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Original Article

Laparoscopic Burch Colposuspension versus Transobturator Tape for Female Genuine Stress Urinary Incontinence

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ABSTRACT

Background: Stress urinary incontinence [SUI] is defined as the involuntary passage of urine during activities lead to increased intra-abdominal pressure. The cause is urethral hypermobility or weakness of intrinsic sphincter. It is a common type of urinary incontinence. No consensus was reached for the standard treatment approach.

Aim of the work: The current study aimed to compare the efficacy and safety of laparoscopic [Burch] colposuspension procedure and Transobturator tape [TOT] procedure in the treatment of female genuine SUI.

Patients and Methods: The study included 30 adult females with grade II or III genuine SUI; according to Blavias and Olsson classification. All were assessed by history taking, physical examination, laboratory and radiological investigations. Then, they were divided into two equal groups according to surgical intervention. the primary outcome was symptoms improvement. Secondary outcomes included intra operative and post-operative complications.

Results: The mean operative time in Burch group was longer than TOT group [70.67 ± 17.48 vs 50.35 ± 25.54, minutes respectively]. However, the difference was non-significant. The intraoperative blood loss was 90.48 ± 31.55 and 64.57 ± 16.22 ml, in Burch and TOT groups respectively. The type of continence was mainly of sole stress type [86.7% and 93.3% in Burch and TOT groups respectively]. Severe postoperative [PO] pain was reported only by one patient in Burch group. Burch had a significantly lower cost that TOT [155.8 ± 1.46 vs 344.39 ± 1.29 \$, respectively], and there was significant reduction of retention, difficulty, dribbling of urine, intermittency and hesitancy [continence status] among Burch than TOT group. In addition, different unwanted aspects of sexual function were significantly lower among Burch than TOT group.

Conclusion: Laparoscopic Burch colposuspension procedure resulted in significantly favorable outcome regarding cost, continence and sexual function. The complications were comparable between both procedures.

Keywords: Burch; Colposuspension; Transobturator Tape; Stress Urinary Incontinence

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* Main subject and any subcategories have been classified according to the research topic

INTRODUCTION

Stress urinary incontinence [SUI] is defined as a spontaneous involuntary loss of urine, produced as a result of increased intra-abdominal pressure. In addition, the pathological etiology includes urethral hypermobility or muscle weakness of the intrinsic urethral sphincter. It is a commonest type of urinary incontinence, as it accounts for about 50% of all SUI cases [1]. Two main categories of sphincter abnormality are present; the urethral hypermobility and intrinsic sphincter deficiency [ISD]. However, both types may coexist. Urethral hypermobility is due to a defect in the bladder neck pelvic support, while ISD is recognized as a loss of bladder outlet closure potential [2].

The surgical treatment for urethral hypermobility SUI was significantly reformed in 1995 by the introduction of a new model, the mid-urethral support without tension, invented by Ulmsten and Petros [3].

The open Burch technique was originally introduced in 1961 and it was a major development in the management of SUI. The Burch technique was the gold-standard surgery for female's SUI. It remains an excellent effective choice with relatively lower complications. However, it is technically difficult [4].

The original design of trans-obturator tape [TOT], initially introduced in 2001 by Delorme, was to introduce the tape between the two obturator foramina, from outside to inside. The reported outcome is closer to tension-free vaginal tape [TVT]. No injuries have been reported, increasing the attractiveness in the trans-obturator route [5]. Another novel technique was introduced at the end of 2003, by de Leval. It included an inside to outside passage of the tape through the obturator foramina. It is termed tension-free vaginal tape-outside [TVT-O]. Reported results of TVT-O showed that, it is a feasible, precise, rapid, and simple maneuver. In addition, it escapes the urethral and bladder destruction. Thus, cystoscopy was not necessary [6].

Studies confirmed that the use of a tension free polypropylene mesh leads to high success rates and the SUI therapy become more simplified. The TVT and the TOT are the most common possibilities for the management of SUI [7]. Thus, the different kits have provided to produce the slings. However, its use was limited due to high costs.

In 1991, the first laparoscopic bladder neck suspension was introduced by Vancaille and Schuessler [8]. Like other laparoscopic techniques, there was lower pain, reduced morbidity, shorter duration of stay in hospitals and rapid return to normal daily activities.

