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TRANSOBTURATOR TAPE ARIS FOR STRESS URINARY INCONTINENCE: A MULTICENTER TRACKER STUDY

Hypothesis / aims of study

The aim of this on going tracker study is to confirm the efficacy and tolerability of ARIS, a new monofilament macroporous, knitted polypropylene tape for the surgical treatment of female stress urinary incontinence (SUI), in a large number of patients.

Study design, materials and methods

510 consecutive patients with Stress Urinary Incontinence (SUI) were recruited by 14 centres, since July 2004. All these patients underwent the trans-obturator outside-in procedure. Inclusion criteria were: SUI, urethral hypermobility with or without previous surgery, and with or without associated prolapse. The preoperative evaluation included: history, physical examination, urodynamic testing and residual. Peri and post operative complications were recorded. Post-operative evaluations were: physical examination, uroflowmetry and residual. Cure was defined as the absence of subjective complaint of urine leakage, and the absence of leakage on cough stress test.

Patients characteristics were: mean age 57.6 years (29-89), mean parity 2.5 (0-11). 308/510 (60.4%) menopausal patients. 106/510 (20.8%) patients had a prior hysterectomy, and 50/510 (9.8%) were previously operated for genital prolapse. Of 510 patients, 51 (10%) had recurrent SUI, with the previous surgical procedures described in table 1. 236/510 (46.2%) patients had pure stress urinary incontinence, 262/510 (51.4%) had mixed incontinence, and in 12 cases data for the type of incontinence was missing.

Table 1: Previous surgical procedures

	51 patients N=58 (interventions)
Burch / Marchall-Marchetti	24
Raz / Stamey / Pereyra	6
Goebell-Stoeckel	2
Retropubic tape	8
Trans-obturator tape	5
Other	13

In 126 patients (24.7%), the implantation of ARIS® was combined with other procedures. 34 patients (6.7%) had an hysterectomy by vaginal route, and 92 patients (18%) had concomitant treatment of prolapse.

The procedure was performed under general anaesthesia for 48.6%, while 43.3% were operated under spinal anaesthesia and 8.1% under local anaesthesia.

Among the 510 patients, 8 patients were lost to follow-up.

Results

The peri-operative complications are listed in table 2.

Table 2: Peri-operative complications

	N= 26/510
Bleeding >200ml	5
Bladder perforation	4
Urethral perforation	2*
Vaginal perforation (sulcus)	19

*the implantation of the tape was postponed on the 2 patients who had the urethral perforation.

Voiding disorders (PVR>100ml) were reported in 20 patients (3.9%). 2 patients were treated by surgical release of the tape. The other 18 patients were treated by temporary self intermittent catheterisation for less than 5 days(N=9), and between 6 days and 38 days for the rest.

Furthermore, 3 patients (0.6%) suffered from haematoma, which disappeared spontaneously in all cases without any drainage.

31 patients (6%) complained of pain but, due to concomitant prolapse repair in 5 patients.

The efficacy results are reported for analyses on 474 patients having at least 1 month of follow-up. Among the 474 patients, 8 were lost for follow-up.

The mean follow up was 6.3 months (1 – 27.1). Cure rates according to duration of follow-up are shown in Table 3.

Table 3: Cure rates

	Follow-up				
	1 to 3 months N=466	Min 6 months N=325	Min 12 months N=134	Min 18 months N=41	Min 24 months N=11
Cured	86.7%	83.7%	82.1%	80.5%	81.8%
Improved	10.3%	9.8%	10.4%	12.2%	-

Failed	3%	6.5%	7.5%	7.3%	18.2%

Among the 134 patients with at least 1 year follow-up, 22 were having pre-operatively a low urethral closure pressure (under 30cm of H_2O). Among them, 20 patients were continent at 1 year follow-up.

Among the 185 patients suffering from urgencies, the urgencies disappeared in 90 patients (48.7%), improved in 46 (24.9%), did not change in 27 (14.6%) and got worse for 11 patients (5.9%), 11 missing data on this item.

23 patients (7.3%) complained from *de novo* urgency.

3 patients (0.7%) had a defect of healing respectively at one month and 2 months. Localized resection was performed in 2/3 cases and local treatment with complete healing in the 3 cases. 2 patients (0.4%) had a tape rejection 8 days after surgery, the tape was removed and the inflammatory symptoms disappeared. 2 patients (0.4%) had lateral vaginal erosion 8 and 13 months after implantation respectively. Both were treated by local antibiotherapy and localised resection of the tape with secundary healing.

Interpretation of results

It is important to point out that no peri-operative vascular, nerve or bowel complication occurred in this important series. Post-operative complications remains very low, and moreover, the vaginal erosion rate is comparable to the published literature on polypropylene knitted monofilament tapes.

Concluding message

This tracker study shows encouraging results for in SUI in terms of peri-operative complications, effectiveness and post-operative retention. This tracker study is still on going with a 5 year follow-up objective.

FUNDING: no

HUMAN SUBJECTS: This study did not need ethical approval because real life observational setting study but followed the Declaration of Helsinki Informed consent was not obtained from the patients.