

Benign prostatic hyperplasia: laser prostatectomy (PVP)

HIPERPLASIA PROSTÁTICA BENIGNA: PROSTATECTOMIA POR VAPORIZAÇÃO A LASER (PVP)

Authorship: Brazilian Society of Urology

Participants: Nunes RLV¹, Oliveira RRM¹, Carneiro A¹, Neto AM¹, Antunes AA¹,

Wanderley Marques Bernardo², Antônio Silvinato²

Final draft: September 3rd, 2016

¹Sociedade Brasileira de Urologia (SBU)

²Associação Médica Brasileira (AMB)

<http://dx.doi.org/10.1590/1806-9282.63.11.929>

The Guidelines Project, an initiative of the Brazilian Medical Association, aims to combine information from the medical field in order to standardize procedures to assist the reasoning and decision-making of doctors.

The information provided through this project must be assessed and criticized by the physician responsible for the conduct that will be adopted, depending on the conditions and the clinical status of each patient.

GRADES OF RECOMMENDATION AND LEVELS OF EVIDENCE

- A: Experimental or observational studies of higher consistency.
- B: Experimental or observational studies of lower consistency.
- C: Cases reports (non-controlled studies).
- D: Opinion without critical evaluation, based on consensus, physiological studies or animal models.

OBJECTIVE

The objective of this guideline is to present the main available evidence comparing transurethral resection of the prostate with laser prostatectomy (PVP) in patients with benign prostatic hyperplasia (BPH) in relation to the main peri- or postoperative outcomes, allowing the formalization of recommendations directly supported by such evidence.

DESCRIPTION OF EVIDENCE COLLECTION METHOD

This guideline followed the standard of a systematic review with evidence retrieval based on the EBM (evidence-based medicine), so that clinical experience is integrated with the ability to critically analyze and apply scientific information rationally, thus improving the quality of medical care. EBM uses existing and currently available scientific evidence, with good internal and external validity for the application of its results in clinical practice.^{1,2}

Systematic reviews are currently considered the level I of evidence for any clinical question by systematically summarizing information on a particular topic through

primary studies (clinical trials, cohort studies, case-control or cross-sectional studies) using a reproducible methodology, in addition to integrating information on effectiveness, efficiency, efficacy and safety.^{1,2}

We use the structured mode of formulating the question synthesized by the acronym PICO, where P stands for patient or population presenting prostatic hyperplasia, I stands for intervention with laser prostatectomy (PVP), C stands for comparison with transurethral resection of the prostate and O stands for the outcome of efficacy and harm. Based on the structured question, we identified the descriptors that formed the basis of the search for evidence in the following databases: Medline, Embase, Central Cochrane, Cochrane Library. Thus, 367 studies were retrieved, and, after applying the eligibility criteria (inclusion and exclusion), 11 were selected to answer the clinical question (Annex I).

CLINICAL QUESTION

What is the effectiveness of laser prostatectomy (PVP) in patients with benign prostatic hyperplasia?

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common disease with high morbidity in the elderly. Patients with urinary symptoms, mainly obstructive, may require surgical treatment, which is usually performed through transurethral resection of the prostate (conventional TURP). Complications of the procedure include bleeding, TURP syndrome (water intoxication), urinary incontinence,

urinary retention and sexual dysfunction, especially regarding ejaculation function.

In an attempt to reduce morbidity, the development of new alternative surgical procedures has been encouraged, including photoselective vaporization of the prostate (PVP) using laser.

The laser emits light at a wavelength of 532 nm, which will be absorbed by hemoglobin, leading to heating of the prostatic tissue. In the beginning, PVP was performed with potassium-titanyl-phosphate (KTP) laser at 60 W and later at 80 W. Then, laser prostatectomy (PVP) using a high-performance system (HPS) 120 W laser or XPS 180 W laser was introduced, aiming at reducing the limitations of KTP, as well as improving results compared with conventional TURP.

The goal is to reduce hospitalization time, bleeding, and other complications, but there is some doubt as to the effectiveness of laser treatment with regard to the replacement of conventional TURP as a first-line treatment.

SELECTED EVIDENCE RESULTS

Patients (> 50 years) with urinary flow (UF) \leq 15 mL/s; prostate symptoms score (IPSS) \geq 12; prostatic volume (PV): 15-85 cm³ (USG); obstruction (AG nomogram) (N: 76), were treated with PVP using KTP 80 W laser and star pulse quasicontinuous wave laser (laserscope) emitting green light at a wavelength of 532 nm (N: 38) compared with transurethral resection of the prostate (conventional TURP) (N: 38), with the following outcomes being assessed: urinary flow, international prostate symptoms score (IPSS), quality of life score (QoL), bother score, postvoid residual volume (PVRV), surgical time, PO Hb, length of catheterization and length of hospitalization after 6 weeks and at 3, 6 and 12-month follow-up. The use of laser leads to significant increase in UF (mL/s), decline in IPSS, increase in quality of life (QoL), increase in bother score, increase in postvoid residual volume (PVRV) (mL), shorter bladder irrigation time (min) and shorter length of hospitalization (days), and less decrease in hemoglobin levels (g/dL). There is no difference in surgical time (min).³ (B)

