IMPACT OF OVERACTIVE BLADDER TREATMENT ON THE QUALITY OF LIFE OF PATIENTS OVER 60 WITH ASSOCIATED PATHOLOGIES

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Summary.- OBJECTIVES: To study the impact of treatments prescribed in usual practice to control Overactive Bladder (OAB) on health-related quality of life (HRQoL) of patients with associated pathologies.

METHODS: 1,434 patients over 60 years with newly diagnosed OAB and at least one associated pathology (urinary or genital-skin infections, sleep disorders, depression, hypertension) were recruited in 300 urological/gynecological practices in Spain. During the first visit, socio-demographic and basic clinical information were registered and the therapeutic strategy for OAB was prescribed following usual clinical practice. The patients filled out the HRQoL SF-12 questionnaire. On the second visit (4-6 months later) the HRQoL was re-evaluated. HRQoL was compared between sexes (Mann-Whitney) and between visits (Wilcoxon for related samples). Multiple regression models were performed in order to study the variables independently associated with HRQoL.

RESULTS: Valid data is given for 1,274 patients for visit 1 and 1,153 for visit 2. 71.51% of the sample were female. Mean age was 68.17 (6.19). A significant improvement in the HRQoL was found on the second visit. Factors independently associated with lower score in both summary index of SF-12: first visit, female gender and Charlson Index. Additional factors associated with reduction of the physical component score: age, all associated pathologies and treatment using vaginal pessaries. Additional factors associated with the mental component score: treatment for depression, sleep disorders, use of vesical reeducation and the modification of treatment using diuretics.

CONCLUSIONS. The treatments prescribed in usual clinical practice to alleviate OAB are effective in notably improving the HRQoL of patients in general, both physically and mentally.

Keywords: Overactive bladder. Health related quality of life. Treatment.

Resumen.- OBJETIVO: Estudio del impacto de los tratamientos pautados en práctica habitual para el manejo de la Véjiga Hiperactiva (VH) en la calidad de vida relacionada con la salud (CVRS) de los pacientes con patologías asociadas.
INTRODUCTION

“Overactive Bladder Syndrome (OAB)” is defined as “urgency”, with or without urinary incontinence (UI), often associated with an increase in frequency and/or nocturia (1). It is also known as “urgency syndrome” or “urgency-frequency syndrome” (2). It is a highly prevalent pathology, reaching estimated figures of 10.7% worldwide (3). In Spain the estimated prevalence, higher in women than men, is situated at 19.9% (4) and it is widely recognized as an under-diagnosed pathology (5).

A recent detailed study has placed the prevalence of OAB in Spain at around 6% in working women of between 25 and 64 years of age, around 5% in working men of between 50 and 65 years of age and over 50% in the institutionalized over-65s of both genders (6-9).

The symptoms of OAB cause considerable disruption to many aspects of the lives of sufferers, such as their day-to-day activities, work, physical and sexual activities, and sleep, significantly affecting their health-related quality of life (HRQoL) (10-13).

It has also been demonstrated that OAB is associated with other general pathologies such as repeated lower urinary tract infections, genital zone skin infections, sleep disorders, depression, sexual dysfunction, and recurrent falls and fractures, the frequency of the majority of which being dependent on sex (14-20). It has also been observed that OAB is associated with the use of diuretics in the treatment of arterial hypertension (21).

OAB and UI treatments routinely used in Spain follow the recommendations of the International Consultation on Incontinence (ICI), and include recommendations on lifestyle, vesical retraining, pelvic floor strengthening, anticholinergic treatment, estrogen treatment and other physical therapies (22).

PRESENTATION

The effects of treatments on patients’ quality of life cover various aspects including the impact on the condition itself and associated pathologies and the burden of the treatment itself upon the patient. Although an association between the Charlson index and patients’ quality of life has been found, medical control of co-morbidities in OAB sufferers has not shown a significant improvement in overall quality of life, except in situations of serious illness (23).

It is unknown as to whether controlling the urinary symptoms, in patients with controlled co-morbidities, could have a positive effect on those patients’ overall quality of life.

The presented work focuses on the study of the quality of life of patients with OAB and associated pathologies and the effect of treatment given.

