

# $\alpha$ -Blockers to assist stone clearance after extracorporeal shock wave lithotripsy: a meta-analysis

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Level of Evidence 1a

## OBJECTIVE

To review the evidence for the use of  $\alpha$ -blockers after extracorporeal shock wave lithotripsy (ESWL) in enhancing the effectiveness of renal and ureteric stone clearance.

## METHODS

We searched MEDLINE, Embase and the Cochrane Library up to January 2009. All randomized controlled trials in which  $\alpha$ -blockers were evaluated after ESWL were eligible for the analysis. Outcome measures assessed were clearance rate (primary) and expulsion time (secondary). Two authors independently assessed study quality and

extracted data. All data were analysed using RevMan 5.

## RESULTS

Of the 29 identified papers, seven trials with a total of 484 patients met the predefined criteria. These studies evaluated the effectiveness of the  $\alpha$ -blocker tamsulosin, and studied clearance rate as the primary outcome. There was large heterogeneity between trials, but their methodological quality was adequate. The pooled absolute risk difference of clearance rate was 16% (95% confidence interval 5–27%) in favour of the tamsulosin group, i.e. an average of six patients have to be treated with tamsulosin after ESWL to achieve clearance in one. Subgroup analysis for the six studies that used a dose of 0.4 mg tamsulosin showed a pooled risk difference of 19 (10–29)%. The expulsion time was analysed in three studies

and the pooled mean difference was 8 (–3–20) days in favour of the tamsulosin group. Pain and analgesic usage was reported to be lower with tamsulosin. Adverse effects of tamsulosin, mainly dizziness, were reported in eight patients (3%).

## CONCLUSIONS

Treatment with tamsulosin after ESWL appears to be effective in assisting stone clearance in patients with renal and ureteric calculi. To make a definite clinical recommendation to use tamsulosin after ESWL for renal and ureteric calculi, a high quality confirmatory trial is warranted.

## KEYWORDS

meta-analysis, lithotripsy, adrenergic  $\alpha$ -antagonists, urinary calculi

## INTRODUCTION

Urinary stone disease is one of the most common reasons for patients visiting a urology practice, affecting 5–10% of the population [1]. An even higher frequency has been reported from other parts of world (so-called 'stone belts') and there are only a few geographical areas in which stone disease is rare, e.g. in Greenland and in the coastal areas of Japan [2].

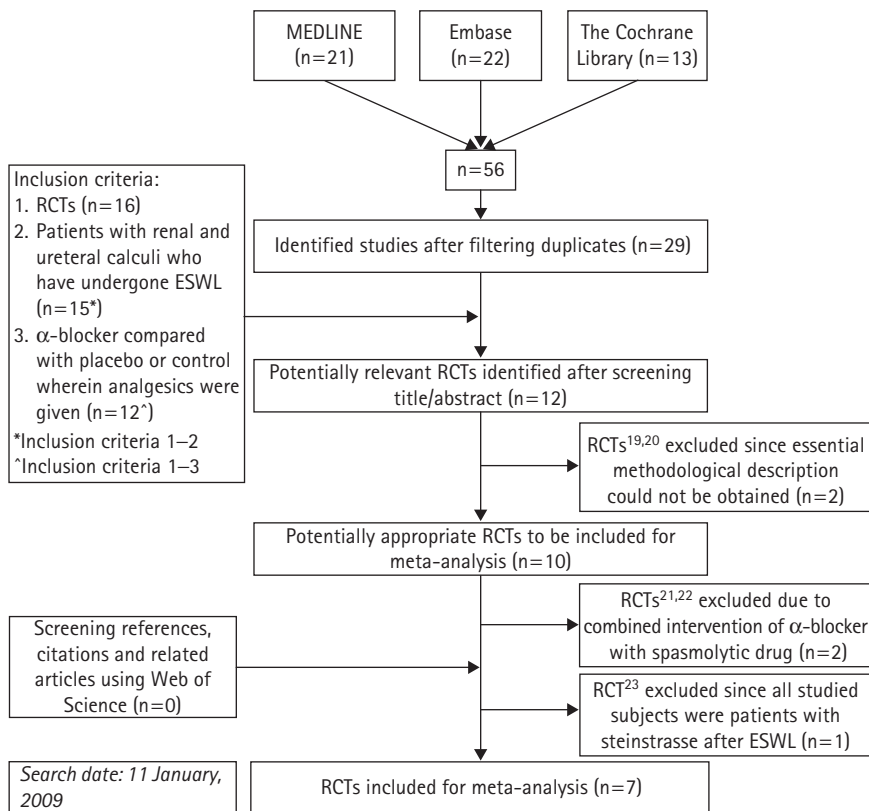
Since its introduction in the early 1980s [3], ESWL has become the initial treatment for patients with kidney and ureteric calculi. Even with the refinement of current endourological methods for stone removal, ESWL remains the

