

Handmade Needleless Midurethral Sling In Comparison With Transobturator Tension-Free Vaginal Tape In Treatment Of Genuine Female Stress Urinary Incontinence

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Abstract

Backgrounds: Stress urinary incontinence is a widely experienced condition among females. Our aim was to compare TOT and handmade needleless midurethral sling regarding safety and effectiveness for management of genuine stress urinary incontinence in females.

Methods: Sixty female cases with genuine SUI randomly allocated to 2 groups: **Group I:** 30 patients were operated on using handmade needleless mid urethral sling (Prolene, Ethicon, USA) mesh 15 x15 cm by cutting 134 mm x 20 mm tape). **Group II:** 30 patients were using TOT (Obtryx transobturator sling system, Boston Scientific, USA) “outside-in” technique. Post-operative evaluation at 3, 6 and 12 months by cough stress test, post-voiding residual urine and uroflowmetry, a negative cough stress test with absence of urine leakage indicated cure.

Results: Group I demonstrated a shorter Operative time than group II 14.17±2.82 min and 25.23±2.63 min respectively (P value <0.05)

however, the postoperative hospital stay and complications were insignificantly different in both groups (P value >0.05). Also, insignificant differences were detected in both groups regarding cure, improvement and failure rate where the cure rate in group I was 90%, in group II was 86.7%, the improvement rate in group I was 6.7%, group II was 10% and the failure only affected one case each group. **Conclusions:** Handmade needleless midurethral sling is a good tool for treatment of genuine female stress urinary incontinence with encouraging results, less operative time, side effects and cost in comparison to commercial TOT especially in developing countries.

Key words: Mid-urethral, Needleless, Transobturator, Stress urinary incontinence.

Introduction:

Stress urinary incontinence affects 17-45% of women worldwide complaining [1] but only 27% of cases seek help, as most cases consider it a natural sequence of aging [2]. SUI is a result of weakened muscles of the pelvic floor which support the bladder and the urethra (urethral hypermobility) and/or a deficient intrinsic sphincter [3]. Such weakness could be precipitated by multiple factors like normal vaginal delivery, obesity, vaginal or pelvic surgeries, old age, long lasting high intra-abdominal pressure as in chronic constipation and chronic cough [3].

Fortunately, there are different surgeries that have been proven to effectively control this condition [4]. TVT techniques and the Burch colposuspension are two surgeries with comparable results proven to be minimally invasive with the former demonstrating less morbidity rates as well [5].

To lower the complications of the needles' track of these surgeries, transobturator tension-free vaginal tape was suggested which is based on placing of a sling through the obturator foramen [6], and to further lower the complications while maintaining the same success rate, a new technique, that apply the principle of tension free sling without needles (Needleless Technique), was suggested which also minimize the

complication of passage through obturator foramen and with no need for skin incision [7].

The cost of available devices used for needleless technique is high, mainly in underdeveloped countries, which limits their widespread use; a surgeon tailored mesh was used through needleless technique to decrease the cost and obtain satisfactory results [8, 9].

We fabricated this handmade needleless sling to decrease the cost and to obtain good results.

Methods:

A prospective randomized study was performed on 60 females with genuine stress urinary incontinence, who attended the Urology outpatient clinic of Benha University Hospital between May 2015 and April 2018. Following the Declaration of Helsinki, all patients signed an informed written consent before joining the study which had secured the approval of the local ethics committee of Faculty of Medicine, Benha University (REC-FOMBU) with study protocol No : Ms.12-5-2015.. Female patients suffering from genuine stress urinary incontinence were included in this study. Female patients suffering from pelvic organ prolapse, overactive bladder, intrinsic sphincter deficiency, other bladder pathology (stone & tumor) and those who

were subjected to previous surgical treatment of (SUI) were excluded from the study. Randomization was carried out before the procedure; a sealed envelope system containing a piece of paper written either groups I or group II. The envelope was opened at the time of the operation. Sample size was calculated using the Open Epi software version 3.

Patients were allocated to two groups:

Group I (30 cases): Subjected to the handmade needleless mid urethral sling.

Group II (30 cases): Subjected to the transobturator tension- free vaginal tape “outside-in” technique (TOT).

All cases were thoroughly evaluated before the operation via history taking, physical examination, uro-gynecologic examination with cough stress test. Abdominal and pelvic ultrasound was done before and after the surgery to detect any other urologic diseases and the post voiding residual urine volume.

