# Urinary lithiasis: evaluation of the use of laser vs. Pneumatic ureteral lithotripsy

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The Guidelines Project, an initiative of the Brazilian Medical Association, aims to combine information from the medical field in order to standardize producers 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.

Urinary lithiasis is a frequent pathology, and procedure indication is based on the confirmation of the stone, its size, location, and density. The goal of this evaluation is to define the role of the use of laser power in comparison to the conventional method(s) for treating patients with an indication of fragmentation of urinary calculi through ureterolithotripsy. It was conducted from a systematic review of the literature and performed without period restriction, in the MEDLINE database, retrieving 86 papers, of which 9 (Nine) were selected to respond to clinical doubt. The details about the methodology and the results are set out in Appendix I.

#### INTRODUCTION

Urinary lithiasis is a frequent pathology, which makes it noteworthy among pathologies of the uri-

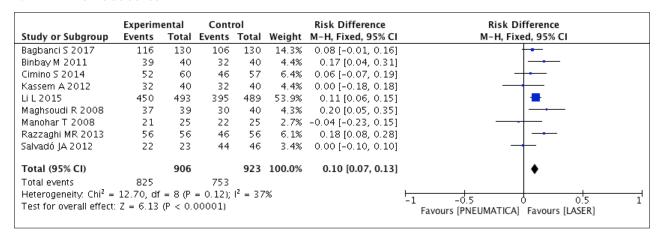
nary tract. Its diagnosis and treatment have changed with the incorporation of new technologies to extract stones via the urinary route. These changes have had a great impact on the cost of treatment, and the procedures need to be evaluated regarding their effectiveness and risks.

Procedure indication is based on the confirmation of the stone through exams that indicate precisely its size, location, and density, essential information to determine the type of technology to be used: the type of lithotritor [extracorporeal (EC) or intracorporeal (IC)] and the type of energy (ballistic/pneumatic (EC); ultrasound (US); Electro-hydraulic (EH) or laser (L).

The goal of this evaluation is to define the role of the use of laser power in comparison to the conventional method(s) for treating patients with an indication of fragmentation of urinary calculi through ureterolithotripsy.

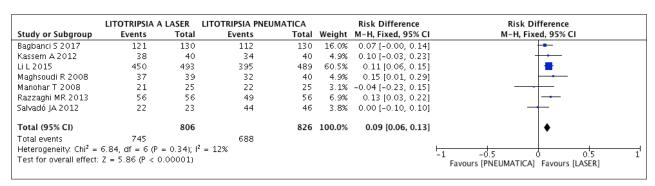
#### **RESULTS OF THE COMPARATIVE ANALYSIS OF THE OUTCOMES**

#### 1.. THERAPEUTIC SUCCESS



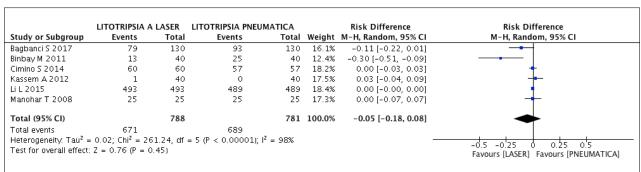
Regarding the outcome of therapeutic success, we included nine studies<sup>1-9</sup> for analysis, totaling 1,829 patients (906 laser and 923 pneumatic). The analysis revealed a higher rate of therapeutic success with patients undergoing laser treatment: an increase of 10% (NNT: 10), ranging from 7% to 13%. Heterogeneity of <50%.

#### 2. STONE FREE RATE INDEX



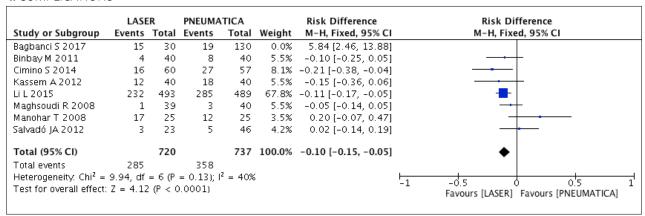
Regarding the outcome of stone free rate, we included seven studies<sup>1,4-9</sup> for analysis, totaling 1,632 patients (806 laser and 826 pneumatic). The analysis revealed a higher rate of stone free rate with patients undergoing laser treatment: an increase of 9% (NNT: 11), ranging from 6% to 13%. Heterogeneity of <50%.

