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The impact of age, gender, and severity of overactive bladder wet on quality of life, productivity, treatment patterns and satisfaction.

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ABSTRACT

Objective: To determine the impact of idiopathic overactive bladder wet (OAB wet) severity, age and gender on health-related quality of life (HRQoL), productivity, treatment patterns and treatment satisfaction.

Materials and methods: A prospective, cross-sectional online survey of adults in the United Kingdom was performed to screen for self-reported symptoms of
OAB wet. Respondents completed the Kings Health Questionnaire or the Incontinence Quality of Life, as well as the Euroqol 5D, and the Work Productivity and Activity Impairment Specific Health Problem questionnaire, which contain questions pertaining to distress, treatment and treatment satisfaction.

**Results:** 249 of 1126 respondents (22.1%) met the criteria for OAB wet. Respondents with moderate/severe OAB wet and all women experienced significantly worse HRQoL and work productivity than those with mild symptoms and all men, respectively. Among all OAB wet responders, 62.7% were receiving treatment for their condition, predominantly pads (40.2%); only 1.6% were receiving specialised treatment. Nearly one-half (44.6%) were somewhat or completely dissatisfied with their current treatment.

**Conclusion:** In individuals with OAB wet, severity and gender negatively impact HRQoL and work productivity. A substantial proportion of OAB wet individuals were untreated, and low treatment satisfaction was reported in those receiving treatment. Treatment was generally conservative.

Keywords: Overactive bladder, urinary incontinence, healthcare resource utilisation, health-related quality of life, productivity
INTRODUCTION

Idiopathic overactive bladder (OAB) is defined as urinary urgency, usually with urinary frequency and nocturia without any obvious pathology.¹ In some patients, urgency, a sudden and strong desire to void that cannot be postponed, results in urge urinary incontinence (UUI). OAB wet is the accepted term for OAB with UUI.

The prevalence of idiopathic OAB wet increases with age from 2% to 19% in women and from 0.3% to 8.9% in men within age groups 18 to 24 years and 65
to 74 years, respectively. Patients with OAB wet rank UUI as one of the most bothersome symptoms, and the degree of bother increases significantly with UUI frequency. OAB wet results in significantly worse health-related quality of life (HRQoL), bother and sleep compared to stress urinary incontinence. OAB wet impacts HRQoL, and causes distress and depression significantly more often than OAB dry. However, there is limited information on how HRQoL varies with UUI severity, gender or age among those with OAB wet. OAB in general and OAB wet also impose a burden on patient productivity, and employment and medical resource use, and UUI severity is significantly associated with productivity loss.

The objectives of this study were to determine the impact of idiopathic OAB wet severity, age and gender on HRQoL, productivity, treatment patterns and treatment satisfaction.

MATERIALS AND METHODS

Study design and respondents

Primary data were collected in a prospective cross-sectional online survey of adults in the UK in 2014 performed by Patients Direct Limited, Scotland. Participants were recruited through social media, hard copy invitations
distributed in clinics and pharmacies, and incontinence product catalogues. Respondents were not compensated for their participation.

Selection began with screening for adults (aged at least 18 years) with urinary incontinence not associated with a neurological disease or urinary tract infection. To determine incontinence status, respondents were asked, “How often do you leak urine?” The analysis restricted respondents further by excluding those with stress urinary or mixed urinary incontinence, thereby including only persons with urgency, the hallmark of OAB. Double incontinence patients were also excluded.

**Questionnaires**

Respondents were asked about bladder symptoms, symptom distress, HRQoL, work productivity, and treatment. Disease-specific HRQoL was assessed using the King’s Health Questionnaire (KHQ) or the Incontinence Quality of Life (I-QoL) questionnaire, as recommended by the International Consultation on Incontinence. The administration of the KHQ and the I-QOL was alternated to reduce response burden. Generic health status was measured using the five level Euroqol 5D (EQ-5D-5L). Work productivity was assessed with the Work Productivity and Activity Impairment Specific Health Problem questionnaire,
version 2.0 (WPAI-SHP). The EQ-5D-5L and the WPAI-SHP were administered to all respondents.

