TITLE: Extracorporeal Shock Wave Lithotripsy for Kidney Stones: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 01 September 2016

RESEARCH QUESTIONS

1. What is the clinical effectiveness of extracorporeal shock wave lithotripsy for the treatment of kidney stones?

2. What is the cost-effectiveness of extracorporeal shock wave lithotripsy for the treatment of kidney stones?

3. What are the evidence-based guidelines regarding the use of extracorporeal shock wave lithotripsy for the treatment of kidney stones?

KEY FINDINGS

Twelve systematic reviews, nine randomized controlled trials, two economic evaluations, and one evidence-based guideline were identified regarding extracorporeal shock wave lithotripsy for kidney stones.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 01 2012 and August 16 2016. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.
SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

<table>
<thead>
<tr>
<th>Table 1: Selection Criteria</th>
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<tbody>
<tr>
<td><strong>Population</strong></td>
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<tr>
<td><strong>Intervention</strong></td>
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</tbody>
</table>
| **Comparator**              | Q1 and Q2: Any active comparator  
|                             | Q1 and Q3: No comparator required |
| **Outcomes**                | Q1: Clinical benefits and harms  
|                             | Q2: Cost–effectiveness outcomes (e.g., cost per benefit, outcome, or QALY)  
|                             | Q3: Evidence-based guidelines regarding the use of lithotripsy |
| **Study Designs**           | Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines |

QALY = quality-adjusted life year.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

Twelve systematic reviews, nine randomized controlled trials, two economic evaluations, and one evidence-based guideline were identified regarding extracorporeal shock wave lithotripsy for kidney stones.

Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

Twelve systematic reviews,¹⁻¹² nine randomized controlled trials,¹³⁻²¹ two economic evaluations,²²⁻²³ and one evidence-based guideline²⁴ were identified regarding extracorporeal shock wave lithotripsy (SWL) for kidney stones. Due to a large number of relevant studies identified, non-randomized studies were included in the appendix.

A summary of the systematic reviews¹⁻¹² and their conclusions is provided in Table 2, and a summary of the randomized controlled trials¹³⁻²¹ and their conclusions is provided in Table 3.

Two economic evaluations²²⁻²³ were identified regarding the cost-effectiveness of extracorporeal SWL for kidney stones compared with uteroscopic lithotripsy. Two economic evaluations reported the conditions under which SWL is cost-effective:

- When stone-free rates with SWL are at least 60% to 64%²² or 65% to 67%²³, and
- When stone-free rates with uteroscopic lithotripsy are less than 57% to 76%²² or 72% to 84%²³
One evidence-based guideline was identified regarding the use of extracorporeal SWL for kidney stones. The guideline provided a number of recommendations regarding SWL and uroscopy (URS), including:

General recommendations
- “Clinicians should inform patients that SWL is the procedure with the least morbidity and lowest complication rate, but URS has a greater stone-free rate in a single procedure.” Strong recommendation, Grade B, page 2
- “In patients with mid- or distal ureteral stones who require intervention, clinicians should recommend URS as first-line therapy. For patients who decline URS, clinicians should offer SWL.” Strong recommendation, Grade B, page 2
- “SWL should not be used in the patient with anatomic or functional obstruction of the collecting system or ureter distal to the stone.” Strong recommendation, Grade C, page 3
- “Clinicians should offer URS or SWL for pediatric patients with ureteral stones who are unlikely to pass the stones or who failed observation and/or medical expulsive therapy, based on patient-specific anatomy and body habitus.” Strong recommendation, Grade B, page 4

Treatment according to renal stone size:
- ≤ 10 mm: SWL or URS may be used (Strong recommendation, Grade B)
- > 10 mm: SWL should not be used as first-line therapy (Strong recommendation, Grade B)
- ≤ 20 mm: SWL or URS may be used (Strong recommendation, Grade B)
- > 20 mm: SWL should not be used as first-line therapy (Moderate recommendation, Grade C)