# 3. NEED FOR URETERAL STENT



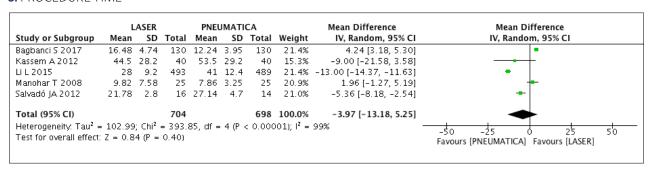
Regarding the outcome of need for ureteral stent, we included six studies<sup>1-5.7</sup> for analysis, totaling 1,569 patients (788 laser and 781 pneumatic). The analysis showed no difference regarding the risk of ureteral stent between the two modalities of treatment — heterogeneity of  $\geq$  50%.

#### 4. COMPLICATIONS



Regarding the outcome of complications, we included eight studies  $^{1-7.9}$  for analysis, totaling 1,457 patients (720 laser and 737 pneumatic). The analysis revealed a lower rate of complication risk with patients undergoing laser treatment: an increase of 10% (NNT: 10), ranging from 5% to 15%. Heterogeneity of <50%.

#### 5. PROCEDURE TIME



Regarding the outcome of procedure time, we included five studies  $^{1,4,5,7,9}$  for analysis, totaling 1,402 patients (704 laser and 698 pneumatic). The analysis showed no difference regarding the procedure time between the two modalities of treatment — heterogeneity of  $\geq 50\%$ .

In the analysis of the outcomes of therapeutic success, stone free rate, and complications there was no bias of inconsistency (heterogeneity <50%). However, in the analysis of the outcomes of need for ureteral stent and procedure time, the heterogeneity was  $\geq50\%$ .

# **SUMMARY OF EVIDENCE - WEAK**

In patients with urinary lithiasis and stones <20 mm affecting the ureter.

There is no difference in the procedure time and the need for ureteral stent between the two types of treatment (laser and pneumatic ureterolithotripsy).

The laser treatment offers increased rates of therapeutic success and stone free rate outcomes and reduces the risk of complications when compared with pneumatic ureterolithotripsy.

# **APPENDIX I**

# Clinical question

In the treatment of urinary lithiasis by ureterolithotripsy, is the use of a laser energy source superior to the conventional one (pneumatic)?

# Structured clinical question

Р	Patients with urinary lithiasis						
I	Laser ureterolithotripsy						
С	Conventional ureterolithotripsy						
0	Therapeutic success, stone free rate index, ureteral stent, complications, procedure time						

# Eligibility criteria

**PICO** 

Study design: Systematic Reviews (SR) and Randomized Clinical Trials (RCT)

Period: no limit for RCTs; two years for SR Languages: English, Portuguese, and Spanish Full texts available

# Search for papers

Database

The scientific databases consulted were Medline (via PubMed), Embase, and manual search.

Search strategy

(Urolithiasis OR Nephrolithiasis OR Ureterolithiasis OR Ureteral Calculi OR Urinary Calculi OR Kidney Calculi OR Ureteral Calculi OR Urinary Bladder Calculi) AND laser AND Random\*

Manual search - Reference of references, reviews, and guidelines.

### Critical evaluation

Relevance - clinical importance

This guideline was prepared by means of a clinically relevant question in order to gather information in medicine to standardize approaches and assist in decision-making.

Reliability - Internal validity

The selection of the studies and the evaluation of the titles and abstracts obtained from the search strategy in the databases consulted were independently and blindly conducted in total accordance with the inclusion and exclusion criteria. Finally, studies with potential relevance were separated. When the title and the summary were not enlightening, we sought for the full article. Only studies with texts available in its entirety were considered for critical evaluation.

