Original – Voiding dysfunction

Impact of urinary incontinence and overactive bladder syndrome on health-related quality of life of working middle-aged patients and institutionalized elderly patients

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ABSTRACT

Introduction: Health-related quality of life (HRQoL) is considered by patients with urinary symptoms as the main outcome variable. Descriptive data about HRQoL in patients with urinary incontinence (UI) and/or overactive bladder (OAB) are reported. These data may serve as a reference for comparison purposes.

Materials and methods: Data were taken from EPICC, a national, multicenter, observational, epidemiological study. Data from representative samples of four population groups were analyzed: working patients of both sexes aged 50-64 years, and institutionalized elderly patients of both sexes with no cognitive impairment. In addition to demographic and clinical data, HRQoL data from the Overactive Bladder Questionnaire (OAB-q SF) and the SF-12 Health Survey were also analyzed.

Results: Of the total patients in the EPICC study, 26.53% completed the HRQoL questionnaires. Patients with both UI and OAB symptoms had poorer scores than those with OAB or UI respectively in the PCS (41.34 vs. 47.17 and 45) and MCS (46.01 vs. 49.04 and 47.78) of the SF-12, and in the symptom (32.21 vs. 19.19 and 16.65) and quality of life (82.32 vs. 86.72 and 89.45) dimensions of the OAB-q SF. Impact of OAB and UI on HRQoL was higher in men over 65 years of age as compared to women of the same age (76.76 vs. 82.79).

Conclusions: Concurrent symptoms of both UI and VH have a greater impact on HRQoL than those of either UI or VH alone. Impact on HRQoL is similar in middle-aged men and women, but higher in elderly men.
Introduction

Health-related quality of life (HRQoL) is defined as the objective assessment of the influence of health on the ability of subjects to have a functioning that allows them for carrying out activities which are important for them and have an impact on their wellbeing. Assessment of HRQoL, usually through standardized questionnaires, is essential for making adequate clinical decisions because it allows for evaluation of the efficacy of medical interventions and quality of care, particularly in follow-up of patients with chronic diseases.

On the other hand, urinary incontinence (UI) is an involuntary urine loss which may be objectively documented, and overactive bladder (OAB) syndrome is defined as the presence of urinary urgency, with or without urge UI, often associated to urinary frequency and nocturia. Both conditions do not involve by themselves a severe prognosis. However, many studies have shown the significant impact they have on quality of life. In fact, a population study comparing the impact of different conditions on quality of life showed that knee or hip osteoarthritis, depression, back problems, and UI are the chronic diseases causing a greater loss of HRQoL.

More recently, it has been shown that different urinary symptoms, in addition to be associated to a poorer HRQoL, are predictors of anxiety and depression in both females and males. OAB has also been shown to be associated to the presence of erectile dysfunction and a decreased sexual activity in males and females, and UI has been associated to relevant problems with sexual life in females.

According to a study conducted on people over 65 years of age institutionalized in 11 European nursing homes, 45% of males and 47% of females have UI, which gives an idea of its significance in this population group. In this age group, the presence of UI at admission to an institution predicts for subsequent dependence for activities of daily living. On the other hand, urinary symptom severity in elderly subjects appears to be similar in both sexes despite the differences in type of symptoms. A study conducted in 89 elderly patients concluded that voiding symptoms were more common in males than in females, unlike filling symptoms, but severity of urinary symptoms was similar in both sexes, as also stated in another study.

This significant impact of UI and OAB on HRQoL varies in each subject and should be individually assessed in each case from the patient viewpoint when the physician in charge decides on the treatment approach to be used. In fact, it appears obvious that physicians underestimate the relevant
changes in urinary symptoms as compared to patients themselves\textsuperscript{20}. It should also be taken into account that HRQoL is considered as the main outcome measure when patients with UI are consulted\textsuperscript{21}.

Few studies have been conducted in Spain on HRQoL of patients with UI and/or OAB, and the available studies recruited selected samples of patients, most often taken from clinical trials or efficacy studies of therapeutic alternatives. Availability of descriptive HRQoL data from subjects with UI and/or OAB would be extremely helpful as a population reference framework when studies intended to assess or compare different therapeutic strategies are conducted in selected patient samples.