MATERIALS AND METHODS

Epidemiological, descriptive, longitudinal and analytical study, lasting 12 months. A total of 1,504 patients were planned to be enlisted in 300 urology and gynecology practices in Spain.

Selection criteria were the following: Patients over 60 years of age, presenting newly-
diagnosed OAB and at least one of the following associated pathologies: urinary infections, genital zone skin infections, sleep disorders, depression, and hypertension. The ability to understand the information in the study and the signing of a corresponding informed consent form were essential prerequisites for participation in the study.

The study consisted of two visits, 4-6 months apart, in accordance with normal clinical practice in each study centre. In the first visit, demographic information about the patient was taken along with information regarding the diagnosed urinary pathology, associated pathologies and the general co-morbidity measurement via the Charlson index. The patients had to fill out the generic quality of life questionnaire SF-12. In this visit the therapeutic strategy for OAB was laid out in line with the usual clinical practice for treating OAB in Spain and following the recommendations of the International Consultation on Incontinence (ICI). Patients were recruited from March to October 2010. In the second visit a follow-up assessment of urinary symptoms and associated pathologies was done. The patients once again filled out the quality of life evaluation questionnaire.

Information of 1,434 patients was received. After verification of the inclusion criteria, through study of the corresponding variables in the database, the sample was reduced to 1,274 eligible patients for visit 1 and 1,153 for visit 2.

The SF-12 is a generic instrument to assess HRQoL, validated for use in Spanish, consisting of a subset of 12 items from the SF-36, a previously-developed more detailed instrument, selected through multiple regression, from which two summary components can be drawn: physical and mental (24,25). The scoring summaries are standardized with population norms, so that 50 (standard deviation of 10) is the mean of the general population. Values above or below 50 should be interpreted as better or worse, respectively, than the general population reference.

**Statistical analysis**

The statistical analysis was carried out using the statistics software STATA 10. Firstly, a descriptive analysis of all variables gathered was carried out. For the quantitative variables, measurements of central tendency (mean and median) and dispersion (standard deviation, maximum value and minimum value) were calculated. For the qualitative variables, a frequency analysis was done.

The distribution of scores in the SF-12 questionnaire was studied both for the baseline and the second visit for the sample as a whole and for gender sub-samples. Contrasts between the scores of the baseline and second visit were made using the Wilcoxon test for related samples, both for the whole sample and for the gender sub-samples. Male and female scores in the same visit were compared using the Mann-Whitney test.

In order to study a possible independent association of the presence of each of the associated pathologies and gender with the scores of the SF-12, a multiple regression model was calculated with random patient effects, given that the same patients were observed in two moments in time (longitudinal data). Variables indicating the presence of OAB and each of the associated pathologies (urinary infections, genital zone skin infections, sleep disorders, depression, and hypertension) for both moments of the study (baseline and final), the variables “age”, “sex” and “visit”, and the variables of treatments indicated on the first visit were introduced. The interpretation of the coefficients is exactly the same as that of the regression model. The meaning of the scores of the SF-12 questionnaire should be taken into account: the higher the score the better the quality of life.

A level $\alpha = 0.05$ of statistical significance was used.

**RESULTS**

71.51% of the sample were female. The mean age of the sample was 68.17 (6.19), with a minimum age of 60 and a maximum of 95. Regarding the association between urgency and UI, it was found that 24.10% of the participants presented urinary urgency without urgency UI and 75.90% urgency associated with UI (42.31% associated with urgency UI and 33.59% urgency with stress UI). Regarding pathologies associated with OAB 53.14% presented symptoms compatible with lower urinary tract infection, 24.73% with genital zone skin infection, 27.86% were undergoing treatment for depression, 56.44% suffered from sleep disorders and 29.54% arterial hypertension. The general characteristics of the sample, such as the treatments laid out in the first visit and the distribution between the sub-samples of males and females, has been described previously (26).

In Figure 1 the scores and contrasts are presented for the generic quality of life questionnaire SF-12 (meanings are specified in the figure footnote). As can be seen, quality of life improved significantly
in both components in the second visit, both in the sample as a whole and in the sub-samples of males and females. With regards to contrasts between genders, no differences can be observed in the physical component in either visit, whereas quality of life in the mental component is notably better in males in both visits.

