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Article

Safety and clinical efficacy of retropubic tension-free vaginal tape versus anti-incontinence pessary for treating women with stress urinary incontinence

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Abstract

Background: Anti-Incontinence pessary use has long been reserved for patients with significant comorbidities, incontinence during pregnancy, elderly population or patients refusing surgery. The pessary utilization rate is lowest in Africa. The Tension-Free Vaginal Tape (TVT) was first approved by the FDA in 1998 then underwent systematic review in 2009-2011 to establish safety and efficacy, FDA is still approving the use of TVT for stress urinary incontinence, however, permanent vaginal mesh use for pelvic organ prolapse has been banned by FDA. The rising complication rates with TVT might result in imposed restriction of its use, can the pessary provide alternative solution. *Methods*: 2 phase parallel group non-randomized clinical trial design was used, phase 1 was the baseline assessment followed by phase 2 which was the clinical design, 80 patients received intervention A (Retropubic Tension-Free Vaginal Tape), while the other group received intervention B (Anti-Incontinence Pessary). Prospective cohort was, however, due to COVID-19 implication on the operative time and urogynecology clinic, retrospective cohort was used to complete the sample size. Interrupted time series analysis approach was used to assess the outcomes at 6 weeks, 6 months and one year using a urogynecology questionnaire derived from UDI-6 and IIQ-7. *Results*: UDI-6 showed a statistically significant difference between both groups at baseline with TVT mean 41.66$\pm$ 11.86 compared to pessary group 34.37$\pm$12.04 (p=0.008), another statistically significant difference was seen at the 1-year mark; however, the difference was not significant from clinical perspective, TVT mean was 16.87$\pm$12.34 compared to 22.69$\pm$10.83 for pessary group (p=0.028). The IIQ-7 showed a statistically significant difference between both groups at baseline with TVT mean 201.58$\pm$63.34 compared to 122.47$\pm$14.01 for pessary group (p=0.00), however, this significant difference did not exist at the 1- year mark period with the TVT mean 60.89$\pm$58.83 when compared to 75.99$\pm$75.78 for the pessary group (p=0.323). Conclusion: TVT has a higher success rate according to UDI-6, however, the IIQ-7 shows no difference at 1-year period suggesting Anti-Incontinence pessary can be used as an alternative to TVT with comparable result in the general quality of life.

Keywords: SUI, Anti-incontinence, Pessary, TVT , UDI-6, IIQ-7 , Quality of life

Introduction

Stress urinary incontinence is the complain of involuntary leakage on effort, exertion, coughing or sneezing, urge urinary incontinence is complain of involuntary leakage accompanied by or immediately preceded by urgency, mixed urinary incontinence is a complain of involuntary leakage associated with urgency and with exertion, effort, sneezing or coughing. (1)

Urinary incontinence (UI) is a common health problem with an estimated prevalence of 35 %, of whom 70% will have stress (SUI) or mixed Urinary incontinence. (1,2)

Historically, pessary used was reserved for cases who are not candidate for surgery because of significant medical comorbidities or those who decline surgery, pregnancy-associated incontinence, and incontinence in elderly. (3,4) Incontinence pessary supports the urethrovesical junction in the same way a vaginal sling implanted surgically would. (5), pessary should be considered in all women presenting with stress urinary incontinence, few contraindications exist for pessary use and thus allowing physician to almost offer pessary to every patient with stress urinary incontinence, those contraindications are active pelvic or vaginal infection, presence of severe ulceration, allergy to rubber and silicone and lastly uncompliant patient who is unlikely to follow up. (6) The successfully fitting is the guarantee for high continuation rate that can reach up to 90%. (7) Multicenter studies showed 80-92% successful fitting for patients with stress urinary incontinence, however, the main challenge is the continuation rate where 6 months continuation rate was 55% and 16% at 1 year. (8-10)

According to a survey made by the international urogynecology association (IUGA), 61.5% of medical practitioners worldwide always or frequently offer a pessary to patients with SUI, number of providers prescribing a pessary was highest in North America and lowest in Africa. (11) Other studies reported that pessaries are being used in daily practice by 86% of gynecologists and 98% of urogynecologists. (12,13).

