CLINICAL STUDY

Health related quality of life in 2002 and 2015 in patients undergoing hemodialysis: a single center study

Signe de Place Knudsen, Inge Eidemak and Stig Molsted

Department of Clinical Research, Nordsjællands Hospital, Hillerød, Denmark; Department of Public Health, University of Southern Denmark, Odense M, Denmark; Department of Nephrology P, Rigshospitalet, Copenhagen University Hospital Copenhagen Ø, Denmark

ABSTRACT

Health related quality of life (HRQOL) has become a recognized outcome in studies of the treatment of patients undergoing hemodialysis (HD). The aim of this study was to assess changes in HRQOL reported by two different samples of patients undergoing HD in the same dialysis center in 2002 and 2015. Two samples of patients from the same Danish dialysis center completed the HRQOL questionnaire Kidney Disease Quality of Life version 1.3 in 2002 (n = 71) and 2015 (n = 81), respectively. The associations between KDQOL summary scores and the time frame were analyzed in multivariable regression analyses. The 2015 sample of patients were older compared to the 2002 sample (66 ± 13 vs. 59 ± 16 years, p = 0.003, respectively), they comprised more obese patients (20.6 vs. 3.2%, p = 0.002) and more patients with hypoalbuminemia (66.7 vs. 42.9%, p = 0.006). After confounder adjustment the time period 2015 versus 2002 was not associated with changes in the generic summary scales Physical Component Scale (β 3.9, 95% CI −0.1; 7.9, p = 0.051) and Mental Component Scale (β −2.5, 95% CI −7.6; 2.5, p = 0.322) or the disease specific summary scale Kidney Disease Component Scale (β 1.0, 95% CI −5.1; 7.1, p = 0.746). This study indicated an unchanged HRQOL when recent data were compared with data collected 13 years earlier in patients undergoing HD from a Danish dialysis center. We suggest that the included dialysis center monitor HRQOL and pay attention on interventions that may be associated with improvements of HRQOL and reduce the elevated frequency of patients with obesity or hypoalbuminemia.

Introduction

More studies have reported that patients with end-stage renal disease undergoing hemodialysis (HD) have a significantly impaired health related quality of life (HRQOL) compared to the general population.1–3 As the majority of patients undergoing HD are dependent on the dialysis treatment for the rest of their lives; HRQOL has become a recognized outcome measure together with objective health measurements used in treatment evaluations.3,4

In patients undergoing HD, impaired HRQOL is associated with an elevated risk of morbidity and mortality.5–7 In addition, HRQOL scores are associated with several variables including age, gender, clinical factors and treatment effects.8 Thus, improvements in clinical practice may lead to increased HRQOL scores. During the last decades there have been some changes in the treatment and care of patients undergoing HD. In the dialysis center where this study was conducted, patient education have been implemented with a focus on shared decision making. More patients are now offered more frequent or longer HD sessions than “standard”: 3 h thrice weekly. Furthermore, the treatment of calcium-phosphate metabolism and secondary hyperparathyroidism has in general been improved as a result of new agents with fewer side effects.9–11 On the other hand, during the same period the Danish patient population undergoing HD has become older in age and their level of comorbidities has been elevated12 with a corresponding increased need for care, whilst the relative number of nurses in the center where this study was conducted has been reduced. The question remains as to whether the patients’ HRQOL has changed during the same period. Mazairac and colleagues found an increased HRQOL in Dutch patients undergoing HD from 1995 to 2006.13 Another study from the US showed, however, that HRQOL was unchanged from 1997 to 2006 with the exception of an increased score
in the Short Form 36 (SF36) questionnaire scale Role Emotional.\textsuperscript{14} In the two mentioned studies, HRQOL was assessed using the generic quality of life questionnaire SF36, whereas no disease specific tool was used. Indeed, disease specific questionnaires may be more sensitive to measure differences in dialysis populations’ HRQOL. Based on the above mentioned positive and negative changes in the treatment, we hypothesized that HRQOL reported by patients undergoing HD in 2015 was not improved compared to HRQOL reported by patients undergoing HD in 2002. Thus, the aim of this study was to assess generic as well as disease specific HRQOL in patients undergoing HD from a Danish dialysis center in 2015 and to compare the HRQOL scores to data reported by another sample of patients who underwent HD in the same dialysis center in 2002. The HRQOL was assessed using the questionnaire Kidney Disease Quality of Life (KDQOL).

