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Summary of EchoLaser Main Publications in Urology

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Benign Prostatic Hyperplasia

Full-text Papers on TPLA™

37. Preserving erectile and ejaculatory function in patients undergoing minimally invasive techniques: the first randomized clinical trial comparing convective water vapor ablation and transperineal laser ablation.

Zucchi A, Bartoletti R, Antonov P, Salonia A, Ivanov A, Macrì G, Sollazzi E, Autorino R , Liguori G , Bini V , Pacini M.

The Journal of Sexual Medicine, 2025, 1–8, https://doi.org/10.1093/jsxmed/qdaf150

Background: Benign prostatic hyperplasia (BPH) significantly impacts patients' quality of life, both from a urinary and sexual perspective. Surgical techniques for the treatment of BPH, such as transurethral resection of the prostate and laser enucleation techniques, are associated with postoperative sexual and ejaculatory dysfunctions. For these reasons, there has been growing interest in minimally invasive techniques (MISTs), which aim to improve urinary symptoms while preserving erectile and ejaculatory function.

Aim: With this randomized trial (RCT), our aim is to analyze the impact of transperineal laser ablation (TPLA) and convective water vapor ablation (CWVA) on erectile and ejaculatory function of patients undergoing these MISTs and to compare the two techniques to assess any potential differences between them.

Methods: This RCT included 80 patients 1:1 randomized to TPLA and CWVA between January and July 2024 based on their International Prostate Symptoms Score. Inclusion criteria included prostate volume > 30 ml, age > 50 years, IPSS>7, PSA < 4 ng/ml, and maximum flow rate < 15 ml/s with post-void residual>50 ml. Categorical variables were compared using the $\chi 2$ test with Yates' correction or Fisher's exact test. A General Linear Model for repeated measures was used to evaluate within- and between-group differences over time.

Outcomes: The Male Sexual Health Questionnaire—Ejaculatory Dysfunction (MSHQ-EjD) and International Index of Erectile Function 5 (IIEF5) were collected 3- and 6-months after treatment.

Results: Among 61 sexually active patients (31 CWVA, 30 TPLA), baseline characteristics were comparable, except for a larger prostate volume in the TPLA group ($P < 0.001$). IIEF-5 scores remained stable at 6 months, with no significant differences between groups [19 (9-24) TPLA vs. 16.5 (1.75-20) CWVA, $P = 0.11$]. A transient decline at 3 months in the TPLA group resolved by 6 months. At 6 months, MSHQ-EjD scores improved significantly in both groups (+51% TPLA, +33.3% CWVA, $P < 0.0001$). The MSHQ-EjD Bother domain also showed significant improvement ($P < 0.0001$). All patients, except one, were same day discharged and were free from prostate medications at the last evaluation.

Clinical Implications: The results indicate that both TPLA and CWVA effectively preserve patients' sexual function. Strengths and Limitations: Although this is the first randomized study comparing these MISTs, the exclusion of sexually inactive patients from the analysis reduced the sample size. Furthermore, the findings are limited to short-term outcomes.

Conclusions: Both techniques effectively preserve erectile function and improve MSHQ-EjD scores.

36. Outcomes and safety of trans perineal laser ablation of the prostate: a systematic review.

Altieri VM, Di Bello F, Saldutto P, Rocca R, Romani ML, Vena W, di Mauro E, Verratti V, Sangiorgi G, Iacono F, Pezone G, Creta M, Napolitano L, Patelli G.

World J Urol. 2025 Jun 23;43(1):385. doi: 10.1007/s00345-025-05753-8. PMID: 40548982.

Objective: Prostate trans-perineal laser ablation (TPLA) is a minimally invasive treatment for benign prostatic hyperplasia (BPH) that is gaining importance as an alternative to the standard of care, namely transurethral resection of the prostate (TURP). To evaluate the functional outcomes and rates of complication in BPH patients with LUTS who underwent TPLA.

Materials and methods: We performed a scoping systematic review (PROSPERO id CRD42024612152) on PubMed/Medline, Embase, and the Cochrane Library in June 2025 according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) statement. Identified reports were reviewed according to the methodological index for non-randomized studies (MINORS).

Results: Overall, 17 studies (13 prospective and four retrospective studies) involving 717 patients were analyzed. However, study heterogeneity and limited long-term data hinder a comprehensive and unbiased comparison with TURP. Prostate TPLA was associated with improvements at 12-month in LUTS (Δ of IPPS and QoL ranged from 40.7 to 72.7% and from 50 to 75%, respectively) as well as patient satisfaction, and uroflowmetry measures (Δ of Qmax and Post-voidal residuum ranged from 42.8 to 127.7% and from 28.4 to 86.4%). Moreover, ejaculatory functioning was preserved. Prostate TPLA-related complication rates were low, with most adverse effects classified as Clavien-Dindo grade II.

Conclusions: Retrospective evidence widely suggests that prostate TPLA is a suitable option for BPH treatment. Future research, especially randomized controlled trials, are needed to confirm prostate TPLA efficacy over a period longer than the standard 12-month follow-up and assess its cost-effectiveness relative to TURP.

35. Short term results after minimally invasive treatments for benign prostatic enlargement: the first randomized trial comparing transperineal laser ablation and water vapor ablation.

Pacini M, Zucchi A, Salonia A, Sollazzi E, Macrì G, Volterrani R, Bini V, Antonov P, Ivanov A, d'Arma A, De Nunzio C, Bartoletti R.

Prostate Cancer Prostatic Dis. 2025 Apr 25. doi: 10.1038/s41391-025-00972-x

Background: Interest in minimally invasive techniques (MISTs) for treating benign prostatic hyperplasia (BPH) has increased over the years due to their ability to improve symptoms while minimizing complications. Moreover, these procedures can be performed in an outpatient setting, potentially reducing patients' discomfort. The aim of our randomized trial is to evaluate and compare the efficacy of Transperineal Laser Ablation (TPLA™) and Water Vapor Ablation (WVA) in the treatment of BPH.

Methods: Eighty consecutive patients were randomized 1:1 to the two techniques between January and July 2024. Both procedures were under conscious sedations and patients were same day discharged. All patients underwent standardized follow-up, including International Prostate Symptoms Score (IPSS) and uroflowmetry assessments at 3- and 6-months post-treatment.

Results: At 6 months, IPSS and Quality of Life (QoL) scores improved significantly from baseline ($p < 0.001$), in favor of TPLA at both time points ($p \leq 0.03$). General Linear Model analysis showed that QoL improvement was faster in the TPLA group (p: 0.005), though no significant difference persisted at 6 months. Uroflow parameters, including maximum flow, average flow, and post-void residual volume, demonstrated significant improvement without notable differences between the two groups ($p < 0.001$ for all comparisons). All patients were same day discharged, except one who required prolonged continuous bladder irrigation. Postoperative complications occurred in 11 cases, with only one (a prostatic abscess) classified as Clavien-Dindo ≥3. The main limitations of the study are the sample size and short follow-up duration.

Conclusions: TPLA and WVA are safe outpatient procedures that provide comparable functional outcomes. However, TPLA appears to offer a faster improvement in patient-reported symptoms.

34. Laser-focused ablative therapy for prostate cancer and benign prostatic hyperplasia: A review of current applications and future directions.

Cornud F, Walser EM, de Bie KC, Lefevre A, Galiano M.

Diagn Interv Imaging. 2025 Apr 16:S2211-5684(25)00072-5. doi: 10.1016/j.diii.2025.04.001.

Abstract: Focal Laser ablation (FLA), or interstitial Laser thermotherapy, is a promising minimally invasive approach for the treatment of localized prostate cancer and benign prostatic hyperplasia. This technique is gaining popularity among patients due to its ability to preserve pre-treatment quality of life. The examination is performed under magnetic resonance imaging (in bore) or ultrasound guidance, via a percutaneous transrectal or transperineal route. Under transperineal ultrasound guidance, FLA can use up to four Laser fibers to create confluent zones of tissue ablation, enabling treatment of larger prostate- or tumor volumes. Primary indications for FLA include intermediate-risk localized prostate cancer and benign prostatic hyperplasia refractory to medical treatment due to ineffectiveness or side effects. The intervention is typically performed under light sedation or under locoregional anesthesia. FLA lasts approximately 10 min, with a total intervention time of < 60 min on an outpatient basis. Patients are often discharged with either a suprapubic or bladder catheter to prevent urinary retention, especially if the ablated area is close to the urethra. Minor complications are rare and limited to transient voiding dysfunction, urinary tract infection, or hematuria. Major complications, such as rectoprostatic fistula, are avoided by rectoprostatic hydrodissection. FLA is an effective, well-tolerated option in the minimally invasive treatment of prostate disease, offering rapid treatment times, low complication rates, and preservation of quality of life for appropriately selected patients. However, variability in recurrence rates following FLA for prostate cancer highlights the need for further investigation into optimal patient selection for this treatment.

33. A systematic review of novel surgical treatments for benign prostatic hyperplasia.

Panayi Z, Musgrave H, Adeyoju A.

Journal of Clinical Urology. 2025;0(0). doi:10.1177/20514158251321623

Background: The range of surgical benign prostatic hyperplasia (BPH) treatments has hugely expanded in recent years. There is a need to keep up-to-date with ongoing innovations in BPH surgery and critically appraise the new emerging treatments. The aim of this systematic review was to critically analyse the recent evidence for novel BPH therapies, not presently discussed in urological guidelines

Methods: An initial scoping search was conducted to identify relevant BPH treatments for inclusion: Optilume® BPH, transperineal laser ablation (TPLA), novel implantable nitinol devices, transurethral columnar balloon dilatation (TUCBD) and transurethral ultrasound ablation (TULSA). A systematic review was conducted of these treatments, searching MEDLINE, SCOPUS and PubMed databases, limited to within 5 years.

Results: A total of 26 independent studies were included: 14 TPLA, 2 Optilume BPH, 2 TULSA, 5 TUCBD and 3 novel nitinol devices (ClearRing, Urocross Expander, Butterfly stent). For TPLA, most studies demonstrated significant improvement in efficacy outcomes in the absence of adverse events, although most trials were of small patient numbers with short follow-up. The highest quality evidence was presented by the randomised sham-controlled PINNACLE study for Optilume BPH, showing sustained significant International Prostate Symptom Score (IPSS) improvements at 2 years, and low retreatment rates. The evidence for TULSA was limited, showing

unclear benefit and concerns about cost-effectiveness. The three novel nitinol device studies were of low evidence quality, with a high number of device-related events for the ClearRing and Butterfly implants. The Urocross Expander had a better safety profile, but limited efficacy data. The TUCBD studies showed contradictory outcomes, with possible confounding from combined bladder neck resection.

Conclusion: This review has identified that TPLA and Optilume BPH appear to have the strongest evidence base and show promise as future BPH treatments. Further higher quality research is required for TULSA, TUCBD and novel nitinol devices.

32. Transperineal laser ablation in the management of benign prostatic hyperplasia: an updated systematic review and pooled analysis.

Alberti A, Lo Re M, Nicoletti R, Polverino P, Cadenar A, Ciaralli E, Solazzi F, Giustozzi B, Sessa F, Rivetti A, Campi R, Sebastianelli A, Serni S, Gacci M.

Prostate Cancer Prostatic Dis. 2025 Mar 12. doi: 10.1038/s41391-025-00952-1

Introduction: Standard surgical options for Benign Prostatic Hyperplasia [BPH], despite their excellent functional outcomes, are associated with multiple side effects and require general/spinal anesthesia and hospitalization. In this scenario, Transperineal Laser Ablation of the Prostate [TPLA] emerged as an ultra-minimally invasive ejaculation-sparing procedure, showing promising functional results, with a good safety profile. This systematic review aimed to provide an overview of the current role of TPLA in clinical practice, focusing on operative setting, safety, and efficacy.

Evidence acquisition: Literature search was performed on June 12th, 2024 using PubMed, Embase, and Cochrane Central databases, following the EAU Guidelines Office and the PRISMA statement recommendations. All studies reporting outcomes after TPLA procedures were included.

Evidence synthesis: Seventeen studies were included in this systematic review, of which 2 RCTs compared TPLA with TURP, 12 prospective and 3 retrospective non-randomized studies (of which 1 comparing TPLA and Prostatic Artery Embolization [PAE]). All procedures were performed using the same EchoLaserTM system (SoracteLiteTM) (Elesta s.r.l., Calenzano (FI), Italy), however great heterogeneity exists considering inclusion criteria, peri- and post-operative management. Mainly low-grade complications (Clavien-Dindo [CD] Grade ≤ II) were reported, while no major adverse events (CD grade > III) occurred. In all studies TPLA led to a great improvement in urinary function, up to 5 years after the procedure, while not significantly impacting erectile and ejaculatory functions.

Conclusions: TPLA showed promising results both in the short- and mid-term, improving urinary function while preserving sexual function and keeping a good safety profile.

31. Anatomic and Clinical Effects of Focal Laser Ablation of the Prostate on Symptomatic Benign Prostatic Hyperplasia.

Walser EM, Zimmerer R, Nance A, Masood I, Saleem A.

Cancers. 2025; 17(3):475.
https://doi.org/10.3390/cancers17030475

Background/Objectives: Laser ablation is a promising technique for tissue-debulking in patients with symptomatic benign prostatic hyperplasia (BPH). This study evaluated the effects of focused laser ablation of the prostate (FLA) on urinary symptoms for patients with BPH.

Methods: Since 2018, 62 patients had bilateral prostate FLA for prostate cancer and/or symptomatic BPH, defined as an international prostate symptom score (IPSS) ≥11, and have 6-month follow-up data. Urinary and sexual health were scored with standardized surveys while imaging defined prostate anatomy. FLA was performed as an outpatient procedure with either transrectal MRI-guided (n = 24) or transperineal ultrasound-guided (n = 38) laser fiber placement to debulk the prostate and/or ablate cancer foci plus margins. Enhanced prostate MRI was performed immediately or up to 2 days later to assess the treatment zones. Follow-up then consisted of PSA levels every 6 months and MRI at 6–12 months and then yearly combined with patient sexual/urinary surveys and clinical assessments.
Results: All patients had technically successful FLA and 6-month clinical and imaging follow-up. At 6-month follow-up, mean IPSS was reduced by 43% relative to baseline (10.4 vs. 18.4), mean prostate volume was reduced by 30% (42.2 vs. 60.5 mL), and mean PSA was reduced by 58% (4.3 vs. 10.2 ng/mL). All of these changes were statistically significant ($p \leq 0.008$). Compared with baseline, there was no significant change in the SHIM score at 6 months (16.0 vs. 16.8; $p = 0.59$). In a subset of patients for whom 12-month data were available, there were significant reductions in PSA (61%; 4.1 vs. 10.5 ng/mL; $p < 0.002$) and IPSS (45%; 9.9 vs. 17.9; $p < 0.002$), while the 12-month SHIM score was not significantly different from baseline (15.2 vs. 16.0; $p = 0.27$). Mean laser irradiation time was 19 min with a mean energy deposition of 13,562 J. The most frequent adverse events were prolonged urinary catheterization in 10 patients (16%) and urinary tract infection in 8 (13%).

Conclusions: FLA is a safe and effective tissue-debulking technique for patients with symptomatic BPH. This outpatient procedure requires minimal procedure time and can be performed without the need for operating rooms or cystoscopy. Our results are consistent with those of previous studies indicating that FLA preserves sexual function.

BIBLIOGRAPHY

30. Contrast-enhanced ultrasound imaging following transperineal laser ablation for lower urinary tract symptoms.

van Kollenburg RAA, van Riel LAMJG, Oddens JR, de Reijke TM, van Leeuwen TG, de Bruin DM.

Urology. 2024 Nov 25:S0090-4295(24)01089-6. doi: 10.1016/j.urology.2024.11.043

Objectives: To describe the shape and volume of ablations created by TPLA using multiple fiber configurations. Furthermore, to measure the change in the ablation zone and prostate volume over time, and to assess inter-patient ablation volume variability.

Methods: Data from a prospective, single center, interventional pilot study including 20 patients is used. All subjects underwent TPLA using the EchoLaser® system, using two to four fibers, depending on prostate size and shape. Contrast-enhanced ultrasound (CEUS) was performed post-treatment and at 1 and 12 months. The prostate and ablation zone volumes were calculated on segmented CEUS imaging.

Results: The ablation zones were clearly identified on CEUS as non-perfused areas. Depending on fiber configuration, their shape varied from an ellipsoid to a clover profile. Ablation volumes varied from 0.9 (0.6 - 2.2)cm3 using a single fiber and 1800J to 8.7 (3.9 - 19.0)cm3 (median, range) using two fibers and 7200J energy per lobe at one month. At 12 months the majority of the ablation zones showed a volume reduction. Median prostate volume decreased from 78 (37 - 145)cm3 at baseline to 46 (27 - 124)cm3 at 12 months (p=0.0002). There was a relation between prostate volume reduction and Qmax (slope = 0.18) and IPSS (slope = -0.18) improvement.

Conclusions: This study described ablation zone shape and measured the ablation volume following TPLA by various fiber configurations using CEUS, and compared these to functional outcomes. Prostate volume reduced significantly during follow-up. Segmentation showed substantial inter-patient ablation volume variation, which limits treatment predictability and thus accuracy.

29. Complication rate across the minimally invasive surgical treatments (MISTs): where do we stand? A systematic review of the literature.

Lambertini L, Sandulli A, Coco S, Paganelli D, Cadenar A, Dell'Oglio P, Puliatti S, Di Maida F, Grosso AA, Amparore D, Bertolo R, Campi R, Lombardo R, Ferro M, Rocco B, Vittori G, Antonelli A, De Nunzio C, Minervini A, Mari A.

Prostate Cancer Prostatic Dis. 2024 Oct 22. doi: 10.1038/s41391-024-00900-5

Background: Over the past decade, the range of surgical options to benign prostatic obstruction (BPO) has expanded significantly with the advent of minimally invasive surgical therapies (MISTs). Nevertheless, the available evidence in the field is heterogeneous. Efficacy and safety thresholds are yet to be determined.