The Tension-Free Vaginal Tape (TVT) was first approved by the FDA in the 1998 in the United States. The complications related to mesh use for pelvic organ prolapse (POP) then started to reveal leading to a controversy in the use of the TVT, however, between 2009 and 2011 FDA conducted a systematic review of literature and thus found the safety and efficacy of TVT was well established, the FDA found that the success rate of the TVT is comparable to the retropubic urethropexy ranging from 70-80%,(14,15) and the risk of mesh erosions sits at around 2%.(16,17) The FDA shortly stopped the mandatory registering of TVT sling use to monitor complication rate, however, they issued a guideline to the use of TVT.(18)

TVT complications in the order of frequency are pain, mesh erosion through the vagina (also called exposure, extrusion, or protrusion), infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuromuscular problems, and vaginal scarring. (18) Sling related pain usually requires surgical excision or release of tension. Erosions can be treated with topical estrogen, but in experience of many

urogynecologist, surgical excision or covering the mesh with vaginal epithelium is the most effective treatment. (19)

Although the FDA is still approving the Tension-Free Vaginal Tape for management of stress urinary incontinence, hundreds of women joined a lawsuits against Johnson and Johnson over pelvic floor product, the FDA has banned the use of permanent mesh in the vaginal repair of pelvic organ prolapse, urogynecologist especially juniors who were not trained to perform other procedure for SUI as rectus fascia sling or retropubic urethropexy are concerned regarding the possibility of FDA banning mesh use for SUI which will leave them without surgical options for treatment of SUI, this will result in the need to extend training to be able to perform alternative surgeries than mesh-based surgery. The mesh lawsuits and the hot media topic regarding mesh based vaginal surgery was the main derive to propose this research.

Materials and methods

Women with Stress Urinary Incontinence who met the inclusion and exclusion criteria presented to Urogynecology outpatient clinic at Victoria Hospital and Children's Hospital, London Health Science Center located in London, Ontario were recruited to participate in the study depending on their intervention preference, whether it is the Anti-Incontinence pessary or the Retropubic Tension-Free Vaginal Tape.

Inclusion criteria**:** Women aged 18 years and older, diagnosed with Stress Urinary Incontinence (SUI) on basis of clinical history, clinal examination or Urodynamic testing. Exclusion criteria: Patient less than 18 years old, pregnant women**,** patient refusal to be involved in the study, patient with history of extensive pelvic floor surgery, patient with previous Anti-incontinence surgery, patient with psychiatric disorder**,** patient with neurological disorder, patient with prolapse greater than first degree according to International Continence Society Classification, patient with urodynamic evidence of detrusor overactivity.

Sample size:160 patients were recruited, 80 received the proposed intervention A and the other 80 received the proposed intervention B. We had to go back to the database to complete our sample size, we investigated 7 years period when the urogynecology questionnaire was first implemented in the clinic, we were able to find data to complete the 80 patients in each group, incomplete data or exclusion criteria were the main reasons we couldn't include more than 80 patients in each group. Another challenging point during this study was to include only patients who continue using the pessary for 1 year, some patients used pessary just for the time they were waiting for surgery or stopped using it once complications happen, during the 1-year period we fitted 90 incontinence pessaries but only 29 remained using the pessary for 1 year.

