METHODS: A retrospective study was performed of men undergoing self UBD from 1/2011 to 6/2019. Patients with no follow-up in the clinic and those who performed UBD only a single time were excluded. Comorbidities, stricture details, need for subsequent intervention, and frequency of annual UTIs were collected. All patients were started on daily self UBD and frequency was titrated to the lowest necessary frequency. Descriptive statistics are reported.

RESULTS: Forty six patients were identified with median (range) follow-up of 45.5 (2-94) months. Mean (SD) age at the start of dilations was 67.8 (10.6), and mean (SD) BMI was 32.7 (6.1). Twenty-two (47.8%) had a history of radiation treatment, 9 (19.6%) had a history of prostatectomy, 11 (23.9%) had a history of prior urethroplasty, and 45 (97.8%) reported prior endoscopic intervention in the form of dilation or DVIU. The site of stricture was bladder neck contracture in 15 (32.6%), membranous in 10 (21.7%), bulbar in 11 (23.9%), panurethral in 8 (17.4%), and fossa in 2 (4.3%). At most recent follow-up, 15 (32.6%) performed UBD daily, 3 (6.5%) performed UBD 2-3 times a week, 6 (13.0%) performed UBD weekly, 4 (8.7%) performed UBD every 2-4 weeks, and unknown in one. Seventeen (37.0%) no longer performed UBD, of which nine (52.9%) no longer required intervention for the stricture, three opted to have SP tube placed, two underwent urinary diversion, two have chronic catheters due to being moved to nursing facilities, and one is scheduled for definitive urethroplasty. Eleven (23.9%) patients failed UBD and required a definitive intervention. Transient urethrorrhagia was reported by 14 (30.4%) patients. Thirty seven (80.4%) patients reported 0-1 UTIs per year, 6 (13.0%) reported 2-3 per year, and 3 (6.5%) reported $>$ 3 annual UTIs. No patients required hospitalization for complications related to the UBD or secondary to infections.

CONCLUSIONS: Self urethral balloon dilation offers patients with complex strictures, particularly those with a history of radiation, an opportunity to avoid surgical intervention which can be associated with many adverse effects. Risks are low and include infection, mild urethrorrhagia, and need for further intervention.

Source of Funding: None

MP56-06

THE OPTILUME DRUG COATED BALLOON FOR RECURRENT ANTERIOR URETHRAL STRICTURES: 3-YEAR RESULTS FROM THE ROBUST I STUDY

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INTRODUCTION AND OBJECTIVE: Mechanical dilation and direct visualization internal urethrotomy (DVIU) are the most widely utilized treatments for urethral stricture disease, but recurrence rates are high after re-treatment. This single arm study investigates the safety and efficacy of the Optilume® paclitaxel drug-coated balloon (DCB) for the treatment of recurrent anterior strictures.

METHODS: Ethics committee approval was gained prior to enrollment commencing. Men with recurrent bulbar strictures $\leq$ 2cm with 1-4 prior endoscopic treatments were treated with the DCB. Patients have been followed at 3 months, 6 months, and annually through 3 years. The primary safety endpoint was serious urinary adverse events. The primary efficacy endpoint was the proportion of subjects with $\geq$ 50% improvement in International Prostate Symptom Score (IPSS) at 3 years. Subjects receiving secondary treatment were treated as failures for this endpoint. Secondary outcomes included quality of life, freedom from repeat intervention, erectile function, flow rate, and post-void residual urine volume.

RESULTS: A total of 53 subjects were enrolled and treated; 43 were evaluable at the 3-year follow-up for the primary endpoint. 43% of men had undergone $\geq$2 previous dilations, with a mean of 1.7 prior dilations. There were no serious adverse events related to treatment at 3 years. Success was achieved in 29/43 (67%), which is consistent with 2-year results. IPSS improved from a mean of 25.2 at baseline to 5.5 at 3 years ($p < 0.001$). Freedom from repeat intervention of the study stricture was 33/43 (77%). Quality of life, flow rate, and post-void residual urine volumes improved significantly from baseline. There was no impact on erectile function.

CONCLUSIONS: Subjects with recurrent bulbar strictures treated with Optilume® DCB exhibited significant improvement in symptomatic and functional outcomes through 3 years post treatment. The rate of success is consistent with reported 2-year outcomes. Long-term follow-up will continue through 5 years in the ROBUST I study and a randomized study is ongoing.

Source of Funding: Urotronic; the maker of the device

MP56-07

INTERIM RESULTS FOR THE ROBUST III TRIAL EVALUATING THE OPTILUME DRUG COATED BALLOON FOR ANTERIOR URETHRAL STRICTURES

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INTRODUCTION AND OBJECTIVE: Endoscopic management of anterior strictures includes dilation or direct visualization internal urethrotomy (DVIU). Multiple treatments lead to progressively worse outcomes. The Optilume® Drug Coated Balloon (DCB) is a dilation balloon with a paclitaxel coating that combines mechanical dilation with local drug delivery to maintain urethral patency. The ROBUST III study is a randomized, single blind trial evaluating the safety and efficacy of the Optilume DCB against endoscopic management of recurrent anterior urethral strictures.

METHODS: 127 subjects were enrolled at 23 sites. Men who were randomized to endoscopic management received dilation and/or DVIU based on surgeon preference. Key eligibility criteria included anterior strictures with $\geq$2 prior treatments and a length $\leq$3cm. Subjects with previous urethroplasty or unresolved confounding etiologies were excluded. The primary endpoint was the proportion of subjects that were stricture free at 6 months, measured by the ability to pass a 16Fr flexible cystoscope. Key secondary endpoints included freedom from repeat treatment, International Prostatic Symptom Score (IPSS), and peak flow rate (Qmax). The primary safety endpoint included freedom from serious device or procedure related complications.

RESULTS: Baseline characteristics were similar between groups, with subjects having an average of 3.6 prior treatments and average length of 1.7cm. Primary 6 month follow up is complete and one year follow up is ongoing. Stricture free rate for Optilume DCB was significantly higher than Control at 6 months (76% vs 27%, $p<0.001$). Outcomes were consistent among subgroups with $\geq$5 vs $<$5 dilations and for lengths $<$2cm vs $\geq$2cm. Freedom from repeat intervention was significantly higher in the Optilume DCB arm. Immediate symptom improvement was significant in both groups, with the benefit being more durable in the Optilume DCB group. Improvement in Qmax showed a similar trend. No subjects experienced a serious device related complication. The most frequently adverse events included common events such as urinary tract infection, post-procedural hematuria, and dysuria.

CONCLUSIONS: The DCB group had a significant improvement in both objective and subjective outcomes compared to endoscopic management through 1-year post treatment. Long term follow-up is planned through 5 years to further define the durability of the results.

Source of Funding: Urotronic; the maker of the Optilume DCB