ORIGINAL ARTICLE

Profile of lower urinary tract symptoms in the male and their impact on quality of life∗

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KEYWORDS
Lower urinary tract symptoms; Male; Urology; Quality of life

Abstract
Objectives: Following current European guidelines, lower urinary tract symptoms (LUTS) are produced by several causes and, thus, thorough clinical assessment should be undertaken for a correct therapeutic management. This study was conducted in order to assess the symptoms profile and their impact on health-related quality of life (HRQL) of male patients attending urology outpatient clinics.

Materials and methods: Epidemiological, cross-sectional study including adult male patients (n = 826) presenting with at least one de novo previously untreated LUTS. Socio-demographic and clinical variables were collected. Patients completed IPSS, Bladder Control Self-Assessment Questionnaire (B-SAQ) and SF-12 questionnaires.

Results: Mean age (SD) was 65 (10) years. A combination of storage, voiding and post-micturition symptoms were present in 69% of subjects and 30% showed ≥2 urgency episodes and ≥6 micturitions daily (storage symptoms – 55 – sub-population). Storage symptoms were the reason for consultation in 86%. Mean peak urinary flow (Qmax) was 11.4 mL/s, in 44% of patients, prostate volume was 20–40 mL and 91% showed moderate or severe symptoms on IPSS with an overall mean (SD) score of 17 (7). SS sub-population had higher B-SAQ scores (6.9 versus 4.8 for symptoms; 7.8 versus 5.1 for bother), and worse HRQL (IPSS item 8).

Conclusions: These findings support the importance of addressing treatment adequately according to patient profile, bothersomeness and impact on HRQL.

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PALABRAS CLAVE
Síntomas del tracto urinario inferior; Varón; Urología; Calidad de vida

Perfil de síntomas del tracto urinario inferior en el varón y su impacto en la calidad de vida

Resumen
Objetivos: La etiología multifactorial de los síntomas del tracto urinario inferior (STUI) justifica su evaluación detallada para un adecuado abordaje terapéutico según las guías europeas actuales. Para conocer el perfil sintomático e impacto en la calidad de vida relacionada con la salud (CVRS) de pacientes varones que acuden a consulta de urología se desarrolló el siguiente estudio.

Material y métodos: Estudio epidemiológico, transversal en 826 varones adultos con ≥1 STUI de novo tratados previamente. Se recogieron variables sociodemográficas y clínicas. Los pacientes cumplimentaron la Puntuación internacional de síntomas prostáticos (IPSS), Cuestionario de autoevaluación del control vesical (CACV) y cuestionario SF-12.

Resultados: La edad media (DE) fue de 65 (10) años. El 69% presentaba una combinación de síntomas de llenado, vaciado y posmiccionales. El 30% tenía ≥2 episodios de urgencia y ≥8 micciones al día (subpoblación con síntomas de llenado [SLL]). Los SLL fueron el motivo de consulta en el 86% de los casos. El flujo urinario máximo medio fue 11,4 ml/s y el 44% tenía volumen prostático entre 20-40 cc y el 91% síntomas moderados o graves (IPSS) con puntuación media (DE) de 17 (7). La subpoblación con SLL tenía puntuaciones mayores del CACV (síntomas 6,9 vs 4,8; molestias 7,8 vs 5,1). La subpoblación con SLL presentaba peor CVRS (IPSS item 8).

Conclusiones: Estos hallazgos evidencian que es importante conocer el perfil de síntomas de cada paciente y el grado de molestia e impacto en la calidad de vida para orientar adecuadamente el tratamiento.

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Introduction

The International Continence Society proposed the term “lower urinary tract symptoms” (LUTS) to describe those symptoms associated with the filling and voiding phases of the voiding cycle.1 LUTS are classified into filling, voiding and post-void symptoms.2 LUTS in men have generally been attributed to prostate disease, including benign prostatic hyperplasia (BPH) and bladder outflow obstruction (BOO), and treatment was based on such an approach. Nowadays, the European Association of Urology (EAU) guidelines acknowledge that LUTS in men can have a different etiology, and that they may be associated with the prostate (LUTS/BPH), the bladder (detrusor overactivity – overactive bladder syndrome [OAB]) or with the kidney (nocturnal polyuria), and a paradigm change has taken place in the management of male LUTS.