primary treatment for most patients with uncomplicated calculi [4]. ESWL has many advantages, e.g. patients can be treated in an outpatient setting (with no anaesthesia), a low morbidity rate, and high patient compliance.

Success rates of ESWL depend on the type of lithotripter used, stone size and location [5]. With the first-generation HM3 (Dornier MedTech, Wessling, Germany) stone-free rates were 72–99% [3,6–10]. Current lithotripters are considered more comfortable for both user and patient, due to smaller focal zones and balloon coupling. However, newer generation machines never reproduced the high success rate of the Dornier HM3 [11,12].

In the last years, new treatments have been developed aiming to further improve the success rate after ESWL.  $\alpha$ -blockers were introduced as a treatment for LUTS suggestive of BPH [13], and later the effectiveness of  $\alpha$ -blockers to facilitate urinary stone passage was reported in several studies [14–16]. More innovative studies also evaluated  $\alpha$ -blockers after ESWL, but the evidence for their effectiveness in assisting stone clearance remains conflicting. A meta-analysis combining the studies reported to date would offer a unique opportunity to produce an overall effect estimate of  $\alpha$ -blockers. The direction and magnitude of this effect will help in guiding decisions about clinical practice.

FIG. 1. A flowchart of the search strategy.



**METHODS**

Computer-based searches were used to compile all relevant published randomized controlled trials (RCTs) into the effects of α-blockers after ESWL on renal and ureteric calculi. MEDLINE (1950 to January 2009), Embase (1950 to January 2009) and the Cochrane Library (Issue 1, 2009) were searched using the terms 'α-blocker', 'ESWL' and their synonyms and plurals (see Appendix 1 for search terms). In addition, a reference and related article search was performed using Web of Science. A flowchart of the search strategy is shown in Fig. 1.

The inclusion and exclusion criteria for studies were independently assessed by two authors (Y.Z. and D.D.). Inclusion criteria were: RCTs, patients with renal and/or ureteric calculi who were treated with ESWL, and α-blockers as an intervention compared with placebo or a control group wherein only analgesics were allowed. Outcome measures that should be reported were clearance rate and/or expulsion time. Exclusion criteria were: trials

investigating only steinstrasse in patients after ESWL, and trials in which combined intervention of α-blocker with other proven spasmolytics (e.g. corticosteroids, calcium channel blockers) were applied.

The methodological quality of the eligible papers was critically appraised independently by two authors (Y.Z. and D.D.) using the quality-assessment tool of the Cochrane Collaboration [17], including a judgement on sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and evaluation of other possible bias. Any discrepancy was resolved by discussion with a third author (T.M.L.).

Differences in clearance rate and expulsion time were analysed either as a rate or mean differences with their corresponding 95% CIs. Results of the meta-analysis are also reported as rate or mean difference; the number needed to treat was also calculated.

Heterogeneity was assessed using the I-square test as well as by visual inspection of

the Forest plots. When heterogeneity was present (I-square >25%) the data were analysed using the random-effects model, otherwise a fixed-effect was used. Publication bias was assessed with a funnel plot. For all analyses we used RevMan 5 [18]. Subgroup analysis was used to explore possible sources of heterogeneity (e.g. participants, interventions and study quality).

**RESULTS**

Our search strategy identified 29 studies, of which 12 were potentially relevant trials (Fig. 1). Two papers were excluded from analysis as the essential methodological description could not be obtained, despite several attempts to contact the authors [19,20]. Of the remaining 10 trials, three were excluded on predefined exclusion criteria [21–23]. In the first and second trial, an α-blocker was combined with a spasmolytic drug, and its use could bias the final results, so we therefore excluded these studies from further analysis [21,22]. The last study investigated only patients with steinstrasse after ESWL [23]. The population therefore differs significantly from that in other trials. The characteristics and results of the seven included studies are summarized in Table 1 [24–30].