Objective: To evaluate perioperative and long-term complications after MISTs - including Aquablation, steam injection (Rezūm), Transperineal laser ablation of the prostate (TPLA), implantation of a prostatic urethral lift (PUL) and temporary implantable nitinol device (iTIND) - in patients with lower urinary tract symptoms due to BPO.

Evidence acquisition: A systematic literature search was conducted in January 2024 using Medline (via PubMed), Embase (via Ovid), Scopus, and Web of Science. The search strategy used PICO criteria (Patients, Interventions, Comparisons, Outcomes) [1], focusing specifically on patients with BPH-associated LUTS who underwent MIST or other comparative treatments, aiming to assess both perioperative and long-term safety outcomes. Article selection was conducted in accordance with the PRISMA guidelines. The risk of bias and the quality of the articles included were assessed. A dedicated data extraction form was used to collect the data of interest.

Evidence synthesis: The initial electronic search identified 3660 records, of which 24 ultimately met the inclusion criteria and were included in the analysis. Overall, Aquablation was associated with a higher major complications rate of 14% (IQR 6-22), particularly in the case of patients with prostates <70 ml. PUL showed a higher early postoperative acute urinary retention rate (10.9%, IQR 9.2-12.3%), while 1.4% of patients treated with iTIND experienced major perioperative complications. Urinary tract infections were mostly reported in series assessing TPLA and Rezūm.

Conclusions: The adoption of MISTs for LUTS due to BPH is associated with a varied spectrum of perioperative and long-term complications. Our findings showed an acceptable safety profile with specific complications dependent on the type of MIST performed, highlighting the importance of individualized patient selection and procedure-specific considerations.

28. Transperineal Laser Ablation of Prostate (TPLA™)

Sessa F, Polverino P, Moscardi L.

In "Diseases of Prostate – Management Strategies and Emerging Technologies", IntechOpen. doi: 10.5772/intechopen.1006649

Abstract: This chapter provides a comprehensive overview of Transperineal Laser Ablation of the prostate (TPLA™) as a therapeutic option for Benign Prostatic Hyperplasia (BPH). BPH is a prevalent condition among aging men, characterized by non cancerous enlargement of the prostate gland, leading to lower urinary tract symptoms (LUTS) and impacting quality of life. TPLA™ emerges as a minimally invasive technique leveraging the precision of laser energy to induce coagulative necrosis in targeted prostatic tissue, thereby reducing prostate volume and alleviating symptoms. The chapter systematically reviews the procedural aspects of TPLA™, including patient selection criteria, preoperative preparation, and step-by-step surgical technique. Clinical outcomes are discussed, with a focus on symptom relief, improvement in urinary flow rates, and reduction in prostate volume. Furthermore, the safety profile of TPLA™ is examined, documenting the incidence

and management of potential complications. In conclusion, TPLA™ represents a promising addition to the therapeutic armamentarium for BPH, offering a balance of efficacy and safety, ensuring high rates of preservation of sexual function

27. Transperineal laser ablation (TPLA) of the prostate for benign prostatic obstruction: the first 100 patients cohort of a prospective, single-center study.

Lo Re M, Polverino P, Rivetti A, Pecoraro A, Saladino M, Pezzoli M, Siena G, De Nunzio C, Marzi VL, Gacci M, Serni S, Campi R, Sessa.

F. World J Urol. 2024 Jul 10;42(1):402. doi: 10.1007/s00345-024-05077-z. PMID: 38985193

Purpose: Transperineal laser ablation (TPLA) is a new minimally-invasive surgical treatment for patients with benign prostatic obstruction (BPO). We report the perioperative and mid-term functional results of the first 100 consecutively patients undergoing TPLA at our institution.

Methods: Clinical data from consecutive patients undergoing TPLA at our institution from April 2021 to July 2023 were prospectively collected. Primary endpoints were the postoperative changes in IPSS, QoL and MSHQ 3-item questionnaires and in Qmax and post-void residual volume (PVR).

Results: Overall, 100 consecutive patients underwent the procedure. Median age and prostate volume were 66 (IQR 60–75) years and 50 (IQR 40–70) ml, respectively. In the cohort, 14 (14%) patients had an indwelling catheter and 81 (81%) were under oral BPO therapy at the time of TPLA. Baseline median Qmax (ml/s) and PVR (ml) were 9.1 (IQR 6.9–12) and 90 (IQR 50–150), respectively, while median IPSS and QoL were 18 (IQR 15–23) and 4 (IQR 3–4). At all the follow-up timepoints, the evaluated outcomes on both symptoms and functional parameters showed a statistically significant improvement ($p < 0.001$). Antegrade ejaculation was preserved in all sexually active patients. No postoperative Clavien-Dindo > 2 complications were recorded.

Conclusions: TPLA represents a safe option for selected well-informed patients swith LUTS due to BPO. Our prospective study confirms the feasibility and favorable perioperative and functional outcomes in a real-world cohort with heterogenous prostate volumes and patient characteristics.

26. Transperineal Laser Ablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: Long-Term Follow-Up in 40 Patients.

Patelli G, Altieri VM, Ierardi AM, Carnevale A, Chizzoli F, Baronchelli G, Trimarchi R, Carrafiello G.

J Vasc Interv Radiol. 2024 May 3:S1051-0443(24)00326-9. doi: 10.1016/j.jvir.2024.04.023

Purpose: To evaluate the long-term efficacy and safety of proprietary transperineal laser ablation (TPLA) of the prostate.

Materials and Methods: Patients with symptomatic benign prostatic hyperplasia underwent TPLA with a 1064-nm continuous-wave diode laser. IPSS, QoL, PVR and prostate volume were evaluated at baseline and successive timepoints.

Results: Forty prospectively enrolled patients had post-TPLA follow-up of ≥ 36 months. Median duration of follow-up was 56.5 months (range: 36-76 months). Compared with baseline, the median reduction in IPSS at 12-month follow-up was 74% (interquartile range [IQR]: 60-81%) ($P < .001$). Median QoL score at 12 months was improved from 5 (IQR: 4-5) at baseline to 1 (IQR: 0-1) ($P < .001$). Median PVR at 12 months decreased from 108 mL (IQR: 38-178 mL) to 13.5 mL (IQR: 0-40.5 mL) ($P < .001$), a median reduction of 88% (IQR: 61-100%). At 12 months, median prostate volume was significantly reduced from 66 mL (IQR: 48.5-86.5 mL) to 46 mL (IQR 36-65 mL) ($P < .001$), a median reduction of 32% (IQR: 21-45%). For all of these parameters, the benefit of TPLA persisted at last follow-up and all changes were statistically significant vs baseline. There were no intraoperative adverse events; perioperative adverse events consisted of one case of prostatitis and one case of urinary tract infection (both mild according to the modified SIR classification system).

Conclusion: TPLA for symptomatic BPH produced durable benefits across a range of clinical outcomes and was well tolerated in 56.5 months median duration follow-up.

25. Office-Based Transperineal Laser Ablation for Benign Prostatic Hyperplasia Under Local Anesthesia: 2-Year Results from a Dose Range Confirmatory Trial.

Bianco FJ, Luna E, Lopez-Prieto A, González P, Gheiler EL, Kaufman AM, Avila L, Maiolino G.

JU Open Plus 2(2):e00007, February 2024. | DOI: 10.1097/JU9.0000000000000105

Purpose: To evaluate the safety and tolerability profile of transperineal laser ablation (TPLA) for patients with benign prostatic hyperplasia in an office setting under sedative-free anesthesia, including the functional outcome results at 24 months.

Materials and Methods: This is a prospective, single-center, dose range confirmatory trial involving 20 male patients. TPLA was performed by urologists in an office setting, using nonsedative local anesthesia. Self-administered nitrous oxide/oxygen dissociating gas was optional. Tolerability was assessed using a visual analog scale. Safety was evaluated by recording Grade 3 or worse adverse events within 30 days after the procedure. International Prostate Symptom Score, Sexual Health Inventory for Men, ejaculation function, and uroflowmetry parameters were assessed at 6, 12, and 24 months.

Results: All 20 procedures were performed as intended without request of cessation from any patient, who tolerated them very well, recording a median pain score of 2 (range 1-4). It is important to note that there was a rapid escalation of dose, and the last 18 consecutive patients were initiated at the maximal energy dose of 7 watts. No hospital transfers were recorded, and no urgent hospital admissions within 30 days post-procedure occurred. There was 1 Grade 3 complication

registered during the 24-month study interval. We observed a statistically significant and sustained reduction in the median International Prostate Symptom Score at 6 months (6, 3-8), 12 months (3, 5-2), and 24 months (3, 2-4) when compared with baseline values (14, 12-17). Uroflowmetry parameters showed a similar trend. The median Sexual Health Inventory for Men values did not change significantly, and only approximately 10% of patients reported absence of anterograde ejaculation at 12 and 24 months.

Conclusions: TPLA for benign prostatic hyperplasia is a safe and well-tolerated office-based procedure, with durable benefits on functional outcomes over 2 years of follow-up. Further studies are required to confirm these results.

24. Minimally invasive techniques in quest of Holy Grail of surgical management of enlarged prostates: a narrative review.

Porto JG, Titus R, Camargo F, Bhatia A, Ahie N, Blachman-Braun R, Malpani A, Lopategui DM, Herrmann TRW, Marcovich R, Shah HN.

World J Urol. 2024 Jan 13;42(1):35. doi: 10.1007/s00345-023-04747-8 PMID: 38217727

Purpose: Past decade has seen a renewed interest in minimally invasive surgical techniques (MISTs) for management of enlarged prostate. This narrative review aims to explore newer MIST for benign prostatic hyperplasia (BPH) which are not yet integrated into established societal guidelines.

Methods: We conducted a literature search across PubMed, Google Scholar, and FDA ClinicalTrials.gov databases on June 1st, 2023, to identify studies published within the past decade exploring various MISTs for BPH. Additionally, we gathered insights from abstracts presented in meetings of professional associations and corporate websites. We broadly classified these procedures into three distinct categories: energy-based, balloon dilation, and implant/stent treatments. We collected detail information about the device, procedure details, its inclusion and exclusion criteria, and outcome.

Results: Our review reveals that newer energy-based MISTs include Transperineal Laser Ablation, Transurethral Ultrasound Ablation, and High-Intensity Focused Ultrasound. In the sphere of balloon dilation, Transurethral Columnar Balloon Dilation and the Optilume BPH Catheter System were gaining momentum. The noteworthy implants/stents that are on horizon include Butterfly Prostatic Retraction Device, Urocross Expander System, Zenflow Spring System, and ProVee Urethral Expander System.

Conclusion: The exploration of various MISTs reflects ongoing efforts to enhance patient care and address limitations of existing treatments. This review provides a bird-eye view and valuable insights for urologists and researchers seeking to navigate the dynamic landscape of MISTs in the quest for effective and minimally invasive solutions for enlarged prostates.

23. Could transperineal interstitial laser ablation of the prostate be the right option for highly-comorbid patients with lower urinary tract symptoms due to benign prostatic obstruction? A preliminary single-center experience focusing on functional and safety outcomes.

Polverino P, Lo Re M, Saladino S, Pecoraro A, Moscardi L, Rivetti A, Resta GR, Pezzolo M, Romano A, Somani BK, Siena G, Cocci A, Gacci M, Minervino A,Serni S, Campi R, Sessa F

Minerva Urol Nephrol. 2023 Dec 13. DOI: 10.23736/S2724-6051.23.05479-4

In this paper, we aimed to highlight functional and safety outcomes of highly-comorbid patients undergoing transperineal laser ablation (TPLA) of prostate at a referral academic center. Patients undergoing TPLA from April 2021 and February 2023 with moderate to severe lower urinary tract symptoms (LUTS), prostate volume ranging from 30 to 100 mL, and an American Society of Anesthesiologists (ASA) Score ≥3 were included. All patients were evaluated as unfit for standard surgery. Procedures were performed in an outpatient setting using local anesthesia. Failure after the procedure was defined as the shift to other ultra-minimally invasive surgical treatment or the need for long-term indwelling catheter replacement. Overall, 23 patients were enrolled with a median age of 76 years. Median ASA Score and Charlson Comorbidity Index were 3 and 5, respectively. Of these, 11 (48%) were under antiplatelets, 4 (17%) under new oral anticoagulants (NOACs) and 3 (13%) under warfarin. Six (26%) patients had an indwelling catheter preoperatively. Median prostate volume was 42 mL. Median follow-up was 12 months. No Clavien-Dindo Grade ≥2 complications were recorded. Four/six (66%) patients with an indwelling catheter before TPLA achieved spontaneous micturition. Treatment failure occurred in 2 (8.5%) patients. Of the remaining 21 patients, 12/21 (57%) patients reported an improvement in International Prostate Symptoms Score (IPSS) symptoms class (i.e., severe to moderate, moderate to mild, etc.); all patients whose IPSS symptoms class remained stable (N.=8 [38%]) had a significant improvement of the IPSS score as compared to the preoperative period, while 1 (4.5%) patient reported worsening of LUTS. In conclusion, TPLA appears to be a safe and feasible ultra-minimally-invasive option for LUTS due to benign prostatic obstruction (BPO) in patients with significant comorbidities at high-risk for standard surgical options.

22. Minimally invasive surgical therapies (MISTs) for lower urinary tract symptoms (LUTS): promise or panacea?

Busetto GM, Checchia A, Recchia M, Tocci E, Falagario U , Annunziata G , Annese P , d'Altilia N , Mancini V, Ferro M , Crocetto F , Tataru OS , Di Gianfrancesco L, Porreca A, Del Giudice F , De Berardinis E, Bettocchi C, Luigi Cormio, Carrieri G.

Asian Journal of Andrology (2023) 25, 1–9; doi: 10.4103/aja202357

The increasing importance of treatment of lower urinary tract symptoms (LUTS), while avoiding side effects and maintai-

ning sexual function, has allowed for the development of minimally invasive surgical therapies (MISTs). Recently, the European Association of Urology guidelines reported a paradigm shift from the management of benign prostatic hyperplasia (BPH) to the management of nonneurogenic male LUTS. The aim of the present review was to evaluate the efficacy and safety of the most commonly used MISTs: ablative techniques such as aquablation, prostatic artery embolization, water vapor energy, and transperineal prostate laser ablation, and nonablative techniques such as prostatic urethral lift and temporarily implanted nitinol device (iTIND). MISTs are becoming a new promise, even if clinical trials with longer follow-up are still lacking. Most of them are still under investigation and, to date, only a few options have been given as a recommendation for use. They cannot be considered as standard of care and are not suitable for all patients. Advantages and disadvantages should be underlined, without forgetting our objective: treatment of LUTS and re-treatment avoidance.

21. Trans - Perineal laser ablation of the prostate in high surgical risk patients affected by severe lower urinary tract symptoms related to benign prostatic obstruction.

Destefanis P, Sibona M, Vitiello F, Vercelli E, Micai L, Montefusco G, Mangione C, Bracco F, Colucci F, De Nunzio C, Gontero P.

Prostate Cancer Prostatic Dis (2023). https://doi.org/10.1038/s41391-023-00736-5

Background: In our study, we aimed to test the efficacy and safety of Trans-Perineal Laser Ablation of the prostate (TPLA®) in the surgical treatment of high-risk Benign Prostatic Obstruction (BPO) patients.

Methods: We defined a high-risk BPO patient as an elderly man affected by severe comorbidities, among which coagulation issues due to pre-existent medications or diseases. From October 2020 to June 2022, we prospectively enrolled high-risk patients affected by a moderate to severe and/or complicated BPO condition. The analysis of the efficacy of the Trans-Perineal Laser Ablation was defined as the primary endpoint of the study. Secondary endpoints were post-operative surgical complications and patient-reported quality of life.

Results: Globally, 40 consecutive patients were enrolled. Median (IQR) age was 80 (72.5–84) years. Median Charlson Comorbidity Index was 6 (5–7). Median prostate volume was 38 (30.5–73) cc. In all cases, a TPLA® procedure was performed under local anesthesia, and patients being discharged within the same day of the procedure. A progressive reduction of median prostate volumes was reported at 3 and 6 months post-operatively, compared to baseline [38 (30.5–73) vs 35 (26–49) vs 34 (28–49) cc, $p < 0.001$]. Median International Prostate Symptom Score (IPSS) improved accordingly [25 (19–30) vs 10.5 (7.5–13) vs 8 (6–11.5), $p < 0.001$]. A permanent bladder catheter was successfully removed in 13 out of 23 (56.5%) cases. Within 90 days from surgery, 19 (47.5%) patients experienced at least one surgical complication. According to the Clavien-Dindo classification, complications were classified as grade I in 16 (40%) cases, grade II in 9 (22.5%), and grade III in 1 (2.5%). We did not observe any grade IV or V complications. **Conclusions:** The Trans-Perineal Laser Ablation of the Prostate is a feasible, safe, and effective Minimally Invasive Surgical Technique, when offered to elderly, high-risk patients affected by severe Benign Prostatic Obstruction.

20. Transperineal laser ablation as a new minimally invasive surgical therapy for benign prostatic hyperplasia: a systematic review of existing literature.

Tzelves L, Nagasubramanian S, Pinitas A, Juliebø-Jones P, Madaan S, Sienna G, Somani B.

Ther Adv Urol. 2023 Sep 21;15:17562872231198634. doi: 10.1177/17562872231198634

Introduction: Transperineal laser ablation (TPLA) of the prostate is a new, minimally invasive technique for benign prostatic hyperplasia (BPH) with promising effectiveness and safety outcomes. This systematic review aims to provide an update of existing literature.

Methods: A literature review was performed in Pubmed/MEDLINE, Embase, Cochrane Library, and clinicaltrials.gov from January 2000 up to April 2023. Data extraction and risk of bias were performed independently by three authors.