LUTS occur commonly in men and their prevalence and seriousness increase with age. According to the EPIC study, 63% of men reported one or more LUTS,4 and 10.8% of men reported urgency, a key symptom of OAB.5 Men with filling symptoms-OAB reported more and more severe symptoms than general population.4 LUTS do not only occur in isolation, but they frequently occur in combination, with increased symptomatic discomfort for the patient. Data from the EpilUTS study show that 47% of men reported LUTS belonging to more than one symptomatic group, 23.4% of men showed filling, voiding and post-void symptoms.6 Subjects with filling, voiding and post-void symptoms significantly reported greater symptomatic discomfort and poorer health-related quality of life (HRQOL).7

The multifactorial etiology of LUTS warrants a detailed evaluation of them in order to recommend the most appropriate therapeutic choice depending on the symptomatic and sociodemographic profile of the patient. In this regard, the recommendations of the European guidelines consider antimuscarinics for the treatment of moderate to severe LUTS in men, both in monotherapy and combined with other drugs (alpha blockers).8

These symptoms are becoming more prevalent and have a significant impact on healthcare services due to the fact that the number of patients with LUTS increases with age, and that the life expectancy of the population is rising.9 Knowledge of these symptoms in men, especially filling symptoms, as well as their impact, is essential to find out about the problems they pose and to manage them in urological clinical practice. The present study was performed for that purpose.

Materials and methods

Design of the study

We conducted a cross-sectional, multi-center, naturalistic, epidemiological study involving 277 specialists in urology from all over Spain. The study included men, older than 18 years, who attended urology clinics because of the presence of one or more de novo LUTS and who had not received prior treatment. Patients with suspected prostate cancer, urological disease that may interfere with LUTS and patients treated with any drug that might affect LUTS were excluded. Each of the researchers had to include the first 3 consecutive patients who attended the outpatient clinic, who met the
study selection criteria and who had given informed, written consent. The study was approved by the Clinical Research Ethics Committee of the Hospital General Universitario Gregorio Marañón (Madrid).

Variables of the study

In the study visit, sociodemographic (age, size, weight, habitat and working activities), lifestyle (caffeine intake, physical exercise and smoking habits) and clinical variables (origin of the consultation request, voiding symptomatology, prostate volume by digital rectal examination or ultrasound as part of a routine clinical practice), PSA and peak urinary flow rate \( (Q_{\text{max}}) \) if available were included. During the visit, patients were given the following questionnaires: the International Prostate Symptom Score (IPSS), the Bladder control Self-Assessment Questionnaire (B-SAQ), the Patient Perception of Intensity of Urgency Scale (PPIUS) and the Quality of Life-Short Form questionnaire (SF-12).

The IPSS questionnaire contains 7 items to measure the frequency and intensity of urinary symptoms in men; scores range from 0 (asymptomatic) to 35 (with many symptoms), which enables the classification of patients into 3 groups: 0–7 points (mild symptoms), 8–19 points (moderate symptoms) and 20–35 points (severe symptoms).\(^9\) The B-SAQ questionnaire is specific for patients with OAB, it is composed of 8 items which are grouped into 2 scales ("discomfort and symptoms") and higher scores reflect worse condition.\(^10\) The PPIUS scale evaluates patients’ perceptions of intensity of urgency and scores range from 0 (absence of urgency) to 4 (urge incontinence).\(^11\) The SF-12 health questionnaire includes 8 dimensions (physical functioning, social functioning, role physical, role emotional, mental health, vitality, bodily pain, general health), with lower scores corresponding to worse condition.\(^12,13\)

Statistical analysis

A minimum sample of 737 evaluable patients was required to assess dichotomous variables with \( p \)-value of 0.5, a precision of 0.05, a level of significance of 0.01 and assuming a 10% rate of non-evaluable patients.

