New perineal tense transobturator tape (T-TOT) for postprostatectomy urinary incontinence.

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Abstract: Bulbourethral transobturator sling data from other investigators report a success rate from 53% to 85%. Since the degree of sling tension and its adjustment seems to be important for achieving complete urinary continence we present results on the first consecutive 12 patients, with mild post prostatectomy stress urinary incontinence – defined as – less than 500 ml, who underwent a new perineal tense transobturator polypropylene tape (T-TOT) procedure at our institution.

Results: Pre-operative mean abdominal leak point pressure (ALPP) was 23 cm H₂O (sd +/- 10), retrograde leak point pressure (RLPP) was 24 cm H₂O (sd +/- 6) and the mean pad test was 324 g (sd +/- 176). The overall success rate has been of 58.3% (7 patients) complete responders (CR), 33.3% (4 pts) partial responders (PR) and 8.33% (1 patient) failure. No significant urodynamic outlet obstruction nor urethral erosion occurred at 9-month follow up occurred. Post operative ICIQ-SF questionnaire score dropped from 11 to 3 with significant statistical evidence (p < 0.01).

Conclusion: perineal T-TOT showed safe and effective results similar to conventional bulbourethral transobturator male slings without obstructive symptoms despite maximal tension was used. Anyway longer prospective follow up is needed to determine the long-term efficacy of this procedure and the effective preservation from urethral erosion.

Key words: Postprostatectomy urinary incontinence; Transobturator bulbourethral sling; Urinary continence.

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Introduction

Urinary incontinence after radical prostatectomy impacts quality of life negatively (1) and ranges from 5% to 30% (2-4). Sphincter dysfunction alone or combined with detrusor functional abnormalities are recognized causes for over 96% of cases (5-10). Surgical damage to pubourethral ligaments or muscolofascial urethral support may lead to sphincter dysfunction while bladder neck demilation may lead to bladder decentralization. Prophylaxis is carried on intraoperatively at the time of the radical prostatectomy (11-14) by procedures that preserve anatomical urethral and rabdomyosphincter integrity at the prostatic apex (15), the bladder neck (11, 16), the pubprostatic ligaments (17) or the urethral rabdomyosphincter (13, 18). Postprostatectomy treatments include conservative and second-line therapy involving artificial urinary sphincter (AUS) placement, urethral bulking agents injections, periurethral balloons and bulbourethral sling procedures.

High revision rates with the AUS and low success rates with bulking agents and periurethral balloons have prompted the development of efficient urethral sling procedures. Sling data from other investigators report a success rate from 53 to 85% (8, 19, 20) with curve of success rates stabilizing at 6 month follow up (21). Retropubic and perineal slings are based on active bulbar compression with increase of outlet resistance (8, 21-24) but may erode urethra up to 6% of cases as erosion occurs with excessive urethral pressure (25).

Transobturator tapes (TOT) are less obstructive by means of attachments to the obturator foramen preventing from sling-tension related urethral erosion (26). The tape function is based on a cranial cephalization of the urogenital diaphragm posterior to the uretha replacing its functional support lost by the time of the prostatectomy after pubourethral ligaments and/or muscolofascial plate cut. Since the degree of sling tension and its adjust-
ment seems to be important for achieving complete urinary continence (27) many intraoperative measurement have been used to gain the optimal one such as retrograde urethral pressure (27-29), cough test (30) or urethral resistance (24). Anyway intraoperative urethral pressure decreases in the follow up indicating a sling relaxation (20) with possibility of incontinence recurrence (27). Sling relaxation may be prevented by its maximal tension. We present results on the first consecutive 12 patients who underwent a new tensive perineal body transobturatore polypropylene tape (T-TOT) procedure at our institution from March 2007 to February 2009 for mild-moderate post radical prostatectomy urinary incontinence.

**Materials and Methods**

12 patients with stabilized moderate post radical prostatectomy underwent an original perineal body T-TOT placement at our institution. All patients reported a mean daily pad test less than 500 ml. According to the International Continence Society (31) preoperative supine 50 ml/min medium fill videourodynamics and retrograde leak point pressure test (RLPP) with static urethral pressure profile selected patients with simple sphincter deficiency (SD) or combined with decreased bladder compliance. In mild incontinence patients abdominal leak point pressure test (ALPP) may be negative despite anatomical and functional sphincter deficiency (14). For this reason it has not been considered specific for SD. Based on other studies we used for compliance the cut off value of 10 ml/cm H2O (5, 32, 33).

