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CLINICAL ARTICLE

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Associations between the Patient Perception of Bladder Condition score and overactive bladder syndrome symptoms at baseline and upon treatment

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Abstract

Background: Patient-reported outcomes such as the Patient Perception of Bladder Condition (PPBC) score are frequently used to characterize overactive bladder syndrome (OAB) patients and their treatment outcomes. However, little information is available on the relationship of such scores to OAB symptoms at the individual patient level.

Methods: We have performed a post hoc analysis of two large noninterventional studies ($n = 1345$ and 745) in which patients received propiverine extended release (30 or 45 mg/day) for 12 weeks to determine the strength of nonparametric correlations between PPBC and OAB symptoms at baseline, after treatment and with treatment-associated changes thereof.

Results: PPBC was not correlated with age but with episode frequencies of urgency, incontinence, micturitions, and nocturia, but the strength of correlations was only moderate (Spearman rank correlation coefficient 0.2045−0.3553). Similarly moderate correlations were observed after treatment and when changes in PPBC were compared to those of OAB symptoms, although these correlations were somewhat stronger.

Conclusions: PPBC is only moderately correlated to OAB symptoms indicating that it characterizes patients beyond what is captured by their symptoms.

KEYWORDS

nonparametric analysis, overactive bladder syndrome, patient perception of bladder condition, symptom score

Abbreviations: CI, confidence interval; IQR, interquartile range; NIS, noninterventional study; OAB, overactive bladder; PPBC, patient perception of bladder condition; PROM, patient-reported outcome measure; QoL, quality of life.

1 | INTRODUCTION

Based on the definition of the overactive bladder syndrome (OAB) by the International Continence Society,[1,2] studies of the severity of the condition and of treatment effects typically focus on the (mostly diary-derived) variables of urgency, incontinence, frequency, and nocturia. While urgency is the defining symptom for OAB (1; 2), incontinence and frequency are the symptoms most often used as primary endpoints, at least partly because of requirements from regulatory agencies for phase III studies. However, it has been found that these symptoms only partly describe clinical reality. Different symptoms may be particularly bothersome for a given patient, and the OAB symptoms are only poorly correlated to each other.[3,4]

Patient-reported outcome measures (PROM) are increasingly used as well to characterize OAB patients, sometimes even as primary outcome parameter of studies. They are typically based on symptom scores that at least to some extent reflect the impact of OAB and/or its treatment on quality of life (QoL) in general and on disease specific QoL in particular.[5,6] Many PROM are available in the field of OAB research[7] including the King's Health Questionnaire, overactive bladder questionnaire (OABq), overactive bladder symptom score (OABSS), or the Patient Perception of Bladder Condition score (PPBC). The latter consists of a single question ("which of the following statements describes your bladder condition best at the moment?") and six options ranging from "does not cause me any problems at all" to "causes me many severe problems." It has been validated for content[8] and for test–retest validity.[9] Moreover, validated translations exist for 16 languages including German.[10] Accordingly, the PPBC has been used to define fulfillment of inclusion criteria or to assess the impact of treatment on disease specific QoL in many controlled and noninterventional studies, including treatment with muscarinic receptor antagonists such as darifenacin, fesoterodine, oxybutynin, propiverine, solifenacin, or tolterodine, with β_3-adrenoceptor agonists such as mirabegron, or with onabotulinum toxin.

The general observation is that treatments improving OAB symptoms such as urgency, incontinence, frequency, or nocturia also improve the PPBC score and other indicators of QoL.[11] However, the situation is less clear at the single-patient level: the original validation report[8] and one large, noninterventional study (NIS) found that baseline levels of PPBC correlated only moderately with those of OAB symptoms.[3] Moreover, these studies had all been based on use of tolterodine and no comparable data exist with other OAB treatments. Thus, it remains unclear what drives PROM such as the PPBC. Therefore, we have analyzed data from two previously reported large NIS based on administration of propiverine extended release (ER)[12,13] to explore how PPBC and its changes upon treatment relate to OAB parameters such as urgency, incontinence, frequency, and nocturia.

