantly higher overall cure rate with 89% cure for TFS compared to TOT, which had a cure rate of 78% at 5 years of follow-up (13). In our study, the 5-year objective cure rate was 77.8% in the hammock-shaped group and 70.0% in the U-shaped group, and we did not find a significant difference between them. As expected, when comparing the results at 18 and 60 months in both groups, a significant decrease was observed in objective and subjective cure rates. In cohort studies, the reoperation rates at 5 years ranged from 0–19% for TOTs (four studies), 0–13% for TVTs (11 studies), and 0–19% for mini-slings (two studies) (14). In our study, the rates were 12.5% for the hammock group and 20% for the U-shaped group. A review comparing seven procedures found no statistical difference between SIMS and TO-TVT in terms of treatment efficacy, perioperative outcomes, and postoperative complications, which is consistent with our findings (15). A limitation of our study is that some patients were lost to follow-up after 5 years. Interestingly, the non-responsive women in both groups were generally younger. This could potentially be explained by the satisfaction of a considerable number of these women with the operation, leading to their non-response. Consequently, we might have somewhat underestimated the cure rates in both groups due to this factor.

Conclusion

In conclusion, without a significant difference, it is difficult to state that there is the superiority of needleless mini-slings placed either retropubically (U-shape) or transobturatorly (hammock-shape) for treating stress urinary incontinence (SUI).

References

1. D’Ancona C, Haylen B, Oelke M, Abranches-Monteiro L, Arnold E, Goldman H, vd. The International Continence Society (ICS) report on the terminology for adult male lower urinary tract and pelvic floor symptoms and dysfunction. Neurourol Urodyn. Şubat 2019;38(2):433-77.

2. Collinet P, Ciofu C, Costa P, Cosson M, Deval B, Grise P, vd. The safety of the inside-out transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. Int Urogynecology J. Mayıs 2008;19(5):711-5.
3. Molden SM, Lucente VR. New minimally invasive slings: TVT Secur. Curr Urol Rep. Eylül 2008;9(5):358-61.
4. Cornu JN, Lizée D, Sèbe P, Peyrat L, Ciofu C, Cussenot O, vd. TVT SECUR Single-Incision Sling After 5 Years of Follow-Up: The Promises Made and the Promises Broken. Eur Urol. Ekim 2012;62(4):737-8.
5. Oliveira R, Botelho F, Silva P, Resende A, Silva C, Dinis P, vd. Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up. Eur Urol. Haziran 2011;59(6):940-4.
6. Lenz F, Doll S, Sohn C, Brocker KA. Single-Incision Mini-Slings: Obturator Complex Pull-Out-Force Measurements. Gynecol Obstet Invest. 2017;82(4):376-81.
7. Palma P, Siniscalchi RT, Maciel LC, Bigozzi MA, Dal Fabbro I, Riccetto C. Primary fixation of mini slings: a comparative biomechanical study in vivo. Int Braz J Urol. Nisan 2012;38(2):258-66.
8. Dogan O, Basbug A, Kaya AE, Pulatoglu C, Yassa M. A randomized prospective comparison of the needleless mini-sling “hammock” and “U-shape” configurations for management of stress urinary incontinence: 18 month follow-up results. Arch Gynecol Obstet. Haziran 2018;297(6):1483-93.
9. Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, vd. An international urogynecological association (IUGA)/international continence society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Neurourol Urodyn. Ocak 2011;30(1):2-12.
10. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol. Temmuz 2003;189(1):98-101.
11. Liapis A, Bakas P, Creatsas G. Comparison of the TVT SECUR System “hammock” and “U” tape positions for management of stress urinary incontinence. Int J Gynecol Obstet. Aralık 2010;111(3):233-6.
12. Lee KS, Lee YS, Seo JT, Na YG, Choo MS, Kim JC, vd. A Prospective Multicenter Randomized Comparative Study Between the U- and H-type Methods of the TVT SECUR Procedure for the Treatment of Female Stress Urinary Incontinence: 1-Year Follow-Up. Eur Urol. Haziran 2010;57(6):973-9.
13. Sivaslioglu AA, Unlubilgin E, Aydogmus S, Keskin L, Dolen I. A Prospective Randomized Controlled Trial of the Transobturator Tape and Tissue Fixation Mini-Sling in Patients with Stress Urinary Incontinence: 5-Year Results. J Urol. Temmuz 2012;188(1):194-9.
14. Guillot-Tantay C, Van Kerrebroeck P, Chartier-Kastler E, Dechartres A, Tubach F. Long-term Safety of Synthetic Midurethral Sling Implantation for the Treatment of Stress Urinary Incontinence in Adult Women: A Systematic Review. Eur Urol Open Sci. Ağustos 2023;54:10-9.
15. Chen Y, Zhang J, Zeng Y, Chen W, Liu F, Xing J, vd. The Efficacy and Safety of Single-Incision Mini-Slings for Stress Urinary Incontinence: A Network Meta-Analysis. Urol J. 11 Mart 2023;20(Vol. 20