In patients aged 68 years, BPH; PV: 70 to 100 mL; UF < 15 mL/s; PVRV > 150 mL; IPSS > 7 (N: 76), PVP with KTP/532 high-power laser emitting green light (80W) (N: 39) was compared with transurethral resection of the prostate (conventional TURP) (N: 37), and the following outcomes were assessed: IPSS and IIEF-5 scores; PV; PVRV; UF; urinary retention; transfusion; re-intervention after 6 months. There was a significant benefit with the use of PVP laser in relation to all analyzed outcomes; however, there was an increased risk of urinary retention (NNH: 8) and re-intervention (NNH: 6).⁴ (B)

Patients with BPH; IPSS > 16; UF < 15 mL/s; PV < 100 mL; PVRV < 100 mL (N: 120) treated with HPS 120-W laser using lithium triborate (LBO) crystal, producing 532-nm waves (N: 60) or transurethral resection of the prostate (conventional TURP) (N: 60) were assessed regarding surgical time; Hb; transfusion; length of catheterization; length of hospitalization; complications; IPSS; PVRV; PV; UF at 1, 3, 6, 12, 24 and 36 months. The use of laser compared with conventional TURP significantly increased the outcome of surgical time, but reduced the outcomes of bleeding, length of catheterization and length of hospitalization. There is a decline in the risk of transfusions (NNT: 6) and intraoperative complications (NNT: 5), but also an increase in the number of early (NNH: 2) and late (NNH: 8) complications.⁵ (B)

PVP treatment using HPS 120-W laser in 50 patients was compared with transurethral resection of the prostate (conventional TURP) in other 50 patients, the following inclusion criteria being adopted: BPH; IPSS > 15; PV < 80 cm³; urinary flow < 15 mL/s. At 1, 3, 6, 12 and 24 months, the following outcomes were assessed: IPSS; urinary flow; surgical time; Hb; transfusion; complications; length of hospitalization; length of catheterization. The results of laser intervention reduced blood loss, length of catheterization and length of hospitalization compared with conventional TURP. Nevertheless, they increased surgical time. Regarding catheterization with a probe < 20 Fr, intraoperative and late complications, there is a benefit to using laser with NNT = 1, 10 and 6, respectively.⁶ (B)

In patients with BPH; > 50 years; IPSS \geq 12 and bother score \geq 3; Qmax < 12 mL/s; prostatic volume between 25 mL and 80 mL; PVRV < 300 mL (N: 139), two treatment modalities were compared: PVP HPS 120-W laser (N: 69) and transurethral resection of the prostate (conventional TURP) (N: 70) based on IPSS; length of hospitalization; Qmax; PVRV; complications; sexual symptoms; quality of life at 12 months. Only surgical time was shorter using laser treatment, while none of the other outcomes presented significant differences, although length of hospitalization was shorter with conventional TURP.⁷ (B)

Bleeding (measured by Hb) and length of catheterization were less noticeable in 64 patients with BPH (age > 50 years; IPSS > 7; prostatic volume > 20 and < 80 cc; urinary flow (Q max) < 15 mL/s) treated with PVP (laser emitting green light at a wavelength of 532 nm, 30 to 80W) compared with 64 patients treated with conventional TURP, at 12-month follow-up. Nevertheless, surgical time was longer in the group treated with PVP.⁸ (B)

In patients with lower urinary tract symptoms due to BPH (N: 20) treated with PVP HPS 120-W laser) or transurethral resection of the prostate (conventional

TURP), there is no difference between the two treatment modalities regarding outcomes expressed by IPSS, IIEF-5 and ICIQ-SF scores, or the following measures: PVRV and Qmax, at 12-month follow-up.⁹ **(B)**

In patients with BPH, IPSS > 15, treatment failure, Qmax < 15 mL/s and prostatic volume < 100 mL (N: 200), comparison between PVP (HPS with 80-W KTP laser) (N: 100) and transurethral resection of the prostate (conventional TURP) (N: 100) made it possible to assess the outcomes of length of catheterization, length of hospitalization, peri- and postoperative complications, IPSS and QoL, Qmax, PVRV and prostatic volume, at 1, 3, 6, 12, 24 and 36-month follow-up. The outcomes measured at 24 months did not present significant difference between the two treatment modalities in relation to the scores: quality of life (QoL), IPSS, urinary flow, PVRV and PO Hb. But there was significant benefit in favor of the laser in the following outcomes: prostatic volume, length of catheterization and length of hospitalization. Conventional TURP yielded a shorter surgical time. Regarding complications, there was a decline in the rate of transfusion and perforation of the prostatic capsule with the use of the laser.¹⁰ **(B)**

