Systematic review and meta-analysis of the clinical effectiveness of shock wave lithotripsy (SWL), retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PNL) for lower pole renal stones

James F. Donaldson MRCS [a *], Michael Lardas FEBU [a], Duncan Scrimgeour MRCS [a], Fiona Stewart MSc [b], Steven MacLennan PhD [b], Thomas B. L. Lam FRCSEd(Urol) [a,b], Samuel McClinton MD, FRCSI & Ed [a,b]

[a] *Department of Urology, Aberdeen Royal Infirmary, Aberdeen, United Kingdom*

[b] *Academic Urology Unit, University of Aberdeen, Aberdeen, United Kingdom*

[*] Corresponding author. Mr James F. Donaldson Department of Urology, Aberdeen Royal Infirmary, Foresterhill, Aberdeen, AB25 2ZN. United Kingdom.

Tel: +441224 438133; Fax: +441224 438165;

e-mail:james.donaldson@doctors.org.uk

Keywords:

Nephrolithiasis, Urolithiasis, Kidney stones, Lithotripsy, Shock Wave Lithotripsy, Extracorporeal shock wave lithotripsy, Uretero-renoscopy, Retrograde intrarenal surgery, Percutaneous nephrolithotomy

Word count: 1001

This is the authors' final version, post peer-review, of an article published in European Urology 2015 Apr;67(4):612-6. The definitive version is available from www.sciencedirect.com

Abstract

The prevalence of urolithiasis is increasing. Lower pole stones (LPS) are the most common renal calculi and most likely to require treatment. A systematic review comparing SWL, RIRS and PNL in the treatment of ≤20mm LPS in adults was performed. Comprehensive searches revealed 2741 records: 7 RCTs recruiting 691 patients were included. Meta-analyses for stone-free rate (SFR) ≤3 months favoured PNL over SWL (RR 2.04; 95% CI 1.50-2.77) and RIRS over SWL (RR 1.31; 95% CI 1.08-1.59). Stone size subgroup analyses revealed PNL and RIRS were considerably more effective than SWL for >10mm stones, but the magnitude of benefit was markedly less for ≤10mm stones. The quality of evidence (GRADE) for SFR was moderate for these comparisons. Median SFR from reported RCTs suggest PNL is more effective than RIRS. The findings regarding other outcomes were inconclusive due to limited and inconsistent data. Well-designed prospective comparative studies that measure these outcomes using standardised definitions are required, particularly for the direct comparison of PNL vs. RIRS. This systematic review which, used Cochrane methodology and GRADE quality of evidence assessment, provides the first level 1a evidence for the management of LPS.

The prevalence of urolithiasis is increasing [1]. Lower pole stones (LPS), defined as stones lying within a lower (inferior) pole calyx, are the commonest renal stones. LPS are more likely to require treatment because they are less likely to pass spontaneously. The treatment of LPS is controversial, especially ≤20mm stones [2], with competing interventions possessing advantages and disadvantages. Treatment options include percutaneous nephrolithotomy (PNL), retrograde intrarenal surgery (RIRS), or shock wave lithotripsy (SWL).

We performed a systematic review and meta-analysis to compare the benefits and harms of PNL, RIRS and SWL, in the treatment of LPS (≤20mm) in adults. Only randomised controlled trials (RCTs) were included, and Cochrane Collaboration standards and PRISMA guidelines were strictly followed (Supplement 1). The primary outcome was stone-free rate (SFR) at ≤3 months. Risk of Bias (RoB) and Grading of Recommendations Assessment, Development and Evaluation (GRADE) assessments were performed to appraise the quality of the evidence (level 1a) synthesised.

The search identified 2741 records which were doubly screened, and 21 articles were scrutinised for eligibility. Twelve articles reporting on 7 RCTs recruiting a total of 691 patients were included (PRISMA diagram, Supplement 2). Baseline characteristics and intervention protocols are summarised in Supplement 3. RoB assessment findings included a low risk of selection, attrition and reporting biases in most studies (see Supplement 2). Two studies reported industry funding [3-5].

