

Extra-corporeal shock wave lithotripsy (ESWL) versus ureteroscopic management for ureteric calculi (Review)

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ABSTRACT

Background

Ureteral stones frequently cause renal colic and if left untreated can cause obstructive uropathy. Extracorporeal Shock Wave Lithotripsy (ESWL) and ureteroscopy, with or without intracorporeal lithotripsy, are the two most commonly offered interventional procedures in these patients. ESWL treatment is less invasive but has some limitations such as a high retreatment rate and lack of availability in many centres. Advances in ureteroscopy over the past decade have increased the success rate and reduced complication rates.

Objectives

To examine evidence from randomised controlled trials (RCTs) on the outcomes of ESWL or ureteroscopy in the treatment of ureteric calculi.

Search strategy

We searched the Cochrane Central Register of Controlled Trials (CENTRAL in *The Cochrane Library* Issue 2, 2006), MEDLINE (1966 - March 2006), EMBASE (1980 - March 2006), reference lists of articles and abstracts from conference proceedings without language restriction.

Selection criteria

RCTs comparing ESWL with ureteroscopic retrieval of ureteric stones were included. Participants were adults with ureteric stones requiring intervention. Published and unpublished sources were considered.

Data collection and analysis

Two authors independently assessed trial quality and extracted data. Statistical analyses were performed using the random effects model and the results expressed as relative risk (RR) for dichotomous outcomes or weighted mean difference (MD) for continuous data with 95% confidence intervals (CI).

Main results

Five RCTs (732 patients) were included. The stone-free rates were lower in the ESWL group (RR 0.83 95% CI 0.70 to 0.98). The retreatment rates were lower but not significant in the ureteroscopy group (RR 2.78 95% CI 0.53 to 14.71). The rate of complications was lower in the ESWL group (RR 0.44 95% CI 0.21 to 0.92). Length of hospital stay was less for ESWL treatment (MD -2.10 95% CI -2.55 to -1.64).

Authors' conclusions

Ureteroscopic removal of ureteral stones achieves a higher stone-free state but with a higher complication rate and a longer hospital stay.

PLAIN LANGUAGE SUMMARY

People who undergo ureteroscopy for the treatment of ureteric stones achieve a higher stone-free rate, but have more complications and a longer hospital stay.

Ureteral stones frequently cause renal colic (pain) and if left untreated can cause obstructive uropathy (obstruction of the urinary tract). Both ureteroscopy and ESWL achieve a high success rate in the management of ureteric stone disease. Analysis of five RCTs (732 patients) indicates a higher stone-free rate after ureteroscopy treatment but with a longer hospital stay and a higher risk of complications. However, with continuous advancements in the field of ureteroscopy and variation between trials (heterogeneity) further evaluation and research is required in this field.

BACKGROUND

Nephrolithiasis is a common disease affecting the population with a peak incidence around the third to fourth decade of life (Ramello 2000). The lifetime risk of urolithiasis in the general population is approximately three times higher in men as compared to women. The prevalence of stone disease is increasing with increasing annual expenditure (Pearle 2005). Socioeconomic status, environmental factors, genetic predisposition and certain metabolic disorders are some of the known risk factors of this disease (Coe 1992). History of previous stone disease increases the probability of a second stone within five to seven years to approximately 50% (Stamatelou 2003). Most commonly, pain is the presenting symptom, often in the form of colic. This is caused by irritation of submucosal nerve fibres due to movement of stones resulting in spasm, dilatation, peristalsis and obstruction. Ureteric calculi are usually formed in the renal collecting system and progress downward into the ureter. They tend to get lodged at three common narrowing sites in the ureter namely the pelvi-ureteric junction, over the iliac vessels and at the ureteric meatus. The accepted management of ureteric calculi ranges from observation (expectant management with or without expulsive treatment using different drugs) to surgical exposure of ureter and removal of stone (ureterolithotomy). Various factors such as size of calculi, severity of symptoms, degree of obstruction, renal function, location of stone and the presence/or the absence of associated infection influence the choice of one type of intervention over the others. Although, there are a few recent reports (Dellabella 2005; Kupeli 2004) of beneficial effects of medical treatment especially use of alpha adrenergic blockers in enhancing clearance of stones in the distal ureters, this review will limit itself to the ureteroscopic and the extracorporeal shock wave lithotripsy (ESWL) management of ureteric stones.

Open surgical procedures for the treatment of ureteric stones have gradually disappeared in the last 30 years due to the emergence of increasingly efficacious minimally invasive techniques such as ESWL and ureteroscopy. The choice of ESWL or ureteroscopy for ureteric stone management is one of the most commonly debated controversies in endourology. This is partly due to a parallel advancement in technologies in both the fields. The success rate following ureteroscopic management using different ureteroscopes

and intracorporeal devices has been reported in the range of 86% to 100% (Pearle 2001). Miniaturization of instruments has decreased the rate of serious complications such as ureteric perforation and development of stricture. The rate of ureteric perforation and stricture formation remains around 2% to 4% and 0% to 2% respectively following ureteroscopic management of ureteric calculi (Pearle 2001; Peschel 1999; Wu 2004). On the other hand, the reported success rate following ESWL has been 80% to 100% in different studies (el-Faqih 1988; Pearle 2001). Non-invasive nature, acceptance and outpatient treatment are the attractive attributes of ESWL treatment. These are countered by proponents of ureteroscopy with immediacy of stone-free rate, availability of equipment and lower cost, especially for lower ureteric stones.

In the American Urological Association's 'Ureteral Stones Clinical Guidelines Panel summary report on the management of ureteral calculi', ESWL is recommended as first line treatment for most patients with stones 1 cm or less in the proximal ureter while similar stones in the distal ureter can be treated with either ESWL or ureteroscopy (Segura 1997). The report accepts the poor nature of the evidence available from a review of the literature. Most of the studies were retrospective with wide variation in the reported incidence of outcome and wide variability in reported treatment data. The recommendations of the panel were based on the available large number of retrospective and few prospective clinical series. In fact, the authors admitted that little could be said about the benefits and harms of various treatments of ureteric stones, if clinical series were excluded. There are new randomised trials (Pearle 2001; Wu 2005) reported since the publication of these recommendations and it was felt worthwhile to carry out a systematic review in order to address this question.

It remains uncertain if one treatment modality is better than the other and which calculi are best suited to a particular modality of treatment. The considerable variability in their use even within a single healthcare system such as the National Health Service (UK) reflects this uncertainty. It is therefore important to determine whether any one treatment has important clinical benefits in the management of ureteric calculi.

OBJECTIVES

To compare various outcome measures and complications of ureteric calculi treatment using ESWL and ureteroscopic retrieval techniques.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled trials (RCTs) comparing ESWL with ureteroscopic management of ureteric calculi.

Types of participants

- Any patient requiring treatment intervention for ureteric stone.
- Patients of all age groups were included.

Types of intervention

Any patients with ureteric stone requiring intervention (conservative treatment with or without alpha blockers not included) using ESWL or ureteroscopy were included. The outcome measures of these two modalities of treatment were compared. Wherever possible, subgroup comparisons were to be made such as stented versus no stent ESWL treatment and outcome using different intracorporeal lithotripsy devices.

