Article Title:

Validation of the IPOS-Renal Symptom Survey in advanced kidney disease: a cross-sectional study

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Word Account:
Abstract – 255 words; Article 2514 words

Abstract

Context:

The significant symptom burden in advanced renal disease is often poorly recognized by clinicians. Recently, the Integrated Palliative Outcome Score (IPOS) – Renal survey was developed from pre-existing tools to capture these symptoms and other common concerns.

Objectives:

We studied the validity and reliability of the IPOS-Renal survey (patient and staff versions) in an Australian population.

Methods:

Adult patients with advanced renal disease and nurses caring for them participated. We initially administered the IPOS-Renal survey simultaneously with other validated surveys, then re-tested the IPOS-Renal after 7-14 days. We tested the construct validity of (a) IPOS-Renal patient version in relation to the Edmonton Symptom Assessment Survey- revised and the KDQOL-SF v1.3 questionnaire; and (b) IPOS-Renal staff version in relation to the Support Team Assessment Schedule (STAS) survey.

Results:

81 patients (65 haemodialysis, 10 peritoneal dialysis and 6 on supportive care; average age 64.9 years) and 53 nurses (average renal nursing experience 10.9 years) participated. Intra-class coefficients for test-retest reliability were >0.7 for most queries; Cronbach's alpha for internal consistency was 0.84 (patient version) and 0.91 (staff version). In tests of construct validity, Spearman's coefficient of correlation between surveys and their comparators for similar questions was significant, at 0.61 to 0.77 (patients) and 0.24 to 0.76 (staff). As expected, symptom scores and total symptom burden were negatively correlated with summary scores of quality of life.

Conclusion:

The IPOS-Renal surveys, patient and staff versions, have good test-retest reliability, internal consistency and construct validity in patients with advanced kidney disease and their nurses. We recommend their use in symptom assessment.

Keywords

Dialysis

Symptoms

Surveys

IPOS-Renal

PROMs

Validation

Running Title:

Validation of the IPOS-Renal

Introduction:

Patients with end-stage kidney disease (ESKD) suffer a multitude of pervasive symptoms (1-3). Persistent physical symptoms contribute to a lower HRQOL - both directly and indirectly through their effects on functional status, health perceptions and feelings of subjective well-being (4). These negative effects of symptoms on quality of life have been shown repeatedly in patients with kidney disease (5 - 9). The optimal identification and appropriate management of symptoms in kidney failure have the potential not only to facilitate symptom relief but also to improve the overall quality of life.

Symptom recognition by health professionals caring for these patients is often inadequate (10,11). We have previously shown that when doctors and nurses rely on standard consultations with patients in outpatient clinics or dialysis facilities, they demonstrate poor sensitivity to patients' symptoms and only 'weak' agreement with their ratings of severity (5). Similar findings have also been shown in a North American healthcare setting (12). Symptom surveys which are completed by patients and then passed on to clinicians are potential solutions to bridge this gap (13). Recommendations by the Australia New Zealand Society of Nephrology support these patient-completed surveys as enhancements to comprehensive care (14).

An optimal patient-reported outcome measure (PROM) ought to be easy to administer, short, relevant to kidney disease and sensitive to change. Several patient-reported measures are widely used, despite limited validation data (15,16). A national survey of nephrology units across Australia found that while the majority collected patient-reported data, the most popular instrument used was the IPOS-Renal symptom survey - a relatively new tool that has not yet been adequately validated (ANZDATA Working Group on PROMs 2017; unpublished data).

The IPOS-Renal is part of a suite of patient-reported outcome measures (PROMs) developed in the United Kingdom. The original Palliative Outcome Score (POS) and subsequently, a symptom module, the POS-symptoms (POS-S) and finally, the generic IPOS tool (a synthesis of the POS and POS-S) were developed for the comprehensive assessment of patients with advanced disease and receiving palliative care (17-22). The kidney disease-specific surveys,

initially the POS-Renal and later the IPOS-renal, were developed based on the POS and IPOS palliative care surveys, but with the additional inclusion of symptoms common in chronic kidney disease such as pruritus and restless legs (23,24). These surveys offer staff and patient -completed versions assessing the same domains. While the generic questions in the survey have been tested for content and face validity, construct validity of the IPOS-Renal in a population with advanced kidney disease has not been established. We conducted this study to assess the reliability and construct validity of the IPOS-Renal (patient and staff versions) in an Australian population of patients with advanced kidney disease and the nurses who care for them.

Materials and Methods

IPOS-Renal Patient Version

Study population:

We included a convenience sample of adult (>18 years) patients with advanced kidney failure (eGFR < 15ml/min/1.73 m2 on two occasions 3 months apart) who were treated with either hemodialysis / peritoneal dialysis or with conservative, non-dialytic management in a renal supportive care clinic. Participants were recruited from outpatient clinics or dialysis services at two regional hospitals in Tasmania, Australia. Exclusion criteria included those clinically assessed by treating nurses to be cognitively impaired or too unwell to participate. Patients completed these surveys independently or with help from their carers

Survey Instruments

Participating patients completed the IPOS-Renal, the Edmonton Symptom Assessment System - revised (ESAS-r) and the Kidney Diseases quality of life - short form version 1.3 (KDQOL-SF v1.3). (See Table 1).