The α-blocker used in all seven trials was tamsulosin. The pooled results of the studies included 240 patients who were treated with tamsulosin and 244 controls. Only one trial was placebo-controlled [24]; the others compared tamsulosin with a control group in which only analgesics were allowed [25–30]. All patients were treated on an outpatient basis. The mean age of patients in the tamsulosin group was 37–57 years and the mean stone size was 8.5–12 mm. In the controls, the mean age was 36–53 years and stone size was 8.2–13 mm. Five trials investigated patients with ureteric calculi [25–28,30], one evaluated patients with renal calculi [29], whereas the seventh included both renal and ureteric calculi [24]. Six studies used a tamsulosin dose of 0.4 mg/day [24,25,27–30] and one of 0.2 mg [26]. Treatment duration and follow-up was 14 days to 3 months. One article reported that treatment was continued until stones were cleared [26]. The clearance rate was the primary outcome of all studies, defined in five as stone-free status or presence of clinically insignificant asymptomatic residual

TABLE 1 Characteristics of the included studies, the treatments, results and quality assessment

Characteristic	Intervention/control						
	[24]	[25]	[26]	[27]	[28]	[29]	[30]
Participants, n	30/30	30/31	38/34	24/24	28/21	51/65	40/40
Lithotripter used	Dornier Compact S	Dornier S II	Dornier	Siemens Lithostar +	Dornier S	Lithostar-Multiline	NR
Mean age, years	42.3/35.9	48.8/49.2	56.8/52.3	43.4/42.5	45/46	37.2/39.4	39.7/38.5
Mean stone size, mm	NR/NR	8.5/8.3	10.6/19.9	8.6/8.2	10/9.9	12.1/13.1	8.6/8.2
Stone location	Renal+ureteric	Ureteric	Ureteric	Ureteric	Ureteric	Renal	Ureteric
Follow-up	1 month	1 month	28 days	15 days	60 days	3 months	2 weeks
<b>Results</b>							
Treatment, mg	T 0.4 + pro/P	T 0.4+*/*	T 0.2+†/†	T 0.4+*/*	T 0.4+*†/†	T 0.4/NR	T 0.4+*/*
Assessment	Fluoroscopy + KUB	KUB + US	KUB + US and/or IVU	KUB, IVU, CT and/or US	KUB, US and/or IVU	KUB and/or US	KUB and/or US
Stone clearance, %	96.6/79.3	63.3/51.6	84.2/88.2	33.3/70.8	82.1/57.1	94.1/84.6	77.5/45
P value	0.04	0.05	0.343	0.019	0.05	0.14	<0.05
Mean expulsion time, days	NR	12.95/13.22	15.66/35.47	NR	NR	35.53/47.22	NR
P value		>0.05	0.042			0.006	
<b>Quality assessment</b>							
Adequate sequence generation	Yes	No	Unclear	Yes	Unclear	Yes	Yes
Allocation concealment	Yes	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Blinding	Yes	Unclear	Unclear	Yes	Unclear	Unclear	Unclear
Incomplete outcome data addressed	Yes	Yes	Yes	Yes	Yes	No	Yes
Free of selective reporting	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Free of other bias	Yes	Yes	Yes	Yes	Yes	Yes	Yes

NR, not reported; \*diclofenac orally; †diclofenac suppositories; ‡ketoprofene 50 mg; KUB, plain film of the kidney, ureter, bladder; US, ultrasonography; P, placebo; T, tamsulosin; pro, propoxyphene + acetaminophen.

fragments of <3 mm [24–26,28,29]. Two studies did not include clinically insignificant residuals as a successful outcome [27,30].