Results application - External validity

The level of scientific evidence was classified by type of study, according to Oxford<sup>10</sup> (Table 1).

# **TABLE 1.** GRADES FOR RECOMMENDATION AND LEVELS OF EVIDENCE

A: Experimental or observational studies of higher consistency.

B: Experimental or observational studies of lower consistency.

C: Uncontrolled case/study reports.

D: Opinion deprived of critical evaluation, based on consensus, physiological studies, or animal models.

The selected evidence was defined as a randomized controlled clinical trial (RCT) and submitted to an appropriate critical evaluation checklist (Table 2).

The critical evaluation of RCTs allows to classify them according to the Jadad score<sup>11</sup>, considering Jadad trials < three (3) as inconsistent (grade B) and those with score  $\geq$  three (3), consistent (grade A), and according to the Grade<sup>13</sup> score (strong or moderate evidence).

When the evidence selected was defined as a comparative study (observational cohorts, or non-randomized clinical trial), it was subjected to an adequate critical assessment checklist (Table 3), allowing for the classification of the study, according to the NEWCASTLE OTTAWA SCALE  $^{12}$ , which considered consistent cohort studies with scores  $\geq$  6, and inconsistent <6.

**TABLE 2.** PROCESS FOR CRITICAL EVALUATION OF RANDOMIZED CONTROLLED TRIALS

Study data Reference, study design, Jadad, level of evidence	Sample size calculation Estimated differences, power, significance level, total number of patients
Patient selection Inclusion and exclusion criteria	Patients Recruited, randomized, prog- nostic differences
Randomization Description and blinded allocation	Patient follow-up Time, losses, migration
Treatment protocol Intervention, control, and blinding	Analysis Intention to treat, analyzed intervention and control
Outcomes considered Primary, secondary, mea- surement instrument for the outcome of interest	Results Benefits or harmful effects in absolute data, benefits or harm- ful effects on average

**TABLE 3. PROCESS FOR CRITICAL EVALUATION OF COHORT STUDIES** 

Representativeness of the exposed and selection of the non-exposed (Max. 2 points)  Exposure definition (Max. 1 point)	Demonstration that the outcome of interest was not present at the beginning of the study (Max. 1 point)	Comparability on the basis of the design or the analysis (Max. 2 points)	Outcome assessment (Max. 1 point)	Adequate follow-up time (Max. 2 points)	Scores and level of evidence
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# Method of extraction and result analysis

For results with available evidence, the population, intervention, outcomes, presence or absence of benefits and/or harmful effects, and controversy will be specifically defined whenever possible.

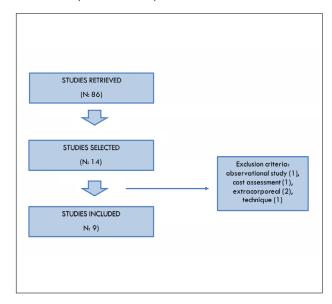
The results will be presented, preferably in absolute data, absolute risk, number needed to treat (NNT) or number needed to harm (NNH) and, eventually, in mean and standard deviation values (Table 4).

**TABLE 4.** SPREADSHEET USED FOR DESCRIBING AND PRESENTING THE RESULTS OF EACH STUDY

Evidence included
Study design
Selected population
Follow-up time
Outcomes considered
Expression of results: percentage, risk, odds, hazard ratio, mean