Results: A total of 11 studies were included, among which 9 were observational, 1 randomized controlled trial, 1 animal study, while 2 of them were comparative (1 with prostatic artery embolization and 1 with transurethral resection of the prostate). Functional outcomes were improved in the majority of studies both for objective (maximum flow rate and post-void residual) and subjective outcomes (improvement of International Prostate Symptom Score and quality of life). Complication rates ranged between 1.9% and 2.3% for hematuria, 3.7% and 36.3% for dysuria, 1.9% and 19% for acute urinary retention, 0.6% and 9.1% for orchitis/urinary tract infections, and 0.6% and 4.8% for prostatic abscess formation. Regarding sexual function, >95% of patients retained their ejaculation while erectile function was maintained or improved.

Conclusion: TPLA of the prostate is an innovative, minimally invasive technique for managing patients with BPH. Existing studies indicate an effective technique in reducing International Prostate Symptom Score and quality of life scores, post-void residual reduction, and increase in Qmax, albeit the measured improvements in terms of Qmax are not equal to transurethral resection of the prostate. Although sexual function is maintained, the mean catheterization time is 7 days, and no long-term data are available for most patients.

BIBLIOGRAPHY

19. Transperineal laser ablation as treatment for benign prostatic obstruction: Safety, feasibility and functional outcomes—A pilot study.

van Kollenburg, R, van Riel, L, Bloemen, P, de Reijke, T, Beerlage, H, de Bruin, D, et al.

IBJUI Compass. 2023. https://doi.org/10.1002/bco2.278

Objectives: The aim of this study is to assess safety, feasibility and functional outcomes of TPLA for the treatment of LUTS in men fit also for standard surgery.

Methods: This prospective, multicentre, interventional pilot study included 20 patients. Eligible patients were men ≥40 years of age, with urodynamically proven bladder outlet obstruction, a peak urinary flow of 5–15 mL/s and a prostate volume of 30–120 cc. All subjects underwent Soractelite™ TPLA using the Echolaser® X4 system. Two to four fibres were placed in the prostate, whereafter laser light induced coagulative necrosis. Twelve months of follow-up included uroflowmetry, an ultrasound of the prostate and PROMs (IPSS and IIEF).

Results: Twenty patients were treated with TPLA using local anaesthetics and optional sedation. Sixteen patients were treated in an outpatient setting, using only local anaesthetics in 12 of them; four were treated in the operating room, whereof two under general anaesthesia. No device related adverse events occurred, nor did any grade ≥3 adverse events during follow-up. Post-TPLA, 10 men continued spontaneous voiding, and 10 men developed a urinary retention treated by a temporary indwelling catheter for 15.2 ± 3.5 days. At 12 months, Qmax improved from 9.7 ± 3.5 to 14.9 ± 6.0 ($p = 0.015$), IPSS improved from 21.3 ± 5.2 to 10.9 ± 5.5 ($p < 0.0001$), QoL improved from 4.9 ± 0.9 to 1.9 ± 1.1 ($p < 0.0001$), IIEF-15 total score remained stable and 11/13 patients (85%) preserved antegrade ejaculation.

Conclusions: TPLA is a safe and feasible treatment for men with LUTS due to BPO. TPLA can be performed in an outpatient setting under only local anaesthetics. Functional and quality of life outcomes improved significantly at 12 months, and erectile function remained stable.

18. Transurethral resection of the prostate (TURP) versus transperineal laser ablation (TPLA) due to benign prostatic hyperplasia (BPH): prospective and comparative study.

Canat HL, Gurbuz C, Bozkurt M.

Int Urol Nephrol. 2023 Jul 27. doi: 10.1007/s11255-023-03717-8

Aim: We aimed to compare the first-year results of Transurethral resection of the prostate (TURP), the gold standard method, and Transperineal laser ablation (TPLA) techniques.

Material and methods: This study was designed as a prospective, randomized, controlled, and single-center and was conducted between November 2021 and February 2023. TURP candidates were included in the study. Demographic data and perioperative data were recorded. Preoperative and first-year International Prostate Symptom Score (IPSS), International Erectile Function Index (IIEF-5), Male Sexual Health Questionnaire-Ejaculatory Dysfunction (MSHQ-EjD), QoL, peak urinary flow rate (Qmax), prostate volume (PV) and postvoid residual (PVR) data were recorded.

Results: Fifty patients were included in the study and were assigned to equal numbers of groups. TPLA group had a higher ASA score ($p = 0.03$). There was improvement in IPSS, Qmax, and PVR parameters compared to baseline values in both groups at 1 year ($p < 0.01$). The improvement in Qmax was better in the TURP group ($p < 0.01$). IIEF-5 score was similar between groups ($p = 0.83$ and $p = 0.12$, respectively). The MSHQ scores in the first year did not change according to their baseline values in the TPLA group ($p = 0.54$ and $p = 0.34$, respectively).

Conclusion: According to the first-year results of TPLA, the symptomatic improvement effect without sacrificing ejaculatory functions is comparable to TURP. We think that this method will can be an alternative, especially for patients who want to avoid ejaculatory dysfunction, who have a high risk of anesthesia, and whose anticoagulant/antiplatelet therapy cannot be discontinued.

17. Transperineal laser ablation of the prostate as a treatment for benign prostatic hyperplasia and prostate cancer: The results of a Delphi consensus project.

Cocci A et al.

Asian Journal of Urology, 2023, ISSN 2214-3882, https://doi.org/10.1016/j.ajur.2023.07.001

Objective: To evaluate trans-perineal laser ablation (TPLA) with Echolaser® (Echolaser® TPLA) as a treatment for benign prostatic hyperplasia (BPH) and prostate cancer (PCa) using the Delphi consensus method.

Methods: Italian and international experts on BPH and PCa participated in a collaborative consensus project. During two rounds, they expressed their opinions on Echolaser® TPLA for the treatment of BPH and PCa answering online questionnaires on indications, methodology, and potential complications of this technology. Level of agreement or disagreement to reach consensus was set at 75%. If the consensus was not achieved, questions were modified after each round. A final round was performed during an online meeting, in which results were discussed and finalized.

Results: Thirty two out of forty invited experts participated and consensus was reached on all topics. Agreement was achieved on recommending Echolaser® TPLA as a treatment of BPH in patients with ample range of prostate volume, from <40 mL (80%) to >80 mL (80%), comorbidities (100%), antiplatelet or anticoagulant treatment (96%), indwelling catheter (77%), and strong will of preserving ejaculatory function (100%). Majority of respondents agreed that Echolaser® TPLA is a potential option for the treatment of localized PCa (78%) and recommended it for low-risk PCa (90%). During the final

round, experts concluded that it can be used for intermediate-risk PCa and it should be proposed as an effective alternative to radical prostatectomy for patients with strong will of avoiding urinary incontinence and sexual dysfunction. Almost all participants agreed that the transperineal approach of this organ-sparing technique is safer than transrectal and transurethral approaches typical of other techniques (97% of agreement between experts). Pre-procedural assessment, technical aspects, post-procedural catheterization, pharmacological therapy, and expected outcomes were discussed, leading to statements and recommendations.
Conclusions: Echolaser® TPLA is a safe and effective procedure that treats BPH and localized PCa with satisfactory functional and sexual outcomes.

16. Three years outcomes of transperineal laser ablation of the prostate.

Minafra P, DE Rienzo G, Gerbasi S, Cindolo L, Battaglia M, Ditonno P.

Minerva Urol Nephrol. 2023 Jun 14. doi: 10.23736/S2724-6051.23.05270-9 Epub ahead of print. PMID: 37314812.

Background: Ultra-minimally Invasive Surgical Techniques (uMISTs) play an increasingly significant role in treating benign prostatic obstruction (BPO) as an alternative to both medical therapy and surgery. Transperineal laser ablation of the prostate (TPLA) is an uMIST that has shown its efficacy in symptom relief and improvement of urodynamic parameters while sparing ejaculatory function and having a low risk of complications. This is the 3-year follow-up of a pilot study on TPLA.

Methods: TPLA was performed using the SoracteLite™ system. It consists of ablating prostate tissue through a diode laser, eventually causing prostate volume reduction. We recorded International Prostate Symptom Score (IPSS), uroflowmetry parameters, the Male Sexual Health Questionnaire (MSHQ-EjD), and prostate volume at baseline and after 3 years. The Wilcoxon Test was employed to compare continuous variables.

Results: Twenty men completed a 3-year follow-up after TPLA. The median prostate volume was 41.5 mL (IQR: 40.0-54.3). Preoperative median IPSS, Qmax, and MSHQ-EjD were 18 (IQR: 16-21), 8.8 mL/s (IQR: 7.8-10.8), and 4 (IQR: 3-8). TPLA showed significant improvement in IPSS (-37.2%; P<0.01) and Qmax (45.8%; P<0.01); median MSHQ-EjD improvement was by 60% (P<0.01) and median prostate volume reduction was by -20.4% (P<0.01).

Conclusions: This analysis shows that TPLA maintains satisfactory results within 3 years. Therefore, TPLA confirms its role in the treatment of patients unsatisfied or intolerant to oral therapies but not eligible for surgery to avoid impact on sexual function or due to anesthesiologic contraindications.

15. Ablative minimally invasive surgical therapies for benign prostatic hyperplasia: A review of Aquablation, Rezum, and transperineal laser prostate ablation.

Nguyen DD, Li T, Ferreira R, Baker Berjaoui M, Nguyen AV, Chughtai B, Zorn KC, Bhojani N, Elterman D.

Prostate Cancer Prostatic Dis. 2023 Apr 20. doi: 10.1038/s41391-023-00669-z PMID: 37081044.

Introduction: Benign prostatic hyperplasia (BPH) is one of the most common diseases affecting men and can present with bothersome lower urinary tract symptoms (LUTS). Historically, transurethral resection of the prostate (TURP) has been considered the gold standard in the treatment of LUTS due to BPH. However, TURP and other traditional options for the surgical management of LUTS secondary to BPH are associated with high rates of sexual dysfunction.

In the past decade, several novel technologies, including Aquablation therapy, convective water vapor therapy (Rezum), and transperineal prostate laser ablation (TPLA), have demonstrated promising evidence to be safe and effective while preserving sexual function.

Methods: In this review, we discuss three ablative minimally invasive surgeries: Aquablation, Rezum, and TPLA. We review their techniques, safety, as well as perioperative and functional outcomes. We go into further detail regarding sexual function after these ablative minimally invasive surgical therapies.

Results: Aquablation is a surgeon-guided, robot-executed, heat-free ablative waterjet procedure with sustained functional outcomes at 5 years while having no effect on sexual activity. Rezum is an innovative office-based, minimally invasive surgical option for BPH that delivers convective water vapor energy into prostate adenoma to ablate obstructing tissue. Rezum leads to significant improvements in Qmax, IPSS while preserving sexual function. TPLA is another office-based technology which uses a diode laser source to produce thermoablation. It leads to improvement in Qmax, IPSS, and QoL while preserving ejaculatory function.

Conclusions: Overall, ablative minimally invasive surgical therapies have demonstrated excellent safety and efficacy profiles while preserving sexual function. These modalities should be discussed with patients to ensure informed and shared decision-making. Ablative minimally invasive surgical therapies may be particularly interesting to patients who value the preservation of their sexual function.

14. Ejaculatory Function following Transperineal Laser Ablation versus TURP for Benign Prostatic Obstruction: A Randomized Trial.

Bertolo R, Iacovelli V, Cipriani C, Carilli M, Vittori M, Antonucci M, Maiorino F, Signoretti M, Petta F, Travaglia S, Panei M, Bove P.

BJU Int. 2023 Mar 14. doi: 10.1111/bju.16008 PMID: 36917033.

Objectives: To evaluate the reliability of trans-perineal laser ablation of prostate (TPLA) in preserving antegrade ejaculation compared to trans-urethral resection of prostate (TURP).

Patients and methods: In this single-center, prospective, randomized, open-label study, consecutive patients with indication to surgical treatment for benign prostatic obstruction (BPO) were enrolled between January 2020 and September 2021 (NCT04781049). Randomization defined two treatment arms: Group A: patients assigned to TPLA (experimental); Group B: patients assigned to TURP (standard). Primary endpoint was change in ejaculatory function (assessed by EJ-MSHQ) at 1 month after surgery. Secondary endpoints included comparison of visual analogue scale (VAS), changes in sexual function (by IIEF-5), ΔIPSS and ΔQoL, and Qmax improvement at 1-6 months, as appropriate.

Results: Fifty-one patients (26 TPLA versus 25 TURP) were analyzed. No differences were found in the perception of pain assessed by VAS. No differences in IIEF-5 score were found between groups. Distribution of ejaculatory function assessed by the EJ-MSHQ remained unmodified after TPLA (p=0.2) while a median 30% decrease in EJ-MSHQ score was observed after TURP (p=0.01). Absence of antegrade ejaculation was reported in one patient within the TPLA group (18 patients s/p TURP). A statistically significant difference between the treatment groups was found in terms of postoperative Qmax (15.2 (IQR 13.5-18.3) versus 26.0 (IQR 22.0-48.0) ml/s, TPLA versus TURP, p<0.001). Both treatments significantly improved Qmax : mean 23.9 ml/s improvement s/p TURP (95% C.I. 17.1-30.7) versus 6.0 ml/s s/p TPLA (95% C.I. (5.0-7.0); and IPSS: mean 11.6 decrease (95% C.I. 9.7-13.5) versus 5.8 s/p TPLA (95% C.I. (2-9.6) with respect to baseline.

Conclusion: In our study, TPLA preserved ejaculatory function in 96% of cases in addition to providing significant relief from BPO.

13. Transperineal Laser Ablation for Benign Prostatic Enlargement: A Systematic Review and Pooled Analysis of Pilot Studies.

Tafuri A, Panunzio A, De Carlo F, Luperto E, Di Cosmo F, Cavaliere A, Rizzo M, Tian Z, Shakir A, De Mitri R, Porcaro AB, Cerruto MA, Antonelli A, Cormio L, Carrieri G, Karakiewicz PI, Abreu AL, Pagliarulo V.

J Clin Med. 2023 Feb 26;12(5):1860. doi: 10.3390/jcm12051860 PMID: 36902647; PMCID: PMC10003190.

Abstract: Transperineal laser ablation (TPLA) of the prostate is a new minimally invasive treatment option in men with lower urinary tract symptoms (LUTS) due to benign prostatic enlargement (BPE). The aim of this systematic review was to investigate the efficacy and safety of TPLA in the management of BPE. The primary outcomes were the improvement in urodynamic parameters (maximum urinary flow (Qmax) and postvoiding residue (PVR)) and LUTS relief, assessed using the IPSS questionnaire. The secondary outcomes were the preservation of sexual and ejaculatory functions, assessed with the IEEF-5 and MSHQ-EjD questionnaires, respectively, and rates of postoperative complications. We reviewed the literature for prospective or retrospective studies evaluating the use of TPLA in the treatment of BPE. A comprehensive search in PubMed, Scopus, Web of Science, and ClinicalTrials.gov was performed for English language articles published between January 2000 and June 2022. Pooled analysis of the included studies with available follow-up data for the outcomes of interest was additionally performed. After screening 49 records, six full-text manuscripts were identified, including two retrospective and four prospective non-comparative studies. Overall, 297 patients were included. All the studies independently reported a statistically significant improvement, from baseline, in Qmax, PVR, and IPSS score at each timepoint. Three studies additionally demonstrated that TPLA did not affect sexual function, reporting no change in the IEEF-5 score, and a statistically significant improvement in MSHQ-EjD score at each timepoint. Low rates of complications were recorded in all the included studies. Pooled analysis showed a clinically meaningful improvement in both micturition and sexual outcomes mean values at 1, 3, 6, and 12 months of follow-up, compared with baseline. Transperineal laser ablation of the prostate for the treatment of BPE showed interesting results in pilot studies. However, higher level and comparative studies are needed to confirm its efficacy in relieving obstructive symptoms and preserving sexual function.

12. Ultrasound-guided SoracteLite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience.

Laganà A, Di Lascio G, Di Blasi A. et al.

World J Urol (2023). https://doi.org/10.1007/ s00345-023-04322-1

Purpose: To evaluate the efficacy and safety of ultrasoundguied transperineal laser ablation (TPLA) in patients with symptomatic BPH.

Materials and methods: From January 2020 to January 2022, 63 prospectively enrolled patients underwent TPLA with a 1064-nm continuous-wave diode laser (EchoLaser, Elesta SpA). Primary endpoints were the change in IPSS, QoL, Qmax, PVR and prostate volume at 3 and 12 months.

Results: At 3 months, IPSS improved from 20.8 ± 7.4 to 11.0 ± 6.6 (p < 0.001), QoL from 4.7 ± 1.4 to 1.5 ± 1.2 (p < 0.001) and Qmax from 8.6 ± 3.5 mL/s to 13.2 ± 5.7 mL/s (p = 0.083). PVR decreased from 124.8 ± 115.4 mL to 43.6 ± 53.6 mL (p < 0.001), and prostate volume decreased from 63.6 ± 29.7 mL to 45.6 ± 21.8 mL (p = 0.003). At 12 months, IPSS improved from 20.8 ± 7.4 to 8.4 ± 5.9 (p < 0.001), QoL from 4.7 ± 1.4 to 1.2 ± 0.8 (p <

0.001), and Qmax from 8.6 ± 3.5 mL/s to 16.2 ± 4.3 mL/s (p = 0.014). PVR decreased from 124.8 ± 115.4 mL to 40.6 ± 53.6 mL (p = 0.003), and prostate volume decreased from 63.6 ± 29.7 mL to 42.8 ± 14.2 mL (p = 0.071). Transient complications consisted of two patients with prostatic abscess (Clavien-Dindo grade IIIa) and one patient with orchitis (Clavien-Dindo grade II).

Conclusions: TPLA for symptomatic BPH provides clinica benefits at 3 and 12 months, and the treatment is well tolerated.

11. Standard approach and future perspective for the management of benign prostatic hyperplasia from a health-economics point of view: the role of transperineal laser ablation.

Lorenzoni V, Palla I, Manenti G, Ditonno P, de Reijke TM and Turchetti G.