2 | MATERIALS AND METHODS

The present work analyzes data from two previously reported NIS[12,13] in which patients seeking treatment of OAB symptoms received propiverine ER (30 or 45 mg/day) based on physician's judgment for a planned observational period of 12 weeks ($n = 1335$ and 745, respectively). Details of the study design and primary study outcomes have been reported previously.[12,13]

The present findings should be considered as a post hoc analysis because the analyses presented here had not been defined before performing the study and after initial summarizing results had been seen; however, the protocols for the analyses were finalized before the analyses related to the present study question were performed. All analyses were performed identically for both studies. In this regard, study I was considered as hypothesis-generating and study II was used to explore the robustness of the findings (not as a formal hypothesis-testing study).

Because PPBC is an ordinal variable, all data are reported as medians with interquartile ranges (IQR) and correlation analyses were based on nonparametric Spearman rank correlations. The use of medians, IQR, and nonparametric analysis is further supported by the observation that the distribution histogram of baseline PPBC from both studies indicated a skewed distribution (Figure 1).

We determined median values of PPBC at baseline and after 12 weeks (in study I also after 4 weeks) and median intra-individual alterations of PPBC between baseline and Week 12. In a next step we performed nonparametric correlation analysis of baseline values of PPBC with age and with those of urgency, incontinence, frequency, and nocturia and performed similar analyses for the end-of-study values. Finally, we performed nonparametric correlation analyses for rank changes of PPBC from baseline to end-of-treatment with corresponding %changes of urgency, incontinence, frequency, and nocturia. Correlation of baseline values was performed in parallel for all patients and excluding those lacking a given OAB symptom at baseline (i.e., those with a reported baseline value of 0 such as OAB dry patients not having incontinence). Strength of correlation was determined by Spearman's correlation coefficient r with its 95% confidence interval. r^2 was used to describe the fraction of variability in PPBC that could mathematically be attributed to that in the other variables.

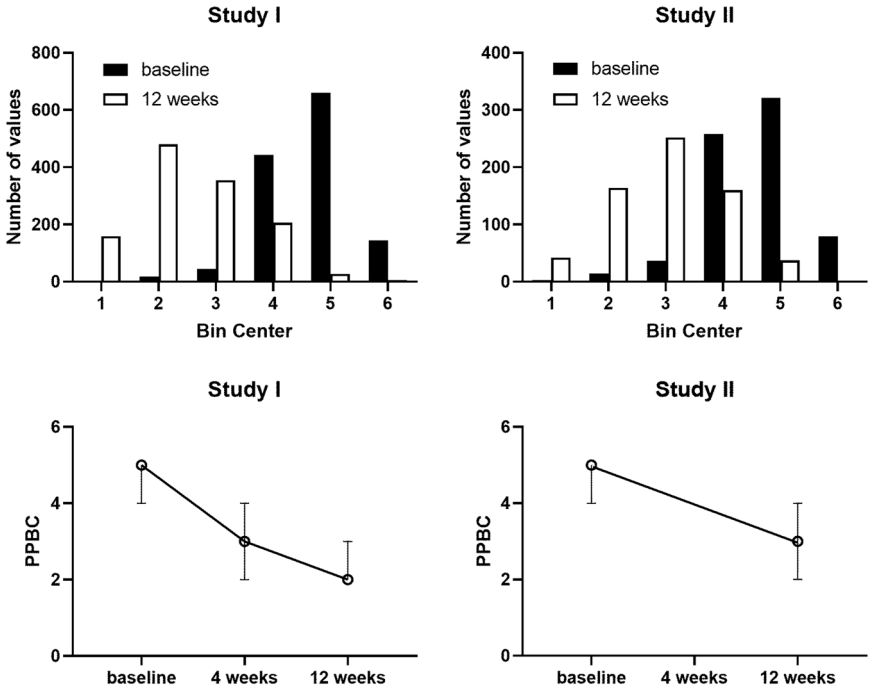

FIGURE 1 Distribution of PPBC at baseline and after 12 weeks of treatment (upper row) and median PPBC with 95% confidence intervals over time (lower row) in studies I and II. PPBC, patient perception of bladder condition.

