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The Importance of Treating the Median Lobe in BPH

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The role of the median lobe in benign prostatic hyperplasia (BPH) in relation to lower urinary tract symptoms (LUTS) may be underappreciated. The median lobe is located between the ejaculatory ducts and the urethra in the central zone of the prostate; the upper portion of the median lobe abuts the trigone of the bladder. Although median lobe enlargement (MLE) is seen in clinical practice, the prevalence of MLE among men with BPH is unknown. Instead, there is literature on intravesical prostatic protrusion (IPP), which arises when the median or lateral lobes grow into the bladder. The prevalence of severe IPP in men 40-70 has been seen in 10-42% of the population.[1,2]

Medical Therapy in BPH and IPP

There are numerous studies documenting poor response to medication in men with moderate to severe IPP. In a study by Park and colleagues, men with IPP > 10 mm did not respond as much to tamsulosin as those with IPP < 5 mm based on International Prostate Symptom Score (IPPS), IPPS irritative sub score, IPSS obstructive score, quality of life (QoL), Qmax, and post-void residual (PVR) urine.[2]

The updated AUA guidelines indicate that minimally invasive or surgical interventions may be considered as first-line treatment in select patients.[3] Although the AUA does not provide an exhaustive list of such clinical scenarios, the inadequate symptom relief of medication in patients with Trilobar IPP suggests that earlier intervention with minimally invasive or surgical therapy may be considered.

Surgical Treatment of an Obstructing Median Lobe

The importance of the median lobe in BPH is underscored by the effect of median-lobe-only transurethral resection of the prostate (TURP) on LUTS and ejaculation dysfunction (EjD) in men with bladder outlet obstruction (BOO) stemming from IPP. In one study, 312 men with LUTS (N=147) or urinary retention (N=175) and IPP $\geq$ 10 mm were treated with monopolar or bipolar TURP of the median lobe. At baseline, mean IPPS was 18.6, with an average IPP of 13.6 mm.[4]

Compared to baseline, significant improvement was maintained at five years, with mean IPSS of 8.9. There was improvement in EjD to 1.27, while MSHQ-EjD increased to 10.4. There was improvement in EjD while MSHQ-EjD increased. There was one instance of new onset erectile dysfunction (ED). This is notable, as EjD typically occurs for 50%-75% of patients following TURP. This strongly suggests that median-lobe-only TURP could reduce the incidence of post-procedure EjD.[4]

A small study (N=27) compared ejaculatory hood-sparing PVP or bipolar plasma vaporization of the prostate (BPVP) to assess preservation of ejaculatory function.[5] Although MLE or IPP were not part of the inclusion criteria, the procedures included resection of the median lobe and avoided ablation of the verumontanum, prostatic apex and muscle fibers in the bladder neck. Both PVP and BPVP were effective at relieving symptoms. PVP reduced IPSS from 18.5 at baseline to 8.5 at six months, with similar improvements for those who underwent BPVP. Flow parameters also improved, with no significant between-group differences. Ejaculatory function, i.e., antegrade ejaculation, was preserved in 85% of patients undergoing PVP and 78% who had BPVP.[5]

Minimally Invasive Treatment of BPH with an Enlarged Median Lobe

There are two minimally invasive treatments (MITs) for BPH: Rezūm™ Water Vapor Therapy and UroLift™ System. Rezūm Therapy is recommended by the AUA for treatment of men with BPH and obstructive median lobes.[3] The AUA does not recommend the UroLift System for treatment of BPH with enlarged median lobes.[6,3]

Rezūm Therapy: Convective Water Vapor Thermal Therapy

The Rezūm Therapy pivotal trial enrolled men aged ≥ 50 years with IPPS ≥ 13, Qmax ≤ 15 mL/s, and prostate size of 30 cc-80 cc. Individuals were randomized in a 2:1 manner to treatment with Rezūm Therapy (N=136) or a sham control group (N=61). Prior to randomization, patients were stratified by IPSS score to ensure that both arms had equal distribution of individuals with moderate and severe symptoms. The presence of MLE, which occurred in 31.1% of the cohort, was not an exclusion criterion. Treatment of the median lobe was at the discretion of the physician, and 30 patients in the treatment arm with MLE or central zone hyperplasia at the bladder neck received treatment.[7]

