Research Article

Correction of Cystocele and Stress Urinary Incontinence with Combined TVT and Classical Repair versus Bologna Operation

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ABSTRACT

Objective: To evaluate the effectiveness of combined correction of cystocele and tension free vaginal tape (TVT) versus Bologna procedure for treating cystocele with urinary stress incontinence.

Study design: Eighty ladies with cystocele with USI. Forty cases experienced, careful repair of cystocele joined with TVT activity and the other forty submitted to the Bologna strategy. All patients were examined and evaluated via questionnaire.

Results: Urinary continence was restored in 90% of patients subjected to TVT operation compared with 87.5% for those subjected to the Bologna procedure.

Conclusion: Both TVT and Bologna procedure are the safe methods to treat cystocele with stress urinary incontinence and yield good results.

Keywords: Anterior prolapsed, Cystocele, Urinary stress incontinence, TVT, Bologna operation.

INTRODUCTION

Stress urinary incontinence (SUI) is a complaint of involuntary leakage of urine on effort or exertion, or on sneezing or coughing [1]. More than 50% of incontinent women have pure stress urinary incontinence (SUI) and a further 30% experience mixed incontinence [2]. Female urinary incontinence (UI) represents a contemporary challenge as approximately 20% of women in the western countries have undergone surgery for UI [3]. More interestingly high proportion of women do not seek medical advice [4]. This problem affects the physical, mental, and sexual aspects of women and causes deprivation of social status and decreases quality of life [5-6].

SUI is essentially caused by a urethral deficiency, which can be due to urethral hypermobility (diagnosed on physical examination) or intrinsic sphincter deficiency [7]. The primary cause of female SUI is laxity or looseness of connective tissue supporting the sphincteric mechanism [8-10].

A high proportion of women with pelvic organ prolapsed (POP) will demonstrate SUI on POP reduction, which is referred to as occult SUI or latent SUI [11]. This may have implications for surgical management or planning [12], and it is therefore advised to perform stress testing during physical examination and/or during UDS with prolapse reduction with a pessary, ring

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forceps or vaginal pack [13]. POP may also be associated with bladder outlet obstruction or with detrusor underactivity and hence bladder flow studies may help in predicting postoperative bladder function.

Mc Guire et al. in 1980 observed that some patients in whom multiple retropubic operations failed had a deficient sphincteric mechanism characterized by an open vesical neck and proximal urethra at rest, with minimal or no urethral descent during stress. This led to the classification of stress incontinence into type I and II (due to urethral hypermobility) and type III (due to internal sphincter defect) [14].

SUI due to ISD may be treated by bladder neck slings using biological or synthetic materials, injections, or artificial urinary sphincter [15]. However, the use of synthetic materials carries the risk of erosion and postoperative voiding dysfunction [16]. Moreover, synthetic slings and artificial sphincters are expensive and may not be affordable for patients in low income countries. Thus, the current study was conducted to evaluate the use of the rolled fortified vaginal flap (RFVF) operation in the treatment of SUI due to ISD, addressing its technical feasibility, complications, outcome, and its impact on the quality of life of those women.

Over many years, various procedures have been introduced for the treatment of SUI, with modifications to minimize associated morbidity [17].

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A tension-free vaginal tape (TVT) procedure is surgery to treat stress urinary incontinence in women. In this procedure, a synthetic tape is placed around the urethra to form a slingthis supports the urethra to prevent leakage. This procedure involves the implantation of a polypropylene tape around the mid-urethra via a minimal vaginal incision. Petros and Ulmsten were the first to come up with the treatment TVT in 1996 [18].

Bologna's operation to relieve stress incontinence in patients with large cystoceles uses two vaginal strips to form a subcervical sling. Because of the simplicity of technic of Bologna's operation, its low morbidity and its very great reliability with respect to urinary results, this method is now practiced routinely in cases of prolapse with marked cystocele and patent or potential stress incontinence, even in the presence of major sphincter incompetence [19].

