213

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COMPREHENSIVE HEALTH-RELATED QUALITY OF LIFE IS INFLUENCED BY NOCTURIA AND SLEEP DISTURBANCE: INVESTIGATION BASED ON THE SF-8.

Hypothesis / aims of study

Health-related quality of life (HRQOL) questionnaires can be classified as comprehensive or disease-specific. The Medical Outcomes Study 8-item Short Form Health Survey (SF-8), a typical comprehensive questionnaire, is very practical for evaluation of the actual condition of patients and their clinical response in combination with other questionnaires because of its simplicity. Few studies have evaluated the influence of nocturia and sleep disturbance on comprehensive HRQOL using the SF-8. In this study, we investigated the influence of nocturia and sleep disturbance on HRQOL by the SF-8 in patients with nocturia (Study 1). We also assessed therapeutic intervention of an anticholinergic agent on the SF-8 (Study 2).

Study design, materials and methods

One hundred and eighty-four patients who voided at least once per night were surveyed in Study 1. The SF-8 includes 8 subscales (physical functioning: PF, role physical: RP, bodily pain: BP, general health: GH, vitality: VT, social functioning: SF, role emotional: RE, and mental health: MH), and 2 summary scores (physical health component summary score: PCS and mental health component summary score: MCS). The score for each subscale, the PCS, and the MCS were calculated by using the norm-based scoring method (the mean score and standard deviation of the general Japanese population are 50 and 10, respectively). For evaluation of sleep disturbance, the global and component scores of the Pittsburgh Sleep Quality Index (PSQI), and the total score of the Epworth Sleepiness Scale (ESS) were investigated. Cut-off values of 5.5 for the PSQI and 11 for the ESS have been established as defining the presence/absence of sleep disturbance.

Study 2 was performed in 51 patients with nocturia associated with OAB. Imidafenacin, a novel anticholinergic agent; its superiority to placebo and noninferiority to propiverine have been demonstrated in placebo- and propiverine-controlled clinical studies, and it has been marketed in Japan since 2007, was administered at a dose of 0.1-0.2 mg twice daily for 12 weeks. The effect of the drug was investigated at baseline and every 4 weeks during the treatment period by using the SF-8, PSQI, and ESS. For statistical analysis, the Jonckheere-Terpstra trend test, or the Wilcoxon signed-rank test was used according to the data. In all analyses, $p<0.05$ was considered to indicate significance. The clinical study design has been posted at http://www.umin.ac.jp/ctr/ (Unique ID UMIN000004341).

Results

The SF-8 PCS showed a significant decrease along with an increasing night-time frequency. The MCS values were 47.1 and 47.6 (which were lower than the standard value of 50) in the group with a night-time frequency of 1 (1/night group) and ≥ 3/night group, respectively. There was a negative association with an increasing night-time frequency for the PCS and 6 subscales of the SF-8 (shown in Fig.1). In addition, with an increase of night-time frequency, the PSQI global score showed a significant increase. In the ≥ 3/night group, the mean score was 7.28, which exceeded the cut-off value of 5.5. Similarly, the PSQI component scores for sleep quality, sleep efficiency, and sleep disturbance showed an significant association with the night-time frequency.

Nocturia associated with OAB was significantly improved after treatment of imidafenacin, and SF-8 scores, both PCS and MCS and several subscales, were also improved (shown in Fig.2). The PSQI global score was decreased from 6.51 ± 4.10 at baseline to 5.44 ± 3.22 at 12 weeks and the scores at 4, 8, and 12 weeks were below the cut-off value of 5.5. The ESS total score was changed from 5.55 ± 3.98 to 4.40 ± 2.92. The PSQI component scores for sleep quality and sleep latency were also significantly decreased after 4, 8, and 12 weeks compared with those at baseline.

Interpretation of results

The SF-8 allows us to compare HRQOL between patients with different diseases and also to make international comparisons of diseases. In Study 1, patients who voided twice/night had a PCS of 44.7 and an MCS of 50.8, while those voided ≥3 times/night had a PCS of 43.1 and an MCS of 47.6. These values are similar to or lower than those obtained in patients with diabetes (47.20 and 48.22, respectively), hypertension (48.33 and 49.32, respectively), and osteoarthritis (45.73 and 49.16, respectively) by a study performed in the US[1], or those for outpatients with cancer (44.3 and 47.6, respectively) obtained in Japan[2]. It is noteworthy that patients voided ≥3 times/night had a very low PCS score, which was similar to that of cancer patients. This indicates that nocturia can seriously impair HRQOL and requires therapeutic intervention. The results of Study 1 showed that an increase of the night-time frequency is associated with the deterioration of Sleep quality, rather than a decrease of Sleep duration. A qualitative factor, rather than a quantitative factor, contributes to sleep disturbance.

