QUALITY OF LIFE ASSESSMENT IN PATIENTS WITH CHRONIC KIDNEY DISEASE

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INTRODUCTION

Due to the increasing number of patients suffering from end-stage renal disease, the high mortality, the life-long care and the increasing treatment costs, more and more studies are focusing on those psychosocial aspects, which are considered to be in relation to the patients’ condition and quality of life.

Numerous tools have been developed and validated to assess these factors, including generic and disease specific questionnaires.

While this problem has been widely investigated on international level, there is little data available in Hungary about this issue. This is partly due to the lack of specific, validated Hungarian quality of life questionnaires, that can be used to assess both generic and kidney disease specific domains of quality of life and in addition widely used, which is important for the comparison of the data.

The Kidney Disease Quality of Life (KDQOL-SF™) questionnaire is a widely applied tool in nephrology, that was used in several large, multinational studies to assess quality of life in populations with chronic kidney disease. However the questionnaire was translated to several languages, the appropriate psychometric validation of these local versions were rarely published.

In my research work the basic psychometric characteristics of the Hungarian version of the KDQOL-SF™ questionnaire were determined and subsequently I analysed the data obtained with the questionnaire from different kidney disease populations.
OBJECTIVES

In my PhD dissertation my intention is to present the results from my studies aimed to assess the different factors associated with the quality of life of patients with chronic kidney disease. First we developed the Hungarian version of a modular quality of life questionnaire widely used in nephrology and determined it’s basic psychometric characteristics. Further on - applying this questionnaire – we assessed the relationship between certain sociodemographic and clinical parametres and comorbidity, and patients’ quality of life or particular components of quality of life.

My goal was to verify the following hypothesis in the studies:

1/ The Hungarian version of the Kidney Disease Quality of Life modular quality of life questionnaire (KDQOL-SF™) is reliable and valid tool to assess the quality of life of patients on hemodialysis.

2/ The Hungarian version of the Kidney Disease Quality of Life modular quality of life questionnaire (KDQOL-SF™) is reliable and valid tool to assess the quality of life of patients after kidney transplantation.
3/ In patients on hemodialysis elder subjects report worse quality of life than younger, especially along physical dimensions.

4/ In hemodialysed patients the serum albumin level (a marker of general, clinical condition) and comorbidity strongly correlates with physical dimensions of quality of life.

5/ In hemodialysed patients the degree of anaemia predicts significantly the patients’ health related quality of life.

6/ In patients on hemodialysis the subject’s general perception and the degree of illness intrusiveness correlates with comorbidity.

7/ The degree of illness intrusiveness is more considerable amongst female patients.
METHODS

Validation of the Hungarian KDQOL-SF™

In this study the basic psychometric characteristics of the Hungarian version of the Kidney Disease Quality of Life Questionnaire (KDQOL-SF™) questionnaire were determined in patients on hemodialysis and after kidney transplantation.

To our knowledge, the Hungarian KDQOL-SF™ is the first quality of life questionnaire which includes disease specific part and also validated in Hungarian. The original version of the questionnaire was translated by the Functional Assessment of Chronic Illness Therapy (FACIT) group according to an internationally accepted method. Based on the comments received during the early pilot study, the Hungarian version of the KDQOL-SF™ was finalised after two minor modifications.

After the above mentioned early test of the questionnaire the basic psychometric characteristics of the Hungarian version were determined by collecting data on different kidney disease populations.

One study group was formed by including patients, who are dialysed for more than 3 months, from 9 dialysis units in Budapest.
The second group consisted of 418 patients randomly selected from 942 patients treated at the Semmelweis University Budapest, Transplantation and Surgery Clinic.

The battery of questionnaire that was completed by the patients consisted of the Center for Epidemiologic Studies-Depression (CES-D) questionnare used for the assessment of depressive symptoms, as well as of the KDQOL questionnaire. Patients were completing the questionnaires either during dialysis sessions or – in case of transplanted patients – waiting for their regular checkups.

In addition to the questionnaires, basic demographic and laboratory data (serum albumin, hemoglobin) were collected from the patients. In the kidney transplanted population, patients were grouped based on estimated GFR according to Kidney Disease Outcomes Quality Initiative (K/DOQI) criteria.