Although different previous reports are present about the outcome of TVT, TOT and open Burch techniques in SUI treatment, the prospective randomized studies comparing these procedures are still lacking. Thus, the current study was designed to address this situation.

AIM OF THE WORK

The current trial aimed to compare the efficacy and safety of laparoscopic [Burch] colposuspension and TOT procedures in treatment of female genuine SUI.

PATIENTS AND METHODS

This prospective interventional study had been carried out at the departments of Urology, Al-Azhar University Hospitals [Al-Zahraa and Damietta], Egypt. It was completed from March 2020 to March 2021. It included 30 adult females with grade II or III genuine SUI; according to Blavias and Olsson classification, 1988 [9]. The Exclusion criteria included pregnancy, concomitant neurological pathology affecting the bladder, previous history of radio- or chemo-therapy, uncorrectable coagulation disorder, antipsychotic treatment, or urogenital prolapse of more than the 2nd degree according to Baden and Walker classification 1992 [10].

All eligible females were randomly allocated [1:1 allocation ratio] into one of the two treatment group; the first group for laparoscopic Burch colposuspension, and the second group for TOT procedure.

At the preoperative stage, all females were evaluated by full medical history taking, general clinical examination, local pelvic examination including stress test and laboratory investigations [to check their fitness to surgical intervention]. The laboratory workup included complete urine analysis and culture, blood chemistry [e.g., blood urea, serum creatinine, fasting and postprandial blood glucose, liver function tests and coagulation profile], and complete blood cell count [CBC]. Furthermore, a pelvi-abdominal ultrasonography to evaluate of the urinary bladder, its capacity and upper urinary tract, was performed. Finally, urodynamic studies in the form of uroflowmetry and cystometry were done. Uroflowmetry aimed to evaluate the maximum and average flow rates, and the pattern of the flow. On the other side, cystometry aimed to evaluate the bladder capacity, Valsalva leak point pressure, and presence of uninhibited detrusor contraction.

Surgical procedures

Laparoscopic Burch colposuspension: All procedures were completed under general anesthesia. The patient was positioned in a dorsal lithotomy. Briefly, it was completed

through extraperitoneal approach. Just below the umbilicus, a midline incision was created [about 1.5 cm]. The preperitoneal distention balloon [PDB] cannula was introduced towards the pubis alongside the posterior rectus sheath. A laparoscope 10-mm Hasson-style blunt tip balloon trocar was introduced after expansion of the space of Retzius. Two extra 5 mm trocars were inserted, one in each lower quadrant at a point one third lateral to the rectus muscle. With CO₂ insufflation at a pressure of 8-10 mmHg, mobilization of the bladder was done with dissection of the periurethral fat from the pubocervical fascia. Then, exposure of the Cooper's ligaments was achieved followed by cleansing of the areolar tissue and fat around the ligaments. One or two non-absorbable sutures were sited at the level of the mid-urethra without penetration of the vaginal mucosa. Then, a tension-free knotting technique was used to fix it to the Cooper's ligament. An intraoperative cystoscopy was done as the final step of the surgery to exclude any urethral or bladder injuries. Twenty-hours after surgery, the Foley catheter was removed, and then intermittent self-catheterizations were done until the post-void residual urine was < 50 mL [11].

Transobturator tape procedure: Through a vaginal small incision site and in the femoral/pelvic fold, insertion of a bilateral transobturator mesh by means of needle was achieved. Figures [1] to [11] are describing the surgical procedure.

Post-operative care consisted of vaginal pack for one day, abstinence from sexual intercourse for 4 to 6 weeks, regular vaginal douche for one month, and oral fluoroquinolones and metronidazole for 10 days. Postoperatively the patients were assessed after 1, 2 weeks and 1, 3, months by clinical evaluation, pelvi-abdominal ultrasound and urodynamic study.

The outcome measures

1. Improvement of symptoms [the primary endpoint]; cure was defined if no SUI occurred postoperatively [the absence of any subjective urine leakage complaint, and the leakage absence on cough, stress testing and urodynamics [negative Valsalva leak point pressure]]. Otherwise, they were considered improved if SUI still present but to a milder degree than pre-operative condition. Failure was documented if the patient still complaining of SUI whether the condition was the same or worse than before surgery.

