

## **INSIDE-OUT TRANSOBTURATOR VAGINAL TAPE (TVT-O): ONE-YEAR RESULTS OF A PROSPECTIVE STUDY**

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**INTRODUCTION & OBJECTIVES:** The aim of this study was to prospectively assess the efficacy of a new surgical technique, the inside-out transobturator vaginal tape (TVT-O), for the treatment of female stress urinary incontinence (SUI).

**MATERIAL & METHODS:** From 03/2003 through 10/2003, a TVT-O tape was inserted in 83 consecutive patients with clinical evidence of SUI. Preoperative evaluation included complete history, physical examination, urodynamics, urine analysis, and cystoscopy. None of the patients presented the following exclusion criteria: post-void residual (PVR) >100 cc, detrusor overactivity or acontractility, pregnancy, neurological pathology, active urinary or vaginal infection, age >85 years, negative stress test, and maximum cystometric capacity <300 mL. Post-operative evaluation was carried out using symptom scoring and quality of life (QoL) questionnaires, visual analog scales, physical examination, uroflowmetry, and PVR measurement. Cure was defined as no leakage based on both symptom scale scoring and physical examination. Improvement was defined as  $\geq 50\%$  decrease in symptoms based on the questionnaire's results.

**RESULTS:** Mean age of the patients was 61 years. The TVT-O procedure was associated with pelvic organ prolapse cure in 15 patients (18%). Follow-up time was  $\geq 12$  months in all women (mean = 14); 3 patients were lost to follow-up. No significant blood loss ( $\geq 100$  cc), vaginal wall, urethral, or bladder perforation was encountered. No hematoma, vaginal or urethral erosion, or neurological complication was observed. No patient complained of persistent pain. At the latest follow-up visit, max flow rate was  $\geq 10$  mL/sec and PVR was <100 cc in 90% and 94% patients, respectively. Two patients underwent an immediate tape release procedure while the tape was sectioned in 2 other patients for retention and/or urgency associated with obstruction. Sixty eight patients (85%) were cured of their SUI while 9 patients (11%) were improved. Urgency questionnaire's results showed that 5 (5/46) patients developed de novo urgency. Twenty and 14 out of the 34 patients with preoperative urge symptoms reported either disappearance or no change of urgency, respectively. Obstruction symptoms appeared or worsened in 3 patients and were unchanged or decreased in all other patients. Analysis of the incontinence visual analog and QoL scale scores showed that the majority of patients reported disappearance of incontinence together with significant improvement of their QoL.

**CONCLUSIONS:** The one-year results of this study suggest that TVT-O is associated with a low incidence of peri- and post-operative complications and high objective and subjective SUI cure rates.

## **A PROSPECTIVE MULTICENTRE RANDOMIZED STUDY COMPARING TRANSVAGINAL TAPES (SPARC SLING SYSTEM) AND TRANSOBTURATOR SUBURETHRAL TAPES (MONARC SLING SYSTEM) FOR THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE**

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**INTRODUCTION & OBJECTIVES:** To evaluate the results of a prospective multicentre randomized trial comparing the Sparc™ and the Monarc™ sling system for the treatment of stress incontinence in women.

**MATERIAL & METHODS:** One hundred thirty women with stress incontinence were treated with either the Sparc™ sling (n = 65), or Monarc™ sling (n = 65), between November 2003 and May 2004 in 5 centres in Korea. Operation technique complied with the manufacturer's instructions. The patients' characteristics and urodynamic evaluations were similar in the 2 groups. The preoperative evaluation included a careful history taking, physical examination, voiding diary, stress & pad test, and a comprehensive urodynamic examination. The postoperative evaluation included a questionnaire, stress & pad test, and uroflowmetry with postvoid residuals.

