

## **Tension-Free Vaginal Tape And Burch Colposuspension For Managing Stress Urinary Incontinence ( Types I And Ii ): A Comparative Clinical Trial.**

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### **Abstract:**

**Objectives:** To conduct a retrospective study of the clinical outcomes between tension-free vaginal tape (TVT) and Burch colposuspension for managing types I and II stress urinary incontinence (SUI) in women. **Patients and methods:** Between 1999 and 2002 a total of 32 TVT procedures and 43 Burch colposuspensions were used for managing 75 women with types SUI (types I and II) for a minimum follow-up period of one year. **Results:** The overall short-term (one year follow-up) success rates for TVT were 87.5% versus 90.7% for Burch colposuspension. The cure rates were sustained in the vast majority of patients during the short-term follow-up period (one year). Postoperative transient obstructive voiding dysfunctions were significantly more severe and common in Burch colposuspension (25.6%) versus (15.6%) for TVT. Further details of the clinical outcome and complications are presented. **Conclusion:** Both options are effective in managing SUI (types I and II) with comparable success rates. The success rate is marginally higher for the Burch colposuspension. However, the TVT procedure had shorter operative time, shorter hospital stay, fewer and milder complication rate, and is feasible under local anaesthesia. Nevertheless, the long-term results regarding the durability of the improvement rates are still to be further awaited for the TVT procedure.

**Keywords:** stress incontinence, tension-free vaginal tape, colposuspension.

### **Introduction:**

More than a hundred different techniques are described for surgical management of stress urinary incontinence (SUI) in women. This reflects the existence of no ideal option and the complex interplay of different factors in the pathogenesis of SUI. It follows that urologists has to be familiar and gain the experience of the main surgical techniques in order to be able to treat SUI in its different stages and types. The surgical options include retro-pubic colposuspensions, sling procedures, needle suspension techniques, periur -

ethral injection of bulking agents, prosthetic sphincters, and tension-free vaginal tape (TVT) with the first two being the most invasive options. Burch colposuspension and pubo-vaginal autologous facial sling procedures are the most studied ones and are considered to be the gold standard options, against them all other options should be judged [1,2,3]. Burch colposuspension is recommended for types I and II SUI with no or minor intrinsic sphincteric deficiency (ISD) factor [4]. Pubo-vaginal slings are used

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mainly whenever the main causative factor is ISD (type III) or in complicated recurrent cases [5]. Needle suspension techniques are more suitable for elderly women [6]. More recently, other less invasive options are available and include periurethral injections of different bulking agents [7], bone anchor suspension procedures [8] and the TVT procedure [9]. These forms the current platform for the armamentarium of surgical options available for surgical management of SUI whenever indicated.

### **Aim of the work:**

To compare the clinical outcome of TVT procedure against the Burch colposuspension in the management of SUI (types I and II) in women.

### **Patients and methods:**

Between 1999 and 2002 a total of 75 women (mean age 49.7 years) with urodynamically-proven SUI (types I and II) were managed surgically in two different centers, El Sahel Teaching Hospital, Cairo, Egypt; and Mouwasat Hospital, Dammam, Saudi Arabia. Burch colposuspension was done for 43 women (mean age 49.7 years) and TVT procedure was done for 32 women (mean age 53.6 years).

The study included only types I and II SUI who failed to respond to other medical conservative options. Urodynamically, genuine SUI is defined as involuntary urinary leakage with increased intra-abdominal pressure without associated detrusor contractions. According to the classification of Blaivas, in types I and II the urinary leakage is due to urethral hypermobility without intrinsic urethral sphincteric deficiency [10]. In both, the bladder neck is closed at rest and urine leaks only during straining associated with urethral descent below the inferior

margin of symphysis pubis. However, in type I, the descent is less than 2 centimeters and there is no or minimal associated cystocele. In type II, the cystocele is more evident and the urethral descent is more than 2 cm. In type III, the bladder neck is open at rest with maximum urethral closure pressure less than 20 cm water. The urine leaks with no or minimal stress and even by gravity due to deficient intrinsic sphincteric activity with no urethral hypermobility. In mixed SUI, the genuine SUI is associated with detrusor overactivity or hyper-reflexia. All cases with type III stress urinary incontinence (intrinsic sphincteric deficiency) or mixed SUI (detrusor overactivity + SUI) were excluded. Exclusion criteria included also patients with previous surgical management for SUI, and cases with previous major pelvic surgeries like abdominal or vaginal hysterectomy.