Materials and methods

Patients

In this study, two samples of patient undergoing HD were compared: a sample from a cross-sectional study of 2002\textsuperscript{3} and a sample from 2015. Patients in both samples were recruited from the Department of Cardiology, Nephrology and Endocrinology, Nordsjællands Hospital, Denmark. The patients were recruited after a screening of the total patient population and then through a personal contact during HD. The department’s dialysis center was in both time points placed in the same buildings in the hospital. To be included the patients should be above 18 years of age, undergoing HD for at least three month and having no hospitalization within the past month. Patients with cognitive impairment and inability to understand Danish were excluded. The patient sample from 2002 has been presented in a previous publication.\textsuperscript{3}

In the patient sample from 2015, 90 out of 152 patients undergoing HD were initially recruited to the study due to the inclusion criteria. Four of the 90 patients were excluded due to the exclusion criteria and five patients did not want to participate. Thus, 81 patients undergoing HD participated in the 2015 sample. Due to the relatively high mortality rate on 20% in Danish patients undergoing dialyses, only two patients from the 2002 sample were alive and included in the 2015 sample. All patients gave their informed consents after written and oral information about the study, and the study protocol was in accordance with the rules of the local ethical committee (H-6–2015-103) and The Danish Data Protection Agency.

Study measures

Clinical data for duration of dialysis, primary cause of renal disease, body mass index (BMI), and the two quality indicators blood (b)-hemoglobin and plasma (p)-albumin were obtained from the patients’ case records and electronic laboratory database in parallel with questionnaire completion. The BMI was measured using the patients’ post HD body weight.

The patients’ HRQOL were obtained using the Danish version of the self-administrated questionnaire the KDQOL Instrument version 1.3 (http://www.rand.org/health/surveys_tools/kdqol.html). The KDQOL is an instrument widely used with self-reported measurements that includes the generic core SF36\textsuperscript{15} and a disease specific core developed for dialysis patients.\textsuperscript{16} SF36 consists of 36 items transformed into eight dimensions of health: Physical Function, Role Limitation – Physical, Bodily Pain, General Health, Vitality, Social Function, Role Limitation – Emotional and Mental Health. Furthermore, two summary dimensions can be scored: Physical Component Scale (PCS) and Mental Component Scale (MCS).\textsuperscript{17} The disease specific core targeting particular concerns related to a life with dialysis treatment consist of 43 items transformed into nine disease specific scales: Symptoms and Problems, Effect of Kidney Disease, Burden of Kidney Disease, Work Status, Cognitive Function, Quality of Social Interaction, Sexual Function, Sleep, Social Support, and the three scales Dialysis Staff Encouragement, Overall Health and Patient Satisfaction.\textsuperscript{16} The subscales’ scores from the disease specific part of the KDQOL can be summarized in an overall Kidney Disease Component Scale (KDCS)\textsuperscript{8} by a mean score. The KDQOL data were scored according to the KDQOL manual. For each scale, a score from 0 to 100 were calculated, with a higher score indicating a more favorable HRQOL.\textsuperscript{16} The translation procedure and reliability of the Danish version of HRQOL 1.3 has been presented previously.\textsuperscript{18} The patients’ generic HRQOL were compared with data from the general Danish population collected from the Danish manual to the SF36.\textsuperscript{17} In addition, the patients were asked about their civil and employment status, and level of education, which was stratified into three levels: low level (up to 7th grade), middle level (9–10th grade or lower secondary education or middle school graduation) and high level (high school graduation).

Statistics

The summery scales PCS, MCS and KDCS were primary outcomes in three models and their residuals’ distributions were tested using Q–Q plots. The two patient
samples’ characteristics from 2002 and 2015 were compared using an unpaired Student’s t-test when data were continuous and using a Chi² test when data were categorical. An unpaired Student’s t-test was used to compare the two samples’ KDQOL scores and to compare the patients’ SF36 scores with scores from the general Danish population. The general Danish population had the same age and gender distribution as the patients’ age and gender distribution, since the patients’ data for age and gender were used as weight when the general populations’ SF36 data were collected from previously presented data.¹⁷

Multivariate linear regression analyses were used to investigate the association between the period from 2002 to 2015 and HRQOL. The summery scales PCS, MCS and KDCS were analyzed as dependent variables in the three models. Independent variables included the time period (2002 or 2015, dichotomous data), age, gender, BMI, level of education, HD duration and p-albumin. Variance inflation factors were tested in all three models and were in all cases below 2.0. Interactions between the time period and other variables were not significant and were not included in the models. As the local p-albumin analysis method was changed between the two test periods, p-albumin data from 2002 were adjusted in terms of a 12% reduction based on an internal evaluation (data not published). In addition, p-albumin data from the 2002 sample were converted from μmol/L to g/L. Data are presented as mean ± SD, percent, β with a corresponding 95% confidence interval (CI) and SE. Results were considered significant (two-tailed) when p < 0.05.