Treatment according to renal stone size in pediatric patients:
- ≤ 20 mm: SWL or URS may be used (Moderate recommendation, Grade C)
- > 20 mm: SWL and percutaneous nephrolithotomy are acceptable treatments (Expert opinion)
  - If SWL is used, an internalized ureteral stent or nephrostomy tube should be placed (Expert opinion)
### Table 2: Summary of Systematic Reviews and Meta-Analyses

<table>
<thead>
<tr>
<th>Author (Year)</th>
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<tr>
<td>Cui et al. (2015)</td>
<td>Patients with ureteral stones &gt; 10 mm in size</td>
<td>ESWL</td>
<td>Ureteroscopic lithotripsy</td>
<td>• Effectiveness (stone-free rate, retreatment rate) • Safety (complication rate)</td>
<td>“For treating large (&gt;10 mm) proximate ureteral stones, ureteroscopic lithotripsy tends to be more effective than ESWL, yet without adding significant risk.”</td>
</tr>
<tr>
<td>Deng et al. (2015)</td>
<td>Patients with urinary stones</td>
<td>SWL</td>
<td>No comparator</td>
<td>Safety (risk of developing new-onset diabetes mellitus)</td>
<td>“…there is no association between shock wave lithotripsy for urinary stone and new-onset [diabetes mellitus].”</td>
</tr>
<tr>
<td>Donaldson et al. (2015)</td>
<td>Adult patients with &lt; 20 mm lower-pole stones</td>
<td>SWL</td>
<td>• RIRS • PNL</td>
<td>Effectiveness (stone-free rate)</td>
<td>“Meta-analyses for stone-free rate at &lt;3 months favoured PNL over SWL and retrograde intrarenal surgery over SWL. Stone size subgroup analyses revealed PNL and retrograde intrarenal surgery were considerably more effective than SWL for &gt;10 mm stones, but the magnitude of benefit was markedly less for &lt;10 mm stones.”</td>
</tr>
<tr>
<td>Fankhauser et al. (2015)</td>
<td>Patients with nephrolithiasis and ureterolithiasis</td>
<td>ESWL</td>
<td>No comparator</td>
<td>Safety (adverse events)</td>
<td>“…no strong evidence exists to support the hypothesis that ESWL causes long-term adverse...”</td>
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<td>Lee et al. (2015)</td>
<td>Patients treated for lower pole renal calculi &lt; 20 mm in size</td>
<td>ESWL</td>
<td>• PNL • Ureterorenoscopy • ESWL with adjuvant therapy (such as inversion, hydration, and forced diuresis)</td>
<td>• Effectiveness (stone clearance) • Safety (adverse events)</td>
<td>“In stones of &lt;10 mm, ESWL with an adjuvant therapy appears to have better stone clearance, lower risk of [adverse events], and need for further treatment.”</td>
</tr>
<tr>
<td>Zhang et al. (2015)</td>
<td>Patients with lower pole renal stones</td>
<td>ESWL</td>
<td>• RIRS • PNL</td>
<td>• Effectiveness (stone-free rate) • Safety (complication rate)</td>
<td>“PNL provided a significantly higher stone-free rate compared with RIRS and ESWL. Furthermore, no statistical significant difference was found when PNL was compared with RIRS and ESWL for complication rate. Compared with the other two treatments, RIRS had a longer operative time and PNL had a longer hospital stay. ESWL was associated with significantly higher re-treatment rate compared with RIRS and PNL.”</td>
</tr>
<tr>
<td>Srisubat et al. (2014)</td>
<td>Patients with kidney stones</td>
<td>ESWL</td>
<td>• PNL • RIRS</td>
<td>• Effectiveness (success of treatment, re-treatment) • Safety (hospital stay)</td>
<td>“…ESWL is less effective for kidney stones than PNL, but not significantly different from RIRS. Hospital stay and duration”</td>
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Extracorporeal Shock Wave Lithotripsy for Kidney Stones
### Table 2: Summary of Systematic Reviews and Meta-Analyses