The preoperative work-up included a detailed medical history, physical examination, gynecologic examination, abdominopelvic ultrasound and with estimation of post-voiding residual volume. The urodynamic assessment protocol included uroflowmetry, filling cystometry, and urethral pressure profile at rest and during stress recording the leak point pressure (Duet<sup>®</sup> Multi-P, Medtronic, Denmark). The diagnosis of stress urinary incontinence was made whenever urine leakage occurred during coughing, or straining with no associated detrusor activity. The filling rate was 50 ml/min with the patient in a semi-sitting position. The same urodynamic evaluation was repeated for all cases at 6 and 12 months postoperatively.

Our postoperative follow-up protocol included regular outpatient clinic visits at 4 weeks, and months 3, 6, 9, and 12. After 12 months, all patients were instructed to attend the urology

clinic in case of any urological complaint or yearly for longer-term follow-up. In each visit subjective assessment of patient's satisfaction, clinical examination, urinalysis, and pelvic ultrasound examination with full bladder and post-voiding were done.

For the 32 TVT procedures, the surgical technique followed the original one described by Ulmsten *et al* in 1996 [9]. The tape used is a synthetic polypropylene mesh tape (Ethicon Gynecare™, UK). Spinal anaesthesia was used in 12/32 (37.5%) patients, epidural anaesthesia in 9/32 (28.1%) patients, and local infiltration anaesthesia using an average dose of 40 ml of lidocaine 2% in 11/32 (34.4%) patients

With the patient in the lithotomy position, a midline anterior vaginal wall incision is made over the urethra with 18 Fr Foley's catheter in situ to facilitate urethra-bladder neck orientation. Creation of two para-urethral tunnels is then performed and the two TVT needles are then passed para-urethrally at a mid-urethral position and directed posterior to the symphysis pubis to come out through two separate small suprapubic incisions. Each needle-path is checked endoscopically to avoid and detect any bladder or urethral perforations. Then, both needles and the tape plastic covers are removed without exerting any tension on the tape. An on-table stress test is done through asking the patient to cough or strain with a bladder containing 250-300 ml of normal saline. Postoperatively, we did not fix urethral catheter routinely unless a bladder or urethral perforation has occurred or excessive dissections were performed. This occurred in 2/32 (6.3%) patients where a urethral catheter was kept for 2-3 days and both voided freely after catheter removal.

The standard principles of Burch colposuspension [4] were followed using the modification described by Jarvis in 1994 [10]. Spinal anaesthesia was used for 18/43 (41.9%) patients and epidural anaesthesia in 25/43 (58.1%) patients. With the balloon of an 18 Fr Foley's catheter at the bladder neck, the lateral wall of the bladder is identified and cleared laterally avoiding dissection of the urethra and bladder neck walls. Two to four size zero monofilament polypropylene sutures are then placed on each side to the paravaginal tissue. To assure sutures stability, each suture should entangle a good bite of fascia and vaginal wall without passing through the vaginal skin. Starting distally, the most distal suture is placed two centimeters lateral to the bladder neck level keeping about one centimeter inter-distance between each paired suture level. Then, each pair of leveled sutures is placed to its corresponding site into the Cooper's ligament (ileopectineal). Sometimes, the most distal suture has to be placed to the periosteum of the posterior pubis or the fibrous insertion of the rectus muscle. Care is to be given to avoid suture over-tightening allowing the free insertion of a surgeon's index finger between the urethra and the symphysis pubis. Intra-operative stress test is then conducted by asking the patient to strain or cough to assure no leakage of urine. Then, a 20 Fr suprapubic cystocatheter and an 18 Fr urethral catheter are fixed for all patients. The urethral catheter is removed after five days. The patients learned how to open and close their suprapubic catheters. Starting on postoperative day five, we asked our patients to record-up a voiding diary through instructing them during day time to keep their suprapubic catheter closed and try to micturate normally on desire and record the voided volume.