**Materials and methods**

The results of EPICC\textsuperscript{22}, an institutional study of the Spanish Urology Association conducted to detect signs and symptoms of UI, nocturnal enuresis, and OAB (as defined by the ICS) in the general population to ascertain the prevalence of these conditions in Spain, were recently reported. Data were separately collected from representative samples of four population groups: 1) working women aged 25-64 years; 2) working men aged 50-64 years; 3) primary school children aged 6-11 years; and 4) institutionalized subjects over 65 years of age with no cognitive impairment (for details on the surveyed population and collected variables, see the study reference).

In addition to demographic variables, questions about the existence of urinary symptoms, and epidemiological data on UI and OAB prevalence, previously reported, HRQoL data were collected from the surveyed population. This study analyzes HRQoL data in the subgroups of working women and men aged 50-64 years and in institutionalized subjects of both sexes over 65 years of age.

In the abovementioned EPICC study, recruited subjects were asked to answer the OAB-q SF questionnaire on OAB and the SF-12 health questionnaire. It should be noted that not all subjects completed the questionnaires, and that analysis of these data was a secondary study objective.

Based on subject answers to questions about the presence or not of given urinary symptoms (uncomfortable urge to urinate, sudden urge to urinate, urinary frequency greater than 8, waking up at night more than once to urinate, urinating more than 2 times during the night, and urine losses during the past year), subjects were included in each of the following groups: 1) UI group: subjects with urinary loss more than once in the past year and at least 3 times per year; 2) OAB group: subjects reporting a sudden urge to urinate at least 3 times a year; 3) “other urinary symptoms”: subjects who reported any urinary symptom other than the two previous ones (uncomfortable need to urinate, urinary frequency greater than 8 times daily, waking up at night more than once to urinate, and urinating more than 2 times during the night); and 4) “no urinary symptoms”: subjects who did not report any of the above urinary symptoms.

The OAB-q SF is the short version of the OAB-q questionnaire\textsuperscript{23}, developed by Rash Analysis (methodology that uses the item response theory). The OAB-q SF consists of 6 questions about the discomforts caused by some symptom (a “symptom bother” dimension) and 13 questions assessing the impact of OAB on HRQoL (“quality of life” dimension). This questionnaire has been included in the module assessing the impact of OAB on patient lifer of the International Consultation on Incontinence Modular Questionnaire (ICIQ-OAB). The OAB-q SF was retrospectively validated using data from 919 subjects participating in a cross-sectional survey and 865 patients participating in a clinical trial. The questionnaire has shown adequate reliability, concurrent and discriminating validity, and sensitivity to change\textsuperscript{24}. Score may range from 0-100 for both dimensions, with a higher score in the “symptom bother” dimension suggesting a greater discomfort or symptom severity, while a higher score in the “quality of life” dimension indicates a better HRQoL.

The SF-12 health survey\textsuperscript{25}, a generic instrument to measure HRQoL which is the short version of the SF-36 health survey, consists of only 12 items which represent a sample of the contents of health concept included in the 8 subscales of SF-36: two items each from the physical functioning, role physical, role emotional, and mental health subscales and one item each from the remaining 4 subscales of bodily pain, general health vitality, and social functioning. Studies on the psychometric properties of the SF-12 questionnaire have shown that while this provides for a lower validity and reliability as compared to SF-36 when assigning scores to individuals, such differences between SF-12 and SF-36 are less significant in studies with large samples (n≥500) because of the influence of sample size on the amplitude of confidence intervals of estimators. Thus, in studies of populations or groups based on large sample sizes, the SF-12 is a useful questionnaire to be used instead of SF-36. The score of the two dimensions is standardized to a mean distribution of 50 and a standard deviation of 10, with a score ranging from 45 and 55 indicating a HRQoL similar to that of the average Spanish population, while a score under 45 suggests a worse HRQoL and a score higher than 55 a better HRQoL than the average for the Spanish population.

**Statistical analysis**

For data processing, dual data entry by independent staff and generation of consistency filters were used. Logical data clearance was performed. Data management software validated by regulatory agencies (Oracle® Clinical) was used throughout, and statistical analyses and tables were generated using SPSS Version 12.0 software.