The goals of this study were to evaluate and compare the efficacy of combined cystocele repair with TVT and the Bologna operation for the treatment of genuine stress incontinence associated with anterior vaginal prolapse. This was a cohort study with a 3-year follow-up. Complications and results regardingprolapse were also assessed.

PATIENTS AND METHODS

Patients

This study was performed at Tanta University Hospital upon eighty women from those attending the outpatient clinic of obstetrics and gynecology department, Tanta University Hospital in a period between January 2017 and December 2018.

Patients included within the study after informed consent obtained for each case. All patients included were complaining of involuntary urine loss which was severe enough to constitute a social or hygienic problem that was objectively demonstrable.

Patient selection criteria

Primary sling surgery is an option for patients who have:

No urinary infection

Normal voiding and bladder-filling function

Urethral hypermobility on examination

SUI on a cough-stress test

No general systemic disease

Patient exclusion criteria

Previous incontinence surgery

Lower urinary tract anomaly

Previous radiation therapy of the pelvis

Active malignancy

Neurogenic disease which can be associated with bladder disorders

Chronic chest disease as emphysema

Pregnancy

Active urinary tract infection as evidenced by positive urine culture

Patients grouping

The eighty patients included within the study were divided randomly into three groups, each of which included twenty patients:

Bologna Group: Comprised forty patients subjected to Bologna procedure.

TVT Group: Incorporated forty patients in whom TVT prolene mesh sling was done.

The preoperative evaluation

In keeping with the European Association of Urology (EAU) guidelines, diagnostic evaluation of lower urinary tract symptoms should start with a thorough medical history, physical examination, completion of a validated symptom and the degree of pelvic organ prolapse was assessed and graded according to the POP quantification system (POPQ) [20].

Prior to any treatment for SUI, a complete diagnostic evaluation should be performed in accordance with the established guidelines such as the 2016 European Association of Urology (EAU) guideline [21].

Special tests

Cough and Valsalva stress test

Questionnaires on quality of life, Urogenital Distress Inventory (UDI) (134).

Laboratory evaluation: Routine pre-operative evaluation, including urine analysis, blood urea& serum creatinine, complete blood picture, complete liver function, fasting, post prandial blood sugar and Urine analysis &culture.

Imaging: Pelviabdominal ultrasound (was done as routine to exclude any upper urinary tract abnormality.

Urodynamic tests

All patinas underwent preoperative urodynamic testing, which consisted of cystometrogram (CMG), a pressure flow study (PFS) using a standardized research protocol that followed the International Continence Society (ICS) recommended Good Urodynamic Practice Guidelines.

Methods

The Bologna procedure: The technique used was based on Umberto Bologna description [22].

TVT operation using A GYNECARE TVT $^{\text{\tiny TM}}$ Retropubic System was used.

The intra operative blood loss was calculated by using the WHO grading system: Grade 0: No bleeding, Grade I: Petechial bleeding, Grade II: Mild blood loss (clinically significant): Grade III: Gross blood loss requires transfusion (severe), Grade IV: Debilitating blood loss, retinal or cerebral associated with fatality [23].

DISCUSSION

The objective of this research was to assess and look at

the viability of consolidated cystocele repair with TVT and the Bologna procedure for the treatment of genuine stress incontinence associated with anterior vaginal prolapse.

After the recognition and adoption of mesh materials in hernia repair, sling materials became an attractive option and were widely introduced. Initially, they provided good functional results [24]. However, surgical learning curves are still considered steep due to insufficient anatomical and biochemical understanding, as well as a lack of predictability of the interaction between these foreign materials and the body. Our improved understanding of tissue biomechanics will elucidate important aspects of pelvic floor reconstruction and enhance our approach to pelvic floor dysfunction [25]. In the early 1990s, a major "game changer" appeared with the introduction of the tension-free vaginal tape (TVT) by Ulmsten and Petros [26].

The Bologna procedure was introduced in 1982. The Bologna procedure is a colposuspension by the vaginal route using two flaps of excess anterior vaginal wall tissue, which are brought up through the space of Retzius and attached to the rectus fascia [27].