**Results**

In the 2002 sample, 77% (n = 71) of the patients undergoing HD participated in the study², and in the 2015 sample, 90% (n = 81) of the patients participated in the study. The characteristics of patients from the 2002 and 2015 samples are summarized and compared in Table 1.

| Variables          | 2002 (n = 71) | 2015 (n = 81) | p   |
|--------------------|--------------|--------------|-----|
| Age (years)        | 59 ± 16      | 66 ± 13      | 0.003|
| Gender, male (%)   | 76.1         | 67.9         | 0.265|
| Married or having a partner (%) | 52.9 | 64.6 | 0.147|
| Occupation (%)     |              |              | 0.993|
| Working full-time  | 4.2          | 3.9          |     |
| Working part-time  | 7.0          | 6.6          |     |
| Unemployed         | 2.8          | 2.6          |     |
| Retired            | 78.9         | 77.6         |     |
| Other              | 7.0          | 9.2          |     |
| Education (%)      |              |              | 0.862|
| Low                | 36.6         | 32.5         |     |
| Middle             | 39.4         | 42.9         |     |
| High               | 23.9         | 24.7         |     |
| Cause of renal failure (%) | 0.011 |
| Type I diabetes    | 4.2          | 2.5          |     |
| Type II diabetes   | 7.0          | 22.2         |     |
| Hypertensive nephropathy | 8.5 | 16.0         |     |
| Polycystic kidney disease | 2.8 | 12.3         |     |
| Glomerulonephritis | 18.3         | 11.1         |     |
| Pyelonephritis     | 5.6          | 2.5          |     |
| Intestinal nephritis | 1.4         | 0.0          |     |
| Obstructive uropathy | 8.5          | 4.9          |     |
| Nephrosclerosis     | 7.0          | 9.9          |     |
| Others/unknown     | 36.6         | 18.5         |     |
| Body mass index (kg/m²) | 23.4 ± 3.7    | 26.6 ± 5.8   | <0.001|
| Underweight, <18.5 kg/m² (%) | 6.3          | 4.4          |     |
| Normal weight, ≥18.5–<25 kg/m² (%) | 61.9         | 30.9         |     |
| Overweight, ≥25.1–<30 kg/m² (%) | 28.6         | 44.1         |     |
| Obese, ≥30 kg/m² (%) | 3.2          | 20.6         |     |
| Duration of dialysis (years) | 3.2 ± 4.9 | 3.9 ± 3.7 | 0.321|
| Blood hemoglobin (mmol/L) | 6.9 ± 0.7 | 7.0 ± 0.7 | 0.445|
| <6.5 mmol/L (%) | 19.4         | 22.2         |     |
| ≥6.5 mmol/L (%) | 80.6         | 77.8         |     |
| Plasma albumin (g/L) | 36.5 ± 3.9   | 34.1 ± 4.2   | 0.001|
| <36 g/L (%) | 42.9         | 66.7         |     |
| ≥36 g/L (%) | 57.1         | 33.3         |     |

Data are presented as mean ± SD or percent.

In the adjusted analyses, the test year (2015 vs. 2002) was not significantly associated with PCS, MCS or KDCS (Table 4). Increased BMI had a negative association with PCS with a β-coefficient that was −0.6 (95% CI −1.0; −0.1), p = 0.001. An increased p-albumin was positively associated with PCS with a β-coefficient at 0.5 (<0.1; 0.9), p = 0.043. The MCS scores were associated with a higher level of education and a longer duration of HD treatment with β-coefficients 3.3 (0.3; 6.3), p = 0.030 and 0.6 (<0.1; 1.1), p = 0.042, respectively. There were
no significant association between the disease specific dimensions summarized as KDCS and the time frame (β 1.0, 95% CI −5.1; 7.1, p = 0.746) or other included variables in the multivariable regression analysis (data not shown).

