

EFFICACY AND SAFETY OF A NEW ADJUSTABLE ARTIFICIAL URINARY SPHINCTER (AROYO™) FOR THE TREATMENT OF MALE STRESS URINARY INCONTINENCE: RELIEF I STUDY WITH 12 MONTHS FOLLOW-UP

Hypothesis / aims of study

The AMS 800™ is the gold standard for the treatment of moderate-to-severe stress urinary incontinence (SUI), especially in men after radical prostatectomy (RP) or transurethral resection of the prostate (TURP). The concept of circular compression of the urethra to restore continence has stood the test of time but, the AMS 800™ has several disadvantages. These are, besides others: no possibility to change the intra-device pressure postoperatively unless the entire balloon is replaced in a second operation; need to connect all components of the AMS 800™ during the operation, thereby increasing the operation time significantly; difficulties to use the pump because of the small size and mobility in the tissue; difficult procedure to deactivate or activate the device; no possibility of increasing the intra-device pressure during maneuvers with high intraabdominal pressure [1]. Thus, a new artificial urinary sphincter system was necessary to overcome these disadvantages and to provide optimal treatment for men suffering from SUI. Consequently, the AROYO™ device has been developed. AROYO™ offers the following advantages compared to the AMS 800™: all components are pre-connected leading to a simpler and faster implantation, possibility to incrementally increase the urethral occlusive pressure post-operatively by adding fluid to the system to further reduce urinary leakage according to the individual needs of the patient, a simplified, easier to operate ON-OFF mechanism for use only with one hand, and a secondary mechanism to temporarily increase the urethral occlusive pressure during stressful events, such as sneezing or coughing.

The aims of this pilot study were to evaluate the efficacy and safety of the new adjustable AROYO™ device for the treatment of male SUI.

Study design, materials and methods

RELIEF I was a prospective, single arm, feasibility study that was performed in 10 men with SUI after RP or TURP in two centers between April 2013 and January 2015. Patients were suitable for the study when they were ≥ 21 years of age, had SUI for a minimum duration of 12 months after RP or TURP, had conservative treatment of SUI for ≥ 6 months, demonstrated primary SUI in multichannel urodynamics, and had urinary leakage of ≥ 50 g (1-hour pad-test) or ≥ 100 g (in three consecutive 24-hour pad-tests). Main exclusion criteria were simultaneous participation in other trials, planned surgeries 3 month before and after sphincter implantation, primary urgency incontinence or mixed incontinence with a predominant urgency incontinence component, neurogenic bladder dysfunction, bladder outlet obstruction, bladder low compliance, previous sphincter implantations, radiotherapy of the pelvis, abnormal PSA values, urinary tract infection, postvoid residuals ≥ 100 ml or $\geq 25\%$ of bladder capacity, need for (intermittent) catheterization, or known allergy to silicone, nickel or titanium. All patients signed informed consent [2]. Devices were allowed to be implanted via the perineal or peno-scrotal approach with proximal cuff placement. The device remained deactivated (OFF mode) for 6 weeks and was activated in the implantation center. All patients were followed-up at month 1, 3, 6 and 12 after device activation. Re-pressurization of the AROYO™ device was allowed at any time after activation. The primary study endpoint was the change in 24-hour pad weight from device activation to month 3. Secondary endpoints were changes in the 1-hour pad weight test, number of incontinent episodes per day, average number of pads per day, questionnaire scores (QoL, ICIQ, ICIQ-MLUTS, IIEF), subject opinion on ease of device use, summary of subject diary on the use of manual compression feature and surgical parameters. All data were collected and summarized at month 3, 6 and 12 after device activation. The primary safety endpoint was the occurrence of any major device-related complications at month 3 post-device activation as reported by the investigational site. The components of this composite safety endpoint were device extrusion, device migration, device-related infection requiring i.v. antibiotics, device-related re-hospitalization, device revision due to device malfunction, erosion in any tissue other than the urethra, infection requiring revision, urethral erosion, or urethral obstruction. In this abstract, we report only details of the patient population, implantation, incontinence follow-up, and adverse events.

