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EFFICACY AND SAFETY OF A NEW ADJUSTABLE ARTIFICIAL URINARY SPHINCTER (AROYO®) FOR THE TREATMENT OF MALE STRESS URINARY INCONTINENCE: PRELIMINARY 3 AND 6 MONTH FOLLOW-UP RESULTS OF THE RELIEF II STUDY

Hypothesis / aims of study

The Aroyo® Artificial Urinary Sphincter (Aroyo® AUS) was developed as a result of the disadvantages of the AMS 800®, the standard AUS for the treatment of male stress urinary incontinence (SUI). Continued or recurrent SUI after AMS 800® implantation requires surgical removal and replacement of the pressure regulating balloon or down-sizing of the urethral cuff. During AMS 800® implantation, the tubes of the cuff and ballon have to be connected with the tubes of the control pump which requires significantly greater operative time and special equipment. Tube disconnections may appear in the early or late follow-up period. Additinally, the pump may be difficult to operate for the patient due to its small size and surrounding tissue mobility. The Aroyo® AUS has been developed to overcome these disadvantage and offers the following advantages over currently available AUS systems:

- pre-connected components eliminating tubing disconnections and reducing surgical time
- a 'one-size-fits-all' adjustable urethral cuff for urethral circumferences of 3.5–6.0 cm
- 'One Touch' open–close buttons designed to ease patient operation and simple use for nocturnal deactivation
- a mechanism allowing 'On Demand' occlusive pressure increases to counter SUI
- quantifiable, post-implant adjustment of the intra-device pressure for safe and effective personalized continence outcomes

The aims of this study are to evaluate the efficacy and safety of the new adjustable Aroyo® AUS for the treatment of male SUI. Preliminary 3 and 6-month results are reported here. A full report of results will follow the completion of the ongoing RELIEF II study.

Study design, materials and methods

RELIEF II is a prospective, single arm, multi-center, multi-national study to treat SUI after radical prostatectomy (RP) or transurethral resection of the prostate (TURP) in 14 centers with a total enrollment goal of 82 men. Patients are suitable for the study when they are aged ≥21 years, have SUI >6 months after RP or TURP, had conservative treatment of SUI for ≥6 months, demonstrate SUI in multichannel urodynamics, have urinary leakage of ≥300 g (24-hour pad-test) and post-void residuals <50 ml at baseline. Main exclusion criteria are simultaneous participation in other trials, planned surgeries 3 month before or after AUS implantation, primary urgency incontinence or mixed incontinence with a predominant urgency incontinence component, neurogenic bladder dysfunction, bladder outlet obstruction, previous AUS implantations, abnormal PSA values, urinary tract infection, need for (intermittent) catheterization, or known allergy to silicone or stainless steel. All patients signed informed consent. Subjects who have received previous radiation therapy of the prostatic fossa will account for no more than 60% of the total subject population or no more than 49 subjects for the entire study. Ethics approval was obtained before the start of the study.

Study participants were preoperatively treated with i.v. antibiotics for one day, shaved in the operation room, and disinfected with alcohol solution for ~10 min. Patients received a transurethral catheter at the beginning of the operation. Devices were allowed to be implanted via the perineal or peno-scrotal approach with cuff placement at the bulbous urethra. Removal of the transurethral catheter was based on the decision of the surgeon and oral antibiotic treatment was continued until day 5. The device remained deactivated (OPEN mode) for 6 weeks and was activated in the investigator's clinic. All patients are being followed-up at months 1, 3, 6 and 12 after device activation. Re-pressurization of the Aroyo® AUS device is allowed at any time after activation.

The primary study endpoint is the change in 24-hour pad weight from pre-implant screening to month 3 after activation. Secondary endpoints examined 24-hour pad weight changes at 6 and 12-months, changes in the 1-hour pad weight test, average number of pads per day, and questionnaire scores (IQoL, ICIQ, ICIQ-MLUTS, IIEF). Primary safety endpoint is occurrence of major device-related complications at month 3 post-device activation. The components of this composite safety endpoint are device extrusion, device migration, and device-related infection requiring i.v. antibiotics, device-related re-hospitalization, device revision due to device malfunction, erosion, infection requiring revision, urethral atrophy, device repositioning, revision and removal. In this abstract, we report only the early details of the patient population, implantation, incontinence follow-up, and adverse events.

Following implantation, further decreases in urinary leakage were accomplished by percutaneous saline injection into the Aroyo® AUS via an injection port located on the scrotal control unit. A kit including a disposable pressure monitor, non-coring needle, syringe, infusion tube and stopcock is supplied. A pressure range of 80-130 cm H_2O within the Aroyo® AUS was earlier identified as providing favorable reductions in 24-hour pad weights.

Results

In total, 48 men have so far participated in the study with 15 having passed the 3-month follow-up primary endpoint and 12 having passed the 6-month follow-up. All patients were operated under general anesthesia and implanted by either the peno-scrotal or perineal approach. Anecdotal reports indicate that the peno-scrotal approach offers the greatest ease of implantation, tubing

placement and pain reduction as compared to the perineal approach. 24-hour pad weight test reduction and number of pads per day for those patients completing 3 and 6-month follow-ups are reported below (**table**). Average intra-device pressures of 84 cm H_2O (±17 cm H_2O) at 3-months and 112 cm H_2O (±23 cm H_2O) at 6-months were recorded. Further analysis supports the hypothesis that an intra-device pressure ≥80 cm H_2O provides a ≥80% improvement in 24-hour pad weight reduction.

RELIEF II: 24-hour Pad Weight Reduction and Pad Usage					
	24-hour pad weight		**Pads Used per Day**		
	3-months	6-months	Screening	3-months	6-months
Subjects	15	12	15	15	12
Average	-80%	-84%	7	2.8	2.8
SD (±)	15%	18.3%	1	1.2	1.1
Range	-42% to -97%	-40% to -108%	4 – 7.5	1 – 6	1 – 4

To date, 7 serious adverse events (SAE) have been identified: 1 explantation for surgical damage to device, 1 explantation for scrotal fistula, 2 explantations for urethral erosion (both <30 days post-implant with 1 occurring in a patient with previous urethrolasty), 1 explantation for device infection, and 2 revisions to correct the position of the control device in the scrotum.

Interpretation of results

Preliminary results of the Relief II study support results achieved in the Relief I study. Procedural data demonstrates that the new Aroyo® AUS sphincter for the treatment of SUI has an acceptable efficacy and acceptably low complication rate. The 15% SAE rate compares to an SAE range of 5–53% for revision and explantation reported for the AMS 800® AUS in the scientific literature. Quantifiable pressure adjustment is an effective method by which patient continence may be customized. Further improvement of patient continence is expected with close attention paid to the careful pressure adjustment procedure. A full reporting of results will be made at the completion of RELIEF II.

Concluding message

Early results of the Relief II study show that the Aroyo® AUS can be easily implanted with device activation and post-operative adjustment of internal cuff pressure being simple and effective. Preliminary results from this study confirm that the Aroyo® AUS is a promising alternative to the current surgical management of male SUI.

Disclosures

Funding: Funded by sponsor (GT Urological) **Clinical Trial:** Yes **Registration Number:** clinicaltrials.gov NCT02288455 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Thomayer University, Prague, Czech Republic Bellberry Human Research Ethics Committee, NSW, Australia University of Wollongong Human Research Ethics Committee The University Hospital Ostrava, Ethics Committee of FN Ostrava, Czech Republic **Helsinki:** Yes **Informed Consent:** Yes