Cross-sectional validity of a modified Edmonton symptom assessment system in dialysis patients: A simple assessment of symptom burden

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Subjective symptom assessment should be a fundamental component of health-related quality of life (HRQL) assessment in end-stage renal disease (ESRD). Unfortunately, no symptom checklist has established reliability or validity in ESRD. We report the validation of a modified Edmonton Symptom Assessment System (ESAS) in 507 dialysis patients who concurrently completed the Kidney Dialysis Quality of Life-Short Form (KDQOL-SF) questionnaire. The ESAS demonstrated a mean of 7.5 ± 2.5 symptoms. The symptoms reported as most severe were tiredness, well-being, appetite, and pain. The overall symptom distress score was strongly correlated with the KDQOL-SF subscales symptom/problem list ($r = -0.69$, $P < 0.01$), effects of kidney disease ($r = -0.52$, $P < 0.01$), and burden of kidney disease ($r = -0.50$, $P < 0.01$), as well as lower RAND-12 physical health composite (PHC) ($r = -0.54$, $P < 0.01$) and lower RAND-12 mental health composite (MHC) ($r = -0.62$, $P < 0.001$). In the multivariate regression analysis, after controlling for potential confounding variables including comorbidity using the modified Charlson Comorbidity Index, the ESAS symptom distress score remained strongly associated with the MHC (slope = −0.82 ± 0.07, $P < 0.01$) and PHC (slope = −0.48 ± 0.07, $P < 0.01$). The ESAS symptom distress score accounted for 29% of the impairment in PHC and 39% of the impairment in MHC. The intraclass correlation coefficient for the total symptom distress score in a 1-week test–retest was 0.70, $P < 0.01$. Symptom burden is high and adversely affects HRQL in dialysis patients. The modified ESAS is a reliable, valid, simple, and useful method for regular symptom assessment in this patient population.

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Health-related quality of life (HRQL) is a critical issue in the treatment of end-stage renal disease (ESRD) and is used to assess the effectiveness of healthcare interventions. In fact, patient-reported HRQL is becoming as important as morbidity and mortality in evaluating outcomes in patients with ESRD. The relevance of HRQL is derived not only because it is a basic aspect of health, but also because a close relationship exists between HRQL, morbidity, and mortality.[1–3]

In the oncology and HIV literature, there is a clear inverse relationship between symptoms and HRQL, leading investigators to focus on decreasing symptom burden as a way to improve patient well-being.[4,5] ESRD patients are known to have a high symptom burden[6,7] yet similar work in nephrology is limited. Recent research suggests that dialysis patients' perceptions of symptom burden may be more important than objective clinical assessments in determining HRQL.[8–13] A comprehensive assessment of physical and emotional symptom burden in dialysis patients is essential if efforts to improve HRQL of this patient population are to be successful. Although many instruments currently used to evaluate the HRQL of dialysis patients have items pertaining to symptoms, a comprehensive and psychometrically tested questionnaire for the assessment of physical and psychological symptoms in this population is lacking. The tools used to evaluate symptom burden must be simple, easily understood by the patient and staff, and take little time to complete. They must also be reliable, and valid, and have sufficient sensitivity and responsiveness. Symptom checklists have been used in ESRD[14–16] but none have established reliability or validity. We report the validation of a modified Edmonton Symptom Assessment System (ESAS) in a population of dialysis patients who concurrently completed the Kidney Dialysis Quality of Life-Short Form (KDQOL-SF) questionnaire.[17]

RESULTS

Five hundred and seven of 560 eligible dialysis patients (90.5%) completed both the ESAS and the KQOL-SF. Patients were elderly (63.5 ± 16.0 years), mostly Caucasian (72.6%), on hemodialysis (89.9%), and diabetic (42.4%)

(Table 1). The majority of patients completed the surveys themselves (73.3%): 24.5% were caregiver assisted and 2.2% were completed by the caregiver (family member or nurse). Table 2 summarizes the symptom burden and HRQL scores for these patients. The ESAS demonstrated a mean of 7.5 ± 2.5 symptoms, and a mean of 4.5 ± 2.9 moderate or severe symptoms. The symptoms reported as most severe were tiredness, well-being, appetite, and pain. HRQL was also markedly impaired. The most frequently reported symptoms were tiredness (92.1%), decreased well-being (91.5%), poor appetite (83.2%), and itching (77.3%) (data not shown).