Procedures

Demographic data collected for patient participants from their medical record included age, gender, and physician-assigned comorbid conditions. The Charlson Comorbidity Index was assigned based on the comorbidities (31).

Survey data collection occurred at two time points, concurrently for patient and staff participants. Different survey instruments were used at each time point, as shown in Table 2. At the second time point, which was 7 to 14 days after the first surveys had been completed, patient participants repeated the IPOS-Renal survey and also indicated if "their condition had

changed" by answering "yes" or "no" to a direct question. Patients on hemodialysis completed these surveys during a dialysis session, while those on peritoneal dialysis or conservative care completed them during routine outpatient visits initially, and then mailed in completed surveys from home for the follow-up IPOS-Renal survey.

Ethics approval for the conduct of the study was obtained from the Human Research Ethics Committee (Tasmania) Network (Ref no: H0016005)

Data Analysis

Demographic data were reported using descriptive statistics. We tested for reliability and validity as follows (all statistical analysis was done with Stata® v 12, StataCorp LLC, Texas, USA).

Tests of reliability:

Test-retest reliability using intra-class correlation coefficients (ICC) were calculated between the repeated IPOS-renal surveys in stable patients - i.e., those patients for whom, at time point two, patients answered "no" to the question: "Has your condition changed?". ICC estimates and their 95% confidence intervals were calculated based on a mean-rating ($k = 2$), absolute-agreement, 2-way mixed-effects model (32). Internal consistency was tested by estimating Cronbach's alpha.

Tests of validity:

In testing for convergent validity, we hypothesized that there would be a positive correlation between similarly worded items on the IPOS-Renal and the ESAS-r surveys; and a negative correlation between the IPOS-Renal and the composite scores of kidney disease burden, physical and mental QOL on the KDQOL - SF v1.3 survey. Convergent validity was ascertained by testing the Spearman's correlation coefficient (33). Divergent validity was explored by testing the correlation between symptom scores and QOL subscales on separate surveys - we hypothesized that there would be only weak correlations between items that were not directly related.

We checked for sensitivity to change by comparing IPOS-Renal scores at time point one and time point two using the Wilcoxon signed-rank test, among patients who indicated that their clinical condition had changed at time point two.

IPOS-Renal - Staff Version

Study Population

For staff participants, we recruited from registered nurses who were directly involved in the care of the participating patients in hemodialysis, peritoneal dialysis or renal supportive care clinics. We ensured at least two nurses per patient; one nurse could report on multiple patients.

Survey Instruments

Participating staff completed two surveys at initial participation on the same day as the patient - the IPOS-Renal (staff version) and the Support Team Assessment Schedule (STAS). 7 to 14 days later (on the same day as the patient), one nurse per patient completed a second IPOS-Renal staff version survey. Additionally, staff scored patients on the Australia-modified Karnofsky Performance Scale (AKPS) and the Phase of Illness Scores on both occasions. (see Table 1).

Procedures

Demographic data collected about participating staff nurses included age, gender and years of experience in renal nursing.

Procedures were similar to those in the patient group of participants, other than differences in the instruments used (Table 2). Surveys were completed on the same day as patients at both time points (7 to 14 days apart). At the second time point, staff also noted "yes" or "no" to the question - "has your patient's condition changed?". Staff participants completed the surveys in the dialysis or outpatient clinics at both time points.

Data Analysis

Analysis methods were similar to those described for patients above. We estimated test-retest reliability between repeated surveys of patients whose condition staff participants reported as unchanged. To test convergent validity, we compared similarly worded questions on the IPOS-Renal (staff version) and the STAS surveys.

Results

IPOS-Renal - Patient Version

81 patients participated in the study - 65 patients treated with hemodialysis, 10 patients peritoneal dialysis and 6 patients with renal supportive (non-dialysis) care. The average age of participants was 64.9 years, 56% of patients were male. Other demographic details are listed in table 3.

Tests for Reliability:

Of the 81 participants, 69 (85%) completed the second IPOS-Renal survey - among them, 56 reported no change in their status between the two time points. Intra-class coefficients demonstrating test-retest reliability showed "good" correlation (0.75 - 0.9) for 13/23 of the survey questions, and "moderate" (0.5 - 0.75) for 8/10 of the remaining ones (see Table 4) (32-34). Cronbach's alpha for determining internal consistency was 0.84 for the questionnaire, showing good consistency (32-34).

Tests for Validity

In testing for convergent validity, we compared the IPOS-Renal with corresponding items on the ESAS-r as well as with summary scores on the KDQOL-SF v1.3 (see Table 5). 'High' to 'moderate' correlations (Spearman correlation coefficient values of 0.61 to 0.77, $p < 0.05$) were seen for total symptom burden scores and for all individual items that queried the same domains in the IPOS-renal and ESAS-r surveys.