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<td>Xu et al. (2014)⁶</td>
<td>Patients with ureteral calculi</td>
<td>ESWL</td>
<td>Ureteroscopic lithotripsy</td>
<td>• Effectiveness (stone-free rate, repeat treatment rate, operation time, hospital stays)</td>
<td>“Compared to the ureteroscopic lithotripsy treatment, ESWL provided a significantly lower post-treatment stone free rate, but it also obviously brought out less postoperative complications, shorter operation time and hospital stays.”</td>
</tr>
<tr>
<td>Aboumarzouk et al. (2012)⁹</td>
<td>Adults with ureteric stones</td>
<td>ESWL</td>
<td>Ureteroscopy</td>
<td>• Effectiveness (stone-free rate, hospital stays) • Safety (complication rate)</td>
<td>“Compared with ESWL, ureteroscopic removal of ureteral stones achieves a greater stone-free state, but with a higher complication rate and longer hospital stay.”</td>
</tr>
<tr>
<td>Matlaga et al. (2012)¹⁰</td>
<td>Patients with distal and proximal ureteral stones and renal stones</td>
<td>SWL</td>
<td>• PNL • Ureteroscopy</td>
<td>• Effectiveness (stone-free rate, retreatment) • Safety (complication rate)</td>
<td>“Semirigid ureteroscopy is more efficacious than SWL for distal ureteral stones.”</td>
</tr>
<tr>
<td>Matlage et al. (2012)¹¹</td>
<td>Patients with ureteral and/or renal stones</td>
<td>SWL</td>
<td>Ureteroscopy</td>
<td>• Cost-effectiveness (stone-free rate and cost)</td>
<td>“...most studies demonstrated that ureteroscopy was more favorable than SWL for ureteral stones in stone-free rate and cost.”</td>
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</table>
| Picozzi et al. (2012) | Patients with ureteral stones | SWL | No comparator | • Effectiveness (stone-free rate)  
• Safety (complication rate) | “…immediate SWL for a stone-induced acute renal colic seems to be a safe treatment with high success rate.” |
|               |            |              |               |            |             |

ESWL = extracorporeal shock wave lithotripsy; PNL = percutaneous nephrolithotomy; RIRS = retrograde intrarenal surgery; SWL = shock wave lithotripsy.

Verbatim conclusions as presented in the abstract.

### Table 3: Summary of Randomized Controlled Trials

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<tr>
<td>Kamel et al. (2015)</td>
<td>98 patients with radiopaque lower ureteric stones &lt; 10 mm in size</td>
<td>SWL</td>
<td>No comparator</td>
<td>Effectiveness (stone-free rate, success rate)</td>
<td>“Transgluteal SWL while patient in supine position proved efficacy for treatment of distal ureteric stones.”</td>
</tr>
</tbody>
</table>
| Kumar et al. (2015) | 45 patients with a single 1-2 cm radiolucent lower calyceal renal stone | SWL | • RIRS  
• Miniperc | • Effectiveness (stone-free rate, operative time)  
• Safety (complication rate, radiation exposure) | “Miniperc and [RIRS] were more effective than [SWL] to treat 1 to 2 cm radiolucent lower calyceal renal calculi in terms of a better stone-free rate, and less auxiliary and re-treatment rates. However, miniperc resulted in more complications, greater operative time and radiation exposure, and a longer hospital stay.” |
| Kumar et al. (2015) | 106 pediatric patients (< 15 years) with a | SWL | Miniperc | • Effectiveness (stone-free rate, retreatment rates)  
• Safety (complication) | “Miniperc is more efficacious than SWL for treatment of radiopaque
Table 3: Summary of Randomized Controlled Trials