Table 2. The 2015 HD sample’s Short Form 36 scores compared to scores from an age and gender adjusted general Danish population.

| Scales                        | 2015 (n = 81) | General population (n = 4080) | p     |
|-------------------------------|---------------|-------------------------------|-------|
| Physical function             | 58.7 ± 26.0   | 76.7 ± 9.7                   | <0.001|
| Role limitation – physical    | 33.7 ± 37.9   | 68.8 ± 11.4                  | <0.001|
| Bodily pain                   | 63.6 ± 31.8   | 77.1 ± 3.9                   | <0.001|
| General health                | 44.2 ± 22.4   | 68.0 ± 5.3                   | <0.001|
| Vitality                      | 48.3 ± 26.5   | 68.2 ± 4.3                   | <0.001|
| Social function               | 73.8 ± 27.7   | 88.7 ± 4.0                   | <0.001|
| Role limitation – emotional   | 55.2 ± 40.9   | 78.3 ± 8.8                   | <0.001|
| Mental health                 | 77.0 ± 22.4   | 82.1 ± 2.5                   | 0.046 |
| Physical component scale      | 37.4 ± 10.2   | 46.7 ± 10.2                  | <0.001|
| Mental component scale        | 49.1 ± 11.9   | 54.8 ± 1.5                   | <0.001|

Data are presented as mean ± SD.

Table 3. HRQOL scores from the 2002 and 2015 samples.

| Scales                        | 2002 (n = 71) | 2015 (n = 81) | p     |
|-------------------------------|---------------|---------------|-------|
| Physical function             | 52.1 ± 28.4   | 58.7 ± 26.0   | 0.137 |
| Role limitation – physical    | 34.9 ± 39.3   | 33.7 ± 37.9   | 0.852 |
| Bodily pain                   | 70.1 ± 27.2   | 63.6 ± 31.8   | 0.184 |
| General health                | 46.1 ± 20.5   | 44.2 ± 22.4   | 0.604 |
| Vitality                      | 50.4 ± 25.5   | 48.3 ± 26.5   | 0.615 |
| Social function               | 76.6 ± 27.5   | 73.8 ± 27.7   | 0.529 |
| Role limitation – emotional   | 55.9 ± 41.3   | 55.2 ± 40.9   | 0.920 |
| Mental health                 | 77.3 ± 19.2   | 77.0 ± 22.4   | 0.925 |
| Physical component scale      | 36.5 ± 8.8    | 37.4 ± 10.2   | 0.588 |
| Mental component scale        | 50.6 ± 10.3   | 49.1 ± 11.9   | 0.422 |

Data are presented as mean ± SD.

Table 4. Multivariate linear regression analyses of independent variables’ associations with physical component scale and mental component scale.

|                | Physical component scale | Mental component scale |
|----------------|-------------------------|------------------------|
| β              | 95% CI                   | SE                     | p    | β              | 95% CI                   | SE                     | p    |
| Year (2015 vs. 2002) | 3.9                      | <−0.1; 7.9              | 2.0  | 0.051          | −2.5                      | 7.6; 2.5                | 2.5  | 0.322 |
| Age (years)     | −0.1                     | −0.2; <−0.1             | 0.1  | 0.208          | 0.1                       | <−0.1; 0.3              | 0.1  | 0.169 |
| Gender (male vs. female) | 3.4                      | −0.4; 7.2               | 1.9  | 0.075          | 2.7                       | −2.1; 7.6               | 2.4  | 0.263 |
| Body mass index (kg/m²) | −0.6                    | −1.0; −0.3              | 0.2  | 0.001          | 0.3                       | −0.2; 0.7               | 0.2  | 0.254 |
| Educational level (three levels) | <−0.1                   | −2.3; 2.3              | 1.2  | 0.993          | 3.3                       | 0.3; 6.3               | 1.5  | 0.030 |
| Duration of dialysis (year) | 0.4                     | −0.1; 0.8              | 0.2  | 0.110          | 0.6                       | <0.1; 1.1               | 0.3  | 0.042 |
| Plasma albumin (g/L) | 0.5                     | <0.1; 1.0              | 0.2  | 0.043          | 0.2                       | <0.4; 0.8               | 0.3  | 0.480 |

β-coefficient, 95% confidence interval, SE and p-value.

