

## SHORT-MEDIUM TERM RESULTS WITH 250 TVT-OBTURATOR INSIDE OUT OPERATIONS

### Hypothesis / aims of study

The TVT-Obturator "inside-out" operation was designed to minimize the typical TVT related complications, mainly needle bladder penetration and post operative outlet obstruction. This patients' series short-medium term data, regarding the urinary incontinence cure rate and intra and postoperative complications, were evaluated to verify the TVT-Obturator safety and efficacy.

### Study design, materials and methods

A total of 250 patients with urodynamically proven urinary stress incontinence had the TVT-Obturator operations, performed by a single surgeon. The patients were followed up for 10 to 24 months. Subjective and objective cure as well as treatment complications were recorded prospectively.

### Results

The TVT-Obturator procedure does not require bladder catheterization neither intra-operative diagnostic cystoscopy. Operative complications, such as bleeding or visceral injury, were not recorded. Ten patients (4%) were diagnosed with postoperative voiding difficulties: six (2.4%) had complete outlet obstruction and were treated successfully by loosening tape tension on the postoperative day while the other four (1.6%) had partial obstruction and responded well to self catheterization for up to one week. No infective or hemorrhagic complications and no tape protrusion to the vagina and urethra were recorded. Cured patients both subjectively and clinically, were 210 (84%). Twenty two (9%) patients had minimal residual urinary stress leak and 18 (7%) patients were diagnosed with therapeutic failure. Ten of the TVT-Obturator failed patients had a following successful TVT operation on a three-month interval.

### Interpretation of results

Since being described by Ulmsten in 1996, the TVT procedure has become very popular. Common complications of former operations for the treatment of urinary stress incontinence, such as intra-operative blood loss, pelvic and abdominal organ injury, post-operative de-novo Detrusor instability, dyspareunia and urethral erosion, are rare in the TVT era. Prospective randomized multi-centres studies, comparing TVT and the former gold standard Burch colposuspension, demonstrated similar therapeutic impact for both. However, TVT had a higher intra-operative complication rate while colposuspension had a higher post-operative complication rate and a longer recovery period. Among the well-documented typical TVT complications are bladder penetration, intra-operative bleeding, post-operative field infection and bowel injury. Against this background, De Leval described a novel TVT-related procedure. This new operation enables mid-urethral support for the treatment of female stress urinary incontinence, without coming close to the bladder, the femoral blood vessels or the bowel. This is achieved by using the Obturator fossa, rather than the retropubic space, as a route for the Prolene tape. However, long-term data is required prior to incorporating this operative technique to the armamentarium of anti-incontinence procedures. No typical surgeon's learning-curve complication reduction rate effect was noticed, but this might be due to former experience with the TVT procedure.

### Concluding message

The TVT-Obturator, a novel mid-urethral sling operation for the treatment of female stress urinary incontinence, seems to be an effective and safe procedure. Intra-operative diagnostic cystoscopy and bladder catheterization are not mandatory with this newly launched surgical approach. The TVT-Obturator procedure had fewer complications than reported previously for the TVT, both intra-operatively and early post-operatively. This included reduced occurrence of operative bleeding and post-operative field infections and voiding difficulties. Randomized controlled trials and long-term follow-up are needed for proper evaluation of this operation.

### Reference

De Leval J: Novel surgical technique for the treatment of female stress urinary incontinence: Trans-Obturator vaginal tape inside-out. *European Urology* 2003;44:724-730.

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**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study did not need ethical approval because no special ethical committee approval is required but followed the Declaration of Helsinki Informed consent was obtained from the patients.