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Comparison of single-incision mid-urethral tape (Ophira™) and transobturator tape (Obtryx™) sub-urethral sling procedures for female stress urinary incontinence

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This non-randomised study prospectively compared clinical efficacy and patient satisfaction of single-incision mid-urethral tape (Ophira™) against transobturator tape (Obtryx™). Objective cure rates were defined at 12 months follow-up as negative cough stress test and subjective cure was assessed by patient perception of improved symptoms, using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) questionnaire. Thirty patients received the Ophira, 29 (93.3%) reported significantly improved symptoms and 27 (90%) had a negative cough stress test. Thirty-one patients received the Obtryx, 29 (93.5%) reported significantly improved symptoms and 29 (93.5%) had a negative cough stress test. Twelve month follow up showed the procedures were comparable in objective and subjective cure rates.

Key words: Transobturator tape (TOT) procedure, mini-sling, stress urinary incontinence (SUI).

INTRODUCTION

Urinary incontinence is a common complaint causing suffering and embarrassment as well as significant costs to women and societies around the world (Department of Health, Modernising Health and Social Services, 1999-2002). It has been estimated that between 10 to 40% of adult women suffer from urinary incontinence, of these 3 to 17% are considered severe (Hunskaar et al., 2000). Stress urinary incontinence (SUI) is the most common type and is defined as the complaint of involuntary urine leakage on effort, or exertion, or on sneezing, or coughing, without a rise in detrusor pressure (Haylen et al., 2010). It is thought to be caused by 2 mechanisms (Petros and Woodman, 2008):

1) Hyper-mobility or significant displacement of the urethra and bladder neck during exertion.
2) Intrinsic urethral sphincter deficiency.

Tension-free vaginal tape (TVT) procedure has been the standard minimally invasive treatment for SUI since 1995, when it was first described by (Ulmsten and Pteros, 1995; Delorme 2001), cused the 'outside-in' technique of a transobturator route for suburethral tape placement, the transobturator tape (TOT) procedure (Delorme, 2001). This 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% (Ulmsten et al., 1999). Despite its improved safety profile and excellent cure rates, the procedure still involves passing needles through the

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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
USI	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 incontinence; SUI, stress urinary incontinence; MUI, mixed urinary incontinence. * Chi-Square test.

groin, which in certain patients can result in groin pain (Latthe et al., 2007). Although the risk is very low, especially with the outside-in approach like the TOT tape, the risk still exists.

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 (Deole et al., 2011; Abdel-Fattah et al., 2012; Barber et al., 2012; Sivaslioglu et al., 2012). A study that compared primary fixation of five different mini slings and one polyproylene mesh showed that the Ophira™ mini sling system presented the best fixation in Wister rats (Palma et al., 2012). However, it is important that we must critically evaluate these technologies in daily practice. We aim to assess the efficacy of Ophira™ comparing the Obtryx™ suburethral sling at a median 6 months follow-up.

METHODOLOGY

This prospective observational study was performed in the Urology Department of the City Hospital in Birmingham, England. A total of 61 women with SUI between January, 2009 and August, 2010 were self-selected for either Ophira™ (30) or Obtryx (31) procedure based upon their choice of anaesthetic. In all cases, informed consent was obtained and the procedure was performed in a day-case setting. The clinical effectiveness department of the unit granted approval for this project.

As part of the pre-operative workup, a detailed case history was compiled including the type, timing and severity of incontinence, associated voiding, and other urinary symptoms. The patients were asked to fill in the International Consultation on Incontinence modular Questionnaire Short Form (ICIQ-SF), which is a validated measure of overactive bladder syndrome and health-related quality of life (Abrams et al., 2006). A physical examination was performed that included a cough stress test (CST). Prior to the CST all women were assessed with a bladder scan to ensure a bladder volume of at least 250 ml. Where clinical assessment was inconclusive or suggestive of a mixed urinary incontinence, urodynamic evaluation was performed. Once urodynamic stress incontinence (USI) had been established and the conservative measures of lifestyle advice and pelvic floor exercises had failed to show satisfactory improvement, affected women were offered surgical intervention.

Objective cure was defined when physical examination of the patient yielded a negative cough stress test, while subjective cure was assessed based on woman's perception of improvement in stress urinary incontinence symptoms (significantly improved, same, worse) at the 12th month follow up visit.

The Ophira™ Mini-Sling System was performed under local anaesthesia, using 30 to 40 ml of 1% lignocaine injected at the mid-urethra towards the vaginal fornix, advancing 2 cm into the obturator internus muscles. A small vertical incision in the vagina and dissection was performed as for the Obtryx™ transobturator tape. The polypropylene mesh was then inserted into the obturator internus muscles using self-anchoring arms. The Ophira™ system then allowed adjustment of the sling to achieve the right tension. Finally, the vaginal incision was closed with no need for a catheter.

The Obtryx™ transobturator mid-urethral sling system was performed under a general anaesthesia. To fit the polypropylene sling, a small vertical incision was made into the vagina, 1 cm from the urethral meatus. Minimal dissection was performed laterally towards the ascending ramus of the ischiopubic bone, preserving the endopelvic fascia. Two small incisions were then made in the skin above the obturator space. The curved needle system was then used in all cases to place a synthetic mesh from one skin incision, towards the vagina, around the urethra and back out through the second skin incision. The mesh was then adjusted to keep it tension free, before closing the vaginal incision. The bladder was catheterised and removed immediately following completion of the procedure.

