COMPARISON BETWEEN TENSION FREE VAGINAL TAPE VERSUS AUTOLOGUS FASCIAL SLING TECHNIQUE IN THE MANAGEMENT OF STRESS URINARY INCONTINANCE IN DUHOK CITY

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ABSTRACT

Background: Stress urinary incontinence is a common urogynecological problem worldwide that impact the quality of life which mandates either conservative approach or corrective surgery.

Objective: To compare the postoperative outcomes of tension free vaginal tape (TVT) and autologous fascial sling (AFS) in the management of stress urinary incontinence.

Methods: A quasi-experimental study was conducted from September, 2014 through September, 2015 at Azadi Teaching hospital and Vajeen private hospital. A sample size of 40 cases was taken comprising 23 TVT cases and 17 AFS. The recruited patients at childbearing age and menopause presented with the diagnostic criteria of stress urinary incontinence were included in the study. Patients were followed-up at 2 weeks, 3 months and 6 months.

Results: Patients undergone tension free vaginal tape took shorter operative time (30.63 versus 73.58 minutes) and less hospital stay days (1.87 versus 4.18 days). Both techniques have almost the same postoperative outcomes.

Conclusions: Both TVT and AFS have comparable efficacy and safety in the treatment of SUI with almost the same postoperative outcome in a short and medium term follow up. However, when Compared to AFS, TVT technique takes shorter operative time and less hospital stay.

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Keywords: Stress urinary incontinence, Autologous fascial sling, Tension free vaginal tape, Incontinence surgery, Short-medium term follow up

Urinary incontinence (UI) is a worldwide common clinical condition affecting women of all ages and across different cultures and races. UI is not considered as a disease in its entity, but rather a symptom occurring due to impairment of the bladder sphincter mechanism[1]. The most common types of UI are stress, urge, and mixed[2]. Stress urinary incontinence (SUI), defined as an involuntary leakage of urine on effort or exertion, sneezing or coughing, is prevalent but it differs across countries[3].

Two main mechanisms underpin development of urinary incontinence: urethral hypermobility (due to impaired pelvic floor support), or intrinsic sphincter deficiency (usually secondary to pelvic surgeries). Multiple factors play role in increasing the risk for SUI including age, white race, obesity, menopause, childbirth and chronic diseases[4].

Management includes both conservative and surgical interventions. While it is safe, conservative approach is left for women who prefer avoidance of long term implication of surgeries or when surgery is contraindicated[5].

Surgical interventions remain the mainstay of the treatment which leads to long term

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subjective and objective improvement. A variety of corrective surgical interventions have been introduced with different success and failure rates[6].

The current study aimed at comparing the postoperative outcomes of autologous fascial sling (AFS) and tension free vaginal tape (TVT) in the management of SUI.

MATERIALS AND METHODES

Through a Quasi interventional study conducted from September, 2014 through September, 2015, a sample size of 40 cases was taken comprising 23 TVT cases and 17 AFS. These operations were performed by two surgeons (Urologist and Gynecologist) in both Azadi Teaching Hospital and Vajeen Private Hospital. Inclusion criteria include all women at childbearing age and menopause presented with criteria of SUI were included in the study. The diagnostic criteria for SUI include any history of urine leak after coughing, laughing, sneezing and standing from sitting position, positive one hour pad test, positive cough stress test and post void residual volume of 50 ml or less in ultrasound examination. Exclusion criteria include nulliparous women, those presented with concomitant urge incontinence and grade III cystocele. All patients were assessed preoperatively by history and physical examination with inspection of vulva and vagina for any lesion or atrophy. Assessment of degree of anterior vaginal wall prolapse (cystocele) was done. Patients were asked to lie on left lateral position. Sims' speculum was inserted on the posterior wall of vagina. Anterior vagina was observed for bulging and its grade.

All patients underwent special tests for diagnosis of SUI and to exclude other type of incontinence and other concomitant pathology. Positive cough stress test. Patient was asked to lie down in supine position and to cough or do Valsalva maneuver while observing any leak of urine. Later on, additional assessment was performed when the patients was in standing position with legs apart and then the same maneuver was applied for observation of any leak of urine. One hour pad test: This test was performed for all patients. A dry pad was weighed initially and then was put on vulva.

One hour later, the same pad was weighed again for any increase in the weight or if there was any wetness in the pad. Increase in the weight or wetness of the pad was considered as positive. Sonography is done for all patients when the urinary bladder was full. Then after voiding, sonography was repeated to observe any post voiding residual urine.