Front. Urol. 3:1100386. doi: 10.3389/fruro.2023.1100386

Introduction: Benign prostatic hyperplasia (BPH) is a common diagnosis among the ageing male population over 60 years and it is associated with the development of lower urinary tract symptoms (LUTS): dysuria, nocturia, increased frequency of urination, etc. LUTS negatively affect the patient's daily activities and the quality of life. Patients with severe and persisting symptoms, not responding to pharmacological therapy, are candidates for surgical intervention. Transurethral resection of the prostate (TURP) has been the gold standard for surgical approach despite it can be associated with significant complications. Indeed, laser vaporization or enucleation are today the most broadly used surgical techniques and other minimally invasive surgical therapies (MISTs) have been introduced to reduce some complications during- and post-surgery. Moreover, a new microinvasive approach for LUTS is represented by EchoLaser SoracteLite™ transperineal laser ablation (TPLA), an innovative, safe and feasible approach that can be performed under local anaesthesia and in an outpatient setting.

Objective: The paper aims to analyse and discuss the economic implications of standard surgical techniques and innovative approaches with a focus on TPLA thought a literature review.

Results: The literature review highlights that at present there are few studies related to the economic implications of surgical therapies for LUTS. Preliminary results show that the TPLA is a promising technique in terms of clinical and economic benefit for the treatment of obstructive LUTS. Furthermore, TPLA can be performed in an outpatient setting implying an advantage from an economic and also organizational point of view, in particular in a health emergency situation.

Conclusions: Economic literature on minimally invasive techniques and surgical approaches for the treatment of BPH is still lacking. Multicentre and long-term economic studies are needed to assess the estimated disease burden. However, direct and indirect costs associated with TPLA are minimized vs TURP and laser vaporization/enucleation.

10. Transperineal Laser Ablation of the Prostate (TPLA) for Lower Urinary Tract Symptoms Due to Benign Prostatic Obstruction.

Sessa F, Polverino P, Siena G, Bisegna C, Lo Re M, Spatafora P, Pecoraro A, Rivetti A, Moscardi L, Saladino M, et al.

J. Clin. Med. 2023, 12, 793. https://doi.org/ 10.3390/jcm12030793

Abstract: We aimed to review the current evidence on surgical and functional outcomes of Transperineal Laser Ablation for LUTS due to BPH. A comprehensive review of the English-language literature was performed using the MEDLINE and Web of Science databases until 1 August 2022, aiming to select studies evaluating TPLA for the treatment of LUTS due to BPH. Additional records were found from Google Scholar. Data were extracted and summarized in Tables. An appropriate form was used for qualitative data synthesis. Seven studies were included in the review, with all being single arm, non-comparative studies. In all studies, functional outcomes were evaluated with uroflowmetry parameters and validated questionnaires, showing a promising effectiveness at short- and mid-term follow-up. There is a lack of standardized pathways for preoperative assessment of patients suitable for TPLA, and even the technique itself has been reported with a few nuances. A good safety profile has been reported by all the authors. Although promising results have been reported by different groups, selection criteria for TPLA and few technical nuances regarding the procedure were found to be heterogeneous across the published series that should be standardized in the future. Further research is needed to confirm these findings.

09. Efficacy and safety of ultrasonography guided transperineal percutaneous laser ablation for treating benign prostatic hyperplasia: a randomized controlled trial.

Chen L, Zhang W, Meng Z, Guo Q, Cao N, Xu Y, Fu Q, Hu B.

https://doi.org/10.21203/rs.3.rs-2433606/v
Pre-print, not peer-reviewed

Background: There are many ways to treat prostatic hyperplasia; these are currently more inclined to minimally invasive treatment. We mainly compared the differences between two treatment methods, ultrasound-guided transperineal laser ablation (USTPLA) and prostatic artery embolization (PAE).

Purpose: To evaluate the efficacy and safety of US-TPLA and PAE in the treatment of benign prostatic hyperplasia (BPH).

Material and methods: The clinical information for 40 patients with BPH admitted to our hospital between June 2018 and January 2021 were retrospectively analyzed. The changes in International Prostate Symptom Score (IPSS), quality of life (QoL), maximum urinary flow rate (Qmax), postvoid residual (PVR), prostate volume (PV), and the incidence of complications were compared between groups.

Results: The IPSS ($P < 0.001$; $P < 0.001$), QoL ($P < 0.001$; $P < 0.001$), Qmax ($P < 0.001$; $P < 0.001$), PVR ($P < 0.001$; $P < 0.001$),

and PV (P < 0.001; P < 0.001) at three and six months after US-TPLA and PAE improved with respect to those before surgery. There was no significant difference in IPSS (P = 0.235; P = 0.151), QoL (P = 0.527; P = 0.294), Qmax (P = 0.776; P = 0.420), PVR (P = 0.745; P = 0.607), and PV (P = 0.527; P = 0.573) between the groups at three and six months after surgery. No serious complications occurred in either group.

Conclusion: US-TPLA and PAE seem to have a similar short-term efficacy. The efficacy of the two procedures is comparable, and neither is associated with serious complications. US-TPLA and PAE are both effective complementary measures for the treatment of BPH.

08. Transperineal laser ablation of the prostate with EchoLaser™ system: perioperative and short-term functional and sexual outcomes.

Sessa F, Polverino P, Bisegna C, Siena G, Lo Re M, Spatafora P, Pecoraro A, Rivetti A, Conte FL, Cocci A, Villari D, Minervini A, Gacci M, Li Marzi V, Serni S and Campi R.

Front. Urol. 2:969208. doi: 10.3389/fruro.2022.969208

Objective: To date, several ultra-minimally-invasive surgical techniques are available for the treatment of male LUTS due to benign prostatic obstruction (BPO). Herein we report our preliminary experience with SoracteLite™ TPLA for the treatment of carefully selected patients with LUTS due to BPO.

Methods: Data from all consecutive patients undergoing TPLA at our institution between April 2021 and February 2022 were prospectively collected in a specific database. Data regarding functional and sexual outcomes evaluated by validated questionnaires and uroflowmetry were analyzed. All the procedure were performed in an outpatient setting, under local anesthesia and conscious sedation, using EchoLaser device, a multisource diode laser generator.

Methods: Data from all consecutive patients undergoing TPLA at our institution between April 2021 and February 2022 were prospectively collected in a specific database. Data regarding functional and sexual outcomes evaluated by validated questionnaires and uroflowmetry were analyzed. All the procedure were performed in an outpatient setting, under local anesthesia and conscious sedation, using EchoLaser device, a multisource diode laser generator.

Results: Overall, 38 patients underwent TPLA at our institution during the study period. The median prostate volume was 46 ml (IQR 38-71). The median time to complete the procedure was 31 min (IQR 28-37). All patients but one were discharged within 8 hours of hospital stay. No perioperative Clavien-Dindo grade ≥2 complications were recorded. Median improvement in Qmax was 17%, 24% and 32% at 1 month, 3 months and last follow-up after surgery; as a result, the median postoperative IPSS at 1 month, 3 months and at last follow-up decreased by -14%, -36% and -35%, respectively. All patients preserved ejaculatory and sexual function. Two patients (5%), catheter carriers before the procedure, experienced acute urinary retention after TPLA treatment and required replacement of an indwelling catheter.

Conclusions: TPLA can be a feasible, safe and effective ultra-minimally- invasive procedure for carefully selected patients with LUTS due to BPO.

07. Transperineal laser ablation of the prostate (TPLA) for selected patients with lower urinary tract symptoms due to benign prostatic obstruction: a step-by-step guide.

Sessa F, Bisegna C, Polverino P , Gacci M, Siena G , Cocci A , Li Marzi V, Minervini A, Serni S , Campi R.

Urology Video Journal, Volume 15, 2022, 100167

Objective: Transperineal interstitial laser ablation of the prostate (TPLA) has been shown to be a novel option for minimally invasive treatment of benign prostatic obstruction (BPO). Herein we provide an educational step-by-step overview of our technique ofTPLA, focusing on the standardization of its surgical steps, the logistical aspects of its performance in an outpatient setting, as well as its early perioperative and functional outcomes.

Patients and surgical procedure: The procedure can be performed in the outpatient clinic with the patient in a lithotomic position. After local disinfection, two 21G transperineal needles are introduced and located in the middle of each lobe, under ultrasound guidance, with their orientation parallel to the longitudinal axis of the gland. A needle placement verification is required to guarantee the right security distances from the urethra and from the bladder neck. Once the fibers are placed, the energy can be delivered. The starting power energy is 5 W, reduced in about 2 minutes to 3,5 W, when a cavity starts to grow with vapor formation resulting in bubbles hyperechoic images at US.

Results: Overall, 30 patients underwent TPLA at our Institution between April 2021 and December 2021. The median prostate volume at TRUS was 42 ml (IQR 40-53). The median time to complete the procedure was 31.5 min (IQR 28-37). All patients were discharged within 8 hours of hospital stay (median 6.4h; IQR 5.9-7.2). No perioperative Clavien-Dindo grade ≥2 were recorded. An objective improvement in the postoperative flowmetry indexes and quality of life was recorded for all patients, who preserved ejaculatory function.

Conclusions: Our experience provides additional evidence supporting the feasibility and safety of TPLA for the treatment of carefully selected patients with LUTS due to BPO.

06. Ultrasound-guided transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a new minimally invasive interventional therapy.

Cai HJ, Fang JH, Kong FL, Xu CK, Chen CH, Wang W, Huang B.

Acta Radiol. 2022 Apr;63(4):553-558

Background: Although there are different treatments for benign prostate hyperplasia, their efficacy and safety differ. We are currently exploring a new minimally invasive interventio-

nal therapy for benign prostatic hyperplasia (BPH).

Purpose: To determine the feasibility, effectiveness, and safety of ultrasound-guided transperineal laser ablation (US-TPLA) for the treatment of BPH.

Material and methods: Twenty patients with BPH (mean age = 73.9 ± 9.2 years) who underwent US-TPLA from June 2018 to January 2020 with a subsequent six-month follow-up were retrospectively reviewed. After local anesthesia, a 21-G trocar was inserted into the prostate tissue under ultrasound monitoring, followed by 1064 nm diode laser irradiation. Changes in international prostate symptom score (IPSS), quality of life (QoL), maximum urinary flow rate (Qmax), postvoid residual (PVR), prostate volume, and complications were evaluated six months after surgery.

Results: All patients underwent the operation successfully without serious complications. After six months, the average IPSS improved from 22.7 ± 5.3 to 9.1 ± 3.2 ($P < 0.001$), the QoL improved from 4.9 ± 1.7 to 2.3 ± 1.3 ($P < 0.001$), the Qmax improved from 8.5 ± 3.0 to 15.2 ± 4.8 mL/s ($P < 0.001$), the PVR increased from 78.7 ± 58.8 to 30.3 ± 34.2 ($P < 0.05$), and the mean prostate volume ranged from 70.8 ± 23.8 to 54.7 ± 20.9 mL ($P < 0.05$).

Conclusion: US-TPLA is safe and feasible for the treatment of BPH. An evaluation at the six-month follow-up is effective.

05. Feasibility, safety, and efficacy of ultrasound-guided transperineal laser ablation for the treatment of benign prostatic hyperplasia: a single institutional experience.

Frego N, Saita A, Casale P, Diana P, Contieri R, Avolio PP, Lazzeri M, Hurle R, Buffi NM, Guazzoni GF, Lughezzani G.

World J Urol. 2021 Oct;39(10):3867-3873

Purpose: To evaluate the feasibility, safety, and efficacy of ultrasound-guided transperineal laser ablation (TPLA) as a new minimally invasive surgical therapy (MIST) for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Materials and methods: Under local anesthesia and conscious
sedation up to two laser fibers for each prostatic lobe were inserted under US-guidance by a percutaneous approach. TPLA was performed using a continuous wave diode laser (SoracteLite-EchoLaserX4) able to generate a light-induced thermal heating and subsequent coagulative necrosis of the prostatic tissue. Patients were evaluated at 3, 6, and 12 months after TPLA.
Results: Twenty-two consegutive patients were prospectively enrolled (median age 61.9 years). All procedures were well tolerated and no procedural complications were recorded. Median catheterization time was 7 days, while the median hospitalization time was 1 day. Three out of twenty-two patients (13.6%) experienced acute urinary retention and two (9.1%) of them urinary tract infection requiring major antibiotic treatment. At 3, 6, and 12 months, median prostate volume significantly decreased by a - 21.3%, - 29%, and - 41%, respectively. At the same time point, median IPSS was 8 (- 63.6%), 5 (- 74%), and 6 (- 75%), while median QoL score was 1 in all the scheduled timepoints of followup. The median postoperative Qmax at 3, 6, and 12 months improved by + 57.8%, + 98%, and + 115.8%, respectively. Ejaculatory function was preserved in 21 out of 22 patients (95.5%).
Conclusions: TPLA of the prostate appears to be a promising MIST for BPH. Long-term results and comparative studies against standard treatments are warranted before implementations of this technique in the urologist's armamentarium.

04. 3-T MRI and clinical validation of ultrasound-guided transperineal laser ablation of benign prostatic hyperplasia.

Manenti G, Perretta T, Calcagni A, Ferrari D, Ryan CP, Fraioli F, Meucci R, Malizia A, Iacovelli V, Agrò EF, Floris R.

Eur Radiol Exp. 2021 Sep 17;5(1):41.

Background: Transperineal laser ablation (TPLA) of the prostate is a novel, mini-invasive option for men with lower urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH). Our aim was to assess the impact of ultrasound-guided TPLA regarding urodynamic improvement and sexual function, monitoring clinical data, postprocedural complications and imaging findings at 3-T multiparametric magnetic resonance imaging.

Methods: Forty-four patients aged ≥ 50 affected with moderate to severe LUTS (International Prostate Symptoms score ≥ 12) due to benign prostatic obstruction and refractoriness, intolerance or poor compliance to medical therapies underwent US-guided TPLA between May 2018 and February 2020. Clinical measurements included PSA, uroflowmetry, sexual function assessment (using the International Index of Erectile Function and Male Sexual Health Questionnaire-Ejaculatory Dysfunction short form) and quality of life questionnaire. Adverse events were evaluated using the Clavien-Dindo scale. Volume changes were measured by MRI and automatic segmentation software during 1- year follow-up.

Registration: NCT04044573 - May 5th, 2018, https://www.clinicaltrials.gov RESULTS: MRI assessed the changes over time with a 53% mean reduction of adenoma volume and 71% of the ablated area, associated with clinical and functional improvement and resolution of LUTS in all cases. Five of 44 patients (11.3%) had urinary blockage due to clots and required re-catheterisation for 2 weeks. The overall adverse event rate was 7%.

Conclusion: US-guided TPLA performed as a safe, manageable and effective treatment for LUTS. It could be considered an alternative effective mini-invasive procedure to standard treatments for BPH in the outpatient setting

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03. Transperineal interstitial laser ablation of the prostate, a novel option for minimally invasive treatment of benign prostatic obstruction.

De Rienzo G, Lorusso A, Minafra P, Zingarelli M, Papapicco G, Lucarelli G, Battaglia M, Ditonno P.

Eur Urol. 2021 Jul;80(1):95-103.

Background: In the algorithm of treatment of benign prostatic obstruction (BPO), the shift from medical therapy to surgery is steep in terms of invasiveness. Recently, a lively interest has developed on alternative micro-invasive options. Transperineal interstitial laser ablation (TPLA) was recently proposed for BPO treatment.

Objective: This work aims to illustrate feasibility, efficacy and safety profile of TPLA in BPO treatment.

Design, setting, and participants: We prospectively analyzed the results of TPLA performed between September 2018 and March 2019 for LUTS due to BPO, in men with prostate volume <100 ml.

Surgical procedure: TPLA was performed in OR, under local anesthesia, using Soracte Lite-EchoLaserX4. Diode laser light is conveyed through 300 µm optical fibers introduced transperineally by 21 Ga needles and placed at a security distance from urethra and bladder neck. EchoLaser Smart Interface eases needle positioning and increases the safety.

Measurements: The primary endpoint was the variation of Qmax and IPSS at 1, 3 and 6 months. We also assessed the ejaculatory function and recorded complications. These outcomes were further investigated at 12 months by phone call.

Results and limitations: 21 men with prostate volume of 43.5 ± 8.5 ml underwent TPLA. All were discharged after 24 h, keeping the transurethral catheter for 8.7 ± 2.5d. At one month all patients but one discontinued medical therapy, showing significant advantage in Qmax (+3.4 ± 5.7 ml/s; $p < 0.01$) and IPSS (-5.6 ± 7.0; $p < 0.01$). Functional results were still progressing at 6 months, with Qmax (+4.7 ± 6.0 ml/s; $p < 0.01$) and IPSS improvement (-13.1 ± 4.7; $p < 0.01$). The ejaculatory function was preserved as the MSHQ-EjD increased ($p < 0.05$). The only complication was a prostatic abscess, treated with transperineal drainage and antibiotic.

Conclusions: TPLA is a micro-invasive treatment for BPO showing good functional and safety outcomes.

Patient summary: This work illustrates the results of TPLA to reat LUTS due to BPO, showing high efficacy, preservation of the ejaculation, and low complication rate.

02. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study.

Pacella CM, Patelli G, Iapicca G, Manenti G, Perretta T, Ryan CP, Esposito R, Mauri G.

Prostate Cancer Prostatic Dis. 2020 Jun;23(2):356-363.

Purpose: To investigate the effectiveness and safety of SoracteLite™-transperineal percutaneous laser ablation (TPLA) in the treatment of patients with symptomatic benign prostatic hyperplasia (BPH) at 6 and 12 months follow-up.

Methods: Patients with urinary symptoms secondary to BPH underwent TPLA under local anesthesia in four centers. Under US guidance, up to four 21G applicators were inserted in the prostatic tissue. Each treatment was performed with diode laser operating at 1064 nm changing the illumination time according to prostate size. The primary end-points of this study were change in IPSS, PVR, Qmax, QoL, and prostatic volume at 6 an 12 months from SoracteLiteTM TPLA treatment. Secondary endpoint was the assessment of complications.