In order to evaluate the factors independently associated with quality of life inherent in the subjects themselves and the treatments carried out, a multiple regression model was constructed with random subject effects for the summary scores of the SF-12 questionnaire. The results are shown in Table I.

According to the SF-12 questionnaire, the factors associated with a better quality of life with regards to the physical component (PCS) were the visit in question (better in the second visit), being male, being younger, and having a lower Charlson index; those associated with a worse quality of life with regards to the same component were having some of the studied associated pathologies (urinary infections, genital zone skin infections, sleep disorders, depression, and hypertension). OAB and treatment with a vaginal pessary. For the mental component score (MCS) an association was observed between a better quality of life and the second visit, being male and having a lower Charlson index; a worse quality of life was associated with being treated for depression, suffering from sleep disorders, the use of vesical re-training and the modification of treatments using diuretics.

DISCUSSION

In this study the impact of the management of patients with newly-diagnosed OAB and associated pathologies following usual clinical practice on quality of life has been analyzed. Patients who present with pathologies associated with OAB have a reduced quality of life compared with those that don’t (20). The positive impact of OAB treatment on symptoms of urgency and associated pathologies has previously been shown (26). The results presented here show that a significant improvement in patients’ quality of life is achieved following the use of treatments laid out for OAB.

Looking at the results gathered from the generic SF-12 questionnaire, in the first visit a reduced quality of life can be seen in the sample when compared with the mean of the general population. However, taking into account the fact that the sample is comprised of individuals over 60 years of age with a mean age of 68.17 (6.19), it can be concluded that the level obtained in the physical component [41.94 (9.96)] is actually very close to the corresponding value of that age group [48.02 (13.75) for those of between 50 and 64 years of age and 42.18 (14.48) for the over-65s (25)] whereas it is the mental component which is seen to be more greatly reduced [45.35 (11.98) as opposed to 49.58 (14.24) for those of between 50 and 64 years of age and 48.72 (14.96) for the over-65s (25)]. It is notable that in the second visit the value of both scores are similar to those values found in the same age range among the general population, indicating that the treatments laid out for OAB have a positive impact in improving the quality of life of patients with associated pathologies. The physical scale results were similar to those obtained in a previous case-control study conducted in Italy with a female sample of similar size to the one included in the present study. A higher score in the mental scale was observed in our study, probably due to the inclusion of both genders in our study. It should be kept in mind that while the Italian study compares...
Table 1. Multiple regression models with random patient effects for the SF-12 questionnaire.

