Severity profiles in patients diagnosed of benign prostatic hyperplasia in Spain

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KEYWORDS
Prostatic hyperplasia; Prostatism; Prevalence; Severity; Disease progression

Abstract
Objectives: To analyze the severity profiles and progression criteria in patients diagnosed of benign prostatic hyperplasia (BPH) in urology clinics in Spain.
Results: A total of 1.115 patients were evaluated. Mean age was 65.7 years. Mean time from the onset of symptoms to diagnostic was 18.8 months. Mean IPSS score was 17.2. 63 patients (5.7%) had mild symptoms; 670 (60.1%) had moderate symptoms with a mean IPSS score of 14.6 and 382 (34.3%) had severe symptoms with a mean IPSS score of 23.7. Mean PSA was 2.6 ng/ml and ultrasound measured prostatic volume was 49.2 cc. A total of 713 (63.9%) patients met progression criteria (PSA > 1.5 ng/ml and volume > 30 cc). Symptoms severity was directly correlated with age, prostatic volume, PSA, presence of progression criteria and time from the onset of symptoms and inversely correlated with urine flow rate (p < 0.001). Progression criteria were directly correlated with age, symptoms severity and inversely with urine flow rate (p < 0.01).
Conclusions: More than 90% of patients diagnosed of BPH in urology clinics in Spain had moderate to severe symptoms. Two-thirds met progression criteria that correlate with age and severity of symptoms.
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Perfiles de severidad en pacientes diagnosticados de hiperplasia benigna prostática en España

Resumen
Objetivos: Analizar los perfiles de severidad y presencia de criterios de progresión en pacientes diagnosticados por primera vez de hiperplasia benigna prostática (HBP) en consultas de Urología.

Material y métodos: Estudio observacional, transversal, multicéntrico español, realizado entre mayo y noviembre de 2008, en el que participaron 392 urólogos, que recogieron la información de 3 nuevos pacientes consecutivos con diagnóstico clínico de HBP.

Resultados: Se reclutaron un total de 1.115 pacientes. La edad media fue de 65,7 años. El tiempo promedio desde el inicio de los síntomas hasta la consulta fue de 18,8 meses. La media de puntuación IPSS fue de 17,2. Sesenta y tres pacientes (5,7%) presentaron síntomas leves; 670 (60,1%) síntomas moderados con un IPSS medio de 14,6 y 382 (34,3%) síntomas severos con un IPSS medio de 23,7. El PSA promedio fue de 2,6 ng/ml y el volumen prostático ecográfico de 49,2 cc. Setecientos trece pacientes (63,9%) presentaron criterios de progresión (PSA > 1,5 mg/ml y volumen > 30 cc). Se observó una correlación directa de la severidad de los síntomas con la edad, volumen prostático, PSA, criterios de progresión y tiempo de evolución e inversa con el flujo urinario (p < 0,01). La presencia de criterios de progresión se correlacionó directamente con la edad y severidad de los síntomas, e inversamente con el flujo urinario (p < 0,01).

Conclusiones: Más del 90% de los pacientes diagnosticados de HBP en las consultas de Urología presentan síntomas moderados o severos. Dos tercios tienen criterios de progresión que se correlacionan con la edad y severidad de los síntomas.

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range from 0 (delighted) to 6 (very bad), measured the impact on life quality.

In order to quantify the prostate volume measured by digital rectal examination and to correlate it with the ultrasound measurement, four qualitative groups were defined according to standard practice: volume I (≤30 cc); volume II (31–50 cc); volume III (51–75 cc) and volume IV (>75 cc), depending on subjective criteria of the urologist.

A prostate volume ≥ 30 cc (volume by touch degrees II–IV) and a PSA ≥ 1.5 ng/ml were considered as risk of progression.

**Statistical analysis**

Descriptive analysis of sociodemographic, clinical and patient-centered variables determining mean, standard deviation (SD) and confidence interval 95% (95% CI). Comparison between groups was performed using the chi-square test or Kruskal Wallis, and Tukey test was used for multiple comparisons.

The agreement between the assessment of prostate volume by digital rectal examination and external ultrasound was performed by analysis of variance and the degree of agreement was measured by the weighted kappa statistic with CI 95%.

Data analysis was performed using SPSS 15.0 for Windows. We considered statistical significance level of 0.05.

**Results**

A total of 1115 patients were enrolled. The mean age (SD) was 65.7 (7.9) years, 5% were from an urban or metropolitan environment and 45.6% reported a family history of HBP.

**Clinical severity**

The mean (SD) IPSS score was 17.2 (5.9). Sixty-three patients (5.7%) presented mild symptoms with an average score of 5.3 (1.7); 670 (60.1%) had moderate symptoms, with an average score of 14.6 (3.1); finally, 382 (34.3%) showed severe symptoms with an average score of 23.7 (2.9) (Fig. 1). The severity was directly correlated with age, time to consultation, prostate volume, PSA and presence of progression criteria and inversely with urinary flow (p < 0.01) (Table 1).

The median time from symptom onset to consultation was 18.8 (22.0) months.

**Figure 1** Presence of progression criteria by age group.

The mean prostate volume by digital rectal examination was between 31 and 50 cc (volume II) in 50.9% of cases and the prostate volume by echography was 49.2 cc. The agreement between the determination of volume by digital rectal examination and by ultrasound was acceptable with weighted kappa of 0.68 (95% CI: 0.64–0.72).

