

# Efficacy and Adverse Effects of Monarc Versus Tension-free Vaginal Tape Obturator: a Retrospective One-year Follow-up Study

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**Objective:** To compare the efficacy and complications of the transobturator tape (Monarc) versus tension-free vaginal tape obturator in local women with urodynamic stress incontinence at the 1-year follow-up.

**Methods:** A retrospective study was conducted in patients who underwent transobturator tape therapy for urodynamic stress incontinence in the period from August 2005 to August 2009 in United Christian Hospital, Hong Kong. A total of 74 patients were recruited, of which 44 had the Monarc procedure performed and 30 were treated by the tension-free vaginal tape obturator. The objective and subjective cure rates, and complications were reviewed at 1-year post-intervention.

**Results:** There was no statistically significant difference between the groups in terms of objective cure rate or subjective outcome rate. The objective cure rates at the 1-year follow up were 54.1% for Monarc and 79.3% for tension-free vaginal tape obturator, while the respective subjective outcome rates were 83.9% and 87.3%. The postoperative complication rate in our study population was low. There were no differences between the two groups in terms of postoperative fever, urinary tract infection, bladder injury, vaginal perforation, haematoma formation, and analgesic requirements. Functional outcomes including de-novo urgency and voiding dysfunction assessed at the 1-year follow-up were also similar.

**Conclusion:** At the 1-year follow-up, both procedures yielded similar effectiveness and safety for the treatment of urinary stress incontinence in our local population.

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**Keywords:** Postoperative complications; Suburethral slings; Treatment outcome; Urinary incontinence, stress; Urodynamics

## Introduction

The introduction of the suburethral slings has revolutionised the surgical treatment of female stress incontinence. They have a similar success rate to Burch colposuspension<sup>1,3</sup>, and the use of suburethral slings offers the benefits of shorter operating times, reduced blood loss, and the feasibility performing the procedure on a day-case basis<sup>4</sup>. In 1995, Ulstem et al<sup>4</sup> introduced the tension-free vaginal tape (TVT) technique which is now widely practised and considered the new gold standard treatment. In 2001, Delorme<sup>5</sup> introduced the transobturator tape (TOT) that conferred a similar success rate. The difference between TVT and TOT is that the sling in the former runs through the obturator membrane instead of through the retropubic space and out to the abdomen. This technique avoids the risk of bladder injury and reduces voiding difficulty<sup>6</sup>.

After the introduction of TOT by Delorme<sup>5</sup>, de Leval<sup>7</sup> introduced another similar technique — tension-free vaginal tape obturator (TVT-O). The two techniques differ

in how the needles are placed: TOT is inserted ‘outside-in’ and TVT-O adopts an ‘inside-out’ approach and the introducers differ in design. Because the transobturator technique has only been introduced in recent years, there is a lack of data comparing the two techniques. The aim of this study was to compare the outcomes and complication rates between TOT (Monarc) and TVT-O.

## Methods

Patients who underwent the Monarc or the TVT-O procedure in the period from August 2005 to August 2009 in United Christian Hospital, Hong Kong were included in this study. Only patients with urodynamically confirmed stress incontinence were included, whether or not they had had concomitant gynaecological procedures. Patients lost

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to follow-up at 1 year were excluded.

The surgical outcomes, as well as the complication rates were evaluated 1-year post-procedure. The objective outcome was assessed by urodynamic studies and the objective cure rate was defined as the absence of stress incontinence demonstrated in the urodynamic study. The subjective outcome depended on the patient's perception of clinical improvement in response to asking them about the degree of improvement they experience in terms of percentage. Other outcome measures included operating time, blood loss, postoperative use of analgesics, discharge day, and readmission rate. Complications assessed included bladder injury, vaginal perforation, postoperative haematoma, postoperative retention of urine, postoperative urinary tract infection, voiding dysfunction, the need for tape manipulation or revision, de-novo urgency, and tape erosion.

All patients underwent general or spinal anaesthesia and received antibiotics at induction. The procedures were carried out by one of four surgeons in the Division of Urogynaecology — one overseas urogynaecology expert, one urogynaecology subspecialist, and two HKCOG Fellows undergoing training. Use of the Monarc and the TVT-O systems depended on the preference of the operating surgeon. The inside-out procedure was performed as described by de Leval<sup>7</sup>, and the TVT-O (Gynaecare) was used. The outside-in method was performed as advised by the manufacturer and the Monarc (American Medical System) was used. Cystoscopy was performed routinely after each procedure. The bladder was emptied at the end of the operation. Concurrent operations could be performed before or after the TOT procedure.