<table>
<thead>
<tr>
<th></th>
<th>SF-12 Score PCS</th>
<th></th>
<th></th>
<th></th>
<th>SF-12 Score MCS</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coef.</td>
<td>Std. Err.</td>
<td>z</td>
<td>P&gt;</td>
<td>z</td>
<td>[95% CI]</td>
<td>Coef.</td>
<td>Std. Err.</td>
</tr>
<tr>
<td>1 Visit 2</td>
<td>1.99</td>
<td>0.25</td>
<td>8.07</td>
<td>0.00</td>
<td>1.51</td>
<td>2.47</td>
<td>1.76</td>
<td>0.28</td>
</tr>
<tr>
<td>2 Male</td>
<td>1.39</td>
<td>0.56</td>
<td>2.48</td>
<td>0.01</td>
<td>0.29</td>
<td>2.49</td>
<td>1.13</td>
<td>0.59</td>
</tr>
<tr>
<td>3 Age</td>
<td>-0.36</td>
<td>0.04</td>
<td>-9.53</td>
<td>0.00</td>
<td>-0.43</td>
<td>-0.29</td>
<td>0.03</td>
<td>0.04</td>
</tr>
<tr>
<td>4 Charlson Index</td>
<td>-0.93</td>
<td>0.12</td>
<td>-7.50</td>
<td>0.00</td>
<td>-1.18</td>
<td>-0.69</td>
<td>-0.64</td>
<td>0.13</td>
</tr>
<tr>
<td>5 Urinary infections</td>
<td>-1.52</td>
<td>0.40</td>
<td>-3.84</td>
<td>0.00</td>
<td>-2.30</td>
<td>-0.75</td>
<td>-0.33</td>
<td>0.43</td>
</tr>
<tr>
<td>6 Genital area infections</td>
<td>-3.11</td>
<td>0.49</td>
<td>-6.40</td>
<td>0.00</td>
<td>-4.06</td>
<td>-2.16</td>
<td>-0.39</td>
<td>0.52</td>
</tr>
<tr>
<td>7 Treatment for depression</td>
<td>-1.04</td>
<td>0.47</td>
<td>-2.21</td>
<td>0.03</td>
<td>-1.95</td>
<td>-0.12</td>
<td>-1.23</td>
<td>0.50</td>
</tr>
<tr>
<td>8 Sleep disorders</td>
<td>-2.30</td>
<td>0.40</td>
<td>-5.79</td>
<td>0.00</td>
<td>-3.08</td>
<td>-1.52</td>
<td>-2.65</td>
<td>0.43</td>
</tr>
<tr>
<td>9 AHT</td>
<td>-1.45</td>
<td>0.53</td>
<td>-2.76</td>
<td>0.01</td>
<td>-2.48</td>
<td>-0.42</td>
<td>0.74</td>
<td>0.57</td>
</tr>
<tr>
<td>10 OAB</td>
<td>-2.84</td>
<td>1.58</td>
<td>-1.80</td>
<td>0.07</td>
<td>-5.93</td>
<td>0.25</td>
<td>-0.82</td>
<td>1.78</td>
</tr>
<tr>
<td>11 Apply recommendations about lifestyle guidelines</td>
<td>0.37</td>
<td>0.49</td>
<td>0.75</td>
<td>0.45</td>
<td>-0.59</td>
<td>1.33</td>
<td>0.54</td>
<td>0.54</td>
</tr>
<tr>
<td>12 Apply vesical re-training: Programmed urinations</td>
<td>0.13</td>
<td>0.40</td>
<td>0.33</td>
<td>0.74</td>
<td>-0.66</td>
<td>0.92</td>
<td>-1.01</td>
<td>0.44</td>
</tr>
<tr>
<td>13 Apply pharmatological treatment using anti-cholinergics</td>
<td>-0.31</td>
<td>0.74</td>
<td>-0.43</td>
<td>0.67</td>
<td>-1.76</td>
<td>1.13</td>
<td>0.27</td>
<td>0.81</td>
</tr>
<tr>
<td>14 Apply pharmatological treatment with vaginal estrogens</td>
<td>-0.70</td>
<td>0.52</td>
<td>-1.34</td>
<td>0.18</td>
<td>-1.72</td>
<td>0.33</td>
<td>0.18</td>
<td>0.56</td>
</tr>
<tr>
<td>15 Apply modifications to the treatment using diuretics</td>
<td>-0.59</td>
<td>0.66</td>
<td>-0.89</td>
<td>0.38</td>
<td>-1.89</td>
<td>0.71</td>
<td>-1.46</td>
<td>0.73</td>
</tr>
<tr>
<td>16 Apply suspension of treatment using diuretics</td>
<td>0.83</td>
<td>0.96</td>
<td>0.87</td>
<td>0.39</td>
<td>-1.05</td>
<td>2.72</td>
<td>-0.81</td>
<td>1.05</td>
</tr>
<tr>
<td>17 Apply pelvic floor muscle contraction exercises (PFM)through own initiative</td>
<td>-0.12</td>
<td>0.42</td>
<td>-0.29</td>
<td>0.77</td>
<td>-0.94</td>
<td>0.70</td>
<td>-0.42</td>
<td>0.46</td>
</tr>
<tr>
<td>18 Apply sessions with a PFM training therapist using biofeedback and/or Electrostimulation</td>
<td>0.01</td>
<td>0.82</td>
<td>0.01</td>
<td>0.99</td>
<td>-1.60</td>
<td>1.61</td>
<td>1.61</td>
<td>0.89</td>
</tr>
<tr>
<td>19 Apply vaginal pessary</td>
<td>-3.20</td>
<td>1.44</td>
<td>-2.22</td>
<td>0.03</td>
<td>-6.03</td>
<td>-0.37</td>
<td>-2.22</td>
<td>1.56</td>
</tr>
<tr>
<td>20 Apply another treatment</td>
<td>0.02</td>
<td>0.65</td>
<td>0.04</td>
<td>0.97</td>
<td>-1.26</td>
<td>1.30</td>
<td>1.11</td>
<td>0.71</td>
</tr>
<tr>
<td>21 Constant</td>
<td>73.73</td>
<td>3.09</td>
<td>23.89</td>
<td>0.00</td>
<td>67.68</td>
<td>79.78</td>
<td>49.55</td>
<td>3.30</td>
</tr>
</tbody>
</table>

Square root = 0.2079

Square root = 0.3292
quality of life of OAB versus a control group, the present study analyses the improvement in quality of life after treatment.