Results: Analysis was performed on data 160 patients (mean age 69.8 ± 9.6 years) with at least 6 months follow and of 83 patients mean age 67.9 ± 8.7 years) with at least 12 months follow-up. At 6 months, IPSS improved from 22.5 ± 5.1 to 7.7 ± 3.3 ($P < 0.001$), PVR from 89.5 ± 84.6 to 27.2 ± 44.5 ml ($P < 0.001$), Qmax from 8.0 ± 3.8 to 14.3 ± 3.9 ml/s ($P < 0.001$), QoL from 4.5 ± 1.1 to 1.8 ± 1.0 ($P < 0.001$), volume from 75.0 ± 32.4 to 60.3 ± 24.5 ml ($P < 0.001$). At 12 months, IPSS improved from 22.5± 4.5 to 7.0 ± 2.9 ($P < 0.001$), PVR from 71.7 ± 93.9 to 17.8 ± 51.0 ml ($P < 0.001$), Qmax from 8.6 ± 5.2 to 15.0 ± 4.0 ml/s ($P < 0.001$), QoL from 4.2 ± 0.6 to 1.6 ± 0.9 ($P < 0.001$), volume from 87.9 ± 31.6 to 58.8 ± 22.9 ml ($P < 0.001$). 7/160 (4.3%) grade I and 1/160 (0.6%) grade III complication occurred.

Conclusions: SoracteLite™ TPLA allows significant improvement of IPSS, Qol, Qmax, PVR, and reduction of prostatic volume at 6 and 12 months.

01. Transperineal Laser Ablation for Percutaneous Treatment of Benign Prostatic Hyperplasia: A Feasibility Study.

Patelli G, Ranieri A, Paganelli A, Mauri G, Pacella CM.

Cardiovasc Intervent Radiol. 2017 Sep;40(9):1440-1446.

Purpose: To assess the feasibility and safety of transperineal laser ablation (TPLA) for treating benign prostatic hyperplasia (BPH).

Materials and methods: Institutional review board approval was obtained for this prospective non-randomized trial. Eightteen patients (age 71.7 ± 9.4 years) with urinary symptoms secondary to BPH underwent TPLA under local anesthesia. Under US guidance, up to four 21G applicators were

inserted in the prostatic tissue. Each treatment was performed with diode laser operating at 1064 nm changing the illumination time according to prostate size. Primary endpoints were technical success and safety of TPLA. Secondary endpoints included operation time, ablation time, energy deployed, hospitalization time, catheterization time, and change in International Prostate Symptom Score (IPSS), Quality of Life (QoL), peak urinary flow rate (Q max), post-void residual (PVR), and prostatic volume at 3 months. χ 2 and Fisher exact tests were used.

Results: All procedures were technically successful. No complications occurred. Mean operation time was 43.3 ± 8.7 min, mean ablation time 15.9 ± 3.9 min, mean energy deployed 10,522 ± 3290.5 J, mean hospital stay 1.5 ± 0.4 days, and mean catheterization time 17.3 ± 10.0 days. At 3 months, IPSS improved from 21.9 to 10.7 ($P < 0.001$), QoL from 4.7 ± 0.6 to 2.1 ± 1.2 ($P < 0.001$), Q max from 7.6 to 13.3 mL/s ($P = 0.001$), PVR from 199.9 ± 147.3 to 81.5 ± 97.8 ($P < 0.001$), and mean prostate volume from 69.8 to 54.8 mL ($P < 0.001$).

Conclusions: TPLA is feasible and safe in the treatment of BPH, providing significant clinical results at 3 months.

Benign Prostatic Hyperplasia

Abstracts on TPLA™

A0690 - Transperineal fusion laser ablation for BPH: 100 consecutive patients with 1 year results.

Maiolino G, Avila LA, Gonzalez PG, Gheiler E, Kaufman A, Bianco FJ.

European Urology, Volume 85, Supplement 1,2024, Pages S1644-S1645, ISSN 0302-2838, https://doi.org/10.1016/S0302-2838(24)01262-4

Introduction & Objectives: Transperineal laser ablation (TPLA) is an innovative method that preserves the urethra and is ultra-minimally invasive. Unlike most procedures for Benign Prostatic Hyperplasia (BPH) that require general or regional anesthesia, we present a one-year update on the NCT04760483 registry that evaluated TPFLA using local anesthesia in the office setting. Our report assesses the impact of
TPFLA on subjective and objective measures of urinary outcomes, including Uroflowmetry, IPSS, as well as erectile function and ejaculation.

Materials & Methods: We conducted a study comprising of 100 patients, aged 50-80 years, with prostate volumes ranging between 30 and 120 cc. The patients exhibited IPSS scores higher than 9, with peak flows lower than 15 cc/s and PVR lower than 250 ml. For this study, we planned to use TPLA, with the aid of Ai algorithms based on mpMRI databank, to establish ablation goals and fiber placement localization, while TPLA was carried out. During the procedure, Focalyx Fusion Device (Focalyx, USA) was used to monitor and visualize the affected area in 3D. The EcholaserX4 (ELESTA SPA, ITALY) was used to deliver energy through single or multiple fibers. The patients were followed up at 3 and 12 months, where we measured IPSS, flow studies, SHIM Scores, and prostate volumes. Upon performing Bayesian analysis and chi2 tests, we have obtained the following results, which we wish to present.

Results: For the cohort, the median Age, BMI, PSA and Prostate volume were 68.9 yrs, 29.3 kg/m2, 2.2ng/ml and 47.4 cc, respectively. Salvage TURP was required in 4 patients, those weren excluded from urinary and ejaculatory function follow-up. The hard data results are presentes in the table.

Conclusions: TPLA in the office setting is feasible and safe. One-year outcomes showed subjective and objective sustained improvement in urinary function the vas majority of patients without major erectile or ejaculatory sequela.

Parameter	Baseline	6 months	12 months	p*
Qmax, ml/s (n=96)[a] Mean ± SD Mean Δ p value	11.1 ± 3.86	16.6 ± 6.05 5.5 <0.001	18.3 ± 5.6 7.2 <0.001[#]	<0.001 ANOVA Rep
Qave, ml/s (n=96)[a] Mean ± SD Mean Δ p value	5.8 ± 2.43	8.7 ± 3.7 2.9 <0.001	8.9 ± 2.9 3.1 <0.001	<0.001 ANOVA Rep
PVR-R, % (n=96)[a] Mean ± SD Mean Δ p value	26.4 ± 12.9	14.4 ± 11.9 -12 <0.001	11.5 ± 6.8 -15 <0.001[#]	<0.001 ANOVA Rep
IPSS (n=96)[a] Mean ± SD Mean Δ p value	17.1 ± 3.8	7.4 ± 3.8 -9.6 <0.001	5.7 ± 2.6 -11.4 <0.001[#]	<0.001 ANOVA Rep
IPSS-QoL (n=96)[a] Mean ± SD Mean Δ p value	4 (3-5)	1 (1-2) -2.6 <0.001	1 (1-2) -2.7 <0.001	<0.001 Friedman
SHIM (n=72)[a] Mean ± SD Mean Δ p value	19 (9.5 - 22)	18.9 (10.7 - 22) 0.21 0.65	17.8 (14.4 - 20.5) 0.43 0.68	0.61 Friedman
Anterograde ejaculation (n=96)[a] Absent - n(%) p value	96/96 (100%)	84/96 (87.5%) <0.001	84/96 (87.5%) <0.001	<0.001 Cochran's Q test

A0693 - Transperineal Laser Ablation (TPLA) and Convective Water Vapor Ablation (CWVA) for minimally invasive treatment of benign prostatic hyperplasia: A randomized controlled trial.

Pacini M, Bartoletti R, Sollazzi E, Macrì G, Zucchi A, Claps F, Greco P.

European Urology, Volume 85, Supplement 1, 2024, Page S1650, ISSN 0302-2838, https://doi.org/10.1016/S0302-2838(24)01265-X

Introduction & Objectives: Minimally invasive techniques are becoming increasingly important treatment options for benign prostate hyperplasia (BPH). We evaluated the safety and efficacy of Transperineal Laser Ablation (TPLA) and convective water vapor ablation (Rezum) in patients with BPH.

Materials & Methods: From February to December 2022 , patients who were candidates for BPH treatment were randomized 1:1 to TPLA or Rezum. The primary endpoint was the the improvement in urodynamic parameters (Qmax, Qave and PVR). Secondary endpoints included patients' reported outcome measures according to International Prostate Symptom Score (IPSS) and the International Index of Erectile Function (IEEF-5) questionnaires, and rates of perioperative complications as per Clavien-Dindo classification.

Results: A total of 80 patients were included: 40 (50.0) treated with TPLA, 40 (50.0) with Rezum, respectively. Median follow-up of 3 months. Median prostate adenoma volume was 59.8 ml (25-200 ml) for TPLA candidates, and 33.0 ml (10-60 ml) for their counterpart (p value < 0,01). Overall, indwelling catheter was present in 10 (12,5 %) and 3 (3,75 %) patients treated with TPLA and Rezum, respectively. At 3 months, median postoperative Qmax and Qave improved by 57.9% and 68.2% in TPLA group and by 57.4% and 68.2% in Rezum group, respectively (p value < 0,001, p value < 0,001). Median PVR decreased by 63.1% after TPLA and by 56.0% after Rezum (p value < 0,001). At the same time point, median IPSS improved by 42.7% after TPLA and 34.6% after Rezum (p value < 0,001). Whereas, no differences were found considering IIEF-5 measures and ejaculatory function. Overall, perioperative complications consisted of 1 patient with prostatic abscess after TPLA procedure treated with (Clavien Dindo grade 3a). 7 (8,75%) patients underwent TURP after minimally invasive treatment.

Conclusions: Both TPLA and Rezum are safe and feasible alternatives for BPH treatment in well selected patients providing significant clinical benefits at 3 months. Longer follow-up and larger cohorts are needed to confirm these findings, to asses the superiority of one a technique over the other and mostly which treatment would be best suited for each patient.

A0698 - Efficacy and safety of ultrasonography guided transperineal percutaneous laser ablation for treating benign prostatic hyperplasia: A randomized controlled clinical trial compared with transurethral resection of the prostate.

Fu Q, Zhang W, Cao N, Meng Z, Guo Q, Xu Y, Chen L, Hu B.

European Urology,Volume 85, Supplement 1, 2024, Pages S1656-S1657, ISSN 0302-2838, https://doi.org/10.1016/S0302-2838(24)01270-3

Introduction & Objectives: To evaluate the efficacy and safety of TPLA treatment by randomized controlled trial (RCT), comparing that of TURP and to provide convincing evidence for its clinical application.

Materials & Methods: BPH patients between 6/2019 to 12/2021, with Qmax≤15 mL/s and IPSS ≥8 were included and randomly assigned to TURP or TPLA group at 1:1, the follow-up was conducted at 1, 3, 6, and 12 months after the operation. Interventions: TPLA was conducted with Esaote MyLab Twice equipped with flexible optical fiber, and TURP was performed by Olympus UES-40 SurgMaster System under standard procedure. The primary efficacy endpoint was the IPSS score variation at 3 months from baseline. The primary safety endpoint was the incidence of complications within 3 months after treatment. We also compared the Qmax, QoL score, MSHQ-EjD score, blood loss, and catheter indwelling time between the groups. Variables were compared by t-test, Wilcoxon test, or Fisher's exact test accordingly.

Results: The IPSS decreased by 14.17±6.13 at 3 months after TPLA, and by 13.19±5.86 after TURP (P=0.706). The complication rate of TPLA and TURP was 16% and 19.23% respectively (P=0.811).TPLA proved less Intraoperative blood loss (6.84±3.1mL, P<0.001) and better ejaculatory protection within 6 months (P<0.05). TURP has advantages in catheter indwelling time(P=0.012) and Qmax within 6 months(P<0.05).

Conclusions: This randomized controlled clinical trial between TPLA and TURP confirms that TPLA is not inferior to TURP in relieving symptoms of BPH. TURP has more advantages in the improvement of Qmax and TPLA exceeds in preserving ejaculation within 6 months. In addition, TPLA has shorter operation time and hospitalization time, less blood loss and pain, and may be more suitable for elderly patients who are unwilling or unable to tolerate TURP, or for those with anemia and other basic diseases.

BIBLIOGRAPHY

A0688 - Trans-perineal laser ablation of the prostate for the treatment of benign prostatic obstruction in high surgical risk patients. One-year results from a prospective cohort of extreme patients.

Sibona M, Vitiello F, Montefusco G, Vercelli E, Micai L, Bracco FM, Mangione C, Colucci F, Destefanis P, Gontero P.

European Urology, Volume 85, Supplement 1,2024, Page S1642, ISSN 0302-2838, https://doi.org/10.1016/S0302-2838(24)01260-0

Introduction & Objectives: Trans-Perineal Laser Ablation of the prostate (TPLA) is an acknowledged Minimally Invasive Surgical Technique (MIST) for the treatment of Benign Prostatic Obstruction (BPO). It was promisingly proposed for the treatment of both standard or high-risk BPO patients (pts). Short-term results from our prospective cohort of elderly/comorbid pts already suggested efficacy together with a high safety profile. The aim of our study was to report one-year results from the same cohort.

Materials & Methods: A full Local Ethics Committee approval was obtained (n. 00161/2020). From 10/2020 to 06/2022, consecutive BPO pts were prospectively enrolled. Inclusion criteria were: 1) ongoing anticoagulant or double antiplatelet therapies or severe nonpharmacological coagulopathies (i.e. low platelet syndromes) or American Society of Anesthesiologists (ASA) score > 3 together with 2)
moderate to severe LUTS (IPSS > 8 and IPSS bother score >=3), maximum flow rate < 15 ml/min or indwelling bladder catheter. All patients underwent TPLA under local anesthesia with the SoracteLite® system (Elesta s.r.l., Calenzano, Italy). Baseline, 6 and 12-months follow-up data were recorded.

Results: Globally, 40 pts were enrolled. Median (IQR) age was 80 (72.5-84) years. 23/40 (57.5%) pts were chronic catheter carriers. Median Charlson Comorbidity Index was 6 (5-7). Median prostate volume was 38 (30.5-73) cc. A TPLA procedure was performed in all pts, without intraoperative complications. Within 3 months from surgery, we reported 19 complications (47.5%). According to the Clavien-Dindo
classification, 13 were grade I (32.5%), 5 grade II (12.5%), 1 grade III (2.5%, endoscopic re-intervention for hematuria). We did not report any grade IV-V complications. After 6 months, the median IPSS score decreased from 25 (19-30) to 8 (6-11.5), p=0.001. A chronic bladder catheter was successfully removed in 13/23 pts (56.5%). After 1 year, 9 pts were reported dead for non-urological causes (22.5%); 3 pts
(7.5%) underwent further surgery for persistent obstruction. 5 pts (12.5%) were still chronic bladder carriers. However, a persistent benefit from the intervention was reported in 23/40 pts (57.5%), with similar IPSS scores compared to the 6-months results.

Conclusions: Elderly men with severe comorbidities have few chances of treatment of BPO. In these cases, TPLA can be a safe alternative. The efficacy of the procedure varies among patients, with a persistent benefit detectable in 50% of them after one year. An accurate candidate selection is mandatory to optimize surgical outcomes.

C56 Ultrasound-guided Soractelite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience.

Di Lascio G, Laganà A, De Carolis A, Di Blasi A, Tufano A.

Vol. 75 - Suppl. 1 to No. 5, October 2023 Minerva Urology and Nephrology.

Background: The aim of this study was to evaluate the efficacy and safety of ultrasound-guided transperineal laser ablation (TPLA) in patients with symptomatic BPH.

Methods: : Inclusion criteria were: 1) patients with BPH with several comorbidities; 2) patients with a desire to spare anterograde ejaculation; and 3) patients intolerant of or poorly compliant to medical therapy, with no indication for surgery. Exclusion criteria were: 1) acute and chronic prostatitis; 2) prior prostatic abscess; 3) prostate volume >85 mL; and 4) all patients with PSA>4.0 ng/mL without a negative MRI scan or negative biopsy for prostate cancer. From January 2020 to March 2023, 90 prospectively enrolled patients underwent TPLA with a 1064-nm continuous-wave diode laser (EchoLaser; Elesta SpA, Calenzano, Florence, Italy). Primary endpoints were the change in IPSS, QoL, Qmax, PVR and prostate volume at 3 ,12 months and 24 months. TPLA procedure involves the coagulative necrosis of prostate tissue; this is achieved by laser illumination delivered by up to two laser fibers per prostatic lobe that are inserted transperineally under US guidance.

Results: A total of 90 patients aged 74.3±11.0 years with symptomatic BPH underwent TPLA. At 3-month follow-up, IPSS was significantly improved from 20.8±7.4 to 11.0±6.6 (P), QoL significantly improved from 4.7±1.4 to 1.5±1.2 (P<0.001) and Qmax increased numerically from 8.6±3.5 mL/s to 13.2±5.7 mL/s (P=0.083). PVR was significantly reduced from 124.8±115.4 mL to 43.6±53.6 mL (P<0.001), and prostate volume significantly decreased from 63.6±29.7 mL to 45.6±21.8 mL (P=0.003). Of the 27 patients who were receiving alpha-blockers at baseline, 15 (55.6%) discontinued this therapy at 3-month follow-up. Of the six patients who were taking a 5-ARI preoperatively, three (50%) discontinued this therapy. At 12-month follow-up, IPSS was significantly improved from 20.8±7.4 to 8.4±5.9 (P<0.001), QoL from 4.7±1.4 to 1.2±0.8 (P<0.001), and Qmax significantly increased from 8.6±3.5 mL/s to 16.2±4.3 mL/s (P=0.014). PVR was significantly reduced from 124.8±115.4 mL to 40.6±53.6 mL (P=0.003), and prostate volume decreased from 63.6±29.7 mL to 42.8±14.2 mL (P=0.071). At 24-month follow-up, IPSS was improved from 20.8±7.4 to 8.0±6.9 (P<0.001), QoL from 4.7±1.4 to 1.3±0.9 (P<0.001), and Qmax significantly increased from 8.6±3.5 mL/s to 18.2±4.8 mL/s (P=0.011). PVR was significantly reduced from 124.8±115.4 mL to 38.1±55.6 mL (P=0.003), and prostate volume decreased from 63.6±29.7 mL to 39.8±12.2 mL (P=0.071). At 24-month follow-up all patients had discontinued medical therapy.