Discussion

The primary finding of this study was that generic and disease specific HRQOL in patients undergoing HD in a Danish dialysis center remained unchanged from 2002 to 2015. The patients’ generic HRQOL remained significantly reduced compared to the general population.

In the context of potential technical, pharmacological and non-pharmacological improvements in the clinical treatment of patients undergoing HD, these initiatives were not reflected in parallel in the patients’ HRQOL during the 13 year time frame. However, in the adjusted analysis the time period almost reached a significant association with an increase in the PCS scores (p = 0.051).

The results from this study were divergent compared to the study by Mazairac and colleagues, who showed an improvement in four generic SF36 scales in Dutch patients undergoing HD when two cohorts were compared over a 10-year time frame. The present data are, however, more in line with the results presented by Gabbay and colleagues, who only found one SF36 scale to be improved over a decade in patients undergoing HD in the US. It is, however, difficult to compare this study with the two previous studies from the Netherlands and the US, from 1995 to 2006 and from 1997 to 2006, respectively. This study covered a later period, and the different periods may be associated with different trends, which make comparisons difficult. Furthermore, HRQOL among patients undergoing HD may differ between continents.

Elevated BMI and lower p-albumin were associated with lower PCS scores. The estimates of these associations may however not be of clinical relevance. Nevertheless, the association between reduced PCS scores and elevated BMI and hypoalbuminemia corresponds to findings in other studies. Even though, that the BMI’s and p-albumin’s associations with PCS may not individually be of clinically relevance, the results of the two measurements need attention. BMI increased significantly with a great amount of overweight and obese patients in the 2015 sample compared to the 2002 sample, a trend that also was found...
in the general population recently. The increase of overweight and obese patients need attention in clinical practice as these conditions may lead to medical complications, among them type 2 diabetes. Whilst the BMI mean value increased, more surprisingly the p-albumin mean value decreased. Furthermore, 66.7% of the 2015 patients were found to have p-albumin levels below the lower limit of the dialysis center’s reference interval. We have no explanation to the present decrease in p-albumin. This finding needs, however, further attention since hypoalbuminemia is a predictor of death among patients undergoing dialysis. Thus, the patient information and patient education may need to be revised in an attempt to improve the patients’ nutritional status.

The results of this study indicated that elevated MCS scores were associated with a higher level of education. Indeed such a finding may not be surprising as other studies have reported the same relation between HRQOL and level of education. A higher level of educational status may give a more adequate understanding of the disease and treatment progress and it may also reflect a higher financial status and personal resources. The MCS scores were also found to be associated with an increased duration of dialysis treatment measured in years. A longer period of HD treatment may be associated with better HRQOL via a satisfaction or gratitude to be alive. On the other hand, the association between HD treatment duration and MCS scores may simply be the result of having more survivors among patients with a longer duration of dialysis.

The results of this study may be limited as a result of residual confounding. Clinical parameters among them phosphate may have an effect on patients’ medical condition and HRQOL. Due to limited data from the 2002 sample it was not possible to include further variables in the analyses. In addition, in the Introduction we have mentioned some changes which have occurred in clinical practice during the observed period. The study investigated, however, not causal associations between the mentioned changes in clinical practice and HRQOL. The results may also be biased by including patients undergoing HD at home in the 2015, a treatment that was not introduced in the center in the first cohort from 2002. Among strengths of the study it should be emphasized that the two samples came from the same dialysis center and that the outcome included a disease specific HRQOL core.

This study may have clinical implications in terms of an increased attention on physical activity among the patients in the center: the scores of the Physical Function and Role Limitation – Physical scales remained significantly reduced in the 2015 sample, and several studies have reported positive effects of physical activity on physical function in patients undergoing HD. Furthermore, studies have also suggested that physical activity may reduce bodily pain, which also remained reduced in the 2015 sample reported through the score in the Bodily Pain scale. Thus, future studies should investigate the effects of interventions that aim to improve physical function, and nutritional status in HD patients in relation to both obesity and hypoalbuminemia.

In conclusion, this study found an unchanged HRQOL in patients undergoing HD from a Danish dialysis center over the 13 year time period spanning 2002–2015. Compared to the general Danish population the patients undergoing HD’s HRQOL remained seriously impaired in 2015. Thus, it remains crucial to focus on interventions which may be associated with enhanced quality of life in patients undergoing HD. Based on the results of this study, an increased focus on weight loss among overweight and obese patients and an improved nutritional status may need attention in the present dialysis center.

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Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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