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LETTER TO EDITOR

New minimally invasive solutions for Benign Prostatic Obstruction (BPO) management: A position paper from the UrOP (Urologi Ospedalità Gestione Privata)

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To the Editor,

In recent years, alternative solutions have been proposed to obtain effective results comparable to TURP, which is currently considered the gold standard, and laser vapo-enucleation techniques (1, 2), but with the possibility of maintaining sexual functions. In recent years there has been a growing trend towards ejaculation preservation. Although the results of TURP (3), and most laser enucleation techniques are undoubted in the *Benign Prostatic Hyperplasia* (BPH) and *Lower Urinary Tract Symptoms* (LUTS) management, they often lack in the preservation of ejaculation. All the alternative recently proposed interventions (*Rezum, AquaBeam, Urolift, TPLA, i-TIND, LEST*) are procedures considered by some authors to be promising in both managing BPO and preserving sexual functions. However, all these methods are limited by a lack of long-term follow-up that would evaluate the efficacy over time, possible complications related to the method and the correct patient selection for a specific method.
The aim of this letter is to summarize the available evidence and provide clinicians with practical recommendations on the use of the brand new minimally invasive techniques for the management of BPO.

LEONARDI EJACULATION SPARING TECHNIQUE (LEST)

The LEST is an ablative technique fully described in 2019 (4). It is the evolution of a technique described in 2009 (5) that achieved outcomes similar to TURP, while expanding the indication to larger prostates and preserving ejaculation. This is a debulking laser technique with the aim of preserving the "*genital sphincter*" (anatomical structure that include the para-urethral musculature, distinguished in proximal and distal portion, and in part the musculature of the bladder neck). Other anatomical landmarks, essential to preserve ejaculation, are the orifices of ejaculatory ducts and the floor of prostatic urethra. The preliminary results showed an IPSS improvement of about 59% ($p < 0.001$) at 3 months follow-up and 67% ($p < 0.001$) at 12 months follow-up. Similarly, the Q max improvement was about +179% ($p < 0.001$) and +163% ($p < 0.001$) at 3- and 12-months follow-up, respectively (5). The *Quality of Life* (QoL) was 3.5+/-1.2 at the baseline while 1.3+/-1.2 and 1.2+/-0.4 at 3 and 6 months, respectively. An antegrade ejaculation is maintained in about 80% of cases in patients without a middle lobe, although in the presence of a middle lobe this rate drops to about 50% (5).
In the beginning, prostates with a size of no more than 60 grams were included (5). Currently, the technique is proposed for any prostate size, with pure vaporization for a small prostate and enucleation for a large prostate (4, 5). No severe

complications were described, except for minor bleeding at the beginning of urination, which usually occurs for 40 days after surgery. The reason for this lies in the preservation of mucosal areas of the prostatic urethra, that obviously must not be coagulated, that cover the structure to be preserved and that represent the key points of the technique. The authors are working to a variation of technique for the treatment of prostates with median lobe and the preliminary results show an increasing preservation of anterograde ejaculation compared to the past.