Results

In total, 9 men after RP and 1 man after TURP with a mean age of 68.8 ± 4.7 years and a mean body-mass index of 26.9 ± 1.8 kg/m² participated in the study. Mean duration of SUI before implantation was 1.9 ± 0.9 years, and all men used pads. All patients were operated in general anesthesia and implanted by the peno-scrotal approach. Mean implantation time (from insertion of the transurethral catheter to final stitch) was 80 minutes, with a relevant reduction of the last procedures (first two procedures 105-117 min vs. last two procedures 60-70 min). Mean estimated blood loss during the implantation was 16.5 ± 18.6 ml. Of the ten patients enrolled in the study, nine men (90%) completed the 12 month follow-up visit. One man was explanted 3 weeks after device implantation and before activation due to procedure-related urethral injury. One device malfunction was observed in one man who remained enrolled in the study and was follow-up according to the protocol until month 12. Mean follow-up was 424.4 ± 136.3 days.

Two patient populations were defined for the purpose of elucidating a practical sense of device performance, an Intent-to-Treat (ITT) population, which includes nine of ten enrolled patients (the patient explanted for a procedure related SAE was excluded), and a Per-Protocol (PP) population, which includes seven of ten enrolled patients (exclusions include 1 patient with the procedure-related serious AE, 1 patient with a device malfunction, and 1 patient with an incorrect 24-hour baseline pad weight measurement). Results of the ITT- and PP-study populations (compared to baseline) were as followed (numbers in mean \pm standard deviation):

ITT-population			
	Month 3	Month 6	Month 12
Change of pad weight in 24-h pad test [g]	-521 ± 553	-507 ± 573	-547 ± 487
Change of pad number in 24-h pad test [n]	-1.9 ± 1.5	-2.0 ± 2.3	-2.6 ± 2.2
Change of 24-h pad weight [%]	-23.3 ± 110.7	-25.2 ± 88.9	-61 ± 41.9
Success rate ≥50% reduction [%]	62.5	55.6	66.7
Success rate ≥60% reduction [%]	50	55.6	55.6
PP-population			
Change of pad weight in 24-h pad test [g]	-613 ± 528	-691 ± 506	-675 ± 480
Change of pad number in 24-h pad test [n]	-1.9 ± 1.6	-2.7 ± 1.9	2.7 ± 2.3
Change of 24-h pad weight [%]	-29.2 ± 118.2	-55.4 ± 64.3	-68.1 ± 44.3
Success rate ≥50% reduction [%]	71.4	71.4	71.4
Success rate ≥60% reduction [%]	57.1	71.4	71.4

In total, 3 adverse events occurred in 3 patients during the study of which 2 were classified as serious adverse events: 1 patient had urethral injury during the implantation and was explanted approx. 6 weeks after the implantation and 1 patient developed an ischemic stroke which was unrelated to the AROYO™ device. The remaining patient had a device malfunction due to malfunction of the ON-OFF device; despite the inability to use the control assembly, this patient is still satisfied with the result of the operation and opted for study continuation.

Interpretation of results

This feasibility study showed that the new AROYO™ sphincter for the treatment of post-prostatectomy SUI was implanted quickly, showed acceptable efficacy, and a low complication rate. However, the standardized re-pressurization procedure recommending intra-device pressures between 80 and 130 cm H₂O was only derived at the 6 month follow-up point of the study. Therefore, a further reduction in pad weight and incontinence is likely. A larger study investigating more patients has to be conducted to confirm the results of this feasibility study.

Concluding message

The new adjustable artificial urinary sphincter AROYO™ has proven to be effective and safe in the treatment of male SUI with a follow up of 12 months.

References

1. Trost, LE, Daniel S. Male Stress Urinary Incontinence: A Review of Surgical Treatment Options and Outcomes. Adv Urol. 2012; 2102: 287.
2. Lai HH, Hsu EI, Boone TB. Urodynamic testing in evaluation of postradical prostatectomy incontinence before artificial urinary sphincter implantation. Urology. 2009;73(6):1264–1269.

Disclosures

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