Conclusion: In conclusion, TPLA represents an effective and safe treatment for symptomatic BPH, providing clinically significant benefits on prostate volume, bladder function and QoL.

SC58 Transperineal interstitial laser ablation (TPLA) of the prostate for comorbid patients with benign prostatic obstruction: short- and mid-term functional and safety outcomes from a single center experience

Polverino P, Lo Re M, Saladino M, Bisegna C, Pecoraro A, Moscardi L, Resta GR, Mariottini R, Rivetti A, Nicoletti R, Mazzola L, Spatafora P, Li Marzi V, Gacci M, Siena G, Cocci A, Minervini A, Serni S, Campi R, Sessa F.

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Background: Nowadays, despite the technological progress they have undergone in recent decades, standard surgical techniques for benign prostatic obstruction (BPO) are still not devoid of side effects, requiring general or spinal anesthesia and hospitalization. Recently, several ultra-minimally invasive surgical techniques ensuring good functional results and a high safety profile were developed, often not requiring general anesthesia and/or hospitalization. Among these, transperineal interstitial laser ablation (TPLA) of prostate adenoma has showed promising results in preliminary series. Our work aims to evaluate functional and safety outcomes in comorbid patients undergoing TPLA for LUTS due to BPO.

Methods: We prospectively collected data from consecutive patients undergoing TPLA at our institution between April 2021 and February 2023. Inclusion criteria were moderate to severe LUTS (International Prostatic Symptoms Score ≥8); a prostate volume ranging from 30 to 100mL and an ASA Score of 3. In case of indwelling catheter an invasive urodynamic evaluation was performed preoperatively to exclude bladder impaired contractility. Procedures were performed in an outpatient setting using local anesthesia and mild oral benzodiazepine administration, using EchoLaser™ multisource diode laser generator (Elesta SpA, Calenzano, Florence, Italy). Data regarding functional outcomes evaluated by validated questionnaires (IPSS and QoL) and uroflowmetry parameters, as well as patient management (catheterization, medications, complications) were recorded pre- and postoperatively at 1-, 3-months and last follow-up (LF-UP) for descriptive analyses.

Results: Overall, 22 patients were enrolled with a median age of 76.5 (IQR 67.3-81.3). Median follow-up time was 12 months (IQR 6.5-15). Median prostate volume was 52.5 mL (IQR 38.3-72.5); median preoperative IPSS and QoL were 21 (IQR 15-26.5) and 4 (IQR 3-5), respectively; median preoperative Qmax and PVR were 8 (IQR 5.9-9.6) and 110 (IQR 92.5-132.5), respectively. 4 patients had an indwelling catheter before the procedure. All patients were discharged on the same day as the procedure. Median catheterization time was 7 days (IQR 0). Median IPSS and QoL were 13.5 (IQR 9.5-22.8) and 2 (IQR 1-4), 13 (IQR 10-20.5) and 2 (IQR 1 – 3.5), 16 (IQR 11.8-22) and 3 (IQR 1-3.3) at 1-, 3-months and LF-UP, respectively. Median Qmax and PVR were 9.1 (IQR 6.4-11) and 44 (IQR 12.5-67.5), 9.1 (IQR 8.1-9.7) and 67.8 (IQR 25-115), 10 (IQR 8.3-11.5) and 90 (IQR 30-100) at 1-, 3-months and LF-UP, respectively. 2 (9%) patients failed to remove the catheter (both with an indwelling catheter before the procedure). No Clavien-Dindo Grade ≥2 postoperative complications were recorded.

Conclusion: In our preliminary experience, TPLA appears to be a safe and feasible minimally invasive option for LUTS due to BPO in comorbid and frail patients, showing promising functional and safety outcomes. Larger series are needed to confirm these results.

SC162 Ejaculation preservation in patients treated with transperineal interstitial laser ablation (TPLA) for LUTS due to benign prostatic obstruction

Polverino P, Lo Re M, Saladino M, Bisegna C, Pecoraro A, Moscardi L, Resta GR, Mariottini R, Rivetti A, Nicoletti R, Li Marzi V, Siena G, Cocci A, Gacci M, Minervini A, Serni S, Campi R, Sessa F.

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Background: Ejaculatory disorders (EjD) are prominent postoperative side effects in men who are treated for benign prostatic obstruction (BPO) with traditional prostate surgeries, such as transurethral resection of the prostate (TURP). Recent surgical techniques were developed to preserve antegrade ejaculation with promising short-term results. Among these, transperineal interstitial laser ablation (TPLA) of prostate adenoma seems to play a relevant role. Herein, we report perioperative and short-term sexual outcomes of patients treated with TPLA for LUTS due to BPO.

Methods: Data from consecutive patients with moderate to severe LUTS and a prostate volume ranging from 30 to 100 mL undergoing TPLA at our institution between April 2021 and February 2023, were prospectively collected in a dedicated database. Procedures were performed in an outpatient setting using local anesthesia and oral benzodiazepine administration, using EchoLaser (Elesta SpA, Calenzano, Florence, Italy) multisource diode laser generator. The International Index of Erectile Function (IIEF-5), Male Sexual Health Questionnaire-Ejaculatory Dysfunction Short Form 3-items (MSHQ-EjD SF 3-items) and patient management (catheterization, medications, PSA) data were recorded pre- and postoperatively at 1-, 3-months and last follow-up (LF-UP) for descriptive analyses.

Results: Overall, 95 patients were enrolled. Median follow-up time was 9 months (IQR 4 - 14). Median prostate volume was 50 mL (IQR 40-70); median preoperative IIEF5 and MSHQ-EjD SF 3-items were 20 (IQR 13.5-40) and 5 (IQR 2-11), respectively. All patients except one were discharged on the same day as the procedure, recording no Clavien-Dindo Grade ≥2 perioperative complications. Median catheterization time was 7 days (IQR 7-8). Median IIEF-5 and MSHQ-EjD SF 3-items were 21 (IQR 12-25) and 10 (IQR 6-13), 21 (IQR 12-25) and 9 (IQR 4-13), 22 (IQR 12-25) and 11.5 (IQR 5-13) at 1-, 3-months and LF-UP, respectively. In all patients, ejaculation and sexual function were preserved. 12 (12.6%) patients required re-introduction of alpha blocker therapy at 6 months, with a potential a significant negative impact on ejaculatory function.

Conclusions: According to our experience, TPLA appears to be a safe and feasible option in the treatment landscape for LUTS due to BPO in carefully selected patients, ensuring the preservation of ejaculatory function.

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Transuretral water vapour thermal therapy (Rezum™) versus Transperineal Laser Ablation of the Prostate (TPLA) for the treatment of benign prostatic hyperplasia: A realworld prospective comparative analysis.

Fernández-Pascual E, Bocchino AC, Balmori C, Martín C, Bianco Jr. FJ, Martínez Salamanca JI.

European Urology, Volume 83, Supplement 1, 2023, Pages S334-S335, ISSN 0302-2838, https://doi.org/10.1016/S0302-2838(23)00286-5

Introduction & Objectives: To compare transuretral water vapour thermal ablation (Rezum™) with TransPerineal Laser Ablation (TPLA) using Echolaser® as a treatment for benign prostatic hyperplasia (BPH).

Materials & Methods: We reviewed our prospective database to identify patients with prostate sizes <80 cc who underwent Rezum™ or TPLA for treatment of BPH between May 2019 and April 2022. Both treatments were performed under IV sedation and outpatient setting. Pre- and post-operative outcomes including International Prostate symptom score (IPSS), maximum flow (Qmax), post-void residual (PVR), presence of ejaculation and postoperative complications within 90 days were analysed.

Results: A total of 55 and 12 patients underwent either RezumTM or TPLA surgery. The perioperative and follow-up (6-months) variables are shown in the following Table. No major differences in intraoperative complications were observed between both groups. No complications required reoperation.

Conclusions: Our initial experience using Echolaser® TPLA seems to be as safe and effective than Rezum™ treatment, with the advantage of preventing urethral damage. Both treatments could be considered for patients with moderate LUTS interested in preserving ejaculation in an outpatient setting and without major complications.

Transperineal Laser Ablation for Benign and Malignant Prostate Disease.

Walser E, Nance A, Masood I.

Journal of Vascular and Interventional Radiology, Volume 34, Issue 3, S130 - Abstract No. 287

Purpose: Evaluate the safety and efficacy of transperineal laser ablation (TPLA) of the prostate gland for benign prostatic hyperplasia (BPH) and organ-confined prostate cancer (PCA). Materials and Methods: 48 male patients with a mean age of 67 had TPLA of the prostate. Twelve had BPH, 19 had BPH and PCA, and 17 had PCA only. Symptomatic BPH is an International Prostate Symptom score (IPSS) of 10 or greater. Prostate cancers were confined to the gland in all 36 patients. A transrectal ultrasound probe guided the transperineal placement of 21-gauge needles into the prostate. The bladder was catheterized and a cannula inserted between the rectum and prostate to infuse saline and protect the urethra and rectum from thermal damage. Laser fibers were advanced through the needles and activated at 3-5 watts for a total of 1800J per ablation (Elesta s.r.l, Florence, Italy). PCA ablations involved the hemigland containing the malignancy. Patients had a follow-up prostate MRI to evaluate ablation zones 48 hours after TPLA. Patients had a follow-up clinic visit at one week and again at 6 months. SHIM (Sexual Health in Men) scores were calculated before TPLA and 6 months post procedure to evaluate for erectile dysfunction.

Results: All procedures were successful with minor complications of urinary retention requiring catheterization for over one week (15 patients or 31%) and 5 urinary tract infections (UTI 10%). For all patients, the average time of laser irradiation was 16 minutes and all procedures were done in less than one hour. Average energy deposited was 10,440 Joules. The IPSS dropped significantly from 13.6 to 6.9 at 6 months (P = 0.001) and the prostate volume reduced from 51.6 cc to 36.8 cc post TPLA (P = 0.001). At 6 months, the PSA fell from 10.2 to 4.2 ng/dL (P = 0.01). For prostate cancer patients, the gland treatment was smaller so that less laser energy and time occurred (9,083 joules and 14 minutes, respectively). SHIM scores did not change significantly. Two of the 36 patients treated for PCA had recurrent cancer detected at 1 and 2.5 years after ablation and were successfully retreated with TPLA.

Conclusion: TPLA is effective and provides significant prostate debulking and focal cancer ablation. The prostate size and PSA levels decreased significantly at 6 months. More importantly, the BPH symptom reduction was significant with no change in SHIM scores. Most common minor complications were urinary retention and UTI. TPLA is an outpatient procedure lasting less than one hour and requiring no vascular access or radiation exposure and can be repeated as necessary.

Prostate Cancer

Full-text Papers

Sexual function outcomes in men undergoing minimal invasive ablative techniques for prostate cancer: a ESRU/YAU urotech systematic review and pooled analysis.

Piramide F, Veccia A, Tzelves L, Nikles S, Ortega Polledo LE, Nocera L, et al.

Minerva Urol Nephrol 2025;77:285-97. DOI: 10.23736/S2724-6051.25.06007-0

Introduction: In the latest years the advent of minimally invasive focal treatment for prostate cancer (PCa) has gained a wide diffusion. Different platforms and sources of energy have been developed (HIFU, cryotherapy, focal brachytherapy…) and reported to be able to effectively treat PCa with minimal impact on sexual function. The aim of this systematic review is to summarize, evaluate and compare the impact of these focal therapies on the sexual function (erectile and ejaculatory function) of men harboring low to intermediate risk PCa.

Evidence acquistion: A systematic literature search was conducted in October 2022 and updated in August 2024 using Medline (via PubMed), Embase (via Ovid), Scopus, and Web of Science (registered on PROSPERO as CRD42022370237). The search strategy used PICO criteria and article selection was conducted following the PRISMA guidelines. The risk of bias and the quality of the articles included were assessed. A dedicated data extraction form was used to collect the data of interest.

Evidence synthesis: Overall, our electronic search identified 4465 papers, 96 of which ultimately met the inclusion criteria and thus were included in the analysis. Among them, 87 were single arm studies, eight were comparative studies, whilst only 1 was a randomized prospective study. Overall, 6244 patients were evaluated (2318 HIFU, 2034 focal cryoablation, 1194 irreversible electroporation [IRE], 346 focal laser ablation [FLA], 147 high-dose brachytherapy [HDB], 247 Vascular photodynamic therapy [VPT], 21 focal microwave ablation [FMA], 151 low-dose brachytherapy [LDB], 10 focal bipolar radiofrequency ablation [FBRA] and 22 trans-urethral ultrasound ablation [TULSA]). The most reported measure of sexual function was IIEF-5, with baseline scores ranging from 16.2 (IRE) to 22.35 (VPT). At 12 months post-treatment, VPT and high-dose brachytherapy had the highest IIEF-5 scores (20.01 and 19.90, respectively), while cryotherapy, low-dose brachytherapy, and HIFU had the lowest (14.08, 14.94, and 15.40, respectively). Ejaculatory function was underreported, with only two studies assessing its preservation after HIFU. Safety analysis showed an overall complication rate of 21%, with major complications occurring in 1.4% of cases.

Conclusions: FT offers a promising balance between oncologic control and functional preservation in low- to intermediate-risk PCa. However, significant variability in FT modalities, ablation strategies (focal vs. hemigland vs. zonal), and outcome assessment methods limits direct comparisons. Future prospective studies with standardized protocols and long-term follow-up are essential to optimize patient selection and improve functional outcomes.

Echolaser Focal Treatment for Prostate Cancer Guided by Fiducial Marker Placement.

Granitsas T, Anastassakis I, Brempos S, Brempos K.

Cancers. 2025; 17(10):1707. https://doi.org/10.3390/cancers17101707

Background: Focal therapy has emerged as a viable alternative to radical prostate cancer treatment, offering oncologic control while minimizing morbidity. EchoLaser focal laser ablation (FLA) is a minimally invasive technique that utilizes high-precision laser energy for tumor destruction. This study evaluated the oncologic outcomes, procedural efficiency, and safety of EchoLaser focal therapy, comparing fiducial-assisted (FM+) and non-fiducial (FM–) approaches.

Methods: A retrospective cohort study was conducted at Athens Medical Center, Greece, including 50 patients with localized prostate cancer treated with EchoLaser therapy. Patients were categorized into FM+ (n = 31) and FM– (n = 19) groups. Oncologic control (MRI and PSA levels at six months), procedural efficiency (operative time), and safety (adverse events) were assessed.

Results: At six months, 80% of patients (n = 40) had no residual disease on MRI, while 20% (n = 10) showed persistent or recurrent tumor activity. PSA levels declined from 10.26 ± 14.99 ng/mL to 2.70 ± 2.67 ng/mL, reflecting a 74% median reduction. Procedure time was shorter in FM+ patients (33.48 ± 2.41 min vs. 45.79 ± 2.92 min, $p < 0.01$). Adverse events occurred only in the FM– group, including one case of urinary retention.

Conclusions: FLA with EchoLaser using fiducial marker enhances procedural efficiency and could have a positive impact on oncologic control. These findings suggest that fiducial markers should be integrated into focal therapy protocols. Longer follow-up studies are needed to confirm the long-term outcomes.

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Laser-focused ablative therapy for prostate cancer and benign prostatic hyperplasia: A review of current applications and future directions.

Cornud F, Walser EM, de Bie KC, Lefevre A, Galiano M.

Diagn Interv Imaging. 2025 Apr 16:S2211-5684(25)00072-5.
doi: 10.1016/j.diii.2025.04.001.

Abstract: Focal Laser ablation (FLA), or interstitial Laser thermotherapy, is a promising minimally invasive approach for the treatment of localized prostate cancer and benign prostatic hyperplasia. This technique is gaining popularity among patients due to its ability to preserve pre-treatment quality of life. The examination is performed under magnetic resonance imaging (in bore) or ultrasound guidance, via a percutaneous transrectal or transperineal route. Under transperineal ultrasound guidance, FLA can use up to four Laser fibers to create confluent zones of tissue ablation, enabling treatment of larger prostate- or tumor volumes. Primary indications for FLA include intermediate-risk localized prostate cancer and benign prostatic hyperplasia refractory to medical treatment due to ineffectiveness or side effects. The intervention is typically performed under light sedation or under locoregional anesthesia. FLA lasts approximately 10 min, with a total intervention time of < 60 min on an outpatient basis. Patients are often discharged with either a suprapubic or bladder catheter to prevent urinary retention, especially if the ablated area is close to the urethra. Minor complications are rare and limited to transient voiding dysfunction, urinary tract infection, or hematuria. Major complications, such as rectoprostatic fistula, are avoided by rectoprostatic hydrodissection. FLA is an effective, well-tolerated option in the minimally invasive treatment of prostate disease, offering rapid treatment times, low complication rates, and preservation of quality of life for appropriately selected patients. However, variability in recurrence rates following FLA for prostate cancer highlights the need for further investigation into optimal patient selection for this treatment.

Transperineal Focal Laser Ablation of the Prostate for Prostate Cancer: A Systematic Review of the Literature.

Polverino P, Lo Re M, Moscardi L, Resta GR, Caneschi C, Conte F, Giustozzi B, Rivetti A, Pecoraro A, Li Marzi V, et al.

Cancers. 2025; 17(6):968.
https://doi.org/10.3390/cancers17060968

Objectives: The aim of this work was to review the available evidence on transperineal focal laser ablation (FLA) for patients with localized PCa, focusing on both functional and oncological outcomes.

Methods: A comprehensive review of the English-language literature was performed using the MEDLINE (via PubMed) and Web of Science (WOS) databases until 30 December 2024, using a combination of free text and MeSH subject headings. The review process was carried out according to the PRISMA guidelines.

