

ASSESSING OUTCOMES IN OAB: WHAT IS THE WAY OF THE FUTURE?

Hypothesis / aims of study

Over the past two decades, traditional outcome measurement of overactive bladder (OAB) symptoms has been based on the 'gold standard' bladder diary supplemented with various psychometrically tested patient reported outcome (PRO) measures. Although diary measures have proven useful in clinical research, challenges have been noted in their implementation: A training or self-monitoring effect in the completion of diaries and the complexity of a daily diary are good examples. Also noted is a strong correlation between diaries and various patient reported outcome measures; which may indicate that a PRO could serve as an alternative, possibly more patient-centric and comprehensive endpoint measure. In order to determine the best future measurement strategy in OAB the aim of this literature review was to assess the use of a PRO as an alternative or complementary tool to a bladder diary in clinical research and clinical practice.

Study design, materials and methods

We conducted a review of the OAB literature available in the online PubMed database. The main goal of the search was to identify articles that examined the utility of daily bladder diaries compared with other patient reported outcomes measures. Inclusion criteria were: (1) published within the last ten years (2004-2014); (2) written in English language; and (3) contain key search terms in the title or abstract. Key search terms were: "overactive bladder", "lower urinary tract dysfunction", "lower urinary tract symptoms", "urinary incontinence", "urge urinary incontinence" AND "randomized controlled trial", "bladder diary", "voiding diary", "urinary diary", "patient-reported outcomes", "patient satisfaction", "placebo-effect", and "quality of life". In addition, we examined literature in other disease areas where daily diary completion is common to determine how outcomes are assessed (i.e., interstitial cystitis, restless leg syndrome, migraine and chronic pain).

Results

The review of the literature reveals the ongoing discussion regarding recommended endpoints in OAB and appropriate ways to measure OAB response. For example, experts of the International Consultation on Incontinence Research Society (ICI-RS) have highlighted the need for inclusion of a global measure in all outcome evaluations in order to increase comparability and standardize the scope of assessment between different treatment evaluations and different populations. The ICI-RS recommends the evaluation of satisfaction, symptoms, HRQoL, and adverse events as necessary elements of a minimum outcome measure dataset. The review also noted:

1. A lack of psychometric validation of existing bladder diaries [1];
2. The potential for increased placebo response and variability in clinical trials due to bladder diary training effects[2];
3. A strong and positive correlation between OAB PRO measures and bladder diaries and other outcome measures [3];
4. Good correspondence between weekly recall and daily diary assessments in other therapeutic areas.

Interpretation of results

This literature review summarizes the existing issues with the traditional use of bladder diaries as endpoints in the treatment of OAB syndrome. Most significantly, the results highlight the unique contribution (and limitation) that bladder diaries may contribute to the placebo effect and variability in pharmacologic treatment of OAB in clinical trials. The authors of this study support this claim as they believe bladder diaries allow for a unique "training effect" and visual feedback that educates the patient to change their behaviour and subsequently influence treatment outcomes. Instead, they hypothesize that the development of a new PRO, completed less frequently, as an alternative to bladder diaries would allow for better understanding of the efficacy of OAB treatments, reduce patient burden and decrease the high placebo effect observed in trials of OAB.

Concluding message

Strong correlations between existing OAB symptom measures and bladder diaries support our stance that other PROs might provide an alternative to bladder diaries as main endpoints in clinical trials and real world studies. We acknowledge, however, that issues with current PRO instruments do exist. Therefore, we propose a new, composite, multidimensional PRO measure that would correlate strongly with all aspects of a bladder diary, and would also quantify OAB symptoms as well as incorporate the evaluation of patient satisfaction and HRQoL. This would not only decrease the documented burden of bladder diary reliance, but would create a new patient-centered measure that would increase comparability of outcomes in OAB studies.

References

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2. 2 Magera A, Chapple CR, Kopp ZS, Pledsted M. The placebo effect in overactive bladder syndrome. *Nature Reviews Urology*. 2011;8:495-503
3. 3 Homma Y, Kakizaki H, Yamaguchi O, Yamanishi T, Nishizawa O, Yokoyama O, Takeda M, Seki N, Yoshida M. Assessment of overactive bladder symptoms: comparison of 3-day bladder diary and the overactive bladder symptoms score. *Urology*. 2011;77(1):60-64.

Disclosures

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