HEALTH TECHNOLOGY INQUIRY SERVICE (HTIS)

TITLE: **Lithotripsy for Kidney Stones or Gallstones: A Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines**

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CONTEXT AND POLICY ISSUES:

Kidney stones, or renal calculi, are common and affect up to 5% of the population.[1] The general term of "kidney stones" are used to describe the stones found in the kidney, ureters, and the bladder.[2,3] Treatment modalities for kidney stones include modifying the lifestyle, medical therapy, and surgical treatment, which is usually adopted for symptomatic stones or large stones.[2] At present, kidney stones are rarely removed by open surgery (i.e. nephrolithotomy); both minimally invasive [endoscopic treatment or percutaneous nephrolithotomy (PCNL)] and noninvasive shockwave lithotripsy (SWL) have accounted for almost all urinary stone removal therapy.[3,4]

Extracorporeal shock wave lithotripsy (ESWL) is a technique for breaking kidney stones into smaller pieces with a shock wave produced outside the body, so that the stones can pass from the body more easily than a large stone.[2] Shock waves can be generated by electrohydraulic (EH), electromagnetic, or piezoelectric sources.[5,6] Endoscopic treatment is a less invasive modality than open surgery for treatment of kidney stones.[7] Under the direct visualization by ureteroscopy (URS), the stones can be extracted with a baskets or graspers when possible, or fragmented using endoscopic lithotripsy.[7,8] The latter, also known as intracorporeal lithotripsy, refers to the visualization of stone(s) in the urinary tract via a URS and the simultaneous application of energy to fragment the stone(s) into smaller pieces to facilitate the pass.[8] Common endoscopic lithotripsies include ultrasonic, EH, laser, and mechanical devices.[8] Percutaneous nephrolithotomy (PCNL) can be used for most stones. In PCNL, the surgeon makes a small incision in the patient's back and creates a tunnel directly into the kidney.[2] The stones then can be removed via nephroscopy. Large stones can be broken into smaller pieces by a variety of energy sources, such as ultrasonic lithotripsy, EH lithotripsy, or holmium laser, and extracted thereafter.[2] PCNL is associated with greater morbidity than ESWL or the ureteroscopic approach.[7] Currently, open surgery may only be considered for complex stone burden, failure of ESWL, or for endourological treatment and anatomical abnormalities.[9] Gallstone disease is a common problem. In Canada, one in five men and one in three women are expected to develop gallstones in their lifetime.[10] Common bile duct stones occur in 10% to 15% of patients with gallstones.[11] The current surgical interventions for symptomatic stones in the gallbladder are laparoscopic or open cholecystectomy, and endoscopic management (i.e. endoscopic retrograde cholangiopancreatography, endoscopic sphincterotomy, and endoscopic papillary balloon dilation).[10,12] The techniques to remove common bile duct stones include balloons, baskets, a combination of endoscopic sphincterotomy and papillary balloon dilation, and lithotripsy. The latter includes mechanical lithotriptors, EH lithotripsy, laser lithotripsy, and ESWL to break the stones into small pieces.[11]

The first use of SWL to destroy kidney stones in people was in 1980.[13] Within a few years, it became the standard treatment for renal stones. SWL of gallstones began in 1985.[13] Even though lithotripsy is a noninvasive treatment, it is associated with higher stone recurrence rate that may be related to higher treatment costs and more complications.[14] The technique of lithotripsy has been advanced significantly since their initial use.[15,16] The long-term effect and safety outcomes need to be addressed.

The current review was undertaken to evaluate the clinical and cost-effectiveness of lithotripsy in treating patients with kidney stones or gallstones, as compared with other surgical modalities. Canadian and international guidelines for recommendations related to the use of lithotripsy in patients with kidney stones or gallstones are also examined. Efforts also were made to identify if there are any standards to gauge utilization rates for lithotripsy.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of lithotripsy for treatment of kidney stones or gallstones?