All data analyses were performed using the Prism 9.3.1 software (GraphPad Software, Los Angeles, CA, USA). Based on the exploratory nature of the analyses, all calculated *p* values are descriptive only and not intended to be hypothesis-testing. Moreover, only univariate correlation analyses were performed based on the exploratory nature of the analyses.

3 | RESULTS

3.1 | Descriptive results

The distribution of PPBC at baseline was highly skewed with rank 5 ("my bladder condition causes me severe problems") being most frequent, followed by rank 4 ("my bladder condition causes me (some) moderate problems"; Figure 1). Following 12 weeks of treatment, the distribution remained highly skewed but exhibited a major shift to lower ranks, now rank 2 ("my bladder condition causes me some very minor problems") and rank 3 ("my bladder condition causes me some minor problems") being reported most frequently in Studies I and II, respectively (Figure 1).

Out of 1216 and 647 analyzable patients in studies I and II, some exhibited an unchanged PPBC (87 and 94) whereas almost all others exhibited improvement, typically by 1−3 ranks. While the number of patients exhibiting an improvement by 5 ranks was low in either study (13 and 4), these were more than those reporting a worsening (8 and 2). Accordingly, the median baseline PPBC rank in both studies was 5 (IQR 4; 5). It improved over time with a median change after 12 weeks of treatment of 2 ranks (IQR study I; 1; 3 and study II; 1; 2) to reach median scores of 2 (IQR 2; 3) and 3 (IQR 2; 4) in studies I and II, respectively (Figure 1). Baseline and treatment-associated changes for urgency, incontinence, frequency, and nocturia have previously been reported.[13]

3.2 | Associations of PPBC at baseline

PPBC was not associated with age in either study (Table 1). In contrast, PPBC correlated with urgency, incontinence, frequency, and nocturia (Spearman rank correlation $p < 0.0001$). However, the correlations were of moderate strength only in both studies with *r* ranging from 0.2045 to 0.3553 (Table 1), indicating that only 4% −13% (r^2 0.04−0.13) of the variability of PPBC could mathematically be attributed to that in any of the other OAB variables. Similar findings were obtained when only patients exhibiting a given symptom at baseline were included in the analyses (Table 1).

3.3 | Associations of PPBC after 12 weeks of treatment

After 12 weeks of treatment, PPBC and other OAB parameters were also correlated (Table 2). Strength of correlation as assessed by the correlation coefficient *r*

TABLE 1 Correlation of PPBC and OAB symptoms at baseline reported as *r* and its 95% confidence interval based on Spearman rank correlation (except for age, all $p < 0.0001$).

	Study I		Study II	
	r	***n***	***r***	***n***
Analyses based on all patients				
Age	0.0175 (−0.0385 to 0.0733)	1305	0.0453 (−0.0307 to 0.1208)	707
Urgency	0.3528 (0.2992−0.4041)	1136	0.2573 (0.1796−0.3318)	614
Incontinence	0.3108 (0.2557−0.3640)	1135	0.2932 (0.2139−0.3687)	569
Frequency	0.3553 (0.3052−0.4035)	1288	0.3413 (0.2719−0.4071)	697
Nocturia	0.2045 (0.1502−0.2575)	1298	0.3203 (0.2499−0.3872)	697
Analyses based only on patients reporting a given symptom at baseline				
Urgency	0.3495 (0.2955−0.4014)	1121	0.2639 (0.1853−0.3391)	597
Incontinence	0.3140 (0.2472−0.3779)	775	0.1868 (0.0878−0.2822)	402
Frequency	0.3553 (0.3052−0.4035)	1288	0.3413 (0.2719−0.4071)	697
Nocturia	0.1897 (0.1341−0.2442)	1249	0.3284 (0.2573−0.3960)	675

Abbreviations: OAB, overactive bladder; PPBC, patient perception of bladder condition.

TABLE 2 Correlation of PPBC and OAB symptoms after 12 weeks of treatment reported as *r* and its 95% confidence interval based on Spearman rank correlation (all $p < 0.0001$).