Ellipse 4 Andromeda Medizische system with Free flowmetry was used to identify the effect of the surgery on the maximum flow rate (Qmax) and Cystometry was applied to detect any detrusor over-activity and the maximum cystometric capacity as well.

The valsalva leak point pressure (VLPP) or (stress leak point pressure) to exclude those having intrinsic sphincter deficiency (ISD) where VLPP <60 cm H₂O. Patients were categorized preoperatively according to valsalva leak point pressure into 2 groups: Patients with VLPP ≥ 90 Cm H₂O type I SUI and Patients with VLPP ≥ 60 < 90 Cm H₂O type II SUI. Urethral pressure profile; (UPP) was done preoperatively to assess maximal urethral closure pressure (MUCP) to diagnose patients with ISD if (MUCP) <20 cm H₂O to be excluded.

Our handmade sling:

The needleless sling used in this study is a handmade one that was fabricated from the original Contasure- Needleless® (C-NDL®) made of polypropylene monofilament (114×12 mm) with slightly wider detrusor ends forming pockets. Our handmade one was fabricated from (Prolene Ethicon, Summerville, Newberys ,USA) mesh 15 x15 cm by cutting 134 mm x 20 mm tape .A distal 1 cm in either side was folded and fixed by prolene suture 2/0 to form the pockets. The width between the 2 pockets was tailored by cutting 4 mm on either side to make a width of 12 mm as original sling, then a central prolene suture 2/0 as a landmark. Fig.(1)

Operative technique:

Spinal anesthesia and dorsal lithotomy position were used for all cases. After inserting a urethral catheter (16- Fr) a longitudinal incision (1 – 2 cm.) was applied at the vaginal mucosa under (0.5 cm) of the urethral meatus Fig. (2) and to reach the endopelvic fascia, a submucosal blunt dissection of the paraurethral spaces to this incision were performed on both sides at 10 and 2 o'clock.

Group I (handmade needleless mid urethral sling): An artery forceps was placed, firstly hyper extended then closed inside the pocket of the needleless mesh. At 10 o'clock the folded mesh was introduced into the paraurethral space with Rt hand palm supported forceps and performing a controlled pushing force to penetrate the obturator internus muscle. The forceps was then opened to extend the T pocket on the tip of the needleless sling and then withdrawn semi closed and pulled off the vagina. At 2 o'clock the same maneuver was repeated with Lt Hand palm support maintaining the prolene suture in the midline. Finally, we cut the prolene suture and close vaginal incision with an absorbable vicryl suture 2/0. Cystoscopy was done for diagnosis of bladder injury. The urethral catheter was removed after full recovery of the anesthesia.

Group II (Patient underwent transobturator tension-free vaginal tape “outside-in” technique (TOT)): The tape is made of polypropylene monofilament mesh with plastic cover sheath (Obtryx transobturator mid-urethral sling system Boston Scientific, Marlborough,USA). A stainless-steel introducer needle was attached to the end of the tape to allow placing it. Then two paraurethral dissections were done on both sides using scissors. Helical needle designed for the transobturator process were inserted through two minimal cutaneous incisions at the level of a horizontal line passing at the level of the clitoris at inguinofemoral crease Fig. (3) The surgeon' index finger was placed in the vaginal dissection to protect the urethra and guide the needle out after being tunneled through the obturator foramen. The tape is introduced into the eye of the needle and pulled out through the skin. Same steps were repeated on the other side Fig. (4) A forceps was placed between the urethra and the mesh to guarantee a tension-free sling before pulling both ends of the mesh. Cystoscopy was done to exclude bladder injury then an absorbable Vicryl 2/0 suture was used for both, the vaginal and groin incisions. The urethral catheter was only removed after full recovery from anesthesia.

Postoperative follow up:

All cases were followed up for 3, 6 and 12 months post operatively by physical examination including cough stress test and vaginal examination, measurement of post-voiding residual urine and uroflowmetry.

Patients were considered: Cured, Improved or Failed.