2. What is the cost-effectiveness of lithotripsy for treatment of kidney stones or gallstones?

3. What are the current guidelines for using lithotripsy for treatment of kidney stones or gallstones?

4. Are there any benchmarks or standards to gauge utilization rates for lithotripsy for treatment of kidney stones or gallstones?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 3, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and September 2009. Filters were applied to limit the retrieval to health technology assessments (HTAs), systematic reviews, meta-analyses, randomized controlled trials (RCTs), controlled clinical trials, economic studies, and guidelines.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, HTA reports, systematic reviews, and meta-analyses are presented first. These are followed by RCTs, controlled clinical trials, economic evaluations, and evidence-based guidelines.

SUMMARY OF FINDINGS:

Two RCTs,[17,18] two controlled clinical trials,[19,20] and two clinical practice guidelines[5,21] regarding the treatment with lithotripsy for kidney stones were included in our review. Two guidelines[12,22] providing recommendations on the use of lithotripsy for gallstones were also identified. There were no systematic reviews, HTAs, or economic evaluations identified from the literature search examining the clinical and cost-effectiveness of lithotripsy in patients with kidney stones or gallstones.

No direct information was identified from the literature about the capacity of lithotripsy units. A report by the Department of Veterans Affairs in the United States estimated that "each lithotripter has the capability of performing about 1,200 procedures annually".[23] It was also estimated that each ESWL procedure takes 30-90 minutes.[24] Newer generation lithotriptors may take longer time for each treatment session compared to older systems.[16] These figures may be helpful in predicting reasonable utilization rates.

Randomized controlled trials

Preminger conducted a multi-center RCT to compare the effectiveness of intracorporeal shock wave lithotripsy through ureteroscopy to PCNL in patients with lower pole renal calculi.[17] One hundred and twenty-two adult patients with a stone burden less than or equal to 30 mm were randomized to receive treatment with holmium:YAG laser lithotripsy (SWL) or PCNL. Separate randomization methods were used at each center depending on stone size. No details with respect to the baseline patient's characteristics and the techniques used in the two groups were provided. Data for 112 patients were available for analysis. The stone-free rates following the procedure varied based on the stone size. Overall, the stone-free rates were 35% for SWL therapy compared to 96% for PCNL. For stones less than 10 mm in diameter, the rates were 67% for SWL therapy compared with 100% for PCNL. When stone size was between 11 mm and 20 mm, the rates were 21% for SWL therapy compared to 92% for PCNL. For stones measuring 21 mm to 30 mm in diameter, the rates dropped to 14% for SWL compared with 100% for PCNL. All the differences between the two groups were statistically significant. The complication rate for PCNL was higher than for SWL, but no further information was provided. This trial suggested that while SWL is less invasive than PCNL, it is less effective for lower pole calculi, especially for stones larger than 10 mm in diameter.

Pearle et al. conducted an RCT to compare SWL to endoscopic treatment for patients with small lower pole stones.[18] Seventy-eight patients with 1 cm or less isolated lower pole stones were randomized to SWL or URS, according to a random number table. A variety of lithotriptors and ureteroscopies were used in SWL and URS. In the URS group, the stones were removed intact or by using intracorporeal lithotripsy. Patients' baseline characteristics in the two groups were comparable with regard to age, body mass index, and stone size. There were no significant differences between SWL and URS in stone-free rates and the number of patients needed re-treatments at 3-month follow-up. Patients in the SWL group returned to work significantly sooner compared with those in the URS group, and more patients would choose SWL over URS if they required the procedure again. The authors concluded that there were no statistically significant differences in stone-free rates between SWL and URS for the treatment of small lower pole renal stones, yet SWL was associated with shorter recovery and greater patient acceptance than URS.

Details of the included RCTs are shown in Table 1.