Then to re-open the suprapubic catheter and record the residual volume drained within five minutes after re-opening. The suprapubic catheter was removed when the residual urine is less than 50 ml. The statistical analysis and comparison of results were done using the Student 't' test with a P value considered significant when less than 0.001.

### Results:

Table (1), summarizes the overall patients, procedural, and clinical outcome data. Local anaesthesia was feasible in the TVT procedure being used for 11/32 (34.4%) patients. Suprapubic drainage was used for all Burch cases for an average mean time of 8.9 days. In no TVT procedure, a suprapubic drainage was needed. There was no statistically significant difference between both groups of patients regarding the age, the follow-up period, or the overall success rates. However, strong statistically significant differences were recorded regarding the mean hospital stay period, the mean operative time, the postoperative obstructive voiding dysfunctions, the overall postoperative urological, and general surgical complications rates. The overall success rate for the Burch colposuspension was marginally higher being 90.7% (39/43 patients) versus

87.5% (28/32 patients) for TVT. These rates remained durable without significant declines during the short-term one year follow-up in both groups. The mean hospital stay was longer in Burch colposuspension group with a mean of 4.6 days versus 1.2 days in the TVT group with most of TVT cases done as day-cases (25/32 cases "78.1%"). The mean operative time was shorter in TVT group being 25.6 (20-54) minutes versus 67.9 (55-123) minutes for Burch colposuspension.

Obstructive voiding dysfunctions were significantly higher and severer among the Burch colposuspension group occurring in 11/43 (25.6%) patients versus 5/32 (15.6%) patients for the TVT procedure. No case of persistent retention of urine occurred among the TVT group versus 2/43 (4.6%) cases among the Burch colposuspension group. Furthermore, the TVT group did not show cases of postoperative general complications versus 3/43 (7.0%) cases for Burch group. Two cases of mild pulmonary atelectasis and one case of deep venous thrombosis. All the three cases responded well to conservative management. No major complications or postoperative mortalities were recorded in both groups.

## Tensioin-Free Vaginal Tape

**Table [1] Patients, Procedural, and Clinical Outcome Data.**

	<b>Burch Colposuspension</b>	<b>TVT</b>
<b>Number of Patients</b>	43 patients	32 patients
<b>Age Mean (years)</b>	49.7 years (31-66 Ms)	53.6 years (36-64 months)
<b>Mean Follow-up Period</b>	17.1(13-43) months	19.4 (12-50) months
<b>Anaesthesia:</b>		
- Local	None*	11/32 (34.4%) patients.
- Spinal	18/43 (41.9%) patients	12/32 (37.5%) patients.
- Epidural	25/43 (58.1%) patients.	9/32 (28.1%) patients.
<b>Mean Operative Time</b>	67.9 (55-123) minutes*	25.6 (20-54) minutes.
<b>Mean Hospital Stay:</b>	4.6 (3-12) days*	1.2 (12-72) days. 25/32 (78.1%) as day-cases.
<b>Post-operative Bladder Drainage:</b>		
- Urethral catheter	All Cases (5 days)*	Not Routine (2/32 cases)
-Suprapubic catheter	All Cases (mean 8.9 days)*	None
<b>Success Rates:</b>		
- Complete Symptom Cure	29/43 (67.4%) patients.	21/32 (65.6%) patients.
- Marked Improvement.	8/43 (18.6%) patients.	5/32 (15.6%) patients.
- Improved.	<u>2/43 (4.6%) patients.</u>	<u>2/32 (6.3%) patients.</u>
<b>Overall</b>	39/43 ( <b>90.7%</b> ) patients	28/32 ( <b>87.5%</b> ) patients.
<b>Failure Rates:</b>		
- Persistent Retention	2/43 (4.6%) patients.*	None
- No Improvement.	2/43 (4.6%) patients.	4/32 (12.5%) patients.
- Getting Worse.	None	None
<b>Success Durability at One Year:</b>		
-Recurrent SUI (of milder severity)	38/39 (97.4%) patients. 1/39 (2.6%) patients.	26/28 (92.9%) patients. 2/28 (7.1%) patients.