AQUABEAM/AQUABLATION

Aquablation, first described in 2015, uses a heat-less robotic system called AcquaBeam (*AcquaBeam®, Procept BioRobotics, Redwood Shores, CA, USA*), which combines ultrasound-guided waterjet technology with advanced planning software for precise ablation of prostate tissue and real-time monitoring during the procedure (6).
The technique is recommended for patients with desires of preservation of sexual function and in case of moderate, to severe LUTS secondary to benign prostatic enlargement (volume 30-80 gr) and/or obstruction with underlying BPH (7). The procedure is performed under loco-regional or general anesthesia and 2-4 days of hospitalization are usually required (7-9). One of the main advantages of Aquablation is the short median operative time and resection time [30.5, IQR (24-35) and 4, IQR (3.1-4.9), respectively (10)]. Sexual outcomes are promising with de novo ejaculatory dysfunction observed in 26.7% of patients and absence of de novo erectile dysfunction (10).
The efficacy of Aquablation was demonstrated in the *United States* (U.S.) cohort of the *Waterjet Ablation Therapy for Endoscopic Resection* of prostate tissue (WATER) study, a double-blinded, multicenter, prospective, *randomized controlled trial* (RCT) comparing TURP vs. Aquablation in patients with moderate-severe LUTS and a prostate size of 30-80 mL (8). The hypothesis of non-inferiority of Aquablation in improving IPSS was demonstrated at 6 months (8) and 1 year (11). The benefits in symptom relief were not at the expense of sexual dysfunction. Among sexually active men, patients treated with Aquablation experienced statistically significant lower rate of anejaculation (at 6 months: 10% *vs* 36% in TURP, p = 0.0003; at 1 year: 9% *versus* 45% in TURP, p = .0006) (8, 11). Symptom reduction and Q_{max} improvement results were maintained at 2 years (12) and 3 years of follow-up (9), with statistically comparable improvements in IPSS scores between groups (3-year improvement difference: 0.6 points, 95% CI -3.3-2.2, p = 0.7) (9). The same results were reported in patients with large prostates (80-150 mL) (8) at 1 year and 2 year follow-up (WATER II) (13-15). The non-inferior efficacy of Aquablation was objectively demonstrated in another RCT (Aquablation *vs.* TURP), were bladder outlet obstruction was measured at 6-month follow-up by using the urodynamic test (16). *Bhojani et al.* reported an increase in Q_{max} of 14.3 ml/sec and a IPSS decrease of 15.6 points (17). Enthusiasm for the functional outcomes is tempered by concerns about its effectiveness in achieving hemostasis. After ablation, haemostasis is usually achieved using a Foley balloon catheter on traction or diathermy or low-powered laser (18). Because of the risk of bleeding, hospitalization for monitoring and bladder irrigation is usually required (19). In the WATER II trial, 7.9% of the patients required transfusion and/or reintervention due to postoperative bleeding (15). The 6-month rates of grade 2 and 3 Clavien-Dindo events account for 13.3% (10). Most authors found no significant change in IIEF-15 at 1 year follow-up (20, 21). In most series 0% to 2% of patients required surgical reintervention (i.e. TURP/HoLEP) for unsuccessful therapy (15, 21). According to the EAU and AUA guidelines (2, 22), Aquablation should still be considered under investigation considering the lack of long term follow-up and the uncertainties about bleeding risk.

REZŪM

In the Rezūm system, thermal energy obtained with high frequency is released in the form of water vapor when the vapor changes from the gaseous to the liquid phase upon contact with the tissue. After the injections, the steam at 107°C distributes into the interstitial tissue spaces and releases stored thermal energy to the prostate tissue, causing cell necrosis. The procedure can be performed in an out-patient setting, using a local transurethral anesthesia. Transrectal prostatic block can be performed, if required (23).The operative time is usually less than 1 hour (23, 24) The efficacy of Rezūm has been evaluated in RCTs and systematic reviews (24-30). *McVary at al.* reported the results of a blinded trial in which patients were randomized 2:1 between Rezūm System thermal therapy and control (they received no treatment other than rigid cystoscopy simulating surgery) up to 4 years of follow-up. They found symptom relief at three months follow-up which was confirmed after 12 months, 2 years and 4 years (25, 26, 28). Only the Rezum group was followed up. No de novo erectile dysfunctions were recorded at one year while erectile and ejaculatory functions were preserved (25). Antegrade ejaculation is maintained between 100% and 96.6% (31, 32). Patients with troublesome LUTS but low prostate volume (< 30 g) also experienced significant relief of LUTS (33). The Rezūm could effectively treat patients with median lobes (25, 34, 35), urinary retention (36, 37) and large prostate volumes (≥ 80 g) (31, 33, 35, 38, 39). Nevertheless, the improvement of Q_{max}, IPSS and QoL was assessed only in an early to intermediate follow-up period (maximum 5 years). The gold standard TURP improved IPSS, QoL, and Q_{max} at 3 months and maintained its effect for at least 10 years (40). Medical and surgical retreatment rates for Rezūm were reported up to 18.9% at 5 years (26) and 10.8% at 2 years (41), respectively.The Rezūm system could be a viable alternative option for the treatment of LUTS due to BPO leading to an improvement in BPH symptoms, preserving sexual function with a 3%-6% risk of developing ejaculatory dysfunction, and being associated with a low surgical recurrence rate over five years (26, 29). Nevertheless, the level of evidence is low and impaired by several limitations (27) including the lack of a RCT directly comparing the Rezūm system with the gold standard, and providing a long-term follow-up.