The KHQ\textsuperscript{17,18} comprises 21 items across eight domains divided in two parts (Part 1: General Health perception, Incontinence Impact; Part 2: Role Limitations, Social Limitations, Physical Limitations, Personal Relationships, Emotions, Sleep/Energy, Severity/Coping Measures) and a symptoms severity scale (Part 3). The scores for domains in Parts 1 and 2 are transformed to a scale of 0-100 such that a higher score denotes a worse HRQoL in each part. Part 3 is scored by calculating the percentage of respondents selecting one of three response items asking how much they are affected (a little, moderately, a lot). The minimal clinically important difference (MCID) specific to OAB is at least five points for the domains in Parts 1 and 2.\textsuperscript{19}

The I-QOL consists of 22 items across three domains (Avoidance & Limiting behaviour, Psychosocial Impact, Social embarrassment). Items’ scores are transformed to a scale of 0-100 for all three domains and for the total score. A higher score indicates a better HRQoL. The MCID for the I-QOL total score and each domain is four points.\textsuperscript{20}

The EQ-5D-5L comprises five single item dimensions (Mobility, Self-care, Usual activities, Pain/discomfort, and Anxiety/depression) and a general health status score elicited using a visual analogue scale (EQ-5D VAS score; range: zero,
worst health imaginable to 100, best health imaginable). The scores elicited from the five dimensions are transformed into a weighted utility index that ranges from zero (death) to one (full health).

The WPAI-SHP questionnaire has nine items to assess the impact of a person’s health problem on four domains: Absenteeism, Presenteeism, Work productivity loss (overall work impairment/absenteeism plus presenteeism) and Activity impairment. For this survey, the health problem was referenced as “urinary incontinence”. Scores are transformed and expressed as impairment percentages; higher values indicate greater productivity loss and impairment. To our knowledge, a MCID has not been developed for either the WPAI-SHP specific to OAB, or for the EQ-5D-5L.

Respondents were also asked which bladder problem caused them the most distress, and about treatment they had used or were currently using, treatment satisfaction, and alternative treatments they had considered.

**Statistical Analysis**

All respondents who completed the survey and met the eligibility criteria for the current analysis were included in the analyses.
The number of participants responding to the survey was reported. Data were analyzed descriptively reporting the number and percentage for categorical variables and the mean and standard deviation for continuous variables. All variables were reported for OAB wet respondents overall, urinary incontinence severity, age and gender groups. In the absence of a universal definition of OAB wet severity, mild urinary incontinence was defined as up to three incontinence episodes a week (OAB wet mild), and moderate/severe urinary incontinence was defined as greater than this.

Estimates for the differences between OAB wet mild and moderate/severe groups were obtained for continuous and categorical outcomes using linear and ordinal logistic regression models respectively, adjusting for gender and age. Models used to compare age groups were adjusted for gender and vice versa. P-values were reported for between-group differences. The difference across all age groups was tested and p-value reported (pairwise age group differences were not investigated).

For all analyses, a p-value <0.05 was considered to indicate a statistically significant difference. Statistical analyses were performed using SAS software, Version 9.2© (Cary, NC, USA).

MCIDs for the KHQ and the I-QOL were applied to the domains with a between-group adjusted difference with a p-value < 0.05.
RESULTS

Respondent characteristics and symptoms

From a total of 1126 respondents, 249 (22.1%) met the selection criteria for OAB wet comprising 122 (49.0%) with mild and 127 (51.0%) with moderate/severe urinary incontinence. The mean age of respondents with mild or moderate/severe OAB wet was 57.3 and 58.1 years, respectively; the mean age of the overall sample was 57.7 years. Overall, the most populated age group was 60-69 years (30.1%), and the least populated was under 40 years (10.4%). Similarly, in the mild and moderate/severe OAB wet groups, the most populated was 60-69 years (30.3% and 29.9%, respectively), and the least populated was under 40 years (11.5% and 9.4%, respectively). Just over one-half of all respondents with OAB wet were male (54.6%). Over half of those with moderate/severe (55.1%) OAB wet were male.

HRQoL

Compared with respondents with mild OAB wet, those with moderate/severe OAB wet reported significantly worse HRQoL, as measured using the KHQ (Part 1, \( p < 0.001 \); and Part 2, \( p < 0.001 \)), the I-QOL (total score, \( p = 0.016 \); Avoidance and limiting behaviour, \( p = 0.049 \); Psychosocial impact, \( p = 0.048 \);
Social embarrassment, \( p = 0.002 \), and the EQ-5D-5L (utility score, \( p = 0.014 \)), adjusted for sex and age (Table 1, Figure 1). Regardless of severity of urinary incontinence, age or gender, respondents reported the greatest impact of symptoms on the domains Incontinence impact (KHQ Part 1) (Figure 2) and Social embarrassment (I-QOL) (Figure 1).

The difference between respondents with mild and moderate/severe urinary incontinence was statistically significant for all KHQ domains \((p \leq 0.019)\) with the exception of General health perception \((p = 0.072)\), indicating a worse HRQoL in physical, emotional, and social aspects of life for those with more severe OAB wet (Figure 2).