Types of outcome measures

- Stone-free rate
- Retreatment rate
- Auxiliary procedures and need for unplanned secondary intervention
- Efficacy quotient (EQ = % stone-free/(100% [1 treatment] + % requiring retreatment + % requiring auxiliary treatment) x 100%)
- Complications (ureteric injury, haematuria, haematoma and urinary tract infection (UTI))
- Ureteric stricture rate
- Loss of kidney
- Mean size (in mm)
- Location of stone, composition of stone, wherever available
- Mean procedural time (minutes)
- Mean operating room time
- Mean hospital stay
- Mean time to convalescence
- Lower urinary tract symptoms and pain score
- Timing of stone-free rates
- Patient satisfaction measures (any reported measures accepted)
- Death

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

The search strategy was conducted by two authors (GN and SM) independently. Relevant trials were obtained from the following sources (Table 01 - *Electronic search strategies*):

1. MEDLINE (1966- March 2006)
2. EMBASE (1980- March 2006)
3. Cochrane Central Register of Controlled Trials - CENTRAL (in *The Cochrane Library* - Issue 1, 2006)
4. CINAHL (1872-March 2006)
5. Authors of studies identified as potentially eligible for inclusion were contacted both to clarify missing data or methodological details and to ask for additional published or unpublished studies.
6. Studies presented in conference proceedings were included.
7. Reference lists of previous reviews (including systematic reviews) and previous trials were included
8. The Trials Search Co-ordinator of the Cochrane Renal Group were contacted for references of studies not yet identified by the search process.
9. Papers in languages other than English were included and translation facilities within the Cochrane Collaboration were used wherever needed.
10. Duplicate publications: The most recently published version was used. Where relevant outcomes are only published in earlier versions their data was included.

METHODS OF THE REVIEW

Data extraction

The review was carried out initially by two authors (GN,SM) and other authors (PD,GW,FK) were consulted for a specific urological opinion. The titles and abstracts of the studies relevant to the review were searched using a strategy described. The screening and assessment of retrieved abstracts was independently carried out by GN and SM who discarded studies that were not applicable. Data extraction of included studies was carried out by the same authors independently using data extraction forms. Any additional information required from the original author was requested by written correspondence. The inclusion of trials was then discussed and agreed with other authors.

An independent quality assessment of the included studies was carried out by GN and SM without blinding to authorship or journal using the checklist developed for the Cochrane Renal Group. Discrepancies were resolved by discussion with PD. The quality items assessed were allocation concealment, blinding, intention-to-treat analysis and completeness to follow-up.

Quality checklist

1. Allocation concealment

A. Adequate - Randomisation method described that would not allow investigator / participant to know or influence intervention group before eligible participant entered in the study.

B. Unclear - Randomisation stated but no information on method used is available.

C. Inadequate - Method of randomisation used such as alternate medical record numbers or unsealed envelopes; any information in the study that indicated that investigators or participants could influence intervention group

2. Blinding

Blinding of participants - Yes / No / Not stated.

Blinding of outcome assessor - Yes / No / Not stated.

Blinding of data analysis - Yes / No / Not stated.

3. Intention-to-treat analysis

Yes - Specifically reported by authors that intention-to-treat analysis was undertaken and this was confirmed on study assessment.

No - Not reported and lack of intention-to-treat analysis confirmed on study assessment. (Patients who were randomised were not included in the analysis because they did not receive the study intervention, they withdrew from the study or were not included because of protocol violation).

Not stated.

4. Completeness of follow-up

Number of participants lost to follow-up

Statistical assessment

For dichotomous data (mortality, number of hospital admissions, presence of complications, re-treatment rate, significant infections) relative risk (RR) was used with 95% confidence intervals (CI). For continuous data (length of hospital stay), weighted mean difference (MD) with 95% CI was used. Data was pooled using the random effects model but the fixed effects model was also analysed to ensure robustness of the model chosen, susceptibility to outliers and during sub group analysis. Heterogeneity was analysed using a Chi squared test on N-1 degrees of freedom, with a P value of 0.05 used for statistical significance and the I² statistic (Higgins 2003).

DESCRIPTION OF STUDIES

Five RCTs (732 patients) were identified (Hendriks 1999; Lee 2006; Pearle 2001; Peschel 1999; Zeng 2002). All were published as full articles in English language journals. One trial (Zeng 2002) had a dual publication in the Chinese language.

Three trials (Pearle 2001; Peschel 1999; Zeng 2002) included patients with lower ureteric stone (distal to lower margin of bony pelvis), one trial (Hendriks 1999) with extended middle (between lower level of transverse process of the second lumbar vertebra and lower part of the sacroiliac joint) and distal ureteric stones and one trial with upper ureteric stones (Lee 2006).

The ureteroscopic retrieval of stones were carried out using semi-rigid ureteroscopes with various sizes ranging from 6.5F to 9.5F (Pearle 2001; Peschel 1999; Zeng 2002). One study allowed occasional use of an 11.5F rigid ureteroscope (Pearle 2001). The stones were either extracted via basket or forceps, or disintegrated using intracorporeal lithotripsy. The intracorporeal lithotripsy was carried out using either a pneumatic lithoclast (Peschel 1999; Zeng 2002) or Holmium:YAG/pulse dye laser (Hendriks 1999; Pearle 2001), or ultrasound (Lee 2006) or electrohydraulic probes (Hendriks 1999; Lee 2006). The placement of ureteric stents at the conclusion of the procedure was routine (Peschel 1999; Zeng 2002) or left to the discretion of operating surgeon (Lee 2006; Pearle 2001). One study reported selected use of stents following ureteroscopy in patients with ureteral wall damage, questionable evacuation of fragments and the need for a second look ureteroscopy (Hendriks 1999). The extracorporeal shock wave lithotripsy machines included unmodified HM3 (Pearle 2001), mobile Dornier HM4 (Hendriks 1999); Dornier MFL 5000 (Peschel 1999); Siemens Lithostar (Lee 2006) and HB-ESWL-V (Zeng 2002) with different power setting (15 to 22 kV in Pearle 2001; 8.3 to 15.0 kV in Zeng 2002). Three studies (Pearle 2001; Lee 2006; Hendriks 1999) mentioned the number of shock waves used. The lithotripsy procedure was carried out under general or epidural anaesthesia (Peschel 1999) or intravenous sedation (Lee 2006; Zeng 2002).

The procedure related parameters were reported in four studies (Hendriks 1999; Lee 2006; Pearle 2001; Peschel 1999). The time to stone-free state and follow up protocols varied between studies. The failure to achieve stone-free rate at 3 months (assessed radiographically) or need for further surgical intervention during follow up was defined as failure in two studies (Hendriks 1999; Pearle 2001), whereas failure to achieve stone-free rate at 43 days was considered as treatment failure in another study (Peschel 1999). The others assessed this outcome at four weeks (Zeng 2002). The definition of auxiliary procedures also varied. The placement of ureteric stents, use of guidewires, placement of nephrostomy, nephrostomy flushing, use of Dormia basket and use of frusemide were considered as auxiliary procedures in one study (Hendriks 1999). Others did not include definitions of auxiliary procedures. Procedure related complications were reported in all studies and ranged from minor such as bleeding to major such as ureteric perforation (Hendriks 1999; Pearle 2001; Peschel 1999; Zeng 2002). Two studies assessed patient satisfaction and their willingness to undergo the same procedure again, if required (Pearle 2001; Peschel 1999). Cost effectiveness was evaluated in one study (Pearle 2001). The inclusion and exclusion criteria were clearly mentioned in two trials (Pearle 2001; Peschel 1999). Two trials did not report on inclusion and exclusion criteria (Hendriks 1999; Zeng 2002). One trial included patients with renal failure and urinary tract obstruction (Zeng 2002). Patient satisfaction was assessed in three studies by a single question (Peschel 1999) or rated on scale of 1-100% (Pearle 2001) or scored using a self administered questionnaire on a scale of 0 to 5 (Lee 2006). Two studies

also reported whether the patients would be willing to undergo the same procedure again for recurrence and if not why (Pearle 2001; Peschel 1999).

METHODOLOGICAL QUALITY

Allocation concealment and randomisation

Two RCTs described methods of treatment allocation and randomisation (Hendriks 1999; Pearle 2001). The presence of a pre-treatment stent did not influence the randomisation (Pearle 2001). One trial (Peschel 1999) randomised patients with distal ureteric stones only if these had not passed spontaneously after three weeks of conservative treatment. For two trials the papers did not mention a randomisation method clearly and the authors did not respond to attempts at clarification (Hendriks 1999; Zeng 2002).

Blinding

There was no reported attempt to blind patient, investigator or assessor to treatment allocation in three studies (Hendriks 1999; Peschel 1999; Zeng 2002).

