

$p=0.008$ ). After stage 2, mean daily UIIE reduction at 24 months was less for patients with an intra-op sensation response at electrode 3 (mean  $\pm$  SD =  $-2.5 \pm 2.2$ ,  $N=115$ ) than without ( $-5.0 \pm 3.2$ ,  $N=22$ ,  $p=0.005$ ). No intra-op variables predicted change in UIIE at 6 months.

**CONCLUSIONS:** Intraoperative data during stage 1 sacral neuromodulation show a limited ability to predict trial stimulation outcome, but were constrained by small sample size. Future research into optimal stimulus parameters is needed.

**Source of Funding:** NICHD PFDN

### **LBA01-05 SIMULATION IN UROLOGICAL TRAINING AND EDUCATION (SIMULATE): AN INTERNATIONAL RANDOMISED CONTROLLED CLINICAL AND EDUCATIONAL TRIAL TO DETERMINE THE EFFECT OF SIMULATION-BASED SURGICAL TRAINING**

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**INTRODUCTION:** With increasing challenges in modern surgical training, simulation has been hypothesised to enhance progression along the initial phase of the surgical learning curve. SIMULATE is the first international multicentre study investigating the effect and transferability of surgical simulation on operating performance and patient outcomes.

**METHODS:** This international, multicentre randomised controlled superiority trial recruited urology trainees ( $n=94$ ) who had performed  $\geq 10$  ureterorenoscopy (URS) cases, as a selected index procedure, with no prior simulation experience. Recruits were randomised to simulation-based training (SBT) or non-simulation-based training (NSBT) groups, the latter of which is the current standard of training. Training sessions were conducted for the SBT arm, utilising an expert-developed training curriculum. The primary outcome was the number of procedures required to achieve proficiency, defined as achieving an OSATS score of  $\geq 28$  on 3 consecutive operations, without complications. Secondary outcomes included number of surgical complications and stone-free status in each arm. All participants were followed up for 25 procedures or over 18 months.

**RESULTS:** A total of 65 participants continued follow-up from the SBT ( $n=32$ ) and NSBT ( $n=33$ ) arms, performing a total of 1140 procedures (593 vs 547). Proficiency was reached in 21 SBT and 18 NSBT participants (OR: 1.59 [95% CI 0.59-4.33]) over 9.6 and 10.9 sessions (HR: 1.41 [95% CI 0.72-2.75]), respectively. Sub-analysis for semi-rigid URS demonstrated proficiency in 19 SBT and 16 NSBT participants ( $p=0.38$ ) over 7.8 vs 9.9 sessions. In flexible URS, 20 SBT and 9 NSBT participants reached proficiency ( $p=0.04$ ) over 8.1 vs 7.3 sessions. The SBT group scored  $\geq 28$  (OSATS) in 310 (52.3%) cases in comparison to 234 (42.8%) in the NSBT group ( $p<0.0001$ ). In total, 15 vs 36 surgical complications were reported ( $p=0.15$ ), with fewer Grade  $\geq 3$  Clavien-Dindo seen in the SBT ( $n=3$ ) group compared to NSBT ( $n=9$ ). Fewer non-stone-free patients were observed ( $p=0.87$ ) in SBT ( $n=39$ ) than NSBT ( $n=50$ ).

**CONCLUSIONS:** There was no statistical significance in the overall number of procedures required to reach proficiency between the two groups. However, fewer complications, better clinical outcomes, and a higher number of participants reaching proficiency in flexible URS indicate a positive trend in favour of SBT and affirm the role of simulation training for more complex procedures; (ISCRN 12260261).

**Source of Funding:** The Urology Foundation

### **LBA01-06 FIVE YEAR RESULTS OF THE PROSPECTIVE, RANDOMIZED CONTROLLED TRIAL OF WATER VAPOR THERMAL THERAPY FOR TREATMENT OF LOWER URINARY TRACT SYMPTOMS DUE TO BENIGN PROSTATIC HYPERPLASIA**

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**INTRODUCTION:** We report the five-year results for the active treatment arm of the multicenter, randomized, controlled trial of water vapor thermal therapy in men with moderate-to-severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) with the inclusion of the final surgical and BPH medication retreatment rates.

**METHODS:** 197 subjects  $\geq 50$  years old with IPSS  $\geq 13$ , maximum flow rate (Qmax) 5-15 ml/s and prostate volume 30-80 cc were randomized 2:1 (thermal therapy Rezum System: sham control rigid cystoscopy). Thermal therapy involved injection of water vapor into obstructive tissue, possibly including the middle lobe and/or enlarged central zone. The primary outcome was change in IPSS; other outcomes assessed included changes in quality of life and Qmax. The study assessed each subject for retreatment of BPH after the index procedure. Subjects who received secondary surgical treatment for LUTS/BPH were included in the surgical retreatment results and subjects who initiated BPH medication (alpha-blocker, or 5-ARIs) were included in the medication retreatment results.

**RESULTS:** In the randomized comparison at 3 months, mean IPSS reduction from baseline was 11.2 and 4.3 pts for active ( $n=136$ ) and control ( $n=61$ ) subjects, (Rezum: Sham respectively)  $p<0.0001$ . Reduction in IPSS was sustained in the active treatment arm at five years, with a mean reduction from baseline of 10.4 points. The change from baseline in maximum urinary flow rate was 6.4 ml/sec at 3 months and 4.3 ml/sec at five years. Within the active treatment group, the surgical retreatment rate was 4.4%, while 11.1% of the treatment-arm subjects initiated BPH medication at 5 years. On a per subject basis, improvements of symptoms (50% IPSS), quality of life (46% IPSS-QOL, 46% BPH Impact Index) and flow rate (69% Qmax) occurring within  $\geq 3$  months were sustained to five years with improvements of 48%, 46%, 49%, and 49%, respectively ( $p<0.0001$ ).

**CONCLUSIONS:** Treatment-arm results show that the minimally invasive water vapor thermal therapy offers significant improvements in LUTS, QOL and flow rate sustained through 5 years.

**Source of Funding:** Boston Scientific Corporation

### **LBA01-07 PROSTATIC URETHRAL LIFT REAL-WORLD EXPERIENCE IS CONSISTENT WITH CONTROLLED TRIAL RESULTS IN BOTH NON-RETENTION AND RETENTION SUBJECTS**

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**INTRODUCTION:** Real world studies reflective of heterogeneous populations should serve as litmus tests for new technologies, including those within the minimally invasive field for BPH. To assess UroLift System performance in a real-world setting compared to experience in controlled settings, an analysis was conducted comparing the large, actively enrolling Real World Retrospective (RWR) study to the