A descriptive analysis of all study variables was performed, using the statistical package SPSS 17.0 for Windows. Continuous variables were described using the mean and standard deviation (SD), and the number of valid cases \( (n) \). Categorical variables were summarized using counts of cases for each category and the relative frequency out of the total answers received.

From the total of patients enrolled, a comparative analysis of all study variables was performed, identifying a subpopulation with a predominance of filling symptoms which were defined for the purpose of the analysis, as well as the occurrence of \( \geq 8 \) voids and \( \geq 2 \) daily urgency episodes reported by patients. The comparison between groups of patients was performed using the analysis of variance (ANOVA) for quantitative variables and the chi-square test for qualitative variables. A level of significance of 0.05 was used for all comparisons.

Results

Description of population

826 evaluable patients were included between October 2009 and March 2010. A subpopulation with a predominance of filling symptoms was identified, corresponding to 30% \( (n = 244) \) of the study population. The mean age was 65 (10) years and the average body mass index was 27 (4), in the overweight range \( (Table \ 1) \).

Clinical profile of men with lower urinary tract symptoms

95% of patients came from primary care. The main symptoms leading to consultation were filling symptoms (86%), especially nocturia (65.7%) and voiding frequency (57.5%) \( (Fig. \ 1) \). The types of LUTS reported by patients are presented in \( Fig. \ 2 \), which shows that 69% of patients had a combination of filling, voiding and post-void symptoms, and that 96% of cases reported filling symptoms. The evolution time of symptoms was longer than a year in 48.7% of cases.

The daily symptom episodes reported by the patient, the analyzed clinical variables (prostate volume, PSA and \( Q_{\text{max}} \)) including LUTS, of the total population by subpopulation (filling symptoms and non-filling symptoms) are shown in \( Table \ 1 \). 44% of the total population had a grade II prostate volume \( (20–40 \text{ cc}) \) estimated by digital rectal examination and, according to the abdominal ultrasound, an average volume \( (\text{median}) \) of 47.5 cc \( (44 \) \( (n = 555) \)). In those cases where flowmetry was performed \( (n = 308) \), the mean \( Q_{\text{max}} \) value was 11 (4) ml/s. No statistically significant differences were observed in prostate volume, PSA or \( Q_{\text{max}} \) among subpopulation groups.

The average score on the PPIUS was 17 (7), 57% of patients had moderate LUTS and 34% of them severe LUTS. Besides, the subpopulation group named "filling symptoms" had a significantly higher average score on the IPSS than the rest of patients: 18.9 (5.8) versus 16 (6.6) \( p < 0.001 \). The percentage of patients with severe symptomatology (scores between 20 and 35) was significantly higher in the subpopulation with filling symptoms.

According to the PPIUS, 26% of the study population showed a score of \( \geq 3 \), an indicator of severe urgency or urge incontinence, and according to the B-SAQ questionnaire 31.6% of patients had a score greater than or equal to 6 (an indicator of symptoms suggestive of OAB). These data were consistent with 30% of the subpopulation defined as filling symptoms.