Patients with BPH and moderate or severe lower urinary tract symptoms (IPSS > 16), therapeutic failure, maximum flow rate (Qmax) < 15 mL/s, PVRV > 100 mL and prostatic volume < 100 mL (N: 62) were treated comparatively with PVP (HPS 180-W laser) (N: 31) and transurethral resection of the prostate (conventional TURP) (N: 31). At the 12-month follow-up, surgical time was longer using laser, but the lengths of hospitalization and catheterization were shorter, with lower rates of transfusion (NNT: 5) and perforation (NNT: 6). The other outcomes did not differ: hemoglobin and transfusion, other peri- and postoperative complications, IPSS, QoL, Qmax, PVRV and prostatic volume.¹¹ **(B)**

Except for a shorter length of hospitalization, the treatment of patients with symptoms of BPH obstruction; 64 years; IPSS > 7; Qmax < 15 mL/s; prostatic volume < 80 mL; PVRV > 150 mL (N: 124) with PVP 120-W laser (N: 60), compared with transurethral resection of the prostate (conventional TURP) (N: 64), failed to demonstrate superiority or inferiority when analyzed in relation to the following outcomes: IPSS; length of hospitalization; Qmax; PVRV; complications; sexual symptoms; re-intervention or transfusion at 24 months.¹² **(B)**

In patients with lower urinary tract symptoms due to BPH with obstruction; aged 40 to 80 years; IPSS ≥ 12; Qmax < 15 mL/s; prostatic volume ≤ 100 mL (N: 281), there was no difference between treatment with transurethral resection of the prostate (conventional TURP) (N: 142) and PVP with 180-W XPS laser vaporization (N: 139),

at 24 months, regarding the following outcomes: quality of life (QoL); IPSS; urinary flow (mL/s); PVRV; prostatic volume; re-treatment and complications.¹³ **(B)**

EVIDENCE SUMMARY

There is evidence, with high risk of bias, of the benefit of laser prostatectomy (PVP) in patients with BPH compared to conventional TURP regarding UF, IPSS, QoL, bother score, IIEF-5 score, postvoid residual volume (PVRV), bladder irrigation/length of catheterization, length of hospitalization (days), Hb decline, prostatic volume, urinary retention, transfusion (NNT: 6), re-intervention (?), intraoperative complications (NNT: 5), early (NNT: 10) and late (NNT: 6) complications at different times, from 6 to 24 months.

There is evidence, with the same high risk of bias, of lower PVP benefit compared to conventional TURP regarding risk of urinary retention (NNH: 8), re-intervention (NNH: 6), surgical time, number of early (NNH: 2) and late (NNH: 8) complications, as well as length of hospitalization.

There is no difference between the two treatment modalities in relation to the outcomes expressed by the scores: IPSS, IIEF-5 and ICIQ-SF, or the following measurements: urinary flow, PVRV, prostatic volume and Qmax, length of hospitalization, complications, sexual symptoms, re-intervention, need for transfusion or re-treatment at 12 to 24 months of follow-up.

RECOMMENDATION

Due to controversies regarding the superiority or inferiority of treatment of benign prostatic hyperplasia using laser PVP compared to transurethral resection, it is not possible to recommend treatment with PVP instead of conventional TURP. **(C)**

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

1. Nobre MR, Bernardo WM, Jatene FB. A prática clínica baseada em evidências. Parte I – Questões clínicas bem construídas. *Rev Assoc Med Bras.* 2003; 49(4):445-9.
2. Bernardo WM, Nobre MR, Jatene FB. A prática clínica baseada em evidências. Parte II – Questões clínicas bem construídas. *Rev Assoc Med Bras.* 2004; 50(1):104-8.
3. Bouchier-Hayes DM, Anderson P, Van Appledorn S, Bugeja P, Costello AJ. KTP laser versus transurethral resection: early results of a randomized trial. *J Endourol.* 2006; 20(8):580-5.
4. Horasanli K, Silay MS, Altay B, Tanriverdi O, Sarica K, Miroglu C. Photosensitive potassium titanyl phosphate (KTP) laser vaporization versus transurethral resection of the prostate for prostates larger than 70 mL: a short-term prospective randomized trial. *Urology.* 2008; 71(2):247-51.
5. Al-Ansari A, Younes N, Sampige VP, Al-Rumaihi K, Ghafouri A, Gul T, et al. GreenLight HPS 120-W laser vaporization versus transurethral resection of the prostate for treatment of benign prostatic hyperplasia: a randomized clinical trial with midterm follow-up. *Eur Urol.* 2010; 58(3):349-55.

