new transurethral therapy in patients with moderate to severe symptoms.

METHODS: This is the first prospective study of Rezum cases performed in the UK with follow-up planned to 12 months. 181 patients were included, of whom 16 had retention of urine. Prostate volumes ranged between 20-121mls, and patients with an obstructing median lobe were included. Pre- and post-procedure assessments included the validated IPPS questionnaire with quality of life (QoL), urinary flow rate (Qmax), prostate volume and trial without catheter success. Complications were classified using the Clavien-Dindo grading system.

RESULTS: 50 of 181 procedures were performed under general or regional anaesthetic with the remainder under local anaesthetic with sedation. A mean of 5.8 steam injections were delivered to the prostate; 123 patients had a median lobe treatment. Mean operative time was 17.5 minutes. Mean IPPS was significantly improved (-14.9 points, p<.0001) at 3 months as was QoL. QMax improved by 3.8mL/s as early as 4 weeks and 6.5 mL/s at 3 months. These results were maintained at 6 and 12 months. Overall prostate volume was reduced by 35% by 3-6 months post-operatively, p<.001. After first trial without catheter, 132 patients were free of an indwelling catheter and 7 patients remained catheter dependent at 3 months. There were 11 early post-procedure events: 8 patients had a urinary tract infection requiring antibiotics (grade 2), one of whom required HDU admission (grade 4a) and 3 patients returned to theatre for either secondary haemorrhage or for resection of infected prostate tissue (grade 3b).

There were 2 patients who required further surgery for ongoing LUTS following their review at 6 months.

CONCLUSIONS: Results of this UK experience with the Rezum minimally invasive procedure confirms an early response to treatment with significant relief of LUTS and low morbidity. It is applicable to treatment of patients with an enlarged median lobe and can be performed reliably as a day case procedure. Longer term follow-up will include treatment durability, comparison of outcomes to standard BPH treatments and the assessment of cost-effectiveness.

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THE RESULTS OF ONE ARM MULTICENTER PROSPECTIVE STUDY ON AN INNOVATIVE MINIMALLY INVASIVE SURGICAL TECHNIQUE FOR LUTS MANAGEMENT: THE SECOND GENERATION TEMPORARY IMPLANTABLE NITINOL DEVICE (i-TIND) MEDITATE®

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INTRODUCTION AND OBJECTIVES: A new, minimally invasive, surgical technique to treat benign prostatic hyperplasia (BPH) symptoms is represented by the Temporary Implantable Nitinol Device (TIND-Meditate). We present the results of a one-arm, multi-center, international prospective study to define the efficacy of second generation of MediTate i-TIND in subjects with BPH.

METHODS: The i-TIND is composed of three nitinol elongated struts and an anchoring leaflet. It is preloaded by crimping it into the delivery system. When positioned, the struts of expand and determine a radial force with ischemic necrosis and incision of bladder neck and prostatic urethra. The inclusion criteria were: IPPS > 10; peak urinary flow (Qmax) < 12 mL/sec and prostate volume < 75 cc. All patients stopped alpha-blockers and 5alpha-reductase inhibitors before the implantation. The procedure was performed using a rigid 17F cystoscope, under light sedation. 5 days after the implantation the device was removed, without anesthesia. We evaluated demographic, perioperative, functional results and quality of life (QoL) questionnaire. We reported the results at 3, 6 and 12 months.

RESULTS: The mean (SD) patient age was 65 (8.9) years, the mean (SD) prostate volume was 40.5 (12.25) mL, mean (SD) Qmax was 7.3 (±2.6) mL/sec, mean (SD) IPSS score was 22.5 (±5.6) and median (SD) IPSS QoL was 4 (2.5). No intraoperative complications were recorded. The devices were retrieved 5.9±1.1 days following implantation. No > grade 2 complications were recorded.

Mean Qmax at 1 month follow-up stood at 11.2±5.7 mL/sec and continued to improve thereafter, reaching 14.9±8.1 mL/sec at the 12 month follow-up visit (+100%). IPSS urinary symptom scores was 11.7±8.0 after 1 month and further improved to 8.8±6.4 at the 12th month follow-up (-60%). Mean QoL IPSS score drop reached 1.6±1.3 by the end of the study. During the 12 month period, 2 patients (2.4%) required medications for BPH, 2 patients (2.4%) required TURP. As compared to baseline, none of the 61 sexually active patients who completed the 1 year follow up period reported sexual or ejaculatory dysfunction.

CONCLUSIONS: More studies are necessary to define the durability of the results but second generation i-TIND implantation is a safe and effective minimally-invasive technique for the treatment of BPH related symptoms until one year follow up.

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