UJ
ISSN 0391-5603

Urologia 2017; 00 (00): 000=000
DOI: 10.5301/uj.5000271

ORIGINAL RESEARCH ARTICLE

Open Access

Comparative study of urodynamic tests after AMS 800 and ZSI 375 insertion

Thomas Ripert, Jean Pierrevelcin

Polyclinique de Courlancy, Reims - France

ABSTRACT

Study design: Retrospective, non-randomised, single-centre study.
Objectives: Comparative study of urodynamic tests in patients presenting social continence after AMS 800 or ZSI 375 insertion.
Materials and methods: Study was open to patients with social continence, implanted with AMS 800 or ZSI 375. Vesical pressure (VP), urethral functional length (FL), maximal urethral pressure (MUP), maximal urethral closure pressure (MUCP), maximal urinary flow rate (Q_{max}) were registered with standard urodynamic equipment.
Results: From March 2012 to September 2014, 27 male patients with AMS 800 and 28 with ZSI 375 were recruited. In the AMS 800 group mean VP was 25.03 cmH_2O (range 13-47), mean FL 31.96 mm (range 20-52), mean MUCP 88.29 cmH_2O (range 32-160), mean MUP 119.55 cmH_2O (range 77-180), mean Q_{max} 22.86 mL/s (range 5.6-54.6). In the ZSI 375 group, mean VP was 24.89 cmH_2O (range 6-40), mean FL 30.53 mm (range 12-87), mean MUCP 70.11 cmH_2O (range 38-108), mean MUP 99.89 cm H2O (range 63-134), and mean Q_{max} 19.25 mL/s range (7.3-39.6).
Discussion: Results of urodynamic tests are similar for both artificial urinary sphincters. AMS 800 cuff pressure over 70 cmH_2O could be explained by the pelvis pressure and the difference of altitude between the pressure-regulating balloon (PRB) and the cuff. ZSI 375 pressure-regulating tank (PRT) is not influenced by these factors. Very high MUP could be explained with too tightened cuffs.
Conclusions: AMS 800 and ZSI 375 urodynamic tests are similar. Pressure of the pelvis and difference of altitude between the AMS balloon and the cuff can lead to high MUP.

Keywords: AMS 800, Artificial sphincter, Urodynamic, ZSI 375

Introduction

Artificial urinary sphincter (AUS) appears to be the best treatment for male severe stress urinary incontinence with intrinsic sphincter deficiency (ISD) (1, 2).

The AMS 800 device (Boston Scientific, USA), in use since 1983, is an evolution of the Brantley-Scott AUS introduced in 1973 (3).

Most implanted AMS 800 devices are inserted with a 61-70 cmH_2O pressure-regulating balloon (PRB) in vitro (4). ZSI 375 AUS (Zephyr Surgical Implants, Switzerland) was first implanted in 2009 (5). It is a one-piece AUS with an adjustable cuff moulded on a circular form and a pressure-regulating tank (PRT) associated with a pump placed in the scrotum (Fig. 1). The pressure is adjustable after device activation.

Accepted: September 1, 2017
Published online: September 21, 2017

Corresponding author:
Thomas Ripert
Polyclinique de Courlancy
38bis Rue de Courlancy
51100 Reims, France
thomasripert@yahoo.fr

Three ranges of operating pressure were available at the time of the study, 60-70 cmH_2O, 70-80 cmH_2O and 90-100 cmH_2O, but total continence (0 pads per day) and social continence (0-1 pad per day) are mainly reached with an operating pressure of 90-100 cmH_2O (5-8). This paper evaluates and compares the maximal urethral pressure (MUP), maximal urethral closure pressure (MUCP), urethral functional length (FL), maximal urinary flow rate (Q_{max}) in 27 patients implanted with an AMS 800 device and 28 patients implanted with ZSI 375 device. Both group of patients presented a social continence (0-1 pad per day).