All cases received 1.2 g intravenous co-amoxiclav, or gentamicin 120 mg if penicillin allergic, peri-operatively to prevent infection. Women were discharged once comfortable and having passed urine with less than 100 ml residual in the bladder. The surgeon performing the procedure prospectively collected the data regarding any complications. Statistical analysis of the data was performed by using Student's t-test, chi-square test, and Fisher's exact test, for which statistical package for social sciences (SPSS) ver. 16.0 (SPSS Inc., Chicago, IL, USA) was used. Statistical significance was set at $p < 0.05$.

RESULTS AND DISCUSSION

A total of 61 patients were suitable for a day case surgical procedure. Table 1 shows the baseline characteristics of the patients in each group: age, parity, pre-op CST, urodynamic stress incontinence (USI), mixed urinary incontinence (with a predominant SUI) and pure SUI (defined as a positive CST and only symptoms of SUI). There were no significant intergroup differences found. Table 2 shows that of the 30 patients that received the single-incision midurethral tape (Ophira™), 28 (93.3%) reported significantly improved symptoms and 27

Table 2. Follow-up at 6 months.

Variable	Ophira™ (30)	Obtryx™ (31)	P value
Significantly improved	93.3% (28/30)	93.5% (29/31)	0.68*
Same	6.7% (2/30)	6.5% (2/31)	1.0*
Positive CST	10% (3/30)	6.5% (2/31)	0.67*
Negative CST	90% (27/30)	93.5% (29/31)	0.62*
ICIQ-SF Pre Procedure Score	16.5± 5.2	17.1±1.69	0.79**
ICIQ-SF Post Procedure Score	3.8±2.2	4.2±2.3	0.62**

CST, cough stress test; ICIQ-SF, International Consultation on Incontinence Modular Questionnaire Short Form. *Fisher's exact test, ** student t test.

Table 3. Follow-up at 12 months.

Variable	Ophira™ (30)	Obtryx™ (31)	P value
Significantly improved	93.3% (28/30)	93.5% (29/31)	0.68*
Same	6.7% (2/30)	6.5% (2/31)	1.0*
Positive CST	10% (3/30)	6.5% (2/31)	0.67*
Negative CST	90% (27/30)	93.5% (29/31)	0.62*
ICIQ Pre Procedure Score	16.5± 5.2	17.1±1.69	0.79**
ICIQ Post Procedure Score	4.2±1.8	4.1±2.1	0.56**

CST, cough stress test; ICIQ-SF, International Consultation on Incontinence Modular Questionnaire Short Form. *Fisher's exact test, ** student t test.

(90%) had a negative cough stress test. This is compared to the 31 patients that received the transobtuartor tape (Obtryx™), where 29 (93.5%) reported significantly improved symptoms and 29 (93.5%) 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 (Obtryx™) suburethral sling procedures.

Table 3 shows the results of follow-up at 12 months. The only difference from the results at 6 months follow-up is with the ICIQ-SF results. However, there remained no significant difference between the single-incision midurethral tape (Ophira™) and transobturator tape (Obtryx™) suburethral sling procedures. For the three patients with a positive CST that were treated with a single-incision midurethral tape (Ophira™), two had a transobturator tape procedure and one had TVT procedure, because of a previous pelvic fracture which meant the transobturator route would be difficult. Of the two patients with a positive CST who were treated with a transobturator tape (Obtryx™), one declined further treatment and one had a TVT procedure.

On comparison of the peri-procedural complications, the only significant difference was found on blood loss. Of the 31 patients that received the transobturator tape (Obtryx™), three had more than average blood loss compared to one patient of the 30 that received the single-incision mid-urethral tape (Ophira™) P = 0.04.

SUI is a common distressing condition that significantly impairs quality of life for affected women. 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 (Ophira™) and transobturator tape (Obtryx™). After a follow-up period of 12 months, the Ophira™ and Obtryx™ procedures were comparable in terms of both objective and subjective cure rates. The major advantage of Ophira™ when compared to TVT or TOT is the possibility of performing this procedure under local anaesthesia on an ambulatory basis. There have been other comparison studies of various single incision mid-urethral tape procedures, but none have looked at the Ophira™ system. The cure rates in these studies ranged from 55.8 to 90% (Deole et al., 2011; Abdel-Fattah et al., 2012; Barber et al., 2012; Sivaslioglu et al., 2012). The higher cure rates in our study can be partly explained by the short follow-up period. A study on another single incision mid-urethral tape showed a decrease in cure rate from 90 to 83% from 3 to 5 years follow-up (Sivaslioglu et al., 2012).

One of the weaknesses in this study is that the patients were not randomised to a surgical procedure, but self-selected to either Ophira or Obtryx based on their anaesthetic choice. This could have potentially introduced a source of bias where lifestyle and health

matters influence anaesthetic choice. However, there was no significant difference in either average age or anaesthetic grade of the two groups of patients. Another weakness in this study is that the objective measure of improved SUI was the CST. Some women were found to have a negative CST before the procedure, although these women would have shown urinary loss at low bladder pressures when urodynamic testing was performed. Other objective measures that could be employed to look for improvement include: repeating urodynamic assessment after the procedure, comparison of pad weights before and after treatment.

It is thought that the less invasive technique of the single-incision midurethral tape (Ophira™) could lead to less post-operative pain and intra-operative complications. This study showed greater blood loss in the group with the TOT procedure. However, it would be difficult to pick up significant differences in complications with such low study numbers. This study provides useful data on a comparison of the 2 products using a small representative population, however is limited by being non-randomised and with a short follow up period. To demonstrate any significant comparable outcomes there is a call for larger randomised controlled studies with long-term follow-up to provide a more rigorous critical analysis of these products.

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