The reduced quality of life found in women when compared to men on the mental scale of the SF-12 contrasts with the findings published in another study (9), in which no differences were found between middle-aged men and women, and a worse quality of life was found in institutionalized men than institutionalized women. In this present work it has been shown via a multiple regression model study that gender is associated with quality of life scores analyzed independently from other factors of the sample which may have changed the result, such as associated pathology or treatment type.

There are significant improvements in both components of the questionnaire between the two visits.

In those models carried out to detect variables independently associated with HRQoL, as well as the positive association of the second visit and of being male, and the negative association of a higher Charlson index, an independent negative effect of the studied associated pathologies (all of them, in the prediction of physical scores, and only depression and sleep disorders, in the prediction of mental scores) was also found. An independent negative effect on quality of life from the prediction of the mental component score was also found among patients who had been recommended some treatments to alleviate OAB used in normal clinical practice such as vesical re-training and the modification of treatments using diuretics. It should be highlighted that the use of vaginal pessaries showed an independent negative effect on the physical component score. The fact that these treatments, in which an independent association is found, have a direct negative impact on the patients’ quality of life, despite the fact that as a whole quality of life increased on the second visit, is very noteworthy. This study demonstrates, therefore, that the guidelines that the patient must follow in treatments involving vesical re-training, despite being a treatment proven to reduce UI episodes and urinary frequency (26-28), do themselves independently imply a level of patient discomfort and concern reflected in the independent negative association with the mental component of the SF-12 questionnaire. The same can be seen in the physical component of those patients recommended the use of vaginal pessaries: despite reducing the sensation of genital swelling (29), there seems to be a negative impact on the physical component of quality of life, possibly due to guidelines reducing physical activity and exertion recommended to prolapse patients. When recommending these treatments it is therefore worth considering that they are not in themselves wholly free from physical and/or psychological discomfort for the patient, even though, it is worth repeating, the overall impact of those treatments normally laid out in clinical practice is one of improving quality of life in all dimensions. The negative influence of certain treatments can also be interpreted in a distinct, yet complementary, way: in the first visit, during which treatment is decided upon, those patients who receive certain treatments are in a worse clinical state than others; in the second visit it could be that either those patients are still in a worse clinical state or that those treatments involve a greater physical and/or psychological burden than others.

The study limitations are those of observational studies, firstly the lack of homogeneity in treatments, dosages and follow-up of patients with OAB. In contrast, a true representation of the current clinical practice in our healthcare setting for the treatment of OAB is presented. This objective has been met with the inclusion of over 1,200 patients from 300 different urology practices. Secondly, the lack of control for confounding factors that could bias the results. However the present study design was considered appropriate in order to assess whether the VH treatments carried out in usual clinical practice improve the quality of life of patients. The estimation of quality of life was adjusted by general factors as age and Charlson comorbidity index.

All of the above points to the fact that, as with chronic patients, it is essential that patients with OAB and associated pathologies receive continued information and support during the treatments laid out to alleviate their incontinence, in order to neutralize the negative physical and psychological impacts of said treatments and maximize both the positive clinical impact and the overall improvement in quality of life.

CONCLUSION

In the detailed study into the HRQoL of patients with OAB and associated pathologies, gender, the associated pathologies, the comorbidities and some of the treatments laid out in normal clinical practice have been found to be independent predictors in patients’ quality of life. Most importantly it has been found that those treatments laid out to alleviate OAB in usual clinical practice are effective in notably improving HRQoL in patients with associated pathologies, not only in those aspects related specifically with their urinary symptoms, but also overall, both physically and mentally.
REFERENCES AND RECOMMENDED READINGS
(*of special interest, **of outstanding interest)