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<td></td>
<td>single radiopaque lower caliceal renal stones 1-2 cm in size</td>
<td></td>
<td></td>
<td>rate)</td>
<td>lower caliceal renal calculi 1 to 2 cm in children in terms of higher stone-free rate and lesser auxiliary and re-treatment rates. Miniperc, however, resulted in more complication, operative time, radiation exposure, and hospital stay.</td>
</tr>
<tr>
<td>Kumar et al. (2015)\textsuperscript{16}</td>
<td>90 patients with single radiopaque upper ureteral stones &lt; 2 cm in size</td>
<td>SWL</td>
<td>Semirigid ureteroscopy</td>
<td>• Effectiveness (stone-free rate, retreatment rate) • Safety (complication rate)</td>
<td>&quot;Both SWL and semirigid ureteroscopy are safe and highly efficacious for treating patients with proximal ureteral stones &lt;20 mm. For stones &lt;10 mm, SWL was a safer, less invasive, and of comparable efficacy with semirigid ureteroscopy. For stones between 10 and 20 mm, however, ureteroscopy was more effective, with a lesser re-treatment rate.&quot;</td>
</tr>
</tbody>
</table>
| Kumar et al. (2015)\textsuperscript{17} | 195 patients with single radiopaque lower caliceal calculi < 2 cm in size | SWL | RIRS | • Effectiveness (stone-free rate, retreatment rate) • Safety (complication rate) | "Both SWL and RIRS are safe and efficacious for lower caliceal calculi <20 mm. For stones <10 mm, SWL was less invasive and safer than RIRS with
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<td>Wazir et al. (2015)</td>
<td>112 patients with distal ureteric stones 6-12 mm in size</td>
<td>ESWL</td>
<td>Ureteroscopy</td>
<td>Effectiveness (stone clearance)</td>
<td>“[ESWL] shows acceptable stone clearance but ureteroscopy with intracorporeal lithotripsy shows superior results in distal ureteric stones.”</td>
</tr>
<tr>
<td>Manzoor et al. (2013)</td>
<td>190 patients with 10-15 mm proximal ureteric stones</td>
<td>ESWL</td>
<td>Ureterorenoscopic manipulation with intracorporeal lithotripsy</td>
<td>• Effectiveness (success rate, retreatment rate) • Safety (complication rate)</td>
<td>“Although ESWL is regarded as the preferred choice of treatment for proximal ureteric stone, the present results suggest that ureterorenoscopic manipulation with intracorporeal lithotripsy is safe alternative, with an advantage of obtaining an earlier or immediate stone-free status.”</td>
</tr>
<tr>
<td>Islam et al. (2012)</td>
<td>136 patients with lower ureteric stone</td>
<td>ESWL</td>
<td>Ureteroscopic pneumatic lithotripsy</td>
<td>• Effectiveness (stone-free rate) • Safety (complication rate)</td>
<td>“Ureteroscopic pneumatic lithotripsy proved more effective than ESWL for the treatment of ureteric calculi. However, ESWL performed as an outpatient procedure showed fewer complications.”</td>
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</table>
| Lopes et al. (2012) | 48 patients with large proximal ureteral stones (greater than 1 cm in size) | ESWL | • Semirigid ureterolithotripsy  
• Laparoscopic ureterolithotomy | • Effectiveness (success rate, stone-free rates, number of treatment sessions)  
• Safety (complication rate) | "[ESWL] had a 35.7% success rate, semirigid ureterolithotripsy 62.5% and laparoscopic ureterolithotomy 93.3%. Stone-free rates showed a statistically significant difference among the groups. Patients treated with Laparoscopic ureterolithotomy vs semirigid ureterolithotripsy vs ESWL required fewer treatment sessions. Neither major nor long-term complications were observed." |

ESWL = extracorporeal shock wave lithotripsy; RIRS = retrograde intrarenal surgery; SWL = shock wave lithotripsy.

* Verbatim conclusions as presented in the abstract.
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses


PubMed: PM22592707

PubMed: PM22591962

PubMed: PM22698623

PubMed: PM22699356

Randomized Controlled Trials

PubMed: PM25440820

PubMed: PM25066869

PubMed: PM25633506

PubMed: PM23914770


Economic Evaluations


Guidelines and Recommendations

See: Recommendations 10 and 11, page 2;
Recommendation 21, 25, 30, 31, 43, page 3;
APPENDIX – FURTHER INFORMATION:

Previous CADTH Reports


Randomized-Controlled Trials – Alternate Comparators


Non-Randomized Studies


Review Articles
