Intravesical prostatic median lobe size as a trial without transurethral catheter result predictor in patients with acute urinary retention

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Abstract

**Background:** Acute urinary retention (AUR) is a urologic emergency commonly treated with bladder catheterization and the administration of alpha-adrenergic antagonists, followed by a trial without catheter.

Intravesical prostatic protrusion (IPP) is an enlargement of the prostate in which the median lobe protrudes into the bladder. It has been suggested that the size of this lobe can predict the result of a trial without catheter.

**Aims:** To determine the relation between the size of the intravesical prostatic lobe and the success of spontaneous voiding recovery in patients treated with alpha blockers.

**Methods:** Men above the age of 50 years that presented with urinary retention within the time frame of September 2010 to February 2013 were randomly included in one of the 3 study groups: group 1 tamsulosin; group 2, alfuzosin; and group 3, placebo.

The catheter was removed on the fifth day and transrectal ultrasound was carried out, categorizing the size of the prostatic lobe as grade I: <5 mm, grade II: 5-10 mm, and grade III: >10 mm.

Success was considered if the first micturition volume was > 100 mL and residual urine < 200 mL.

**Results:** A total of 78 patients were included. The success percentages of grades I-III were: 37.5%, 36.8%, and 41.7%, respectively. Logistic regression analysis showed that the size of the intravesical lobe was not a predictive factor of success (OR=0.857; 95%CI=0.184-3.983; p=0.844).

**Conclusions:** The intravesical lobe is not a predictive factor for successful micturition after catheter removal, regardless of the drug used.
Introduction

Acute urinary retention (AUR) is a urologic emergency that is defined as the inability to urinate. It usually presents suddenly and is accompanied by pain.\(^1\) The annual AUR incidence in different countries varies from 2.2 to 6.8 per 1,000 men.\(^2,6\) Unfortunately, there are no studies in Mexico describing the incidence or prevalence of this condition.

The majority of AUR cases are caused by benign prostatic hyperplasia. Some of the identified predictive factors are advanced age, a flowmetry with low values, increased post-micturition residual urine, significant prostate enlargement, and an elevated prostate-specific antigen (PSA) level.

Preliminary management involves the gradual emptying of the bladder with transurethral catheter placement. Until recently, the majority of patients were referred for surgery after an AUR event. However, surgery in these patients is associated with a high risk for transfusion, postoperative complications, and mortality in the first 30 days.\(^7,9\)

The risk associated with the permanence of transurethral catheter has increased the practice of its removal after 1-8 days of pharmacologic treatment, enabling the recovery of spontaneous micturition in 34%-60% of the patients.\(^10,12\) The most frequently used drugs for this purpose are the alpha-adrenergic antagonists, alfuzosin and tamsulosin. Their similar effectiveness has been reported.\(^13,16\) The direct benefit is improved quality of life and reduced morbidity associated with transurethral catheter.\(^17\)

On the other hand, a particular form of prostatic growth is the so-called intravesical median prostatic lobe, in which the median lobe protrudes into the interior of the bladder. Previous studies have suggested that this growth may be a factor in predicting the result of a successful trial without catheter in patients treated with alpha blockers like alfuzosin and tamsulosin.\(^18-20\) However, up to the present, there are no studies directly comparing alfuzosin and tamsulosin that determine if this particular type of growth constitutes a prediction factor in the result of a trial without transurethral catheter.

The aim of this study was to investigate the relation between the size of the intravesical prostatic protrusion (IPP) and the successful recovery of spontaneous micturition after transurethral catheter removal in patients treated with tamsulosin, alfuzosin, and placebo, as well as to determine whether the size of the prostatic median lobe could predict and identify patients with a greater probability of trial without transurethral catheter failure.

Methods

Patient selection

The inclusion criteria were the following: men above the age of 50 years, with first symptoms of AUR secondary to benign prostatic hyperplasia, that sought medical attention at the outpatient service of the Hospital General de México.