(2023): Instant 2023):7218.

Figures

Figüre 1.

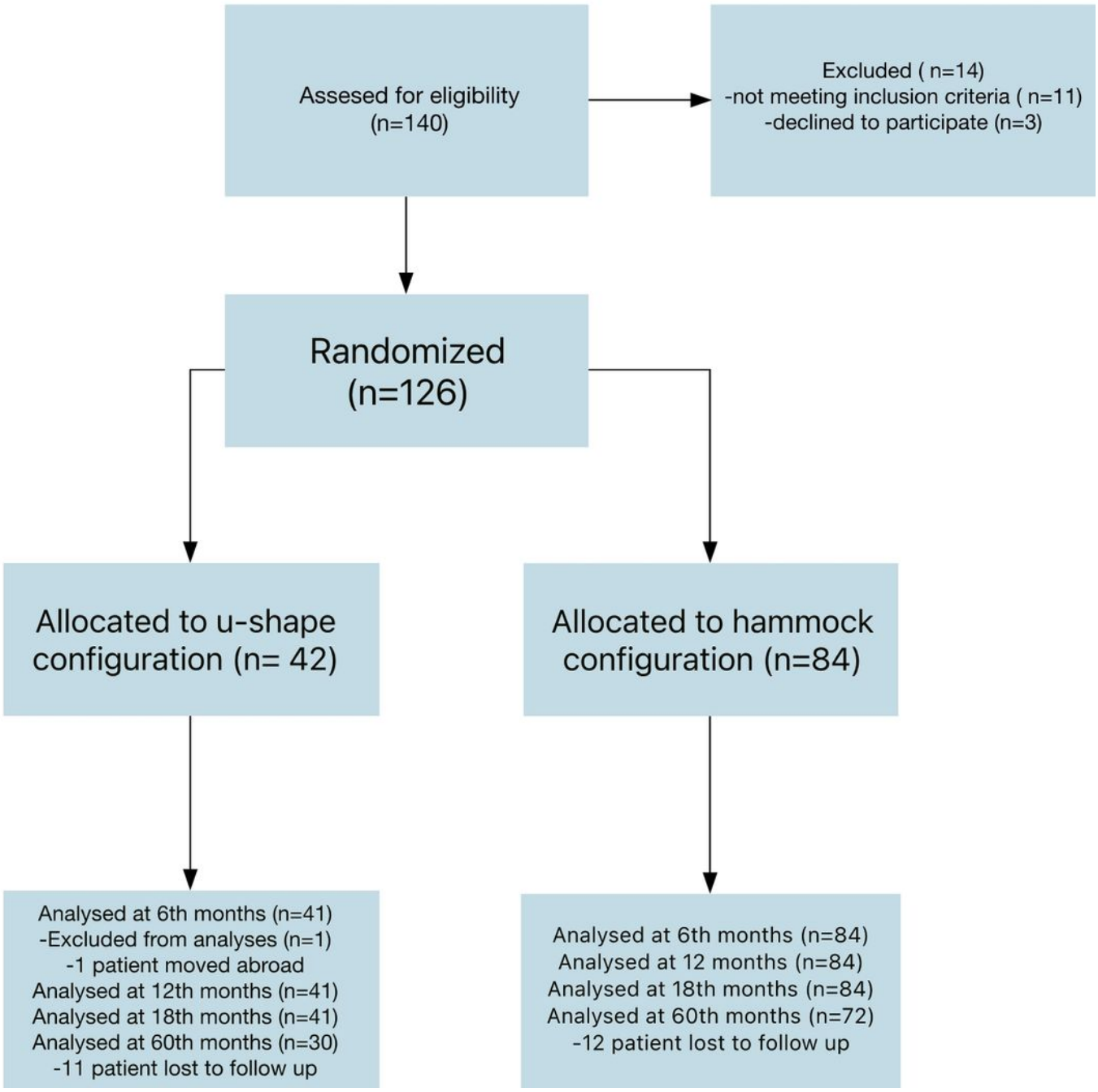
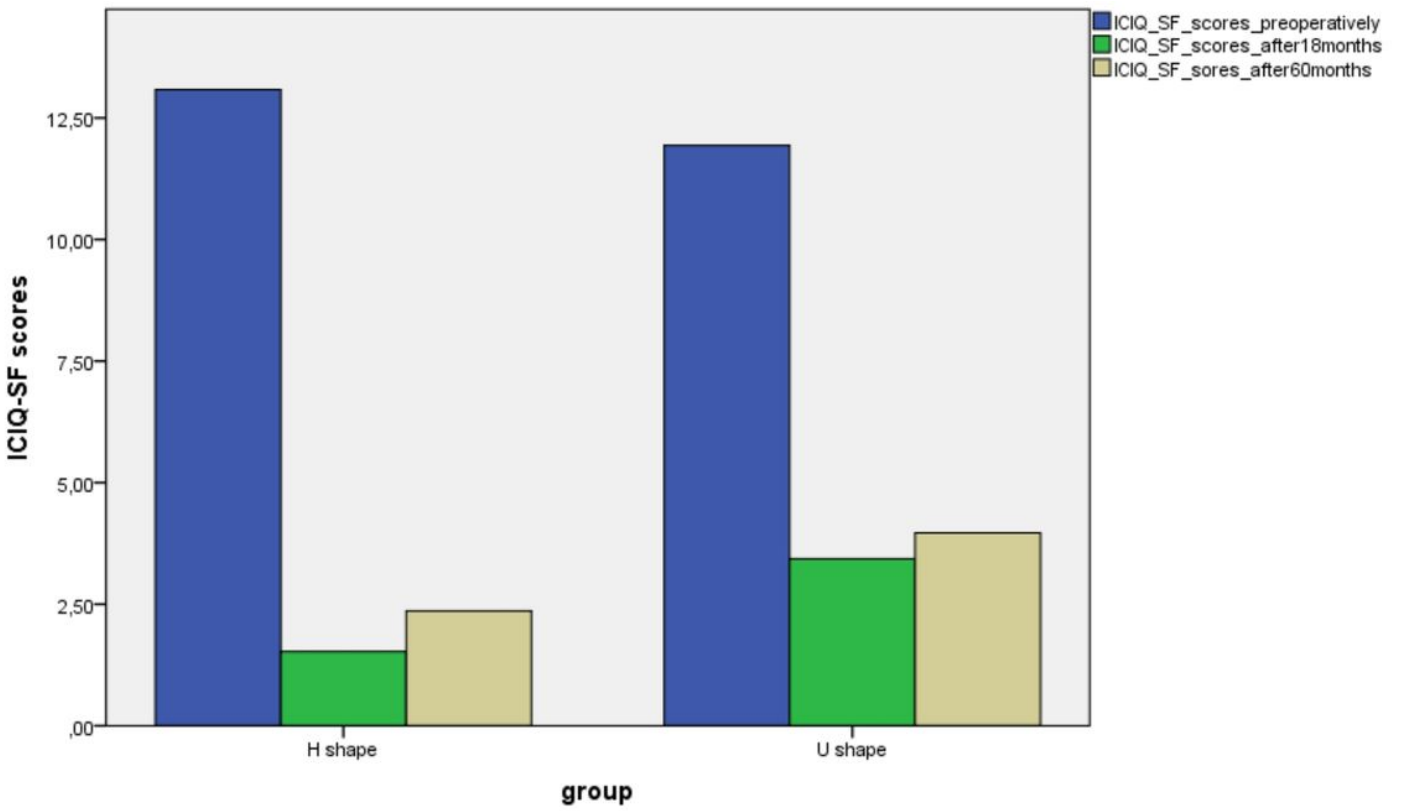


Figure 1

Legend not included with this version



The effectiveness of the H shaped and U shaped minilings based on International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) preoperatively, at 18 months, and at 60 months after the operation.