At four-year follow-up, patients treated with Rezūm Therapy showed sustained improvements in each IPSS with a 47% reduction (P<0.0001), and Qmax increased by 50% from baseline (P<0.0001). MSQHQ-EjD and bother from EjD improved by 14% (P<0.004) and 6% P<0.65), respectively. There were no new cases of ED, and no late AEs were observed. The surgical retreatment rate was 4.4% at four years. Of the six patients who had surgical retreatment, four had an enlarged middle lobe that was not treated during the index procedure.[8] This retreatment could possibly have been avoided reducing the retreatment rate to 2.2%.[8] 5.2% of patients initiated treatment with an alpha blocker at four years.[8] No disturbances in sexual function were reported.[8]

Results were similar for patients who had treated MLE compared to those without MLE. At three-year follow-up, the average IPSS for those with treated MLE was 11.8 (versus 22.4 at baseline) and 9.9 for those without MLE (versus 21.7 at baseline). Qmax increased 46% at three years for patients with MLE compared to 31% for those without MLE. A more marked reduction was evident in PVR. Men with MLE had higher baseline PVR than those without MLE. At three years, PVR had decreased 36% more for men with treated MLE compared to those without.[9]

UroLift: Prostatic Urethral Lift (PUL)

The UroLift pivotal trial, L.I.F.T., enrolled men aged ≥ 50 years with IPSS ≥ 13, Qmax ≤ 12 mL/s, and prostate size of 30 cc-80 cc. Individuals were randomized in a 2:1 manner to treatment with PUL (N=140) or a sham control group (N=66). Men with BPH and MLE were excluded from the study. Of 430 men with BPH screened, 38% were excluded from the study. According to later analysis, 5.3% of screened patients had an obstructive median lobe and were not enrolled in the study.[10]

IPSS and Qmax improved by 44.2% and 54.5%, respectively (P<0.0001 for both metrics) at five-year follow-up. There was no de novo sustained ED or EjD. MSHQ-EjD rose 9.6% and EjD bother decreased by 12.8%. The surgical reintervention rate was 13.6% at five years. Of the patients requiring retreatment, 4.3% received PUL implants and the remainder had TURP or a laser procedure. In addition, 10.7% of PUL patients were taking medical therapy to treat LUTS.[11]

The MedLift Study, an extension of the L.I.F.T. pivotal trial, evaluated PUL in patients with BPH and an obstructive median lobe. Enrollment criteria were similar to those in L.I.F.T. but required enlarged median lobes. The single-arm MedLift study compared outcomes with those recorded in patients with lateral lobe enlargement in L.I.F.T. Seventy-one patients were screened. Patients were confirmed to have a median lobe that would have been a contraindication for inclusion in the L.I.F.T. study. Forty-five patients were enrolled in the MedLift study. Compared to the L.I.F.T. study, patients enrolled in the MedLift study were younger, with fewer symptoms.[12]

The primary endpoint was for > 30% improvement in IPSS at six months compared to baseline. On average, IPSS significantly declined 57.7% at six months. Mean IPSS improved 55.1% from baseline (P<0.0001). Qmax also significantly improved 87.5% at 12 months.[12] EjD was found in 6.7% of patients.[13] Mean catheter duration was 1.2 days averaged over the total cohort.[12]

Conclusion

An enlarged median lobe is important in the setting of BPH and should be considered in treatment planning. Medication is not as effective for men with moderate-to-severe MLE or IPP compared to those without and is associated with poorer outcomes. Evidence shows that TURP and GreenLight™ Laser Therapy of median lobes provides significant symptom relief, with a low rate of EjD.[4] Rezūm Therapy is available for MIT of obstructing median lobes and the data from the clinical trial support the use in patients with MLE.

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