

COMPARISON OF SINGLE-INCISION MID-URETHRAL TAPE (OPHIRA™) AND TRANSOBTURATOR TAPE (SAFYRE™) SUBURETHRAL SLING PROCEDURES FOR FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Tension-free vaginal tape (TVT) procedure has been the standard treatment for SUI since 1995, treatment of female SUI has become a minimally invasive operation.

Transobturator tape (TOT) procedure technique reduced the risk of bladder perforation and injuries to the bowels and large vessels compared with TVT. The cure rates of both procedures were similar, ranging from 90 to 95%. But the procedure still involves passing needles through the groin, which in certain patients can result in groin pain. Various single-incision mid-urethral tapes involving only one incision in the vagina and no needle passages through the abdomen or groin have been developed. We aim to assess the efficacy & pain of single-incision mid-urethral tape (Ophira™) comparing the transobturator tape (Safyre™).

Study design, materials and methods

42 women with SUI were assigned to undergo either the Ophira™ (n=21) or Safyre™ (n=21) procedure from April 2007 and February 2011. All female patients performed urodynamic study, and were confirmed urinary leakage during filling cystometry study. The degree of pain was assessed by NRS on the next day of surgery. Objective cure rates were defined at 12 months follow-up as negative cough stress test (CST) and subjective cure was assessed by patient perception of improved symptoms, using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) questionnaire.

Results

The mean age was 52.1±6.8 years for the Ophira™ group and 55.0±5.4 years for Safyre™ group. There were no statistically differences in number of parity, Staemy grade of incontinence and urodynamic parameters between two groups. The average operation time was 8.7±5.1 minutes for Ophira™ group and 6.9±5.5 minutes for Safyre™ group.

Variable	Ophira™	Safyre™	P value
Age	52.1±6.8	55.0±5.4	0.14
Parity	2.8±1.6	2.7±1.4	0.92
VLPP	92.9±11.4	88.6±16.8	0.35

After a follow-up period of 12 months, the 21 patients that received the single-incision midurethral tape (Ophira™), 18 (85.7%) reported significantly improved symptoms and 18(85.7%) had a negative CST. This is compared to the 21 patients that received the transobtuator tape (Safyre™), where 19 (90.5%) reported significantly improved symptoms and 18 (85.7%) had a negative CST. 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 in either the objective or subjective cure rates between the single-incision midurethral tape (Ophira™) and transobturator tape (Safyre™) suburethral sling.

NRS pain scores measured by surgery the next day was 1.9±2.2 for the Ophira™ group and 3.8±2.3 for Safyre™ group

Variable	Ophira™	Safyre™	P value
Significantly improved	85.7% (18/21)	90.5%(19/21)	0.62
Negative CST	85.7% (18/21)	85.7% (18/21)	0.68
NRS pain scores	1.9±2.2	3.8±2.3	0.008

Concluding message

The single-incision midurethral tape (Ophira™) and the transobtuator tape (Safyre™) procedures were both effective for treatment of stress urinary incontinence. It is thought that the less invasive technique of the single-incision midurethral tape (Ophira™) could lead to less post-operative pain. Long-term follow up study including comparative studies with current procedure are required to define efficacy.

References

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Disclosures

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