The average PSA was 2.6 (2.4) ng/ml and the $Q_{\text{max}}$ in uroflowmetry was 11.3 ml/sc.

**Progression of benign prostatic hyperplasia**

Prostate volume was >30 cc in 82.2% of cases and PSA >1.5 ng/ml in 71.9%. A total of 713 (63.9%) patients showed progression criteria (95% CI: 61.1–66.7%). These criteria were more common in older patients (p < 0.01) and with greater severity, and less common in patients with higher $Q_{\text{max}}$ (p < 0.01) (Fig. 2).

**Quality of life associated with benign prostatic hyperplasia**

Overall, 42.7% reported being “mostly dissatisfied” with their clinical situation. The quality of life score increased with the severity of symptoms (p < 0.01). 50% of patients with mild symptoms reported being “mostly satisfied.” 39% of those with moderate symptoms declared being “mostly dissatisfied” and 34.1% were “equally satisfied than

**Table 1** Mean values (standard deviation) of the clinical variables and patient-centered according to severity.

<table>
<thead>
<tr>
<th></th>
<th>Mild (IPSS &lt; 8)</th>
<th>Moderate (IPSS 8–19)</th>
<th>Severe (IPSS 20–35)</th>
<th>p</th>
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<tbody>
<tr>
<td>N</td>
<td>63</td>
<td>670</td>
<td>382</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.2 (7.5)</td>
<td>64.7 (7.9)</td>
<td>67.9 (7.2)</td>
<td>&lt;0.01</td>
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<tr>
<td>Months of evolution</td>
<td>13.4 (33.1)</td>
<td>17.2 (21.5)</td>
<td>20.6 (20.1)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ultrasound prostate volume (cc)</td>
<td>41.7 (26.9)</td>
<td>46 (17.6)</td>
<td>55 (20.2)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>$Q_{\text{max}}$ (ml/sc)</td>
<td>14.4 (4.1)</td>
<td>11.5 (2.7)</td>
<td>10.35 (3.1)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Volume &gt; 30 cc</td>
<td>60.3%</td>
<td>79%</td>
<td>91.4%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>PSA &gt; 1.5 ng/ml</td>
<td>58.7%</td>
<td>68.4%</td>
<td>80.4%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Progression criteria</td>
<td>46%</td>
<td>59%</td>
<td>75.7%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>IPSS</td>
<td>5.2 (1.7)</td>
<td>14.6 (3)</td>
<td>23.6 (2.9)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*a PSA > 1.5 ng/ml and volume > 30 cc.
Severity profiles in patients diagnosed of benign prostatic hyperplasia

Table 2  Average patient characteristics in this study and other international studies.

<table>
<thead>
<tr>
<th></th>
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<th>PLESS14</th>
<th>MTOPS15</th>
<th>CombAT16</th>
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<tr>
<td>N</td>
<td>1.115</td>
<td>3.040</td>
<td>3.047</td>
<td>4.844</td>
</tr>
<tr>
<td>Age (years)</td>
<td>65</td>
<td>64</td>
<td>62</td>
<td>66</td>
</tr>
<tr>
<td>IPSS</td>
<td>18.7</td>
<td>15</td>
<td>16.8</td>
<td>16.4</td>
</tr>
<tr>
<td>Ultrasound prostate volume (cc)</td>
<td>49.2</td>
<td>55</td>
<td>36.3</td>
<td>55</td>
</tr>
<tr>
<td>PSA (ng/ml)</td>
<td>2.62</td>
<td>2.8</td>
<td>2.3</td>
<td>4</td>
</tr>
<tr>
<td>Qmax (ml/sc)</td>
<td>11.3</td>
<td>11</td>
<td>10.5</td>
<td>10.4</td>
</tr>
</tbody>
</table>

![Figure 2](distribution_of_clinical_severity.png) Distribution of clinical severity in patients with newly diagnosed BPH in specialty care consultations in Spain.

BPH in primary care, Fourcade et al. detected IPPS of 16, similar to the IPPS of 17 of the present study, in the Spanish subgroup during specialized consultations.15 These data, together with the observed average evolution time of 18 months, suggest both a delayed consultation by patients as an early referral from primary care. It would explain that the scientific societies in our country have agreed guidelines for management and referral from primary care to specialized care, that were not in force at the time of this study.16

The average patient characteristics in Spain are equivalent to those observed in other international studies, suggesting that the sample is truly representative17-19 (Table 2).

The present study establishes that 64% of patients have progression criteria when they come to consultation. This would mean that 1/3 of them will be candidates for an exclusive treatment with AB since they do not show prostatic growth. The remaining 2/3 would be candidates for treatment with AB, 5 ARI or a combination of both.

The presence of criteria for progression was more likely in patients with higher clinical severity. 75% of those presenting severe symptoms had progression criteria and would be eligible for combined treatment in the beginning. The determinant of the treatment is not the presence itself of progression criteria, due to the fact that they are observed in 46% of those with mild symptoms, but the severity of symptoms, which affects the quality of life.

**Conclusions**

The majority of patients attending urology consultations occur with moderate or severe symptoms that can be treated. Two-thirds have progression criteria at diagnosis, which augurs a progressive evolution of the disease that should be taken into account when selecting therapy.

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**Conflict of interests**

Dr. Emilio Pedrosa and Dr. Marta Prieto belong to the medical department of Astellas. The remaining authors declare no conflicts of interest.
References