Statistical analysis

The SPSS software (version 16) was used for tabulation and analysis of the study data presenting the categorical data as numbers and percentages and the quantitative data as range, mean and standard deviation. To detect the significance, the Paired “t” test was applied and the significance level was set at 0.05 (P <0.05 is significant). **Results**

Baseline characteristics of the studied groups:

Insignificant statistical differences were detected regarding parity, the mode of delivery and the duration of preoperative S.U.I between the study groups (P value > 0.05). Table (1)

According to Stamey’s grading system which estimated the severity of SUI, Grade I was detected in 18 cases in group I (60%) and 15 cases in group II (50%) while 12 cases in group I (40%) and 15 cases in group II (50%) classified as grade II SUI and no cases in both

groups classified as grade III. The grade of SUI was insignificantly different in both groups (P value >0.05). Post-menopausal state was found in 13 patients (43,3%) in group I and 15 Patients (50%) in group II (P value >0.05). VLPP was insignificantly different in both groups (P value > 0.05). Table (1)

Operative and post-operative data

Operative data:

Operative time was significantly shorter in group I compared to group II 14.17±2.82 min and 25.23±2.63 min respectively (p value <0.05) while, intra operative blood loss and postoperative hospital stay were insignificantly different in both groups (p value >0.05). No iatrogenic bladder perforation or urethral injuries were reported in both groups. Post-operative urinary tract infection (UTI) was reported in 2 cases (6.7 %) in group I and 1case (3.3 %) in group II and the difference was statistically insignificant. All UTI cases were treated medically according to culture and sensitivity. Urine retention was reported in 1 case in group II (3.3%) with no cases in group I and the difference was statistically insignificant (P value > 0.05). Urine retention was treated by urethral catheterization for one week duration. Groin/thigh pain occurred in 4 cases in group

II with no cases in group I and the difference was statistically significant (p value <0.05).

One case in group II reported vaginal erosion which never reported in group I. Dyspareunia occurred in 1 case (3.3%) in group I and in 2 cases (6.7%) in group II with statistically insignificant difference between both groups.

Cure was acknowledged when urine leakage incidents disappeared, cough test became negative and no more need to use incontinence pads. Improvement was acknowledged when there was a 50% reduction in the use of incontinence pads, a yes answer to “Are you satisfied with the result of the surgery” question, yet, leakage incidents and cough test are still positive. Other than the aforementioned conditions, failure was the result.

Group I achieved a cure rate of 90% and group II 86.7%. While improvement rate in group I was 6.7% and in group was 10% and failure rate was the same in both groups 3.3% (1 case). These were statistically insignificant differences regarding the cure, improvement and failure rate in both groups. Table (2)

Post- operative follow up

A postoperative follow up plan was applied to all cases at 3, 6 and 12 months where physical examination, cough stress test, measurement of post-voiding residual urine and free flowmetry were performed.

Regarding group I pre-operative Q max was 25.77 ± 1.48 and post-operative was 21.87 ± 1.1 . There is highly significant difference (paired t = 11.46, P value < 0.001). In group II pre & post-operative Q max was 25.93 ± 1.36 & 22.03 ± 0.89 respectively. This difference was also highly significant (paired t = 4.11, P value < 0.001). However, no significant differences between groups regarding Q max (P value > 0.05), pre and post-operative residual urine (table 3). No differences were documented all over follow up period.

Regarding the cost of our handmade mesh was about 10-15 US dollars which was cheaper than commercial available kits 350-400 US dollars.

Table 1. Baseline characteristics of the studied groups.

	Needleless N = 30	TOT N = 30	P value
Mean age (years)	56.27 ± 9.06	52.73 ± 8.87	>0.05
Mean parity (times)	4.2±1.56	3.93±1.86	>0.05
Mean vaginal delivery (times)	3.37±1.67	2.93±2.08	>0.05
Mean cesarean section (times)	0.83±0.83	0.93±0.87	>0.05
Mean duration of SUI (years)	7.43±2.01	7.6±1.96	>0.05
Grade of SUI:			
Grade I: No (%)	18(60)	15 (50)	>0.05
Grade II: No (%)	12 (40)	15(50)	>0.05
Menopause:			
Premenopausal: No (%)	17 (56.7)	15 (50)	>0.05
Postmenopausal: No (%)	13 (43.3)	15(50)	>0.05
VLPP:			
60-90: No (%)	23(76.7)	25 (83.3)	>0.05
>90: No (%)	7 (23.3)	5 (16.7)	>0.05

Table 2. Operative and post-operative data

	Needleless N = 30	TOT N = 30	P value
Mean Operative time (minutes)	14.17±2.82	25.23±2.63	<0.05
Mean blood loss (ml)	91.17±9.26	93.83±10.14	>0.05
Mean hospital stay (day)	1.03±0.18	1.23±0.63	>0.05
Postoperative UTI: No (%)	2(6.6)	1(3.3)	>0.05
Postoperative urine retention: No (%)	0(0)	1(3.3)	>0.05
Postoperative groin/thigh pain: No (%)	0(0)	4(13.2)	>0.05
Vaginal erosion: No (%)	0 (0)	1 (3.3)	>0.05
Dysparunia : No (%)	1 (3.3)	2 (6.7)	>0.05
Outcome:			
Cured: No (%)	27(90)	26 (86.7)	>0.05
Improved: No (%)	2(6.6)	3 (10)	>0.05
Failed: No (%)	1(3.3)	1(3.3)	>0.05