The tension-free vaginal tape procedure (Intervention A): All patients received a single dose of intravenous Ancef 1g preoperatively. A standardized, conventional TVT sling procedure was performed. A 1.5-cm long incision in the midline of the sub-urethral vaginal wall was created, starting approximately 0.5 cm from the outer urethral meatus. Laterally from this incision, a dissection of 0.5 to 1.0 cm was created using the Metzenbaum scissors using combination of blunt and sharp dissection creating para-urethral tunnel to each side of the urethra till the level of perineal membrane but not piercing the membrane. Two 0.5-cm transverse abdominal skin

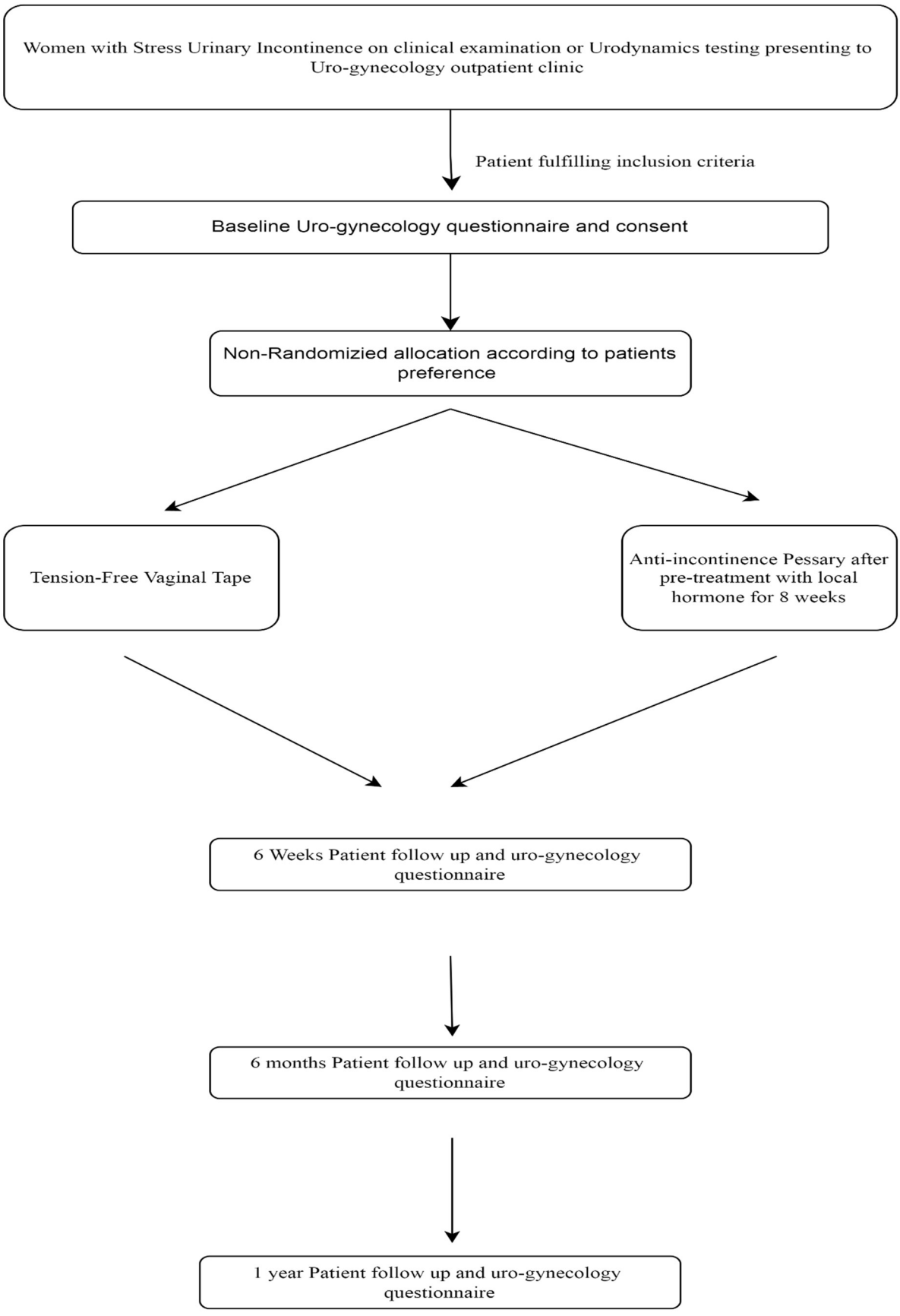
incisions were made close to the superior rim of the pubic bone to facilitate trocar exit. Using the handle with the trocar attached, the TVT tape was placed around the mid-urethra: the tip of the trocar was inserted into the paraurethral tunnel on the right side of the urethra. The perineal membrane was perforated, and the tip of the trocar brought up to the abdominal incision hugging the posterior aspect of the pubic bone to prevent traumatic injury to the bladder or ureter. When the trocar tip reached the abdominal skin incision, the proximal end of the trocar was disconnected from the handle and the tape, covered by the plastic sheath, and was brought into position on this side of the urethra by pulling the needle upwards with the tape attached. The procedure was then repeated on the left side. Cystoscopy was performed after application on each side to check for bladder perforation. When the tape was placed in a U shape around the mid-urethra, the plastic sheath was withdrawn. A Kelly clamp was used to adjust the tape into position to ensure it is place under tension free fashion.

