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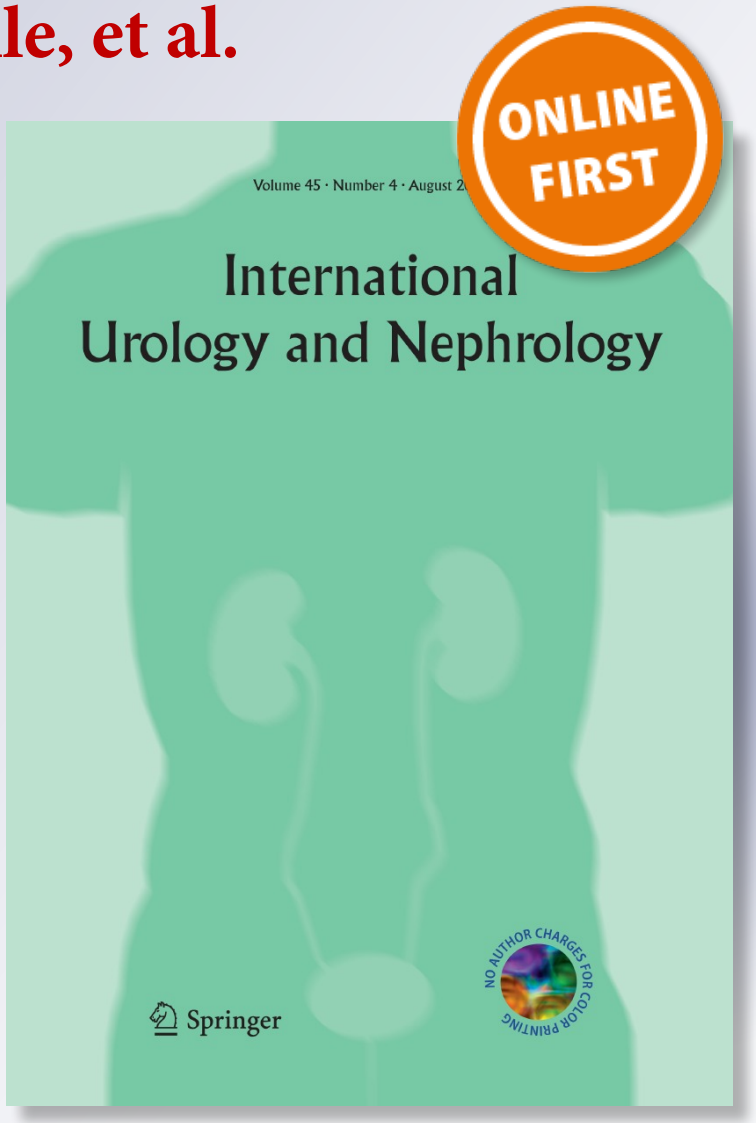

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UROLOGY - ORIGINAL PAPER

A comparative study on the use of tamsulosin versus alfuzosin in spontaneous micturition recovery after transurethral catheter removal in patients with benign prostatic growth

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Abstract
Purpose To compare the efficacy and safety of tamsulosin and alfuzosin in patients with acute urinary retention (AUR) secondary to benign prostatic hyperplasia (BPH).
Methods Ninety men with AUR due to BPH underwent urinary catheterization and were randomly assigned to treatment groups with tamsulosin 0.4 mg (37 patients), alfuzosin 10 mg (34 patients), and placebo (19 patients). After 4 days of the drug treatment, the catheters were removed, and the patients underwent trial without catheter (TWOC). A TWOC was considered successful if the patient had a voided volume >100 ml and post-void residual urine <200 ml.
Results TWOC was successful in 16 patients (43.2 %) in the tamsulosin group, 12 patients (35.2 %) in the alfuzosin group, and 5 patients (26.3 %) in the placebo group. Logistic regression analysis showed that both drugs were equally effective and that the type of alpha-blocker was not a predictive factor for TWOC success (OR 1.137, 95 % CI 0.639–2.022) ($p = 0.662$).
Conclusion Even though there were no statistically significant differences when comparing the three groups, tamsulosin showed a tendency to be more effective in a successful catheter removal. The lack of objective criteria in the definition of successful micturition leads us to believe that the effectiveness of both drugs reported in the literature is overestimated.

Keywords Urinary retention · Tamsulosin · Alfuzosin · Prostatic hyperplasia · Urinary catheterization · Mexico

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Introduction

Acute urinary retention (AUR) is a urologic urgency that is defined as the inability to micturate. Its onset is usually sudden and painful. The annual AUR incidence in different countries varies from 2.2 to 6.8 per 1,000 men [1, 2]. In the majority of cases, the cause of AUR is attributed to the natural history of benign prostatic hyperplasia (BPH). Predictive factors include advanced age, low flowmetry values, increased post-micturition residual urine, and elevated prostate-specific antigen (PSA) [3–5]. Initial management of this urgency involves gradual emptying of the

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bladder through transurethral catheter placement. However, there is a higher association with morbidity such as bacteriuria, urosepsis, and fever in those patients with transurethral catheter [6, 7]. In addition, emergency prostate surgery (within the first few days) is associated with a greater risk for transfusion, postoperative complications, and mortality in the first 30 days [8, 9].