Considering the differences between respondents with mild and those with moderate/severe urinary incontinence, the \textit{a priori} determined MCIDs of at least five points for all KHQ domains (Parts 1 and 2) were exceeded. The MCID of at least four points for the total and domain scores of the I-QOL was also exceeded.

Females with OAB wet reported significantly worse HRQoL compared to males in five out of eight KHQ domains (Incontinence impact, \( p = 0.005 \); Role limitations, \( p < 0.001 \); Physical limitations, \( p = 0.002 \); Sleep/energy, \( p = 0.001 \); Severity measures, \( p < 0.001 \)), in KHQ Part 1 \((p = 0.005)\), KHQ Part 2 \((p = \)
0.010), the overall and all domain scores of the I-QOL (p ≤ 0.005), and the EQ-5D-5L utility score (p = 0.002) (Table 1).

The total score (p = 0.003) and all three domains of the I-QOL (Avoidance and limiting behaviour, p = 0.032; Psychosocial impact, p < 0.001; Social embarrassment, p = 0.023) showed a significantly worse HRQoL across age groups; those aged at least 70 years reported the best, and those aged 40-49 years the worst HRQoL (Table 1). Neither the EQ-5D-5L utility score (p = 0.806), nor any KHQ scores (p ≥ 0.094) showed a significant difference by age group.

The most distressing bladder problems (“a lot” in Part 3 KHQ) were urgency (59.3%), frequency (54.2%) and urge incontinence (51.7%) in the moderate/severe group, and frequency (45.0%), urgency (37.7%) and nocturia (32.3%) in the mild group.

**Employment and Productivity**

According to responses to the WPAI-SHP, 46.2% of OAB wet responders (43.3% of those with moderate/severe OAB wet, 49.2% of those with mild OAB wet) were employed (Table 2). Employment rates were similar between genders (males 47.8%; females 44.2%) and decreased with age. Significantly more
respondents with moderate/severe OAB wet reported worse overall Work ($p = 0.003$) and Activity impairment ($p < 0.001$) and significantly more Impairment while working due to incontinence (presenteeism) ($p = 0.001$) compared to the mild group (Table 2). The difference between groups in Work time missed due to incontinence (absenteeism) was not statistically significant ($p = 0.677$).

**Treatment**

Among respondents with mild or moderate/severe OAB wet, 42.6% and 32.3%, respectively, were not receiving any treatment for their condition at the time of the survey (Figure 3). Use of specialised treatments (referred to as: ‘drug injections into the bladder (e.g. onabotulinumtoxinA)’, ‘temporary electrical stimulation’, ‘permanent implantable device for electrical stimulation’ and ‘surgery’) was reported only by 1.6% of respondents in both severity groups (Figure 3). The most reported treatment combination in both severity groups was pads plus oral medication (23.8% in both groups).

When asked about treatments they had ever used, 29.3% of respondents with OAB wet reported never having received treatment. Specialised treatments had only ever been used by 10.0% of all OAB wet respondents, and 9.0% and 11.1% of those with mild or moderate/severe OAB wet, respectively (Figure 4a).
None of the respondents had ever received an implantable device for electrical stimulation (Figure 4).

Overall, 44.6% of respondents were dissatisfied with their current treatment, 18.5% reported satisfaction, and 36.9% were 'neither satisfied nor dissatisfied'. Satisfaction with current treatment did not vary by severity (p = 0.055) or age (p = 0.178), but did with gender, with more females reporting dissatisfaction (p = 0.037) (Figure 5).

When asked if they would consider seeking alternative treatments to those they already tried, 84.7% (n=211) OAB wet respondents answered positively. Of these, one-third would try specialised treatments: 33.2% surgery, 28.9% drug injections into the bladder, 19.4% temporary electrical stimulation, and 17.1% permanent implantable device for electrical stimulation.
DISCUSSION

The results demonstrate that those with moderate/severe urinary incontinence and women experienced statistically and clinically significantly worse disease-specific and generic HRQoL than those with mild urinary incontinence and men, respectively. In addition, impairment while working, overall work impairment and activity impairment, all due to incontinence, were significantly worse for the moderate/severe group.

Treatment was not ongoing for 37% of all OAB wet respondents, and when treated, pads were most frequently used. Specialised treatment options were rarely prescribed in spite of up to 33% of respondents having considered them. Low levels of satisfaction with treatment were prevalent. These findings may be indicative of limited access to specialised treatments in this patient population.