Data were collected retrospectively from the operative record and consultation notes in the patient files. The Statistical Package for Social Sciences (SPSS 14.0. Chicago, USA) was used for statistical analysis entailing Student's *t* test and the chi-square test; a *p* value of <0.05 was considered statistically significant.

## Results

During the study period, 54 patients underwent the Monarc procedure, whereas 38 underwent the TVT-O. After exclusion, 44 women in the Monarc group and 30 in the TVT-O group were included. The excluded patients consisted of those who were lost to follow-up at 1 year (11% in the Monarc group vs 13% in the TVT-O group) and those who had no urodynamically proven stress incontinence.

There were no differences between the two groups except that patients who underwent TVT-O were of older age and of higher parity. There was also a higher proportion of patients with uterovaginal prolapse in the TVT-O group. The menopausal status, proportion of patients post-hysterectomy, previous pelvic floor repair prior to the operation, previous continence surgery, and patients with co-existing detrusor overactivity were similar in both groups (Table 1).

There were no significant differences between the groups with respect to the type of anaesthesia and the number of patients with concurrent operation performed. The duration of operations and blood loss were calculated after excluding those having concurrent procedures; these were comparable in both groups. The mean duration of the operation was 34.3 minutes in Monarc group and 31.8 minutes in TVT-O group (*p* = 0.3; 95% confidence interval

**Table 1. Patient's characteristics**

| Characteristic                                   | Monarc* (n = 44) | TVT-O* (n = 30) | p Value; MD (95% CI)       |
|--------------------------------------------------|------------------|-----------------|----------------------------|
| Age (years)                                      | 56.7 ± 10        | 63.2 ± 12.2     | 0.02; -6.4 (-11.6 to -1.3) |
| Parity                                           | 2.6 ± 1.5        | 3.8 ± 2.3       | 0.008; -1.2 (-2.1 to 0.3)  |
| Menopausal status                                |                  |                 | 0.79                       |
| Menopausal                                       | 32 (72.7%)       | 21 (70.0%)      |                            |
| Premenopausal                                    | 12 (27.3%)       | 9 (30.0%)       |                            |
| Previous hysterectomy                            | 6 (13.6%)        | 8 (26.7%)       | 0.33                       |
| Previous pelvic floor therapy prior to operation | 30 (68.2%)       | 16 (53.3%)      | 0.29                       |
| Previous continence surgery                      | 1 (2.3%)         | 4 (13.3%)       | 0.16                       |
| Women with uterovaginal prolapse                 | 12 (27.3%)       | 16 (53.3%)      | 0.036                      |
| Women with co-existing detrusor overactivity     | 5 (11.4%)        | 7 (23.3%)       | 0.29                       |

Abbreviations: TVT-O = tension-free vaginal tape obturator; MD = mean difference; CI = confidence interval

\* Data are shown as mean ± standard deviation or No. (%)

[CI], -2.1 to 7.0) and the blood loss of 23 ml in both groups ( $p = 1.0$ , 95% CI, -9.7 to 9.4) [Table 2].

Postoperatively, there was no statistically significant difference in analgesic use and length of hospital stay between the two groups. In terms of operative complications, both groups showed similar rates of postoperative urinary tract infection and postoperative fever. There was no bladder injury or postoperative haematoma in either group. One patient in the Monarc group underwent postoperative tape traction for voiding difficulty. One patient in each

group was readmitted within 2 weeks. In the Monarc group, the patient had voiding difficulty which was managed conservatively by means of bladder training; in the TVT-O group, the patient was complicated with vaginal perforation with mesh exposure and repair was done (Table 3).

At the 1-year postoperative follow-up, 37 (84.1%) of the patients in the Monarc group and 29 (96.7%) of those in the TVT-O group had urodynamic studies performed. There was no statistically significant difference in the objective cure rate, 54.1% in the Monarc versus 79.3%

**Table 2. Operative characteristics**

| Characteristic                          | Monarc* (n = 44) | TVT-O* (n = 30) | p Value; MD (95% CI)    |
|-----------------------------------------|------------------|-----------------|-------------------------|
| Type of anaesthesia                     |                  |                 | 0.73                    |
| General anaesthesia                     | 25 (56.8%)       | 15 (50.0%)      |                         |
| Spinal anaesthesia                      | 19 (43.2%)       | 15 (50.0%)      |                         |
| Concurrent operation                    |                  |                 | 0.49                    |
| None                                    | 31 (70.5%)       | 18 (60.0%)      |                         |
| Vaginal                                 | 11 (25.0%)       | 9 (30.0%)       |                         |
| Laparoscopic surgery                    | 1 (2.3%)         | 2 (6.7%)        |                         |
| Laparotomy                              | 0                | 1 (3.3%)        |                         |
| Others                                  | 1 (2.3%)         | 0               |                         |
| For those without concurrent procedures | (n = 31)         | (n = 18)        |                         |
| Duration of operation (mins)            | 34.3 ± 6.8       | 31.8 ± 8.9      | 0.3; 2.4 (-2.1 to 7.0)  |
| Blood loss (ml)                         | 23.0 ± 14.0      | 23.0 ± 18.0     | 1.0; -0.2 (-9.7 to 9.4) |