Figure 2

Legend not included with this version

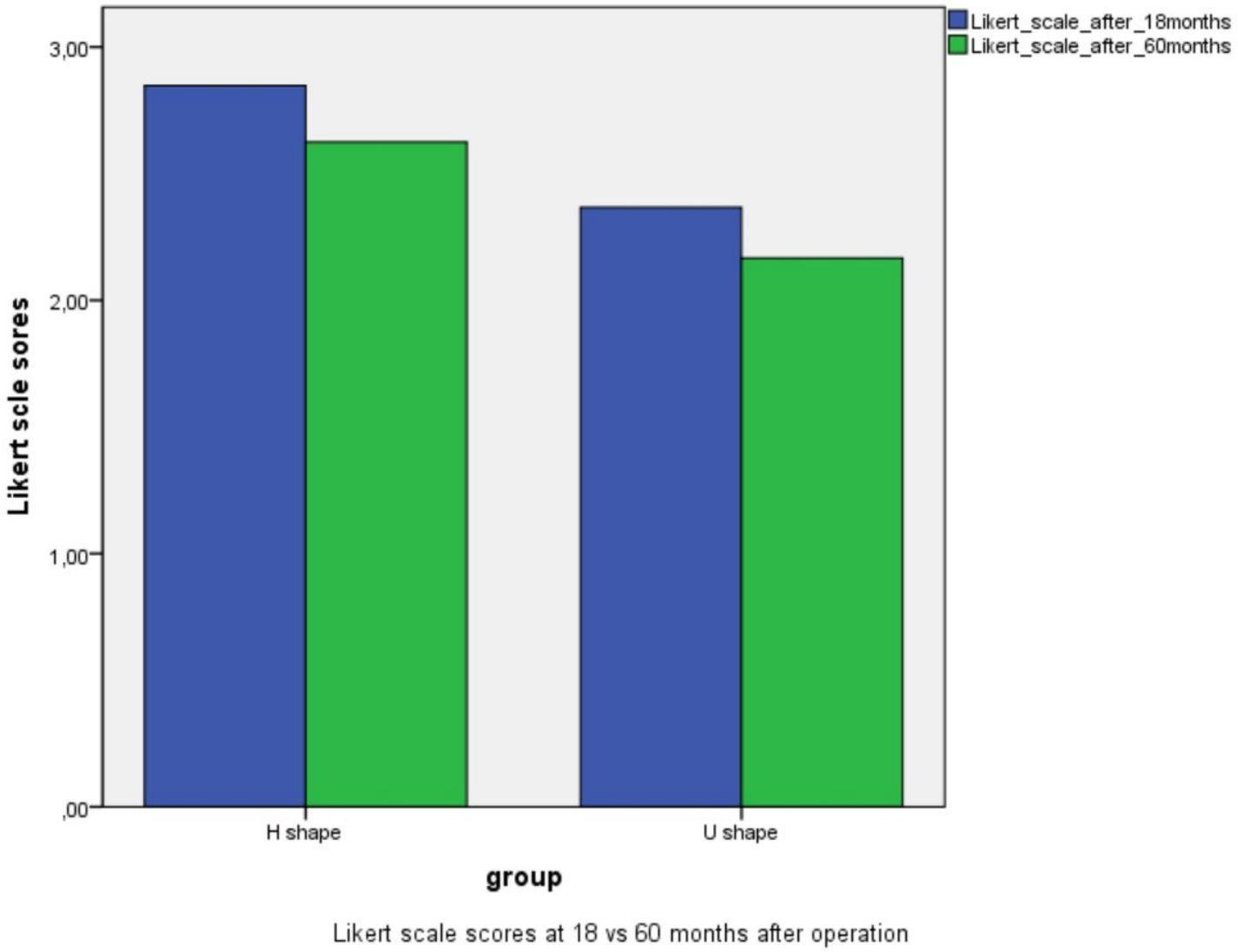
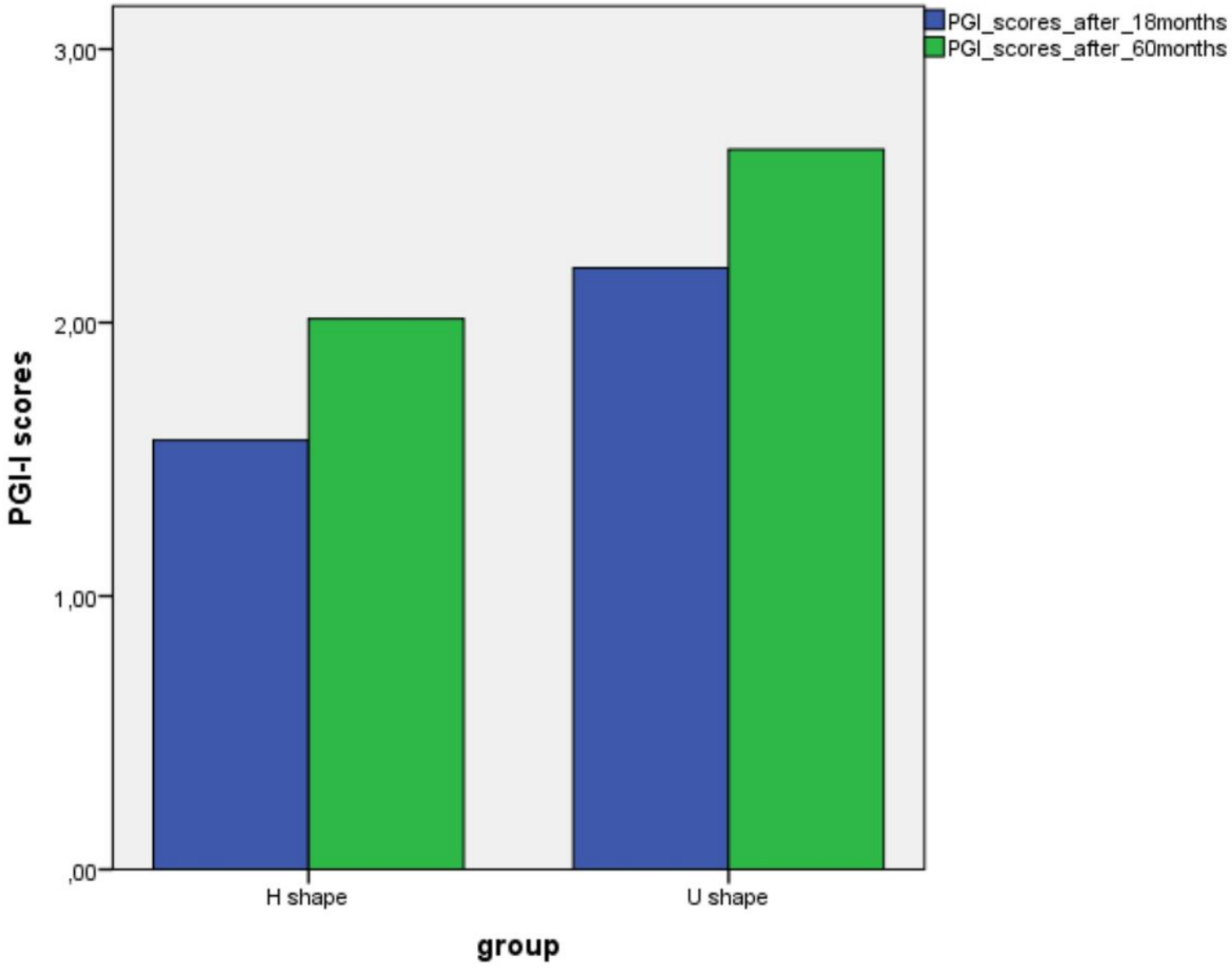


Figure 3

Legend not included with this version



Patient Global Index of Improvement (PGI-I) scores at 18 vs 60 months after the operation.

Figure 4

Legend not included with this version