Methods

This was a retrospective, non-randomised, single-centre study (Reims-France), open to patients with social continence (0-1 pad per day), aged >18 years, implanted with AMS 800 device with 61-70 cmH_2O pressure-regulating balloon (PRB) or a ZSI 375 device with 90-100 cmH_2O pressure-regulating tank (PRT), with proven urodynamic stress urinary incontinence (SUI) after radical prostatectomy (RP), radiotherapy (RT), trans-urethral resection of the prostate (TURP), radical cystectomy (RC), or other causes of stress incontinence.

All patients included in the study had severe incontinence (≥4 pads per day) with failure of other treatments for

Fig. 1 - Artificial urinary sphincter ZSI 375.

a minimum of six months before artificial sphincter implantation. Activation of the artificial sphincter was performed six to eight weeks after implantation. The main exclusion criteria for the investigation were erosion of the urethra, detrusor over-activity and urinary tract infection.

Standard urodynamic equipment (Laborie Delphis) and air sensor 7 Fr (air charged dual sensor catheter) were used to perform the urodynamic test. Urinalysis and culture was required for every patient before the urodynamic test. The patients were placed in semi-seated positions to avoid any over pressure in the pelvis.

Bladder was filled via a urethral catheter by using sterile saline solution at room temperature at a fill rate of 50 mL/min. We waited for the cuff of the artificial sphincter to be closed then we registered the vesical pressure (VP), urethral functional length (FL), MUP, and MUCP. After opening of the cuff, we registered the maximal urinary flow rate (Q_{max}).

Results

From March 2012 to September 2014, we recruited 27 male patients with an AMS 800 device and 28 male patients with a ZSI 375 device into the study. All patients presented a social continence (0 to 1 pad per day). Mean age was 77 years (range 53-88 years) in the AMS 800 group. Causes were 20 RP, 2 RP + RT, 4 TURP, 1 ISD after several spinal infiltrations (Tab. I). AMS 800 devices were implanted with perineal approach; cuff size was 4 cm in 16 patients, 4.5 cm in 8 patients, 5 cm in 3 patients.

The 27 patients received the 61-70 cmH_2O PRB. Mean delay for urodynamic test was 46.96 months (6-84 months) after AMS 800 device insertion.

Mean age of ZSI 375 group was 67 years (range 53-86). Causes for severe incontinence before AUS insertion were 21 RP, 6 TURP, 1 RC. The ZSI 375 devices were implanted with perineal approach. Cuffs were adjustable, the operating pressure was 90-100 cmH_2O. Mean delay for urodynamic test was 22 months (6-36 months) after ZSI 375 device insertion.

TABLE I - Causes for severe USI

Causes	AMS 800 n = 27	ZSI 375 n = 28
RP	20	21
RP + RT	2	0
TURP	4	6
RC	0	1
Other	1	0

n = number of patients; RC = radical cystectomy; RP = radical prostatectomy; RP + RT = radical prostatectomy + radiotherapy; TURP = trans-urethral resection of prostate; USI = urodynamic stress incontinence.

Result of urodynamic tests (Tab. II). In the AMS 800 group the mean VP was 25.03 cmH_2O (range 13-47), mean FL 31.96 mm (range 20-52), mean MUCP 88.29 cmH_2O (range 32-160), mean MUP 119.55 cmH_2O (range 77-180), mean Q_{max} 22.86 mL/s (range 5.6-54.6), micturition volumes were over 100 mL, and no patient presented a residual volume in the bladder >30 mL. There was no correlation between high MUP, dysuria and low Q_{max}. In the ZSI 375 group, mean VP was 24.89 cmH_2O (range 6-40), mean FL 30.53 mm (range 12-87), mean MUCP 70.11 cmH_2O (range 38-108), mean MUP 99.89 cmH_2O (range 63-134). Mean Q_{max} 19.25 mL/s range (7.3-39.6), micturition volumes were over 100 mL and no patient presented a residual volume in the bladder >30 mL.

There was no correlation between high MUP and low Q_{max}.

