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Urinary artificial sphincter ZSI 375 for treatment of stress urinary incontinence in men: 5 and 7 years follow-up report

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ABSTRACT

Study design: This is a retrospective, non-randomised study.
Objectives: The aim of this study was to evaluate safety and efficacy of artificial urinary sphincter ZSI 375 inserted in male patients with stress urinary incontinence (SUI).
Methods: Between May 2009 and January 2017, 45 men with SUI underwent ZSI 375 device insertion. Operations were performed in two French centres by one surgeon. Complications and pad used to manage continence were recorded.
Results: From May 2009 to January 2012, 45 patients with a mean age of 70.42 years underwent placement of the ZSI 375 device in France. The most common cause for incontinence was radical prostatectomy (RP, 33/45 patients, 73.33%). The minimal period of incontinence was 6 months. Twenty-seven out of 45 patients (60.00%) had a severe incontinence (at least four pads per day), 13 patients (28.89%) had moderate incontinence (three pads per day) and five patients (11.11%) had two pads per day. With a long follow-up, the ZSI 375 device was considered to be successful in 73.33% patients after 5 years (60 months) and 72% of patients after 7 years (84 months). The infection rate was 2.2 % affecting one in 45 patients. Six out of 45 patients presented a urethral erosion (13.33%). Mechanical failure with a revision occurred in three patients (6.67%).
Conclusions: The ZSI 375 device is a safe and effective device to treat severe SUI in men.

Keywords: Artificial urinary sphincter, Male incontinence, ZSI 375

Introduction

Since 1973, the artificial urinary sphincter (AUS) manufactured by American Medical System (AMS), Minnesota, USA is the gold standard for the treatment of urinary incontinence (UI) (1, 2). AMS 800 was improved with a double cuff (3), but it is a complex procedure, without any option to adjust the issued pressure or to adjust the cuff in case of urethral atrophy (4, 5).

ZSI 375 (Zephyr Surgical Implants, Geneva, Switzerland) was designed to facilitate US insertion. It is a pre-connected two-component device. It has no abdominal reservoir so as to reduce operating time and to avoid abdominal incision and dissection in scarred retroperitoneum (6, 7). The cuff is adjustable and the pressure can be increase for continence control (6, 7). First, ZSI 375 insertion was 7.5 years ago. The aim of the present study was to report our experience with this AUS in 45 male patients to assess its safety and efficacy.

Patients and methods

We performed a retrospective study of patients who underwent ZSI 375 placement in two French centres by one surgeon. Indication for ZSI 375 insertion was for moderate stress UI (two to three pads/day) and severe stress incontinence (four and more pads/day). All patients had failed previous rehabilitation by pelvic floor training and electrostimulation. The preoperative evaluation included patient history, pad use, a physical examination and cystoscopy looking for stricture, urine analysis and urodynamic examination to exclude an overactive bladder.

Between May 2009 and January 2012, 45 men with stress urinary incontinence underwent ZSI 375 device insertion. Patients reported incontinence after RP, RP and radical radiotherapy (RP + RR), transurethral resection of the prostate (TURP), radiotherapy and transurethral resection of the prostate (RT + TURP), radical cystectomy and an orthotopic neobladder formation and neurological condition (medullar RT). The patients were followed up until January 2017.

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Fig. 1 - Artificial Urinary Sphincter ZSI 375.

The device

ZSI 375 is an AUS mainly made from medical grade silicone (Fig. 1). It works like a typical artificial sphincter. It is made up of a cuff connected by kink-resistant tubing to a pump unit. The inflatable and adjustable cuff moulded curved fits around the urethra. The pump with the pressure-regulating tank is placed in the scrotum. ZSI 375 hydraulic circuit and compensation pouch circuit were filled with saline solution before insertion. After activation of the AUS, the issued pressure in the hydraulic circuit can be increased or decreased to improve patient continence.

Surgical technique

The implantation procedure was carried out under general anaesthesia with patients in the lithotomy position. A 16F Foley catheter was placed for guidance and to calibrate the urethra. The surgical technic consists of a perineal incision for cuff placement and inguinal incision for pump unit scrotal placement. During the procedure, the sphincter closure pressure set ranged from 60 to 70, from 70 to 80 or rom 90 to 100 cmH_2O.

A 12F Foley catheter was inserted at the end of the procedure for 24 hours. Patients were discharged 24-48 hours after procedure. The device was activated 8 weeks later. After activation, the issued pressure could be increased in situ by trans-scrotal injection of saline into the compensation pouch; 1 ml saline increased pressure by 10 (range 8-12) cmH_2O.