Table 3. Preoperative and postoperative Q max and residual urine

Group	Needleless (N=30)		TOT (N=30)		St. "t"	P
	Mean	SD	Mean	SD		
Preop. Qmax	25.77	1.48	25.93	1.36	0.454	>0.05
Postop. Q_{max}	21.87	1.11	22.03	0.89	0.643	>0.05
Paired "t" P	11.46 <0.001		4.11 <0.001			
Preop. Residual urine	24.93	2.59	25.2	2.5	0.406	>0.05
Postop. Residual urine	25.43	2.22	25.77	2.53	0.542	>0.05
Paired "t" P	0.48 >0.05		0.23 >0.05			

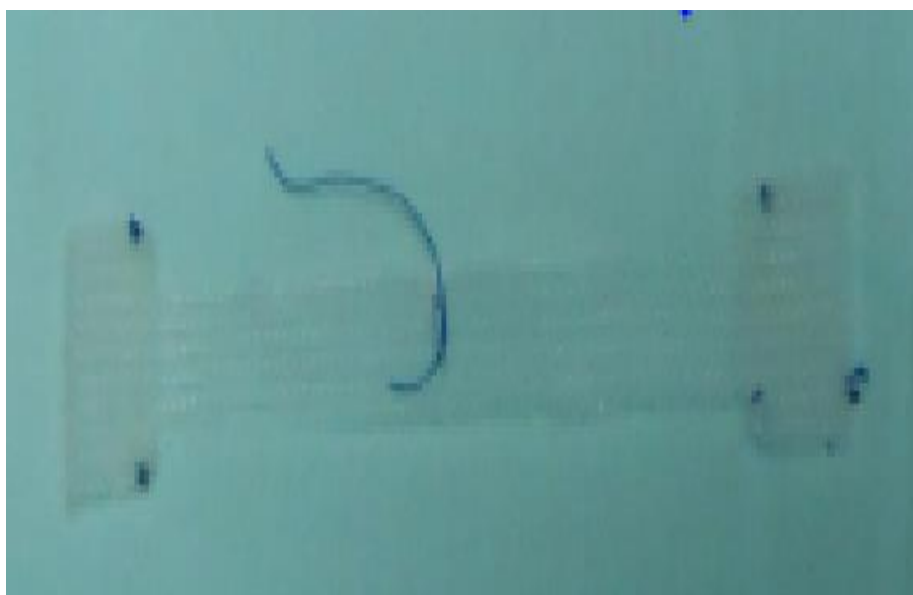


Figure (1): Handmade tape

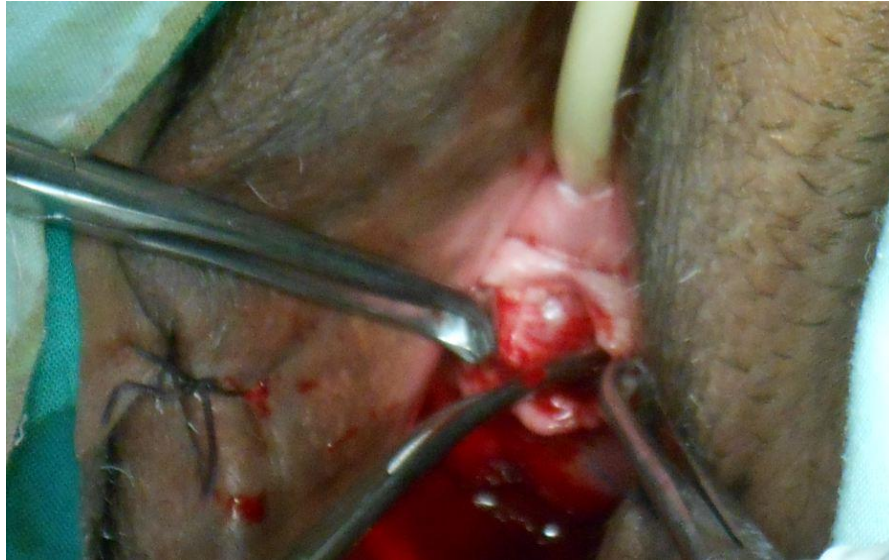


Figure (2): Longitudinal incision 2 cm long



Figure (3): Needle passage guided by index finger in one side.