**Study assessing different factors associated with the quality of life in patients with end-stage renal disease.**

In this part of our research, factors associated with chronic kidney patients’ quality of life have been analysed in two separate studies. In the first study, 257 patients – all patients from four dialysis units in Budapest who were not on the transplantation list – completed a battery of questionnaire, which included the Hungarian version of the Kidney Disease Quality of Life Questionnaire. In
addition, in frame of the TransQol-HU cross-sectional Qol study, 214 patients from 9 dialysis centres have completed a similar battery between August 2002 and February 2003. Demographic parameters (age, gender) and anamnesis (cause of kidney disease, diabetes and other comorbid conditions) were recorded when patients were included in the study.

In the second study focusing on factors associated with quality of life, 78 patients on long term dialysis have completed a set of questionnaires containing tools assessing the presence of sleep disorders, the patients’ general health perception and the degree of illness intrusiveness.

Basic socio-demographic and laboratory parameters were collected. Patients were completing the questionnaires either during dialysis sessions or – in case of transplanted patients – waiting for their regular checkups.

If needed, a trained nurse helped the patients to complete the questionnaire. Patients’ health perception – which proved to be an important component of health related quality of life - was measured by the EuroQol visual analogue scale, whereas the degree of illness intrusiveness was assessed by the Hungarian version of the Illness Intrusiveness Ratings Scale.
RESULTS

Psychometric validation of KDQOL-HU questionnaire

The mean scores and standard deviations of most of the sub-scales obtained in the Hungarian dialysis sample were similar to values obtained in dialysis patients during the validation of the US and the Dutch version of the instrument (although no formal statistical comparison was carried out), suggesting that comparable data can be obtained with these versions.

Results of test-retest reliability analysis showed that the test-retest correlations of the Hungarian version were above 0.6 for 7 out of 8 generic scales and 7 out of 11 kidney disease specific scales.

Internal consistency of all the generic scales was very good and the respective alpha values were quite similar in both patient populations studied. Furthermore, the closely kidney disease related domains (symptom list, effect and burden of kidney disease) and also the sub-scale assessing sleep quality yielded satisfactory characteristics both in the dialysis sample and for transplanted patients, as well. The alpha values for four sub-scales ("work status", "cognitive function", "quality of social interaction" and "social support") were lower than the recommended 0.70. Alpha values for two of these sub-scales, namely for "cognitive function" and "quality of social interaction" were less than satisfactory for the original US version. Furthermore, the "quality of social interaction" dimension...
was found to be problematic in the Dutch version of the instrument, as well.

Multiple sets of analyses were carried out to assess the validity of the KDQOL-SF™ in the transplant population. The SF-36 scores and most of the disease targeted domains showed moderate positive correlations with an overall health rating score and moderate to strong negative correlation with the CES-D score that measures psychological distress. Those dimensions that measure mental/emotional aspects of QoL correlated more strongly with the CES-D scores than those that assess physical functioning. These results support the underlying construct validity of the instrument in the transplant population.

The clinical discriminant validity of the SF-36 scales and most of the disease targeted dimensions is supported by the statistically significant differences found in the mean scores of groups that are expected to be clinically different. Quite substantial, statistically strongly significant differences were seen between the Dial and the Tx groups. Furthermore, older patients had significantly lower scores along the domains that assess physical functioning and the differences were less pronounced along the domains assessing mental aspects of QoL. We found similar results in groups formed by tertiles of the serum albumin concentration, that reflects overall clinical condition and also in groups formed on the basis of renal function in the Tx group. These results suggest that the most of the sub-scales of the KDQOL instrument are able to capture meaningful
differences between groups with significant differences in their clinical conditions that are likely to have an impact on the quality of life of transplanted patients.

In summary, we provided evidence that most of the subscales of the Hungarian KDQOL-SF™ are psychometrically sound and reliable. Validity of the instrument in kidney transplanted patients was supported by the results of several sets of analyses for both patient groups yielding significant correlations in the expected directions between KDQOL-SF™ scores versus alternative measures of different aspects of quality of life. Finally, clinically and statistically significant differences were seen along many of the assessed dimensions between patient groups that are expected to have different clinical characteristics. Consequently we propose here that the KDQOL-SF™ is a useful, reliable and valid tool that can be used to assess and compare different aspects of HRQoL in different CKD patient populations.