All patients having residual urine more than 50 ml were excluded from the study. General urine analysis, urine culture and sensitivity was done to assess for urinary tract infections and treatment given accordingly. Further culture and sensitivity test to make sure the patient is cured before performing surgery.

Operative Technique

Autologous fascial sling technique

AFS was performed under general anesthesia and sterile conditions in supine position. Pfannenstiel incision was done to remove a ribbon of rectus tissues which cover the muscles of abdomen. Later, the patient was put in lithotomy position with Foley's catheter (Fr-16) inserted. Another small incision was made in the wall of

vagina 1 cm below the urethral orifice followed by dissection on both side of urethra close to internal surface of pubic bone using Mets scissors. The strip of the removed tissue from rectus sheath was applied around urethra and its ends are merged at supra pubic area and cut flushed with rectus sheath without applying tension. Wound was closed in layers and catheter was left for 48 hours. Finally, catheter was opened to see if there is hematuria to exclude bladder injury.

Tension-free vaginal tape technique

The TVT was performed by placing patient in dorsal lithotomy position. Under sterile conditions, two small abdominal incisions above public bone were performed. A 16 Fr Foley's catheter was inserted into the bladder. Under control of Allis tissue forceps, one about one cm below the urethral orifice and the other 2 cm proximal to first forceps, a longitudinal incision was done between the two forceps. Puncturing of the left endopelvic fascia was done with the TVT needle. The needle was pushed more through the Retzius space to the anterior abdominal wall until the needle held the posterior wall of pubic symphysis.

The surgeon hold the abdominal skin with the needle, then incised the skin over the needle until the needle emerged. The same procedure was repeated on the contra-lateral side. Care was taken to make sure that the tape was not twisted during insertion by applying an artery between the tape and wall of urethra. The ends of tape were moved up and down to check for free movement without tension. Cystoscopy was done to exclude bladder injury. Then, tape was cut at both abdominal ends and the needles were removed while the plastic sheath was left in place. Catheter removed 2-3 hours postoperatively.

Postoperative Follow-up

Postoperatively, patients were followed-up at 2 weeks, 3 months and 6 months for any complications and to assess for success of operation. Patient were looked for signs of incontinence depending on history of urine leak, one hour pad test, cough stress test and ultrasound examination for post void residual volume.

ETHICAL APPROVAL

The study was approved by Research Ethics Committee, a joint committee between University of Duhok – Faculty of Medical Science and Directorate General of Health, Duhok. Consent from patients was taken and they were given the right to choose the type of operations regardless of the researchers' randomization process or wishes.

DATA ANALYSIS

Statistical Package for Social Sciences (SPSS) program version 17 was used to analyze data. Data were summarized using mean and SD for quantitative data and frequency (%) for categorical variables. Chi-Square test was used to test differences and relationships. When assumptions of Chi-Square test were violated, Fisher-Exact test was used. Mann-Whitney U test was also used to test for difference among quantitative data. Level of significance was set at 0.05.

RESULTS

During the duration of the study, 40 patients were included for whom AFS was performed on 17 patients and 23

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underwent TVT. For the issue of patient rights to choose the technique of operation, number of patients in the two groups was not equally distributed.

Before the surgical intervention, no statistically significant baseline difference in the characteristics was observed between the two groups as shown in table 1. Of women who underwent AFS, 70.6% were less than 50 year old and in TVT group, 65.2% were below age of 50 years. Three patients (17.6%) of those who did AFS had grand-multiparty compared to 6 (26.1%) in TVT group. Eleven patients (64.7%) had grade II cystocele compared to 15 (65.2%). History of diabetes and hypertension were reported in 1 (5.9%) and 2 (11.8%) patients, respectively in those who did AFS while in TVT group, 3 (13%) of patients had diabetes with a similar percentage for reported history of hypertension. UTI was found in 9 (52.9%) patients who underwent AFS and 11 (47.8%) patients of TVT group.

Furthermore, 3 (17.6%) patients in the AFS had history of complicated delivery versus 7 (30.4%) in the TVT group. In addition, 47% of patients who did TVT had history of obstetrical and gynecological abdominal surgery. History of cesarean section is noticed in 3 (17.6%) of AFS patients compared to 8 (34.8%) of TVT group.

One patient of AFS group and 2 patients of TVT group had undergone previous AFS, as well as one of AFS group had previous TVT surgery.