A strength of the current study is that the population was carefully selected to preserve as much as possible a sample with idiopathic OAB wet, thereby excluding those with a neurogenic etiology, OAB dry, double and stress incontinence. Also, the EQ-5D-5L was selected rather than the 3L version because of its improved convergent validity and discriminatory power. All three questionnaires ask respondents about the present thereby reducing the risk of recall bias. Moreover, the statistical analyses ruled out confounding variables such as age and gender, when appropriate.
A limitation is that the respondents described their own bladder problems from which symptoms of OAB wet were assumed. However, the *a priori* selection criteria, the opportunity to reduce the embarrassment that results when sufferers consult their healthcare provider and potentially inhibits truthful responses, and the lack of filtering respondents by a healthcare provider may, in part, counteract this. It was not possible to exclude people with concomitant urological conditions (e.g. benign prostatic hyperplasia, cystocele) that may result in similar bladder symptoms to those associated with OAB. However, while our sample may not be representative of the overall OAB wet population, the majority (54.6%) are men similar to data reported by Stewart *et al.*

Without published MCID estimates for the EQ-5D-5L or the WPAI-SHP specific to OAB wet, the clinical relevance of the differences between groups for these could not be determined. Reference by previous authors to a seven point WPAI-SHP MCID is based on data elicited from persons with insomnia or Crohn’s disease who may have perceived changes in their health status differently to persons with OAB. Furthermore, we did not collect data on primary care or specialist visits, or hospitalizations based on the concern that patient recall for these parameters bares little correlation to actual events.
CONCLUSIONS

Adults with moderate/severe OAB wet, and women with any severity of OAB wet experienced statistically and clinically significantly worse HRQoL and higher rates of work impairment than those with mild OAB wet and men, respectively. Many with moderate/severe symptoms had never received, and at the time of the survey were not receiving, any treatment. When prescribed, treatment was mainly in the form of pads or other conservative options with limited access to specialised treatments. Treatment satisfaction was generally low.

While significant associations between HRQoL and increasing bother and severity of bladder symptoms among OAB patients has been reported previously,\textsuperscript{7,9,26-28} differences in HRQoL, productivity and treatment between groups categorised by severity, age and gender have not been documented. Therefore, the present study contributes new information to the repository of knowledge about OAB wet severity. Future research should investigate access to both conservative and specialised treatment and its impact on patients’ satisfaction.

1. Conflicting Interests

SM Lloyd declares there is no conflict of interest.
GC and PM report grants from Patients Direct during the conduct of the study. MG was an employee of Medtronic International Trading Sarl, Switzerland, the sole funder of the study. TJG and JLO have received travel and educational sponsorship from Medtronic Limited in the UK.

2. Funding acknowledgments

This work was supported by Medtronic International Trading Sarl, Switzerland. SML benefited by receiving a salary from the Robertson Centre for Biostatistics following receipt of a consulting fee from Medtronic International Sarl, Switzerland. GC benefited by receiving a salary from Patients’ Direct following receipt of a consulting fee from Medtronic International Sarl, Switzerland. PMS benefited by receiving a salary from the Robertson Centre for Biostatistics following receipt of a consulting fee from Medtronic International Sarl, Switzerland. MG benefited by receiving a salary from Medtronic International Sarl, Switzerland. TJG and JLO did not benefit financially from this study.

3. Ethical Approval

Ethical approval was not sought for the present study because the research was only concerned with respondents’ impressions of their illness and was therefore purely observational (non-invasive and non-interactive).
4. Informed Consent

Informed consent was not sought for the present study because the only personal information respondents were asked to provide was their age to the nearest year and email address, neither of which were received by the medical technology company sponsoring the study who only received anonymised data.

5. Trial Registration

Not applicable.

6. Guarantors

JLO.

7. Contributorship

SML supervised the development of the statistical analysis plan, the data analysis, reviewed the results and reviewed and edited the manuscript based on interpretation of the data.

GC participated in the development of the survey questions, managed the recruitment of respondents, reviewed the results, and reviewed and edited the manuscript based on interpretation of the data.

PMS developed the statistical analysis plan, analysed the data, produced the tabulated results, reviewed and edited the manuscript based on interpretation of the data.
MG researched the literature, conceived the study, participated in the development of the survey questions, reviewed the statistical analysis plan and the results, and reviewed and edited the manuscript based on interpretation of the data.

TJG reviewed the results, reviewed and edited the manuscript based on interpretation of the data.

JLO participated in the conception of the study and the development of the survey questions, reviewed the results, and reviewed and edited the manuscript based on interpretation of the data.

All of the authors approve the version submitted to the Journal of Clinical Urology for publication.

