Correlation of pad use with specific overactive bladder symptoms: findings at baseline and after treatment in two non-interventional studies

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Introduction

Pads are an integral part of the management of urinary incontinence and overactive bladder syndrome (OAB). While it appears intuitive that pad use would be driven by number of incontinence episodes, there is little evidence to support this notion from clinical study data.

Therefore, we have analyzed data from two recently reported, large, non-interventional studies to explore the associations between pad use and individual OAB symptoms. Such associations were explored at baseline and after treatment.

Methods and Materials

Two non-interventional studies of similar design were analyzed [1]. Briefly, patients were invited to participate if they started treatment with propiverine ER (30-45 mg/day; dose adjustment during the study was permitted) at the recommendation of their physician. Pad use, diary parameters of urgency, frequency, nocturia and incontinence and the Patient Perception of Bladder Condition score (PPBC) were captured at baseline and after 12 weeks of treatment.

Two types of analysis were done: Firstly, we compared median OAB symptoms at baseline in subgroups of patients using 0, 1, 2-3, 4-5 and ≥6 pads/day. Secondly, non-parametric correlation analyses (Spearman-Rank correlation) were performed between pad use and each OAB symptom at baseline and after 12 weeks of treatment. Other than patients without documented data on pad use, 4 patients from study 1 and 3 patients from study 2 were excluded from analysis because of grossly implausible data such as 0 reported voids or ≥ 50 reported voids, incontinence episodes or pads.

Pad use is described as median values with 95% confidence intervals (CI). Due to the exploratory and post-hoc character of the evaluation, no hypothesis-testing statistical analyses were performed. Instead, we used the data from two studies to test robustness of the results. While the decision to use the data from the two studies was made after the trial had been completed, the statistical analysis plan for the present analyses was finalized before any data related to pad use had been inspected.

Results

Studies 1 and 2 included 1335 (median age: 68 years, 66% female) and 745 (median age: 69 years, 63% female) patients, respectively. Median pad use in studies 1 and 2 was 2 [95% CI: 2; 2] and 2 [2; 3], respectively, at baseline and declined to 1 [1; 1] in both studies after 12 weeks of treatment. The percentage of patients not using any pads increased from 25.9% to 42.5% in study 1 and 24.9% to 36.6% in study 2.

Patients using more pads at baseline also had more incontinence episodes, but only moderately more urgency episodes and frequency, little difference in nocturia or PPBC, and were not consistently older (Table 1).

Table 1: Median age, OAB symptoms and PPBC [95% CI] at baseline in strata of pad use at baseline. N refers to number of patients with the indicated number of pads used per day.

Pad use	N	Age	Urgency	Incontinence	Frequency	Nocturia	PPBC
Study 1							
All	1268	68 [68; 69]	9 [9; 10]	3 [2; 3]	13 [13; 13]	3 [3; 3]	5 [5; 5]
0	328	67 [64; 69]	8 [7; 9]	0 [0; 0]	12 [12; 12]	3 [3; 3]	4 [4; 5]
1	143	69 [67; 71]	8 [6; 8]	1 [1; 1]	12 [11; 12]	3 [2; 3]	5 [4; 5]
2-3	411	68 [67; 70]	9 [8; 10]	3 [3; 3]	13 [13; 13]	3 [3; 3]	5 [5; 5]
4-5	241	67 [67; 70]	10 [10; 12]	5 [5; 6]	15 [14; 15]	4 [3; 4]	5 [5; 5]
≥6	146	70 [67; 73]	12 [11; 13]	8 [7; 9]	16 [15; 17]	4 [4; 5]	5 [5; 5]
Study 2							
All	676	69 [68; 70]	9 [8; 9]	3 [2; 3]	13 [12; 13]	3 [3; 3]	5 [5; 5]
0	168	65 [61; 67]	8 [7; 9]	0 [0; 0]	12 [11; 12]	3 [3; 3]	4 [4; 5]
1	82	70 [66; 74]	8 [6; 10]	1 [1; 2]	12 [11; 12]	3 [3; 3]	4 [4; 5]
2-3	221	71 [69; 72]	8 [8; 9]	3 [3; 4]	12 [12; 13]	3 [3; 3]	5 [5; 5]
4-5	113	70 [68; 72]	10 [8; 11]	6 [5; 6]	14 [14; 15]	4 [3; 4]	5 [5; 5]
≥6	92	68 [65; 71]	11 [10; 12]	8.5 [7; 10]	15 [14; 16]	4 [3; 4]	5 [5; 5]

Pad use at baseline was strongly correlated to number of incontinence episodes in both studies (r = 0.773 and 0.786) but only much weaker to any other OAB symptom, PPBC or age (Table 2).

Table 2: Non-parametric correlation of pad use and age, OAB symptoms or PPBC at baseline reported as r [95% CI] based on Spearman rank correlation.

	Study 1	Study 2
	r	r
Age	0.079 [0.022; 0.135]	0.100 [0.022; 0.177]
Urgency	0.246 [0.192; 0.299]	0.194 [0.118; 0.268]
Incontinence	0.773 [0.749; 0.795]	0.786 [0.754; 0.814]
Frequency	0.287 [0.234; 0.338]	0.321 [0.249; 0.389]
Nocturia	0.234 [0.180; 0.287]	0.237 [0.162; 0.309]
PPBC	0.286 [0.233; 0.338]	0.241 [0.165; 0.314]

Similar correlations were observed after 12 weeks of treatment in both studies (pad use vs. incontinence episodes r = 0.711 and 0.746). Correlations with other OAB symptoms or PPBC strengthened somewhat but remained moderate (e.g. pad use vs. urgency r = 0.388 and 0.367).

Discussion

Pad use is strongly correlated with number of incontinence episodes at baseline and after treatment. The moderate correlation with any other OAB symptom may reflect the relatedness among OAB symptoms. Importantly, the correlation between pad use and PPBC was also moderate only, suggesting that pad use is not a major driver of quality of life.

Conclusions

These data support the hypothesis that pad use is driven primarily by number of incontinence episodes. They suggest that pad use is not per se driving quality of life in OAB patients.

References

1. M. C. Michel et al. (2018) Neurourol Urodyn 37: S401-S402