Table 1. Clinical Outcomes of Lithotripsy – Results from RCTs

Study	Population	Intervention versus comparator (number of patients)	Results
Preminger, 2006[17]	Adults with lower pole renal calculi and stone burden ≤30 mm	SWL (54) PCNL (47)	Stone-free rates (overall): SWL: 35% PCNL: 96%, p<0.001 Stone-free rates (size<10mm): SWL: 67% PCNL: 100%, p=0.017 Stone-free rates (size 11-20mm): SWL: 21% PCNL: 92%, p=0.0001 Stone-free rates (size 21-30mm): SWL: 14% PCNL: 100%, p=0.033
Pearle et al., 2005[18]	Adult pts with lower pole stones <1cm	SWL (32) URS (35)	Stone-free rates at 3-months: SWL: 35% URS: 50%, p=0.92 Number of pts that need re-tx: SWL: 5 pts URS: 2 pts, difference not significant, p value NR Days to return to work (mean±sd): SWL: 3.3±2.7 URS: 8.5±8.3, p=0.003 % would choose procedure again: SWL: 90% URS: 63%, p=0.031

NR=not reported; PCNL= percutaneous nephrolithotomy; pt=patient; sd=standard deviation; SWL=shock wave lithotripsy; tx=treatment; URS=ureteroscopy

Controlled clinical trials

Wadhwa and colleagues conducted a prospective study to compare the effect of ESWL to PCNL on renal functions in children undergoing therapy for upper-tract urolithiasis.[19] Fourteen patients younger than 13 years of age and diagnosed with renal or upper-ureteral stones were enrolled. Information regarding the treatment assignment was not reported. Of the 18 renal units treated in the 14 patients (four patients had bilateral renal stones), ESWL and PCNL were performed in 9 units each. A Dornier Compact Delta lithotripter was used in ESWL. Stone location was determined using fluoroscopic guidance and/or real-time ultrasonic guidance. Stenting was performed in children with a solitary functioning kidney or bilateral stone disease. Patients in the ESWL group had smaller stone size compared to the PCNL group (median 225 mm^2 [range: 110 - 266] in the ESWL group compared to 840mm^2 [range: 625 - 3800] in the PCNL group). Among patients in the ESWL group, all stones were located in renal pelvis, while in the PCNL group the stones were located in renal pelvis, superior calyx, middle calyx, and inferior calyx. A complete clearance was achieved in 88% of the patients in the ESWL group, and the same complete clearance rate was achieved in the PCNL group. Two patients in the ESWL group developed steinstrasse (a complication after ESWL in that multiple stone fragments line up in the ureter and cause obstruction)[25] and one patient in each group had a fever after the procedure. This study showed comparable effectiveness and safety for ESWL and PCNL in treating children with upper-tract urolithiasis.

Eterovic and colleagues compared the effectiveness of ESWL (electromagnetic lithotripsy) with open surgery (pyelolithotomy) in 60 adult patients with unilateral renal stone.[20] The average stone size between the two groups was different, 1.8 cm ± (standard deviation[SD]) 1.1 cm in the ESWL group and 3.2 ± 0.7 cm in the surgery group. Patients were followed for 3 months after the treatment. There were no acute complications developed in either group. More patients in the ESWL group had residual stone fragments (defined as "concrements larger than 5 mm immediately after treatment") compared to the open surgery group. Two patients in the ESWL group had intrarenal hematoma. At 3-month follow-up, the stones recurred (defined as "concrements larger than 5mm at 3 months but not immediately after treatment") in two ESWL patients and eight open surgery patients. The 3-month stone-free rates were similar between the comparison groups (22/30 for ESWL versus 21/30 for surgery). P values were not provided for the reported outcomes. This study implied that the stone-free rates for patients treated with ESWL were comparable to that of open surgery, yet a clear conclusion could not be made due to insufficient data.

Details of the included controlled trials are shown in Table 2.