The average score on the B-SAQ questionnaire was 5.4 (2.6) on the symptom scale and 5.9 (3.2) on the discomfort scale. Patients in the subpopulation of filling symptoms showed significantly higher scores than the rest of patients, both on the symptom scale \( (6.9 \text{ versus } 4.8 \); \( p < 0.01 \)) and on the discomfort scale \( (7.8 \text{ versus } 5.1 \); \( p < 0.01 \). \( Fig. \ 3 \) shows how the severity of LUTS, according to the IPSS, is associated with an increase in both scores (symptom and discomfort scales).
Table 1  Sociodemographic characteristics and clinical profile of the total of patients and by subgroups with and without predominance of filling symptoms.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>FS</th>
<th>No FS</th>
<th>Total</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographic characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years); mean (SD)</td>
<td>66 (10)</td>
<td>64 (10)</td>
<td>65 (10)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Body mass index; mean (SD)</td>
<td>27 (3)</td>
<td>27 (4)</td>
<td>27 (4)</td>
<td>Ns</td>
</tr>
<tr>
<td><strong>Prostate volume (digital rectal examination)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade I (&lt;20 cm³); n (%)</td>
<td>26 (11%)</td>
<td>79 (14%)</td>
<td>105 (13%)</td>
<td>Ns</td>
</tr>
<tr>
<td>Grade II (20–40 cm³); n (%)</td>
<td>101 (42%)</td>
<td>263 (46%)</td>
<td>364 (44%)</td>
<td>Ns</td>
</tr>
<tr>
<td>Grade III (40–60 cm³); n (%)</td>
<td>83 (34%)</td>
<td>165 (29%)</td>
<td>248 (30%)</td>
<td>Ns</td>
</tr>
<tr>
<td>Grade IV (&gt;60 cm³); n (%)</td>
<td>31 (13%)</td>
<td>61 (11%)</td>
<td>92 (11%)</td>
<td>Ns</td>
</tr>
<tr>
<td><strong>Prostate volume (ultrasound, cm³, N = 555); mean (SD)</strong></td>
<td>49 (24)</td>
<td>47 (21)</td>
<td>48 (22)</td>
<td>Ns</td>
</tr>
<tr>
<td>PSA (ng/ml); mean (SD)</td>
<td>3 (2)</td>
<td>3 (2)</td>
<td>3 (2)</td>
<td>Ns</td>
</tr>
<tr>
<td>Peak flow (Qmax, ml/s, n = 308); mean (SD)</td>
<td>11.4 (3.8)</td>
<td>12 (4)</td>
<td>11 (4)</td>
<td>Ns</td>
</tr>
<tr>
<td><strong>Filling symptoms n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency; n (%)</td>
<td>244 (100%)</td>
<td>548 (94%)</td>
<td>792 (96%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Nocturia; n (%)</td>
<td>232 (95%)</td>
<td>493 (85%)</td>
<td>725 (88%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Urgency; n (%)</td>
<td>244 (100%)</td>
<td>288 (50%)</td>
<td>532 (64%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Urge incontinence; n (%)</td>
<td>138 (57%)</td>
<td>138 (24%)</td>
<td>276 (33%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td><strong>Voiding symptoms n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weak stream; n (%)</td>
<td>176 (72%)</td>
<td>435 (75%)</td>
<td>611 (74%)</td>
<td>Ns</td>
</tr>
<tr>
<td>Intermittent stream; n (%)</td>
<td>94 (39%)</td>
<td>191 (33%)</td>
<td>285 (35%)</td>
<td>Ns</td>
</tr>
<tr>
<td>Delay; n (%)</td>
<td>100 (41%)</td>
<td>221 (38%)</td>
<td>321 (39%)</td>
<td>Ns</td>
</tr>
<tr>
<td>Need for abdominal press; n (%)</td>
<td>39 (16%)</td>
<td>80 (14%)</td>
<td>119 (14%)</td>
<td>Ns</td>
</tr>
<tr>
<td><strong>Post-void symptoms n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete voiding; n (%)</td>
<td>187 (77%)</td>
<td>438 (75%)</td>
<td>625 (76%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Post-void dribbling; n (%)</td>
<td>115 (47%)</td>
<td>221 (38%)</td>
<td>336 (41%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>Symptoms present daily n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Frequency; mean (SD)</td>
<td>10.5 (2.9)</td>
<td>4.2 (5.4)</td>
<td>6.1 (5.6)</td>
<td>Ns</td>
</tr>
<tr>
<td>Nocturia; mean (SD)</td>
<td>5.2 (3.3)</td>
<td>1.5 (2.2)</td>
<td>2.6 (3.0)</td>
<td>Ns</td>
</tr>
<tr>
<td>Urgency; mean (SD)</td>
<td>3.3 (1.4)</td>
<td>2.4 (3.3)</td>
<td>2.7 (2.9)</td>
<td>Ns</td>
</tr>
<tr>
<td>Urge incontinence; mean (SD)</td>
<td>1.6 (2.2)</td>
<td>0.6 (1.3)</td>
<td>0.9 (1.7)</td>
<td>Ns</td>
</tr>
</tbody>
</table>

FS: population with predominance of filling symptoms.

a  Reported by patients.