Cystourethroscopy was used to rule out anastomotic or urethral stricture that should be treated and healed before sling surgery. Prospective videourodynamics and urethroscopy were evaluated in all patients, before surgery and at 9 month follow up. The significance of the observed differences in proportions was tested by Pearson’s chi 2 and values < 0.05 were considered significant. A 30 cm × 30 cm polypropylene mesh sling has been shaped for operatively into a sling 30 cm width and 1 cm height distally with a progressive up-to 3 cm height in the middle. Through a midline perineal incision the perineal body is isolated laterally without any bulbar urethral cephalic dissection. Ischiourethral dissection was carried on to guarantee urethral mobilizing when the perineal body is cephalized by the sling. The polypropylene shaped tape has been placed beneath the perineal body 2 cm posterior to the bulbar urethra (Figure 1). Each end passed from the perineal incision into the obturator foramen bilaterally with a out-in percutaneous needle technique accordingly to Gozzi’s technique (26). The medial portion of the shaped sling pushes over the perineal body cephalating the membranous urethra toward the bladder.

Because the tape is actively acting only onto the perineal body with no direct contact to the bulbar urethra, its tightening may be maximal, without risk of urethral obstruction and erosion. Both ends of the tape are finally brought from the subcutaneous obturator tissue to the median incision by a subcutaneous course over the Colles’ fascia. Once the medial superficial perineal tissues have been sutured together to the Colles’ fascia the tape’s ends are
tightened together to prevent from sling slippage (26) or long term de-tensioning. A draining indwelling 18Ch Foley catheter is left and removed within 24 hours.

Questionnaire analysis. Patient’s satisfaction has been assessed by means of ICIQ-L-SF questionnaire for incontinence (31).

Data collection and statistical analysis. Urodynamic data pertinent to outcome assessment were collected and recorded as the means, ranges and SD. Pearson’s chi-square test was used to assess differences among the groups of complete responders (CR), partial responders (PR) and failure (F) using SPSS software. To detect independent predictors of outcome multivariate analysis with the logistic regression model followed by a stepwise forward procedure was done. Two-tailed values of $p < 0.05$ were considered statistically significant.

**RESULTS**

Average age was 72 years. No patients had previous endoscopic, surgical or radiotherapy treatment. Mean follow up was 26 months (from 24 to 27 months). Pre operative mean ALPP was 23 cm $H_2O$ (sd +/- 10), RLPP was 24 cm $H_2O$ (sd +/- 6) and the mean pad test was 324 g (sd +/- 176). The overall success rate has been of 58.3% (7 pts) complete responders (CR), 33.3% (4 pts) partial responders (PR) and 8.33% (1 patient) failure (F). A 10 ml/cm $H_2O$ bladder compliance cut off, similar to the suggested from Leach (32), provided a significant predictive value of the surgical outcome (91% specificity and 75% sensibility). No difference was found in the recovery of maximum urethral pressure or/and functional urethral length after T-TOT procedure, in accord with prior investigators (14). A not statistically significant ($p > 0.05$) mean improvement of 12 cm $H_2O$ in MUCP has been seen in CR patients while of 7 cm $H_2O$ in PR patients. RLPP showed an increase in average from 22 (+- 6.7) to 57 (+- 6.5) cm $H_2O$ ($p > 0.05$). Despite the considerable tension exerted on the sling no clinical significant outlet obstruction happened nor perineal pain longer than a fortnight was recorded in these series as previously experienced in literature (21).

A patient suffering from sling infection was cured conservatively with parenteral wide spectrum antibiotic therapy for one week. Another patient suffered from a perineal “butterfly” hematoma and this was associated to transitory acute complete urinary retention. No post operative residual urine occurred nor urodynamic urethral obstruction at 26 months follow up. A patient complained a “de novo” overactive bladder with low grade relapse of the incontinence within 6 months from surgery. Post operative quality of life SF questionnaire mean score dropped from 11 to 3 with significant statistical evidence ($p < 0.05$).