6. Capitán C, Blázquez C, Martín MD, Hernández V, de la Peña E, Llorente C. GreenLight HPS 120-W laser vaporization versus transurethral resection of the prostate for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia: a randomized clinical trial with 2-year follow-up. *Eur Urol.* 2011; 60(4):734-9.
7. Lukacs B, Loeffler J, Bruyère F, Blanchet P, Gelet A, Coloby P, et al.; REVAPRO Study Group. Photoselective vaporization of the prostate with GreenLight 120-W laser compared with monopolar transurethral resection of the prostate: a multicenter randomized controlled trial. *Eur Urol.* 2012; 61(6):1165-73.
8. Mohanty NK, Vasudeva P, Kumar A, Prakash S, Jain M, Arora RP. Photoselective vaporization of prostate vs. transurethral resection of prostate: a prospective, randomized study with one year follow-up. *Indian J Urol.* 2012; 28(3):307-12.
9. Pereira-Correia JA, de Moraes Sousa KD, Santos JB, de Moraes Perpétuo D, Lopes-da-Silva LF, Krambeck RL, et al. GreenLight HPS™ 120-W laser vaporization vs transurethral resection of the prostate (<60 mL): a 2-year randomized double-blind prospective urodynamic investigation. *BJU Int.* 2012; 110(8):1184-9.
10. Xue B, Zang Y, Zhang Y, Yang D, Gao J, Sun C, et al. GreenLight HPS 120-W laser vaporization versus transurethral resection of the prostate for treatment of benign prostatic hyperplasia: a prospective randomized trial. *J Xray Sci Technol.* 2013; 21(1):125-32.
11. Jovanović M, Džamić Z, Aćimović M, Kajmaković B, Pejić T. Usage of GreenLight HPS 180-W laser vaporisation for treatment of benign prostatic hyperplasia. *Acta Chir Iugosl.* 2014; 61(1):57-61.
12. Telli O, Okutucu TM, Suer E, Burgu B, Gulpinar O, Yaman O, et al. A prospective, randomized comparative study of monopolar transurethral resection of the prostate versus photoselective vaporization of the prostate with GreenLight 120-W laser, in prostates less than 80cc. *Ther Adv Urol.* 2015; 7(1):3-8.
13. Thomas JA, Tubaro A, Barber N, d'Ancona F, Muir G, Witzsch U, et al. A multicenter randomized noninferiority trial comparing GreenLight-XPS laser vaporization of the prostate and transurethral resection of the prostate for the treatment of benign prostatic obstruction: two-yr outcomes of the GOLIATH Study. *Eur Urol.* 2016; 69(1):94-102.
14. Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials.* 1996; 17(1):1-12.
15. Goldet G, Howick J. Understanding GRADE: an introduction. *J Evid Based Med.* 2013; 6(1):50-4.
16. Wells G, Shea B, O'Connell D, Robertson J, Peterson J, Welch V, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. *Eur J Epidemiol.* 2011; 25:603-5.
17. Levels of Evidence and Grades of Recommendations – Oxford Centre for Evidence Based Medicine. Available from: http://cebm.jr2.ox.ac.uk/docs/old_levels.htm.

- #2 – (Laser Therapy OR Laser OR Lasers OR Greenlight)
- #3 – Random*
- #4 – Systematic[sb]

1st RETRIEVAL = (#1 AND #2 AND #3) OR (#1 AND #2 AND #4) = 367

((Prostatic Hyperplasia OR Prostatic Hypertrophy OR Prostatic Adenoma) AND (Laser Therapy OR Laser OR Lasers OR Greenlight) AND Random*) OR ((Prostatic Hyperplasia OR Prostatic Hypertrophy OR Prostatic Adenoma) AND (Laser Therapy OR Laser OR Lasers OR Greenlight) AND Systematic[sb]))

Articles retrieved

The obtaining of evidence to be used to analyze the clinical question followed the steps of: elaboration of the clinical question, structuring of the question, search for evidence, critical evaluation and selection of evidence, presentation of results and recommendations.

The bases of scientific information consulted were: Medline via Pubmed, Embase, Central Cochrane and Cochrane Library.

A total of 367 articles were retrieved, of which 22 were selected after reading the title and abstract; of these 11 had the full text accessed to answer the proposed clinical question (Table 1).³⁻¹³

Inclusion and exclusion criteria

Phase III randomized controlled clinical trials, systematic reviews (with or without meta-analyses), comparative (or non-comparative) studies were included, and, in their absence, the best evidence available to answer the clinical question within the limits of PICO.

According to study design

Narrative reviews, case reports, case series, studies presenting preliminary results only were, in principle, excluded from the selection. Systematic reviews and meta-analyses were used with the principle of retrieving references that may have been lost since the initial search strategy. Controlled clinical trials were assessed based on the Jadad¹⁴ and GRADE¹⁵ scores.

Language

We included studies available in Portuguese, English or Spanish.

According to type of publication

Only full-text studies were considered for critical assessment.

ANNEX I

Clinical question

What is the effectiveness of laser prostatectomy (PVP) in patients with benign prostatic hyperplasia?

Structured question

- P: Prostatic hyperplasia
- I: Laser prostatectomy (photoselective vaporization of the prostate [PVP])
- C: Transurethral resection of the prostate
- O: Effectiveness and harm

Search strategy

- #1 – (Prostatic Hyperplasia OR Prostatic Hypertrophy OR Prostatic Adenoma)

TABLE 1 Description of characteristics of the selected studies.