2. Peri-operative complications: [e.g. bleeding, injuries to the urethra, bladder, vagina, nerves or bowel, urinary retention, hematoma, wound infection, urethral erosions]. In addition, operative time, anesthesia type, post-operative

analgesia [type and dosage], and hospitalization time are reported.

Ethical considerations

The study protocol was introduced and accepted by the local institutional review board [IRB], Damietta Faculty of Medicine, Egypt. In addition, each patient signed a written informed consent. Extreme care was exerted to ensure the safety of participants, and the participant had the full right to withdraw from the study at any time. Data are available on request.

Statistical analysis

At the end of study, data was collected, coded, fed to personal computer and analyzed by Microsoft Excel and Statistical Package for Social Sciences [SPSS] version 18 [SPSS Inc., Chicago, IL, USA]. Appropriate statistical tests were used to assess association or significance between groups. Treatment efficacy and safety analyses were performed as the per-protocol [PP] population. A two-sided probability value [p-value] of < 0.05 was considered significant.

RESULTS

In the current work, there was no significant difference between Burch and TOT, regarding patient age, body mass index [BMI], parity and associated comorbidities [Table 1].

Both groups were comparable regarding operative and postoperative data. The mean operative time in Burch group was longer than TOT group [70.67 ± 17.48 vs 50.35 ± 25.54, minutes respectively]. However, the difference was non-significant. The intraoperative blood loss was 90.48 ± 31.55 and 64.57 ± 16.22 ml, in Burch and TOT groups respectively. The type of continence was mainly of sole stress type [86.7% and 93.3% in Burch and TOT groups respectively]. Severe PO pain was reported only by one patient in Burch group [Table 2]. .

The functional outcome, follow up outcome, incontinence and storage functions, revealed non-significant difference between Burch and TOT groups. However, Burch had a significantly lower cost than TOT [155.8 ± 1.46 vs 344.39 ± 1.29 \$, respectively]. In addition, there was significant reduction of retention, difficulty, dribbling of urine, intermittency and hesitancy [continence status] among Burch than TOT group. In addition, different unwanted aspects of sexual function were significantly lower among Burch than TOT group [Table 3].



Figure [1]:The patient in dorsal lithotomy position and four ports were placed.



Figure [2]: The patient in dorsal lithotomy position and three ports were placed



Figure [3]:Peritoneal incision in midline. 3cm superior to dome of the bladder between the obliterated umbilical ligaments



Figure [4]:Identification of loose areolar tissue confirms a proper plane of dissection to enter the space of Retzius

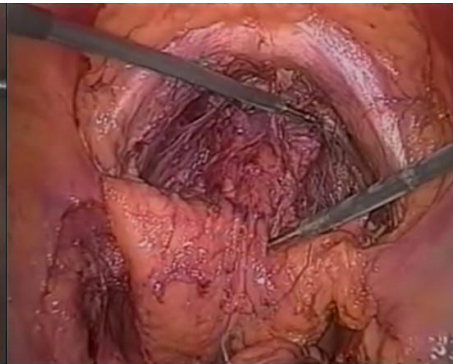


Figure [5]: Retropubic anatomy after blunt dissection anterior, transversalis fascia medially symphysis pubis laterally, pubic rami and cooper's ligament

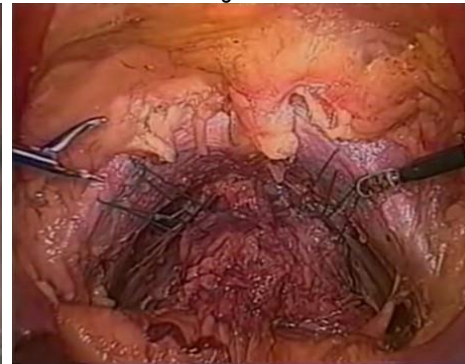


Figure [6]: A 2-0 braided non-absorbable suture [Ethibond] is placed over the para vaginal fascia fixed to cooper's ligament

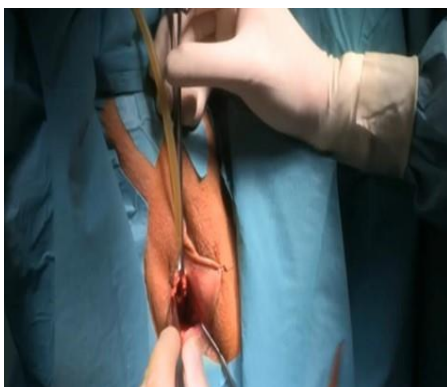


Figure [7]: Suburethral longitudinal midline incision of anterior vaginal wall in presence of urethral catheter.