Trans-Perineal Laser Ablation of the prostate (TPLA)

TPLA is one of the most recent 'ultra-minimally invasive' ablative surgical treatment available. It uses a low-power diode-laser as the energy source and a small needle is inserted percutaneously transperineally (usually one needle for each lobe) (42), preserving the urethra as opposed to the more traditional transurethral approaches. According to the studies available in literature, TPLA was recommended in case of moderate-severe LUTS with an IPSS above 8 or 12 (43, 43-45) and prostate volume > 30 mL. There is one series which did not include patients with a median lobe (46). The procedure can be performed in an ambulatory surgical center, with a relative short operative time [mean setting time 21.33 ± 7.59 and lasing time 8.43 ± 0.79, respectively (44)]. TPLA resulted in statistically significant improvement in IPSS and QoL scores from baseline in most of the available studies (43, 45-48), with *Frego et al.* observing the greatest reduction in IPPS score (Δ = –16.0 at 12 months) (48). The longest follow-up reported in literature is 3 years, with a significant improvement in IPSS (-37.2%; $p < 0.01$), Q_{max} (+ 45.8%; $p < 0.01$) and median MSHQ-EjD (60%; $p < 0.01$) (49). A recent series published by *Minafra et al.* reported that TPLA results are acceptable even after 3 years (49). The results in terms of ejaculatory function are impressive (43, 47, 48, 50). In particular, in some cases, ejaculatory function assessed by the MSHQ-EjD questionnaire was not only preserved but even improved (44, 46, 51). No de novo erectile dysfunction was reported (51) The complication rate is generally low and not severe with a 6-month rates of grade 2 Clavien-Dindo events of 4.6% (44). A case of prostatic abscess was reported by *De Rienzo et al.* and by *Manenti et al.* (4.8% and 4.9%, respectively) managed with percutaneous drainage and antibiotic therapy (44, 46). *Bertolo et al.* recently reported for the first time the results of the comparison between TPLA and the gold standard (TURP) (52). They found a preservation of the ejaculatory function in 96% of cases of TPLA. Both treatments significantly improved the median Q_{max}, but the main advantage was observed for TURP (TPLA vs TURP: 15.2 mL/s *vs* 26.0 mL/s; $p < 0.001$) (52). More research is needed to evaluate the rate of pharmacological or surgical re-intervention in the long term after TPLA. Overall, all available data come mainly from a few pilot studies with short follow-up (maximum 3 years) and a limited number of patients, the strength of evidence for which is low and insufficient to make a recommendation. TPLA remains under investigation, but it could be considered for people interested in preserving sexual and ejaculatory function.

Urolift

The prostatic urethral lift (*PUL, Urolift, Neotract Inc. Pleasanton, CA, USA*) has passed the test of clinical evaluation within 4 years after introduction and was approved by Food and Drug Administration in the 2013 (2). This tissue retracting, permanent implant has a capsular, external tab made of nitinol connected to the plyethylene terephtalate monofilament and a urethral end piece made of stainless steel (53). During urethroscopy, in the ambulatory setting, the tissue-retracting implants are placed at the 2 and 10-o'clock positions guaranteeing integrity of the neurovascular bundle and dorsal plexus. Another advantage that Urolift offers is tailoring the implants based on the patients' anatomy, regulating the monofilaments' length and tension (54). Ideal candidates are patients with prostatic volume between 20 and 70 cc, with 'kissing' lateral lobes of the prostate, IPSS > 12, Q_{max} < 15 mL/s and with less than 350cc of post-void residual volume. To deploy the device, the operator uses a needle that is then anchored, with the internal side in the urethra, and with the outer side on the surface of the prostatic capsule. Usually, catheterization is not necessary following this procedure. Contraindications are men with prostatic volume over 80-100 gr, voluminous median lobe and history of urinary retention (55). The recent evidences did not show superiority of the Urolift when compared to the gold-standard (56-58), TURP, but it does, however reduce severity of LUTS. Currently, the largest RCT available (the L.I.F.T. study) comparing PUL vs. a sham control reported durable improvements in IPSS (36%), QoL (50%), and Q_{max} (44%) at 5-years (58). Also, an increase in maximum urine flow-rate (Q_{max}) from 7.88 to 11.08 was evidenced in the same period. Some comparative studies described superiority of the Urolift to other minimally invasive techniques when it comes to erectile dysfunction. Actually, *Sexual Health Inventory for Men* (SHIM) scores were greater in the Urolift (14.8) *versus* other groups (9.2) (59). Moreover, new generation of the PUL, marketed as Urolift 2, was launched in March 2022. There are some drawbacks to PUL technique, like reported adverse events and high costs. The majority of adverse events were mild, such as transient hematuria, dysuria, pelvic pain, blood clots and incontinence (60), but some Authors reported formation of pelvic hematoma (61), one of which needed surgical intervention (62), and another that resulted in acute kidney injury and progression of chronic kidney disease (63). Also, the LIFT trial reported the need for retreatment or surgical intervention in 13.6% of patients (54). On the other hand, at longer follow-up (5 years), there were no adverse event reported related to sexual function (58). Currently, the Urolift is recommended as an alternative non-ablative technique to men with LUTS interested in preserving ejaculatory function, with prostates < 70 mL and no middle lobe by the guidelines of the European Association of Urology (2).

