Efficacy of tamsulosin with extracorporeal shock wave lithotripsy for passage of renal and ureteral calculi

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CRD summary
This review concluded that tamsulosin adjunctive to extracorporeal shock wave lithotripsy was safe and effective in treating patients with renal stones of 10 to 24mm diameter; evidence was inconclusive for ureteral stone clearance. Given the poor reporting of the review process and lack of adequate primary trial information, the authors’ conclusions should be treated with caution.

Authors' objectives
To evaluate the safety and efficacy of tamsulosin as an adjunct to extracorporeal shock wave lithotripsy (ESWL) in improving renal and ureteral stone clearance

Searching
MEDLINE(1950 to January 2008) and Iowa Drug Information System (1966 to January 2008) were searched. Search terms reported. Reference lists examined for additional studies.

Study selection
Studies that used tamsulosin therapy after a single session of extracorporeal shock wave lithotripsy or after the development of steinstrasse (an accumulation of stone fragments that obstruct the ureter) were eligible for inclusion. Randomised controlled trials (RCTs) and controlled studies were included.

The primary endpoint in most of the included trials was complete clearance of stones or the presence of clinically insignificant residuals (less than 3mm diameter, asymptomatic) and included only patients with a single radiopaque lithiasis in whom hydration was recommended (1.5 to 2.5 litres/day).

The stone locations in the included studies were ureteral, renal and steinstrasse; stones ranged in diameter from 4 to 24mm. The number of shocks delivered and model of lithotripter varied. The dose of tamsulosin was 0.4mg daily for 14 days to six weeks. Outcomes reported included pain related measures (e.g. visual analogue scale scores) and mean expulsion time.

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity, but level of blinding was noted in tables.

Data extraction
The percentages of patients with outcomes of interest or mean values of outcome measures for each treatment were presented in tables.

The authors did not state how data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
The trials were presented in a narrative synthesis. A table of primary trial details was available for examination of between-trial differences.

Results of the review
Six trials were included in the review (n=415 patients); five were randomised and controlled (n=366 patients); one was controlled (n=49 patients). One trial was double-blinded.
In one trial of renal stone clearance, tamsulosin was associated with a significant improvement in renal stone clearance (p=0.037). Rates of overall ureteral stone clearance (five trials) were 66.6 to 96.6% in the tamsulosin groups, compared with 33.3 to 79.3% in the control groups. Pain and supplemental analgesic dosing were consistently lower with tamsulosin (four trials). Adjunctive tamsulosin was associated with improved passage of renal stones of 10 to 24mm diameter. Subgroup analysis in two trials reported significantly increased clearance rates in stones of 10 to 24 mm (p=0.009 and p=0.03).

One trial (n=67) patients showed no difference in passage rates or removal in patients with steinstrasse, but significantly less pain was experienced during resolution.

Authors’ conclusions
Tamsulosin therapy combined with extracorporeal shock wave lithotripsy was safe and effective in enhancing stone clearance in patients with renal stones of 10 to 24mm in diameter. The evidence relating to ureteral stone clearance was inconclusive, but there was evidence of reduced painful episodes with tamsulosin.

CRD commentary
The research question was supported by inclusion criteria for intervention, but they were implied for participants and there were none for study design or outcome; this may have led to subjective decisions during study selection. The authors did not report any attempts to identify unpublished studies, which may have increased the possibility of publication bias. Language restrictions were not reported, so it is not known whether language bias was likely. The authors did not report the process used for study selection or data extraction, so it is not known if steps were taken to reduce the possibility of reviewer error and bias. Validity of the primary trials was not adequately assessed, so the reliability of their results cannot be assessed. Few participant details were provided, so the baseline clinical heterogeneity could not be determined. Data regarding adverse events did not appear to be included, but the authors concluded that tamsulosin was safe. As the review process was poorly reported, the reliability of the primary trials was not known and the conclusions appeared optimistic considering the data available, the authors' conclusions should be treated with caution.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that larger prospective trials are needed to compare different dosages, durations and stone locations. They also stated that evaluation of incidence of repeat extracorporeal shock wave lithotripsy or ureteroscopy, subsequent cost savings and time to stone passage are required.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.