Anti-incontinence pessary fitting Procedure (Intervention B): Before pessary fitting, the patient was examined to estimate the width of the mid-vagina and to demonstrate positive cough leakage test. Premenopausal women were fitted with pessary at initial visit however postmenopausal women with atrophic vaginal changes were pretreated by local estrogen vaginal hormone for 8 weeks prior to trial of pessary fitting. The patients were fitted with the largest pessary that fits comfortably (physician can place a finger between the pessary and vaginal wall and the pessary stays in position during Valsalva Maneuver) and then examined in the supine and standing positions. The patients were then asked to walk around with the pessary and try different maneuver that usually results in stress urinary incontinence as coughing, sneezing, bouncing. If no leakage happened with the pessary, the patients were asked to void and her postvoiding residual were measured using a bladder scanner to make sure that the patient is emptying her bladder properly and the pessary is not causing her to experience urinary retention. Active young women were taught how to self-clean the pessary and reinsert it again however elderly women with ambulatory problems or limitation of ability to perform pessary cleaning were scheduled for pessary cleaning every 3 months by provider. All patients returned to clinic after 6 weeks to assess the effectiveness of the pessary and to assess continuation rate. All postmenopausal women will continue a local Estrogen vaginal hormone either Premarin cream, Vagifem or Estring

Data collection methods and tools

Outcomes were measured using the following: All patients were requested to complete the validated 'Urogynecology Patient Questionnaire' as part of their pre- and post-intervention assessment. It served as a tool for baseline assessment, as well as it assessed the outcome of interventions, evaluated how SUI affected patient's quality of life, identified risk factors that may contribute to patient's condition, and helped in establishing preventive measures for recurrent SUI. The cure of SUI was determined by subjective and objective assessment before and after the interventions. The objective definition of cure was absence of urinary leakage on history taking, physical exam or urodynamic testing at 1-year follow-up.

Flow Chart of the Study (Figure 1)



Outcomes

The primary outcome was to assess the Improvement of SUI-related Quality of Life in the pessary group compared to the TVT group. The secondary outcome was Cure or failure to resolve SUI (Patients will be considered objectively cured if no symptoms of Stress Urinary Incontinence after 1 year on History, Physical Examination or Urodynamic testing or failure/recurrent Stress Urinary Incontinence).

Statistical analysis

Data was analyzed using Statistical Package for the Social Sciences SPSS version 22.0. Descriptive statistics was used to summarize patient demographics and cure rates. The Mann-Whitney *U* test was used to compare continuous variables between the two groups, and the Chi squared test was used to compare categorical variables. Data was also analyzed with the Wilcoxon matched-pairs signed-ranks test. A p-value of less than 0.05 will be considered statistically significant.

Results

Table (1): shows the distribution of the two studied groups relevant to their demographic data and underlying health condition, the TVT group has a mean age of 55.20±8.404, the mean age for pessary group was 68.87±10.73, a statistically significant difference is noticed in age distribution between both groups (p=0.000).

Underlying comorbidities and smoking status exist in both groups with diabetes mellitus and hypertension being the most common, no statistically significant difference was found between both groups in respect of comorbidities and smoking status (p=0.727, P=0.724 respectively).