Within the current study, there were no considerable differences between the two studied groups as regards age and parity. This is followedGloom and Nitti Who concluded that the age and parity as risk factors have no significant impact upon the outcome of anti-incontinencesurgery [28,29].

In harmony with our results in the TVT group, Fernando and Co colleagues studied a total of 263 patients who had clinical evidence of stress urinary incontinence. Prolene mesh was placed under the mid to the distal urethra through the retropubic route, 96.4% of these patients were cured or improved. There were no major complications such as permanent retention, erosion, infection or rejection of the mesh. The mean operative time was 27 minute [30].

Teleb and associates used the prolene sling follows the principles of TVT. They have a success rate of 92% for the prolene sling compared to 87% for AVS, which is similar to our outcome. Bladder perforation happened in two patients, one in the TVT group and one in the AVS group giving an overall rate of 6 % [31].

Likewise, Winckler and co-workers in a study to evaluate the use of a polypropylene mesh to correct SUI in 316 women, following the rules of TVT. The polypropylene group showed a cure in 88.9%, improvement in 7.3%, and failure in 3.2% [32].

Klein and colleagues were the first who reported studies of the Bologna procedure remarked on the simplicity of the technique, its low morbidity and the good correction of incontinence and cystocele. [33] Pigne and collaborates reported that the subjective cure rate of GSI after the Bologna operation is 85%-92% [34].

Giacalone and coworkers found that the incidence of intraoperative and postoperative complications of the Bologna procedure included one case of hemorrhage requiring blood transfusion, was 2.5% of bladder injury, 9% lower abdominal wound sepsis, 2.5% lower abdominal hematoma and 25% for lower urinary tract infection. De novo, urgency developed in 3.7% [35].

Fritel and his group studied the long-term effect of anterior repair using Bologna operation on female SUI In a study on 218

women with cystoceles and reported a success rate of 83%. Urge incontinence occurred in 19% of the cases with a mean follow-up of 69 months. A cure rate of 73% was obtained from the 109 patients suffering from SUI, which compared to our results [36].

De Tayrac and associates reported that the perioperative complications of Bologna procedure,including urinary tract infections occurred in 42%. Anatomic success regarding the prolapse was, and 84.6%. The subjective cure rate of GSI was 87%. The objective cure rate of GSI (negative stress test result) was 84.6%. We concluded that the Bologna operation was more effective for treating GSI associated with anterior vaginal prolapse [37].

As regards the long-term results of the Bologna procedure for SIU, it was 73% of cures after more than 5 years and 63-82% for other authors [38-40].

The intraoperative complications of the TVT procedure were mainly associated with the risk of bladder perforation. In the present study, only two women had perforation, again in keeping with other reports suggesting rates of 0-6% [18].

A 2018 multicenter RCT comparing the TVT and Burch retropubic urethropexy showed a 19% higher rate of overall continence in the TVT arm at 2 years [41]. The slight superiority of TVT against retropubic urethropexy and autologous fascia sling were also confirmed in a 2017 updated systematic review of all surgical methods to treat female SUI [42].

In conclusion, the present study bolsters the view that urodynamic examinations may not be a vital advance in ladies with uncomplicated SUI. This concurs with the perspective of numerous different authors [43].

RESULTS

In the current study, 80 women underwent surgery for the treatment of SUI with the sling technique. Patients were divided into two groups. Each group consisted of 40 patients. Women in the first group were subjected to Bologna operation, and patients from the second group were submitted to TVT operation plus classical repair. The patients were operated under spinal. The mean follow-up time was 12 months.

The average age of the Bologna group was 47.57 ± 9.05 years while within the TVT group the mean age was 46.10 ± 7.40 years. The parity of study groups ranged from 1 to 6 para. The BMI of the Bologna group was 27.5 ± 2.91 compared with 27.5 ± 2.74 for the TVT group.