Figure (4): Needle passage guided by index finger in opposite side

Discussion

SUI is a widely experienced condition among females with an increasing incidence with age. Despite many effective interventions, the cure rate is not satisfactory which could be a result of unawareness of the treatment availability or its efficacy [8, 10].

The last decade have witness revolutionary changes in the management of female SUI providing minimally invasive, yet, effective techniques like the transobturator tape and the tension-free vaginal tape procedures [11, 12].

The transobturator placement of the sling have been acknowledged as a safe approach with few complications compared to the retropubic placement, yet, cases have been reporting a postoperative groin or thigh pain [13]. Such pain could be owed to the passage of the needle through the groin and its exit near the obturator nerve.

To overcome this complication, single-incision slings without turning around any pubic bone and secondary incisions in the abdomen or groin were proposed [14].

The new needleless system adopted the transobturator tape approach placing of the support structure in a subfascial hammock type position, but only using a mesh supported by a pocket system at both ends thus eliminating the need to use needles or a fixating tip and avoiding passing needles through the groin, obturator space, or medial adductor muscles [15].

In our work, the mean age of the patients in group I was 56.27 ± 9.06 years and these results agree with the results of other study [7] in which the mean age was 50 years and the mean age of the patients in group II was 52.73 ± 8.87 years and these results are

comparable to that of another work [16] in which mean age was 52.27 years. This is in agreement with the results of similar study [17] in which the mean age of patients in group I was 59.9 and 60.6 years in group II.

The relationship between parity, vaginal delivery and caesarean section was not always a constant one and the P value between the two groups > 0.05 showed that there was insignificant difference between the studied groups.

As regard our study, the operative time was significantly different in both groups. The mean operative time in group I was 14.17 ± 2.82 min which is consistent with other study results [8] the mean time was 15 min but in another study [9] operative time was longer in the surgeon tailored mesh group than TVT-O group . Other studies reported that the mean operative time 15.6 min and 10 minutes [17, 7]. The mean operative time in group II was $(25.27 + 2.63)$ min, these results are similar to what was mentioned by other study [18] as mean operative time was $25 + 9.48$ min and also consistent with another one [19] which reported a mean surgical time of 6.9 ± 1.83 min in the mini-sling which was significantly less than that reported in the TOT group 11.5 ± 5.01 min. Operative time was shorter in group I as there was no need

for skin or groin incision and no need for trans obturator passage.

The intra-operative blood loss was insignificantly different between both groups which agreed with what was reported by other studies [20,21] but pervious study [19] stated that the mini-sling group demonstrated significantly less blood loss than the other group. Another study [8] reported 47.7 ml blood loss during using surgeon tailored needleless mesh and this was similar to our results. In another study [9] reported that TVT-O group was associated with increased operative blood loss.

No cases in group I required either intra or post –operative blood transfusion as intra operative blood loss in group I was 91.17 ± 9.26 ml and these results are comparable to others [20]. Also no cases in group II required either intra or post- operative blood transfusion, as intra operative blood loss was $93.83 + 10.14$ ml, these results agreed with [22] study.

No intraoperative complications as iatrogenic bladder perforation or urethral injury were reported in any of the included groups which is consistent with the results reported [8,9,23] and agreed with other studies [16,21] which reported no organ perforation but other study [24] reported 3 cases of bladder perforation especially with previous prolapse surgery also

another one [19] reported vaginal perforation in 2 patients of the TOT group.

Urine retention didn't occur in any case in group I which agreed with results reported by other studies [8, 25]. In another study [9] two cases of urine retention was reported one in each group who was catheterized for few days followed by relief of retention. In group II in our study, urine retention occurred in one case (3.3%) which failed to void early after catheter removal which was most probably due to postoperative groin pain and tissue edema, managed by intermittent sterile self-catheterization for 1 week and was improved. This agreed with results obtained [22] in which post-operative urine retention occurred in 5 cases of 206 patients (2.4%) and resolved by intermittent sterile self-catheterization for 3 and 5 days in 2 cases but 3 cases needed intervention with release of the tape 10 days postoperative in 1 patient and tape sectioning in 2 cases; 1.5 and 2 months post-operative also study [21] reported one patient in each group had urine retention and the patient in TOT group was subjected to a surgical mesh loosening to control a persistent urine retention. Also study [17] reported 2 cases of urine retention in each group.