As hypothesized, we observed strong correlations between the ESAS and all the HRQL scores (Table 3). Each individual item on the ESAS was significantly correlated with the physical health composite (PHC) and mental health composite (MHC) scores: pain most highly correlated with the PHC ($r = -0.56$, $P < 0.01$) and depressed most highly correlated with the MHC ($r = -0.57$, $P < 0.01$). The overall symptom distress score was strongly correlated with the KDQOL-SF subscales symptom/problem list ($r = -0.69$, $P < 0.01$), effects of kidney disease ($r = -0.52$, $P < 0.01$), and burden of kidney disease ($r = -0.50$, $P < 0.01$) as well as lower PHC ($r = -0.54$, $P < 0.01$) and lower MHC ($r = -0.62$, $P < 0.001$) (Figure 1). Having a greater number of moderate or severe symptoms was highly associated with lower PHC and MHC scores (Figure 2). There was no correlation between biochemical markers, including K_t/V, serum albumin, hemoglobin, calcium, phosphorous, and any of the ESAS scores or HRQL measures.

In the multivariate regression analysis, after controlling for potential confounding variables including comorbidity using diabetic status and the modified Charlson Comorbidity Index, the ESAS symptom distress score remained strongly

Table 1 | Patient characteristics

	n=507	%
Age in years, mean ± s.d.	63.5 ± 16.0	
Gender		
Male	267	52.7
Female	240	47.3
Ethnicity		
Caucasian	368	72.6
Aboriginal	60	11.8
Asian	31	6.1
Pacific Islander	18	3.6
Indian Subcontinent	16	3.2
Black people	8	1.6
Mid-East/Arabian	5	1.0
Other/multiracial	1	0.2
Cause of ESRD		
DM	185	36.5
GN	103	20.3
HTN	64	12.6
PCKD	22	4.3
Reno-vascular	20	3.9
Other	71	14.0
Unknown	42	8.3
Diabetic		
Yes	215	42.4
No	292	57.6
Dialysis modality		
Hemodialysis	456	89.9
Peritoneal dialysis	51	10.1
Years on dialysis	3.4 ± 2.8	
Charlson comorbidity Index	7.1 ± 2.8	

DM, diabetes mellitus; ESRD, end-stage renal disease; GN, glomerulonephritis; HTN, hypertension; PCKD, polyaptic kidney disease.

Table 2 | Symptom burden and HRQL scores

	Mean ± s.d.	*n*=507 (%)
ESAS symptoms		*Moderate or severe symptom*
Tired	5.1 ± 2.7	374 (73.8)
Well-being	4.2 ± 2.5	305 (60.2)
Appetite	3.7 ± 2.7	246 (48.6)
Pain	3.6 ± 3.1	241 (47.7)
Itching	3.6 ± 3.1	232 (45.8)
Drowsy	3.4 ± 2.8	226 (44.6)
Anxious	2.9 ± 2.9	196 (38.7)
Depressed	2.8 ± 2.8	195 (38.5)
Shortness of breath	2.6 ± 2.8	171 (33.8)
Nauseated	2.1 ± 2.5	128 (25.2)
Total symptom distress score	34.1 ± 18.4	
Number of symptoms	7.5 ± 2.5	
Number of moderate or severe symptoms	4.5 ± 2.9	
KDQOL-SF		
RAND-12 physical health composite	35.9 ± 11.2	
RAND-12 mental health composite	38.9 ± 11.0	
Symptom/problems	70.7 ± 16.6	
Effects of kidney disease	60.8 ± 22.2	
Burden of kidney disease	31.9 ± 31.6	

ESAS, Edmonton Symptom Assessment System; HRQL, health-related quality of life; KDQOL-SF, Kidney Dialysis Quality of Life-Short Form.

Table 3 | Validity and reliability of ESAS scores and HRQL scores (all $P < 0.01$)

	Pearson's correlation coefficient		
ESAS symptom	Physical health composite	Mental health composite	Intraclass correlation coefficient[a]
Pain	−0.56	−0.43	0.70
Tired	−0.45	−0.53	0.65
Well-being	−0.41	−0.45	0.53
Drowsy	−0.35	−0.44	0.71
Shortness of breath	−0.35	−0.35	0.61
Anxious	−0.34	−0.52	0.62
Depressed	−0.32	−0.57	0.53
Appetite	−0.31	−0.34	0.57
Nauseated	−0.28	−0.27	0.67
Itching	−0.19	−0.22	0.61
Total symptom distress score	−0.54	−0.62	0.70

[a]Intraclass correlation for a random sample of one-week test-retest data (*n*=165).
ESAS, Edmonton Symptom Assessment System; HRQL, health-related quality of life.