Completeness of follow-up

One study (Pearle 2001) was closed prematurely as interim analysis showed no difference in the stone-free rate between ureteroscopy and ESWL treatment, and only the secondary outcomes were reported.

RESULTS

Stone-free rate

Stone-free rate was measured in five trials. In two trials, this outcome was measured at three months (Hendriks 1999; Pearle 2001) and in the remaining two at 43 (Peschel 1999) and 28 days (Zeng 2002). In one trial it was not clear (Lee 2006). The stone-free rate favoured ureteroscopy (*analysis 01.01*: RR 0.83 95% CI 0.70 to 0.98). There was significant heterogeneity ($I^2 = 82.0\%$). In the ESWL group there is marked heterogeneity in the lithotripter devices utilised and their power setting. The stone-free rate in the ESWL group differs according to the lithotripter used. Only the study utilising the unmodified HM3 has reported no significant difference in the stone-free rate at three months between the two interventions (Pearle 2001), however this study was stopped prematurely as no significant difference was found in stone-free rates at interim analysis. There is also variation in the size of ureteroscopes, protocols for leaving ureteric stents and the source of intracorporeal lithotripsy used in the reported studies.

Retreatment rate

All the included studies reported data on retreatment rates. The data from one of the trials could not be included in our meta-analysis as it was reported in ratio rather than rate (Hendriks 1999). Patients in the ESWL group had a higher retreatment rate as compared to the ureteroscopic group however this was not significant

(*analysis 01.02*: RR 2.78 95% CI 0.53 to 14.71; $I^2 = 80.3\%$). Again, there is marked heterogeneity in the retreatment rate using different lithotriptors. Pearle 2001 reported no retreatment rate in patients using the HM3 lithotripter. They attributed this to the high power and large focal zone of the HM3 machine as compared to others. The retreatment ratio reported in other studies (Hendriks 1999) was higher in the ESWL group (1.5 versus 1.1), using a mobile Dornier HM4 lithotripter.

Auxiliary procedures

Three trials reported data on auxiliary procedures which could be used for meta-analysis. Patients in the ureteroscopy group required an increased number of auxiliary procedures however this was not significant (*analysis 01.03*: RR 0.31 95% CI 0.08 to 1.16; $I^2 = 87.7\%$). There was significant heterogeneity between these four studies. Most patients required placement of DJ stents following ureteroscopy. This was routinely carried out in some studies (Peschel 1999; Zeng 2002) and selectively in Pearle 2001. In one study the definition of auxiliary procedures was much broader and included flushing of ureters, Dormia basket extraction and administration of frusemide (Hendriks 1999), which according to the American Urological Association guidelines would be considered as routine procedures for ureteroscopy. Excluding these, data was used for meta-analysis from this trial.

Efficacy quotient (EQ)

Two trials calculated and compared EQ (Hendriks 1999; Lee 2006) between ureteroscopy and ESWL. One favoured ESWL (0.50 for ESWL and 0.38 for ureteroscopy; Hendriks 1999) and one found no difference (0.61 for ESWL and 0.63 for ureteroscopy; Lee 2006). The EQ takes into account the stone-free rate, the need for retreatment and auxiliary procedures. The trial favouring ESWL had a broad based definition of auxiliary procedures such as flushing of ureters and use of Dormia basket. If these procedures are considered as routine for ureteroscopic extraction of stones, the EQ for the ureteroscopy group becomes 0.66 (favouring ureteroscopy).

Treatment parameters

Procedural and operating times

Two trials (Hendriks 1999; Pearle 2001) reported procedural times (*analysis 01.05*: MD -8.07, 95% CI -51.77 to 35.64; $I^2 = 96.5\%$).

The operating time was reported in three trials (Lee 2006; Pearle 2001; Peschel 1999), but in one trial the data could not be used for meta-analysis as it was given in average and ranges (Peschel 1999). This trial reported a higher mean operating time for the ESWL group. Meta-analysis of two trials (Lee 2006; Pearle 2001) showed a higher operating time in the ureteroscopy group (*analysis 01.06*: MD -44.66 95% CI -84.82 to -4.50; $I^2 = 88.1\%$).

Hospital stay

Two trials (Hendriks 1999; Lee 2006) reported a significantly higher hospital stay in patients following ureteroscopy (*analysis 01.12*: MD -2.10 95% CI -2.55 TO -1.64; $I^2 = 0\%$). Pearle 2001

reported convalescence time but showed no difference between the two groups (*analysis 01.11*: MD -0.50 95% CI -3.86 to 2.86).

Complications

Procedural-related complications

All the included trials (Hendriks 1999; Lee 2006; Pearle 2001; Peschel 1999; Zeng 2002) reported on procedural-related complications. There was a higher rates of complications in the ureteroscopy group (*analysis 01.10*: RR 0.44 95% CI 0.21 to 0.92; $I^2 = 63.2\%$). Most of the complications in the ureteroscopy group were either minor (Hendriks 1999) or unrelated to the procedure (Pearle 2001). Hendriks 1999 reported a higher rate of minor complications (complications not necessitating therapy) in patients with electrohydraulic intracorporeal shock wave lithotripsy fragmentation of stones during ureteroscopy. One of the studies reported long term complications such as ureteral strictures in both groups of patients (Zeng 2002). This study included patients with renal failure and ureteric obstruction and it is difficult to assess whether the strictures were procedure related or due to long-standing obstruction caused by ureteric stones. With the advancement of techniques, technology and experience in ureteroscopy, these complications rate might change. UTI rates were reported to be higher in patients in the ureteroscopy group (Hendriks 1999; Lee 2006).

Postprocedural symptoms

Two of the trials (Lee 2006; Pearle 2001) reported on postprocedural symptoms. One of the trials (Pearle 2001) reported flank pain, dysuria and haematuria on a scale from 0 to 5, whereas another one reported pain score on a visual analogue scale of 0 to 10. The reported symptoms were higher, but not significantly so, in the ureteroscopy group (*analysis 01.09*: MD -0.49, 95% CI -1.11 to 0.13). This was surprising as most of the patients in the ureteroscopy group (91%) has postprocedural stenting. Lee 2006 also reported a higher pain score in patients undergoing ureteroscopy. The requirement of analgesia was reported by Pearle 2001 who reported a higher requirement of analgesia in the ESWL group (*analysis 01.04*: RR 1.45 95% CI 1.08 to 1.94).

Patients satisfaction

None of the included trials used validated questionnaires for evaluation of procedure related patient satisfaction. Three studies reported patient satisfaction using either a direct question (Pearle 2001; Peschel 1999) or self reported questionnaire (Lee 2006). Two trials (Pearle 2001; Peschel 1999) reported on patients willingness to undergo the same procedure, in case of stone recurrence, one each favouring ESWL and ureteroscopy. Patient satisfaction, reported on a scale of 1% to 100% in one trial (Pearle 2001) was uniformly high in both groups, albeit slightly higher but not statistically significant in the ESWL group. Similarly, in Lee 2006 patient satisfaction, on a scale of 0 to 5 was higher, but not statistically significant, in patients treated with ESWL.

Health-related quality of life

None of the studies reported on health-related quality of life.

Health economics

The cost analysis was reported in two trials (Lee 2006; Pearle 2001). Pearle 2001 reported ESWL costlier by US\$1,255 (cost) and US\$1,792 (charge) as compared to ureteroscopy. A cost effectiveness index (CEI) was calculated in one study (Lee 2006) for both the interventions and reported as US\$1,637 for ESWL and US\$2,154 for ureteroscopy.

DISCUSSION

Principal findings

The main findings of the meta-analysis are that over the duration of follow-up available from current RCTs, ureteroscopic retrieval of stones has a higher stone-free rate, with a higher complication rate and a longer hospital stay. However, due to marked heterogeneity in the type of lithotripter used, size of ureteroscopes, types of intracorporeal lithotripsy sources and experience of surgeon in the different trials, recommendations, for the proposes of clinical decision making, are difficult to make.

