

SHORT-TERM SAFETY AND EFFICACY OF THE MONARCTM TRANS-OBTURATOR TAPE FOR THE SURGICAL TREATMENT OF URODYNAMIC STRESS INCONTINENCE

Hypothesis / aims of study

Mid-urethral tapes are being used extensively for the surgical treatment of urodynamic stress incontinence (USI). Concerns have been raised about complications with retropubic mid-urethral tapes including major haemorrhage from large vessel injury, bladder perforation, and urinary retention rates of up to 10%.(1) To address this alternative pathways for mid-urethral tapes have been devised. Delorme first introduced the transobturator approach(2) which is used by American Medical Systems in the MonarcTM transobturator tape (TOT) sub-fascial hammock. The aim of this review was to evaluate the safety and efficacy of the MonarcTM.

Study design, materials and methods

Forty four USI patients undergoing the MonarcTM TOT operations in 2005-6 were prospectively reviewed. Patients were treated by one of two specialist Gynaecologists with a special interest in urogynaecology, in either a private or public hospital setting. All patients had urodynamic proven stress incontinence, had been previously treated unsuccessfully with conservative measures, and consented to surgery. Patients were typically parous and without overactive bladder (table 1). Two of the patients had previous surgical continence procedures (table 1). The MonarcTM TOT procedure was carried out as described by Mellier *et al* (3) with a check urethrocytoscopy was conducted on completion. Twenty percent of patients had additional vaginal repair/vault supporting procedures and/or vaginal hysterectomy at the time of operation, with the remaining undergoing TOT insertion only. Routine post-operative checks were conducted at approximately six weeks. Data for this review was collected from computerised and hand-written records.

Table 1 Clinical and demographic details of the patient group

Age (yrs) (mean, range)	52.8 (30-71)
Parity (median, range)	3 (0-7)
Previous incontinence operations	
Tension-free vaginal tape (TVT)	1/44
Open Burch colposuspension	1/44
Urodynamic studies	
USI with overactive bladder	3/44
USI without overactive bladder	41/44

Results

The operative duration for the TOT alone was on average 25 minutes with an inpatient hospital stay of 1 day (table 2), although many units do such procedures as a day case.

Table 2 Operation details and duration

Operation performed	
TOT only	35/44
TOT and other (including +/- vaginal hysterectomy, anterior /posterior vaginal wall repair and vault support)	9/44
Operation time (minutes) (mean, range)	
TOT only	25 (16-34)
TOT and other	90 (38-150)
Hospital stay (days) (mean, range)	
TOT only	1.25 (0.3-3)
TOT and other	4.13 (2-5)

No significant intra-operative complications occurred with our patients. One patient required a vaginal pack for 4 hours but did not proceed to further surgery. There was a low rate of minor complications in the early post-operative period. These consisted of a single case of urinary retention and two patients with overactive bladder. Of those with overactive bladder, one was de-novo and the other was an exacerbation of a pre-existing overactive bladder. Both were aided with oxybutynin therapy.

After discharge and up to 6 weeks post-operation four further patients developed de-novo overactive bladder and were treated with Oxybutynin. Three cases of vaginal tape erosion were identified, two of whom required a local anaesthesia and vaginal mucosal re-covering, while the third case was managed conservatively with topical oestrogen. A further patient had a superficial infection and mild discharge from the vaginal incision which healed with oral antibiotics. The subjective cure rate was 95% at 6 weeks (table 3).

Table 3 Intra- and post-operative complications and results

Intra-operative complications (n)	
Bladder perforation	0
Haemorrhage requiring vaginal pack	1
Haemorrhage > 500ml/ blood transfusion	0
Immediate inpatient complications (n)	
Urinary retention	1
Superficial infection/ UTI	0
De-novo overactive bladder	1
Exacerbation of existing overactive bladder	1
Six week follow-up complications (n,%)	
Superficial infection/ UTI	1/44 2.3%
De-novo bladder overactivity	5/44 11.4%
Tape erosion	3/44 6.8%
Major infection leading to tape removal	0/44 0%
Six weeks follow up (n,%)	
Subjective cure rate	42/44 95.5%

Interpretation of results

All but 2 of our 44 patients enjoyed immediate relief from stress incontinence following insertion of the Monarc™ TOT. No significant intra-operative complications occurred. A low incidence of minor post-operative complications were experienced by our patients, including 3 women with tape erosion, and 5 with manageable de-novo overactive bladder symptoms. The results of this review support recent literature indicating that the trans-obturator mid-urethral tapes such as the Monarc™ are safe and efficacious.

Concluding message

We are satisfied that the Monarc™ Trans-obturator tape now being used in our practice appears to be a safe and reliable surgical method for treatment of urodynamic stress incontinence, at least in the short term. Although this review is encouraging, long term follow-up data from this and further studies are still required.

References

- (1) Mid-urethral tapes: which? Review of available commercial mid-urethral tapes for the correction of stress incontinence. BJOG. 111:41-45, 2004
- (2) Transobturator tape for stress incontinence: The North Queensland experience. ANZOG.45:446-9, 2005.
- (3) Suburethral tape via the transoburator route: is the TOT a simplification of the TVT? Int Urogynaecol J Pelvic Floor Dysfuct.190: 602-608, 2004

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HUMAN SUBJECTS: This study did not need ethical approval because This was a review of hospital records and anonymity was preserved and did not follow the Declaration of Helsinki - with approval by the ethics committee - in the sense that his was a review of hospital records and anonymity was preserved
Informed consent was obtained from the patients.