Results: The literature search found 156 papers, and among these, 10 papers were finally accepted and included. A risk of bias assessment was conducted, revealing low-quality evidence and high heterogeneity among the available data. Low- to high-risk cancers were treated across the studies. A drop in PSA values was observed in all studies after FLA, but no definition of biochemical disease-free survival was established. The postfocal presence of cancer rate ranged from 4% to 57%, while clinically significant cancer was detected in 0 up to 31% of cases. Secondary treatments were necessary for 7 to 30%. The overall complication rate ranged from 0% to 66%, most being mild and transient. Functional outcomes appeared to be preserved both in the short- and long-term follow-ups. Quantitative analyses were not performed due to the low number and heterogeneity of the studies included.

Conclusions: Transperineal FLA for the treatment of clinically localized prostate cancer appears to be a feasible, safe technique with an efficacy comparable to other focal therapy modalities.

MRI-directed Micro-US-guided Transperineal Focal Laser Ablation for Localized Prostate Cancer: A 1-year Follow-up Study.

Cornud F, de Bie K, van Riel L, Lefèvre A, Camparo P, Galiano M.

Radiology. 2024 Dec;313(3):e233371.
doi: 10.1148/radiol.233371. PMID: 39718499.

Abstract: Multifiber micro-US–guided focal laser ablation in participants with localized prostate cancer was safe and feasible, with 18% recurrence at 1-year follow-up.

Background: MRI-guided focal laser ablation (FLA) is a promising treatment in localized prostate cancer (PCa). MRI-guided micro-US FLA shows potential for outpatient use, but its clinical application remains unexplored.

Purpose: To evaluate the safety, feasibility, and 12-month functional and oncologic outcomes of MRI-guided micro-US transperineal FLA in localized PCa and to assess the accuracy of micro-US in showing lesions depicted at MRI with Prostate Imaging Reporting and Data System (PI-RADS) score of 3 or higher.

Materials and Methods: This prospective, single-center observational study (July 2020 to June 2023) included participants with localized low- or intermediate-risk PCa and PI-RADS 3 or higher lesions (≤20 mm). Single- or multifiber FLA was performed at 1064 nm, guided by MRI-delineated image fusion. At 12 months, recurrence rates, complications, erectile function scores, and urinary symptom scores were assessed. Mann-Whitney U and Wilcoxon tests were used for comparisons.

Results: Fifty-five male participants (median age, 70 years; IQR, 62–74 years) with 58 lesions that were PI-RADS 3 or higher underwent transperineal FLA, with a 12-month follow-up for 33 participants. The median prostate-specific antigen level was 7.0 ng/mL (IQR, 5.6–9.0 ng/mL), 43 of 58 lesions (74%) had a Gleason score of 3 + 4, and 10 of 58 lesions (17%) had a Gle-

ason score of 3 + 3. Single-fiber and multifiber FLA were used to treat 21 of 58 (36%) and 37 of 58 (64%) tumors, respectively. At micro-US, 53 of 58 (91%) tumors were successfully visualized. Multifiber FLA produced larger ablation volumes than did single-fiber treatment (median, 15 mL [IQR, 8–22 mL] vs 4.5 mL [IQR, 2.8–9.2 mL]; P < .001). At 12 months, biopsies in 35 treated tumors showed 17 recurrences (49%), including 13 in-field and four out-of-field recurrences. In-field recurrences occurred in 10 of 18 (56%) single-fiber and three of 17 (18%) multifiber cases. At 12 months, erectile function scores decreased compared with baseline (median International Index of Erectile Function score, 19 [IQR, 12–24] vs 21 [IQR, 15–24]; P < .001), whereas urinary function remained stable (median International Prostatic Symptom Score, 2 [IQR, 2–9] vs 6 [IQR, 3–11]; P = .72). One rectoprostatic fistula developed and required surgery.

Conclusion: Multifiber micro-US–guided FLA was safe and feasible, with 18% recurrence at 1-year follow-up.

Transperineal Laser Ablation for Focal Therapy of Localized Prostate Cancer: 12-Month Follow-up Outcomes from a Single Prospective Cohort Study.

Iacovelli V, Carilli M, Bertolo R, Forte V, Vittori M, Filippi B, Di Giovanni G, Cipriani C, Petta F, Maiorino F, et al.

Cancers. 2024; 16(15):2620.
https://doi.org/10.3390/cancers16152620

Introduction and objectives: To evaluate the oncological and functional outcomes of transperineal laser ablation (TPLA) as the focal therapy for localized prostate cancer (PCa) after a 12-month follow-up.

Materials and methods: Patients with low- and intermediate-risk localized PCa were prospectively treated with focal TPLA between July 2021 and December 2022. The inclusion criteria were the following: clinical stage < T2b; PSA < 20 ng/mL; International Society of Urological Pathology (ISUP) grade ≤ 2; MRI-fusion biopsy-confirmed lesion classified as PI-RADS v2.1 ≥ 3. Intra-, peri-, and post-operative data were collected. Variables including age, PSA, prostate volume (PVol), Charlson's Comorbidity Index (CCI), International Prostate Symptom Score (IPSS) with QoL score, International Index of Erectile Function (IIEF-5), International Consultation on Incontinence Questionnaire—Short Form (ICIQ-SF), and Male Sexual Health Questionnaire—Ejaculatory Dysfunction Short Form (MSHQ-EjD) were collected at baseline and at 3, 6 and 12 months after TPLA. Post-operative mpMRI was performed at 3 and 12 months. Finally, all patients underwent prostatic re-biopsy under fusion guidance at 12 months. The success of this technique was defined as no recurrence in the target treated lesion at the 12-month follow up.

Results: Twenty-four patients underwent focal TPLA. Baseline features were age [median 67 years (IQR 12)], PSA [5.7 ng/mL (3.9)], PVol [49 mL (27)], CCI [0 (0)], IPSS [11 (9)], IPSS-QoL [2 (2)], IIEF-5 [21 (6)], ICIQ-SF [0 (7)], MSHQ-EjD ejaculation domain [14 (4)] and bother score [0 (2)]. Median operative time was 34 min (IQR 12). Median visual analogue scale (VAS) 6 h after TPLA was 0 (IQR 1). The post-operative course was regular for all patients, who were discharged on the second post-operative day and underwent catheter removal on the seventh post-operative day. No patient had incontinence at catheter removal. A significant reduction in PSA (p = 0.01) and an improvement in IPSS (p = 0.009), IPSS-QoL (p = 0.02) and ICIQ-SF scores (p = 0.04) compared to baseline were observed at the 3-month follow-up. Erectile and ejaculatory functions did not show any significant variation during the follow-up. No intra- and peri-operative complications were recorded. Three Clavien–Dindo post-operative complications were recorded (12%): grade 1 (two cases of urinary retention) and grade 2 (one case of urinary tract infection). At the 12-month follow-up, eight patients showed mpMRI images referable to suspicious recurrent disease (PIRADS v2.1 ≥ 3). After re-biopsy, 7/24 patients' (29%) results were histologically confirmed as PCa, 3 of which were recurrences in the treated lesion (12.5%). The success rate was 87.5%.

Conclusions: The focal TPLA oncological and functional results seemed to be encouraging. TPLA is a safe, painless, and effective technique with a good preservation of continence and sexual outcomes. Recurrence rate at 12 months was about 12.5%.

Transperineal Laser Ablation (TPLA) Treatment of Focal Low–Intermediate Risk Prostate Cancer.

Manenti G, Perretta T, Nezzo M, Fraioli FR, Carreri B, Gigliotti PE, Micillo A, Malizia A, Di Giovanni D, Ryan CP, et al.

Cancers. 2024; 16(7):1404.
https://doi.org/10.3390/cancers16071404

Background: This interventional pilot study aimed to evaluate the short-term (3 years) efficacy of focal laser ablation (FLA) in treating the index lesion of low–intermediate-risk prostate cancer, along with assessing the safety of the procedure (ClinicalTrials.gov ID NCT04045756).

Methods: Forty patients aged between 46 and 86 with histologically proven organ-confined prostate cancer and low-to-intermediate progression risk were included. FLA was performed under percutaneous fusion magnetic resonance/ultrasound guidance in a Day Hospital setting under local anesthesia. Patients underwent regular clinical and functional assessments through the international index of erectile function (IIEF-5) and the International Prostatism Symptom Score (IPSS), PSA measurements, post-procedure MRI scans, and biopsies at 36 months or if positive findings were detected earlier. Statistical analyses were conducted to assess trends in PSA levels and cavity dimensions over time.

Results: Forty patients were initially included, with fifteen lost to follow-up. At 36 months, a mean PSA reduction of 60% was observed, and 80% of MRI scans showed no signs of in-field clinically significant residual/recurrent cancer. Biopsies at 36 months revealed no malignant findings in 20 patients. No deterioration in sexual function or urinary symptoms was recorded.

Conclusions: FLA appears to be safe, feasible, and effective in the index lesion treatment of low–intermediate-risk prostate cancer, with a high rate of tumor eradication and preserva-

tion of quality of life.

Transperineal laser ablation (TPLA) with ultrasound/MRI fusion guidance in the treatment of localized radiotherapy-resistant prostate cancer.

Manenti G, Nezzo M, Ryan CP, Fraioli FR, Carreri B, Gigliotti PE, et al.

BJR Open (2023) 10.1259/bjro.20230042.

Objective: The objective of this study was to assess the technical feasibility, safety, and efficacy of transperineal laser ablation (TPLA) guided by ultrasound/magnetic resonance (MR) fusion as a salvage treatment for refractory focal prostate cancer.

Methods: A total of five patients who had undergone radiation therapy (RT) for prostate carcinoma and biochemical recurrence, confirmed by both prostatespecific antigen (PSA) levels and MRI (3T mpMRI), were enrolled in this study. Focal ablation was performed using a 1064 nm diode laser. Post-ablation follow-up was conducted for a duration of 18 months, which included regular PSA sampling, 3T mpMRI, and ultrasound/MR fusion-guided biopsies systematic and targeted at the site of the focal treatment.

Results: The focal ablation procedure was carried out in an outpatient setting regimen with optimal clinical and biochemical outcomes. No recurrence was detected throughout the follow-up period.

Conclusion: TPLA focal treatment effectively manages local recurrences of RT refractory prostate cancer without side-effects or complications. Preservation of quality of life and functional outcomes, along with a >70% reduction in PSA, were achieved.

Advances in knowledge: Our study investigated TPLA as a salvage treatment for low-risk recurrent prostate cancer after RT, demonstrating its tolerability, feasibility, and effectiveness.

Transperineal laser ablation of the prostate as a treatment for benign prostatic hyperplasia and prostate cancer: The results of a Delphi consensus project.

Cocci A et al.

Asian Journal of Urology, 2023, ISSN 2214-3882, https://doi.org/10.1016/j.ajur.2023.07.001

Objective: To evaluate trans-perineal laser ablation (TPLA) with Echolaser® (Echolaser® TPLA) as a treatment for benign prostatic hyperplasia (BPH) and prostate cancer (PCa) using the Delphi consensus method.

Methods: Italian and international experts on BPH and PCa participated in a collaborative consensus project. During two rounds, they expressed their opinions on Echolaser® TPLA for the treatment of BPH and PCa answering online questionnaires on indications, methodology, and potential complications of this technology. Level of agreement or disagreement to reach consensus was set at 75%. If the consensus was not achieved, questions were modified after each round. A final round was performed during an online meeting, in which results were discussed and finalized.

Results: Thirty two out of forty invited experts participated and consensus was reached on all topics. Agreement was achieved on recommending Echolaser® TPLA as a treatment of BPH in patients with ample range of prostate volume, from <40 mL (80%) to >80 mL (80%), comorbidities (100%), antiplatelet or anticoagulant treatment (96%), indwelling catheter (77%), and strong will of preserving ejaculatory function (100%). Majority of respondents agreed that Echolaser® TPLA is a potential option for the treatment of localized PCa (78%) and recommended it for low-risk PCa (90%). During the final round, experts concluded that it can be used for intermediate-risk PCa and it should be proposed as an effective alternative to radical prostatectomy for patients with strong will of avoiding urinary incontinence and sexual dysfunction. Almost all participants agreed that the transperineal approach of this organ-sparing technique is safer than transrectal and transurethral approaches typical of other techniques (97% of agreement between experts). Pre-procedural assessment, technical aspects, post-procedural catheterization, pharmacological therapy, and expected outcomes were discussed, leading to statements and recommendations.

Conclusions: Echolaser® TPLA is a safe and effective procedure that treats BPH and localized PCa with satisfactory functional and sexual outcomes.

Reliable Visualization of the Treatment Effect of Transperineal Focal Laser Ablation in Prostate Cancer Patients by Magnetic Resonance Imaging and Contrast-enhanced Ultrasound Imaging

Van Riel LAMJG, Van Kollenburg RAA, Freund JE, Almasian M, Jager A, Engelbrecht MRW, Smit RS, Bekers E, Nieuwenhuijzen JA, Van Leeuwen PJ, Van der Poel H, De Reijke TM, Beerlage HP, Oddens JR, De Bruin DM.

European Urology Open Science, Volume 54, August 2023, Pages 72-79

Background: Transperineal focal laser ablation (TPLA) treatment for prostate cancer (PCa) is an experimental focal ablative therapy modality with low morbidity. However, a dosimetry model for TPLA is lacking.

Objective: To determine (1) the three-dimensional (3D) histologically defined ablation zone of single- and multifiber TPLA treatment for PCa correlated with magnetic resonance imaging (MRI) and contrast-enhanced ultrasound (CEUS) and (2) a reliable imaging modality of ablation zone volumetry.

Design, setting, and participants: This was a prospective, multicenter, and interventional phase I/II pilot study with an ablate-and-resect design. TPLA was performed in 12 patients with localized prostate cancer divided over four treatment regimens to evaluate potential variation in outcomes.

Intervention: TPLA was performed approximately 4 wk prior

to robot-assisted radical prostatectomy (RARP) in a daycare setting using local anesthesia.

Outcome measurements and statistical analysis: Four weeks after TPLA, ablation zone volumetry was determined on prostate MRI and CEUS by delineation and segmentation into 3D models and correlated with whole-mount RARP histology using the Pearson correlation index.proving quality of life. Longer follow-up and analysis of predictive factors will be needed in the near future.
Results and limitations: Twelve office-based TPLA procedures were performed successfully under continuous transrectal ultrasound guidance using local perineal anesthesia. No serious adverse events occurred. A qualitative analysis showed a clear demarcation of the ablation zone on T2-weighted MRI, dynamic contrast-enhanced MRI, and CEUS. On pathological evaluation, no remnant cancer was observed within the ablation zone. Ablation zone volumetry on CEUS and T2-weightedMRI compared with histology had a Pearson correlation index of r = 0.94 (95% confidence interval [CI] 0.74–0.99, p < 0.001) and r = 0.93 (95% CI 0.73–0.98, p < 0.001), respectively.

Conclusions: CEUS and prostate MRI could reliably visualize TPLA ablative effects after minimally invasive PCa treatment with a high concordance with histopathological findings and showed no remnant cancer.

Patient summary: The treatment effects of a novel minimally invasive ablation therapy device can reliably be visualized with radiological examinations. These results will improve planning and performance of future procedures.

A single-operator experience using EchoLaser SoracteLite™ for focal laser ablation of prostate cancer: One more arrow in the quiver for the conservative management of the disease.

Meneghetti I, Giardino D, Morganti R, Marino V, Menchini Fabris F, Bartoletti R, Pinzi N.

Archivio Italiano Di Urologia E Andrologia, 94(4), 406–412. https://doi.org/10.4081/aiua.2022.4.406

Background: The aim of this study was to evaluate the outcomes of patients suffering prostate cancer (PCa) treated conservatively using 1064 nm laser energy for focal laser ablation (FLA). The patients included in the study were unsuitable for surgery or unwilling to receive external beam radiotherapy because they were afraid of the possible side effects of whole-gland therapies.

Methods: This study included patients with a diagnosis of nonmetastatic PCa who underwent FLA using SoracteLite™ system. Tissue ablation was performed at a fixed power of 5 W by the diode multichannel laser system EchoLaser X4 that uses laser light transmitted through optical fibres causing the target tissue to undergo irreversible thermal damage. Functional outcomes were evaluated with the International Prostatic Symptoms Score (IPSS) and 5-item version of the International Index of Erectile Function (IIEF-5) before the treatment and one year later.

Results: Ten patients suffering non-metastatic PCa were included. Four decided upon a conservative treatment because of reduced performance status and for six patients the procedure was chosen electively. All patients underwent multiparametric magnetic resonance imaging at 3 and 12 months and eight out of ten patients underwent prostate biopsy at 6 months. Persistent disease was detected in 3 patients who underwent a second ablation. In these patients at the biopsy following the second ablation none harbored residual disease. At followup, no patient suffered urinary incontinence requiring the use of pads. No significant worsening in sexual potency measured with IIEF-5 (p = 0.356) or prostatic symptoms measured at IPSS (p = 0.462) were recorded comparing pre-treatment condition vs one-year follow-up. Compared with baseline, prostatespecific antigen was significantly reduced at one-year follow-up (3.7 ± 1.1 vs 7.9 ± 4.1 ng/mL; p = 0.008).

Conclusions: Although whole gland therapies remain the gold standard treatment for PCa, our results indicate that the SoracteLite™ system for focal laser ablation, as a very preliminary step, appears to offer a short-term oncologic control of PCa with negligible side effects

Safety and Feasibility of Soractelite Transperineal Focal Laser Ablation for Prostate Cancer and Short-term Quality of Life Analysis from a Multicenter Pilot Study.

Van Riel L, van Kollenburg R , Andre´ N. Vis AN , van Leeuwen PJ , de Reijke TM , de Bruin DM , Oddens JR.

Prostate Cancer| Volume 39, P48-54, May 01, 2022

Background: Soractelite™ transperineal focal laser ablation (TPLA) for the treatment of localized prostate cancer (PCa) using the Echolaser® system is a novel minimally invasive technique that has the potential to induce tissue ablation, while reducing treatmentrelated morbidity, when compared with robot-assisted radical prostatectomy (RARP) and radiotherapy.

Objective: To determine the short-term safety and feasibility of single or multifiber TPLA, its functional outcomes, and quality of life (QoL).