Regarding the menopausal status, the table shows statistically significant difference between the study groups (p=0.001) with more menopausal women in pessary group when compared to the TVT group.

Table (2): shows that the TVT group has a higher BMI with a mean of 29.12±6.146 compared to the pessary group with a mean of 24.69±4.580 with a statistically significant difference found between the two groups (p=0.001).

Table (3): Shows comparison between the pessary and the TVT groups as regard the total scores of the UDI-6 at baseline, 6 weeks,6 months and 1 year, there is a statistically significant difference between both studied group regarding baseline total score (p=0.008), at 6 weeks and 6 months both groups show no statistically significant difference (p=0.108, p=0.205 respectively), finally a statistically significant difference is seen between both groups at 1 year (p=0.0280).

Table (4): shows a comparison between both groups regarding the IIQ-7 total score obtained from the urogynecology questionnaire, statistically significant difference exists between the TVT and pessary groups regarding the baseline initial total score (p=0.000), looking forward at 6 weeks

period statistically significant difference continue to be present (p=0.019), however, at the 1-year point this statistically significant difference is not existing anymore (p=0.323).

Table (1): Frequency distribution of the studied groups according to their health-related data

Demographic data		Groups				Test of Significance
		TVT (n=80)		Pessary (n=80)		
		No.	%	No.	%	
Age	40-	20	25.0	4	5.0	X2= 28.296 P= 0.000*
	50-	32	40.0	76	95.0	
	≥60	28	35.0	0	0.0	
	Mean ± SD	55.20±8.404		68.87±10.73		t= 6.343 P=0.000*
Presence of comorbidities	Yes	8	10.0	22	27.5	X2= 4.021
	No	72	90.0	58	72.5	P= 0.045*
		N= 8		N= 22		
Associated comorbidities	Diabetes mellitus	4	50.0	6	27.3	X2= 2.046 P= 0.727
	Hypertension	4	50.0	8	36.4	
	Breast cancer	0	0.0	4	18.2	
	Chronic back pain	0	0.0	2	9.1	
	Delirium	0	0.0	2	9.1	
		N= 80		N= 80		
Smoking status	Smoker	8	10.0	10	12.5	X2= 0.125 P= 0.724
	Non-smoker	72	90.0	70	87.5	
Menopausal status	Pre-menopause	36	45.0	8	10.0	X2= 12.288
	Menopause	44	55.0	72	90.0	P= 0.001*

χ2: Chi square test

t: Student t test

*** Significant p at ≤0.05**

Table (2): Frequency distribution of the studied groups according to their body mass index

Item		Groups				Test of Significance
		TVT (n=80)		Pessary (n=80)		
		No.	%	No.	%	
BMI	Healthy	16	20.0	48	60.0	X^2= 16.787 P= 0.002*
	Overweight	32	45.0	24	30.0	
	Obese class I	16	20.0	2	2.5	
	Obese class II	8	10.0	6	7.5	
	Obese class III	4	5.0	0	0.0	
	Mean ± SD	29.12±6.146		24.69±4.580		t= 3.655 P=0.001*

χ^2: Chi square test

t: Student t test

* Significant p at ≤0.05

Table (3): Comparison between the studied groups (TVT & Pessary) according to mean score of urogenital distress inventory-6 (UDI-6) across the study phases

Items		TVT (n=80)	Pessary (n=80)	Test of significance
		Mean ± SD	Mean ± SD	
Baseline	Min - Max	16.67 – 62.50	16.67 – 58.33	t= 2.728
	Mean ± SD	41.66±11.86	34.37±12.04	P= 0.008*
6 weeks	Min - Max	4.17 – 54.17	8.33 – 50.00	t= 1.623
	Mean ± SD	27.49±14.21	22.91±10.79	P= 0.108
6 months	Min - Max	4.17 – 54.17	4.17 – 50.00	t= 1.279
	Mean ± SD	17.91±13.15	21.43±11.39	P= 0.205
1 year	Min - Max	4.17 – 45.83	4.17 – 45.83	t= 2.242
	Mean ± SD	16.87±12.34	22.69±10.83	P= 0.028*

t: Student t test

* Significant p at ≤0.05

Table (4): Comparison between the studied patients (TVT & Pessary groups) according to mean score of Incontinence Impact Questionnaire-7 (IIQ-7) across the study phases