Table 1 summarises the study findings. GRADE quality assessment was moderate for SFR for RIRS vs. SWL and PNL vs. RIRS but low or very low for all other outcomes (Supplement 3). Meta-analysis was only possible for the outcome of SFR for PNL vs. SWL and RIRS vs. SWL (Figure 1) because of clinical heterogeneity. Overall (≤20mm) median SFRs favoured PNL (96.3%) over RIRS (91.7%), and over SWL (54.5%) (Supplement 3). No studies reported economic outcomes.

Five RCTs compared RIRS vs. SWL [5-9]. Meta-analysis showed higher SFR for RIRS (89.5% vs. 70.5%). Sub-group analyses revealed that RIRS was considerably more effective than SWL for 10-20mm stones but the magnitude of benefit was markedly less for ≤10mm stones. RIRS had a numerically lower unplanned procedure rate, although not statistically significant. Outcomes for re-treatment rates were inconsistent, reflecting different re-treatment thresholds. Complication rates were not significantly different.

Pearle 2008 [5] (<10mm LPS) found SWL conferred a superior QoL, shorter convalescence and lesser analgesic requirements than RIRS. Conversely, Singh 2014 [9] (10-20mm LPS) reported significantly higher satisfaction with RIRS, and comparable convalescence (p=0.36) for ≤3 SWL sessions, although where only a single SWL session was required convalescence was shorter (p=0.0001).

There were conflicting data on patients' willingness to undergo the procedure again; Pearle 2008 favoured SWL (63% vs. 90%; p=0.031), whilst Singh 2014 [9] favoured RIRS (84% vs. 50% p=0.002). Singh 2014 [9] reported significantly worse voiding symptoms (p=0.026) following RIRS (which included routine stent placement).

Procedural duration favoured SWL in Pearle 2008 [5] (p=0.01) but RIRS in Singh 2014 [9] (p=0.1434); however patients only requiring one SWL session had a shorter operative duration (p=0.0001). Singh 2014 [9] reported a shorter hospital stay for ≤3 sessions of SWL (p = 0.0001).

Two RCTs directly compared PNL vs. SWL. Intervention protocols differed slightly including number of sessions. 'Stone-free' (SF) was not defined. Meta-analysis suggested a benefit for PNL (96.2% vs. 46.1%). Albala 2001 [3] stratified SFRs by stone size, suggesting that the magnitude of benefit of PNL was lower for ≤10mm vs. 11-20mm stones. Both studies found a numerically lower rate of re-treatment for PNL although not significant. Unplanned procedure rates were inconsistent, although event rates were low. There was heterogeneity in what constituted retreatment or an unplanned procedure, and intervention thresholds were not defined.

Complications were only reported by Yuruk 2010 [10] and were not defined nor categorised. Albala 2001 [3] reported SF-36 health surveys for 0-30mm stones; no significant differences were demonstrated between PNL and SWL. Yuruk 2010 [10] reported more scintigraphic scarring following SWL (16.1% vs. 3.2%, p=0.13). No patient demonstrated decreased renal function.

One study which reported 'initial results' only compared PNL vs. RIRS [4]. There was no significant difference in SFR although PNL had a longer hospital stay and 'mean recovery.'

A 2009 Cochrane review on nephrolithiasis [1] in any location included only two of the seven RCTs in this review, did not incorporate GRADE assessment and found no difference in SFR between RIRS and SWL for LPS. Present EAU urolithiasis guidelines recommend SWL or RIRS for <10mm LPS. For 10-20mm LPS, treatment should depend “on favourable and unfavourable factors” including anatomical factors. However, two identified RCTs [3,6] found that anatomical factors did not affect SFR following SWL. Present guidelines are not based on a robust systematic review and do not include RoB nor quality of evidence appraisal.

The major limitation of this review is the paucity of evidence for the comparison of PNL vs. RIRS, and the lack of reliable evidence concerning outcomes other than SFR. Reporting of patient-focused (including length of stay, analgesic requirement, and QoL) and economic outcomes was poor. These are critical to inform clinicians' and patients' decision making. Well-designed RCTs that measure these outcomes in a standardised manner are therefore required, particularly for PNL vs. RIRS. Ideally, studies should account for confounding factors including stone size, ancillary procedures, heterogeneity of interventions and thresholds of re-treatment.

