

PATIENT PERCEPTION OF BLADDER CONDITION IS A CLINICALLY USEFUL EFFICACY MEASURE IN THE MANAGEMENT OF OVERACTIVE BLADDER

Aims of Study

Overactive bladder (OAB) is a heterogeneous condition that may include a variety of symptoms, including urinary frequency, urgency, urge incontinence, and nocturia. Previously, most trials of OAB treatments have focused on symptom improvement as assessed by micturition diary variables. However, a limitation of diaries is that not all patients present with all symptoms of OAB and that, even when present, the bothersomeness of symptoms may differ considerably between individuals. Thus, we propose that patient perception of bladder condition (PPBC) may be a more clinically relevant and useful measure of efficacy than micturition diaries in assessing patients with OAB.

Methods

Two identical 8-week multicenter open-label trials of patients with OAB were conducted in parallel in the US: in one study, patients were randomized to extended-release tolterodine (TER) 2 mg or 4 mg once daily and in the other patients were randomized to extended-release oxybutynin (OER) 5 mg or 10 mg once daily. Investigators evaluating one drug were blinded to the existence of the other drug study, to avoid any potential bias. Study centers were recruited based on IMS Health prescribing data, to ensure that the prescription tendency (frequency of writing a prescription for tolterodine ER versus oxybutynin ER) was equivalent for the two groups of centers. Centers were also chosen to ensure a fair representation in both studies of all geographical regions throughout the US. Patients were considered to have urinary frequency if they had ≥ 8 micturitions/24 h, urgency if they reported a strong and sudden need to urinate and urge incontinence if they had ≥ 5 leakage episodes/week. Improvement in PPBC was reported in patients according to symptoms, PPBC being assessed with a validated 6-point scale: my bladder condition; [1] does not cause me any problems at all; [2] causes me some very minor problems; [3] causes me some minor problems; [4] causes me (some) moderate problems; [5] causes me severe problems; [6] causes me many severe problems. Reported symptoms were also compared with those from a managed care database of OAB patients (BCBS).

Results

In the tolterodine ER and oxybutynin ER trials, frequency (F) was reported by 59% and 60%, urgency (U) by 61% and 59% and urge incontinence (UI) by 57% and 51% of patients, respectively (nocturia not reported). In the BCBS database, F was reported by 58%, UI by 33% and nocturia by 9% of patients. Urgency was not reported due to the lack of a diagnostic code and it is likely that the majority of urgency episodes were reported as frequency. Proportions of patients reporting improvements in PPBC by baseline symptoms in the 2 clinical trials were:

| | F | U | UI | F + U |
|----------|--------------|--------------|--------------|--------------|
| TER 2mg | 103/185; 56% | 94/190; 49% | 103/185; 56% | 61/124; 49% |
| TER 4mg | 120/188; 64% | 121/193; 63% | 114/171; 67% | 76/130; 58% |
| OER 5mg | 97/178; 54% | 88/168; 52% | 75/141; 53% | 56/116; 48% |
| OER 10mg | 89/165; 54% | 87/172; 51% | 75/141; 53% | 50/108; 46% |
| | F + UI | U + UI | F + U + UI | All Subjects |
| TER 2mg | 66/119; 55% | 70/141; 50% | 50/97; 52% | 188/313; 60% |
| TER 4mg | 67/108; 62% | 84/137; 61% | 53/93; 57% | 222/316; 70% |
| OER 5mg | 50/101; 50% | 57/112; 51% | 43/86; 50% | 172/286; 60% |
| OER 10mg | 46/100; 46% | 53/117; 45% | 34/81; 42% | 170/285; 59% |

Conclusions

Data from these trials clearly demonstrate the diversity of symptoms in patients with OAB. PPBC can function as a unifying index of efficacy in a symptom-heterogeneous OAB population since an improvement indicates successful treatment irrespective of individual symptomatology. PPBC is a clinically useful and relevant measure in OAB.