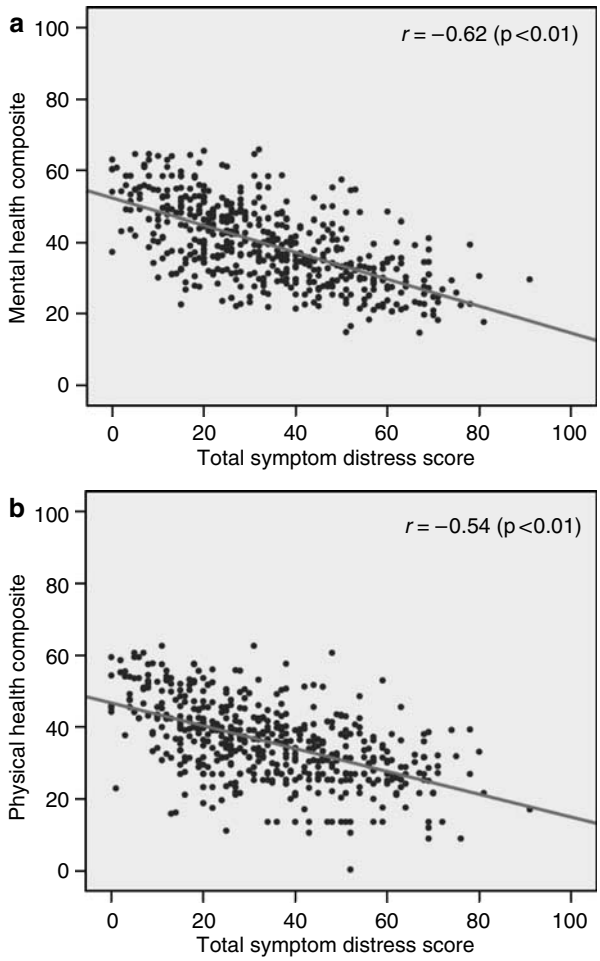

Figure 1 | Correlation between symptom burden and (a) mental and (b) physical HRQL.

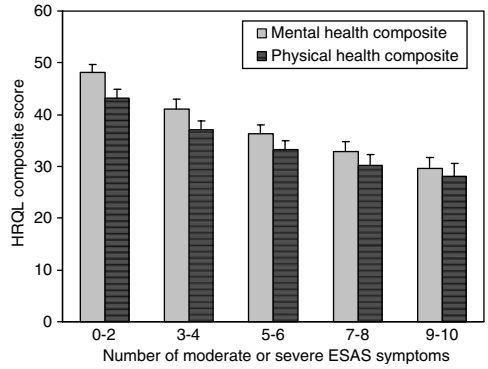

Figure 2 | Relationship between the number of moderate or severe symptoms and physical and mental HRQL.

associated with the MHC (slope = −0.82 ± 0.07, $P<0.01$) and PHC (slope = −0.48 ± 0.07, $P<0.01$). Symptom burden as described by the ESAS symptom distress score accounted for 29% of the impairment in PHC and 39% of the impairment in MHC in these dialysis patients.

A random sample of 165 hemodialysis patients participated in the 1-week test–retest of the ESAS. The intraclass correlation coefficient for the total symptom distress score was 0.70, $P<0.01$ (Table 3).

DISCUSSION

HRQL is intended to be a holistic concept, which includes physical, psychological, and social domains of health. Each domain can be expressed in different ways according to the subjective perception of each patient, resulting in a different assessment of HRQL. Therefore, two patients with similar clinical and therapeutic conditions may assess HRQL differently, because the concept is the result of the interaction between the patient's life conditions and the way in which these are perceived by the patient.[18] These perceptions may be quite different than those of the clinician. It is therefore not surprising that recent research suggests that dialysis patients' perceptions may be more important than objective clinical assessments in determining HRQL.[8–13] Subjective symptom assessment, therefore, should be a fundamental component of HRQL assessment in ESRD. Unfortunately, no symptom checklist has established reliability or validity in ESRD.