For all variables, descriptive parameters were calculated, including mean, standard deviation, and size for quantitative variables, which were fitted to a Gaussian curve (Shapiro-Wilk test). Qualitative variables were expressed as absolute and percent relative frequencies. To compare scores for the OAB-q SF and SF-12 questionnaires, an ANOVA test was used for analysis between the symptomatic groups considered, and a Student’s t test for independent samples was used.
for analysis between sexes in each of the two age groups considered.

**Results**

Of the total adult subjects included in the main study, 26.53% completed the HRQoL questionnaires. This analysis focused on these subjects, divided into the following subgroups: 1) 312 working women aged 50-64 years; 2) 191 working men aged 50-64 years; 3) 298 institutionalized women aged 65 years or over; and 4) 92 institutionalized men aged 65 years or over.

The main characteristics of each study sample subgroup are separately shown in tables 1-4.

Figure 1 and figure 2 show, for the different study subgroups, the relative frequencies of the main urinary symptoms considered in the study and the groups of patients formed based on them. All symptoms, except for increased urinary frequency, were more frequent in the elderly groups of both sexes. An uncomfortable urge to urinate, sudden urge, and waking up at night more than 2 times to urinate the night were symptoms occurring with a similar frequency in men and women from the two age groups studied. Increased urinary frequency and UI were more common in women as

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**Table 1 – Description of the sample of women aged 50-64 years**

<table>
<thead>
<tr>
<th>Valid</th>
<th>Women aged 50-64 years (n=312)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age (SD)</strong></td>
<td>56.63 (4.23)</td>
</tr>
<tr>
<td>Marital status, %</td>
<td>6.19 Single</td>
</tr>
<tr>
<td>Educational level, %</td>
<td>6.19 No schooling</td>
</tr>
<tr>
<td>Occupational activity, %</td>
<td>48.1 Housewife</td>
</tr>
<tr>
<td>Occupational status, %</td>
<td>95.37 Active</td>
</tr>
<tr>
<td>Mean number of children (SD)</td>
<td>2.26 (1.22)</td>
</tr>
<tr>
<td>Menopause, %</td>
<td>79.15 Primary</td>
</tr>
<tr>
<td>Mean age at menopause (SD)</td>
<td>49.6 (4.04)</td>
</tr>
<tr>
<td>Vaginal prolapse, %</td>
<td>38.88 Mathematical</td>
</tr>
<tr>
<td>Hormone therapy, %</td>
<td>57.88 Liberal prof.</td>
</tr>
<tr>
<td>No. of glasses drunk, mean (SD)</td>
<td>7.51 (2.94)</td>
</tr>
</tbody>
</table>

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**Table 2 – Description of the sample of men aged 50-64 years**

<table>
<thead>
<tr>
<th>Valid</th>
<th>Men aged 50-64 years (n=191)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age (SD)</strong></td>
<td>56.49 (4.41)</td>
</tr>
<tr>
<td>Marital status, %</td>
<td>10.05 Single</td>
</tr>
<tr>
<td>Educational level, %</td>
<td>187 No schooling</td>
</tr>
<tr>
<td>Occupational activity, %</td>
<td>117 Liberal prof.</td>
</tr>
<tr>
<td>Occupational status, %</td>
<td>95.86 Active</td>
</tr>
<tr>
<td>Prostate disorders, %</td>
<td>18.2 Yes</td>
</tr>
<tr>
<td>No. of glasses drunk, mean (SD)</td>
<td>7.93 (3.84)</td>
</tr>
</tbody>
</table>

SD: standard deviation; BPH: benign prostatic hyperplasia.
compared to men in both subjects aged 50-64 years and those aged 65 years or over. However, nocturia was more common in women in the 50-64 years age group, but more common in men in the elderly group. As regards symptomatic groups, UI was more common in women and OAB was more common in men in both age groups. Concomitant OAB and UI were more common in women from both age groups.

