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RANDOMIZED TRIAL COMPARING THE SAFETY AND PERI-OPERATIVE COMPLICATIONS OF TRANSOBTURATOR INTRODUCED TENSION-FREE VAGINAL TAPE (TVT-O) AND SINGLE-INCISION TAPE WITH ADJUSTABLE LENGTH AND ANCHORING MECHANISM (AJUST): THREE MONTHS RESULTS

Hypothesis / Aims of Study

Tape surgical methods are at present considered the gold standard for surgical treatment of stress urinary incontinence, but there are some complications associated with them. In an attempt to reduce further the invasive nature of the procedure and the rate of complications, a new generation of tension-free vaginal tapes has been introduced, known as minitapes or single incision tapes. Unfortunately, the first generation of single incision tapes had lower efficacy compared to standard methods. This was explained with reference to the fixed length of the tape and the type of tape introducer, which was not suitable for all patients. The problem was solved in the third generation of single incision tapes, which have adjustable length and a special anchoring mechanism (Ajust). This tape is available on the market and is regularly used for the treatment of stress urinary incontinence worldwide. It is important to establish whether these new, less invasive surgical procedures really do minimize the unfavourable impact of surgical procedures on patients while achieving a comparable curative effect.

The aim of this study was to compare the efficacy of, and the complications involved in, the use of TVT-O and Ajust procedures in the treatment of stress urinary incontinent women. We also compare occurrence, intensity and length of post-operative pain based on subjective evaluation of a visual analogue scale.

Study Design, Materials and Methods

Between May 2010 and May 2012 515 patients were indicated for surgical treatment for SUI. 382 were suitable for this study, and 108 agreed to randomization; they signed informed consent prior to treatment. At the preoperative consultation (approximately 6-12 weeks before surgery) all patients received information about the study and informed consent forms. All patients were admitted to hospital one day before surgery; if they agreed to participate and signed the informed consent forms, they were included in the study. For randomization the envelope technique was used, the envelope being opened shortly before the patients were randomized into a TVT-O group (50) and an Ajust group (50). Based on pre-study statistical calculations it was indicated that the required sample size in each group was 45 patients (allocation ratio 1:1). We calculate with a drop-out rate of 10%, so it was decided to enroll 50 patients into each group. The study was only intended to find the differences in efficacy between TVT-O and Ajust procedure.

All patients underwent a complete urogynecological investigation before the procedure (clinical examination, urodynamics, ultrasound examination), and they filled in the ICIQ and iQol questionnaires. Surgery was only offered if conservative therapy had been unsuccessful.

Inclusion criteria were: age over 18, signed informed consent, urodynamic stress urinary incontinence and agreement to postoperative follow-up. Exclusion criteria were: concomitant surgical procedure, predominant urge incontinence, urodynamic detrusor instability, previously failed anti-incontinence surgery, previous radiotherapy, postvoid residual volume (PVR) greater than 100 ml, bladder capacity less than 300 ml, stage III or IV pelvic organ prolapse according to the International Continence Society pelvic organ prolapse quantification system, planned concomitant surgery, age < 18.

The peri-operative complications were monitored. The intensity and length of postoperative pain was monitored using the visual analogue scale. The patients underwent complete examinations 3 months after surgery (the same examination as before the procedure). In addition, the patients provided an evaluation of their overall satisfaction with the surgery. The next check-ups are planned for one year and two years after surgery and will involve the same examination as at the 3-month check-up, except for urodynamics.

Postoperative follow-up will be terminated if the result of surgery is evaluated as a failure, and reoperation will be offered.

Results

There were no significant differences in age, body mass index, parity, or history of surgery for gynecological disorders among the study participants. Preoperative urodynamic and QoL parameters were not significantly different, either. The mean age was 57.4 (SD 11.4), mean BMI 26.9 (SD 4.5), mean parity 2.0 (SD 0.7), mean ICIQ 14.6 (SD 2.5) and IQoL 56.8 (SD 16.1), mean MUCP 54.7 cm H2O (SD 21.6) and mean Qmax 25.1 ml/s (SD 12.8).

There were no serious perioperative complications in either of the two groups. The mean blood loss in the TVT–O group was 14.3 ml, while in the Ajust group it was 13.6 ml. Transient postoperative urine retention occurred once in the TVT-O and twice in the Ajust group, and this resolved within three days. Mean duration of postoperative pain in TVT-O patients was 6.4 (SD 3.6) days, compared to 4.5 (SD 3) days in the Ajust group. Pain intensity was lower in the Ajust group: on the first day after surgery it was 33.2 (SD 25.3), while in the TVT-O group it was 53.1 (SD 29.2); on the second day the figures were 21.3 (SD 22.7) for Ajust and 37.6 (SD 27.4) for TVT-O; third day 14.8 (SD 18.9) for Ajust and 28.4 (SD 25.7) for TVT-O; fourth post-operative day 7.6 (SD 14.7) for Ajust and 18 (SD 20.1) for TVT-O.

Three months after surgery the stress test was negative in 81.2 % of women in the TVT-O group; in the Ajust group the figure was 85.3%. No tape protrusion was observed in either group, and there was one failure in each group. In the Ajust group one patient mentioned de novo pain during intercourse (clinical examination revealed palpable painful anchor on the right obturator membrane).

Interpretation of Results

The short-term follow-up revealed the same objective cure rates in both groups, with lower intensity and shorter duration of postoperative pain in the Ajust group. Evaluation of the short-term efficacy of new surgical techniques on a selective group of

patient may be confusing, and long-term data are required. Our opinion of the first generation of single incision tape TVT-S indicates that as time after surgery increased there was a significant decline in the cure rate. Different anchoring mechanism, different insertion technique and adjustable length of Ajust tape may increase the efficacy of this procedure, but long-term data are needed.

Concluding Message

The short-term follow-up revealed the same objective cure rates in both groups, with lower intensity and shorter duration of postoperative pain in the Ajust group. Final evaluation will be completed after long-term follow-up.

Disclosures

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