Abbreviations: TVT-O = tension-free vaginal tape obturator; MD = mean difference; CI = confidence interval

\* Data are shown as mean ± standard deviation or No. (%)

**Table 3. Complications and postoperative details**

|                                         | Monarc* (n = 44)      | TVT-O* (n = 30)       | p Value; MD (95% CI)   |
|-----------------------------------------|-----------------------|-----------------------|------------------------|
| Bladder injury                          | 0                     | 0                     | -                      |
| Vaginal perforation                     | 1 (2.3%)              | 1 (3.3%)              | 0.78 (1.0)             |
| Postoperative urinary tract infection   | 5 (11.4%)             | 4 (13.3%)             | 0.79                   |
| Postoperative fever                     | 2 (4.5%)              | 2 (6.7%)              | 0.69                   |
| Postoperative haematoma                 | 0                     | 0                     | -                      |
| Postoperative tape traction             | 1 (2.3%)              | 0                     | 0.40 (1.0)             |
| Analgesic requirement                   |                       |                       |                        |
| None                                    | 8 (18.2%)             | 4 (13.3%)             | 0.95 (0.81)            |
| Simple analgesics                       | 32 (72.7%)            | 23 (76.7%)            |                        |
| Opioids                                 | 4 (9.1%)              | 3 (10.0%)             |                        |
| Length of hospital stay (days)          |                       |                       |                        |
| Overall                                 | 3.3 ± 3.1             | 3.2 ± 2.6             | 0.8; 0.1 (-1.3 to 1.5) |
| For those with no concurrent procedures | 2.0 ± 1.0             | 1.9 ± 1.5             | 0.8; 0.1 (-0.7 to 0.8) |
| Readmission within 2 weeks              | 1 (2.3%) <sup>†</sup> | 1 (3.3%) <sup>‡</sup> | 0.78 (1.0)             |

Abbreviations: TVT-O = tension-free vaginal tape obturator; MD = mean difference; CI = confidence interval

\* Data are shown as mean ± standard deviation or No. (%)

<sup>†</sup> Readmitted for voiding problems and treated conservatively

<sup>‡</sup> Readmitted due to vaginal perforation with mesh exposure and repair was done

**Table 4. Outcomes at 1-year follow-up**

| Outcome                                                              | Monarc* (n = 44) | TVT-O* (n = 30) | p Value; MD (95% CI)     |
|----------------------------------------------------------------------|------------------|-----------------|--------------------------|
| Objective cure rate                                                  |                  |                 | 0.06                     |
| No. of patients with UDS done at 1 year                              | 37 (84.1%)       | 29 (96.7%)      |                          |
| No USI                                                               | 20 (54.1%)       | 23 (79.3%)      |                          |
| USI present                                                          | 17 (45.9%)       | 6 (20.7%)       |                          |
| Subjective cure rate (%)                                             | 83.9 ± 25.3      | 87.3 ± 21.1     | 0.6; -3.4 (-14.6 to 7.9) |
| Failure requiring further surgical treatment for stress incontinence | 4 (9.1%)         | 0               | 0.24 (0.14)              |
| Voiding dysfunction                                                  |                  |                 | 0.97 (1.0)               |
| Conservative treatment                                               | 5 (11.4%)        | 3 (10.0%)       |                          |
| Tape revision                                                        | 1 (2.3%)         | 1 (3.3%)        |                          |
| De-novo urgency                                                      |                  |                 | 0.73 (0.58)              |
| Conservative treatment                                               | 6 (13.6%)        | 6 (20.0%)       |                          |
| Medical treatment                                                    | 3 (6.8%)         | 2 (6.7%)        |                          |
| Tape erosion                                                         | 0                | 0               | -                        |

Abbreviations: TVT-O = tension-free vaginal tape obturator; MD = mean difference; CI = confidence interval, UDS urodynamic study; USI = urodynamic stress incontinence

\* Data are shown as mean ± standard deviation or No. (%)

in the TVT-O groups. Subjective outcome rates were similar in both groups, 83.9% in the Monarc versus 87.3% in TVT-O group. Complications up to the 1-year follow-up included: voiding dysfunction, de-novo urgency, tap erosion, and failure of treatment (having further surgical treatment for stress incontinence) and were comparable in the two groups (Table 4). Given that the cohort of around 70 patients was equally divided between the two treatment arms, and assuming a significance level of 0.05 (two-sided  $\alpha$  value) and a power of 0.80, the sample had sufficient power to detect a difference in objective cure rate of 25% or more, and a difference in the subjective cure rate scoring 10% or more.