Table 5 shows the mean scores in the physical (PCS) and mental (MCS) dimensions of the SF-12 health questionnaire and in the “symptom bother” and “quality of life” dimensions of the OAB-q questionnaire. Overall, the score for the “symptom bother” dimension of the OAB-q questionnaire, assessing discomfort from urinary symptoms, was higher (greater discomfort) in subjects with OAB and UI. Scores for the “quality of life” dimension of the same questionnaire and the PCS and MCS dimensions of SF-12 showed an inverse relationship to symptomatic groups, but it should be reminded that a lower score indicates a worse HRQoL. Thus, subjects showing more severe symptoms according to the relevant dimension of the OAB-q questionnaire showed a greater impact on HRQoL as measured by the “quality of life” dimension of the same questionnaire and the two dimensions of SF-12.

Table 6 compares by sex the scores in the HRQoL questionnaires used for the two age groups separately. This analysis compared only subjects with UI, OAB or both, but did
not include subjects with other urinary symptoms or those with no symptoms. As shown in the table, no statistically significant sex differences in the OAB-q scores were found in the middle-aged group. In the group aged 65 years or over, the impact of urinary symptoms considered in HRQoL was higher in men (lower score in the “quality of life” dimension of the OAB-q questionnaire). As regards PCS and MCS of the SF-12 health survey, table 6 also shows lower scores (worse HRQoL) for middle-aged women, a difference also seen in the elderly group for PCS.
Discussion

According to the results of this analysis, joint occurrence of OAB and UI symptoms had a greater impact on HRQoL than occurrence of OAB and UI alone. A greater discomfort caused by urinary symptoms, as measured by the "symptom bother" dimension of the OAB-q SF questionnaire, was associated to a greater impact on HRQoL as measured by both a generic questionnaire (PCS and MCS of SF-12) and a specific questionnaire ("quality of life dimension of OAB-q SF). Impact of OAB and UI on HRQoL was similar in middle-aged men and women (aged 50-64 years), but greater in men over 65 years of age as compared to women of the same age.

The results reported come from analysis of a subsample of patients enrolled into a Spanish epidemiological study previously conducted for whom data from the OAB-q SF questionnaire (specific HRQoL questionnaire) and the SF-12 questionnaire (generic HRQoL questionnaire) were available. These represent a fourth of patients enrolled into the general study, all those who agreed to complete the HRQoL questionnaires, but are an adequate sample for the analyses conducted: the size of the smallest group, including men aged 65 years or over (n=92), allows for detecting 9-point differences in the "symptom bother" dimension of OAB-q SF, 7-point differences in the "quality of life" dimension of OAB-q SF, and 5-point differences in dimensions of the SF-12 health survey with a 90% power and a 95% significance level. The

Table 5 – Mean scores and standard deviations in the physical and mental dimensions of the SF-12 health survey and the symptom and quality of life dimensions of the OAB-q questionnaire. Comparison between symptomatic groups

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>UI (n=177)</th>
<th>OAB (n=159)</th>
<th>UI+OAB (n=306)</th>
<th>Other urinary symptoms (n=248)</th>
<th>No urinary symptoms (n=491)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12 PCS</td>
<td>45.00</td>
<td>47.17</td>
<td>41.34</td>
<td>49.26</td>
<td>50.95</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SF-12 MCS</td>
<td>47.78</td>
<td>49.04</td>
<td>46.01</td>
<td>50.27</td>
<td>50.59</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>OAB-q symptoms</td>
<td>16.65</td>
<td>19.19</td>
<td>32.21</td>
<td>9.20</td>
<td>6.20</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>OAB-q quality of life</td>
<td>89.45</td>
<td>86.72</td>
<td>82.32</td>
<td>92.94</td>
<td>94.78</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

SD: standard deviation; UI: urinary incontinence; MCS: mental dimension of the SF-12 health survey; PCS: physical dimension of the SF-12 health survey; OAB: overactive bladder.

*One-way ANOVA.

