

MINIMAL MEANINGFUL CHANGE IN URINARY INCONTINENCE FREQUENCY DETECTED BY A QUALITY OF LIFE ASSESSMENT TOOL IN OVERACTIVE BLADDER SYNDROME WITH URGE INCONTINENCE

Hypothesis / aims of study

Overactive bladder syndrome (OAB) is symptom complex with urgency, frequency with or without urge incontinence. Quality of life (QOL) is impaired in OAB, especially OAB with urge incontinence. Therapeutic effects on OAB with urge incontinence have been usually estimated by the reduction in frequency of urinary incontinence. However, the minimal meaningful change of incontinence frequency has not been well studied. We examined a meaningful change of incontinence frequency in OAB patients, using improvement in QOL as the index.

Study design, materials and methods

The patients enrolled for the randomized, double-blind, placebo-controlled study on oxybutynin transdermal patch (n=165) were used for the analysis. The eligibility criteria included age 20 years or more and OAB with urge urinary incontinence 7 times a week or more. They were treated with oxybutynin transdermal patch of 26cm² (n=165), 39cm² (n=165), 52cm² (n=162), or dummy patch (placebo) (n=167) for 8 weeks. QOL was quantified by King's Health Questionnaire (KHQ) for 8 domains (general health, incontinence impact, role limitations, physical limitations, social limitations, personal relationship, emotion, sleep/energy), with each domain scored from 100 (worst) to 0 (best). The tool was validated in Japanese patients with urinary incontinence and OAB [1]. The primary end point of the study is reduction in the number of incontinence frequency from the baseline (during the preceding one week before treatment) to the final week (during the 8th treatment week). The relation of change in QOL measures with reduction in incontinence frequency was examined.

Results

The mean reduction in weekly incontinence frequency was 11.8 regardless of treatment groups. The mean reduction (improvement) of QOL scores was 4.0, 20.1, 15.9, 17.1, 8.8, 5.7, 16.8, and 12.5 in the domain of general health, incontinence impact, role limitations, physical limitations, social limitations, personal relationship, emotion, sleep/energy, respectively. For convenience, 3 domains related to limitations (role limitations, physical limitations, and social limitations) and 2 domains related to emotion (emotion and sleep/energy) were shown together in figure 1 and 2, respectively. General health and incontinence impact were not considered, because they have only a single item for calculation. In addition personal relationship was least responsive to therapy and neglected in the further analysis. When QOL improvement was plotted against the reduction of incontinence frequency, reduction of more than 3 times a week appeared as the threshold for QOL change in terms of both limitations and emotion. When % change rather than reduction in incontinence frequency was considered, % change more than 30% seemed as the threshold for QOL change (figure 3 and 4), although the threshold was less visible compared with reduction (figure 1 and 2).

Interpretation of results

The QOL domains of role limitations, physical limitations, social limitations emotion and sleep/energy were responsive to therapy for OAB. Reduction in incontinence frequency by 3 times a week or by 30% decrease, although the latter is less evident, would be a minimal meaningful change for the patients of OAB with urge incontinence.

Concluding message

Reduction in incontinence frequency by 3 times a week is a minimal meaningful change for OAB patients.

References

1. Reliability and validity of King's Health Questionnaire in patients with symptoms of overactive bladder with urge incontinence in Japan. *Neurourol. Urodynam.*, 23. 94 -100, 2004.

Fig.1: QOL Improvement (Limitations) and Reduction in Incontinence Frequency

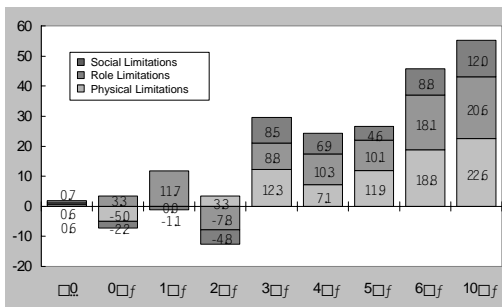


Fig.2: QOL Improvement (Emotion) and Reduction in Incontinence Frequency

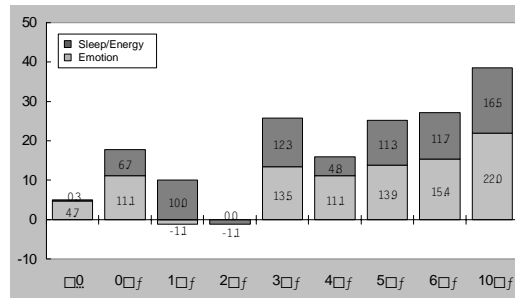


Fig.3: QOL Improvement (Limitations) and % Change in Incontinence Frequency

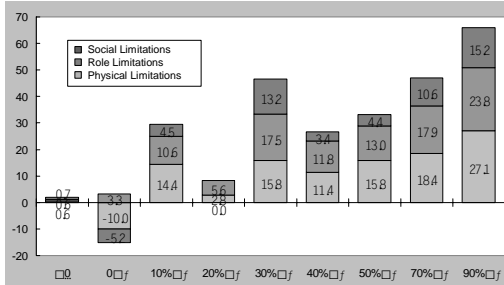


Fig.4: QOL Improvement (Emotion) and % Change in Incontinence Frequency