Table 2. Clinical Outcomes for Lithotripsy – Results from Controlled Clinical Trials

Study	Population	Intervention versus comparator (number of patients)	Results
Wadhwa et al., 2007[19]	Children with upper-tract calculi	ESWL (9 renal units) PCNL (9 renal units)	Complete clearance: ESWL: 88% PCNL: 88%, p value NR
Eterovic et al., 2005[20]	Pts with unilateral renal stone	ESWL (30) Pyelolithotomy (30)	Residual concrements after tx: ESWL: 6 Pyelolithotomy: 1 Stone-free rate at 3-month: ESWL: 22/30 Pyelolithotomy: 21/30, p value NR

ESWL=extracorporeal shockwave lithotripsy; NR=not reported; PCNL=percutaneous nephrolithotomy; pt=patient; tx=treatment

Guidelines and recommendations

Kidney stones

The European Society for Pediatric Urology (ESPU) and the European Association of Urology (EAU) developed pediatric urology guidelines (2009) and provided guidance on stone management in children.[21] This is an evidence-based guideline based on a systematic review of the literature identified from MEDLINE; however the search time frames were not specified. The statements have been classified in terms of level of evidence and grade of recommendation, yet the standards of the classification were not provided in the document. The authors stated that due to the limited availability of large randomized controlled trials, the document would largely be a consensus document. The guideline suggests that ESWL can easily manage most pediatric stones. Self-limiting and transient complications have been observed in children treated with ESWL. Evidence shows no suspicion of long-term morbidity of the kidney and supports the safety of ESWL in children. It indicates that the stone-free rates of ESWL are significantly affected by various factors, such as location, stone size, and type of machine: first-generation machines result in higher fragmentation rates in a single therapy but the patients experience more discomfort, while later-generation machines are associated with lower risk of pulmonary trauma; however, additional treatments may be needed.

An American Urological Association (AUA) guideline (2005) provides recommendations on diagnosis and treatment for staghorn calculi, a type of large branched stones that typically occupy the renal pelvis and branch into several or all of the calices.[5] The guideline was derived from a systematic search of the English-language literature published from July 1992 through July 2003. The guidance on treatment for patients with staghorn calculi focuses on four modalities: PCNL monotherapy, combinations of PCNL and SWL, SWL monotherapy, and open surgery (i.e. anatrophic nephrolithotomy). The guideline statements are classified according to their flexibility to a treatment policy: a guideline is a "standard" when the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and there is virtual unanimity about which intervention is preferred; a guideline is "recommendation" when the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions and an appreciable but not unanimous majority agrees on which intervention is preferred; a guideline is "an option" when the health outcomes of the alternative interventions are not sufficiently well known to permit meaningful decisions or preferences are unclear. In this guideline, for patients with staghorn stone but normal renal functions that can tolerate the surgical treatments mentioned above, it is recommended that 1) PCNL be the first treatment for most patients and SWL monotherapy should not be used for most patients, based on the evidence that shows significantly lower stone-free rates for SWL compared with PCNL; 2) when SWL is undertaken, adequate drainage of the treated renal unit should be established before the treatment; 3) open surgery is not recommended for most patients. These statements have more flexibility in treatment policy implementation and are considered as "recommendations". For patients with small-volume staghorn calculi with normal collecting-system anatomy, the evidence of the health outcomes of SWL are not sufficiently well known. Therefore SWL monotherapy may be an option for these patients, which means there is more flexibility in policy implementation. This guideline indicates that SWL monotherapy has a very limited role in the management of patients with complex renal calculi and should be reserved for use in pediatric patients or in low-volume staghorn stone; percutaneous-based therapy should remain the mainstay for management of staghorn calculi.

Gallstones

A guideline (2007) developed by British Columbia Medical Association and British Columbia Ministry of Health provides recommendations for the management of asymptomatic and uncomplicated symptomatic gallstones in adults.[22] It was labeled as evidence-based guideline, but did not elaborate the methods used to appraise the evidence and generate the recommendations. This document states that the standard therapy for symptomatic gallstones is laparoscopic cholecystectomy, while lithotripsy is not recommended as a primary treatment for simple gallstone disease.