The exclusion criteria were: more than one episode of symptoms of AUR, patients that had been treated for prostate enlargement (alpha blockers, phytotherapy, etc.) raised levels of creatinine and urea (serum creatinine > 120...
mmol/mL), hydronephrosis due to reflux, more than one presentation of urinary tract infection or hematuria, active urinary infection, suspicion of prostate cancer through the digital rectal examination, suspicion of bladder cancer, suspicion of urinary retention distinct from prostatic pathology, neurogenic bladder, urethral stricture, blood clots, bladder lithiasis, confirmed diagnosis or suspicion of prostate cancer, AUR secondary to an anesthetic procedure due to major surgery, patients with an inability to understand or authorize informed consent, patients with a history of postural hypotension (blood pressure reduction >20 mm Hg in the systolic or diastolic value) or syncope, patients with severe or unstable heart failure, patients taking cholinergic, anticholinergic, or MAO inhibiting medication, and patients with severe liver failure.

A comparative, longitudinal, randomized, simple-blind clinical trial was conducted. A total of 78 men were assigned to one of three groups by a randomization table: group I, tamsulosin 0.4 mg p. o. every 24 hours for 4 days; group II, alfuzosin 10 mg p.o. every 24 hours for 4 days; and group III, placebo.

Based on previous studies that reported successful trial without catheter with alfuzosin in 62% of the patients 12 and with tamsulosin in 48%, 10 and due to the reported superiority of either of the 2 alpha blockers with respect to a placebo, we decided to include a 2:1 ratio in relation to the placebo. Contingent on the formula for 2 proportions, assuming an 80% power, and a significance level of 0.05, and assuming a success of 33% when the IPP was greater than 10 mm,19 we required a sample size of 30 patients per alpha blocker group and 15 patients in the placebo group.

Once the diagnosis of AUR due to prostate enlargement was established and it was determined that the patient met the selection criteria to enter the study, the trial characteristics were explained. All the selected patients signed statements of informed consent for participating in the study in accordance with the Declaration of Helsinki principles. In addition, this study was approved by the ethics and research committees of the Hospital General de México, O.D., register DIC/10/1085/04/109.

The information was gathered in a file that contained the personal data of the patient, demographic data, clinical history and complete physical examination, as well as lower urinary tract symptoms based on the International Prostate Symptoms Scale (IPSS), date and time of transurethral catheter placement, digital rectal examination findings, laboratory test results, and transrectal ultrasound images.

The IPP was measured by tracing a transverse line marking the bladder and bladder neck that went from the anterior to the posterior commissure, identified in a sagittal view of the transrectal ultrasound. At the center of that line another vertical line was drawn that went toward the median lobe of the prostate. The transurethral catheter was removed on the fifth day and patients were asked to drink 1.5 L of water. When they had the desire to urinate, the volume of the first micturition was measured in a calibrated cup. Afterwards, a 14 Fr Nelaton catheter for input/output monitoring was placed and the volume of the post-micturition residual urine was measured. The waiting period was a maximum of 4 hours for the first micturition. If spontaneous micturition did not present or the patient was unable to urinate, had suprapubic pain, or presented with a distended bladder, the trial without catheter was considered failed.

The IPP grade was classified into 3 groups:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>under 5 mm</td>
</tr>
<tr>
<td>II</td>
<td>between 5 and 10 mm</td>
</tr>
<tr>
<td>III</td>
<td>above 10 mm</td>
</tr>
</tbody>
</table>

Statistical analysis

The data were described through means ± standard deviation (SD) or percentages, depending on the variable. We carried out analysis of variance (ANOVA) to compare the means of the continuous quantitative variables.

Logistic regression analysis was used to establish the correlation between variables. The SPSS® for Windows version 15 statistics program (SPSS, Chicago, IL, USA) was employed.

Results

Within the time frame of September 2010 to February 2013, a total of 78 patients were consecutively included in the study: 32 in the tamsulosin group, 30 in the alfuzosin group, and 16 in the placebo group.

There were no statistically significant differences in relation to age, weight, height, body mass index, or prostate-specific antigen among the 3 groups. The ANOVA test for comparing the means of the prostatic protrusion