Clinical Interpretation

The stone-free rate (not the success rate) trend favouring ureteroscopy was not surprising given the advantages of direct visualisation, combined with either extraction of stones with baskets /forceps or fragmentation of calculi using intracorporeal lithotripsy that can be achieved in most of the patients in a single setting. Although further large well designed studies are required to confirm this assumption, a few case series suggest that the introduction of the Holmium: YAG laser and the advent of small caliber ureteroscopes has made ureteroscopy a more successful procedure with lower complication rates (Lam 2002; Parker 2004; Wu 2004). Stone size has been reported to influence the success of interventions in ureteric stones (Kim 2006). In all the studies included in this review, there was no statistically significant difference in the stone size in either group as seen in the *Table of included studies*. The number of complications and hospital stay were higher in the ureteroscopy group. The efficiency quotient was reported in two trials (Hendriks 1999; Lee 2006), favouring ureteroscopy in one (efficiency quotient redefined taking out the routine procedure as a part of ureteroscopy) (Hendriks 1999). In this trial stenting was extended for lower ureteric stones (Hendriks 1999). There is an increasing trend to avoid stents in clinical practice as stents have been shown to cause distressful lower urinary tract symptoms and impair quality of life (Joshi 2003). None of the trials used validated questionnaires to assess lower urinary symptoms following stenting or patient satisfaction and this areas needs further research. Surprisingly, two of the trials (Pearle 2001; Peschel 1999) reported higher patient satisfaction in the ureteroscopy group despite the fact that the majority of patients were stented following the procedure. Lee 2006 reported no significant difference in the patients satisfaction between the two groups of intervention using a self administered questionnaire. With the exception of Zeng

2002, there was no report of ureteric stricture following either of the interventions. This trial included patients with renal failure caused by obstructing stones and found no difference in stricture rate between the two groups at a follow-up of four weeks.

Success rates for ESWL treatment have been reported to be machine-dependant in clinical practice (Graber 2003; Kim 2006). Various reports comparing ESWL machines have shown a consistently high stone-free rate and low retreatment rate with the HM3 lithotripter (Gerber 2005; Portis 2003). The only trial in this review (Pearle 2001) comparing ureteroscopic stone retrieval with ESWL treatment using the HM3 device reported no difference in the stone-free rate and higher patients satisfaction rate with ESWL. None of the patients in this trial treated with shock waves required retreatment. Further research is required in this area to compare different lithotripsy devices with ureteroscopic management of stones. However, economical feasibility generally precludes any single centre from having more than one machine at a time. Further research is also required to assess the results of ESWL treatment in the following areas:

- *Stone factors:* Stone size is a significant factor effecting the stone-free state (Kim 2006) following any intervention for ureteric stones. Preoperative assessment of stone size is vital to decision making in the treatment of ureteric stones. In clinical practice, this is often estimated using plain X-ray KUB. However, a recent study by Nadler 2004 has reported CT scan with coronal reconstruction as an alternate and better method of predicting the stone size. Further research with software reconstruction of CT images is required to address this issue. Stone composition is another factor which influences fragmentation during ESWL treatment. A conventional X-ray KUB can accurately predict stone composition in 39% of cases (Ramakumar 1999). Recent case series (Pareek 2005; Gupta 2005) have reported CT scan Hounsfield Units (HU) as a better predictor of stone composition and potential fragmentation during ESWL treatment. This area needs to be explored in future studies.
- *Patient factors:* Body mass index more than 30 has been found to be an independent factor in predicting failure of ESWL treatment in ureteric stones (Delakas 2003; Pareek 2005). None of the studies in this review reported on this important predictor of outcome.
- *Shock wave technologies:* There have been attempts to improve shock wave lithotripsy device designs, in order to maximize stone fragmentation and minimize pain, by reducing the focal point size. However, these designs have higher retreatment rates owing to the difficulty of keeping the stone in the smaller focal zone. Thus, a larger focal zone would maximize erosive and cavitative forces acting on the stone's surface and increase the stone fragmentation rate. Treatment strategies such as improving per shock efficiency of stone fragmentation with decreasing shock frequency (Pace 2005) and synchronous twin-pulse techniques

(Sheir 2005), although promising in preliminary reports, need further studies.

- *Drugs enhancing clearance of ureteric stones following ESWL treatment:* Non-randomised studies (Kupeli 2004) have reported tamsulosin enhances the clearance of ureteric stones following ESWL treatment. Further large randomised controlled trials are required to confirm this data.

Quality of life has not been compared in any of the trials following treatment using ESWL or ureteroscopy treatments. Peschel 1999 reported lower patient satisfaction rates following ESWL treatment citing fear and anxiety over residual segments as reasons. However, they did not mention any quantification method used to assess these two factors.

Economic evaluation reported in two trials showed ESWL treatment to be more cost effective in one trial (Pearle 2001) and ureteroscopy in another (Lee 2006). However, two different ESWL devices were used in these two trials and no quality of life data, using stent specific questionnaires, were reported, hence it is difficult to make recommendations.

Limitations of the review

There are a number of limitations which are related to the data currently available from the reported trials:

- (1) The trials with the largest number of patients in this review had patients with lower ureteric stones, which have a high rate of spontaneous passage following conservative treatment. With the exception of two trials (two weeks in Hendrikk 1999; three weeks in Peschel 1999), there was no mention as to whether a period of conservative treatment was considered before randomisation. This is clearly not a reflection of common clinical practice, particularly in patients with non-obstructing asymptomatic distal ureteric stones. The reported clinical effectiveness of drugs (Kupeli 2000) in enhancing clearance of lower ureteric stones has not been considered in any of the trials reported in this review.
- (2) Practice continued to evolve over the period of these trials and so results from different procedures or devices may not be the same; for example the frequent use of Holmium:YAG laser for intracorporeal lithotripsy, selective use of postprocedural stents especially following uncomplicated ureteroscopy for lower ureteric stones, miniaturisation of ureteroscopic instruments, growing experience with flexible ureteroscopes and new baskets may have reduced the complication rate and need for auxiliary procedures.
- (3) None of the studies has reported on clinical or radiographic predictors of stone fragmentation in ESWL treatment. Defining these predictors of SWL failure could minimize unnecessary treatment, patient discomfort and fiscal waste.
- (4) We could not consider subgroups of patients in the current meta-analysis. There is potential for within and between study heterogeneity related to the type of intracorporeal devices used, type of stones in a particular geographical area and its correlation to fragmentation using ESWL treatment.

(5) Analysis of 'other' events (e.g. UTI, use of antibiotics) were not completed as these were not commonly or consistently reported.

These reasons may limit the generalisability of our review, but nonetheless, an up to date appraisal of available data is presented.

AUTHORS' CONCLUSIONS

Implications for practice

Ureteroscopic retrieval of ureteric calculi increases the stone-free rate, however is associated with higher complications and hospital stay on the basis of the currently available RCTs. Due to marked heterogeneity in such things as trial design, location of stones, type of ureteroscopes, intracorporeal lithotripsy devices, policy of stenting following ureteroscopy and length of follow up of patients, a change in clinical practice cannot be recommended. Deciding on the most appropriate treatment of ureteric stones should be based on the urologist's experience, the burden of stones, and the availability of equipment. The current clinical practice continues to be based on the evidence from number of cases series as pointed out in the AUA recommendations (Segura 1997).

Implications for research

There is a need for re-evaluation of these treatment regimes as the techniques, technologies and experience in the management of ureteric stone disease is growing. Multicentre, well designed RCTs with large number of patients and high quality reporting are required to make comparisons between various parameters such as ureteroscopes, ESWL devices, intracorporeal lithotripsy sources, health related quality of life and cost effectiveness. These trials

should ensure standardised definitions of stone-free state, auxiliary procedures, complications, concealed treatment allocation and blinded outcome assessment. Research is also required to accurately measure stone burden, predict stone fragmentation and assess the design of lithotripsy devices.