Discussion

There have been few studies about MUP and MUPC when an AUS is implanted and activated (9, 10). For many years we have been informed that a good pressure to reach continence is 61-70 cmH_2O (4) and operating pressure over 70 cmH_2O is dangerous for the urethra leading to potential erosion (11). Debruyne et al (10) described lower pressure than expected, but the study included females and children with the cuff placed around the bladder neck. Barrett and Furlow (12) have indicated that they prefer the 50-60 cmH_2O AMS PRB, and achieved excellent continence rates with relatively low pressure. But Lowe et al (9) confessed they were rarely able to achieve their "continence zone urethral closure pressure" during surgery with this balloon and rarely implanted it. In Lowe et al, the urethral closure pressure (UCP) was the pressure required allowing free flow of gas (carbon dioxide) to go into the bladder with cuff closed. In their series, 15/21 patients were dry, with 3/15 patients needing UPC of 65 cmH_2O, 4/15 patients presented a UCP of 75 cmH_2O and 7/15 patients a UCP ≥85 cmH_2O. In this last group mean UCP was 91.86 cmH_2O (85-110).

Some doubts arise about the real operating pressure in the cuff when an AMS 800 61-70 cmH_2O PRB is implanted. Furthermore, we usually observed a recurrent incontinence after AMS 800 PRB 61-70 cmH_2O is out of the pelvis, expelled through the inguinal ring. To the contrary, continence reappears after re-implanting the same PRB into the pelvis.

TABLE II - Urodynamic test results

Urodynamic test	AMS 800	ZSI 375
Vesical pressure (VP)	25.03 cmH_2O (13-47)	24.89 cmH_2O (6-40)
Functional length (FL)	31.96 mm (20-52)	30.53 mm (12-87)
MUCP	88.29 cmH_2O (32-160)	70.11 cmH_2O (39-108)
MUP	119.55 cmH_2O (77-180)	99.89 cmH_2O (63-134)
Q_{max}	22.86 ml/s (5.6-54.6)	19.25 ml/s (7.3-39.6)

MUCP = maximal urethral closure pressure; MUP = maximal urethral pressure; Q_{max} = maximal urinary flow rate.

Another interesting observation regarding the ZSI 375 device first version. Provided with an operating pressure of 60-70 cmH_2O and 70-80 cmH_2O, the pressure had to be increased to 90-100 cmH_2O to reach continence (5). Finally, AUS ZSI 375 and AMS 800 have a different operating pressure in vitro, before implantation. After implantation in 55 patients and social continence reached, results of urodynamic tests (VP, FL, MUCP, MUP and Q_{max}) are similar for both artificial sphincters. In our series, mean MUP was 119.55 cmH_2O for patients implanted with AMS 800 and 61-70 cmH_2O RPB. All 27 patients (100%) presented an MUP >70 cmH_2O and 22/27 patients (81.48%) presented an MUP ≥90 cmH_2O. AMS 800 cuff pressure could be explained by the position of the PRB into the pelvis.

The balloon has to endorse pelvis pressure. The difference of altitude between the PRB and the cuff corresponds to a pressure of 10 to 20 cmH_2O (centimetre of water pressure may be defined as the pressure exerted by a column of water of 1 cm in height at 4°C - temperature of maximum density - at the standard acceleration of gravity). We could approach the AMS 800 cuff operating pressure with: PRB in vitro + pressure in the pelvis + difference of altitude.

The ZSI 375 PRT is not under the pressure of the pelvis and the PRT and the cuff are at the same altitude. This high MUP could be an explanation for more than 35 years of urethral erosion in patients who were supposed to have an AUS with an operating pressure of 61-70 cmH_2O.