The most widely used HRQL instruments such as the KDQOL and the Medical Outcomes Study 36-Item Short form Health Survey (SF-36) do not directly assess patient self-report of troublesome symptoms. In the formal literature review for the Choices for Healthy Outcomes in Caring for ESRD, only 19% of instruments included a patient self-report of HRQL, only 13% queried symptoms, and only 8% inquired about pain.[19] Comprehensive symptom assessments may be time consuming and difficult for patients to complete. Because of the debilitated and symptomatic status of this patient population, there is need for a short, simple symptom assessment instrument that requires minimal effort from both the patient and staff.

In this cross-sectional study, we validated a modified version of the ESAS, a simple method for the assessment of physical and psychological symptoms in dialysis patients. Both overall symptom distress and the number of moderate or severe symptoms as measured by the ESAS were strongly correlated with all domains of HRQL. Prior studies of symptoms in dialysis patients, although limited, support this concept.[15,20] Symptom burden has been described to account for one-third of the impairment observed in HRQL in dialysis patients.[20] This is consistent with the findings in this study where 39% of the mental and 29% of physical HRQL, as measured by the MHC and PHC, respectively, was accounted for by the ESAS overall symptom distress score. The lack of significant association between various clinical parameters and HRQL reinforces the relative importance from a patient perspective of symptom burden on their perception of HRQL. These data add to the increasing evidence suggesting that the symptom burden of dialysis patients is tremendous and that this burden has a significant negative impact on patients' HRQL. The number and severity

of symptoms reported by our patients is similar to that reported by patients hospitalized in palliative care settings with cancer.[21]

There are several limitations to the current study. Participants were recruited from a single program and were primarily Caucasian, potentially limiting the generalizability of the results. Other patient demographics, however, are similar to the general Canadian and US dialysis population.[22,23]

This version of the ESAS is not inclusive of the entire repertoire of symptoms experienced by this population and therefore may under-represent the true symptom burden. It is possible that symptoms of importance to this patient population may have been overlooked. On the contrary, in this study, as in our previous assessment of the ESAS in dialysis patients,[7] additional symptoms were not reported with any significant frequency using the additional, unlabelled visual analogue scale. Regardless, the 10 items on the ESAS are highly associated with HRQL. We also believe that the brevity of this scale is important if this tool is to be clinically useful. The ESAS inquires about current troublesome symptoms. This time frame may result in under-reporting of symptoms by patients.

Lastly, we used a 1-week time period to collect test–retest data. This may be concerning if some of these symptoms are extremely transient. We felt it was important to avoid recall bias and to limit the effect of a non-mid-week dialysis treatment on the results. Further, the correlation coefficients in this study were similar to test–retest reliability data for the ESAS in cancer patients using a similar time frame.[21] Nonetheless, this scale must be further validated in studies looking at longitudinal and predictive validity to determine the impact of change in symptom burden on HRQL and the usefulness of the ESAS in assessing patient long-term outcome.

CONCLUSIONS

Symptom burden is high and adversely affects HRQL in this patient population. The significant symptom burden and impairment in HRQL highlights the importance of efforts to improve these issues. Clinicians wanting to provide comprehensive care and improve dialysis patients' HRQL should pay greater attention to self-reported physical and psychological symptoms. We conclude that this modified ESAS is a reliable, valid, simple, and useful method for regular symptom assessment in dialysis patients. In contrast to the use of HRQL instruments in routine clinical practice, the resources required for data collection, analysis, and reporting of the ESAS are minimal. Better assessment and treatment of patients' symptoms would seem to have the potential to exert a positive effect on dialysis patients' HRQL.

MATERIALS AND METHODS

The Health Research Ethics Board of the University of Alberta approved all study procedures. Prevalent dialysis patients in the Northern Alberta Renal Program, a Canadian university-based renal program were surveyed in May 2004. Participants included peritoneal dialysis patients and in-center and satellite hemodialysis patients from eight hemodialysis units. Patients were excluded if they were <18 years of age, refused or were unable to complete the questionnaires because of cognitive impairment, acute illness, general frailty, or a language barrier. Hemodialysis patients completed the surveys while on dialysis during a mid-week treatment and peritoneal dialysis patients completed the surveys while attending their regular clinic appointment. The hemodialysis or clinic nurse assisted patients in completing the forms when required. We administered the surveys twice, 7 days apart, to a random subset of the hemodialysis patients using the same procedure to obtain test–retest reliability data.