## Discussion

This was the first local study with the primary aim of comparing outcomes and complications of the inside-out versus outside-in transobturator interventions. The study showed that objective and subjective patient outcomes after Monarc or TVT-O procedures were similar, which accorded with other studies<sup>8,9</sup>. Quoted objective cure rates were 90 to 92% for TOT and 86 to 87% for TVT-O, compared to 54.1% and 79.3%, respectively in our study. The lower rate in our series could be explained by the lack of experience when the procedures were first started in our unit; the majority of treatment failures involved the initial cases; our department only started performing TOT procedures in 2005. After excluding the initial 10 cases in each group as part of the learning curve, the objective success rates would be 63% and 79% in the Monarc and

TVT-O groups, respectively. Although not statistically significant, the objective cure rate in the Monarc group appeared lower than in the TVT-O group. One possible reason could be a bias in the calculation; a greater number of patients in the Monarc group (16% vs 3%) defaulted urodynamic study at the 1-year follow-up.

Subjective outcomes were quite satisfactory in both groups; clinical improvements of over 80% (83.9% in the Monarc group vs. 87.3% in the TVT-O group) were similar to those reported by others<sup>8</sup>.

Functional outcomes including development of de-novo urgency and voiding difficulty appeared to be similar in both groups, which also accorded with several other studies<sup>8-10</sup>. Latthe et al<sup>6</sup> has shown that voiding difficulty was less common after transobturator slings than in retropubic slings. Subgroup analysis found no differences between the outside-in or inside-out approach<sup>6</sup>.

The postoperative complication rate in our study population was low. In particular, there was no bladder injury or postoperative haematoma. The risk of bladder injury appeared to be significantly lower after transobturator than retropubic procedures, being 0% vs 5% in a large multicentre randomised trial<sup>11</sup>; an obvious reason was the passage of the sling laterally through the obturator foramen avoiding the retropubic space. It is for this reason that the transobturator approach is advocated as the preferred method when the risk of bladder injury is high. Notably,

patients in our TVT-O group were older, had higher parity, and had a greater proportion with uterovaginal prolapse than those in the Monarc group. Despite the association of these factors with worse urodynamic stress incontinence, objective cure rates were nevertheless comparable in the two groups. One possible explanation for this discrepancy could be a bias in calculation due to a higher default rate for urodynamic study in the Monarc group (16% vs 3%). A larger study appears necessary to better address these factors. Concurrent operations may possibly affect the outcomes of the TOT procedures. If the cases with concurrent operations performed were excluded, the objective cure rates were similar (50% in the Monarc group versus 88% in the TVT-O group). Furthermore, patients often suffer from coexisting problems and the TOT procedures are commonly carried out together with concurrent operations, for examples, vaginal hysterectomy, pelvic floor repair. Therefore, these cases were also taken into account in this study.

One drawback in this study was that the outcomes were assessed only at the 1-year follow-up. The objective and subjective cure rates have been shown to decrease over time. Houwert et al<sup>12</sup> reported a prospective study

comparing the Monarc and the TVT-O with the longest follow-up until now (up to 2-4 years). With cure of stress urinary incontinence defined as women not experiencing any loss of urine upon physical exercise, the cure rates after 2 to 4 years were 72% after TVT-O and 65% after Monarc procedures<sup>12</sup>. Other studies have found an objective cure rate of 83 to 88% at a minimum of 36 months postoperatively<sup>13,14</sup>. Similarly, the frequency of mesh erosions also appeared to increase with time. A second drawback was the lack of assessment of patient satisfaction and quality of life. Studies have shown that there was a statistically significant improvement in quality of life with validated questionnaires, but there were no differences in those having Monarc and the TVT-O procedures<sup>11</sup>. Although these measurements can be partly reflected by subjective outcomes, a formal assessment could provide more information on determining the success of each procedure which may well aid preoperative counselling.

## Conclusion

At the 1-year follow-up, both procedures yielded similar effectiveness and safety, with respect to urinary stress incontinence. More studies are awaited to assess the long-term outcome of both procedures.

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