NOTES

January 2007 - Fong 2004 has been moved from included to excluded studies. This study was not an RCT. There are no changes to results.

POTENTIAL CONFLICT OF INTEREST

None known.

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T A B L E S

Characteristics of included studies

Study	Hendrikx 1999
Methods	Multicentric, randomised trial Randomisation: based on blocks. 156 consecutive patients with stones below the transverse process of L2 vertebra were randomised to ESWL or ureteroscopy. Follow up for 12 weeks Patients waiting for more than 2 weeks for ESWL were changed to ureteroscopy.

Characteristics of included studies (Continued)

Participants	<p>Inclusion criteria</p> <p>Stone size more than 5 mm or less than 5 mm that has not passed spontaneously for 2 weeks; age more than 18 years; fit for anaesthesia, life expectancy of more than 1 year</p> <p>Lithotripsy (ESWL)</p> <p>Number: 69</p> <p>Stone size: 5-11 mm</p> <p>Ureteroscopy</p> <p>Number: 87</p> <p>Stone size: 5-11 mm</p> <p>Exclusion criteria</p> <p>Seriously diminished renal functions (creat > 250 umoll/L), malignancy of urinary tract; bleeding disorders, sepsis, pregnancy, body weight more than 130 kg</p>
Interventions	<p>Lithotripsy (ESWL)</p> <p>HM4 Dornier</p> <p>Ureteroscopy</p> <p>7.0F to 9.5 F ureteroscopes.</p> <p>Electrohydraulic and pulse dye laser used depending on surgeons preference</p>
Outcomes	<p>Stone free rate</p> <p>Auxiliary procedures</p> <p>Retreatment rates (efficiency quotient)</p> <p>Complications</p> <p>Treatment parameters (operation time, hospital stay)</p> <p>Efficacy quotient</p>
Notes	<p>More than 11 mm stone (ESWL- 12 Ureteroscopy- 13)</p> <p>Flushing of ureteric catheters, Dormia basket use and flushing of nephrostomies considered as auxiliary procedures</p>
Allocation concealment	A – Adequate

Study	Lee 2006
Methods	<p>Randomisation: drawing lots.</p> <p>Stone size and degree of hydronephrosis recorded.</p> <p>9 patients came out of trials because of change of mind.</p>
Participants	<p>Inclusion criteria</p> <p>51 patients with upper ureteric stones (above transverse process of L5) and size more than 15 mm were randomised over a period of 3 years</p> <p>M/F: 35/7</p> <p>Age: 53.1 ± 14.5 y (range 25-80)</p> <p>ESWL</p> <p>Number: 22</p> <p>Stone surface area: 175.1 ± 69.9</p> <p>Ureteroscopy</p> <p>Number: 20</p> <p>Stone surface area: 192.3 ± 58.6</p> <p>Exclusion criteria</p> <p>Age younger than 18 years, pregnancy, uncontrolled UTI, pyonephrosis, sepsis, renal insufficiency with serum creatinine greater than 3.0 mg/dL, history of pelvic surgery or irradiation, and history of SWL, URSL, or open ureterolithotomy for treatment of the same side ureteral stone.</p>

Characteristics of included studies (Continued)

Interventions	ESWL Siemen AG Lithostar 2 Lithotripter (Erlangen, Germany). 3000 shock wave pulses, and the average energy density setting was 0.42 mJ/mm ² (energy level 6) Ureteroscopy ACMI 6.9F or a Wolf 9.8F ureteroscope with electrohydraulic, ultrasound or pneumatic lithotriptors
Outcomes	The postoperative evaluation parameters included serum blood urea nitrogen, serum creatinine, GFR, visual analog scale (range 0 to 10) pain scores, self-reported satisfaction scores (range 0 to 5), hospital stay, and complications. The endpoint of the study was defined as radiographic evidence of complete disappearance of the stone or the presence of insignificant residual stone (3 mm or less) within the kidney. Efficiency quotient and Cost effectiveness index calculated.
Notes	The postoperative imaging study included a plain abdominal film, ultrasonography, or intravenous urography, as needed
Allocation concealment	A – Adequate

Study	Pearle 2001
Methods	Multicentre randomised trial Allocation concealment: yes Random number table, randomised in sets of 10
Participants	Inclusion criteria Any patient requiring intervention for the treatment of stone in distal ureter. Distal ureteric stones (below bony pelvis) of 15 mm or less in largest diameter ESWL Number: 32 Age: 41.2 ± 14.9 y M/F: 26/6 Mean stone size: 7.4 Ureteroscopy Number: 32 Age: 41.2 ± 12.8 y M/F: 25/7 Mean stone size: 6.4 Exclusion criteria Multiple ureteric stones, solitary kidneys, renal insufficiency, urteric stricture, UTI, transplanted kidney, Cougulahathy and ipsilateral stone, women of child bearing age
Interventions	Ureteroscopy 6.9 F semirigid, except in two patients 11.5 F rigid instrument was used. 14 patients required balloon dilatation, laser (H-YAG) used in 41% to fragment stones. Stent placment left to the discretion os surgeons. ESWL HM3 lithotripter, prone position, 14 patients required intravenous contrast to visualise stone, power setting 15-22kV, 2,400 shock waves.
Outcomes	Stone-free rate Complications Repeat procedure Retreatment rate Unplanned secondary procedures
Notes	Power of study calculated.

Characteristics of included studies (Continued)

Dropout mentioned, but not clear whether analysed.
 12 patients dropped out of the study following randomisation due to spontaneous passage of stone
 Intervention failure: need for further treatment on follow up or failure to achieve stone-free status at 3 months.

Allocation concealment A – Adequate

Study **Peschel 1999**

Methods Randomised trial
 Randomisation method: not stated
 Ethical approval mentioned

Participants Inclusion criteria
 80 patients with radiodense lower ureteric stones, not passed spontaneously within 3 weeks or required intervention because of infection, coagulation disorder or previous ureteric implantation.
 Exclusion criteria
 Pregnancy, UTI, Coagulation disorder, previous ureteral reimplantation

Interventions ESWL
 Dornier MFL 5000 lithotripter, general or epidural anaesthesia, flourosopic localisation.
 Stone size < 5 mm (20) > 5 mm (20)
 Ureterscopy
 6.5 or 9.5 F semirigid ureteroscope. Lithoclast used, wherever necessary
 Stents placed routinely.
 Stone size: < 5 mm (20); > 5 mm (20)

Outcomes Stone-free rate
 Complications
 Repeat procedure
 Retreatment rate
 Unplanned secondary procedures
 Patients satisfaction

Notes Follow up X-rays at 1, 8, 15, 22, 29, 35 and 43 days.
 Failures at 43 days had ureteroscopy.
 No repeat ESWL allowed.

Allocation concealment B – Unclear

Study **Zeng 2002**

Methods 390 patients with lower ureteric stones were randomised into two groups during a period of 22 months.
 Follow up: X-ray of abdomen and complications recorded

Participants Ureterscopy
 Number: 180 (110 males)
 Bilateral: 13
 Stone size: 0.6 to 2.0 cm
 ESWL
 Number: 210 (125 males)
 Bilateral: 28
 Stone size: 0.5 to 2.1 cm

Interventions Ureterscopy
 Wolf 7.5-9.0 with pneumatic lithotripter
 ESWL

HB-ESWL-V lithotripter, pronated position or postero-oblique position, Discharge voltage 8.3 to 15kV.
Intravenous pethideine as analgesic.