Measurement tools

The ESAS is a, simple, and widely used tool for measuring physical and psychological symptom distress, previously validated in cancer patients.[21] The ESAS consists of nine visual analogue scales, with a superimposed 0–10 scale for pain, activity, nausea, depression, anxiety, drowsiness, appetite, well-being, and shortness of breath. The scale for each symptom is anchored by the words 'No' and 'Severe' at 0 and 10, respectively. Content validity for the ESAS in ESRD was assessed by both expert review and patient participation. We initially reviewed the literature to determine the most common and burdensome of symptoms for dialysis patients. We had also previously surveyed a sample of 531 peritoneal and hemodialysis patients, looking at the frequency of common symptoms.[7] Using this information, we added a 10th item, pruritus, to the ESAS. The sum of the scores for all 10-symptom items was defined as the overall symptom distress score and ranged from 0 to 100. In addition, we provided an additional, unlabelled visual analogue scale for patients to nominate and assess a less common symptom that might be important for them.

We also administered the KDQOL-SF™, Version 1.3[17] as a self-report measure of HRQL. The KDQOL-SF was developed for individuals with kidney disease and incorporates kidney-disease-targeted items as well as a generic core. The generic core of the KDQOL-SF was scored using the recommended methods for the RAND-12.[24] The RAND-12 measures physical and mental dimensions of health and contains the same 12 items as the SF-12, taken from the eight scales of the SF-36/RAND-36.[24] Six of the 12 items create the PHC and the remaining six items create the MHC. The derivation of these summary scores is based on item response theory and oblique (correlated) factor rotations.[24] The RAND method of scoring offers several theoretical advantages over the standard SF-12 scoring, which is based on principle component factor analysis with orthogonal factor rotations.[25] The RAND scoring approach better discriminates between known groups and appears more responsive to change.[26–29]

Age, sex, race, cause of ESRD, comorbidity, duration of therapy for ESRD, K_t/V, dialysis modality, hemoglobin, calcium, phosphorus, parathyroid hormone, and serum albumin concentrations were collected. We determined the modified Charlson Comorbidity Index as a measure of comorbid conditions[30] as this index has been shown to adjust for the potential confounding effect of comorbidity in studies of HRQL.[31]

Statistical analysis

SPSS 13.0 for windows was used to perform statistical analysis. A $P<0.05$ was considered for statistical significance. Patient

characteristics were described as frequencies and percentages or as mean $\pm$ s.d. Similar descriptive statistics were obtained for each of the 10 symptoms on the ESAS as well as the total symptom distress score and the number of moderate or severe symptoms where moderate is defined as 4–6 and severe 7–10 on the ESAS 0–10 Likert scale. Descriptive statistics were also obtained for the PHC, MHC, and the KDQOL-SF summary scores: symptom/problem list, effects of kidney disease, and burden of kidney disease.

Construct validity was tested by the general hypothesis that increased symptom burden would be associated with impairments in HRQL. We therefore expected ESAS scores would be negatively correlated with the KDQOL symptom/problem list, effects of kidney disease, burden of kidney disease, and RAND-12 PHC and MHC scores. Furthermore, we anticipated the magnitude of these correlations to be strong (i.e., Spearman >0.5), with similar constructs (e.g., pain and PHC or depressed and MHC) having the strongest relationships. We anticipated that the overall symptom distress score would be most strongly correlated with the KDQOL-SF symptom/problem list. We also obtained correlations between ESAS overall symptom distress score and modified Charlson Comorbidity Index, K_t/V, hemoglobin, serum albumin, calcium, phosphorous. We hypothesized that these objective clinical parameters would have weaker correlations with self-reported symptom distress.

In univariate analysis, the ESAS symptom distress score, MHC, and PHC were compared by using *t*-test for dichotomous variables (gender, Caucasian vs others, diabetic status and modality of dialysis), and correlation and linear regression analyses were conducted with continuous variables (age, years on dialysis, modified Charlson Comorbidity Index). Multivariate regression analysis was performed using stepwise selection by increasing $P<0.25$ in the initial model and $P<0.05$ in the final parsimonious model.

Test–retest validity was assessed by calculating the intraclass correlation coefficients between the 10 individual ESAS items and the overall symptom distress score for the baseline and 1-week follow-up measurements.

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