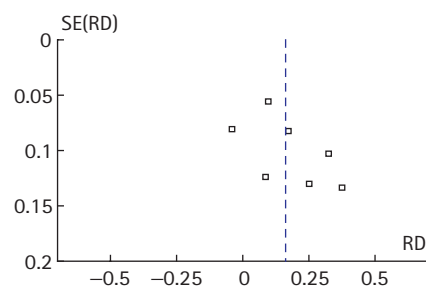
Table 1 also shows the quality assessment of the seven included studies. Two studies did not describe the method of randomization [26,28], and one randomized the groups based on the last digit of their hospital code number, and was consequently assessed as inadequate for sequence generation [25]. In five studies the concealment of allocation was unclear [25–29]; one was double-blinded [24], and in another the outcome assessor was blinded [27]. All studies were free of selective reporting [24–29]. 'Lost to follow-up' was reported in three studies [24,25,29]; in one the incidence of 'lost to follow-up' was 16.5% and no intention-to-treat analysis was used. Hence, for addressing incomplete outcome data, this study was assessed as inadequate [29]. All studies were free of other bias. A funnel plot assessing publication bias is shown in Fig. 2.

The pooled absolute risk difference of the clearance rate was 16% (95% CI 5–27%), indicating an increase in clearance rate in the tamsulosin group compared to controls (Fig. 3a). The corresponding number needed to treat is six, i.e. six patients have to be treated with tamsulosin after ESWL to achieve clearance in one. A subgroup analysis for tamsulosin 0.4 mg daily, evaluated in six studies (Fig. 3b) gave an absolute risk difference of 19% (95% CI 10–29%), resulting in a number needed to treat of five.

The expulsion time was analysed in three of the seven studies [25,26,29]. The pooled results of these three studies included 119 patients treated with tamsulosin and 130 controls, and showed a mean difference of 8 days in favour of tamsulosin (95% CI, –3 to 20 days; Fig. 3c).

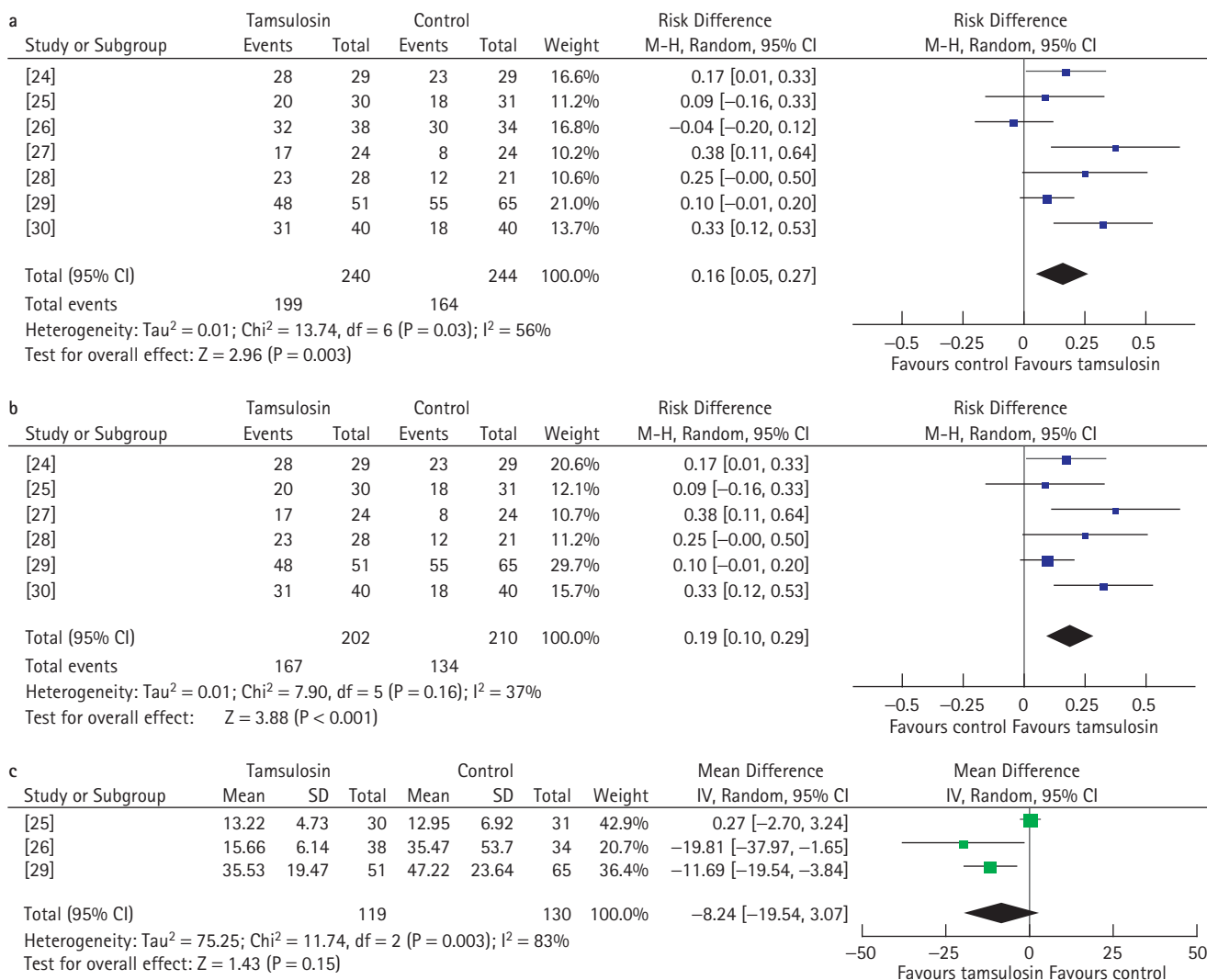
Pain and usage of analgesics was reported in four trials, and were lower in those treated with tamsulosin [24,25,29,30]. Gravas *et al.*