We used imidafenacin to treat nocturia and sleep disturbance in patients with OAB and evaluated the influence of this intervention on HRQOL. Imidafenacin significantly improved the night-time frequency, PSQI, and ESS, as well as the SF-8 score. In general, comprehensive scales are considered to be less appropriate for assessing the effect of medical intervention on specific diseases compared with disease-specific scales. However, a therapeutic effect of imidafenacin was detected in the present study by the SF-8, a comprehensive scale, which suggests that the SF-8 can be used to monitor HRQOL in OAB patients receiving treatment for nocturia. In other words, this study revealed nocturia was a great impact on HRQOL.

Concluding message

This is the first study using the SF-8 to show that nocturia and sleep disturbance have a major influence on comprehensive HRQOL as well as other chronic disease such as diabetes, hypertension, and even cancer in outpatients. Imidafenacin is effective in improvement of HRQOL, nocturia and sleep disturbance.

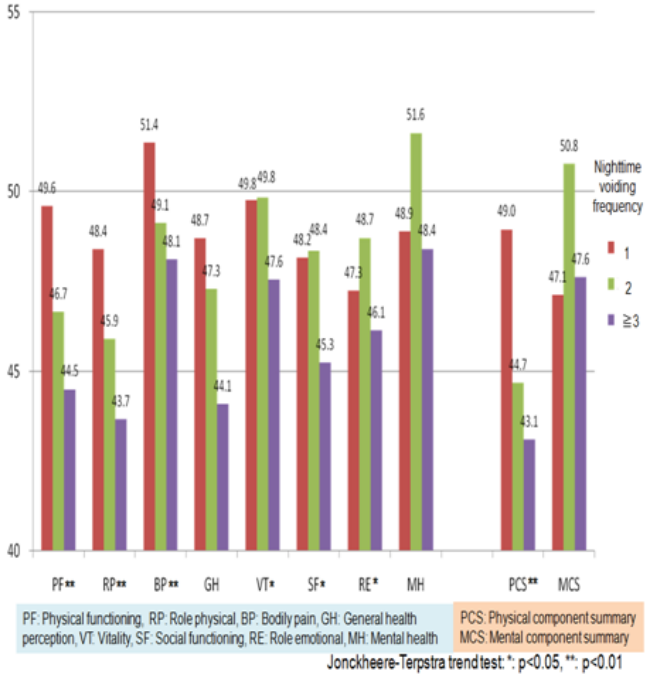

Fig. 1. SF-8 scores stratified by the OABSS nighttime voiding frequency score.

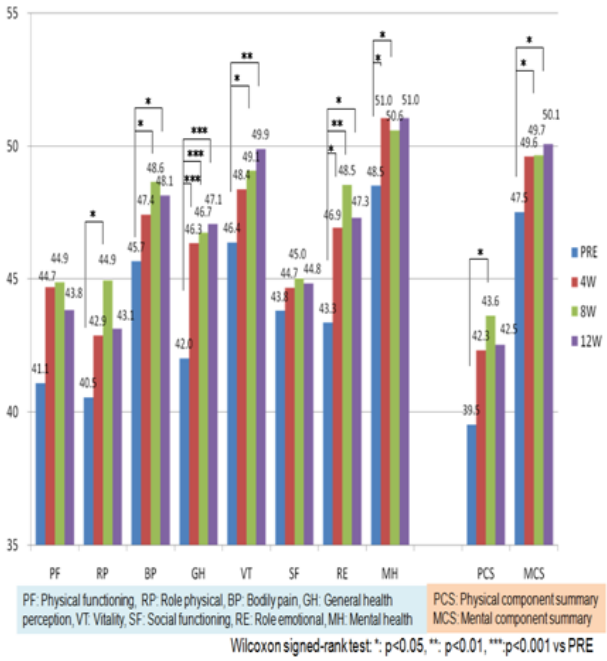

Fig. 2. Changes in SF-8 scores in OAB patients with nocturia treated with imidafenacin.

References

1. Qual Life Res 12: 1003-1012, 2003
2. Anticancer Res 27: 1127-1132, 2007

Disclosures

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