	Study 1		Study 2	
	r	***n***	***r***	***n***
Urgency	0.4905 (0.4421−0.5359)	1070	0.5160 (0.4502−0.5762)	555
Incontinence	0.3665 (0.3114−0.4191)	1053	0.4354 (0.3616−0.5037)	531
Frequency	0.4907 (0.4448−0.5340)	1183	0.4762 (0.4118−0.5358)	636
Nocturia	0.4279 (0.3790−0.4745)	1195	0.4580 (0.3924−0.5189)	637

Abbreviations: OAB, overactive bladder; PPBC, patient perception of bladder condition.

ranged from 0.3665 to 0.5160. Thus, posttreatment correlations appeared stronger than those of baseline symptoms but remained of moderate strength, that is, 13.4%−26.6% of the variability in PPBC could mathematically be attributed to that in OAB symptoms. Correlations between intra-individual improvements of PPBC rank and of %changes of OAB parameters were also observed and correlation coefficients ranged from 0.3709 to 0.5746, that is, were of moderate strength (explaining 13.8%−33.0% of PPBC variability; Table 3).

4 | DISCUSSION

Various OAB treatments improve PROM such as PPBC at the group level, and the present NIS confirm this. While such improvements are routinely observed to occur concomitant with improvements of diary-based OAB symptoms in randomized controlled trials and NIS,[3,14–22] other than the original validation study[8] apparently only one previous study (all based on tolterodine) has explored relationships between PPBC and OAB symptoms at the single-patient level and was limited to analysis of baseline values.[3] The present analyses confirm those findings and extends them to treatment-associated improvements.

4.1 | Critique of methods

We have chosen to perform our analyses based on data from two NIS because PROM such as PPBC report on patient perception, and perceptions may be different under real-world conditions as compared to the artificial situation of being part of a randomized, double-blind trial. Despite large external validity (representing patients in a real-world setting), they have limited internal validity because of lacking a control group. Therefore, NIS data should not be abused to claim efficacy and tolerability in absolute terms;

TABLE 3 Correlation of improvement of PPBC (change of number of ranks) and OAB symptoms (%change) after 12 weeks of treatment reported as *r* and its 95% confidence interval based on Spearman rank correlation (all $p < 0.0001$).

	Study 1		Study 2	
	r	***n***	***r***	***n***
Urgency	0.4396 (0.3869−0.4895)	1008	0.5067 (0.4397−0.5681)	548
Incontinence	0.3709 (0.3030−0.4350)	697	0.4821 (0.3979−0.5583)	375
Frequency	0.5181 (0.4734−0.5601)	1163	0.5746 (0.5183−0.6260)	633
Nocturia	0.3896 (0.3376−0.4393)	1135	0.4555 (0.3884−0.5177)	614

Note: % improvements of frequency were smaller than for the other parameters because normal frequency is not 0; also note that only patients with at least 1 incontinence episode at baseline were included in the calculation of incontinence improvement.

Abbreviations: OAB, overactive bladder; PPBC, patient perception of bladder condition.

moreover, the data do not allow to estimate how much of the observed findings may be attributable to a placebo effect. However, this was not necessary because the efficacy of propiverine had been documented in many randomized trials including comparisons to placebo[23–26] or to other muscarinic antagonists.[25–28]

The present data are likely to be representative for real-world OAB patients because the observed efficacy (improvement in OAB symptoms) in the two studies was similar to that observed in previous NIS with propiverine ER.[29,30] Moreover, the observed baseline PPBC values (mostly rank 4−5) and treatment-associated changes thereof were similar to those observed at baseline in RCT,[14,21,22] open-label trials,[17–19] and NIS[3,15,16] with propiverine and various other OAB drugs.

The reporting of means and use of parametric statistical tests are only meaningful for continuous variables exhibiting a normal distribution. However, the PPBC is an ordinal variable, which should be reported as medians or distributions and analyzed by nonparametric tests. While this has been done in the original validation studies,[8] few other studies in the field have followed that example.[3,15,18] Despite being scientifically unsound, many studies have reported PPBC as means, for instance,[19,21,22] which ignores that PPBC is an ordinal variable. Moreover, we report correlations of treatment-associated improvements concomitantly based on % improvements because the latter are largely unaffected by baseline severity.[12,31] As we did not observe associations between baseline PPBC and age, it was not considered to be necessary to perform multivariate analysis with age as explanatory covariable.