This systematic review, performed using Cochrane review methodology and incorporating RoB and GRADE assessment, provides the first level 1a evidence for the management of LPS. SFRs were highest following PNL. However, PNL is the most invasive intervention and requires the longest hospital stay. It has been suggested that PNL is associated with a higher morbidity and convalescence. Our review was unable to make firm conclusions regarding this. However, these may be reduced with recent modifications (e.g. "tubeless" or "mini-perc") [2].

RIRS offers higher SFRs than SWL, which is the least effective in terms of stone clearance, particularly for 10-20mm LPS. However, SWL is the least invasive intervention, possibly with the shortest convalescence and highest acceptability to patients where multiple sessions are not required. Ultimately, until gaps in the evidence base are addressed especially regarding PNL vs. RIRS, treatment decisions should be influenced by patients' individual characteristics and expectations, as well as the available clinical expertise and facilities.

Conflicts of Interest:

JFD, ML, DS, FS, SM, TL, SMcC: none.

Acknowledgements:

No external funding was received for this research.

Figure Legends:

Figure 1 - Forest plot demonstrating meta-analysis of Stone Free Rate at ≤3 months for LPS ≤20mm: a) PNL vs. SWL, b) RIRS vs. SWL (including sub-analyses for ≤10mm (3.2.1), 10-20mm (3.2.2) and ≤20mm (Total).

References:

[1] Srisubat A, Potisat S, Lojanapiwat B, Setthawong V, Laopaiboon M. Extracorporeal shock wave lithotripsy (ESWL) versus percutaneous nephrolithotomy (PCNL) or retrograde intrarenal surgery (RIRS) for kidney stones. Cochrane Database Syst Rev 2009;CD007044.

[2] Turk C, Knoll T, Petrik A et al. Guidelines on urolithiasis [document on the Internet]. European Association of Urology, 2014. Arnhem. [April 2014]. http://www.uroweb.org/gls/pdf/22%20Urolithiasis_LR.pdf .

[3] Albala DM, Assimos DG, Clayman RV et al. Lower pole I: a prospective randomized trial of extracorporeal shock wave lithotripsy and percutaneous nephrostolithotomy for lower pole nephrolithiasis-initial results. J Urol 2001;166:2072-2080.

[4] Kuo RL, Lingeman JE, Leveillee RJ et al. Lower pole II: Initial results from a comparison of shock wave lithotripsy (SWL), ureteroscopy (URS), and percutaneous nephrostolithotomy (PNL) for lower pole nephrolithiasis. J Urol 2003;169(Suppl.):486.

[5] Pearle MS, Lingeman JE, Leveillee R et al. Prospective randomized trial comparing shock wave lithotripsy and ureteroscopy for lower pole caliceal calculi 1 cm or less. J Urol 2008;179(Suppl.):S69-S73.

[6] Kumar A, Nanda B, Kumar N. A prospective randomized comparison between shock wave lithotripsy and flexible ureterorenoscopy lower calcyeal stones less than 2cm: a single center experience. J Urol 2013;189(Suppl.):e750.

[7] Salem A, Saad I, Emran A et al. Laser lithotripsy versus ESWL for lower calyceal renal stones. J Urol 2013;189(Suppl.):e751.

[8] Sener NC, Abdurrahim Imamoglu M, Bas O et al. Prospective randomized trial comparing shock wave lithotripsy and flexible ureterorenoscopy for lower pole stones smaller than 1cm. Urolithiasis 2014;42:127-131.

[9] Singh BP, Prakash J, Sankhwar SN, et al. Retrograde intrarenal surgery vs extracorporeal shock wave lithotripsy for intermediate size inferior pole calculi: a prospective assessment of objective and subjective outcomes. Urology. 2014;83:1016-22.

[10] Yuruk E, Binbay M, Sari E et al. A prospective, randomized trial of management for asymptomatic lower pole calculi. J Urol 2010;183:1424-1428.