Outcomes	Stone-free rate Complications Repeat procedure Retreatment rate Unplanned secondary procedures
Notes	Patients with renal failure and ureteric obstruction were randomised.
Allocation concealment	B – Unclear
GFR - glomerular filtration rate; UTI - urinary tract infection	
Efficacy quotient = % stone-free/(100% [1 treatment] + % requiring retreatment + % requiring auxiliary treatment) x 100%	
Cost-effectiveness index = treatment cost/stone-free rate + (complication cost x complication rate)	

Characteristics of excluded studies

Study	Reason for exclusion
Andankar 2001	Non-randomised prospective study
Anderson 1994	Retrospective study
Bierkens 1998	Retrospective study
Biri 1999	Retrospective study
Chang 1993	Retrospective study
Deliveliotis 1996	Non-randomised prospective study
Fong 2004	Non-randomised prospective study
Francesca 1993	Retrospective study
Hautmann 2004	Retrospective study
Ikemoto 1988	Not RCT
Kupeli 2000	Retrospective study
Lam 2002	Retrospective study
Liong 1989	Retrospective study
Parker 2004	Retrospective study
Ramello 2000	Not RCT
Strohmaier 1999	Non-randomised prospective study with treatment offered to patients depending upon their choices.
Wu 2004	Non-randomised study comparing the ESWL and ureteroscopic treatment of upper ureteric stones in 82 patients.
Wu 2005	Non-randomised study comparing 222 patients with upper ureteric stones were offered ESWL or ureteroscopy.
el-Faqih 1988	Non-randomised study using patients from two different periods of treatment

ADDITIONAL TABLES

Table 01. Electronic search strategies

database

MEDLINE

Search terms

1. Ureteral Calculi/
2. (ureter\$ adj2 (calcul\$ or stone\$)).tw.
3. nephrolithiasis.tw.
4. ureterolithiasis.tw.
5. urolithiasis.tw.
6. or/1-5
7. exp Lithotripsy/
8. lithotripsy.tw.
9. eswl.tw.
10. litholapaxy.tw.
11. Ureteroscopy/
12. ureteroscop\$.tw.
13. or/7-12
14. and/6,13
15. randomized controlled trial.pt.
16. controlled clinical trial.pt.
17. randomized controlled trials/
18. random allocation/
19. double blind method/
20. single blind method/
21. or/15-20
22. animals/ not (animals/ and human/)
23. 21 not 22
24. clinical trial.pt.
25. exp clinical trials/
26. (clinic\$ adj25 trial\$.ti,ab.
27. cross-over studies/
28. (crossover or cross-over or cross over).tw.
29. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
30. placebos/
31. placebo\$.ti,ab.
32. random\$.ti,ab.
33. research design/

Table 01. Electronic search strategies (Continued)

database

EMBASE

Search terms

34. or/24-33
35. 34 not 22
36. 23 or 35
37. and/14,36

1. Ureter Stone/
2. Ureter Obstruction/
3. ureterolithiasis.tw
4. (ureter\$ adj3 (stone\$ or calculi\$)).tw
5. Nephrolithiasis/
6. nephrolithiasis.tw
7. or/1-6
8. EXTRACORPOREAL LITHOTRIPSY/
9. eswl.tw
10. lithotripsy.tw
11. litholapaxy.tw
12. ureteroscopy/
13. ureteroscop\$.tw
14. or/8-13
15. and/7,14
16. exp clinical trial/
17. evidence based medicine/
18. outcomes research/
19. crossover procedure/
20. double blind procedure/
21. single blind procedure/
22. prospective study/
23. major clinical study/
24. exp comparative study/
25. placebo/
26. "evaluation and follow up"/
27. follow up/
28. randomization/
29. or/16-28
30. controlled study/ not case control study/
31. or/29-30

Table 01. Electronic search strategies (Continued)

database

CENTRAL

Search terms

- 32. (clinic\$ adj5 trial\$).ti,ab.
- 33. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$ or mask\$)).ti,ab.
- 34. random\$.ti,ab.
- 35. placebo\$.ti,ab.
- 36. or/32-35
- 37. 31 or 36
- 38. limit 37 to human
- 39. and/15,38

- #1 Ureteral Calculi, this term only in MeSH
- #2 ureter* near2 (calcul* or stone*)
- #3 nephrolithiasis*
- #4 ureterolithiasis*
- #5 urolithiasis*
- #6 (#1 OR #2 OR #3 OR #4 OR #5)
- #7 Lithotripsy explode all trees in MeSH
- #8 Ureteroscopy, this term only in MeSH
- #9 lithotripsy*
- #10 eswl*
- #11 litholapaxy*
- #12 ureteroscop*
- #13 (#7 OR #8 OR #9 OR #10 OR #11 OR #12)
- #14 (#6 AND #13)

ANALYSES

Comparison 01. ESWL versus ureteroscopy

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Stone-free rate	5	732	Relative Risk (Random) 95% CI	0.83 [0.70, 0.98]
02 Retreatment rate	4	572	Relative Risk (Random) 95% CI	2.78 [0.53, 14.71]
03 Auxiliary procedures	3	278	Relative Risk (Random) 95% CI	0.31 [0.08, 1.16]
04 Requirement of analgesia			Relative Risk (Random) 95% CI	Totals not selected
05 Procedure time (minutes)	2	220	Weighted Mean Difference (Random) 95% CI	-8.07 [-51.77, 35.64]
06 Operating time (minutes)	2	106	Weighted Mean Difference (Random) 95% CI	-44.66 [-84.82, -4.50]
07 Recovery time (minutes)			Weighted Mean Difference (Random) 95% CI	Totals not selected
08 Day care procedure			Relative Risk (Random) 95% CI	Totals not selected
09 Postoperative symptoms (flank pain/dysuria/haematuria)			Weighted Mean Difference (Random) 95% CI	Totals not selected
10 Procedure-related complications	5	732	Relative Risk (Random) 95% CI	0.44 [0.21, 0.92]
11 Convalescence time			Weighted Mean Difference (Random) 95% CI	Totals not selected
12 Hospital stay	2	198	Weighted Mean Difference (Random) 95% CI	-2.10 [-2.55, -1.64]
13 Patient satisfaction			Weighted Mean Difference (Random) 95% CI	Totals not selected

INDEX TERMS

Medical Subject Headings (MeSH)

Lithotripsy [adverse effects; *methods]; Randomized Controlled Trials; Ureteral Calculi [*therapy]; Ureteroscopy [adverse effects; *methods]

MeSH check words

Adult; Humans

COVER SHEET

Title	Extra-corporeal shock wave lithotripsy (ESWL) versus ureteroscopic management for ureteric calculi
Authors	Nabi G, Downey P, Keeley F, Watson G, McClinton S
Contribution of author(s)	Writing of protocol and review - NG, SM FK, PD, GW Screening of titles and abstracts - NG, SM Assessment for inclusion - NG, SM Quality assessment - NG, SM Data extraction - NG, SM Data entry into RevMan - NG, SM Data analysis - NG, SM FK, PD, GW Disagreement resolution - FK, PD, GW
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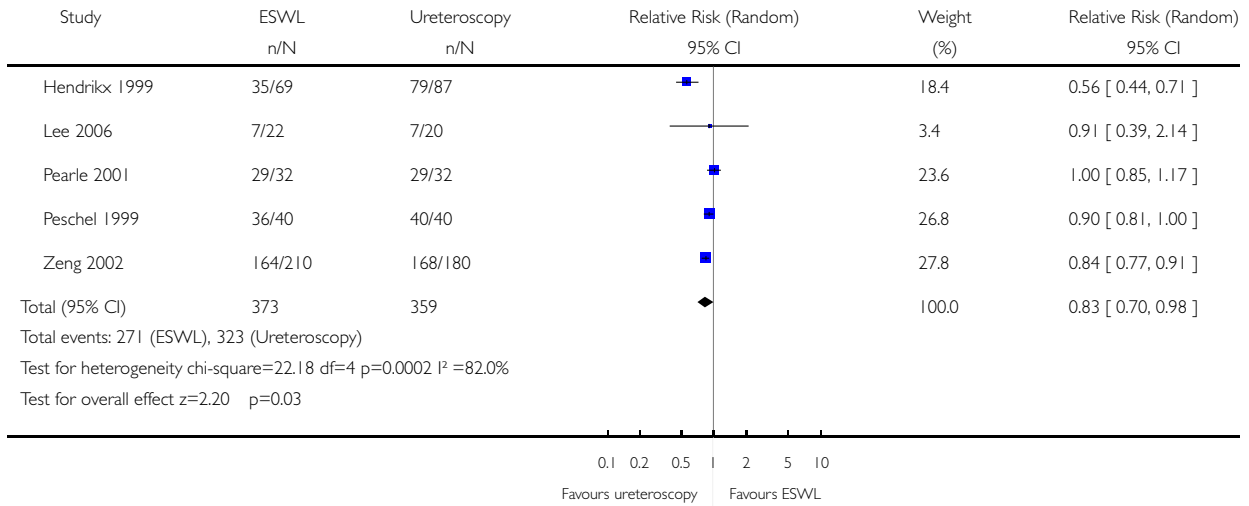
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Comparison: 01 ESWL versus ureteroscopy