Table 1: Background characteristics of the study sample

		Autologous fascial sling No. (%)	TVT No. (%)	p-value
Number of patients		17	23	
Age (Years)	< 50	12(70.6)	15 (65.2)	0.720
	≥ 50	5 (29.4)	8 (34.8)	
Parity	< 8	14 (82.4)	17 (73.9)	0.707*
	≥ 8 (Grand)	3 (17.6)	6 (26.1)	
Cystocele	Grade I	6 (35.3)	8 (34.8)	0.973
	Grade II	11 (64.7)	15 (65.2)	
History of diabetes		1 (5.9)	3 (13)	0.624*
History of hypertension		2 (11.8)	3 (13)	1.000*
History of complicated delivery		3 (17.6)	7 (30.4)	0.471*
History of abdominal surgery		4 (23.5)	11 (47.8)	0.117
History of cesarean section		3 (17.6)	8 (34.8)	0.297*
History of hysterectomy		-	1 (4.3)	1.000*
History of previous AFS		1 (5.9)	2 (8.7)	1.000*
History of TVT		1 (5.9)	0	0.425*
History of UTI		9 (52.9)	11 (47.8)	0.749

***Fisher Exact test is used.**

Table 2 depicts that the average duration of operation was significantly different between AFS and TVT groups. TVT took significantly less time during operation compared to AFS technique (30.63 minutes versus 73.58 minutes, $p < 0.001$).

Table 2: Mean and standard deviation of duration of operation in minutes

	Autologous fascial sling	TVT	p-value
Number of patients	17	23	
Mean	73.58	30.63	
Standard deviation	7.03	3.63	<0.001 *
95% confidence interval	69.97,77.20	29.25, 32.29	

*** Mann Whitney U test**

Patients who underwent TVT had shorter mean days of stay at hospital than those did AFS (1.87 days in TVT group versus 4.18 days in AFS group, $p < 0.001$) as shown in table 3.

Twenty (87%) patients for whom TVT was used were discharged from hospital within 1-2 days while 15 (88.2%) of those who underwent AFS stayed at hospital for 3 or more days ($p < 0.001$) as shown in table 4.

Within the first 2 weeks postoperatively, one case of AFS developed wound infection, 2 (11.8%) got UTI, and 4 (23.5%) had retention of urine while none of the patients in the TVT group got wound infection and only one got UTI and one had urine retention. However, these differences were not statistically significant as illustrated in table 4.

Table 3: Mean and standard deviation of hospital stay days postoperatively

	Autologous fascial sling	TVT	p-value
Number of patients	17	23	
Mean	4.18	1.87	
Standard deviation	1.38	1.359	< 0.001*
95% confidence interval	3.47,4.89	1.28,2.46	
Hospital stay of 1 -2 days: No. (%)	2 (11.8)	20 (87)	
Hospital stay of ≥ 3 days: No. (%)	15 (88.2)	3 (13)	

*** Mann Whitney U test**

Table 4: Two week postoperative complications of autologous fascial sling and TVT in stress urinary incontinence

	Autologous fascial sling No. (%)	TVT No. (%)	p-value
Number of patients	17	23	
Wound infection	1 (5.9)	0	0.425 *
Retention of urine	4 (23.5)	1 (4.3)	0.144 *
UTI	2 (11.8)	1 (4.3)	0.565 *

***Fisher Exact test is used.**

At 3-months postoperatively, all patients of AFS and TVT group shown up in the clinic for check-up. Of these, only one of the AFS still had incontinence (Table 5).

Further follow up at 6 months,all patients with AFS and TVT group showed no relapse of incontinence.

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Table 5: Three month postoperative outcomes of autologous fascial sling and TVT in stress urinary incontinence

	Autologous fascial sling No. (%)	TVT No. (%)	p-value
Number of patients	17	23	
3 month positive cough stress test	0	0	
3 month - PVR less than 50	1 (5.9%)	0	0.375*

***Fisher Exact test is used.**

DISCUSSION

This study was conducted to compare the effectiveness of TVT versus AFS in the management of urinary incontinence. Up to the awareness of the researcher, no study was conducted in Iraq that evaluated the outcomes of these two corrective surgeries for SUI.

Random assignment of patients into either interventional procedure was not fully adopted in this study because ethical issues and patient rights to be center of treatment was considered. Some patients decided to have TVT procedure rather than AFS and so, this preference was considered by the surgeon. The latter led to have more patients in the study for whom TVT was performed. However, this slight difference was not accompanied by a statistically significant difference in the baseline characteristics of patients who undergone both procedures which could have biased the results if the initial difference was the case.