### **RESULTS**

**1.** FLOWCHART OF STUDIES RETRIEVED AND SELECTED (PRISMA 2009)

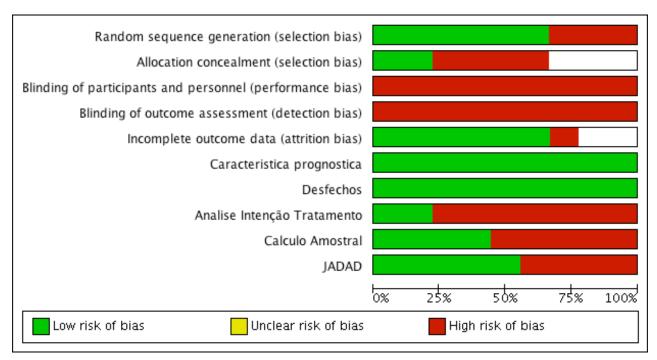


**TABLE 5. CHARACTERISTICS OF STUDIES INCLUDED** 

Study	Population	Intervention	Comparison	Outcomes	Time of follow-up
Bagbanci S 2017 <sup>1</sup>	Superior ureteral stone (260)	Laser (130) 1.0–2.0 J 5–10 Hz	Pneumatic (130)	Success, procedure time, ureteral stent, complication	1 year
Binbay M 2011 <sup>2</sup>	Urethral stone <2 cm (80)	Laser (40) 1.5–2.0 J 5–12 Hz	Pneumatic (40)	Success, surgery time, ureteral stent, complication	15-16 months
Cimino S 2014 <sup>3</sup>	Single ureteral stone (117)	Laser (60) 0.5-1.0 J 5–10 Hz	Pneumatic (57)	Success, surgery time, complication	3 months
Kassem A 2012 <sup>4</sup>	Urethral stone <2 cm (80)	Laser (40) 0.6-1.2 J 5-15 Hz	Pneumatic (40)	Complications, success	1 month
Li L 2015 <b>5</b>	Urethral stone <1.5 cm (982)	Laser (493) 0.8-1.0 J 10-15 Hz	Pneumatic (489)	Complications, success, procedure time	1 year
Maghsoudi R 2008 <sup>6</sup>	Urethral stone <1.5 cm (79)	Laser (39) 0.5-1.0 J 5–10 Hz	Pneumatic (40)	Success, complication	1 year
Manohar T 2008 <b>7</b>	Stone <20 mm (50)	Laser (25) < 1.2 J < 15 Hz	Pneumatic (25)	Procedure time, success	3 months
Razzaghi MR 2013 <b>8</b>	Superior ureteral stone (1-2 cm )(112)	Laser (56) 5–10 Hz	Pneumatic (56)	Complications, surgical time, success	3 months
Salvadó JA 2012 <sup>9</sup>	Distal urethral stone (89)	Laser (23) 0.8-1.5 J 12-20 Hz	Pneumatic (23)	Procedure time, complication, ureteral stent, success	3 months

FIGURE 1. RISK OF BIAS OF THE STUDIES INCLUDED

Salvadó JA 2012	Razzaghi MR 2013	Manohar T 2008	Maghsoudi R 2008	LI L 2015	Kassem A 2012	Cimino S 2014	Binbay M 2011	Bagbanci S 2017	
+	•	•	•	•	•	•	•	•	Random sequence generation (selection bias)
	•	•	•	•	•	+			Allocation concealment (selection bias)
•	•	•	•	•	•	•	•	•	Blinding of participants and personnel (performance bias)
•	•	•	•	•	•	•	•	•	Blinding of outcome assessment (detection bias)
•	•	•	•			+	•	•	Incomplete outcome data (attrition bias)
•	•	•	•	•	•	+	•	•	Caracteristica prognostica
•	+	•	•	•	•	+	•	•	Desfechos
•	•	•	•	•	•	•	•	•	Analise Intenção Tratamento
•	•	•	•	•	•	•	•	•	Calculo Amostral
•	•	•	+	•	•	+	+	+	JADAD



None of the studies is blinded, 30% did not properly randomize, 50% did not have blindfolded allocation, did not calculate the sample, and Jadad was inconsistent (<3), in 80% the analysis was not by intention to treat, and 10% had  $\geq$ 20% losses, thus, by these criteria, with high overall risk of bias.