Study	Population	Intervention	Comparison	Outcome	Follow-up time
Bouchier-Hayes DM 2006	Age > 50 years; Urinary flow (UF) \leq 15 mL/s; IPSS \geq 12; Prostatic volume (PV): 15-85 cm ³ (USC); Obstruction (AG nomogram) N: 76	PVP: Laser KTP 80 W with PVP (StarPulse quasicontinuous wave laser (Laserscope) emitting green light at a wavelength of 532 nm) system N: 38	Transurethral resection of the prostate (conventional TURP) N: 38	Urinary flow; IPSS; QoL; bother score; postvoid residual volume (PVRV); surgical time; PO Hb; length of catheterization; length of hospitalization	6 weeks 3, 6 and 12 months
Horasani K 2008	Age: 68 years; Benign Prostatic Hyperplasia (BPH); PV: 70 a 100 mL; UF < 15 mL/s; PVRV > 150 mL; IPSS > 7 N: 39	PVP: KTP/532 using high-power laser emitting green light (80 W) N: 39	Transurethral resection of the prostate (conventional TURP) N: 37	IPSS and IIEF-5 scores PV; PVRV; UF; urinary retention; transfusion; re-intervention	3 and 6 months
Al-Ansari A 2010	BPH; IPSS > 16; UF < 15 mL; PV < 100 mL; PVRV < 100 mL N: 120	HPS 120-W laser using lithium triborate (LBO) crystal, producing 532-nm waves N: 60	Transurethral resection of the prostate (conventional TURP) N: 60	Surgical time; Hb; transfusion; length of catheterization; length of hospitalization; complications; IPSS; PVRV; PV; UF	1, 3, 6, 12, 24 and 36 months
Capitán C 2011	BPH; IPSS > 15; PV < 80 cm ³ ; urinary flow < 15 mL/s N: 100	HPS 120-W laser PVP N: 50	Transurethral resection of the prostate (conventional TURP) N: 50	IPSS, urinary flow; surgical time; Hb; transfusion; complications; length of hospitalization; length of catheterization	1, 3, 6, 12 and 24 months
Mohanty NK 2012	BPH; age > 50 years; IPSS > 7; prostatic volume > 20 and < 80 cc; urinary flow (Q max) < 15 mL/s N: 128	PVP: Laser emitting green light at a wavelength of 532 nm (30 W to 80 W) N: 64	Transurethral resection of the prostate (conventional TURP) N: 64	IPSS, QOL, IIEF5; prostatic volume, PVRV and Qmax; surgical time and catheterization; hemoglobin and complications	1, 3, 6 and 12 months
Lukacs B 2012	BPH; > 50 years; IPSS \geq 12 and bother score \geq 3; Qmax < 12 mL/s; prostatic volume between 25 mL and 80 mL; PVRV < 300 mL N: 139	PVP (HPS 120-W laser) N: 69	Transurethral resection of the prostate (conventional TURP) N: 70	IPSS; length of hospitalization; Qmax; PVRV; complications; sexual symptoms; quality of life	12 months
Pereira-Correia JA 2012	Lower urinary tract symptoms due to BPH N: 20	PVP (HPS 120-W laser) N: 10	Transurethral resection of the prostate (conventional TURP) N: 10	IPSS; IIEF-5; ICIQ-SF; PVRV; Qmax	1, 3, 6, 9, 12 and 24 months

(continues)

TABLE 1 (Cont.) Description of characteristics of the selected studies.

Study	Population	Intervention	Comparison	Outcome	Follow-up time
Xue B 2013	BPH, IPSS > 15; treatment failure; Qmax < 15 mL/s; prostatic volume < 100 mL N: 200	PVP (HPS with 80-W KTP laser) N: 100	Transurethral resection of the prostate (conventional TURP) N: 100	Length of catheterization; length of hospitalization and peri- and postoperative complications; IPSS; QoL; Qmax; PVRV; prostatic volume	1, 3, 6, 12, 24 and 36 months
Jovanović M 2014	Moderate or severe lower urinary tract symptoms (International Prostate Symptom Score IPSS > 16), treatment failure, maximum flow rate (Qmax) < 15 mL/s, PVRV > 100 mL, prostatic volume < 100 mL N: 62	PVP (HPS 180-W laser) N: 31	Transurethral resection of the prostate (conventional TURP) N: 31	Surgical time; hemoglobin and transfusion. Length of catheterization and length of hospitalization; peri- and postoperative complications; IPSS; QoL; Qmax; PVRV; prostatic volume	1, 3, 6 and 12 months
Telli O 2015	Symptoms of obstruction due to BPH; 64 years; IPSS > 7; Qmax < 15 mL/s; prostatic volume < 80 mL; PVRV > 150 mL N: 124	PVP with 120-W laser N: 60	Transurethral resection of the prostate (conventional TURP) N: 64	IPSS; length of hospitalization; Qmax; PVRV; complications; sexual symptoms; re-intervention; transfusion	6, 12 and 24 months
Thomas JA 2016	Lower urinary tract symptoms due to BPH with an obstruction; 40 to 80 years; IPSS ≥ 12; Qmax < 15 mL/s; prostatic volume ≤ 100 mL N: 281	180-W XPS laser vaporization N: 139	Transurethral resection of the prostate (conventional TURP) N: 142	QoL; IPSS; urinary flow (mL/s); PVRV; prostatic volume; re-treatment; complication-free	6, 12 and 24 months

Critical appraisal method

After applying the inclusion and exclusion criteria, whenever the selected evidence was defined as a randomized controlled trial (RCT), an appropriate Critical Assessment Checklist was applied (Table 2). The critical evaluation of the RCT allows classification according to the Jadad score,¹⁴ so that Jadad < three (3) trials are considered inconsistent (grade B), while those scoring ≥ three (3) are found consistent (grade

A), and according to the GRADE classification¹⁵ (strong or moderate evidence).