**RESULTS:** Mean operative time was shorter in the Monarc™ group, but the difference was not significant (26.8 min±11.8 vs 31.6 min±9.6,  $P>0.05$ ). No bladder injury occurred in the Monarc™ group versus 6.2% (n = 4) the Sparc™ group, but vaginal wall perforation occurred 4.6% (n=3) in the Monarc™ group. The rate of postoperative urethral obstruction including retention was 7.7% (n = 5) in the Sparc™ group versus 6.2% (n = 4) in the Monarc™ group ( $P>0.05$ ). The rates of cure (86.2% vs. 86.2%), improvement (10.7% vs. 9.2%), and failure (3.1% vs. 4.6%) were similar for the Sparc™ and Monarc™ groups, respectively. Three-month outcome data were collected in all women in both groups. No vaginal or urethral erosion occurred in either of the groups. In terms of urethral obstruction, no differences were found between the Sparc™ group and the Monarc™ group.

**CONCLUSIONS:** Transobturator suburethral tapes appear to be as equally efficient as transvaginal tapes for surgical treatment of stress urinary incontinence in women, with minimal complications at short-term follow-up. Although further studies are needed to establish its long-term efficacy and safety, the transobturator procedure might be an attractive alternative tool for the treatment of female stress urinary incontinence.

## **RANDOMIZED TRIAL OF TENSION-FREE VAGINAL TAPE (TVT) VS. TENSION-FREE VAGINAL TAPE OBTURATOR (TVT-O) IN THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE: COMPARISON OF OPERATION RELATED MORBIDITY**

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**INTRODUCTION & OBJECTIVES:** A sling operation using obturator foramen passage for stress urinary incontinence (SUI) has been recently developed. The aim of this study was to prospectively and randomly compare tension-free vaginal tape (TVT) with TVT-Obturator (TVT-O) inside-out in relation to the operation related morbidity and short term complications.

**MATERIAL & METHODS:** Total 80 SUI patients were alternately selected to TVT (n=40) or TVT-O (n=40). Patients were operated under IV and local anaesthesia, and routinely discharged at the operation day. Foley catheter was indwelled for a day when the residual urine volume passed over 50% of the voided volume. Cystoscopy was performed only in TVT. Preoperative evaluation included incontinence-quality of life questionnaires (I-QOL), physical examination, and urodynamic study. Operation time; intraoperative bleeding volume; visual analogue pain scale (VAS); post voided residual urine (PVR) were evaluated at the operation day. Hemoglobin change; analgesia dose; PVR; recovery to normal activity day; I-QOL score; patient's satisfaction rate and short term complication were evaluated after 1 week and 1 month.

**RESULTS:** No difference was found between two groups for preoperative characteristics, urodynamic parameters, and I-QOL score. ( $p>0.05$ ). Although mean operation time was significantly shorter in the TVT-O than TVT ( $11\pm 1.4$  min versus  $15\pm 1.8$  min), intraoperative bleeding volume, pain scale, PVR, analgesia dose were not different between the two groups (Table). Foley catheter insertion was 4 (10% TVT) and 5 (12.5% TVT-O) patients, but all of them could void normally on the next day. I-QOL score increased similarly in both groups and the satisfaction rate was 94.8 % (TVT) and 100 % (TVT-O) respectively. No-intra operative complications occurred. Moderate degree of lower abdominal wound discomfort was occurred in 3 (TVT), and inner-thigh discomfort in 5 (TVT-O), but they disappeared within 1 week.

## **RETROPUBIC VS. TRANSOBTURATORIC APPROACH (TVT VS. TOT) FOR THE TREATMENT OF STRESS INCONTINENCE**

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**INTRODUCTION & OBJECTIVES:** Objective was to evaluate the difference between the established retropubic (type TVT) and the new obturatoric (type TOT) approach to urethral support for the treatment of female urinary stress incontinence in concern to operative time, intra- and postoperative complications, long term results and patients' quality of life.

**MATERIAL & METHODS:** A consecutive prospective series of 84 patients with urinary stress incontinence was treated either with a retropubic tape (tension free vaginal tape, TVT by Ethicon-Gynecare) in 36 cases or with a transobturatoric tape (transobturatoric tape, TOT by Mentor-Porges) in 48 cases. Indication, age and comorbidity were similar in both groups. All procedures have been performed by a single surgeon. All patients with TVT were operated in 2002, all TOTs in 2003. Follow up with questionnaires and examinations were performed 3, 6 and 12 months after surgery.