Outcome: 01 Stone-free rate

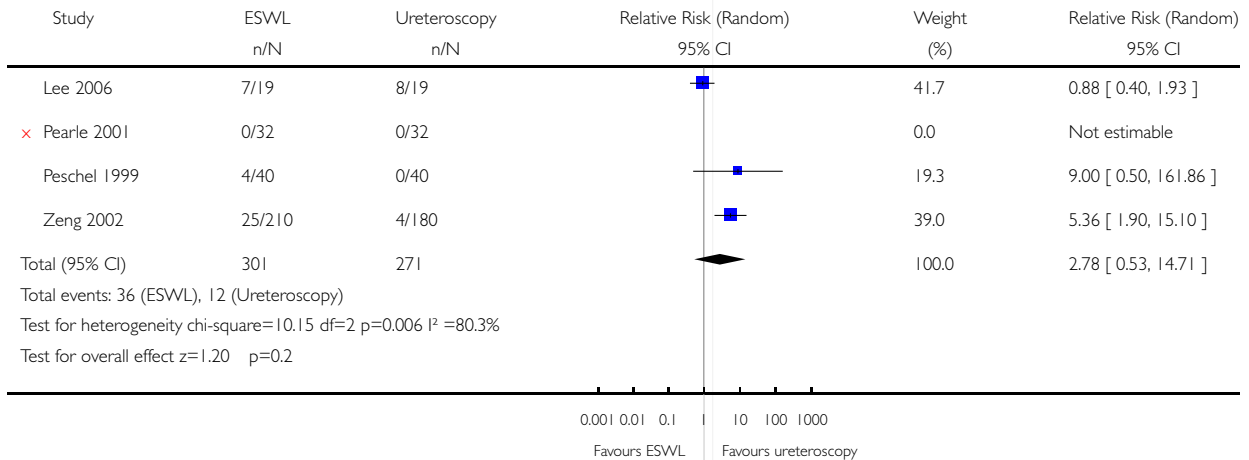


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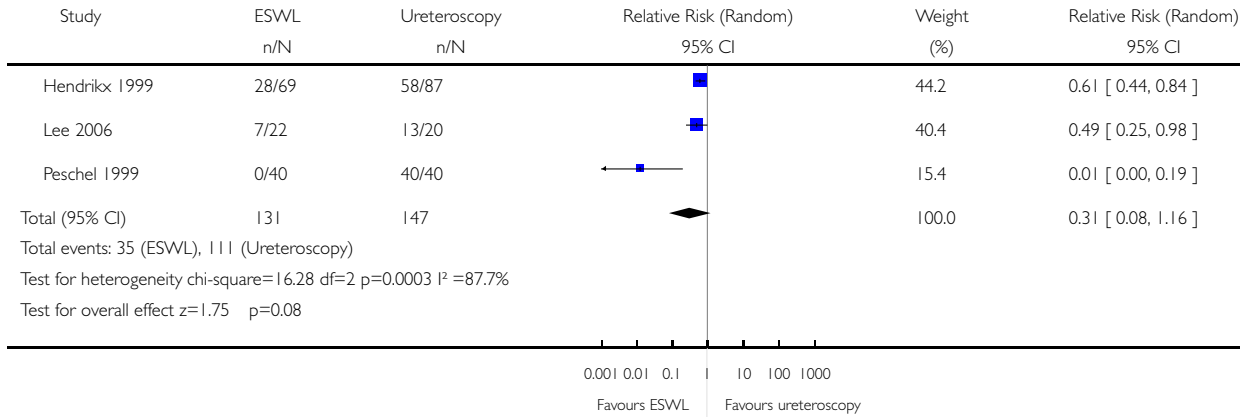


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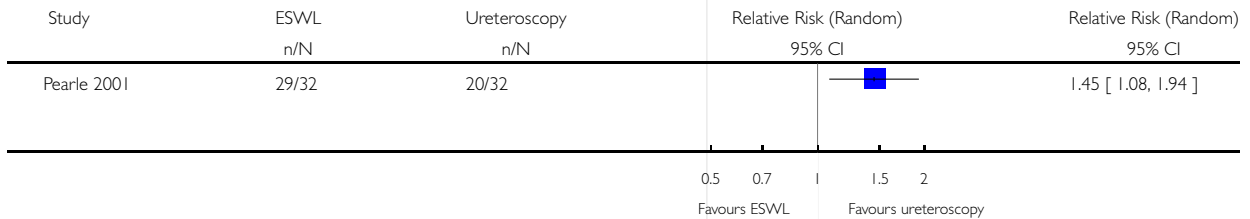


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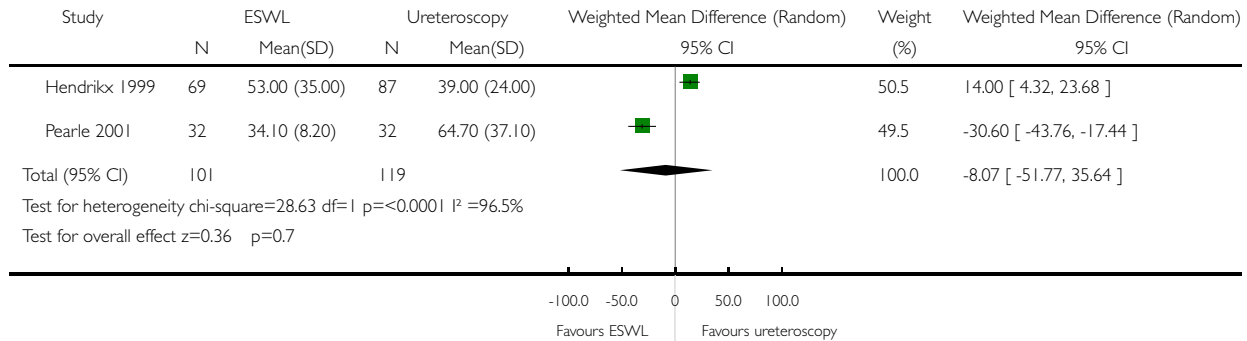


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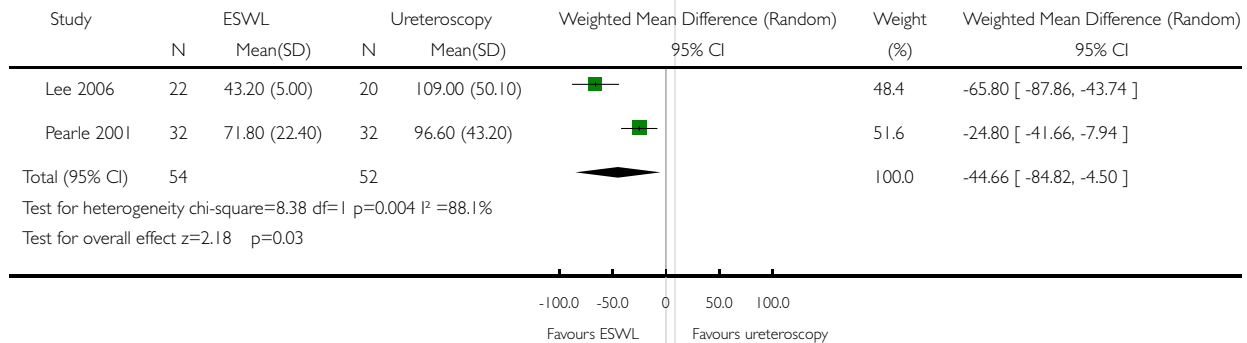