Temporarily implanted nitinol device (iTind)

The temporary implantable nitinol device (first generation: TIND; second generation: iTind) (*Medi-Tate®; Medi-Tate Ltd., Or Akiva, Israel*) is a recent promising non ablative minimally invasive solution for the management of LUTS/BPH (64). One of the advantages of the technique is the fact that most cases can only be achieved with the use of local anesthetic, with light intravenous sedation if required (65). Similarly, most patients can be managed with a day-surgery hospital access. Another advantage, comparing to implantable devices, is that iTind is a temporary device which avoids the potential complications associated with a permanent device. The iTind seems to be of particular benefit to LUTS/BPH patients

(IPSS > 12 points and Q_{max} ≤ 12 ml) seeking a minimally invasive treatment associated with a significant improvement in symptoms with the preservation of sexual function. ITind could be also recommended in case of BPH and sclerosis of the bladder neck. In most series, prostate size was quite small (less than 60-75 cc). *Porpiglia et al.* showed an IPSS and Q_{max} improvement by -45% and +67% respectively, at 12 months follow-up (66). Similar results were found in the MT-02 study, a single arm multicentric study involving 81 patients (67). Other series are published, with good results but with shorter follow-up (68). The device and the procedure appear to be moderately safe, with a low number of complications (mostly urinary retention, UTIs, device displacement, hematuria) and in particular not high grade according to the Clavien-Dindo classification. A randomized trial based on 175 patients showed no de novo ejaculatory or erectile dysfunction (69). At two-year follow-up, 4 of 81 patients required subsequent surgery (TURP/HoLEP) (70). The longest published follow-up is 36 months (71). Currently, the iTind is not recommended in the guidelines, even though considered a promising technique, waiting for the results of ongoing randomized controlled trials comparing iTind to a reference technique.

Discussion and conclusions

All the new minimally-invasive techniques for the treatments of LUTS due to BPO were developed because of the necessity to offer a patient-tailored, successful, viable treatment for BPH while maintaining sexual and ejaculatory function (4, 6, 42, 58). Now more than ever, the patients are well informed about all the possibilities that new technologies can offer and how can we, as urologists, improve their quality of life by maintaining good both functions, urinary and sexual. Also, quick recovery period and rare serious adverse effect of these minimally invasive technologies make them even more attractive (24). Seemingly, they are a relatively easy choice to make when compared to the gold standard, TURP, and maybe should be the first one at some point in well selected candidates, but there are some drawbacks to take in consideration such as, in some cases, higher costs, availability, surgical experience of the operators and higher rates of retreatments (24). These are major reasons why urologists should be very careful when proposing new techniques to the patients, choosing the right candidates for the right procedure, and giving them all the necessary information regarding. Some of the most important parameters to consider are patients' general health status, prostate volume, and strong desire to preserve ejaculation (2, 72, 73). The doctor-patient relationship, patient-tailored therapy, shared decision, and correct informed consent are more important than ever.