4.2 | Correlation analyses

OAB is defined by the presence of urgency, but frequency and/or nocturia frequently are also observed.[1,2] Further, about one-third of OAB patients are incontinent.[32,33] The latter already suggest that the various OAB symptoms may exhibit only a limited correlation. Clinical experience suggests that OAB symptoms often exhibit different severity within a patient, and that patients are differentially bothered by the various symptoms. Accordingly, it was found that the severity of urgency, incontinence, frequency, and nocturia at the single-patient level is moderately correlated at best.[3,4,34] Apparently, this also applies to the PPBC.

The original validation study of the PPBC was based on one prospective open-label and one placebo-controlled trial with tolterodine and found that the PPBC was highly responsive to improvement of OAB symptoms upon treatment at the group level.[8] However, correlation coefficients *r* as derived from Spearman rank analysis were only 0.1−0.4. A later NIS also based on tolterodine data confirmed rather weak relationships between PPBC and OAB symptoms at baseline.[3] The present two NIS based on a different treatment, propiverine, confirm the weak correlations of PPBC with OAB symptoms at baseline, after treatment and with treatment-associated changes thereof. Similar to earlier observations,[8] we found that correlations strengthen somewhat but remain moderate at best if data after treatment or treatment-associated changes are assessed.

Apparently, weak associations are not specific for the PPBC because a similarly weak association had been observed for other PROM including the OABq subscales,[8] the OABSS,[19,35] the Indevus Urgency Severity Scale,[4,35] the Urgency Perception Scale, and the general health and bladder problem questions of the King's Health Questionnaire.[4] This consistent finding across multiple PROM and various study designs including randomized, controlled trials, prospective open-label studies, and NIS supports the assumption that the subjective distress caused by OAB is not predominantly or even exclusively due to any of the four symptoms of urgency, incontinence, frequency, and nocturia. This reflects the clinical observation that individual patients are differentially bothered by a single symptom.

A possible explanation for the weak to moderate associations is that OAB is also influenced by

psychological comorbidities like depression or anxiety disorders. Lai et al. reported that 27.5% and 48% of OAB patients suffer from depression and anxiety disorders, respectively.[36,37] The OAB patients with these psychological comorbidities exhibited greater incontinence symptoms, a greater bother due to OAB and a greater negative impact on their QoL. It has also been found that OAB can negatively affect sleep QoL with depression and thus, in the sense of a self-enforcing negative cycle, worsens the depression.[38] Therefore, the OAB syndrome cannot be only reduced to urgency, urge incontinence, frequency, and nocturia. We recommend that the evaluation of OAB patients at baseline and of treatment outcomes should include at least one PROM. While none of the available PROM exhibits clear superiority over others, the PPBC has the advantage of being based on a single question, which makes administration in routine praxis easy.

AUTHOR CONTRIBUTIONS

Sandra Schönburg, Sandra Murgas, and Martin C. Michel conceptualized the analyses. Sandra Murgas designed the underlying studies. Martin C. Michel analyzed the data. Sandra Schönburg and Martin C. Michel drafted the manuscript. All authors provided critical intellectual input into the manuscript and approved its final version.

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CONFLICTS OF INTEREST

Sandra Schönburg is a consultant and/or lecturer for A.M.I, AstraZeneca, Boston Scientific, and Omega Pharma. Sandra Murgas is an employee of APOGEPHA. The remaining author declares no conflict of interest. Martin C. Michel is a consultant, investigator and/or lecturer to APOGEPHA, Astellas, Dr. Willmar Schwabe, GSK, and Sanofi-Aventis.

DATA AVAILABILITY STATEMENT

The underlying data will be made available to qualified investigators upon reasonable request.

ETHICS STATEMENT

Both studies were based on §67, 3 of the German Drug Act and had been approved by the ethical committee of the state board of physicians in Saxony, Germany (Sächsische Landesärztekammer EK-BR-14/12-1 and EK-BR-18/14-1). Due to the noninterventional character of the analyzed studies and availability of pseudonymized data only, no patient consent was obtained.

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