Assessment of postoperative continence

Urine analysis, bladder ultrasonography to evaluate residual urine volume and flow rate measurements were performed after sphincter activation, 3 months, 6 months after activation and every year up to January 2017.

Patients recorded number of pads used per day in a 7-day diary before their visits. Total continence was given by use of zero pads (i.e. completely dry), and social continence as daily use of zero to one pad. Incontinence was given by daily use of more than one pad.

Success was defined as social continence (zero to one pad per day) and improvement as a decrease in daily pad use (usually two pads per day).

The necessity of issued pressure adjustment was determined according to each patient's requirements.

Results

Forty-five patients with a mean age of 70.42 (53-89) years underwent ZSI 375 AUS insertion. The minimal period of incontinence was 6 months. Twenty-seven patients (60.00%) had a severe incontinence (at least four pads per day), and 13 patients (28.89%) had a moderate incontinence (three pads per day). Five patients (11.11%) had two pads per day. Incontinence was secondary to radical laparoscopic or open prostatectomy (RP) (33/45 patients, 73.33%), RP with adjuvant RT (RP + RR) (2/45 patients, 4.45%), RR + TURP (1/45 patients, 2.22%). The other causes of incontinence included TURP (seven patients, 15.56%), radical cystectomy (1/45 patients, 2.22%) and medullar RT (1/45 patients, 2.22%). Three patients (6.67%) had experienced previous AMS 800 insertion and failure before ZSI 375 insertion. We lost sight of two patients (4.44%) after 1 year and 4 years. Four out of 45 patients (8.89%) died from ageing after a mean follow-up of 5 years. Pre- and postoperative clinical data are presented in Table I.

Implantation and recovery was uneventful in 35 patients (77.78%). No patient experienced bladder overactivity after device activation.

Complications occurred in 10 patients (22.22%): one case (2.22%) of scrotal infection, six cases (13.33%) of urethral erosion and three cases (6.67%) of mechanical failure leading to a revision. Regarding the mechanical failure, one case (2.22%) was due to saline solution leakage and two cases (4.44%) due to armed tubing breakage. The case of saline leakage (2.22%) was due to accidental "micro" intraoperative injury of the silicone tube with the needle. The two cases (4.44%) of armed tubing broken were early in the experience and lead to a reinforcement of the armed tubing and a change in the manufacturing process.

One patient (2.22%) did not have any complication but a persistent incontinence with the use of two pads per day.

The ZSI 375 implantation-related complications by cause of UI are presented in Table II.

Considering number of pads used per day, 38 out of 45 patients (84.00%) reached social continence after 1 year and 33 out of 45 patients (73.33%) after 5 years. One patient (2.22%) was considered as improved with two pads per day. Twenty-five patients (55.56%) have had a follow-up of 7 years with a nonsignificant decrease in the continence rate, and 18 out of

TABLE I - Continence rates before and after device implantation

	Before implantation	1 years follow-up	3 years follow-up	5 years follow-up	7 years follow-up
Patient	45	45	45	45	25
Pads used/day, n (%)					
None	0	10 (22.22)	11 (24.44)	11 (24.44)	5 (20.00)
1	0	28 (62.22)	22 (48.89)	22 (48.89)	13 (52.00)
2	5 (11.11)	1 (2.22)	1 (2.22)	1 (2.22)	1 (4.00)
3	13 (28.89)	3 (6.66)			
≥4	27 (60.00)	3 (6.66)			
Success 0 or 1 pad, n (%)		38 (84.44)	33 (73.33)	33 (73.33)	18 (72.00)
Failure, n (%)		7 (15.56)	12 (26.67)	11 (24.44)	3 (12.00)
Revision rate		1 (2.22)	2 (4.44)	3 (6.67)	2 (8.00)
Lost sight		0	1 (2.22)	2 (4.44)	2 (8.00)
Dead		0	0	4 (8.89)	2 (8.00)

n = number of patients.

TABLE II - ZSI 375 implantation related complications by aetiology of urinary incontinence

Aetiology of incontinence	Infections n, (%)	Urethral erosions n, (%)	Mechanical complications n, (%)
RP	1 (2.22)	3 (6.67)	2 (4.44)
RT	0	0	0
RP + RT	0	2 (4.44)	0
RT + TURP	0	1 (2.27)	0
TURP	0	0	1 (2.27)
Cystectomy	0	0	0
Medullar RT	0	0	0
Total	1 (2.22)	6 (13.33)	3 (6.67)

n = number of patients; RP = radical prostatectomy; RT = radiotherapy; TURP = transurethral resection of the prostate; RC = radical cystectomy.

