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Original article

Tamsulosin efficacy and safety for conservative management of renal colic: Systematic review and meta-analysis of randomized controlled trials $^{\diamond}$



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ABSTRACT

Background and objective: The aim is to evaluate tamsulosin efficacy and safety on the expulsion of distal ureteral stones compared to a standard therapy.

Materials and methods: Systematic searches were conducted on PubMed, SCOPUS and The Cochrane Library so as to identify randomized and controlled clinical trials in patients treated with tamsulosin with ureteral stone expulsion and adverse events published until 2014 December, without language restriction. Treatment effect was calculated along with the 95% confidence interval (95% CI), using the variance inverse method for random effects. Heterogeneity was determined by *I*². Publication bias was assessed by Egger test.

Results: The search identified 480 articles. Thirty-eight met the selection criteria, a total of 3107 patients. The relative risk (RR) of expulsion was 1.53 (95% CI 1.38–1.69; $I^2 = 71\%$), while the RR of adverse effects was 1.79 (95% CI 1.19–2.71; $I^2 = 0$).

Conclusions: Tamsulosin treatment seems to bring on the expulsion of distal ureteral stones, although at the expense of an appreciable risk of side effects.

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Eficacia y seguridad de tamsulosina para el tratamiento conservador del cólico nefrítico: revisión sistemática con metaanálisis de ensayos clínicos aleatorizados

RESUMEN

Fundamento y objetivo: El objetivo fue evaluar la eficacia y seguridad de tamsulosina, comparada con otro tratamiento estándar o con placebo, en la expulsión de las litiasis ureterales distales. *Material y métodos:* Se realizaron búsquedas sistemáticas en PubMed, SCOPUS y The Cochrane Library para identificar los ensayos clínicos aleatorizados y controlados en pacientes tratados con tamsulosina con resultados de expulsión de litiasis ureteral y de episodios adversos, publicados hasta diciembre de 2014, sin limitaciones de idioma. Se calculó el efecto de los tratamientos junto con el intervalo de confianza del

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95% (IC 95%) utilizando el método de la inversa de la variancia para efectos aleatorios. La heterogeneidad se determinó mediante el estadístico l^2 . El sesgo de publicación se evaluó mediante la prueba de Egger.

Resultados: La búsqueda identificó 480 artículos. Treinta y ocho cumplían los criterios de selección, con un total de 3.107 participantes. El riesgo relativo (RR) de expulsión de litiasis de los pacientes tratados con tamsulosina comparado con el tratamiento control fue de 1,53 (IC 95% 1,38-1,69; $I^2 = 71\%$). El RR de cualquier episodio adverso de tamsulosina fue de 1,79 (IC 95% 1,19-2,71; $I^2 = 0\%$).

Conclusiones: El tratamiento con tamsulosina parece favorecer la expulsión de litiasis renales, aunque con un riesgo no desdeñable de efectos secundarios.

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Introduction

Renal colic is a common condition in the general population with significant repercussions for the patient owing to the severe pain and lost work days that it normally involves. It is considered to be the most common reason for visiting emergency departments owing to urological pain. Its prevalence varies according to country. In Europe, according to data by Hollingsworth et al.,¹ it ranges between 5% and 12%, and it is known that 30–40% of those affected by an episode will have a relapse in the following 5 years.^{2–4} It predominantly affects middle-aged men, and its frequency is greater in hot months. Many stones are small in size (less than 5 mm) and are found in the distal ureter. These factors have a positive influence on their expulsion.^{5,6} Among patients affected by renal colic, 3–10% have a family history of urinary tract stones. This figure rises to 25% if only patients with repeated colic are studied.^{2,3}

To date, their emergency treatment has been based on analgesia, without much evidence of the usefulness of other adjuvant treatments. Non-expulsion of a stone results in the possibility of having repeated colic, and spontaneous expulsion varies according to different articles published (between 0 and 35% for those of more than 5 mm,⁷ and more than 80% for those smaller than this size¹). Invasive techniques are not free of risks and are not well accepted by patients. In addition, they are normally used for stones with a diameter of more than 2 cm.⁸ The possibility of there being a drug treatment to facilitate the stone expulsion would be a major advance in addressing this health problem. In this regard, different pharmacological groups such as calcium antagonists and alpha blockers have been tested, with discordant results. Tamsulosin is the most used treatment in Spain owing to its good a priori tolerability and other advantages.

The objective of this study was to conduct a systematic review and a meta-analysis of controlled clinical trials that evaluated the efficacy and safety of tamsulosin, compared with another standard treatment (NSAIDs, analgesics, hydration and/or antibiotics) or with placebo, in distal ureteral stone expulsion.

Materials and methods

Search strategy

A search was conducted in PubMed, SCOPUS and the Cochrane Library using MeSH terms and free text (see Appendix A): "urinary bladder calculi", "urinary calculi" "urolithiasis", and "adrenergic alpha antagonist", "adrenergic alpha 1 receptor antagonist", "alpha blockers" and "tamsulosin" to identify the controlled clinical trials that provided results on ureteral stone expulsion and adverse events, published before December 2014. There were no language constraints. A manual search of related articles was also completed (Fig. 1).

Selection of articles

Two researchers (MBC and MJCH) independently selected the articles that were included in the systematic review. Discrepancies were resolved by means of consensus.

The inclusion criteria were: (a) controlled clinical trials that evaluated the efficacy of tamsulosin compared to another standard treatment (NSAIDs, opiates, hydration and/or antibiotics) or with placebo; (b) participants of or over 18 years of age and (c) inclusion of the response endpoints studied (percentage of expulsion and adverse effects).

The exclusion criteria were: (a) the treatment with tamsulosin was merely as an adjuvant to invasive treatment (for example, lithotripsy) and (b) use of alpha blockers other than tamsulosin.

From articles that, even including an invasive treatment arm, also encompassed patients with conservative treatment with tamsulosin alone, and from those that compared different alpha blockers with normal analgesic treatment, patient outcomes in the analgesia control group and those in the tamsulosin group were gathered.

Data extraction and quality evaluation

The following variables were extracted by means of a standardised form: study design, sample size, stone location, stone size, follow-up time, treatment performed in the control group, dose of tamsulosin, percentage of expulsion and percentage of side effects. Extraction was performed in duplicate and independently by 2 researchers (NML and EMS). Discrepancies were resolved by means of consensus. The quality of the studies was evaluated with the Jadad scale.⁹

Statistical analysis

The effect of the treatments together with the 95% CI confidence intervals (95% CIs) were calculated in both relative terms (relative risk [RR]) and absolute ones (absolute increase in benefit and number needed to treat [NNT]) for stone expulsion. As regards adverse effects, absolute reduction in risk and number needed to treat to cause an adverse event were calculated. For this purpose, a meta-analysis was performed by means of the inversevariance method for random effects. Analyses were performed by intention to treat. Heterogeneity was quantified using the I^2 statistic, which describes the proportion of all estimated variation in the study that is due to heterogeneity.¹⁰ I^2 values of 25%, 50% and 75% correspond to low, medium and high heterogeneity levels. To explore possible causes of heterogeneity, an analysis by subgroups was carried out that compared higher-quality studies $(Jadad \ge 3)$ versus lower-quality ones (Jadad < 3), study blinding (double-blind versus non-double-blind), stone size (<5 mm versus >5 mm), treatment time (<4 weeks versus \geq 4 weeks) and study size (less than or equal to 73 participants versus greater than 73 participants), as well as a meta-regression that included study Download English Version:

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