Table 1 displays the distribution of incontinence grading among the studied patients. It showed that nearly 80% of the Bologna group had grade II incontinence, 10% had grade I and 10% had grade III. Within the TVT group, 20% had grade I, 75% had grade II and 5% had grade III.

	Bologna		T	V T		
	N	%	N	%		
Grade 1	4	10	8	20		
Grade 11	32	80	30	75		
Grade 111	4	10	2	5		
X ²	2.06500000					
P. value	0.35611556					

Table 1: The grading of incontinence among studied groups.

Table 2 demonstrates that mean operative time was 44 minutes for the Bologna group compared to a median of 42.6 minutes for the TVT group. There was an insignificant difference between both groups.

Table 3 displays the distribution of urodynamic parameters within the Bologna group. No significant difference noted between preoperative and three-month postoperative parameters. The maximum flow (Qmax) range was 21-31 ml/s preoperative. The norm was 23.9 \pm 2.22 while the postoperative value ranged from 20-27 ml/s with a mean of 23 \pm 2.15. Residual urine (RU) volume measured 5-20 ml preoperative with a mean of 12.25 \pm 5.23 compared to a range of 7-25 ml postoperative and a mean of 13.65 \pm 5.343. The maximum cystometric capacity (MCC) ranged between 320-477 ml preoperative and 330-470 ml postoperative and also the mean values were 395.80 \pm 43.211and 391.55 \pm 37.424 for preoperative and postoperative values respectively. Valsalva leak point pressure (VLPP) ranged from 32-99 cm $\rm H_2O$ preoperative to 30-95 cm $\rm H_2O$ postoperative.

The urodynamic parameters preoperative and 3 months postoperative of the TVT group are illustrated within the **Table** 4. That table depicts that Qmax ranged from 21-33 ml/s with a mean of 25.65 ± 3.013 preoperative and 6 months postoperative the range was 19-31 ml/s with a mean of 25.10 ± 3.905 . Residual urine volume ranged from 5-20 ml preoperative with mean 12.20 ± 4.774 and postoperative the range was 5-40 ml with mean 13 ± 7.773 . As a regard maximum cystometric capacity, the preoperative values ranged from 330-445 ml with a mean of 383.45 ± 32.066 while the postoperative range was 337-425 ml

	Operative time in minutes				
	Bologna TVT+Classical F				
Mean	44	42.6			
± SD	6.83 7.29				
P. value	0.657				

Table 2: Operative time for sling operation plus anterior colporraphy.

Bologna (A)		Ra	nge	Mean	SD	P value
Qmax (ml/s)	Pre	21.0	31.0	23.90	2.22	0.42121
	Post	20.0	27.0	23.0	2.15	0.42121
RU (ml)	Pre	5.0	20.0	12.250	5.230	0.55276
	Post	7.0	25.0	13.650	5.343	0.55276
M00 (I)	Pre	320.0	477.0	395.80	43.211	0.18655
MCC (ml)	Post	330.0	470.0	391.55	37.424	0.10000
VLPP (cmH2O)	Pre	32.0	99.0	75.70	16.604	0.22228
	Post	30.0	95.0	75.45	14.677	0.22220

Qmax=maximum flow, RU=residual urine, MCC=maximum cystometric capacity, VLPP=Valsalva leak point pressures

 $\begin{tabular}{ll} \textbf{Table 3:} The pre and 3 months postoperative urodynamic parameters of Bologna group. \end{tabular}$

TVT		Range		Mean	SD	P value
Qmax (ml/s)	Pre	21.0	33.0	25.65	3.013	0.94523
	Post	19.0	31.0	25.10	3.905	0.94323
RU (ml)	Pre	5.0	20.0	12.20	4.774	0.05000
	Post	5.0	40.0	13.00	7.773	0.65320
MCC (ml)	Pre	330.0	445.0	383.45	32.066	0.40405
MCC (IIII)	Post	337.0	425.0	383.40	27.331	0.16125
VLPP (cm H ₂ O	Pre	49.0	95.0	74.25	13.741	0.34655
	Post	50.0	93.0	75.45	10.894	

Qmax=maximum flow, RU=residual urine, MCC=maximum cystometric capacity, VLPP=Valsalva leak point pressures

 Table 4: The pre and 3 months postoperative urodynamic parameters of TVT group.

with a mean of 383.4 \pm 27.331, also Valsalva leak point pressure showed a range of 49-95 cm H2O preoperative with a mean of 74.25 \pm 13.741 and postoperative the range was 50-93 cm H₂O with mean 75.45 \pm 10.894.