Figure [8]:Tape applicator [needle] passing through tract created using out in technique by supination movement



Figure [9]: Mesh was fixed to the needle and drawn out through the thigh by pronation movement



Figure [10]: Suburethral straightening of the tape

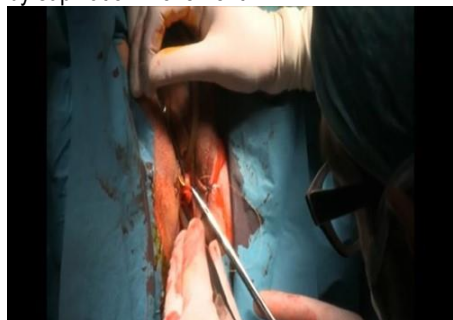


Figure [11]: Closure of vaginal incision by vicryl 3/0 in interrupted manner

Table [1]: Demographic and clinical data of both groups

Variables	BURCH	TOT	Test	P	
Age [years]	40.17±13.01; 19-63	41.35±14.12; 22-65	0.23	0.81	
BMI [kg/m ²]	30.48±4.65	29.71 ± 4.82	0.445	0.659	
Parity	2.64±0.836	2.84 ± 0.972	0.604	0.551	
Comorbidities	Hypertension	4[26.7%]	3[30.0%]	0.186	0.666
	Diabetes mellitus	2[13.3%]	2[13.3%]	0.001	1.00
	Prior hysterectomy	1[6.7%]	2[13.3%]	0.371	0.543
	Hormone replacement therapy	5[33.3%]	4[26.7%]	0.159	0.691
	Menopausal status	7[46.7%]	8[53.3%]	0.133	0.715

Table [2]: Operative and postoperative data in both groups

Variables	Burch [N=15]	TOT [N=15]	Test	p	
Operative time [min]	70.67 ± 17.48	50.35 ± 25.54	0.34	0.532	
Blood loss [ml]	90.48 ± 31.55	64.57 ± 16.22	0.21	0.435	
Type of urinary incontinence	Stress	13 [86.7%]	14 [93.3%]	0.371	0.543
	Mixed	2 [13.3%]	1 [6.7%]		
Hospital stay duration [days]	0.625 ± 0.324	1.02 ± 0.647	1.97	0.056	
Complications	Bladder injury	2 [13.3%]	0 [0.0%]	4.37	0.35
	Bowel injury	0 [0.0%]	1 [6.7%]		
	Wound infection	2 [13.3%]	1 [6.7%]		
	Erosions	0 [0.0%]	1 [6.7%]		
	None	11 [73.3%]	12 [80.0%]		
Postoperative [PO] pain	Mild	9 [60.0%]	8 [53.3%]	1.39	0.499
	Moderate	5 [33.3%]	7 [46.7%]		
	Severe	1 [6.7%]	0 [0.0%]		