Design, setting, and participants: TPLA was performed in 12 patients, consecutively assigned to four treatment regimens, with localized PCa who were scheduled for RARP ("ablate and resect design"). The treatment regimens were as follows: (1) a single fiber at 3 W, (2) two fibers at 5 mm distance at 3 W, (3) two fibers at 10 mm distance at 3 W, and (4) a single fiber at 5 W. TPLA was scheduled 4 wk prior to RARP.

Intervention: TPLA using the Echolaser® system under local anesthesia at the outpatient clinic. Outcome measurements and statistical analysis: Safety and feasibility were determined by the assessment of device-related peri- and postoperative adverse events (AEs), and length of hospital stay. Functional outcomes and QoL were measured using validated questionnaires. Feasibility of RARP was assessed by a questionnaire for the urologist.

Results and limitations: Patients were dismissed after a

median (interquartile range) hospital admission of 3.25 (1.25) h. No device-related AEs occurred. AEs that occurred were mostly related to lower urinary tract symptoms and were mild (grade 1–2). Most AEs resolved within 1 wk. A QoL analysis showed no significant differences for all treatment regimens. Functional outcomes remained unchanged, except for erectile function after 1 wk, which returned to baseline after 4 wk. TPLA treatment did not compromise RARP, based on the questionnaires.

Conclusions: TPLA for the treatment of PCa at the outpatient clinic appears to be safe and feasible with good short-term QoL and functional outcomes; oncological results are awaited.

Patient summary: Focal treatment of localized prostate cancer can safely be performed in a daycare setting using a new technique, based on laser ablation, without compromising quality of life.

Prostate Cancer

Abstract

P061: MRI-directed ultrasound-guided Transperineal Focal Laser Ablation (TPLA) for prostate cancer: One year follow-up of 158 patients

de Bie KCC, Cornud FC, Van Riel LMJG, Regusci S, Martins Favre M, Zimmer RE, Galliano M, Walser EM, Oddens JR

EMUC24 Networking and Abstract Discussion Session

Introduction & Objectives: This study investigates the safety, feasibility, and one-year functional and oncological outcomes of MRI-directed ultrasound (US)-guided transperineal focal laser ablation (TPLA) for patients with organ-confined prostate cancer (PCa).

Materials & Methods: This study is based on a multicentre registry of patients treated with TPLA for biopsy-proven localised PCa at three major clinics in Europe and the USA. Included patients were treated between May 2018 and June 2023, and were followed-up for a minimum of one year. Patients who received whole-gland treatment prior to TPLA were excluded. The EchoLaser system, operating at 1064 nm (3 or 5 Watts), was used in single or multi-fibre mode for PI-RADS ≥ 3 lesions under US guidance. Before treatment, MRI-delineated target volumes were fused with US imaging. Follow-up included PSA assessments every six months, contrast-enhanced MRI scans at six or twelve months, and biopsies as indicated (PSA rise and/or MRI-positive lesion) in two clinics, or standard biopsies at 12 months in the third clinic.

Results: A total of 158 patients received TPLA on 170 PI-RADS ≥3 lesions. The median age was 69 years (IQR 62-73), initial PSA level was 7.5 ng/mL (IQR 5.0-10), prostate volume was 40 cc (IQR 30-60), and tumour diameter was 12 mm (IQR 10-15 mm). Among these patients, 44/158 (28%) had ISUP 1, 79 (50%) ISUP 2, 23 (14.6%) ISUP 3, and 7 (4.4%) ISUP 4 disease. Between one to four fibers were used per patient in one or two treatment cycles, with a median laser treatment time of 15 minutes (IQR 11-15) and a median energy delivery of 3827 Joules (IQR 2400-7208). At the 6-month follow-up, PSA levels significantly decreased from a median of 7.5 ng/mL (IQR 5.0-10) to 3.3 ng/mL (IQR 1.9-6.6) ($p<0.001$). There were no significant changes in erectile function (IIEF) or urinary symptoms (IPSS) at 12 months compared to baseline. Post-FLA, one patient experienced a Clavien-Dindo (CD) Grade 3 complication (a recto-prostatic fistula requiring surgery). CD Grade 1 complications occurred in 32/158 patients (19%) and CD Grade 2 complications in 13/158 patients (8%). At 12 months, PSA levels increased significantly compared to the 6-month mark (median 4.5 ng/mL (IQR 2.5-14) vs. 3.3 ng/mL (IQR 1.9-6.6), $p<0.001$). MRI scans were performed in 134 patients, with 40/134 (30%) showing positive MRI lesions in the treated area. Biopsies were conducted on 82 patients (including all MRI-positive patients), and 42/82 (51%) had positive biopsies, confirming in-field recurrence. Therefore, initial TPLA treatment was successful in 116/158 (74%) of patients.

Conclusions: At the one-year follow-up, nearly three-quarters of patients remained recurrence-free after TPLA for localised PCa. The therapy was safe and did not affect erectile function or urinary symptoms.

Oncological and functional outcomes following MicroUS-guided focal laser ablation of localised prostate cancer: comparison of single and multi-laser fibers settings

Cornud F, Lefevre A, Galiano M.

Abstract ECR 2024

Purpose: This study aimed to evaluate the safety, feasibility, and short-term functional and oncological outcomes of focal laser ablation (FLA) of tumours at low risk of progression, under micro-ultrasound guidance.

Methods or Background: 58 PI-RADS>2 lesions were treated in 55 patients between July 2020 and June 2023 with a follow-up of 12 months for 29 patients. The mean age was 69±7.4 years. The mean PSA level was 7.9±3.5 ng/ml. The large tumour axis was ≤20mm. Gleason score was 6 in 10 lesions (10/58,17.2%) and 3+4 in 43 lesions (43/58,74.5%). The first 21 (21/58,36%) and the last 37 lesions (37/58,64%) were treated with a single and multifiber mode, respectively, using the Echolaser® system operating at 1064nm. Image fusion was used to cover the MRI-delineated target volume. A prosta-to-rectal hydrodissection was performed for posteromedial tumours. DCE-MRI was performed 4 days after FLA to evaluate the ablated volume.

Results or Findings: MicroUS visualised 53 tumours (53/58,91.4%). The multifiber mode achieved larger ablation volumes (19.1±11.8 vs 5.9±3.5cc, $p=0.0001$). A prostate-rectal fistula occurred postoperatively in a patient with a posteromedial lesion, which was treated surgically. Urinary and erectile functions were not affected by FLA. At 12 months follow-up of 34 tumours in 29 patients, in-field targeted biopsies (TB) diagnosed 13 recurrences (13/34,38.2%, Gleason pattern 4 in 8/13 tumours, 61.5%). Ten (10/13,77%) occurred with a single fibre setting. Four out-field recurrences (4/34,11.7%) were diagnosed. After retreatment of 6 recurrences, TB showed, at 12 months, an 80% negative TB-biopsy rate.

Conclusion: Multifiber microUS-guided FLA is a safe and feasible modality with promising short-term oncological and functional outcomes. Caution is required in posteromedial lesions.

A_04 Transperineal laser ablation for low- and intermediate risk prostate cancer: short-term functional outcomes

Carilli M, Iacovelli V, Bertolo R, Chiara Cipriani C, Vittor mi, Petta F, Maiorino F, Signoretti M, Antonucci M, Travaglia S, Panei M, Bove P.

Abstract Congress 17 UrOP, 2023

Aim of the Study: Focal therapy has been proposed as an alternative to radical treatment in carefully selected patients with prostate cancer (PCa). This study aimed to explore the role of transperineal laser ablation (TPLA) on early post-operative functional outcomes.

Materials and Methods: Patients with low- and intermediate-risk localized PCa were prospectively treated with a focal MRI/US guided TPLA between Jan-2022 and Apr-2022. Patients were classified as clinical stage T1c-T2, with a PSA < 20 ng/ml, International Society of Urological Pathology (ISUP) grade ≤ 2, single MRI-fusion biopsy confirmed lesion classified as PI-RADS v2.1 ≥ 3. Intra-, peri-, and postoperative data were collected. Variables including age, PSA, prostate volume (PVol), number of positive cores, International Prostate Symptom Score (IPSS) with quality of life (QoL), International Consultation on Incontinence Questionnaire – Short Form, (ICIQ-SF), International Index of Erectile Function (IIEF-5), maintenance of antegrade ejaculation (yes/no), and Patients' Global Impression of Change (PGI-I) were collected at baseline, 3 and 6 months after TPLA.

Results: Twenty patients were enrolled. Baseline features were age [66.5 years (IQR 54.5-69.5)], PSA [5.0 ng/ml (4.0-7.5)], PVol [62.5 ml (52.0-77.5)], no. positive cores [2.0 (1.5-2.5)], IPSS [9.0 (4.5-14.0)], QoL [2.0 (1.0-3.0)], ICIQ-SF [0 (0-0)], IIEF-5 [19.5 (15.0- 23.0)], MSHQ-EjD [0 (0-0.5)]. At mpMRI, 3 patients had PI-RADS v2.1 = 3, 15 had PI-RADS v2.1 = 4 and 2 had PI-RADS v2.1 = 5. Biopsy positive cores were 2.0 (1.5-2.5) with 12 ISUP 1 and 8 ISUP 2 cases. The median operative time was 32.5 minutes (28.0-37.0), the total delivered energy was 2600 J (1800-3600). Visual analogue scale (VAS) after 12 hours from TPLA was 0 (0-1). The post-operative course was regular for all patients. At 3-months follow-up, a statistically significant reduction was found for IPSS [7.0 (IQR 5.0-11.5), p=0.02], that was stable at 6-months [6.0 (5.0-10.0), p=0.5] and QoL [1.0 (IQR 0.5-2.0), p=0.001] that was stable at 6-months [1.0 (0.0-2.0), p=0.9]. Continence was preserved in all the patients with an ICIQ-SF = 0 at both 3 and 6 months. Sexual outcomes did not report any statistically significant difference during follow-up [3-months IIEF-5 = 20.0 (15.3-23.5), p=0.3; 6-months IIEF-5 = 20.5 (15.5-24.0), p=0.22)]; all patients maintained post-operative antegrade ejaculation. Patients were satisfied about the treatment with a PGI-I at 3-months [3.0 (2.0-4.0)].

Conclusions: Short-term functional TPLA results seemed to be encouraging. TPLA is a safe, painless, and effective technique leading to a good preservation of continence and sexual outcomes.

Kidney Cancer

Image-guided laser ablation in the treatment of recurrence of renal tumours: technique and preliminary results.

Ferrari F, Mauri G, Nicosia L, Varano GM, Bonomo G, Orsi F.

Eur Radiol Exp. 2020 Jan 3;4(1):1.

Abdominal recurrences of renal cell carcinoma (RCC) after surgery might represent a challenge for treatment, often requiring difficult surgeries or anticipated systemic therapy. Our aim is to illustrate a novel application of laser ablation for the treatment of abdominal recurrences of RCC. Patients with abdominal recurrences of renal cancer were treated under ultrasound/computed tomography guidance with a diode laser inserted into the lesion through a thin 21-G needle. A fixed 3-W power protocol was used, changing the illumination time according to lesion dimension and shape. Also, technical success, technical efficacy, local tumour progression, and major and minor complications were retrospectively analysed. Three patients were treated with image-guided laser ablation for abdominal recurrences of RCC. In all cases, it was possible to perform ablation as preoperatively planned and all three nodules (size of 6, 8, and 12 mm) were completely ablated with no evidence of residual enhancement after 6 weeks at contrast-enhanced CT. No minor or major complications were observed. No local tumour progression was reported up to 12 months from ablation. Image-guided laser ablation holds the potential to offer a minimally invasive treatment to patients with abdominal recurrence of RCC. Further studies are needed to evaluate the clinical role of this technique.

Ultrasound-guided percutaneous laser ablation is safe and effective in the treatment of small renal tumors in patients at increased bleeding risk.

Sartori S, Mauri G, Tombesi P, Di Vece F, Bianchi L, Pacella CM.

Purpose: The aim of this retrospective study was to assess the safety and effectiveness of laser ablation (LA) in patients with small renal cell carcinomas (RCC) and increased risk of bleeding.

Material and methods: From 2013 to 2017, nine patients (six males, three females, aged 68.5 ± 12.2 years) at high risk of bleeding underwent ultrasonography-guided LA for an RCC. Patients were considered at increased risk of bleeding because of impairment of coagulation parameters, concomitant antiplatelet therapy, or at-risk location of the tumor (one, five, and three patients, respectively). RCC diameter ranged from 11 to 23 mm. According to tumor size, two or three laser fibers were introduced through 21-gauge needles and 1800 J per fiber were delivered in 6 min with a fixed power of 5 W. Major and minor complications, technical success, and primary and secondary technical effectiveness and tumor recurrence were recorded.

Results: Just one Grade 1 complication was observed: a small asymptomatic hematoma that spontaneously resolved. Technical success was 100%, 1 month technical efficacy was 88.9% (8/9 patients). One patient with residual tumor was successfully retreated 1 month later, and secondary efficacy rate was 100%. No local tumor recurrence occurred during a median follow-up of 26 months (range 11-49 months).

Conclusions: LA is safe and effective in the treatment of small RCC and might represent a valid option in patients with increased risk of bleeding.

Recurrences from Kidney Cancer

Image-Guided Ablations in Patients with Recurrent Renal Cell Carcinoma.

Aurilio G, Mauri G, Rossi D, Della Vigna P, Bonomo G, Varano GM, Maiettini D, Rocca MC, Verri E, Cullurà D, Nolè F and Orsi F.

Journal of Clinical Medicine. 2023; 12(15):4902. https://doi.org/10.3390/jcm12154902

Renal cell carcinoma (RCC) is one of the most frequently diagnosed tumors and a leading cause of death. The high risk of local recurrence and distant metastases represent a significant clinical issue. Different image-guided ablation techniques can be applied for their treatment as an alternative to surgery, radiotherapy or systemic treatments. A retrospective analysis was conducted at our institution, including a total number of 34 RCC patients and 44 recurrent RCC tumors in different locations (kidney, lung, adrenal gland, liver, pancreas, pararenal and other) using microwave ablation, radiofrequency ablation, cryoablation and laser ablation. The estimated time to local and distant tumor progression after treatment were 22.53 ± 5.61 months and 24.23 ± 4.47 months, respectively. Systemic treatment was initiated in 10/34 (29%) treated patients with a mean time-to-systemic-therapy of 40.92 ± 23.98 months. Primary technical success was achieved in all cases and patients while the primary efficacy rate was achieved in 43/44 (98%) cases and 33/34 (97%) patients, respectively, with a secondary technical success and efficacy rate of 100%. At a mean follow-up of 57.52 months ± 27.86 months, local tumor progression occurred in 3/44 (7%) cases and distant progression in 25/34 (74%) patients. No significant complications occurred. Image-guided ablations can play a role in helping to better control recurrent disease, avoiding or delaying the administration of systemic therapies and their significant adverse effects.

CT-guided percutaneous laser ablation of adrenal metastases from kidney cancer.

Oltmanns G.

P167 - ECIO 2023 Book of Abstracts. Cardiovasc Intervent Radiol 46 (Suppl 2), 23–271 (2023). https://doi.org/10.1007/s00270-023-03414-0.

Clinical history: male patient, 80 years, non-treated asymptomatic size stable 8cm ccRCC ISUP grad II right kidney diagnosed 2018. Radiologic T3, N0, M1 (3mm lung metastasis with growth rate 3mm/y) CT control March 2022 detected two 19 and 12mm left adrenal metastases with a growth rate of 8mm/y. Patient was in general good health, active, non-functional atrophic left kidney, non-treated hypertension, no other comorbidities.

Treatment / Results: Two fast growing adrenal metastases were treated using a multi-source 1064 nm wavelength laser device (EchoLaser, Elesta SpA). In March 2022 the 19 mm metastases were treated with 3 simultaneously working fibers introduced by 21-G needles with power of 5 W and 11300J delivered energy using pull-back manoeuvre and repositioning of 2 fibres. In November 2022 the second adrenal metastases that became 18 mm diameter underwent laser ablation using 3 fibers and 7200J total energy delivered. Contrast-enhanced CT after both sessions showed complete ablation. At the end of both treatments occurred hypertensive crisis with measured arterial blood pressure up to 300 mm/hg systolic which was handled instantly with medications. No other complications occurred.

Discussion: The minimally invasive multi-fiber approach enabled treatment of small adrenal metastases without severe complication. Control after ablation confirmed complete treatment. Long term follow-up is required to asses results on local tumor progression.

Take-home points: Fine needle multi-source laser ablation allows precise treatment in small sized tumor and difficult anatomic location. Laser ablation can delay medical treatment or surgery

Image-guided laser ablation in the treatment of recurrence of renal tumours: technique and preliminary results.

Ferrari F, Mauri G, Nicosia L, Varano GM, Bonomo G, Orsi F.

Eur Radiol Exp. 2020 Jan 3;4(1):1. doi: 10.1186/s41747-019-0127-0.

Abstract: Abdominal recurrences of renal cell carcinoma (RCC) after surgery might represent a challenge for treatment, often requiring difficult surgeries or anticipated systemic therapy. Our aim is to illustrate a novel application of laser ablation for the treatment of abdominal recurrences of RCC. Patients with abdominal recurrences of renal cancer were treated under ultrasound/computed tomography guidance with a diode laser inserted into the lesion through a thin 21-G needle. A fixed 3-W power protocol was used, changing the illumination time according to lesion dimension and shape. Also, technical success, technical efficacy, local tumour progression, and major and minor complications were retrospectively analysed. Three patients were treated with image-guided laser ablation for abdominal recurrences of RCC. In all cases, it was possible to perform ablation as preoperatively planned and all three nodules (size of 6, 8, and 12 mm) were completely ablated with no evidence of residual enhancement after 6 weeks at contrast-enhanced CT. No minor or major complications were observed. No local tumour progression was reported up to 12 months from ablation. Image-guided laser ablation holds the potential to offer a minimally invasive treatment to patients with abdominal recurrence of RCC. Further studies are needed to evaluate the clinical role of this technique.

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