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Review: Extra-corporeal shock wave lithotripsy (ESWL) versus ureteroscopic management for ureteric calculi

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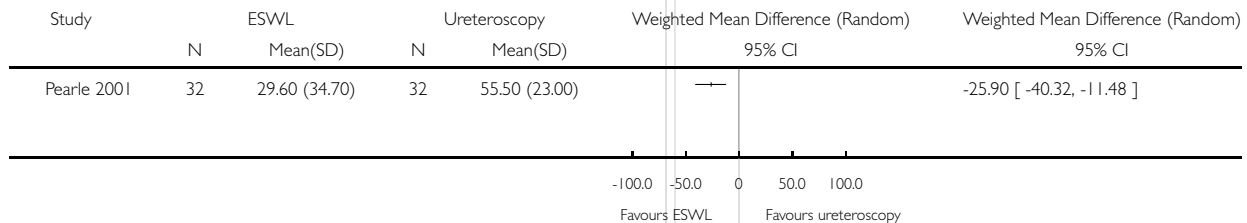


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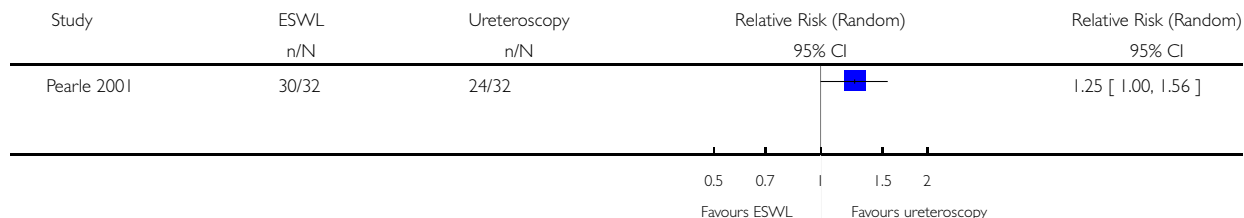


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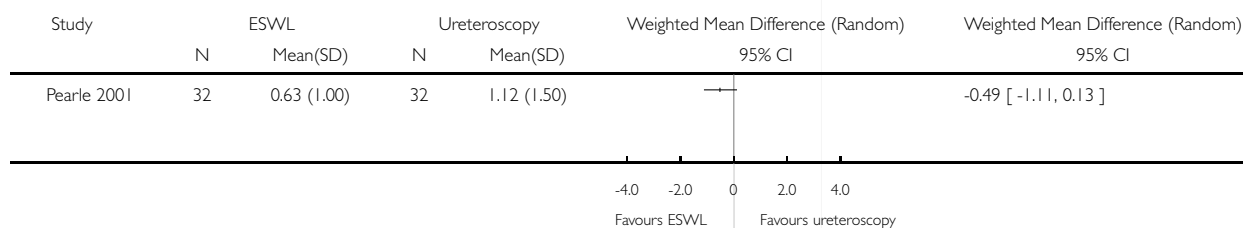


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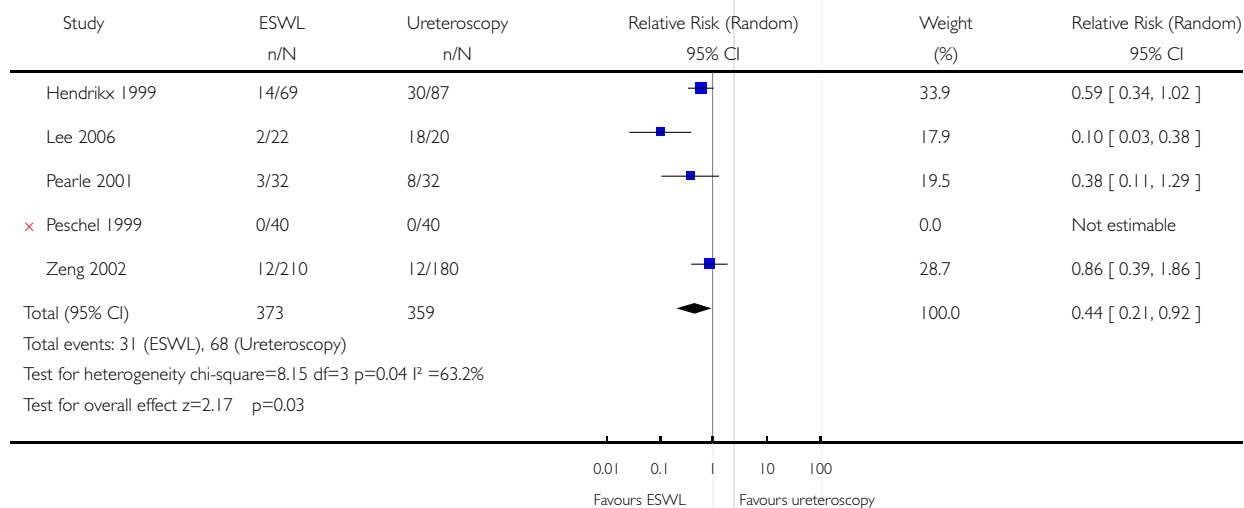


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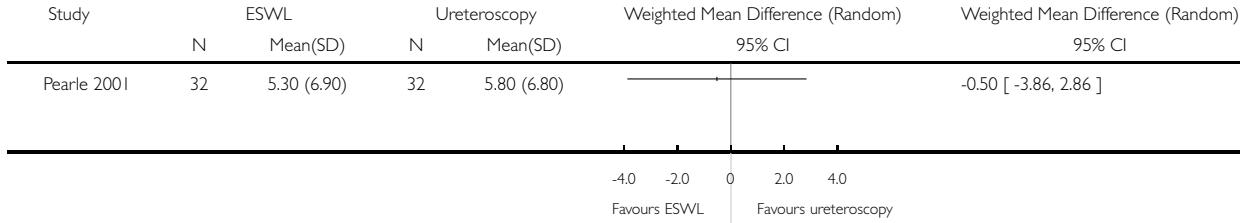


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Comparison: 01 ESWL versus ureteroscopy

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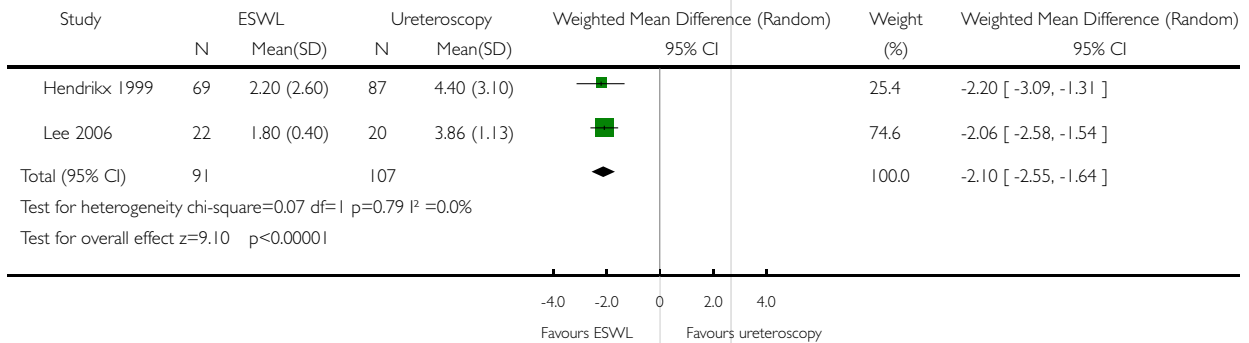


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Analysis 01.13. Comparison 01 ESWL versus ureteroscopy, Outcome 13 Patient satisfaction

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Outcome: 13 Patient satisfaction