These risks associated with transurethral catheter placement have led to an increase in catheter removal after 1–8 days of drug treatment. The most frequently employed drugs for this purpose are the α adrenergic receptor blockers, tamsulosin, and alfuzosin. They enable spontaneous micturition recovery in 34–70 % of patients [10–16]. The action mechanism of both drugs is the competitive antagonism of the adrenergic receptors that produces a reduction in the sympathetic tone at the level of the urethra and bladder neck, reducing bladder exit resistance and facilitating micturition [17–22].

The direct benefit is the quality of life improvement and the reduction in the morbidity associated with transurethral catheter [23]. However, there are few direct comparison studies on both drugs [24]. Therefore, the aim of this study was to compare the effectiveness of tamsulosin versus alfuzosin in the recovery of spontaneous micturition in patients with catheter placement for BPH.

Methods

Patient selection

From September 2010 to July 2012, men above the age of 50 years with the first episode of AUR secondary to BPH who sought medical attention at the outpatient service of the *Hospital General de México* were recruited for the study.

The exclusion criteria were as follows: More than one episode of AUR, patients under treatment for prostatic growth (alpha blockers, phytotherapy, etc.), elevated serum creatinine and urea levels (serum creatinine >120 mmol/ml), reflux hydronephrosis, more than one episode of urinary tract infection or hematuria, active urinary infection, suspicion of prostate cancer upon rectal examination, suspicion of bladder cancer, suspicion of urinary retention unrelated to prostate pathology, neurogenic bladder, urethral stricture, coagulates, bladder lithiasis, confirmed diagnosis or suspicion of prostate cancer, AUR secondary to the anesthetic procedure from major surgery, patients unable to understand or authorize informed consent, patients with a history of postural hypotension (a fall in the systolic or diastolic pressures of at least 20 mm Hg) or syncope, patients with severe heart failure or instability that were taking cholinergic or anticholinergic medication, monoamine oxidases inhibitors, and patients with severe liver failure.

A randomized, single blind, longitudinal, comparative, experimental clinical trial was conducted. Ninety-six men were assigned to one of 3 groups by means of a randomization table: Group I, 0.4 mg of oral tamsulosin every 24 h for 4 days; Group II, 10 mg of oral alfuzosin every 24 h for 4 days, and Group III, placebo. Based on previous studies that reported successful catheter removal with alfuzosin in 62 % of patients [12] and with tamsulosin in 48 % [10], and on the reported superiority of either of the two alpha blockers compared with a placebo, we decided to include a 2:1 ratio in relation to the placebo. Using a formula for 2 proportions and assuming a power of 80 % and a significance level of 0.05, a sample size of 30 patients per α blocker group and 15 patients for the placebo group was required.

Methods

Once the diagnosis for AUR due to prostatic growth was established and the patients fitting the study criteria were selected, the study characteristics were explained to them and all selected patients gave their written informed consent to participate in the study, according to the principles of the Declaration of Helsinki. The study was also approved by the institutional ethics committees in accordance with sound clinical practice. (DIC/10/1085/04/109).

The data was gathered in a case report file that included personal patient information, demographic data, the patient's clinical history, complete physical examination data, as well as lower urinary tract symptoms based on the international prostate symptom score (IPSS), date and time of transurethral catheter placement, rectal examination findings, and results of the laboratory analyses and transrectal ultrasound images.

The transurethral catheter was removed on the fifth day, and each patient was asked to drink 1.5 l of water. The volume of the first micturition was then measured in a volumetric flask. A 14 F Nelaton "in–out" catheter was also placed, and the post-micturition residual urine was measured. A maximum of 4 h was waited for the first micturition. Recovery was considered successful if the volume of the patient's first micturition after catheter removal was above 100 ml, and the post-micturition residual urine obtained by means of the Nelaton catheter was under 200 ml.

Catheter removal was considered failed if the patient was unable to micturate or there was no spontaneous micturition and if there were clinical AUR data such as suprapubic pain and an over-distended bladder.

Table 1 Clinical characteristic of men by study group (mean ± SD)

	Tamsulosin	Alfuzosin	Placebo	*t* test
N	37	34	19	
Age (years)	65.2 ± 9.1	63.6 ± 8.9	69.4 ± 7.3	0.07
Catheterization time (days)	12.7 ± 14.9	9.72 ± 4.9	14.26 ± 19.0	0.45
First micturition volume (ml)	149.86 ± 163	137.5 ± 156.5	74.73 ± 97.2	0.19
Post-micturition residual urine (ml)	266.16 ± 235.4	305.7 ± 231.6	276.68 ± 222.1	0.76
Patient with Successful TWOC (%)	16 (43.2)	12 (35.2)	5 (26.3)	

Statistical analysis

Data were described as mean ± standard deviation (SD) or in percentages. Variance analysis (ANOVA) was used to compare the means of the continuous quantitative variables.