If the selected evidence was defined as a comparative study (observational cohorts or non-randomized clinical trial), an appropriate critical evaluation check-list was applied (Table 3), allowing the classification of the study according to the New Castle Ottawa Scale,¹⁶ so that cohort studies presenting a score ≥ 6 would be consistent, while those scoring < 6 would be inconsistent.

TABLE 2 Script for critical evaluation of randomized controlled clinical trials.

Study data	Sample calculation
References, study design, Jadad, strength of evidence	Estimated differences, power, level of significance, total of patients
Patient selection	Patients
Inclusion and exclusion criteria	Recruited, randomized, prognostic differences
Randomization	Patient follow-up
Description and blinded allocation	Time, losses, migration
Treatment protocol	Analysis
Intervention, control and blinding	Intention to treat, analyzed, intervention and control
Outcomes considered	Result
Primary, secondary, outcome measurement instrument	Benefit or harm in absolute data, mean benefit or mean harm

TABLE 3 Script for critical appraisal of cohort studies.

Representativeness of exposed studies and selection of non-exposed studies (max. 2 points)	Definition of the exposure (max. 1 point)	Demonstration that the outcome of interest was not present at the beginning of the study (max. 1 point)	Comparability based on design or analysis (max. 2 points)	Outcome assessment (max. 1 point)	Appropriate follow-up time (max. 2 points)	Score and level of evidence

TABLE 4 Description of biases in the selected studies.

Study	Question	Randomization	Allocation	Blinding	Losses	Prognosis	Outcomes	ITT analysis
Bouchier-Hayes DM 2006	Yes	No	No	No	Yes (< 20%)	Yes	Yes	No
Horasanli K 2008	Yes	No	No	No	No	Yes	Yes	No
Al-Ansari A 2010	Yes	Yes	No	No	Yes (< 20%)	Yes	Yes	Yes
Capitán C 2011	Yes	Yes	Yes	No	Yes (< 20%)	Yes	Yes	No
Mohanty NK 2012	Yes	No	No	No	Yes (< 20%)	Yes	Yes	No
Lukacs B 2012	Yes	Yes	Yes	No	Yes (< 20%)	Yes	Yes	Yes
Pereira-Correia JA 2012	Yes	Yes	No	No	No	Yes	Yes	No
Xue B 2013	Yes	Yes	No	No	No	Yes	Yes	No
Jovanović M 2014	Yes	Yes	No	No	No	Yes	Yes	No
Telli O 2015	Yes	Yes	Yes	No	Yes (< 20%)	Yes	Yes	No
Thomas JA 2016	Yes	Yes	Yes	No	Yes (< 20%)	Yes	Yes	No

Exposure of results

For results with available evidence, the population, intervention, outcomes, presence or absence of benefit and/or harm, and controversies will be defined in a specific manner, whenever possible (Table 5).

The results will be preferably expressed in absolute data, absolute risk, number needed to treat (NNT), or number needed to harm (NNH), and occasionally using mean and standard deviation (Tables 6-16).

Recommendation

The recommendations will be elaborated by the authors of the review, with the initial characteristic of synthesis of the evidence, and later validated by all the authors who participate in the elaboration of this guideline.

The grade of recommendation stems directly from the available strength of included studies, according to the Oxford scale¹⁷ and the GRADE system.¹⁵

TABLE 5 Worksheet used to describe and present the results of each study.

Evidence included
Study design
Population selected
Follow-up time
Outcomes considered
Expression of results: percentages, risk, odds, hazard ratio, mean

TABLE 6 Results of the selected study.

Bouchier-Hayes DM 2006³

Outcomes	Mean (SD) of the intervention (38)	Mean (SD) of the comparison (38)	Significance
Increase in flow (mL/s)	11.96±8.23	8.56±9.08	p<0.05
Decline in IPSS	14.0±9.8	12.9±10.6	p<0.05
Decline in QoL	2.65±2.1	2.91±2.04	p<0.05
Decline in bother score	1.91±1.29	1.61±1.22	p<0.05
Post-void residual volume (mL)	125±198	86±124.38	p<0.05
Surgical time (min)	30.24 (9-70)	31.33 (5-70)	NS
Time of irrigation (min)	12.2±8.6	44.52±30.23	p<0.05
Time of hospitalization (days)	1.08±0.28	3.39±1.17	p<0.05
Decline in hemoglobin levels (g/dL)	0.45±0.7	1.5±0.15	p<0.05

TABLE 7 Results of the selected study.