Table [3]: Outcome among studied populations

Outcomes	Burch [N=15]	TOT [N=15]	Test	p	
Functional outcome	Urinary retention	3 [20.0%]	2 [13.3%]	0.240	0.624
	Recurrent UTI	1 [6.7%]	0 [0.0%]	1.03	0.311
	De novo urgency	2 [13.3%]	0 [0.0%]	2.14	0.143
	Short-term voiding dysfunction	2 [13.3%]	1 [6.7%]	0.371	0.543
	Long-term voiding dysfunction	1 [6.7%]	0 [0.0%]	1.03	0.311
Follow up outcome	Cured	13 [86.7%]	14 [93.3%]	1.03	0.59
	Improved	1 [6.7%]	1 [6.7%]		
	Failed	1 [6.7%]	0 [0.0%]		
Cost [\$]	155.8 ± 1.46	344.39 ± 1.29	3362	<0.001*	
Incontinence	After 2 weeks	5 [33.3%]	3 [20.0%]	0.682	0.409
	After 3 months	2 [13.3%]	1 [6.7%]	0.371	0.543
Continenence status	Retention	1 [6.7%]	4 [26.7%]	14.13	0.015*
	Difficulty	1 [6.7%]	3 [20.0%]		
	Dribbling of urine	0 [0.0%]	1 [6.7%]		
	Intermittency	1 [6.7%]	3 [20.0%]		
	Hesitancy	1 [6.7%]	3 [20.0%]		
	Frequency	2 [13.3%]	3 [20.0%]		
Storage	Urgency	1 [6.7%]	3 [20.0%]	5.78	0.32
	Nocturia	0 [0.0%]	1 [6.7%]		
	Urgency with fear of leaking	1 [6.7%]	2 [13.3%]		
	Leak during sex	0 [0.0%]	1 [6.7%]		
	Sexual function	Vaginismus	0 [0.0%]		
Possible dyspareunia	1 [6.7%]	3 [20.0%]			
Interference with sexual arousal	0 [0.0%]	4 [26.7%]			
Interference with sexual orgasm	1 [6.7%]	3 [20.0%]			

DISCUSSION

Stress urinary incontinence [SUI] is reported among 13 to 46% of females at a young age. The rate increased if postmenopausal females were considered. It restricts the female quality of life due to affection to different aspects of life [e.g., sexual, physical, social and emotional aspects] [11]. Burch colposuspension is a well-accepted surgical technique for management of SUI. It was the gold standard intervention for a long time [open at first introduction followed by the laparoscopic technique] [12]. The TOT is a tension-free sling used also for treatment of SUI. Its main advantages are lower rate of de novo urge/urge incontinence. The sexual life [frequency, please or pain] is not affected [13].

The current work aimed to compare laparoscopic [Burch] colposuspension and TOT procedures for treatment of female SUI, regarding safety and efficacy. Analysis of our findings revealed that the majority of our patients were in their forties [40.17 ± 13.01 vs 41.35 ± 14.12 in first and second groups]. No significant difference between the two groups was reported, regarding patient age, obesity or parity. In line with these results, Magon and Chopra [14] reported 46.2 years as the mean age of the females with SUI. Only 1 [1.7%] was nulliparous, 13.6% were in primiparous and 84.7% were multiparous women. On the other side, Taweel and Rabah [15] reported 52 years, as a mean age of their patients, while Kaelin-Gambirasio *et al.* [16] reported an average age of 57.9 years. This explained by different sample size and inclusion criteria.

Regarding comorbidities, our results are in accordance with Elserafy *et al.* [17], where urinary incontinence was more prevalent among patients with hypertension and UTI. The percentage of patients with urge and mixed incontinence were significantly higher among the uncontrolled diabetic patients. Mixed incontinence was significantly related to constipation. Obesity was predominant among patients with stress.

Dean *et al.* [18] reported that, the advantages of laparoscopic colposuspension are rapid recovery when compared to traditional open approach, with comparable short and mid-term results. However, when laparoscopic Burch technique compared with recent 'self-fixing' sling maneuvers, the short term of the sling maneuvers provides greater benefits with similar, if not better cure rates.

Operative time was longer in the Burch than TOT groups. However, the difference was statistically non-significant. Magon and Chopra [14] reported that the mean duration of TOT surgery was 21.69 ± 6.41 minutes. Otherwise, authors reported great variability in operative time. For example, Taweel and Rabah [15] reported mean TOT surgery duration of 18 minutes.

Tan *et al.* [19] reported that laparoscopic colposuspension evades many disadvantages of open surgery. The cosmetic aspects of abdominal scar represented one of these advantages. Minimal invasive procedures allow shorter duration of the hospital stay, rapid recovery and return to normal daily activity. Results from the Cochrane review of Dean *et al.* [18] unsurprisingly, showed that laparoscopic intervention was associated with lower morbidity, a shorter duration of hospital stay, fewer postoperative complications, lower blood losses, shorter duration of catheterization, and significantly lower pain.