Items		TVT (n=80)	Pessary (n=80)	Test of significance
		Mean ± SD	Mean ± SD	
Baseline	Min - Max	100.00 – 316.00	0.00 – 316.67	t= 7.713
	Mean ± SD	201.58±63.34	122.47±14.01	P= 0.000*
6 weeks	Min - Max	0.00 – 283.33	0.00 – 266.67	t= 2.382
	Mean ± SD	126.25±85.53	81.85±81.13	P= 0.019*
6 months	Min - Max	0.00 – 200.00	0.00 – 266.66	t= 1.433
	Mean ± SD	61.21±58.33	83.49±79.17	P= 0.156
1 year	Min - Max	4.17 – 45.83	0.00 – 266.67	t= 0.996
	Mean ± SD	60.89±58.83	75.99±75.78	P= 0.323

t: Student t test

* Significant p at ≤0.05

Discussion

In this study, we examined whether anti-incontinence pessary can be comparable to retropubic tension-free vaginal tape in treating SUI and thus improving the patient quality of life. The FDA acted on April 16, 2019, to protect the women's health, they ordered the manufacturers of all surgical mesh products indicated for transvaginal repair for pelvic organ prolapse (POP) to stop selling and distributing their products in the United States and to be effective immediately. The FDA has reclassified the surgical mesh use for transvaginal repair of POP into the highest risk class of device (class III). Mesh use is still permitted for Tension-free vaginal tape however some countries like United Kingdom moved to even stop the use of mesh for incontinence procedure. The multiple lawsuits and media concern about the safety of mesh affected the decision of many patients, this was reflected on patients' feedback when we offered a mesh surgery for treatment of their incontinence in the clinic. This study was conducted due to the concern of probably mesh ban for SUI in the coming years.

Age is an important factor to predict pessary use for treatment of SUI and specifically the continuation of use, in our study we observed a significant difference in age between the TVT and pessary group (Table 1). This can be explained by the underlying comorbidities in elderly group and thus accepting more conservative treatment, less physical activity compared to younger age group and thus less frequent episodes of SUI and finally the acceptance to have the pessary care done by health practitioner every 3 months which is not appealing to younger age group. The age difference

also reflects significant difference in the menopausal status where most of the pessary group were post-menopausal 90 % compared to TVT group 55 %. An independent factor associated with the continued use of pessary is age above 65 years old according to multiple studies, (20-22) which is consistent with the observed results in our study.

Obesity is an independent risk factor for the incidence and prevalence of urinary incontinence in women, Table (2) shows the BMI distribution among both study groups with a normal BMI in 20 % of TVT group compared to 60 % of pessary group reflecting the fact that TVT is more reserved to patients with higher BMI as well as the probability of pessary failure is higher in patients with higher BMI. Obesity can affect the choice of intervention and can result in decrease in the beneficial effect achieved from the intervention. (23) Our result showed that the improvement in the UDI-6 score were less in patients with high BMI when compared to patients with normal BMI.