FIG. 2. A funnel plot of the included studies.



[25] reported a significant lower use of diclofenac in the tamsulosin group than in the controls, with a mean diclofenac dose of 118.9 mg in the control and 56.9 mg in the tamsulosin group ( $P = 0.02$ ). Naja *et al.* [29] found lower visual analogue scale pain scores in the tamsulosin group of 28.67, vs 47.30 in controls ( $P < 0.001$ ). In the trial by Wang *et al.* [30], 20% of the controls needed extra analgesics, vs 5% in the tamsulosin group ( $P < 0.05$ ).

FIG. 3. Forest plots with: a, stone clearance as the outcome; b, stone clearance as the outcome for tamsulosin 0.4 mg; and c, expulsion time as the outcome.



The adverse effects of tamsulosin were evaluated in five studies [24,25,27,29,30] and were reported for eight patients (3%) from three different studies. Six patients reported dizziness [25,30], one postural hypotension [29], and one retrograde ejaculation [29].

**DISCUSSION**

The results of this meta-analysis show that tamsulosin appears to be effective in enhancing stone clearance. There was an absolute risk difference of 16% in clearance rate in favour of the tamsulosin group, based on seven studies. The I-square statistic of 56% implied that there is medium heterogeneity among these studies. Whereas only a

tamsulosin dosage of ≤0.2 mg is accepted in Japan and South Korea, in Europe and the USA a dose of 0.4 mg is common, as a result of a higher body mass. Due to this significant dose difference, a subgroup analysis was done for tamsulosin 0.4 mg, which showed an improvement of the absolute risk difference to 19%, i.e. five patients have to be treated with 0.4 mg tamsulosin after ESWL to achieve clearance in one. The I-square statistic of 37% implied that these six studies are relatively homogeneous. For our secondary outcome, expulsion time, there was a mean difference of 8 days in favour of the tamsulosin group, based on three studies.

Our results are in agreement with earlier reported reviews on this topic [11,31–33].

However, only Schuler *et al.* [33] also conducted a meta-analysis, but at the time of their review only two studies with a total of 94 patients treated with tamsulosin and 94 controls could be included.

To our knowledge, the present is the first meta-analysis with enough power to study the effectiveness of α-blockers after ESWL. Besides the clearance rate, we also evaluated expulsion time, which also is a clinically relevant outcome. Moreover, we consider that the methodological quality of the included studies is adequate. Nevertheless, there are some possible limitations.

