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„Psychometric properties of generic questionnaires to assess health-related quality of life"

Summary

Background

Assessment of the health-related quality of life (HRQoL) has gained importance in recent years, which is reflected in the standardization of reporting of the patient-reported outcomes measures by the international consortium ICHOM. Health-related quality of life is a latent variable and cannot be measured and interpreted directly. For the indirect measurement of HRQoL, questionnaires are used. The assessment of HRQoL is most often inferred based on the results of the range of physical, mental, or social limitations of the respondents. There are generic (non-specific) instruments and specific ones designed to be used in a defined patient population. Before the questionnaire is included in a study or used in clinical practice, it should be validated. The assessment of psychometric properties (i.e., validation) involves checking to what extent – in a given clinical situation and a specific population – the questionnaire results present a realistic assessment of the HRQoL from the respondents. According to the COSMIN guidelines, three psychometric properties are most often analyzed, i.e., validity, reliability, and sensitivity.

Aim of the thesis

The primary aim of the doctoral dissertation was to analyze the psychometric properties of the EQ-5D questionnaire and to analyze the properties of the SF-12 questionnaire in the general population of Poland. An additional question about diabetes used among the survey respondents also allowed to study the psychometric properties of the EQ-5D questionnaire in this specific population (additional goal of the doctoral dissertation).

Assumptions and methodology of work

The publications assessing the psychometric properties of the EQ-5D questionnaires (in the general population and patients with diabetes) and SF-12 (in the general population) were based on the results of a cross-sectional survey conducted with the

support of the Center for Public Opinion Research Foundation (CBOS) under the omnibus survey. The study population was a random sample of the general population of Poland, the representative for the entire country, drawn from the PESEL database. In addition to filling in the Polish language versions of the EQ-5D-5L, EQ VAS, SF-12 and EQ-5D-3L questionnaires in an order mentioned above, the respondents also answered demographic, socio-economic, and health questions (diabetes, smoking cigarettes). The following psychometric properties were assessed in the studies: construct validity (including validation in the known-groups), convergent validity, reliability (internal consistency with the SF-12 questionnaire), sensitivity (ceiling/floor effects), informativity power and inconsistency in the case of comparing the EQ-5D-5L with the EQ-5D-3L version.

Results

In the validation study of the EQ-5D-5L questionnaire in the general population of Poland from March to June 2014, 3,978 people (aged 18–87, 53.2% of women) were examined. The extension of the scale in the EQ-5D-5L version reduced the ceiling effect (from 46.6% to 38%), with a coherent redistribution of results in individual dimensions (the mean inconsistency did not exceed 5%). The construct validity of the questionnaire was positively assessed based on the results of known-groups validation and an innovative approach to validity analysis based on the use of machine learning techniques.

The validation analysis of the SF-12 questionnaire in the general population of Poland included 3,896 respondents (mean age 48.3 years, 53.2% women). No ceiling/floor effect was observed for the summary components of PCS and MCS. High internal consistency was confirmed, exceptional informativity power for the scales was noted, and construct validity was positively assessed based on the known-groups validation and the results of the exploratory factor analysis.

The EQ-5D-5L validation among respondents with diabetes was carried out in a population of 247 respondents. A 34.5% reduction in ceiling effect was demonstrated in the EQ-5D-5L version compared to the EQ-5D-3L one. Informativity power has improved in two dimensions: mobility and pain/discomfort. The construct validity was positively assessed based on the known-groups validation results in groups differing in sex, age, education level and diabetes treatment declaration, as well as the

convergent validity based on the assessment of correlation coefficients between the EQ-5D-5L, EQ-5D-3L dimensions and SF-6D scales.

Discussion and summary

The results of the analysis of the psychometric properties of the EQ-5D and SF-12 questionnaires in the general population indicate that mentioned instruments are reliable tools in assessing health-related quality of life. Construct validity of both of them was positively evaluated based on the known-groups validation, as well as an innovative approach using machine learning techniques (EQ-5D) and factor analysis (SF-12). The results of Cronbach's alpha-coefficients for SF-12 indicate the internal consistency of the questionnaire (reliability analysis). The analysis of the correlation coefficients also showed a convergent validity of both instruments. It was shown that the scale extension in the EQ-5D-5L version reduced the ceiling effect compared to the EQ-5D-3L version. On the other hand, the ceiling/floor effect was not observed for the summary components of the PCS and MCS of the SF-12 questionnaire.

Both in the case of the analysis of the EQ-5D and SF-12 questionnaires, these are the first validation studies in the general population of Poland and the first in a country from Central and Eastern Europe. It gives a chance for the transferability of the obtained results among other countries with similar socio-economic characteristics to Poland. Psychometric analyses were carried out based on the results from the same research samples obtained simultaneously (direct comparison), which significantly increases the credibility of the assessment of construct validity. The EQ-5D index values calculated in the study come from the directly measured value set, which is not the case in other studies comparing the EQ-5D-5L version of the questionnaire with the EQ-5D-3L, which also increases the reliability of the results from the analysis.

The validation analysis of the EQ-5D questionnaire in the population of respondents with self-reported diabetes showed its good psychometric properties both in the descriptive system and in the estimated index results. This study supports the credibility of this tool in the HRQoL assessment, showing that although it is a generic questionnaire, it can be used in a clinically specific population.