(\* ) Denotes statistically significant P value less than 0.001.

**Table [2] Postoperative Complications.**

	<b>Burch Colposuspension</b>	<b>TVT</b>
<b>Urological Complications:</b>		
<b>A) Obstructive Voiding Dysfunctions:</b>		
- Transient Retention.	5/43 (11.6%) patients.*	2/32 (6.3%) patients.
- Transient de novo Urge	<u>6/43 (13.9%) patients.*</u>	<u>3/32 (9.4%) patients.</u>
<b>Total..</b>	11/43 (25.6%) patients*	5/32 (15.6%) patients.
<b>B) Non-Obstructive:</b>		
- Bladder Perforation	None	2/32 (6.3%) patients.
- Urinary Tract Infection	7/43 (16.3%) patients.	4/32 (12.5%) patients.
- Mild Wound Infection	3/43 (7.0%) patients.	1/32 (3.1%) patients.
- Transient Mild Hematuria	3/43 (7.0%) patients.	1/32 (3.1%) patients.
<b>Non-Urological Complications:</b>		
- Deep Venous Thrombosis	1/43 (2.3%) patients.*	None
- Pulmonary Atelactasis.	2/43 (4.6%) patients.*	None

(\* ) Denotes statistically significant P value less than 0.001.

## Discussion:

The success of any surgical procedure in treating female SUI is judged by its long-term cure rates and its durability. The Burch colposuspension procedure had already passed the test of time, proved its efficacy, and durability of success rates. It is considered to be the gold-standard option for managing uncomplicated primary SUI types I and II [1,11]. It can also be used for managing cases with ISD (type III SUI), mixed SUI, and recurrent complicated cases with slightly lower success rates when compared to the pubovaginal sling procedures which form the gold-standard option for those cases [11].

The TVT procedure, its technique, and mechanism of action has been first described by Ulmsten in 1996 who found an 84% subjective and objective cure rate at two years with no significant operative or postoperative complications [9]. It was introduced as a minimally invasive, day-case surgical option which can be done under local anaesthesia for managing female SUI. Its short-term reports are promising showing almost the same success rates of colposuspension with no significant tendency to decline on short-term follow-up [12-14]. Fewer longer-term studies up to five years has documented the efficacy and durability of this procedure [15]. It is estimated that some 250,000 TVT procedures have now been undertaken worldwide [16].

The results of this work showed that both the TVT procedure and the Burch colposuspension have comparable success rates of 87.5% and 90.7% respectively. This comes in agreement with most of the reported studies in this concern [12-15,17-20]. Furthermore, this work documented the feasibility of using local anaesthesia for TVT. The

mean operative time of the TVT procedure is significantly shorter than that of the Burch colposuspension (25.6 minutes and 67.9 minutes respectively). Moreover, the mean hospital stay period was much shorter for TVT (1.2 days) with most of the cases done as a day-surgery cases (25/32 "78.1%") compared to 4.6 days for Burch group.

In both groups, the recorded success rates were durable on the short-term one year follow-up period of this work. It is well documented that success rates of all surgical options for managing SUI tend to decline on longer follow-ups. Most of the studies report a decline of the cure rate from around 90% to 70% when followed for 7-13 years after the gold-standard Burch colposuspension [17-18]. A more decline may be logically expected with long-term results of the TVT procedure.