The problem of the very strong pressure: addition of the PRB (61-70 cmH_2O) + pelvis pressure (0-30 cmH_2O) + difference of altitude between the PRB and the cuff (10-20 cmH_2O) does not explain strong pressure of 140,160 and 180 cmH_2O with AMS 800 device implanted. Other factors are missing. Lowe et al (9) wrote that a *"urethral cuff may be only slightly snug on the urethra and may give a high urethral closing pressure sometimes well over 100 cmH_2O. Additionally a cuff can be slightly too large and the pressure transmitted to the urethra too low".* AMS 800 cuff can be too tighten should the surgeon doesn't add 5 mm to the measure. Additionally, one patient implanted with ZSI 375 presented an MUP of 130 cmH_2O. This particular patient underwent a revision with a re-tightening of the ZSI 375 adjustable cuff without any increasing of the pressure to improve his continence status. Very high MUP could be explained by a too tightened cuff around urethra, without disturbance of the flow rate regarding the good flow rate of these patients.

There were several limitations in the design and outcome analysis of this study that could be improved by future studies. The study was retrospective, and would benefit from a prospective, randomised trial evaluating the same outcomes. We did not include self-administered questionnaires to evaluate quality of life. Urodynamic tests were performed with sensor catheter through the urethra and the cuff. A new study should be done to study the factors contributing to very strong pressure.

Conclusion

Our study showed that AMS 800 PRB of 61-70 cmH_2O does not guarantee a similar operating pressure into the cuff. Pressure of the pelvis and difference of altitude between the balloon and the cuff can increase the cuff operating pressure leading to high MUP. The MUP, MUCP, FL and Q_{max} of AMS 800 (61-70 cmH_2O) and ZSI 375 (90-100 cmH_2O) are similar. For very strong pressure, a new study must be done exploring other factors that have an influence on pressure.

References

1. Montague DK, Angermeir KW, Paolone DR. Long term continence and patient satisfaction after artificial sphincter implantation for urinary incontinence after prostatectomy. J Urol 2001;166(2):547-549.
2. Trigo Rocha F, Gomes C, Mitre A, et al. A prospective study evaluating the efficacy of artificial sphincter AMS 800 for the treatment of post-radical prostatectomy urinary incontinence and the correlation between preoperative urodynamic and surgical outcomes. Urology. 2008;71(1):85-89.
3. Scott FB, Bradley WE, Timm GW. Treatment of urinary incontinence by an implantable prosthetic urinary sphincter. J Urol. 1974;167:1125-1129.
4. Gnessin E, Livne PM, Baniel J, Gillon G. Continence and quality of the life assessment after artificial urinary sphincter implantation. ISR Med Assoc J. 2004;6(10):592-594.
5. Staerman F, Llorens C, Leon G, et al. ZSI 375 artificial urinary sphincter for male incontinence: a preliminary study. BJUI. 2013;111(4 Pt B):E202-206.
6. Llorens C, Pottek T, urinary artificial sphincter ZSI 375 for treatment of stress urinary incontinence in men: 5 and 7 years follow-up report. Urologia. 2017 May 18. doi: 10.5301/uj.500243. [Epub ahead of print].
7. Ostrowski I, Blewniewski M, Neugart F et al Multicentre experience with ZSI 375 artificial urinary sphincter for the

treatment of stress urinary incontinence in men, Urologia. 2017;84(3):148-52.
8. Carvajal A, Gavira F, Gutiérrez A, et al, Efficacy of the artificial urinary sphincter ZSI 375 for treatment of post-radical prostatectomy incontinence in patient with intrinsic sphincter deficiency: a preliminary study. EMJ. 2017;2(2):22-26.
9. Lowe DH, Scherz HC, Parsons CL. Urethral pressure profilometry in Scott artificial urinary sphincter. Urology. 1988;31(1): 82-85.
10. Kil P, de Vries J, Van Kerrebroeck P, Debruyne FMJ. Factors determining the outcome following implantation of the AMS 800 artificial urinary sphincter. BJU. 1989;64(6):586-589.
11. Knight S, Susser J, Greenwell T, et al. A new artificial urinary sphincter with conditional occlusion for stress urinary incontinence: preliminary clinical results. Eur Urol. 2006;50(3): 574-580.
12. Barrett DM, Furlow WL. Radical prostatectomy and the AS 791 artificial sphincter. J Urol. 1983;129(3):528-530.