Horasani K 2008⁴

Outcomes (6 months)	Mean (SD) of the intervention (39)	Mean (SD) of the comparison (37)	Significance
Urinary flow (mL/s)	13.3±7.9	20.7±11.3	p<0.05
IPSS	13.1±5.8	6.4±7.9	p<0.05
IIEF-5	19±5.2	21±6.8	p<0.05
Post-void residual volume (mL)	78.9±62.1	22.9±18.7	p<0.05
Surgical time (min)	87±18.3	51±17.2	p<0.05
Length of catheterization (days)	1.7±0.8	3.9±1.2	p<0.05
Length of hospitalization (days)	2±0.7	4.8±1.2	p<0.05

Outcome	No. of events intervention (39)	No. of events control (37)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Urinary retention	6	1	15.3	2.7	12.6 (ARI)	0.21 to 25.15	8 (NNH)
Transfusion	0	3	0	8.1	8.1 (ARR)	NS	NS
Re-intervention	7	0	17.9	0	17.9 (ARI)	5.90 to 29.99	6 (NNH)

TABLE 8 Results of the selected study.**Al-Ansari A 2010⁵**

Outcomes	Mean (SD) of the intervention (60)	Mean (SD) of the comparison (60)	Significance				
Urinary flow (mL/s)	NS	NS	NS				
IPSS	NS	NS	NS				
Hemoglobin (intraoperative)	13.1±1.5	11.3±1.9	p<0.05				
Post-void residual volume (mL)	NS	NS	NS				
Prostatic volume	NS	NS	NS				
Surgical time (min)	89±18	80±13	p<0.05				
Length of catheterization (days)	1.4±0.6	2.7±0.9	p<0.05				
Length of hospitalization (days)	2.3±1.2	4.1±0.6	p<0.05				
Outcome	No. of events intervention (60)	No. of events control (60)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Transfusion	0	12	0	17.95	17.95 (ARR)	5.90 to 29.99	6 (NNT)
Intraoperative complications	0	13	0	20	20 (ARR)	9.87 to 30.12	5 (NNT)
Early complications	56	19	93.33	31.67	61.67 (ARI)	48.31 to 75.02	2 (NNH)
Late complications	10	3	16.67	5	11.67 (ARI)	0.74 to 22.59	8 (NNH)

TABLE 9 Results of the selected study.**Capitán C 2011⁶**

Outcomes	Mean (SD) of the intervention (50)	Mean (SD) of the comparison (50)	Significance				
Urinary flow (mL/s)	22.56	21.98	NS				
IPSS	8	8.57	NS				
Decline in hemoglobin levels (g/dL)	0.65±1.31	2.30±4.36	p<0.05				
Prostatic volume	27.17	23.8	NS				
Surgical time (min)	54.13±14.40	48.15±14.71	p<0.05				
Length of catheterization (h)	23±22	72±48	p<0.05				
Length of hospitalization (days)	1.6 (1-5)	3.6±2.1	p<0.05				
Outcome	No. of events intervention (50)	No. of events control (50)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Cateter < 20F	50	8	100	16	84 (ARR)	73.94 to 94.16	1 (NNT)
Intraoperative complications	0	5	0	10	10 (ARR)	1.68 to 18.31	10 (NNT)
Early complications	14	8	28	16	NS	NS	NS
Late complications	7	16	14	32	18 (ARR)	1.8 to 34.11	6 (NNT)

TABLE 10 Results of the selected study.**Lukacs B 2012⁷**

Outcomes – 12 months	Mean (SD) of the intervention (69)	Mean (SD) of the comparison (70)	Significance				
QoL	75 (60-85)	77 (69.5-87.5)	NS				
IPSS	6.26 (3.23-9.30)	7.94 (4.9-10.97)	NS				
Urinary flow (mL/s)	16.7 (12-22.7)	16.8 (12.1-24.9)	NS				
PVRV	7 (0-32)	0 (0-43)	NS				
Prostatic volume	30 (22-40)	24.7 (18.5-35)	NS				
Sexual satisfaction	2 (1-4)	2 (1-4)	NS				
Surgical time (min)	55 (45-65)	71 (55-95)	p<0.05				
Length of hospitalization (days)	2.5 (2-3.5)	1 (1-2)	p<0.05				
Outcome	No. of events intervention (69)	No. of events control (70)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Complications	18	27	26.5	39.7	NS	NS	NS

TABLE 11 Results of the selected study.**Mohanty NK 2012⁸**

Outcomes – 12 months	Mean (SD) of the intervention (52)	Mean (SD) of the comparison (50)	Significance				
QoL	1.52±0.50	1.48±0.50	NS				
IPSS	5.96±1.98	6.00±1.95	NS				
Urinary flow (mL/s)	20.12±3.99	19.77±3.12	NS				
PVRV	23.94±13.26	20.40±12.73	NS				
Prostatic volume	26.27±7.35	26.0±8.88	NS				
Hemoglobin (g/dL)	12.42±1.32	11.16±1.31	p<0.05				
Surgical time (min)	53.72±10.23	42.77±12.93	p<0.05				
Length of catheterization (h)	24.65±2.98	49.23±14.17	p<0.05				
Outcome	No. of events intervention (60)	No. of events control (57)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Complications	26	28	43.33	49.12	NS	NS	NS