From the national health-care institutions' prospective these treatments, if preformed in ambulatory setting, can be extremely useful as they can alleviate the long waiting lists for surgical treatments that require surgical staff, hospitalization, and post-operative care. For example, Rezum, iTind and Urolift can all be offered to the patients in 'day surgery' regime (36, 55, 69). This can be an important advantages for healthcare systems in the post SARS-CoV-2 era (74, 75). On the other hand, to be able to offer these kinds of services, urologists preforming them must be adequately prepared and trained, and not only on the procedure itself, but on adverse events and complications. The scarcity of specialized training centers and fairly limited diffusion of these novel techniques pose quite an important obstacle in using them, especially in the smaller, more peripheral hospitals.

In addition to that, it should be mentioned that some of these techniques did never undergo randomized trials (i.e. iTind), and the outcomes of these studies never systematically evaluated using validated outcome measures, therefore the rate of retreatments is still quite uncertain. Furthermore, there is a lack of long-term follow-up results, and for that manner it could be difficult to give the patients precise and complete information. Nevertheless, minimally invasive treatments are on the rise, especially Urolift in the United States (76).

One of the greatest benefits of minimally invasive techniques is the preservation of sexual function. De novo erectile function is anedoctal and ejaculatory dysfunction is generally low (15.4% with LEST, 3-6% in Rezum, 26.7% in Aquablation (24, 30). ITind and Urolift had no impact on ejaculatory dysfunction.

It is worth noting that all minimally invasive techniques are relatively young and have a short follow-up, with the exception of LEST (*Laparoscopic Endoscopic Single-Site Surgery*), which has a follow-up of up to 12 years (4, 5). This remarkable longevity of follow-up data for LEST sets it apart from other procedures and underscores its potential and reliability. In addition, LEST provided immediate relief of LUTS after catheter removal, whereas Rezum, Urolift, and iTind provided good results only after some time (2 weeks to six months).

Obviously, the incorporation in the guidelines and insurance companies are also important factors to consider when implementing them. Moreover, Urolift is mentioned as the valid alternative in some guidelines, while others are not mentioned or are discouraged because of higher retreatment rates (73) Also, not all guidelines agree on the recommendations [NICE *vs.* AUA (72, 73)]. The need for cautious interpretation of current analytical results stems primarily from the ever-evolving landscape of safety and efficacy data on these innovative techniques. Currently, ongoing studies are comparing these procedures not only with transurethral resection of the prostate (TURP) (NCT05762198, NCT05840549) but also with various alternative treatments, including purely medical interventions. Pending the results of these ongoing studies, these techniques are very promising and appear to be attractive alternative options for future treatment of the disease in selected patients.

In conclusion, we would like to provide our position related to each one of the techniques presented.

The LEST showed promising results in terms of functional outcomes with significant improvements in IPSS and Q_{max}, while preserving sexual function.

Aquablation shows efficacy in improving IPSS and Q_{max} with favorable sexual outcomes. Concerns about hemostasis and

bleeding risk remain, but the short operative time and the possibility of an outpatient setting make it a valuable option for patients seeking both symptom relief and preservation of sexual function.
Rezūm provides significant relief for LUTS, with a low risk of ejaculatory dysfunction. Nevertheless, the level of evidence remains low, and further long-term studies are needed to prove its efficacy compared to the gold standard TURP.
TPLA shows a remarkable improvement in IPSS and QoL scores, with impressive results in ejaculatory function preservation. Due to the limited short-term data and the small number of patients, TPLA should remain under investigation.
Urolift proves effective in reducing LUTS severity with durable improvements in IPSS and Q_{max}, and shows superiority in preserving erectile function. Despite the reported adverse events, its outpatient nature and the easy implantation make Urolift an attractive option for selected patients.
iTind is a promising non-ablative solution, that offers significant improvement in symptoms with minimal impact on sexual function. Its temporary nature and low complication rates are the main advantage, especially for patients seeking a minimally invasive treatment approach.
In conclusion, all of these minimally invasive techniques offer multiple options for patients with BOO, balancing efficacy, preservation of sexual function, and potential benefits to the healthcare system. As ongoing studies continue to validate their long-term outcomes and cost-effectiveness, urologists must carefully consider patient preference and individual health context when recommending these innovative approaches.

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