8. Acknowledgements

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REFERENCES


TABLES AND LEGENDS

Table 1 Mean health-related quality of life scores (standard deviation (SD)) by urinary incontinence severity, gender and age and comparisons (adjusted analyses) between groups

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<th>Questionnaire</th>
<th>Mild urinary incontinence (n=122)</th>
<th>Moderate/severe urinary incontinence (n=127)</th>
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Incontinence Quality of life questionnaire ** (n=126)
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<tr>
<td>Visual analogue scale score</td>
<td>69.2 (22.2)</td>
<td>67.3 (21.1)</td>
<td>68.2 (21.6)</td>
<td>68.1 (21.9)</td>
<td>63.9 (23.6)</td>
<td>65.1 (20.2)</td>
<td>69.4 (22.0)</td>
<td>74.5 (20.8)</td>
<td>71.0 (20.3)</td>
<td>65.0 (22.8)</td>
</tr>
</tbody>
</table>

Key: *, a higher score indicates a worse HRQoL; **, a higher score indicates a better HRQoL; φ, $P < 0.001$; §, $P = 0.005$; ≈, $P = 0.002$; ∞, $P = 0.01$; #, $P = 0.03$; ƺ, $P = 0.04$; ∩, $P = 0.05$
TABLES AND LEGENDS

Table 2 Work Productivity and Impairment Questionnaire scores (means and standard deviations (SDs)) by urinary incontinence severity, gender and age and comparisons (adjusted analyses) between groups

<table>
<thead>
<tr>
<th></th>
<th>Mild urinary incontinence (n=122)</th>
<th>Moderate/severe urinary incontinence (n=127)</th>
<th>All OAB wet respondent (n=249)</th>
<th>&lt;40 years (n=26)</th>
<th>40-49 years (n=33)</th>
<th>50-59 years (n=70)</th>
<th>60-69 years (n=75)</th>
<th>≥70 years (n=45)</th>
<th>Males (n=136)</th>
<th>Female (n=113)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently employed, n</td>
<td>60 (49.2)</td>
<td>55 (43.3)</td>
<td>115 (46.2)</td>
<td>18 (69.2)</td>
<td>26 (78.8)</td>
<td>47 (67.1)</td>
<td>21 (28.0)</td>
<td>3 (6.7)</td>
<td>65 (47.8)</td>
<td>50 (44.2)</td>
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<tr>
<td>(%)</td>
<td>Mild urinary incontinence (n=122)</td>
<td>Moderate/severe urinary incontinence (n=127)</td>
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<td>Males (n=136)</td>
<td>Female (n=113)</td>
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<tr>
<td>Mean (SD) % of work time missed due to incontinence (absenteeism)</td>
<td>1.7 (7.6)</td>
<td>1.1 (4.3)</td>
<td>1.4 (6.2)</td>
<td>3.9 (12.4)</td>
<td>1.6 (6.4)</td>
<td>0.8 (3.0)</td>
<td>0.0 (0.0)</td>
<td>0.5 (1.5)</td>
<td>1.2 (4.7)</td>
<td>1.3 (6.5)</td>
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<tr>
<td><strong>Mean (SD) % of impairment while working due to incontinence (presenteeism)</strong></td>
<td>20 (20)</td>
<td>33 (24) ∞</td>
<td>26 (23)</td>
<td>41 (22)</td>
<td>31 (26)</td>
<td>25 (24)</td>
<td>16 (17)</td>
<td>20 (23)</td>
<td>23 (22)</td>
<td>29 (25)</td>
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<tr>
<td>Mean (SD) % Overall work impairment due to incontinence</td>
<td>21.2 (22)</td>
<td>33.5 (24.4) #</td>
<td>27.1 (23.9)</td>
<td>42.4 (24.2)</td>
<td>32.1 (27.0)</td>
<td>25.7 (24.5)</td>
<td>15.9 (17.3)</td>
<td>20.3 (23.1)Ø</td>
<td>23.9 (23.3)</td>
<td>30.0 (25.9)</td>
</tr>
<tr>
<td></td>
<td>Mild urinary incontinence (n=122)</td>
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<tr>
<td><strong>Mean (SD) %</strong></td>
<td>28 (25)</td>
<td>42 (27) φ</td>
<td>35 (27)</td>
<td>46 (27)</td>
<td>43 (29)</td>
<td>37 (25)</td>
<td>36 (27)</td>
<td>34 (27)</td>
<td>30 (24)</td>
<td>42 (27) φ</td>
</tr>
<tr>
<td><strong>Activity impairment due to incontinence</strong></td>
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Key: *, a higher score indicates decreased productivity; φ, $P < 0.001$; ∞, $P = 0.01$