Findings of this study indicated that TVT procedure takes almost one and half times less than the AFS procedure. With the adoption of TVT, the time that patient will take to be in the operation theatre will be reduced from 73 minutes as with AFS to about 30 minutes. This is consistent with several studies conducted elsewhere. Brito et al, performed a study conducted on a sample of 260 women from 2003 to 2009 revealed that mean operative time for AFS was 112 minutes[7]. In a multicenter randomized clinical trial in four units in the United Kingdom, Guerrero et al, showed that AFS took a longer time 54 minutes versus 35 minutes in TVT[8]. Tellez Martinez-Fornes et al, illustrated the mean time in TVT surgery was 41 minutes for a group of 24 patients with SUI[9]. Difference in the surgeon's hand skills, and patients' background characteristics could be reasons for this fluctuation in the operative time for the same procedure but overall all studies showed that TVT takes shorter operative time.

The average hospital stay for patients in TVT group was shorter by two days compared to the average of 4 days for patients with AFS. This result was similar to that ofTellez Matinez-Fornes et al, in which patients stayed 1–2 days at hospitals for TVT patients[9].

Only one followed-up patient in the TVT group had features of urinary incontinence and none had it at 6 months so there was no significant difference between these two groups in short and medium term follow up. Analysis at 36 months also showed no significant differences. This similarity in the postoperative outcomes was consistent with other studies. Amaro et al, performed a randomized study of 41 women, the impact of AFS and TVT on quality-of-life in incontinent patients was assessed at 1, 6, 12, and 36 months. Cure rates were 71% at 1 month, 57% at 6 and

12 months in AFS. In TVT group, cure rates were 75% at 1 month, 70% at 6 months and 65% at 12 months[10].

In another study, Sharifiaghdas and Mortazavi *et al.*, select 100 women who were randomly assigned into TVT and AFS surgical correction showed no significant difference following 6 months. Objective cure was achieved in 88% of the TVT group and in 83% of the AFS group using a cough-induced stress test, and in 76% and 75% of the women in the TVT versus AFS group, respectively, using a 1-hour pad test[11].

Morgan et al performed a cross sectional survey of health related quality of life 1-3 years following anti-incontinence surgeries, showed the severity of incontinence symptoms was not significantly different between AFS and TVT groups[12].

All reported complications (early and late) were marginal and treated conservatively and they were statistically insignificant between TVT and AFS group. These results were comparable to those reported in other studies[13-17].

CONCLUSION

Both TVT and AFS have comparable efficacy and safety in the treatment of SUI with almost the same postoperative outcome in a short and medium term follow up. However, when Compared to AFS, TVT technique takes shorter operative time and less hospital stay. Further studies are recommended to verify the results and to assess cost effectiveness of TVT and to monitor for any long term complications.

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ثوختة

بةراوردى دناظبةرا كظاشتنا ئةندامىَ سيَكسيىَ ذنىَ بكارئينانان شةريتىَ نةحولى بةرامبةر تةكنيكا بهيَزكرنا زةظلةكان يا نة ئيرادى ب ريَظةبرنا وةستيانا ذ ئةنجامىَ وةستيانا ميزىَ ل باذيَرىَ دهوك

ثيَشةكى: ذدةستانا كونترولكرنا ميزا زراظ ذجورىَ ستريسىَ ئيَكة ذ ئاريشةيَن هةظيشكة دناظبةرا تايبةتمةندييَن نيشتةطةريىَ ميزةرو وذنان ل سةرانسةرى جيهانىَ وكارتيكرنا زورهةية لسةر شيوازىَ ذيانىَ، ثيَدظيية دةستكارى لظىَ ئاريشىَ بهيَتة كرن ذبو كيَمكرنا نةخوشى وئالوزييَن وىَ ضبريَكانشتةرطةرى يانبىَ نشتةرطةرى.

ئارمانج: هةلسةنطاندن و بةراوردى دناظبةرا دوو ريَكيَن نشتةرطةرى ييَن ضارةسةريا ظىَ ئاريشىَ ئارمانجا سةرةكى يا ظةكولينىَ بوون. وجورى نيشتةكةري ئةظةنة:

تيَثازىَ يابىَ ستريس TVT دطةل هةلاويستنا ئيك ئالوزى يا راستةوخؤ AFS

ريَكيَن ظةكولينىَ: ئةظ ظةكولينة هاتة ئةنجامدان هةر ذئيلونا 2014 ىَ هةتا ئيلونا 2015ىَ ل نةخوشخانا ئازادى يا فيَركرنىَ ونةخوشخانا ظةذين يا تايبةت ل دهوكىَ. دظىَ ظةكولينىَ دا نمونةك ذ 40 نةخوشان هاتة هةلبذارتن كو نشتةطةري يا تيَثازىَ يا بىَ ستريسTVT بو 23 نةخوشان و نشتةطةري يا هةلاويستنا ئيك ئالوزى يا راستةوخوَ بو 17 AFS نةخوشان هاتة ئةنجامدان. هةر ئافرةتةكا دذيَ زاييىنىَ دا وذيىَ ثشتى راوةستانا خويندينا هةيظانة ئةويَن هةمى ثيظةريَن دةستنيشانكرنا نةكونترولكرنا ميزا زراظ ذ جورى ستريس ذيدطريتو هةروةسا دويفضوونا نةخوشان دهاتة كرن ثشتى نشتةرطةريىَ بـ2 حةفتى، 3 هةيظو 6 هةيظا.

ئةنجام: ئةنجاميَن ظةكولينىَ ديباركرن كو ريَكا TVT كيَمتر وةخت 36,3 خولةك بةراورد دطةل 73,08خولةك دريَكا AFSهةروةسا كيَمتر ثيَدظيية مانىَ ل نةخوشخانىَ 1,87:4,18 روذ ريَكا ئيكى بةراوردى دطةل ريَكا دووىَ. بةلىَ ئةنجاميَن ضارةسةرى هةردوو ريَكا نيَزيكى ئيَك بوون.

دةرئةنجام: هةردوو ريَكيَن AFS, TVT ئةولةهيةكا باش و كاريطةر هةية ذ بو ضارةسةري يا ذ دةستانا كونترولا ميزا زراظ ذ جورىَ ستريسىَ و هةروةسا ئةنجاميَن ضارةسةرى هةردوو ريَكان يَزيكى ئيَكبوون. بةلىَ بةراورد دطةل ريَكا TVT, AFS كيَمتر وةخت د خازيت ذ بو نشتةطةريىَ و هةروةسا مانا نةخوشي د ناف نةخوشخانىَ دا ثشتي نشتةطةريىَ.

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الخلاصة

مقارنة بين الشد المهبلي باستعمال االشريط اللاصقيل الحر مقابل تقنية تقوية العضلات اللاإرادي في إدارة الإجهاد الناتج عن إجهاد البول في مدينة دهوك

خلفية الدراسة: ان سلس الإجهاد هو مشكلة مشتركة بين التخصصات الجراحية البولية والنسائية في جميع أنحاء العالم ولها تأثير على نوعية الحياة، الأمر الذي يستوجب العلاج أما بالنصح التحفظي او بالجراحة التصحيحية.

الهدف : تهدف الدراسة إلى تقييم نتائج نوعين من العمليات الجراحية المستخدمة في العلاج وهي الشريط المهبلي عديم التوتر بالمقارنة مع التعليق اللفافي الذاتي Tension free vaginal tape and Autologous Fascial Sling

طريقةالبحث: اعتمدت الدراسة التصميم الشبه التجريبي وامتدت الدراسة من أيلول–2014 إلى أيلول–2015 في كل من مستشفى آزادي التعليمي ومستشفى ظذين الخصوصي. تم أخذ عينة مكونة من 40 مريض واجراء عملية الشريط المهبلي عديم التوتر TVT لـ23 مريض والتعليق اللفافي الذاتي AFS لـ17 مريض. شملت الدراسة جميع النساء في سن الإنجاب وانقطاع الطمث ممن استوفت فيهن معايير تشخيص سلس الإجهاد المعتمدة هذا وقد تمت متابعة نتائج العمل الجراحي لدى كل النساء لثلاث فترات أي بعد أسبوعين، ثلاثة أشهر وستة أشهر.

النتائج: أظهرت الدراسة بان عملية الشريط المهبلي عديم التوتر استغرقت وقتا أقصر (30,63 مقابل 73,58 دقيقة) وكانت أياما لإقامة في المستشفى أقل (1,87 مقابل 4,18 يوما) بالمقارنة معا لتعليق اللفافي الذاتي علما بان كلتا الطريقتين انتهت تقريبا الى نفس النتائج ما بعد الجراحة.

الاستنتاج: يتمتع كل من TVT وAFS بفعالية وسلامة مشابهتين في معالجة سلس البول مع نتائج متقاربة بعد العملية الجراحية في متابعة قصيرة ومتوسطة المدى، ومع ذلك، عند المقارنة مع AFS، تأخذ تقنية TVT وقتًا أقصر للعملية وتقلل مدة إقامة المريض في المستشفى.