

SINGLE-INCISION MIDURETHRAL TAPE (OPHIRA™) VS TRANSOBTURATOR TAPE (OBTRYX™): PROSPECTIVE COMPARATIVE STUDY – 2 YEAR FOLLOWUP

Hypothesis / aims of study

The purpose of this study is to determine whether Single-incision Midurethral tape (Ophira™) and Transobturator tape (Obtryx™) suburethral sling procedures have equivalent patient satisfaction and clinical efficacy in the treatment of stress urinary incontinence alone or the stress component in mixed urinary incontinence

Study design, materials and methods

A total of 61 women between January 2009 and August 2010 were prospectively self-selected for either Single-incision Midurethral tape (30) or Transobturator tape (TOT) (31) procedure based upon their choice of anaesthetic. All women were assessed clinically and had urodynamic assessment if indicated. Cure was defined at 6, 12 and 24 months follow-up as a negative cough stress test (objective) or the woman's perception of improved symptoms (subjective). Impact on quality of life was assessed using the International Consultation on Incontinence –Short Form (ICIQ-SF) questionnaire at 6, 12 and 24 months.

Results

Table 1.

Baseline characteristics

Variable	Ophira™ (30)	Obtryx™ (31)	P* value
Age	57.1±13.3	52.7±9.1	0.26
Parity	3±1.6	2.8±1.2	0.9
Pre-op Cough stress test (CST)+ve	22(73.6%)	24(77.4%)	0.55
UDSUI	16(53.3%)	17(54.8%)	0.57
Pure SUI	11(36.7%)	8(25.8%)	0.18
MUI	3(10%)	5(16.1%)	0.57

CST, cough stress test; UDSUI, urodynamic stress urinary incontinence; SUI, stress urinary incontinence; MUI, mixed urinary incontinence

* **Chi-Square test**

Table 2.

Follow-up at 24 months

Variable	Ophira™ (30)	Obtryx™ (31)	P value
Significantly improved	90% (27/30)	87.09% (27/31)	0.68*
Same	10% (3/30)	12.9% (4/31)	0.78*
Positive CST	10% (3/30)	12.9% (4/31)	0.68*
Negative CST	90% (27/30)	87.09% (27/31)	0.69*
ICIQ Pre Procedure Score	16.5± 5.2	17.1±1.69	0.79**
ICIQ Post Procedure Score	5.6±1.8	6.8±2.1	0.46**

CST, cough stress test; ICIQ-SF, International Consultation on Incontinence Modular Questionnaire Short Form.

***Fisher's exact test**, ** **student t test**

Interpretation of results

Women reported significantly improved quality of life as measured by the ICIQ-SF questionnaire irrespective of the procedure they received. There was no significant difference between the single-incision Midurethral tape and TOT procedures. Minimally invasive synthetic slings have become the preferred technique for the treatment of SUI. In this study we have compared the single-incision Midurethral tape and TOT. After a follow-up period of 12 months, the single-incision Midurethral tape and TOT procedures were comparable in terms of both objective and subjective cure rates. The major advantage of single-incision Midurethral tape when compared to TVT or TOT is the possibility of performing this procedure under local anaesthesia on an ambulatory basis.

Concluding message

After a follow-up period of 24 months, both the single-incision Midurethral tape and TOT procedures were safe, effective and comparable in terms of both objective and subjective cure rates. However, the Single-incision Midurethral tape can safely be performed under local anaesthesia.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** The clinical effectiveness department of the unit approved this project. Therefore the ethical approval was not required. **Helsinki:** Yes **Informed Consent:** Yes