<table>
<thead>
<tr>
<th>Variable</th>
<th>Tamsulosin (32 patients)</th>
<th>Alfuzosin (30 patients)</th>
<th>Placebo (16 patients)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>65 ± 9.6</td>
<td>65.1 ± 9.1</td>
<td>69.6 ± 7.8</td>
<td>0.210</td>
</tr>
<tr>
<td>PSA (ng/mL)</td>
<td>7.5 ± 4.4</td>
<td>10.2 ± 9</td>
<td>4.58 ± 2.89</td>
<td>0.187</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>69.4 ± 13.1</td>
<td>70.0 ± 12.1</td>
<td>64.8 ± 10.9</td>
<td>0.461</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>160.9 ± 7.3</td>
<td>161.9 ± 7.6</td>
<td>163.4 ± 6.7</td>
<td>0.585</td>
</tr>
<tr>
<td>BMI (Kg/m2)</td>
<td>26.9 ± 5.4</td>
<td>26.6 ± 3.6</td>
<td>24.1 ± 2.9</td>
<td>0.160</td>
</tr>
<tr>
<td>IPP (mm)</td>
<td>14.43 ± 7.88</td>
<td>12.74±6.69</td>
<td>12.97±8.39</td>
<td>0.648</td>
</tr>
</tbody>
</table>

* Significance level p<0.05.

PSA: prostate-specific antigen; BMI: body mass index; IPP: intravesical prostatic protrusion.
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Table 2

<table>
<thead>
<tr>
<th></th>
<th>Tamsulosin</th>
<th>Alfuzosin</th>
<th>Placebo</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I (&lt; 5 mm)</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Grade II (5-10 mm)</td>
<td>9</td>
<td>8</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>Grade III (&gt; 10 mm)</td>
<td>22</td>
<td>19</td>
<td>10</td>
<td>51</td>
</tr>
<tr>
<td>Patient total</td>
<td>32</td>
<td>30</td>
<td>16</td>
<td>78</td>
</tr>
</tbody>
</table>

Measurements showed no statistically significant differences ($p=0.648$) among the 3 groups (placebo 12.97 ± 8.39, tamsulosin 14.43 ± 7.88, alfuzosin 12.74 ± 6.69).

Table 2 shows the patient distribution per drug and IPP grade. Eight patients presented with IPP grade I, 19 with IPP grade II, and 51 with IPP grade III.

The percentage of successful trial without catheter based on the IPP grades was 37.5% for grade I, 36.8% for grade II, and 41.7% for grade III (fig. 1).

Logistic regression analysis showed that the IPP grade was not a significant independent variable that could be regarded as a predictive factor for trial without catheter success, with an odds ratio of 0.857 (95% CI 0.184-3.983) ($p=0.844$) (table 3).

Discussion

The IPP is an ultrasonographic measurement of the median lobe of the prostate that projects into the bladder and it has been suggested that this particular enlargement of the prostate causes "valve effect" obstruction, altering the physiologic funneling mechanism that the bladder neck performs during the dynamics of micturition. This particular anatomic condition would cause major infravesical obstruction if there were growth of the lateral prostatic lobes, exclusively.

Different studies have demonstrated that there is a correlation between the severity of urinary obstruction and IPP grade. Mariappan et al. (2007) reported that those patients with an IPP above 10 mm would present a 6 times higher risk for failed trial without transurethral catheter. Likewise, Tan and Foo (2003) suggested that patients with grade I IPP would benefit from receiving drug treatment and then undergoing the trial without transurethral catheter and that the patients with grade III IPP would not respond to conventional treatment and would require immediate surgical management.

In contrast, the results of the present study showed that IPP grade was not a significant independent variable that could be regarded as a predictive factor in trial without catheter success. This discrepancy is probably due to the fact that the previous studies only made a comparison with a placebo and not directly with an alpha blocker.

Despite the abovementioned, we do not rule out the possibility that the characteristics of our study population are different, given that numerous studies have identified diverse factors that may condition acute urinary retention symptoms. Among the most frequently mentioned are excessive liquid intake, alcohol ingestion, sexual activity, associated urinary tract infection, and generalized weakness of the patient, suggesting that all these mechanisms can be precipitant and that the cause of AUR may not necessarily be the progression of benign prostatic hyperplasia or a type of growth in particular, such as intravesical prostatic median lobe growth.

Conclusions

In the present study, IPP was not a predictive factor of trial without transurethral catheter success, regardless of the drug that was used.

Table 3

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
<th>$p^*$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravesical prostatic protrusion (IPP)</td>
<td>0.857</td>
<td>0.184-3.983</td>
<td>0.844</td>
</tr>
</tbody>
</table>

* Significance level $p<0.05$.
Conflict of interest

The authors declare that there is no conflict of interest.

Financial disclosure

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Acknowledgements

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