25 patients (72%) had a social continence (zero to one pad per day); Table I. Patients who underwent pelvic irradiation were more prevalent in the failure group than in the success group: the three patients who have had RT have had urethral erosion.

Discussion

AMS 800 is considered the gold standard treatment for severe stress UI in men. But AMS 800 single cuff or double cuff is still a complex surgical procedure. After AUS AMS 800 activation, there is no option to adjust the issued pressure of the device or to adjust the cuff in case of urethral atrophy (4). The ZSI 375 AUS with adjustable issued pressure and adjustable cuff was designed and developed in the last 10 years to simplify the surgical procedure.

As a long-term follow-up is necessary to evaluate an artificial sphincter, only few studies have explored its safety and efficacy in male stress UI. (6, 7).

In this retrospective study, we report our first experience with ZSI 375 with a long follow-up period of 5 and 7 years. During the mean follow-up period of 60 months, the success rate was 73.33% and one patient (2.22%) improved with two pads per day when he used to wear more than four pads per day before ZSI 375 insertion. Only seven patients (15.56%) failed the treatment because of infection and urethral erosion. We also demonstrated that the total continence achieved with the ZSI 375 device was stable after 5 and 7 years. Previous studies showed good short-term results, which ranged from 87% to 94.2% (6-8). ZSI 375 efficacy is comparable with AMS 800 efficacy after 2 years follow-up period (≤90%) (4, 5) and in long-term period (9, 10).

Meanwhile, the operations were performed with first version of the ZSI 375 device and we included the patients from the surgeon's learning curve in terms of preparation and procedure in the study; the present series confirms the simplicity of the ZSI 375 surgical procedure.

Unfortunately, a history of RR therapy was associated with complications in our study in agreement with studies about AMS 800 (11, 12). Three patients who underwent pelvic irradiation before the ZSI 375 implantation presented urethral erosion after ZSI 375 activation.

Our short-term complication rate was comparable with AMS 800 (4, 13, 14). Seven out of 10 complications took place

within first 12 months after ZSI 375 insertion, and three out of 10 appeared within 36 months after surgical procedure.

AUS infection occurring without cuff erosion is not common, as most of the erosion will lead to perineal and scrotal infection (15). Our infection rate was 2.22% (one patient had a scrotal infection) in accordance with AMS 800 rate 1-8% (4, 14, 16, 17).

Six patients (13.33%) presented urethral erosion. Three of them have had RT before sphincter implantation. Our urethral erosion rate is comparable to AMS 800 rate (4, 13, 14).

Mechanical failure leading to a revision occurred in three patients (6.67%). One patient presented a leakage at activation of the device and two patients patients presented an armed tubing breakage during the third year of functioning. The leakage was accidental after needle piercing the armed tubing during the procedure (piercing showed by expertise of the devise after removal). The two armed tubing breakage were due to a lack of reinforcement and led to an early change of the mould and manufacturing process. The rate of mechanical failure of ZSI 375 in our series is comparable with that of AMS 800 (4, 17-19).

A last interesting feature of the ZSI 375 device is the absence of an abdominal reservoir leading to an easy surgical procedure reducing risk linked to perineal intrusion after RP.

Our study reports our first experience with the ZSI 375 device implantation in a series of 45 patients and with a follow-up period of 5 years for 45 patients and 7 years for 25 patients. It was long enough to identify all potential complications and to establish the safety and efficacy of the ZSI 375 device. Result can be improved regarding the experience we acquired with the ZSI 375 device, and the use of the last version of the ZSI 375 PF device, prefilled, is now available.

But the present study has further limitation: its design was retrospective, the sample size was small and assessment of continence was based on pad number and not on pad weight.

Conclusions

The ZSI 375 AUS was effective in treating moderate to severe male UI. A large majority (84.44%) of the patients presented a social continence after 12 months with a stabilisation at 73.33% after 3 and 5 years and 72.00% after 7 years.

We encountered low complication rate. The easy surgical procedure with adjustable cuff and adjustable issued pressure make the ZSI 375 device an attractive option to treat severe male urinary stress incontinence.

Disclosures

Financial support: No financial support was received for this study.
Conflicts of interest: Christophe Llorens is a Stock Holder and Patent Inventor of ZSI 375 device.

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