**RESULTS:** The mean operative time for TVTs was 23 minutes and for the TOTs 11 minutes, respectively. Following complications were observed for both groups (TVT vs. TOT): bladder perforation: 1 vs. 0, pelvic hematoma: 1 vs. 0, urinary retention: 2 vs. 1, de novo urge incontinence 8 vs. 7. Continence rate after 12 months were 95% in the TVT group and 98 % in the TOT group. Patients' satisfaction and quality of life scores were higher in the TOT group than in the TVT group.

**CONCLUSIONS:** The transobturatoric access to vaginal urethral suspension is quicker, easier, less complicated and better accepted by patients than the retropubic approach. The transobturatoric way can also be used in patients with severe retropubic adhesions following previous surgery or radiation therapy. Results after 12 months indicate that TOT is a very safe and effective procedure for the treatment of female stress incontinence. This new method might have the potential to replace the conventional retropubic access.

## **IRIS-TOT AND MONARC PROCEDURE FOR STRESS URINARY INCONTINENCE: A COMPARATIVE STUDY**

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**INTRODUCTION & OBJECTIVES:** IRIS-TOT (B. Braun Korea & Dow Medics Co., Ltd, Seoul) and Monarc are minimally invasive procedure based on placing a tape under the middle urethra through the obturator foramen. To compare the efficacy and complications of the IRIS-TOT procedure with Monarc procedure in the treatment of female stress urinary incontinence (SUI).

**MATERIAL & METHODS:** In this controlled, prospective, randomized study, 84 female patients were evaluated with history, physical examination, and urodynamic studies (UDS). They were randomized to undergo IRIS-TOT or Monarc procedure between November 2003 and July 2004. The operative and postoperative morbidity, success rate demonstrated by stress test and subjective satisfaction rate assessed by questionnaire were analyzed.

**RESULTS:** Forty-three patients were randomized into the IRIS-TOT group and 41 into the Monarc group. There was no statistical difference in between the two groups with regards to age, parity, Stamey grade and type of SUI. There was no difference in mean operation time with 15.3min and 16.2min for IRIS-TOT and Monarc groups, respectively. The mean hospital stay was the same for both groups with a mean of two nights. The mean catheter indwelling period was same for both groups with a mean of one day. At mean follow up of 8 months (range 4-10 months), 95.3% of IRIS-TOT patients and 95.1% of Monarc patients were cured or improved. The satisfaction rate was 93.0% in IRIS-TOT group and 92.6% in Monarc group including 2 patients with de novo urgency. Intraoperative complications were limited to 2 vaginal lacerations in IRIS-TOT group and no pain related to sexual activity was reported with repair. No bladder, vascular and nerve injuries were reported. Postoperatively, dysesthesia in thigh area was reported by 2 patients with IRIS-TOT and 2 patients with Monarc during the first two months and spontaneously resolved. One case of IRIS-TOT and 2 cases of Monarc showed temporary voiding difficulty, all of which resolved within 3-5 days without release or resection of tape.

**CONCLUSIONS:** Both the IRIS-TOT and Monarc procedures are safe and effective technique for the surgical treatment of SUI. However, further follow-up is needed for the complications and long term cure rate.

## **TRANSOBTURATOR VAGINAL TAPE (TOT) FOR THE TREATMENT OF FEMALE STRESS INCONTINENCE: ONE YEAR FOLLOW-UP IN 100 PATIENTS**

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**INTRODUCTION & OBJECTIVES:** The aim of this study was to evaluate the suitability of a new minimal invasive surgical procedure (TOT) in the treatment of genuine stress incontinence and to analyze the functional results after one year of follow up.

**MATERIAL & METHODS:** 150 consecutive women underwent the procedure since February 2002 under general or regional anaesthesia. Follow up was at least of one year for 100 patients with urodynamically proven genuine stress urinary incontinence (GSI). 80% of the women completed physiotherapy prior to surgery. The mean age was 57 years (range 31-85). 60% of the patients had a pure GSI. In few cases, repair of pelvic floor defects was mandatory. Collection of the data included operative time, intra and postoperative complications. Patients were postoperatively assessed at 1, 6 and 12 months. A self evaluation by questionnaires (Incontinence impact questionnaire and Urogenital distress inventory) was sent and completed at 6 and 12 months from surgery.