Health-related quality of life

Patients with more severe symptoms (according to the IPSS) showed worse HRQoL on the SF-12 (Fig. 4). These differences were more obvious in the physical dimension. On the other hand, the score on the SF-12 was lower in the subgroup with filling symptoms, especially in the physical dimension (Fig. 4).

According to the answers given by the patients to the quality-of-life question (item 8) from the IPSS, 64% of patients would feel “dissatisfied” or “very dissatisfied” if symptoms persisted for the rest of their lives (Fig. 4).

Among those measurement instruments used in the study to evaluate symptoms, discomfort and quality of life, there is a high correlation between the symptoms and discomfort scales (B-SAQ) and the IPSS/IPSS-L. Furthermore, this correlation is very high, almost linear, between the symptoms and discomfort scales from the B-SAQ and the PPIUS, and between the symptoms scale and the discomfort scale (B-SAQ) (Table 2).

Discussion

Most male patients with LUTS in our study population are not working and they are referred to an urologist by primary care doctors without any treatment. The most frequent symptoms leading to consultation were voiding frequency and nocturia, probably because, along with urgency, they have the most significant impact on HRQoL. The average number of daily symptoms reported by patients are considerable (2.6 episodes of nocturia, 2.7 episodes of urgency and 6 episodes of frequency). 69% of patients in our sample have a combination of symptoms and filling symptoms predominated in 30% of them. The fact that filling symptoms are the main reason for consultation, due to symptomatic discomfort and their impact on quality of life, has already been stated by other authors. and also that the factors most frequently associated with seeking of medical help in the case of patients with LUTS are severity and symptomatic discomfort, age and the impact on quality of life. Data from the epiLUTS study show that there is an overlap of different symptomatic groups in most men, and that discomfort
Profile of lower urinary tract symptoms in the male and their impact on quality of life

Figure 1  Lower urinary tract symptoms that prompted the inquiry by subgroups (FS, no FS and total). FS: population with predominance of filling symptoms.

Figure 2  Types of LUTS reported by patients in consultation for subgroups (FS, no FS and total). FS: population with predominance of filling symptoms.

Table 2  Non-parametric correlations between IPSS, IPSS8, B-SAQ-D, B-SAQ-S and overall PPIUS with OAB (correlation coefficient, Spearman’s rho).

<table>
<thead>
<tr>
<th></th>
<th>IPSS (0–35)</th>
<th>IPSS-8</th>
<th>B-SAQ discomfort</th>
<th>B-SAQ symptoms</th>
<th>Urgency</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPSS (0–35)</td>
<td>1.00</td>
<td>0.30³</td>
<td>0.475³</td>
<td>0.427³</td>
<td>0.420³</td>
</tr>
<tr>
<td>IPSS-8</td>
<td>0.30³</td>
<td>1.00</td>
<td>0.490³</td>
<td>0.455³</td>
<td>0.438³</td>
</tr>
<tr>
<td>B-SAQ discomfort</td>
<td>0.475³</td>
<td>0.490³</td>
<td>1.000</td>
<td>0.834³</td>
<td>0.662³</td>
</tr>
<tr>
<td>B-SAQ symptoms</td>
<td>0.427³</td>
<td>0.455³</td>
<td>0.834³</td>
<td>1.000</td>
<td>0.670³</td>
</tr>
<tr>
<td>Urgency</td>
<td>0.420³</td>
<td>0.438³</td>
<td>0.662³</td>
<td>0.670³</td>
<td>1.000</td>
</tr>
</tbody>
</table>

³ The correlation is significant at the 0.01 level (bilateral).
rates are higher in those patients with multiple symptoms (83% of men report discomfort and filling, voiding and post-void symptoms). 64% of the patients in our study would feel "dissatisfied" or "very dissatisfied" if current symptoms persisted for the rest of their lives, and it is also worth noting that the population with a predominance of filling symptoms felt more symptomatic discomfort.

