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Title: ASSESSMENT OF QOL IMPAIRMENT BY URINARY INCONTINENCE - COMPARATIVE STUDY AND CULRUAL ADAPTATION OF 3 VALIDATED INSTRUMENTS

Aims of study:

There are several validated instruments for the assessment of Quality of Life (QOL) impairment in urinary incontinence. However, no study has been conducted to compare validity of these instruments in a single population of patients or to examine their cultural adaptability in Asian people.

Methods:

Consecutive 217 incontinent patients (192 females and 25 males, mean age of 61.2 years) and 15 continent controls (13 females and 2 males, mean age of 63.7 years) were recruited for the study. They were administered with a questionnaire addressing urinary symptoms and associated overall satisfaction index, an instrument to measure generic QOL, Short Form 36 (SF36), and then 3 questionnaires on incontinence-specific QOL, i.e. Incontinence Impact Questionnaire (IIQ), Incontinence Quality of Life (IQOL), and King's Health Questionnaire (KHQ). These QOL questionnaires had been translated into Japanese in a linguistically valid manner, which consisted of forward translation, backward translation, and negotiation with the original authors followed by in-depth consultation with patients. The sequence of administrating these questionnaires was randomly assigned. Questionnaires were repeated with a 2-week interval to assess reproducibility in 30 patients who were assumed to undergo no symptomatic change during the period. In 72 patients receiving any forms of therapy the questionnaires were examined again 1 month or more post-treatment to evaluate the responsiveness of questionnaire to treatment. The patients were grouped as stress incontinence (n=141), urge incontinence (n=50), mixed incontinence (n=26) based on symptoms. One-hour pad test, cystometric capacity, and Valsalva leak point pressure were used as the external criteria, when available. Statistical analysis was conducted using SAS software.

Results:

Response was obtained in nearly 100% of questions except for items on sexual life; 21% of subjects did not respond to such questions in IIQ and IQOL, and 1% did not respond and as high as 52% checked " not applicable" in KHQ. Floor effect, which was arbitrarily defined as more than a half responding no negative impact by incontinence, was found for questions asking impact on family life, inviting or meeting friends, sleep disturbance, choice of dressing, frustration and anger. It was additionally observed for volunteer activity and sexual life, when no response was included in the floor.

Principal component analysis showed a similar result for 3 instruments; the first factor that correlated

positively with all items explained more than 50% of all scores. Factor analysis and cluster analysis demonstrated that IIQ and IQOL consisted of 2 dominant sub-scales: one of physical limitations and the other of psychological or emotional impact. KHQ appeared differently in that the sub-scale of personal relations emerged first and then physical limitations and psychological impact dispersed. Common to the instruments the domain of physical limitations was further divided into genuine physical limitations and social limitations or role limitations related with social life. The domain of psychological impact was similarly separated into genuine psychological impact and social limitations. Hence the items aggregated into social limitations in the original reports were not readily isolated and mixed up with items categorized as either physical limitations or psychological impact in Japanese people. The aggregated scale and sub-scales had high internal consistency, as Cronbach's alpha was larger than 0.8, and correlated each other irrespective of the belonging instruments ($r > 0.6$). This was true whether the sub-scales were those that were postulated in this study or had been presumed in the original reports. Criterion validity was confirmed by modest relation ($r > 0.4$, mostly > 0.6) between these QOL scales and sub-scales of SF36, pad test results, frequency of incontinence, symptom score or satisfaction index. The association with external criteria was most evident with the sub-scale of physical limitations. Discrimination from control individuals was obvious for any items. Reproducibility was acceptable, as weighted kappa values were larger than 0.55 for almost all items, with 0.7 or larger for aggregated scores. Regarding responsiveness to the treatment effects the instruments are almost equally sensitive, and sub-scales or items related to physical limitations were most sensitive throughout the instruments. By contrast sleep disturbance, social life and personal relations were less sensitive to the change. These observations were consistent among the types of incontinence.

Conclusions:

These results demonstrated that the three instruments to measure QOL impairment in urinary incontinence would be equally valid, sensitive and interchangeable. However, the patients gave no answer or an answer "no impact" to some items, and the sub-scale structures might be too conceptualized to afford high inter-cultural adaptability in Asian people. A shortened questionnaire consisting of selected items to measure predominately physical limitations and psychological impact would be more relevant to QOL, practical in use and adaptable to different cultures.