TABLE 12 Results of the selected study.**Pereira-Correia JA 2012⁹**

Outcomes – 12 months	Mean (SD) of the intervention (10)	Mean (SD) of the comparison (10)	Significance
ICIQ-SF	0 (0)	0 (0)	NS
IIEF-5	23 (22-24)	23 (22-24)	NS
IPSS	6 (2-10)	6 (1-12)	NS
Urinary flow (mL/s)	22.2 (12-38)	18 (10-28)	NS
PVRV	2 (0-10)	2.5 (0-20)	NS
BOOI	-12 (-4 to -68)	-1.2 (-4 to -14)	p<0.05

TABLE 13 Results of the selected study.Xue B 2013¹⁰

Outcomes – 24 months	Mean (SD) of the intervention (100)	Mean (SD) of the comparison (100)	Significance				
QoL	1	1.2	NS				
IPSS	10.4	9.1	NS				
Urinary flow (mL/s)	19.6	20.9	NS				
PVRV (mL)	14.4	15.7	NS				
Prostatic volume	33.8	23.8	p<0.05				
Hemoglobin	13.9±1.8	12.1±1.6	NS				
Surgical time	52.3±15.4	47.6±14.2	p<0.05				
Length of catheterization	1.9±0.8	3.6±1.7	p<0.05				
Length of hospitalization	4.3±1.5	6.8±2.1	p<0.05				
Outcome	No. of events intervention (100)	No. of events control (100)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Transfusion	0	4	0	4	4 (ARR)	0.15 to 7.8	25
TURP syndrome	0	0	0	0	NS	NS	NS
Perforation	0	5	0	5	5 (ARR)	0.7 to 9.2	20
Infection	4	5	0	5	NS	NS	NS
Dysuria	9	8	9	8	NS	NS	NS
Incontinence	3	4	3	4	NS	NS	NS
Urethral stricture	5	2	5	2	NS	NS	NS
Re-intervention	4	1	4	1	NS	NS	NS

TABLE 14 Results of the selected study.Jovanović M 2014¹¹

Outcomes – 12 months	Mean (SD) of the intervention (31)	Mean (SD) of the comparison (31)	Significance				
IPSS	5.2	4.8	NS				
Urinary flow (mL/s)	18.7	18.5	NS				
Surgical time	92±18	82±13	p<0.05				
Length of hospitalization	1.9±0.8	4.4±0.6	p<0.05				
Hemoglobin	13.2±1.5	11.7±1.9	NS				
Length of catheterization	1.1±0.6	2.9±0.9	p<0.05				
Outcome	No. of events intervention (31)	No. of events control (31)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Transfusion	0	6	0	19.4	19.4 (ARR)	5.4 to 33.2	5
Clot retention	0	2	0	6.4	NS	NS	NS
Urethral stricture	1	4	3.2	12.9	NS	NS	NS
Perforation	0	5	0	16.1	16.1 (ARR)	3.1 to 29.0	6
Dysuria/urgency	9	10	29	32.2	NS	NS	NS
TURP syndrome	0	1	0	3.1	NS	NS	NS

TABLE 15 Results of the selected study.**Telli O 2015¹²**

Outcomes – 24 months	Mean (SD) of the intervention (39)	Mean (SD) of the comparison (62)	Significance				
IPSS	75 (30-92)	60 (37-91)	NS				
Urinary flow (mL/s)	22.6±0.9	24.5±1.2	NS				
PVRV (mL)	60 (13-88)	58 (95-100)	NS				
Sexual activity (SHIM score)	32 (27-41)	34 (25-46)	NS				
Prostatic volume	23.9±13	22.4±13.3	NS				
Length of hospitalization	2 (1-4)	5 (3-9)	p<0.05				
Outcome	No. of events intervention (60)	No. of events control (64)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Transfusion	2	2	3.33	3.12	NS	NS	NS
Urinary retention	3	4	4.68	6.66	NS	NS	NS
Urethral stricture	5	12	8.33	18.75	NS	NS	NS
Re-intervention	2	4	3.33	6.25	NS	NS	NS
Infection	4	6	6.66	9.37	NS	NS	NS

TABLE 16 Results of the selected study.**Thomas JA 2016¹³**

Outcomes – 24 months	Mean (SD) of the intervention (128)	Mean (SD) of the comparison (121)	Significance				
QoL	1.3±1.2	1.2±1.3	NS				
IIEF-5	12.9±7.5	13.9±8.2	NS				
IPSS	9.5±3.0	9.9±3.5	NS				
Urinary flow (mL/s)	21.6±10.7	22.9±9.3	NS				
PVRV (mL)	45.6±65.5	34.9±47.1	NS				
Prostatic volume	23.9±13	22.4±13.3	NS				
Outcome	No. Of events intervention (139)	No. Of events control (142)	Risk intervention %	Risk control %	Reduction increase %	95CI	NNT/ NNH
Re-treatment	78	73	56.12	51.41	NS	NS	NS
Complication-free	116	112	83.45	78.87	NS	NS	NS