There was also insignificant statistical difference between both groups regarding early post-operative complications (UTI) and

this was in agreement with the results obtained by study [20] which reported no cases of UTI in both groups.

Groin/thigh pain occurred in 4 cases (13.3%) in group II and treated with non-steroidal analgesics. This agreed with study [9] which reported 4 cases of groin pain in TVT-O group that relieved on analgesic after one month. In other study [26] there was no case in group I as it occurs mainly due to passage of the needles through the obturator membrane. Dyspareunia was reported in one case in group I and two cases in group II. Some studies [17, 20] reported pain mainly during sexual intercourse in 13.5% of the TOT group cases, while the mini sling group reported less painful complications than the TOT group. Studies [8, 9] reported only 2 cases of dyspareunia and 3 cases of dyspareunia respectively. Study [19] had the same issue as the level of pain was significantly less in the mini-sling compared to the TOT group.

Vaginal erosion was insignificantly different in the groups of the current study. Previous study [20] reported a case of vaginal erosion in group II with no cases in group I, however vaginal erosion occurred in group II in one case (3.3 %) and the Patient was asymptomatic, diagnosed with follow up after 3months postoperatively by vaginal

examination and managed conservatively with local estrogen for 6 weeks. This is comparable to other study [27] while [13] reported 3 cases of vaginal erosion but were managed by tape removal. Study [8] reported one case of mesh exposure who needed sling removal. No cases of mesh erosion with handmade needleless mesh up to 29 month follow up [9]. Mesh exposure ≤ 1 cm was 3.4% for both groups (n = 3 for each arm) which was successfully managed by vaginal estrogen. The mesh exposure > 1 cm was 2.2% for both groups (n = 2 for each arm) which was successfully managed by local excision and vaginal estrogen without removal except for one case in the TOT group who needed total excision and Burch colposuspension [21]. The possible causes of vaginal erosion may be foreign body rejection, inadequate dissection, wound infection, dissection of the vaginal wall in a wrong plane, impaired wound healing or inadequate suturing of the vaginal incision [28].

In our study there was insignificant statistical difference between both groups as regard Q max and post voiding residual urine and this correlated with the data observed by similar studies [9,13,15,19,25] which reported insignificantly different pre- and post-operative urodynamic parameters between

both groups. In our work, the hospital stay was 1.103 ± 0.18 days for group I and 1.23 ± 0.63 days for group II. This is comparable to other studies [19, 20]. The mean duration of postoperative hospitalization was shorter in the mini sling group 1.08 ± 0.35 compared to 1.33 ± 0.65 day in TOT group [19].

As a comparative study there was insignificant difference between both groups as regard cure rate which is consistent with another study [20] which reported cure rate of (87.5%) in group I and (90%) in group II . In this study, 27 Patients of group I were cured (90%) and 26 patients in group II (86.7%), while patients improved in group I was 2 patients (6.7%) and 3 patients (10%) group II, on the other hand the procedure failed in one patient in each group (3.3%). This was in agreement with other study [20] but this disagree with another one [17] which reported lower cure rates and higher failure rates for both groups as the results revealed cure rate (71.66% group I) and (64.70% group II) with failure rate (15%), This was agreed with [21] which, at 24 postoperative month follow up, reported similar objective cure rates between the TOT (n = 76/89, 85.4%) and the mini sling group (n = 80/89, 89.9%) and insignificantly different subjective cure rates between the TOT group

(n = 78/89, 87.6%) and the mini sling group (n = 80/89, 89.9%). This was agreed with [9] which reported no significant difference between both groups in cure.

Failure rate in group I it was 3.3%, this agree with other study [15] in which it was 4% and failure rate in group II was 3.3%, this is comparable to another study [26] in which it was 2%. Study [8] reported results near to our results as Thirty-eight (88%) patients were cured, four (9%) were improved and failure in one patient (2%). Another study [29] reported comparable results regarding success and complications between surgeon tailored mesh group and TVT-O group with long term follow up to 5 years. The cost of our handmade mesh was less than TOT kits this agreed with other studies [8, 9, 29]. The limitations of this study could be manifested in the short period of follow up, a single center study and small number of patients.

Conclusion

Handmade needleless mid urethral sling is a minimally invasive, safe therapeutic approach for female SUI, with high efficacy and less complications either intra operative or post-operative with less cost in comparison to TOT sling. Large studies with a longer follow-up duration are recommended for more accurate data.

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