Table 6 – Mean scores and standard deviations in the physical and mental dimensions of the SF-12 health survey and the symptom and quality of life dimensions of the OAB-q questionnaire. Comparison between sexes for subjects showing urinary incontinence, overactive bladder or both

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Men aged 50–64 years (n=52)</th>
<th>Women aged 50-64 years (n=132)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12 PCS</td>
<td>51.18</td>
<td>46.80</td>
<td>0.002</td>
</tr>
<tr>
<td>SF-12 MCS</td>
<td>51.49</td>
<td>48.28</td>
<td>0.044</td>
</tr>
<tr>
<td>OAB-q symptoms</td>
<td>18.56</td>
<td>22.24</td>
<td>0.219</td>
</tr>
<tr>
<td>OAB-q quality of life</td>
<td>86.18</td>
<td>86.74</td>
<td>82.27</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Men aged 65 years or over (n=61)</th>
<th>Women aged 65 years or over (n=237)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12 PCS</td>
<td>41.25</td>
<td>36.93</td>
<td>0.006</td>
</tr>
<tr>
<td>SF-12 MCS</td>
<td>44.42</td>
<td>45.68</td>
<td>0.483</td>
</tr>
<tr>
<td>OAB-q symptoms</td>
<td>35.34</td>
<td>30.55</td>
<td>0.162</td>
</tr>
<tr>
<td>OAB-q quality of life</td>
<td>76.76</td>
<td>82.79</td>
<td>80.36</td>
</tr>
</tbody>
</table>

SD: standard deviation; MCS: mental dimension of the SF-12 health survey; PCS: physical dimension of the SF-12 health survey.

*Student’s t test.
The relative occurrence rates of the different urinary symptoms studied were higher in the groups of elderly patients of both sexes, except for increased urinary frequency, which was similar in women and higher in middle-aged men (50-64 years) as compared to those aged 65 years or over. This was striking, particularly considering that waking up at night more than once to urinate (nocturia) and urinating more than 2 times at night were more common symptoms in elderly subjects of both sexes. The reason for this could be that an increase in the number of daily urinations is easily perceived by middle-aged subjects when it starts to occur and they feel the discomfort it causes, while at a later time it is no longer perceived because the subject has become used to it. As regards symptomatic groups, this analysis reproduces the previously reported results of the overall study.

When the different age and sex groups were considered together (table 5), the discomfort (“symptom bother” dimension of OAB-q SF) caused by joint occurrence of OAB and UI was much greater than that caused by each of these symptoms. When these symptoms were considered separately, OAB and UI caused a similar discomfort. On the other hand, HRQoL based on the “quality of life” dimension of OAB-q SF was worse in patient who reported concomitant OAB and UI, followed by those with OAB alone and those with UI symptoms. The HRQoL of these three patient groups was clearly lower than that of patients with other urinary symptoms and with no urinary symptoms, which confirms an obvious impact of OAB and UI on patient quality of life. According to the generic SF-12 questionnaire, the group of patients with OAB and UI also showed the worst PCS, which also reflected a significant impact on HRQoL (their score was the only lower than 45 points). This significant impairment of HRQoL was already shown in another study using generic HRQoL questionnaires. The greater symptom severity in this patient group with both OAB and UI would justify this greater impact on HRQoL, as measured by both the specific and generic HRQoL questionnaires.

According to the results of the comparison between sexes done separately for the two age groups considered in the analysis and shown in table 6, the only relevant difference occurred in the “quality of life” dimension of OAB-q SF, suggesting a worse HRQoL for men aged 65 years or over as compared to women of the same age. Thus, urinary symptom severity, measured by the “symptom bother” dimension of OAB-q SF, was found to be similar in elderly men and women, as previously reported, but impact on HRQoL was greater in men. As regards sex differences in PCS and MCS of SF-12, it should be noted that these are the differences found in the general population, favoring men and younger subjects, as these scores refer to the population mean unadjusted for age and sex.

In addition to the initial limitation related to selection of the analyzed sample, a further limitation of this study is the impossibility for conducting comparative analyses of the different symptomatic groups for each age group and sex because of the inadequate sample size in some of these groups. Despite such limitations, the results of this study may serve as reference for future studies aimed at comparing different therapeutic approaches in selected samples of patients with OAB and/or UI.

The EPICC Collaborative Study Group


Acknowledgment

We thank all physicians participating in the EPICC study for their collaboration.

Conflicts of interest

We thank Laboratorios Almirall S.A. and Pfizer S.A. for their collaboration by providing the infrastructure required for the conduct of the EPICC study.

REFERENCES


above study had enrolled women aged 25-64 years, of whom only those aged 50-64 years were selected for this analysis to be able to make age-adjusted comparisons to men.

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