The postoperative complications of the TVT procedure compared to the Burch colposuspension were significantly fewer and milder (table 2). This was more obvious for the obstructive voiding dysfunctions which were more common and severe in the Burch group (11/43 "25.6%" in addition to 2 persistent retentions) versus the TVT group (5/32 "15.6%", all transient with no persistent retentions). This fact is well documented in most of the reported literature [12-15,17-20]. However, small bladder perforations are known to occur more with the TVT procedure and usually recognized intraoperatively through monitoring the needle advancement endoscopically. This had occurred in 2/32 (6.3%) TVT cases with no cases in the Burch group. The reported rate for bladder perforations in TVT is 5.4% [19]. Our overall rates of postoperative complications were slightly higher than the reported rates

which may be due to documenting all the adverse events whatever mild they were.

Finally, both the TVT procedure and the Burch colposuspension were reported to be used effectively for managing type III SUI, mixed SUI, and recurrent complicated SUI. However, the cure rates in these regards are more inferior with an average mean of 75% for the Burch colposuspension versus 45% for the TVT procedure [3,17-23].

### Conclusion:

Both options, the TVT procedure and the Burch colposuspensions, are effective in managing SUI (types I and II). The success rate is marginally higher for Burch colposuspension. However, the TVT procedure had shorter operative time, shorter hospital stay, fewer and milder complication rates, and is feasible under local anaesthesia. The long-term results are still to be awaited regarding the durability of improvement rates for the TVT procedure.

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## استخدام الشريط المهبلى بدون الشد او التعليق المهبلى لعنق المثانة بأسلوب بورش

### لعلاج السلس البولى الإجهادى (النوعين 1 و 2) عند السيدات: دراسة إكلينيكية مقارنه.

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**هدف البحث:** إجراء دراسة وتحليل مراجعه مقارن لتقييم المردود الإكلينيكى لإستخدام كلاً من الشريط المهبلى بدون الشد أو التعليق المهبلى لعنق المثانة بأسلوب بورش لعلاج السلس البولى الإجهادى (النوعين 1 و 2) عند السيدات.

**المرضى وأسلوب البحث:** فى الفترة ما بين 1999 وحتى 2002 تم إجراء 32 عملية شريط مهبلى بدون الشد و 43 عملية تعليق مهبلى لعنق المثانة بأسلوب بورش لعلاج 75 سيدة يعانين من سلس البول الإجهادى (النوعين 1 و 2) لفترة متابعة لا تقل عن سنة بعد الجراحة. **النتائج:** كان معدل الشفاء للمدى القريب (مدة متابعة سنة) 87.5% للشريط المهبلى بدون الشد مقابل 90.7% للتعليق المهبلى لعنق المثانة بأسلوب بورش مع ثبات معدلات الشفاء دون انخفاض فى الغالبية العظمى لكلا المجموعتين خلال السنة الأولى للمتابعة. وقد وجد أن الإضطرابات الإنسدادية للتبول أكثر شيوعاً وأشد وطأة بعد جراحة التعليق المهبلى لعنق المثانة بأسلوب بورش (25.6%) مقابل (15.6%) للشريط المهبلى بدون الشد. وسيتضمن متن البحث استعراضاً للنتائج التفصيلية للمردودات الإكلينيكية والمضاعفات.

**الإستنتاج:** كلاً من طريقتى الشريط المهبلى بدون الشد والتعليق المهبلى لعنق المثانة بأسلوب بورش فعالتين فى علاج السلس البولى الإجهادى عند السيدات (النوعين 1 و 2) بمعدلات نجاح متقاربة وإن كانت أعلى هامشياً مع أسلوب بورش. إلا أن الشريط المهبلى تميز بزمن جراحه أقصر وفترة مكوث بالمستشفى أقصر ونسبة مضاعفات أقل وأخف وطأة. كما أنه يمكن إجراؤه باستخدام التخدير الموضعى. ويبقى وجوب انتظار النتائج طويلة الأمد فيما يختص بثبات معدلات الشفاء عتى المدى الطويل لجراحة الشريط المهبلى بدون الشد.