**RESULTS:** The mean operative time was 15 minutes (8-60) and the bladder catheterization time was 0.9 day (0-2). Neither severe bleeding, haematoma nor rejection of the tape was observed. 10 minor tears of vagina, 3 perforations of the urethra and one of the bladder occurred during the learning phase. Recognized during the procedure the tape could be replaced. In 2 cases a re-intervention was necessary for tape removal. 10% of patients had voiding outflow obstruction with 2 urinary retentions and 5 urinary tract infections occurred postoperatively. After one month, 93% women were totally dry. Otherwise *de Novo* urgency occurred in 2 cases only. 86% and 80% of patients were cured at 6 and 12 months respectively. According to preoperative urethral pressure under or over 30 cm H<sub>2</sub>O, continence rates were 76% and 89% after one year. Overall satisfaction of patients was 77% at 6 months and 74% after 1 year but more than 80% women would recommend the procedure to relatives.

**CONCLUSIONS:** The TOT is a rapid, safe and effective new procedure for GSI even in cases of low urethral pressure with a follow up of one year with very few complications

## PROSPECTIVE MULTICENTRE TRIAL OF MONARC TRANSOBTURATOR SLING FOR STRESS INCONTINENCE: 12 MONTH FUNCTIONAL DATA

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**INTRODUCTION & OBJECTIVES:** To evaluate the efficacy and morbidity of Monarc transobturator sling as treatment for women with stress incontinence. This abstract is a planned interim report on the functional results at 1 year follow up.

**MATERIAL & METHODS:** The study was designed as a multicentre prospective non-randomized trial, involving 15 European, Canadian, and Australian centres and was approved by local IRB or Ethical committees. Only women with proven stress incontinence were included. Post implant evaluation was done at 4-6 weeks, 3, 6, 12 and 24 months. The evaluation consisted of registration of number of pads used per day, a 1h pad test, cough test, uroflowmetry and measurement of residual volume and dipstick. Both physician and patients scored the post operative continence. In a subset of patients pre-operative and post-operative multichannel urodynamics were compared. Further evaluation was done using UDI-6, IIQ-7 questionnaires. Efficacy is expressed as the percentage of patients reaching continence, defined by padtest, coughtest, and patient/physician assessment. Appropriate statistical analysis was done using t-test and Mc Nemar's test.

**RESULTS:** 148 patients with proven stress incontinence were enrolled from Jan 03 until Feb 04. 122 have reached 1y follow up and are included in this interim analysis. Patient assessment of continence revealed 83.5% cure rate: 62% completely dry and 21.5 % substantially continent (needing no protection). Some additional protection was needed in 12.4% and 4.1% remained substantially incontinent. Assessment by the physician correlated strongly with these numbers. The post-operative cough test was negative in 89.7%. Pad use on 24h was reduced from 3.5 ±2.2 to 0.6 ±1.3 (p<0.001). Urine loss during a 1 h pad test (n=110) was reduced from 112.4 ±83.3 to 9.7 ±29.8 (p<0.001). The UDI-6 showed significant improvement (62.3 ±15.9 to 16.2 ±21.3, p<0.001) as did the IIQ-7 (54.5 ±25.3 to 9.5 ±20, p<0.001). This improvement was stable over the 12 month period. De novo urgency was seen in 10.6% while 27.6% of patients with pre-operative urge symptoms were relieved of their urgency. Uroflowmetry showed a mean voided volume of 333.8cc ±118.5 with a peak flow rate of 24.9 ±10.7ml/sec and a post-void residual of 8.5 ±21ml.

**CONCLUSIONS:** 1 year data show that Monarc transobturator sling successfully restores continence in women with SUI. Patient and physician assessed continence rate (completely dry and substantially continent) were 83.5% and 84.4%. UDI-6 and IIQ-7 were significantly improved and showed a stable curve over this 12 month period. Given the 10.6% of patients with de novo urge and the 27.6% of patients who were cured of their pre-operative urge,

patients implanted with Monarc are significantly more likely to be cured of urge symptoms than to develop urge symptoms ( $p < 0.01$ ).