First, publication bias cannot be completely excluded, as the funnel plot suggests that

small negative studies appear to be missing. However, we believe that if there were such studies they would only slightly decrease the overall beneficial effect. Second, clinical heterogeneity in study populations, such as variability in stone characteristics, ESWL technique and assessment of stone clearance, might have influenced the results. Different types of lithotripters were used and there was no consistency in the number of shocks (1500–3500) and rates of delivery (70–120/min). Reported studies comparing lithotripters are rather rare, and results are often contradictory [11]. However, it is well documented that shock waves at a slow rate improve the effectiveness of ESWL, but the best rate remains unclear [11,31]. Also, in all included trials the follow-up was assessed by a plain abdominal film, and only in the study by Kupeli *et al.* [27] was CT also used. Although studies comparing plain films and CT in the follow-up of ESWL are sporadic, it has been shown that in patients presenting with acute colic, CT is more sensitive for detecting urolithiasis [34–36]. However, a sensitivity analysis with more homogeneous studies showed similar results. We therefore believe that the results could be pooled.

Last, in our meta-analysis we did not stratify outcomes by stone size. Among the included studies, stratification was used by a few authors. Bhagat *et al.* [24] stratified clearance rate by stone size; for stones with a diameter of 6–10 mm, the difference in clearance was not significant ( $P = 0.35$ ). A statistically significant benefit with use of tamsulosin was only found for stones with a diameter of >10 mm ( $P = 0.03$ ). These findings suggest that tamsulosin would be more effective in larger stones. This is not in accordance with the results of two other studies. Naja *et al.* [29] stratified the expulsion time by stone size; by contrast with the above mentioned trial, there was a statistically significant ( $P = 0.014$ ) difference in favour of tamsulosin only for stones of <10 mm. This implies that with tamsulosin there was a significantly shorter expulsion time for smaller stones after ESWL. In the study by Kobayashi *et al.* [26] there was no correlation between stone size and expulsion time. Based on the findings of the included studies, the evidence is inconclusive as to whether the effectiveness of tamsulosin on stone clearance after ESWL is correlated with stone size; a large confirmatory trial is advisable.

From the results of our meta-analysis, there are several implications for enhanced stone clearance with tamsulosin. One of these is the prevention of unnecessary re-treatment with ESWL or other surgical intervention, and therefore possible complications. The re-treatment rate for ESWL is 4–38% [37]. ESWL-related complications are mostly due to residual stone fragments, infections, and effects on tissues of, e.g. the urinary, gastrointestinal, cardiovascular, genital, and reproductive systems [38]. With a higher clearance rate, some patients are not exposed to further treatment. Also, surgical intervention for urolithiasis is costly, especially when compared with  $\alpha$ -blockers such as tamsulosin, which is a not a generic drug. Therefore, the potential cost savings could be substantial.

One of the most distressing symptoms of stones is the pain of colic. Our results also imply that the use of tamsulosin is associated with less use of pain medication and lower pain scores. Furthermore, common adverse effects of tamsulosin are headache, abnormal ejaculation and dizziness. These side-effects were only reported in 3% of the patients who were given tamsulosin. Therefore, tamsulosin seems to be well tolerated by nearly all patients in the included studies.

In conclusion, due to clinical heterogeneity among the included studies, conclusions drawn from our pooled results should be interpreted cautiously. However, the results suggest that treatment with tamsulosin after ESWL, to assist stone clearance, is effective, implying a higher clearance rate, shorter expulsion time and better pain management in patients with renal and ureteric calculi. In addition, tamsulosin is inexpensive compared to surgical intervention and seems to be well tolerated. Although there is some evidence for the benefits of tamsulosin after ESWL, a high-quality confirmatory trial is warranted before final clinical recommendations can be made.

#### CONFLICT OF INTEREST

None declared.

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e-mail: xiaoyezhu@hotmail.com

**Abbreviation:** RCT, randomized controlled trial.

#### APPENDIX 1

Database Search terms

MEDLINE (search terms in title, abstract)

Embase (search terms in title, abstract or keyword)

The Cochrane Library (search terms in title, abstract or keyword)

1. α block\*
2. α receptor block\*
3. α adrenergic antagonist\*
4. α receptor antagonist\*
5. tamsulosin
6. doxazosin
7. alfuzosin
8. terazosin
9. OR/1–8
10. SWL
11. ESWL
12. shock wave lithotripsy\*
13. shockwave lithotripsy\*
14. ultrasonic lithotripsy\*
15. lithotripter\*
16. OR/10–15
17. AND/9, 16