Other population-based study conducted in our area (Arlandis et al., 2009) with a sample of 1745 men with OAB symptoms, showed an average score of 16 on the IPSS, with the following percentages of moderate and severe symp-
toms: 68% and 27%, respectively. A greater impact on the severity of symptoms was observed in the case of filling items, thus significantly contributing to the worst quality of life level on the IPSS-L questionnaire.16

When comparing subpopulations with or without a pre-
dominance of filling symptoms, no significant differences in prostate volume or in urine flow were found, but there was a difference in symptom scores (IPSS). This suggests that there is a large group of patients with a predominance of filling symptoms, independent of prostatic hypertrophy, and non-secondary to infravesical obstruction. Prostate disease and the existing filling symptoms are not always causally related, and many men with OAB do not have BOO, which underlines the potential role of bladder dysfunction.17,18 The recognition that LUTS may be caused by different patho-
physiological mechanisms has important implications for the clinician, with an appropriate diagnostic evaluation being especially important for an optimal therapeutic approach.7

Drug treatment has traditionally been based on voiding symptoms using phytotherapy, alpha blockers and 5-alpha-reductase inhibitors. Since filling symptoms are the most troublesome ones and since they have the greatest impact on HRQoL, one may think that they should be treated first. The current treatment algorithm provided by the European guidelines identifies several symptomatic profiles, consid-
ering antimuscarinics for the treatment of moderate to severe LUTS, both in monotherapy and in combination with other drugs (alpha blockers) in patients without clinically significant obstruction. Several studies 19-21 provide data on which obstruction is clinically significant, with residual urine volume below 150–200 ml and peak urinary flow rates above 5–8 ml/s being considered as indicators for the safe use of antimuscarinics. In this same vein, the European guidelines recommend regular re-evaluation of IPSS and of post-void residual urine in the follow-up of these patients.

**Conclusion**

Men with one or more de novo LUTS reported prostatic hypertrophy, reduced urinary flow and a combination of symptoms of moderate to severe intensity, with filling symp-
toms being the most frequent ones (mainly nocturia and increased frequency). Urgency was a reason for consulta-
tion in 49% of patients and it is present in 64% of cases. Their impact on HRQoL depends on the type of symptoms and it is proportional to their severity. About 30% of our study population reported at least 8 voids per day and at least 2 urgency episodes. The severity of symptoms and the impact on quality of life is higher in this subgroup.

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**Figure 3**  (A) Severity of symptoms according to the IPSS score by subgroups (FS, no FS and total). (B) Mean score obtained in the B-SAQ questionnaire on discomfort and symptoms according to symptom severity by subgroups (FS, no FS and total). FS: population with predominance of filling symptoms.

**Figure 4**  (A) Mean score obtained in the SF-12 questionnaire on the physical and mental component by subgroups (FS, no FS and total). (B) Quality of life perceived according to HRQOL item of the IPSS questionnaire by subgroups (FS, no FS and total). FS: population with predominance of filling symptoms.
Profile of lower urinary tract symptoms in the male and their impact on quality of life

Our study reflects the variety of symptomatic profiles of those men with LUTS attending urology consultations, and illustrates the necessity of differential diagnosis and an appropriate therapeutic approach in order to alleviate symptomatic discomfort and to improve their quality of life.

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Conflict of interest

Dr. Javier Cambronero is a researcher in clinical trials for Astellas Pharma S.A.

Dr. Salvador Arlandis is a researcher in clinical trials for Astellas Pharma S.A., a member of the Scientific Committee of the INDAS Foundation, a speaker in symposiums sponsored by Astellas Pharma, Allergan and Pfizer.

Dr. Carlos Errando declares no conflicts of interest with respect to this article.

Ana M. Mora is a member of the medical department of Astellas Pharma, Madrid, Spain.

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