Table 5 shows the intraoperative complications, bladder perforation occurred in four patients within the Bologna Group and two patients within the TVT group. One of the four patients of the Bologna group had undergone previous pelvic surgery, and also the others had no history of vaginal surgery. The injury was recognized and repaired with the continuation of the procedure. As regards patients of the TVT group, the bladder injury was small and occurred during dissection and before sling placement. The catheter was left for one week in these three cases. Intraoperative bleeding occurred in six patients within the Bologna group and in two patients of the TVT group, but none of them needed a blood transfusion. No major vascular injury or nerve injury encountered during this study.

As shown in **Table 6**, the blood loss from Bologna operation was on the average of 99 ml which is significantly more than that for the TVT operation, 48.7 ml.

With regard to early postoperative outcome, six patients within the Bologna group, two patients within the TVT group had evidence of superficial wound infection within the variability of suprapubic redness and tenderness, which resolved with antibiotics as demonstrated within the **Table 7**. Eight patients had retention of urine, 6 within the Bologna group and a pair of within the TVT group, resolved after intermittent catheterization for an extra five days. Cases of lower tract infection were managed by antibiotics. De novo, urgency appeared in 10 patients, 6 cases within the Bologna group and four cases within the TVT group, recovered after anticholinergic drugs. Cases of suprapubic and pelvic pain were relieved after proper analgesia within the variability of anti-inflammatory drugs.

As shown in the **Table 8**, the cure rate of SUI after the Bologna technique was 87.5%, and 90% of TVT operation. According to the employable result following three and a year of

	Bologna		TVT	
	N	%	N	%
Bladder perforation	4	10	2	5
Intraoperative bleeding	6	15	12	5
X ²	0.11700000			
P. value		0.73	231129	

Table 5: The intraoperative complications.

	Blood loss in ml without anterior colporraphy				
	Bologna	TVT			
Mean	99	45			
± SD	19.3	13.7			
P value	0	.008			

Table 6: Blood loss in ml in studied groups for sling operation.

	BOLOGNA		TVT		_ X2	D
	N	%	N	%	- A-	P. value
Suprapubic pain	6	15	2	5		
Pelvic pain	4	10	5	10	_	
Wound infection	6	15	2	5	_	
Retention of urine	6	15	2	5	6.75	0.3445871
Dysuria and lower UTI	8	20	2	5	_	
Hematuria	0	0	2	5	_	
De novo urgency	6	15	4	10	_	

Table 7: Early post-operative complications at 1 week.

	Bol	ogna	TVT					
	NO	%	N	%				
Cured	35	87.50	36	90				
Improved	4	10	3	7.50				
Failed	1	2.50 1		2.50				
X ²		1.57						
P value	0.9245							

Table 8: Operative outcome.

	Bologna		TVT		Divelue	
	N %		N	%	- P. value	
3 moths postoperative	35	87.5	36	90	0.000	
One year postoperative	34	85	35	87.5	- 0.028	

Table 9: Subjective Cure Rate on Follow up.

the impedance is delineated in the **Table 9**. At 3 months follow up the subjective cure rate of Bologna procedure was 87.5% and 90% of TVT operation. Follow up at 12 months shows that the subjective cure rate was 85% for Bologna procedure and 87.5% of TVT operation.

CONCLUSION

Both TVT and Bologna procedure are the safe methods to treat cystocele with stress urinary incontinence and yield good results.

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