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TOA ADJUSTABLE MESH FOR SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

There is a delicate balance, after tension-free tape implant, between incontinence, continence and obstruction as it is difficult to calculate the correct degree of tension to be applied during surgery. When the tape is too tight, urinary obstruction is produced. On the other hand, when the tape is too loose incontinence persists.

The possibility to readjust postoperatively the tension applied to the tape has shown to be a fact through a transvaginal approach [1]. To test if this is possible with a new adjustable transobturator mesh is our objective.

Study design, materials and methods

Within-subject study initiated in January 2005. TOA (AMI) is a macroporous polypropylene monofilament non-elastic tape with two groups of polypropylene threads permitting postoperative readjustment of tension that are removed when continence without obstruction is achieved. Seventy-seven incontinent women (29.9% stress incontinence, 70.1% mixed incontinence) received TOA tape.

Patients were monitored 1, 6 and 12 months post-surgery and annually thereafter by medical history, cough test, flowmetry, PVR, I-QoL, ICIQ-SF and PGI-I questionnaires. Objective cure for stress incontinence was defined as no leakage on cough test. Subjective cure was defined as answering “never” to the ICIQ question: How often do you leak urine?. It has also been analyzed whether subjective failure was due to stress, urge, or mixed incontinence (item 6, ICIQ-SF).

Results

Fifty-one (66%) were continent in the immediate postsurgical evaluation. Twenty-six (34%) were incontinent. Eight of the 51 continent patients were obstructed (Qmax. inferior to 10 ml/s and/or more than 50 ml residue)**.** After adjustment, all patients rendered continent, none had PVR and mean Qmax was 16.7±5.7 ml/s. On no occasion was catheterization necessary.

Mean follow-up was 14.8±8.5 months. Objective cure rate was 89.6%, with 7.8% greatly improved. Subjective cure rate: 54.7 % of patients never leak urine. The subjective failure depended on the existence of urgency incontinence 25 patients (32%), mixed incontinence 4 patients (5%) and pure stress incontinence 5 patients (6%). Qmax was 21.3±7.2 ml/s. The QoL questionnaire improved from 31.4±20.3 to 85±17.2 points and the PGI-I showed 91% of patients to be better or very much better than before. There were no cases of bowel, nerve or major vessel injury. No infection or urethral erosions were identified. Two small vaginal erosions were detected.

Interpretation of results

This is the first time that an adjustable transobturator regular mesh has been described that allows post-operative adjustment of the tension applied during surgery. This has allowed that all our patients have been discharged without any incontinence or any PVR.

Our data suggests that with TOA tape better results can be obtained than with the traditional non-adjustable mesh, furthermore without increasing surgical complications.

Concluding message

TOA adjustable tape procedure allows adjustment of tension for a number of days after surgical intervention, thus permitting correction of postoperative incontinence or obstruction.

References

1. Intern Urogynecol J. DOI: 10.1007/s00192-008-0590-2.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of the San Juan de Alicante Universitary Hospital**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**