# Application of evidence - Recommendation

The recommendations will be elaborated by the authors of the review, with the initial characteristic of synthesis of evidence, being subject to validation by all authors who participated in creating the Guideline.

The overall summary will be drafted considering the evidence described; its strength will be estimated (Oxford<sup>10</sup>/Grade<sup>14</sup>) as 1b and 1c (grade A) or strong, and as 2a, 2b, and 2c (grade B) or moderate weak, or very weak.

#### Conflict of interest

There is no conflict of interest related to this review that can be declared by any of the authors.

## Final declaration

The Guidelines Project, an initiative of the Brazilian Medical Association in partnership with the Specialty Societies, aims to reconcile medical information in order to standardize approaches that can aid the physician's reasoning and decision-making process.

The information contained in this project must be submitted to the evaluation and criticism of the physician responsible for the conduct to be followed, given the reality and clinical condition of each patient.

#### **REFERENCES**

- Bagbanci S, Dadali M, Dadali Y, Emir L, Gorgulu O, Karabulut A. Does a retropulsion prevention device equalize the surgical success of Ho: YAG laser and pneumatic lithotripters for upper ureteral stones? A prospective randomized study. Urolithiasis 2016. PMID: 27761633.
- Binbay M, Tepeler A, Singh A, Akman T, Tekinaslan E, Sarilar O, et al. Evaluation of pneumatic versus holmium: YAG laser lithotripsy for impacted ureteral stones. Int Urol Nephrol 2011; 43: 989-95. PMID: 21479563.
- Cimino S, Favilla V, Russo GI, Saita A, Sortino G, Castelli T, et al. Pneumatic lithotripsy versus holmium: YAG laser lithotripsy for the treatment of single ureteral stones: a prospective, single-blinded study. Urol Int 2014; 92: 468-72. PMID: 24481143.
- Kassem A, Elfayoumy H, Elsaied W, Elgammal M, Bedair A. Laser and pneumatic lithotripsy in the endoscopic management of large ureteric stones: a comparative study. Urol Int 2012; 88: 311-5. PMID: 22441150.
- Li L, Pan Y, Weng Z, Bao W, Yu Z, Wang F. A Prospective Randomized Trial Comparing Pneumatic Lithotripsy and Holmium Laser for Management of Middle and Distal Ureteral Calculi. J Endourol 2015; 29: 883-7. PMID: 25578351.
- Maghsoudi R, Amjadi M, Norizadeh D, Hassanzadeh H. Treatment of ureteral stones: A prospective randomized controlled trial on comparison of Ho: YAG laser and pneumatic lithotripsy. Indian J Urol 2008; 24: 352-4. PMID: 19468467.

- Manohar T, Ganpule A, Desai M. Comparative evaluation of Swiss LithoClast 2 and holmium: YAG laser lithotripsy for impacted upper-ureteral stones. J Endourol 2008; 22: 443-6. PMID: 18355139.
- Razzaghi MR, Razi A, Mazloomfard MM, Golmohammadi Taklimi A, Valipour R, Razzaghi Z. Safety and efficacy of pneumatic lithotripters versus holmium laser in management of ureteral calculi: a randomized clinical trial. Urol | 2013; 10: 762-6. PMID: 23504679.
- Salvadó JA, Mandujano R, Saez I, Saavedra A, Dell'oro A, Dominguez J, et al. Ureteroscopic lithotripsy for distal ureteral calculi: comparative evaluation of three different lithotriptors. J Endourol 2012; 26: 343–6. PMID: 22192101.
- Levels of Evidence and Grades of Recommendations Oxford Centre for Evidence Based Medicine. Disponível em URL: http://cebm.jr2.ox.ac.uk/ docs/old levels. Htm
- 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; 17:1-12.
- 12. 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. Disponível em: http://www.ohri.ca/programs/clinical\_epidemiology/oxford.asp
- Goldet G, Howick J. Understanding GRADE: an introduction. J Evid Based Med 2013: 6:50-4.