An evidence-based guideline (2007) on the management of common bile duct stones was developed by a multi-disciplinary guideline writing group and involved experts from the United Kingdom and Ireland.[12] The search time frame for literature was not specified. Strength of the evidence used in this guideline were categorized from grades Ia to IV, in that Ia represents the highest level of evidence that from meta-analysis of RCTs, and IV represents the lowest level of evidence that from expert opinions or clinical experiences of respected authorities. Recommendations in this guideline are graded according to the level of evidence. Based on evidence from well-designed non-experimental descriptive studies (such as comparative studies, correlation studies, and case studies), the guideline recommends that where available, ESWL should be considered for patients with difficult common bile duct stones who are not physically fit or unwilling to undergo open surgery. EH lithotripsy and laser lithotripsy are deemed superior to other forms of lithotripsy with respect to duct clearance.

Limitations

- Limited evidence was identified: there were no HTAs, systematic reviews, or economic evaluations found from the literature in the past five years. Data regarding lithotripsy for gallstones was particularly scant.
- There was a lack of detailed description in the method sections in the RCTs and clinical practice guidelines.
- The included controlled clinical trials were with small sample size (enrolled 14 and 60 patients respectively) and unbalanced patient's characteristics between the comparison groups.
- Various lithotriptors and techniques were used in SWL, thus makes the comparisons more complicated.
- No direct information to address the standards to gauge the utilization rates of lithotripsy was identified.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

ESWL is currently the most common treatment for renal stones due to its noninvasive nature.[26] The two RCTs[17,18] that compared SWL with other minimally invasive surgical modalities for lower pole stones showed lower stone-free rates for SWL, and one study[17] found the difference between comparison groups was significant. Patients in the SWL groups experienced significantly shorter time to recover from the procedure and returned to work faster. In the two controlled trials, ESWL was compared to PCNL and open surgery in treating kidney stones.[19,20] The stone-free rates between the comparison groups after the procedure were similar. ESWL was associated with more residual fragments after the treatment. No serious adverse events related to SWL were reported. In the AUA guideline,[5] SWL monotherapy is not suggested as the first treatment for staghorn stone, and SWL has limited role in patients with complex renal calculi and should be reserved for use in pediatric patients or in patients with low-volume staghorn stone. Another guideline recommends the use of ESWL in treating most urinary stones in children.[21] In summary, based on the limited evidence from a few RCTs and controlled clinical trials, SWL appears to have lower stone-free rates, higher stone recurrence and re-treatment rates in patients with kidney stones, when compared to other minimally invasive surgical modalities. No serious adverse events related to SWL were reported, but patients treated with SWL tended to have more residual stone fragment. A definite conclusion about the clinical effectiveness of SWL cannot be made because of lacking compelling evidence.

Two guidelines provide guidance on the treatment of gallstones.[12,22] Lithotripsy is not recommended as a primary treatment for simple gallstone disease, while ESWL can be considered for patients with difficult common bile duct stones who are not candidates for open surgery. The scarce data does not allow us to assess the effectiveness of lithotripsy in patients with gallstones.

No economic evaluations in the past five years were identified to assess the cost-effectiveness of different treatment modalities for renal stones or gallstones. One review article suggested that the economics of nephrolithiasis are complex, since it would be affected not only by the clinical efficacy of the procedure (stone clearance rate, retreatment rate, morbidities), but also by many other factors such as payer perspectives and cost for treatment in different countries.[14]

In the future, well-designed clinical trials could help to provide more rigorous evidence on the effectiveness of lithotripsy for treatment of kidney stones and gallstones. Economic evaluations, especially within a Canadian context, are needed to evaluate the cost-effectiveness of lithotripsy treatment compared to other minimally invasive surgical interventions. There is also a need to develop benchmarks to gauge utilization rates of lithotripsy for treatment of kidney stones or gallstones.

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