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PRELIMINARY OUTCOMES OF THE EUROPEAN MULTICENTRE EXPERIENCE WITH THE ZSI 375 ARTIFICIAL URINARY SPHINCTER FOR TREATMENT OF STRESS URINARY INCONTINENCE IN MEN.

Hypothesis / aims of study

To evaluate the outcomes of an artificial urinary sphincter implantation, the ZSI 375 device in male patients with stress urinary incontinence at seven unrelated centres in Europe.

Study design, materials and methods

This was a retrospective, non-randomised, multicenter study. From January 2012 to December 2014, consecutive men with SUI were treated with the ZSI 375 device. The primary outcome was continence. The secondary outcomes included improvement and complication rates.

Results

A total of 106 patients with the mean age of 71.56 years underwent placement of the ZSI 375 device at seven centres in Europe. The most common indication for placement was incontinence after radical prostatectomy (82/106 patients, 77.3%). The mean period of incontinence was 48.6 months. Among the total patient population, the mean number of urinary pads used daily was 4.22 ± 2.2 and 96 patients (90.6%) were considered to have had severe incontinence, with a daily pad usage ≥4 at baseline. With the mean follow up of 24.74 months, daily pad usage decreased significantly to 1.07 ± 0.9 pads per day at the last visit. The ZSI 375 device was considered successful in 91.8% of patients. The infection rate was only 1.8% and occurred early in our series. Urethral erosion was the most frequently reported complication in the present study and affected 19 patients (17.9%). Mechanical failure with a resultant device re-implantation occurred in 3 patients (2.8%) early in the study.

Interpretation of results

Table 1. Continence rates before and after device implantation

	Before implantation	3 months after implantation	6 months after implantation	12 months after implantation	24 months after implantation
Patients, n	106	106	106	93	61
Pads used/day, n (%)					
None	0	24 (22.6)	24 (22.6)	23 (24.7)	21 (34.4)
1	0	61 (57.5)	61 (57.5)	56 (60.2)	30 (49.2)
2	0	12 (11.3)	12 (11.3)	9 (9.7)	5 (8.2)
3	10 (10.4)	6 (5.7)	6 (5.7)	3 (3.2)	3 (4.9)
≥4	96 (90.6)	3(2.9)	3(2.9)	2 (2.2)	2 (3.3)
Cured (0,1pad), n (%)		85 (80.1)	85 (80.1)	79 (85)	51 (83.6)
Improvement, n (%)		8 (7.5)	8 (7.5)	7 (7.5)	5 (8.2)
Failure, n (%)		13 (12.4)	13 (12.4)	7 (7.5)	5 (8.2)

Key: n=number of patients

Concluding message

The ZSI 375 device is an acceptable therapy for surgical management of moderate-to severe stress urinary incontinence in men.

Disclosures

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