Logistic regression analysis was done to establish the correlation between the same variables. The model used is described with the estimated OR and 95 % CI. The SPSS statistical program for Windows version 15 (SPSS, Chicago, IL, USA) was employed.

Results

Ninety-six patients were included in the study. Six of them were eliminated; 5 because they did not return to have their catheters removed, and one due to a false urethral tract. All 90 patients were randomly assigned to one of 3 groups: group I, tamsulosin (37 patients); group II, alfuzosin (34 patients); and group III, placebo (19 patients). Table 1 shows the clinical and demographic characteristics of the study patients. No statistically significant differences were observed between the groups ($p > 0.05$).

The results with respect to successful micturition after catheter removal indicated a greater proportion of successful micturition in group I with tamsulosin (16 out of 37 patients, 43.2 %) compared with group II with alfuzosin (12 out of 34 patients, 35.2 %) and the placebo group (5 out of 19 patients, 26.3 %) Fig. 1. However, the logistic regression analysis for evaluating the pharmaceutical influence on catheter removal success showed that the drug employed was not a significant independent variable that could be considered a predictive factor for success in attempted catheter removal ($p = 0.662$) (OR 1.137, 95 % CI 0.639–2.022). No adverse effects presented in any of the patients.

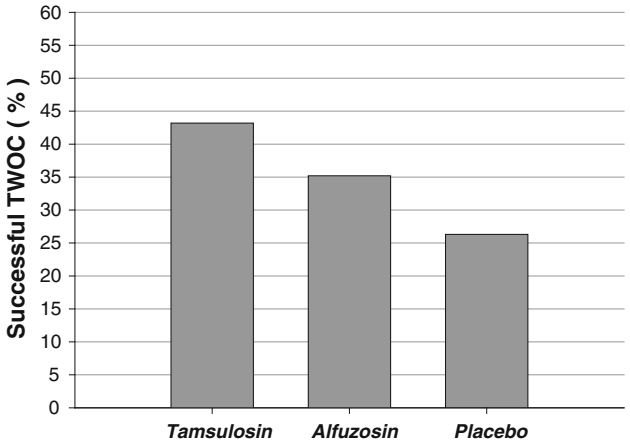

Fig. 1 Successful trial without catheter by group

Discussion

BPH is a highly prevalent disease in the population over 60 years of age. Symptoms increase with time, ending in AUR, its most severe. This precarious clinical condition often leads to prostate surgery, either urgent or elective, presenting with important associated complications [7, 9].

For this reason, catheter removal is attempted after a period of 1–4 days. Various controlled clinical trials have demonstrated that the α-adrenergic blockers, tamsulosin, and alfuzosin are safe and effective in AUR management when compared with a placebo, with successful removal percentages that vary widely from 48 to 70 %.

In the present study, the attempt at catheter removal was successful in 43 % of the patients treated with tamsulosin, which was lower than the effectiveness reported by other authors such as [10], and more recently [24], whose percentages of catheter removal success were 48 and 70 %, respectively. With respect to group II (alfuzosin), 35 % of the patients in the present study had successful catheter removal, a percentage that was also lower than that reported by other authors such as McNeill et al. [12] with successful removal in 62 % of the cases and Agrawal et al. [24] with 66 %. The latter study was a direct comparison of successful catheter removal attempt after tamsulosin or alfuzosin use, and they reported a slight superiority for tamsulosin (70 %) compared with alfuzosin (62 %) that was not statistically significant. However, the criterion for defining "successful removal" was subjective, given that only the patient's verbal reference to "satisfactory micturition" was considered.

Objective parameters were used in the present study to evaluate drug effectiveness, such as volume quantification of the first micturition and post-micturition residual urine. This probably was influential in our study's low success percentages compared with success results for these two drugs reported in the international literature.

Conclusions

We corroborated the fact that the probability of successful catheter removal attempt increases with the use of an α-adrenergic blocker. Even though there were no statistically significant differences when comparing tamsulosin and alfuzosin; tamsulosin showed a tendency to be more effective than alfuzosin and had a good safety profile. However, the lack of objective criteria in the definition of successful micturition leads us to believe that the effectiveness of both drugs reported in the literature is overestimated. We feel it is essential to create a consensus among the international urologic community in relation to a "successful micturition" criterion because without it, there are important inconsistencies in comparing the results of different studies.

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Conflict of interest The authors declare that they have no conflict of interests.

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