**DISCUSSION**

Sphincter deficiency is responsible of 96% of stabilized post prostatectomy incontinence with direct correlation to its degree (5, 34). Surgical cut of the pubo-urethral ligaments leads to an intraoperative kidnap of the distal urethral stump into the urogenital diaphragm and may be followed by a postoperative certain degree of urethral or perineal descent and urinary incontinence (26). A not squared urethral section at the prostatic apex may lead either to shorter urethral functional length or direct damage to urethral sphincter with low MUCP (9, 35).

Postoperative urinary incontinence may last for 12 months stabilizing in 4% of patients as definitive. TENS and Kegel exercises make recovery faster in 80% of patients in the first 4 months without overall continence improvement (unpublished data) enhancing conservative results obtained with Kegel exercises alone (36). Nagouchi (14) and than Rocco (13) demonstrated that a preventive intraoperative anterior or posterior urethral suspension may lead to an early post operative continence status. The lack of significance in long term efficacy may suggest pubourethral ligaments integrity as a major predictive factor in post operative continence preservation. However a posterior support may be also delivered later by cranial cephalisation of the urogenital diaphragm from a bulbar urethral transobturator sling procedure (26) with the result of an enhancement of the residual urethral rhabdomysphincter muscular action (37).

Worldwide a bulbar urethral sling procedure is worth for medium degree of incontinence. For larger amounts of incontinence secondary to complete sphincter deficiency the placement of an artificial urinary sphincter (AUS) is indicated. If bulbar urethral sling procedure is performed in complete sphincter deficiency, incomplete recovery may occur. In these series patients suffered from a daily incontinence lower to 500 ml. Moreover, tape tensioning correlates in literature with clinical outcome (27) but also with urethral erosion(26), despite maximal TOT tension in cadavers showed no possibility to totally obstruct the urethra (26). Urethral erosion may be due to a too distal sling placement on the proximal urethral bulb or to its incomplete mobilization (38) or to the thinning of the ventral bulbar urethra at the dissection (39). Particularly, in our opinion, when a thin urethra is posteriorly sustained by a rough sling in terms of surface rigidity. With a too distal placement of the trans obturato sling, the force is applied directly onto the urethral lumen, not onto the spongy tissue that lies inferior to the urethral lumen. This incorrect placement leads to obstruction or distortion of the urethral lumen (39). Double blinded multicentric prospective trials may be helpful in stating if smoothness of the polypropylene sling may be important as the surgical technique to avoid urethral erosion. However, in these series the anterior perineal body has been interposed between the bulbar urethra and the polypropylene sling ensuring a vascularized muscular cushion preventing from urethral erosion at maximal sling tension, showing clinical outcome similar to that provided from standard bulbourethral trans obturator male slings (26). Correlation in post operative outcome has been found only with urodynamic compliance. If over 10 ml/cm H2O patients resulted totally cured in 80% of cases. If under, only 35.2% of patients were found with CR while 5.8% improved at least. Compliance showed to be a specific (91%) predictor of complete post operative success. Sensibility is lower (75%) perhaps because other factors may act in the con-
tinence balance of the urethral sphincteric unit. Tape fixation differs from original Gozzi's technique (26). Maximal tension in these series has been provided from trans-location of the lateral wings of the tape in a subcutaneous tunnel into the median surgical wound. Maximal tension has been sustained from the ileopubic branch of the obturator foramen, and fixation was obtained by knotting both ends of the tape together. Although placement of the sling with passage of a needle through the perineum is thought to cause symptomatic perineal nerve entrapment (24) in these series symptoms were not significant suggesting that may be due more to bone screws than to a tensive perineal nerve compression. An overall success of 91.6% (CR + PR), is strongly suggestive for clinical efficacy of this tensive sling procedure. In these series T-TOT procedure missed urodynamic statistical evidence of recovery. We may explain this missing value because urodynamics are performed in laying position by default. While tape suspension give active sustain to the urogenital diaphragm deisensus in the standing position.

**CONCLUSION**

Perineal T-TOT showed effective results similar to conventional bulbourethral transoburator male sling in the management of post radical prostatectomy incontinent patients when daily urinary incontinence was less than 500ml, not showing obstructive symptoms despite maximal tension was used. Anyway longer prospective follow up is needed to determine the long-term efficacy of this procedure and the effective preservation from urethral erosion.

**REFERENCES**


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