

A PROSPECTIVE STUDY ABOUT TRANS-OBTURATOR-TAPE (TOT) PROCEDURES WITH THE TAPE FROM THE GYNECARE TVT DEVICE AND A C-SHAPE TUNNELLER -COMPARISON BETWEEN OUTSIDE-IN AND INSIDE-OUT PROCEDURES-

Hypothesis / aims of study

Trans-Obturator-tape(TOT) procedure has become popular worldwide as a safe and efficient treatment for stress urinary incontinence. However, no TOT device is available in Japan now. So we tried to carry out a TOT procedure with the tape from the Gynecare TVT device which is the only device available for mid-urethral sling operations in Japan. We could carry out two procedures of TOT operation (inside-out and outside-in directions) by using a C-shape tunneller (Figure) manufactured by Tanaka-sanseido Inc. The aims of this study are to show the short term results and feasibility of these two procedures as an alternative measure in treating stress urinary incontinence and to compare the results of these two procedures.

Study design, materials and methods

From August to December 2005, 90 women with stress urinary incontinence associated with urethral hypermobility without prolapse planning to undergo operation were randomly selected to undergo inside-out (group I) TOT procedure or outside-in (group O) one . ALL patients were assessed before surgery by clinical and urodynamic examination. All the operations were performed under general anaesthesia. Both outside-in and inside-out TOT procedures were performed with a C-shape tunneller manufactured by Tanaka-sanseido Inc. and the tape from the Gynecare TVT device. In both procedures, the tape is inserted tension-free in a horizontal plane underneath the middle of the urethra between the two obturator foramina. Perioperative complication rate, subjective cure rates and patient's satisfaction rates three months after surgery were assessed. Correlation between these data and difference in procedures were assessed with Chi-square tests.

Results

Characteristics of patients in both groups are shown in Table1. Mean age was 58 years (range 41-74) in the group I and 58 years(range 33-74) in the group O. 5 and 6 patients presented mixed incontinence respectively. Two patients in the group I (hysterectomy 2) and 2 patients in the group O (hysterectomy 1 and anterior colporrhaphy 1) had past history of intra pelvic surgery. Operating time and complications within three months are shown in Table 2. Mean operating time were 22.5min.(range 16-34) and 23.8min. (range 15-43) respectively. No major intra-operative complication was recorded. Three months of follow-up were available for 40 patients in the group I and 42 patients in the group O. There were no problems with urethral erosion, residual pain or functional impairment related to the tape.1/40 and 1/42 patients complained about slight thigh pain temporarily after operation, all of which disappeared within a month. Subjective cure rates 3 months after surgery were shown in Table 3. 36/45 patients were cured in the group I (80.0%) and 36/45 patients were cured in the group O (80.0%). Patient's satisfaction rates were shown in Table 4. 31/45(68.9%) and 34/45(75.6%) patients were satisfied with the operation. Chi-square tests showed the subjective cure rates and the patient's satisfaction rates had no correlation with difference in procedures.

Figure The C-shape tunneller and the tape used

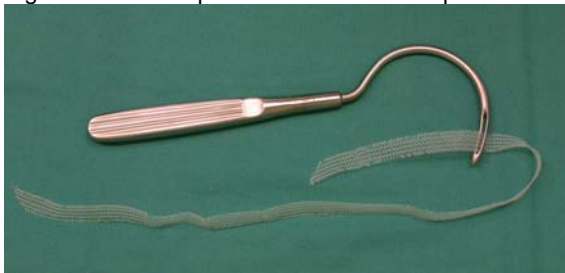


Table1. Subject Characteristics

Groups	Inside-out (n=45)	Outside-in (n=45)
Age	Mean 58 (range41-74)	Mean 58(range33-74)
Mixed incontinence	5/40 patients	6/42 patients
Past history of intra-pelvic surgery	2/40 patients (simple hysterectomy 2)	2/42 patients (simple hysterectomy 1, Anterior colporrhaphy 1)

Table2. Operating time and complications within three months

Groups	Inside-out	Outside-in
Operating time (min.)	Mean 22.5 (range 16-34)	Mean 23.8 (range 15-43)
Perioperative complications	Thigh pain 1	Thigh pain 1
Residual urine more than 50cc 3 months after surgery	1	1
Dysuria needed CIC	1	0

Table 3. Subjective cure rates 3 months after surgery

Groups	Inside-out (n=45)	Outside-in (n=45)
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Cured	36 (80.0%)	36 (80.0%)
Improved	2 (4.4%)	4 (8.9%)
Failed	2 (4.4%)	2 (4.4%)
Missed	5 (11.1%)	3 (6.7%)

Table 4. Patient's satisfaction rates 3 months after surgery

Groups	Inside-out	Outside-in
Satisfied	31 (68.9%)	34 (75.6%)
Slightly satisfied	6 (13.3%)	3 (6.7%)
Not satisfied	3 (6.7%)	5 (11.1%)
Missed	5 (11.1%)	3 (6.7%)

Interpretation of results

These two TOT procedures were proved to be safe since there was no major complication in the following-up period of 3 months. Cure rates of 80% in both procedures were comparable with the result reported about other trans-obturator-tape procedures. More than 80% of patients in each group were satisfied or slightly satisfied with each procedure.

Two TOT procedures in this study proved to have no significant differences in cure rates nor patient's satisfaction rates.

Concluding message

These two trans-obturator-tape procedures with the C-shape tunneller and the tape from the Gynecare TVT device were proved to be feasible, efficient and safe measures in treating stress incontinence patients. There was no significant difference in efficacy and safety between the inside-out procedure and outside-in one.

FUNDING: NONE

DISCLOSURES: NONE

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

HUMAN SUBJECTS: This study was approved by the Osaka central hospital ethics committee and followed the Declaration of Helsinki. Informed consent was obtained from the patients.