Table (3) reflect the comparison between the 2 studied group with respect to the UDI-6 scores at baseline and follow up intervals at 6 weeks, 6 months and 1 year, the baseline score showed a statistically significant difference between both groups denoting that the TVT group had a higher baseline UDI-6 score, however at 1 year interval, both groups UDI-6 scores did not demonstrate a statistically significant difference which can reflect that both intervention can result in adequate improvement in patient symptoms and thus cure rate that can be comparable to each other, our results are consistent with the results from literature were knob pessary can reach a success rate of 83%,(24) pessary fitting is definitely a talent learned by experience and successful fitting is the only guarantee for higher continuation rate that can reach 90%.(6)

Quality of life is an important aspect in assessing patients, the anticipation of treatment effect differs significantly between patients, minor improvement in patients' symptoms might result in significant improvement in quality of life from their own perspective and vice versa where major improvement in symptoms might yield minor improvement in quality of life for other patients. The change in quality of life depends on patient expectations especially with good counselling regarding potential complications and success rates of intervention, one of the examples seen in our current study was a TVT patients whom her UDI-6 scores improved significantly following her TVT surgery, however, because of her concurrent dyspareunia, her IIQ-7 score was affected. The quality of life is very subjective for each patient, and we aimed to have an overall picture of the effects of both TVT and pessary on patient's quality of life obtained from the IIQ-7 questionnaire they filled before intervention, 6 weeks, 6 months and 1 year. Table (4) compare both groups regarding the mean IIQ-7 score at different points of follow up intervals, statistically significant difference is seen at baseline between the TVT group when compared to the pessary group which continue through the 6 weeks follow up interval, however there was no statistically significant difference in the mean IIQ-7 score at 6 months and 1 year intervals denoting that both interventions can result in comparable effect on the quality of life of patients provided patient had a successful pessary fit as well as continuation of use.

We are not aware of any previous study that compared the TVT to pessary with regard to patient quality of life, some studies address the success rate of TVT in preventing SUI or the complications associated with TVT, however no study actually looked on the general effect of the

intervention on the quality of life and whether this difference is significant from other non-invasive modalities as pessary use, in our study we observed that the baseline UDI-6 and IIQ-7 scores were higher in the TVT group compared to the pessary group, these finding can reflect the fact that pessaries might not be the best option for patients with more severe SUI and also pessary failure rate in stress urinary incontinence that the patient did not continue the use of pessary for 1 year and thus was excluded from our study.

The present study has some important limitations, we relied mainly on the recall history from patients to fill the questionnaire which can reflect the incontinence pattern over the last week rather than the months of follow up, if the patient is having a urinary tract infection during or within few days before the clinic visit, the UDI-6 and IIQ-7 scores will be significantly affected. Relying on patient subjective perception of improvement by filling the questionnaire rather than an objective finding of cure of incontinence is another limiting factor as patient sometimes will never admit the fact that they have 100 % improvement and will always think their symptoms can be better, this was reflected on asking patients in the clinic about the percentage of improvement they think the intervention has provided, 7/10 is a common response, however when patients are asked which area can be addressed so we can achieve 10/10, the majority of patients will have no specific symptom to be addressed.

The other limitation we faced was the COVID-19 pandemic with loss of follow up of patients because their clinic visit was deemed non-essential, virtual follow up were done however it was impossible to have the questionnaire filled, we relied on the database to complete the number of cases. The retrospective data collection might not be as accurate as prospective data especially with the lack of motivation for patient to continue the use of pessaries.

The present study is an important addition to the literature for two main reasons, firstly, it addressed an area of research that the majority of urogynecologist will refrain from especially when involving data collection using questionnaires as UDI-6 and IIQ-7 and thus reflect the idea of improving patient quality of life from patient own prospective rather than objective finding of resolution of SUI, Secondary, it reflect the need to council patients about continued use of pessary for longer periods of time rather than proclaiming that patient had failed pessary trial and thus need surgical intervention.

Conclusion

Pessary is an alternative treatment option for SUI with comparable results to TVT with respect to patients' quality of life, age is an important predictive factor for continuation of pessary use, patients with higher BMI are more likely to fail pessary fitting and thus less likely to have improvement in symptoms, pre-treatment with local hormone to decrease discomfort and choice of successful fitting pessary are the mainstay for continued pessary use.

Statement of ethics

Urogynecology questionnaire usage in urogynecology clinic had ethics approval and all participants wrote informed consent while filling the urogynecology questionnaire.

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Conflict of interest

The authors declare no conflict of interest.

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