No significant differences were reported between the two groups for postoperative urgency, voiding dysfunction or de novo detrusor over-activity. McCormack *et al.* [20] reported that laparoscopic colposuspension have shown low perioperative comorbidities, longer operative duration, less pain, shorter hospital stay and a rapid overall recovery. Persson *et al.* [21] reported that laparoscopy has a longer operative and hospital stay durations and slower recovery of the normal daily activities. The one-year re-operation rates were reported in TVT procedures.

Purnichescu *et al.* [22] reported the mean hospital stay duration was 1.25 days in isolated TOT procedure. Kaelin-Gambirasio *et al.* [16] reported a mean duration of 2.2 days. Furthermore, in the current study, we demonstrated that the major postoperative complications were bladder injury and wound infection among both groups, and there was non-significant difference between the two groups regarding any of postoperative complications. Magon and Chopra [14] reported that obstruction of the voiding dysfunction is the commonest complication of TVT. However, the TOT provides less chance for static urethral kinking and the urethral obstruction that may follow, due to transverse positioning.

TOT interventions are overall considered a harmless and effective procedure; however, there are many surgery-related comorbidities that must be considered. Perforation of bladder or vagina, formation of hematoma, neurological complications [numbness and weakness], pain, and mesh exposure as well as lower urinary tract complications [voiding dysfunction, new onset and persistent urgency urinary incontinence], are well documented [23].

Fusco *et al.* [24] in a systematic review compared TVT to TOT slings regarding complications, showed that, bladder/vaginal injuries favored TVT approach. Magon and Chopra [14] reported that, no one of their patients had neurological, vascular, or bowel injury. The most important step to avoid erosion and voiding dysfunction was found to be tape adjustment without any tension or any contact with the urethra.

There were no complaints of thigh pain in our series, which confirms findings of a meta-analysis published in 2007 by Latthe *et al.* [25]; that the outside-in technique is usually not associated with this specific symptom. None of the patients had developed erosion, which was perhaps due to the use of non-woven, polypropylene mono filament with macro pores material to produce the tape. In another study of Persson [26], who compared 1-year cure rates after laparoscopic colposuspension using one double-bite or two single bite sutures on each urethral side, and reported that direct and long-term postoperative complications were few and self-limiting; with no difference between both techniques. However, one female developed pubic bone osteitis. She was treated conservatively by antibiotics [ciprofloxacin and clindamycin] for 4 weeks. Moreover, the current study revealed that there was non-significant difference between the two groups regarding functional and follow up outcomes. Albo *et al.* [27] reported that, success rates were higher for the pubovaginal sling compared to the Burch colposuspension [66% vs. 49%]; however, more females in the pubovaginal arm had UTIs, difficult voiding, and UUI. Other studies reported no significant difference in 18 months' cure rates. TOT was linked to shorter operative time, hospitalization, and time to resume normal activity [28].

Nilsson *et al.* [29] published long-term results of the TVT technique for primary SUI from a multicenter study of 90 patients. 85% were cured, 10.6% were improved, and 4.7% were failed. There were no mesh erosions or permanent retentions. Laparoscopic colposuspension yielded similar results to those for TVT. Cure rates ranged between 69% and 100%.

The limitations of our study include the short follow up period. It is still felt desirable that larger trials with bigger sample size and with a longer duration of follow-up for evaluating long-term success of TOT and laparoscopic Burch colposuspension are required. Further, comparative trials comparing TOT with other surgical options available for treatment of SUI shall be able to give it its right place of honor in the treatment of SUI. It has the possibility to be the new Gold Standard for treatment of female SUI.

CONCLUSION

In conclusion, the laparoscopic Burch colposuspension procedure resulted in significantly favorable outcome regarding cost, continence and sexual function. The complications were comparable between both procedures.

Financial and Non-financial Relationships and Activities of Interest

None

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The cover art features a magnifying glass, a globe, and a stethoscope. The background is a light beige color with a faint, repeating pattern of ECG (heart rate) lines. The magnifying glass is positioned on the left side, with its handle extending towards the bottom. The globe is centered in the lower half of the image. The stethoscope is on the right side, with its chest piece near the globe. The overall color scheme is warm, with shades of beige, brown, and blue.

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