**Studies assessing different factors associated with the quality of life in patients with end-stage renal disease**

In the first study focusing on the analysis of factors associated with quality of life in chronic kidney patients, we assessed the relationship between patients’ age, gender, comorbidity, serum albumin level and quality of life. **Patients’ age** showed correlation with all studied subscales. For all the four studied dimensions the
correlation coefficient was negative, thus – according to our expectations – elder patients reported worse quality of life, than younger.

Having assessed the association between patients’ gender and quality of life, we found that male patients reported better quality of life along all studied dimensions than females.

Confirming our expectations we showed that patients with higher serum albumin levels and better general condition reported better quality of life than patients with lower albumin levels. The difference was more significant in the scales focusing on physical domains of quality of life.

Having analysed the association between comorbidity and quality of life with variance analysis, we found that all generic and kidney disease specific dimensions studied were significantly correlated with the number of comorbid conditions.

Patients suffering from more comorbid conditions reported worse quality of life on all quality of life dimensions than patients with less or without comorbidity. This confirmed our expectation that concomitant diseases are important determinants of patients’ health related quality of life.

Based on the results of our second study, in which we were assessing the relationship between certain sociodemographic and clinical parameters and illness intrusiveness and general health perception, we can conclude that comorbidity is significant predictor of both general health perception and illness intrusiveness. This
supports the hypothesis that comorbidity is very important component of quality of life in chronic kidney disease patients.

CONCLUSION

In my PhD work results of the psychometric validation of the Hungarian Kidney Disease Quality of Life (KDQOL-SF™) questionnaire is presented. Subsequently, results of two studies with the validated questionnaire, focusing on factors associated with quality of life of patients with chronic kidney disease are summarised.

Based on the results of my research the following findings and conclusions can be made:

1. Psychometric characteristics of the questionnaire has been determined in kidney transplanted patients for the first time.
2. Based on the results of the psychometric validation, we can conclude that Hungarian version of the Kidney Disease Quality of Life modular quality of life questionnaire (KDQOL-SF™) is reliable and valid tool to assess the quality of life of patients on hemodialysis.
3. Our data further showed that Hungarian version of the Kidney Disease Quality of Life modular quality of life questionnaire (KDQOL-SF™) is also reliable and valid tool
to assess the quality of life of patients after kidney transplantation.

4. Reliability of some of the scales have proven to be moderate, therefore it is recommended to be cautious when interpreting results on these scales in the future.

5. The results of our studies focusing on factors associated with quality of life of patients with chronic kidney disease have shown that elder patients on hemodialysis report worse quality of life than younger patients, especially along physical dimensions.

6. Based on our data we confirmed our assumption, that serum albumin level – a marker of general clinical condition – and comorbidity correlate with physical dimensions of patients quality of life in dialysis population.

7. We found in our studies, that patients’ perception on their own health status strongly correlates with comorbidity in hemodialysed patients.

8. Based on the results of our study, in which we were assessing the relationship between certain sociodemographic and clinical parameters and illness we can conclude that the degree of illness intrusiveness is more expressed in female patients and that comorbidity is significant predictor of illness intrusiveness.
The work presented above is integral part of the research activity performed by our research group, focusing on the psychosocial aspects, quality of life and sleep disorders of patients with end-stage renal disease.

With the development and psychometric validation of the Hungarian KDQOL questionnaire, a new tool became available for researchers and clinicians in Hungary, which can be used to assess quality of life in both hemodialysed and kidney transplanted patients. In addition the questionnaire can also be used in health technology assessments.

Results of our studies focusing on the association between certain factors and quality of life in patients on dialysis may provide important information to understand background of quality of life in dialysed patients and also may serve as starting point for further studies in this area.
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PUBLICATIONS RELATED TO THE PHD WORK

Original articles:


Abstracts:


Sz. Barotfi, I. Mucsi, J Rethelyi, CM Shapiro, M Novak, MS Kopp: Increased health care utilization amongst insomniacs. 17th Congress of the European Sleep Research Society, 2004 Oct 5-9, Prague


