BPH

BPH6 results will lift the spirits of men with LUTS secondary to BOO

The 12-month results of the BPH6 study have shown that prostatic urethral lift (PUL) is noninferior (and is possibly superior) to transurethral resection of the prostate (TURP) for treating lower urinary tract symptoms (LUTS) secondary to bladder outlet obstruction (BOO) caused by BPH.

Currently, TURP is the gold-standard treatment with regards to symptom relief and improved urinary flow; however, it is associated with considerable morbidity and long-term complications. PUL is a minimally invasive procedure that has been shown to have reduced morbidity whilst maintaining efficacy, and involves the placement of small, permanent Urolift® (Neotract, Inc., USA) implants. These implants comprise a nitinol capsular tab, a polyethylene terephthalate monofilament and a stainless steel urethral end piece. They are delivered to the obstruction under cystoscopic guidance and retract the encroaching lateral lobes of the prostate. Typically, multiple implants are placed to deobstruct the prostatic urethra.

This prospective, randomized-controlled, multicentre trial was conducted in three European countries. Men aged ≥ 50 years were randomly assigned 1:1 to receive either TURP or PUL. Eligibility criteria included an international prostate symptom score (IPSS) > 12 , peak flow rate ($Q_{\max}$) ≤ 15 s for a voided volume of 125 ml and a sexual health inventory for men score > 6 . Follow-up assessments were conducted at 2 weeks, 1 month, 3 months, 6 months and 12 months after the procedure.

The BPH6 primary end point comprised six elements to assess overall outcome, including LUTS relief, recovery experience, erectile and ejaculatory function, continence preservation and safety. Secondary analysis included comparison of IPSS, IPSS quality of life, BPH impact index, $Q_{\max}$, male sexual

health questionnaire for ejaculatory function and post void residual volume (PVR).

Overall, 80 men were enrolled in the study, 45 received PUL and 35 underwent TURP and the participants were well matched between groups. Patients who received PUL consistently had a more rapid recovery than those who had TURP, with 82% of PUL-treated patients achieving the BPH6 recovery end point by the 1 month follow-up assessment, compared with 53% of men in the TURP arm ($P = 0.008$). Significantly more TURP-treated patients required catheterization for > 24 h than men who underwent PUL (74% versus 45%, respectively, $P = 0.01$). PUL-treated men also had significantly fewer mean number of days to discharge and faster return to preoperative activity levels.

Patients who received TURP had better IPSS, $Q_{\max}$ and PVR results than PUL-treated patients, but erectile function was preserved in both treatment groups, with the majority of participants achieving the BPH6 erectile function responder end point. With regards to ejaculatory function, participants who underwent PUL showed an improvement in average ejaculatory score from baseline; however, men in the TURP arm experienced a significant decline ($P = 0.0001$). The BPH6 ejaculatory assessment showed that the

response of the men who received PUL was 100%, which was significantly better than the 60.6% response for the men treated with TURP ($P = 0.01$).

Preservation of continence was similar between treatment arms; however, none of the six PUL-treated patients who failed the BPH6 continence element required pads, whereas six of the eight TURP-treated patients did. Reintervention rates for failure to cure were similar between the two groups, but two patients in the TURP arm needed surgical intervention for adverse events, compared with none in the PUL arm. TURP-treated patients also experienced more treatment-related infections.

Overall, at each follow-up evaluation, responder rates in the PUL arm were significantly higher than rates in the TURP arm. The BPH6 primary end point was met by 52.3% of men who received PUL compared with 20.0% of those who underwent TURP, showing that PUL is noninferior to TURP ($P < 0.0001$) and indicating its superiority ($P = 0.005$).

This study is limited by the small sample size and the inability to blind patients to treatment. Durability of therapy would also be more fully assessed with a 2-year follow-up duration. However, the BPH6 study is the first randomized comparison of PUL and TURP. These results show that PUL is superior to TURP in terms of quality of recovery, preservation of ejaculatory function and the overall primary end point. The BPH6 study suggests that PUL is an improved minimally invasive treatment modality for men with LUTS secondary to BOO owing to BPH.

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