As hypothesized, there was a statistically significant negative correlation between the total symptom burden and the composite QOL scores of KDCS, PCS, and MCS, as measured by the KDQOL-SF v1.3. Several individual symptom scores were also negatively correlated with these summary quality of life scores, with the strength of the correlation ranging from 'moderate' to 'high'.

In checking for divergent validity, we saw that items on the IPOS-renal that were not questions about symptoms (such as "have practical problems been addressed" or "has time been lost on appointments") showed no correlation with the physical or mental composite scores of QOL (data not shown). The sample size was not sufficient to estimate sensitivity to change.

IPOS-Renal Staff Version

53 staff nurses participated in the study, 47 female and 6 male. Their mean age was 47 (standard deviation, SD: 10.5) years. On average, staff participants had spent 21 (SD11.9) years as a nurse; and 10.9 (SD 8) years as a renal nurse.

Tests of Reliability

Test-retest reliability was checked in those staff surveys where no change in the patient's condition was reported (n=42). Intra-class coefficients showed 'moderate' (0.5 - 0.75) or 'good' (0.75 - 0.9) reliability for 20 of 23 items on the survey (32). (See Table 4). Cronbach's alpha for the staff version was 0.91, showing excellent internal consistency.

Tests of Validity

We determined the construct validity by comparing IPOS-Renal (staff version) with scores on the validated STAS survey. Spearman's correlation coefficients for answers to similarly worded questions showed statistically significant correlation; with the strength of correlation being "moderate", as follows (all p values <0.05): Pain (0.76), symptoms other than pain compared to total scores for symptoms other than pain (0.71), patient anxiety (0.65), family anxiety (0.65), and time wasted (0.75).

Divergent validity was demonstrated by the lack of correlation between unrelated items on the IPOS-Renal and STAS surveys (data not shown).

Discussion

Unlike traditional biophysical measures, PROMs like the IPOS-Renal allow the clinician to capture the patient's subjective illness-related concerns (35). Validation of the psychometric properties of such an outcome measure is valuable to clinicians, researchers and health administrators. The paucity of validation studies specifically involving the IPOS-Renal could be considered a disadvantage, and our study sought to rectify this.

Important aspects of psychometric validation include tests of **reliability** (i.e., the extent to which the scores are consistent, typically tested as test-retest reliability and internal consistency), **validity** (i.e., the accuracy of the assessment in measuring what it is supposed to - studied as content, criterion and construct validity) and **sensitivity to change** (32-34). Our study of the patient and staff versions of the IPOS-Renal demonstrated good test-retest reliability and internal consistency, suggesting that the survey is reliable in both versions. In

stable patients, the ICC values for test-retest reliability were in the range ‘poor’ for only two items - “ability to share with family or friends” and “time wasted on appointments”. Both these items may well vary periodically, depending on the opportunities to meet social contacts or the requirement to go to medical appointments. Similarly, ‘poor’ test - retest reliability was seen in the staff versions for the items addressing diarrhea and information received by patients. Staff surveys in our study were completed without asking the patients or their carers direct questions, and reliability may improve if tested in everyday situations where staff members interact freely with patients and carers.

Face and content validity (i.e., the survey addresses the concerns it is supposed to measure) in a patient population has already been shown for the questions in the survey (17-20). Criterion validity (i.e., the survey correctly predicts symptoms) is difficult to test in the absence of a 'gold standard' for symptom elicitation. We tested two aspects of construct validity - namely, convergent (i.e., presence of correlation between item scores that measure the same construct) and divergent validity (i.e., scores for unrelated items do no correlate). The patient survey, compared with other validated symptom and quality of life surveys, showed satisfactory convergent validity. We also showed, as expected, that higher symptom burden reflected in the IPOS-renal survey correlated with lower physical and mental composite scores, further establishing construct validity. Similarly, we were able to demonstrate construct validity for the staff version when compared to the STAS survey.Feedback from staff participants that used the survey was positive, with the staff version being described as easy to understand and score. Both patient and staff versions showed that when unrelated items were compared in different surveys, the correlation was poor, showing divergent validity. Our study was not sufficiently powered to detect sensitivity to change or differences between patient groups.

Patients’ reluctance to mention their problems, and clinician ignorance about symptoms remain important barriers to improving their management in hemodialysis patients (1, 10). Patient-reported symptom surveys such as the IPOS-Renal are a potential solution to bridge this gap. The IPOS-Renal survey has features that recommend its use over other similar surveys. It is short and easy to complete, and its domains also span concerns relevant to chronic disease such as information needs, carer anxiety, time wasted on appointments and other practical issues. It invites patients to use free text to list their most important problems first, so clinical attention can focus specifically on issues that matter most to the patient. It

also provides space to record other symptoms that may not be included in the survey (21). Its popularity across units in Australia, where it is used for both clinical management and for research, suggests that clinicians are already finding the survey useful in practice (ANZDATA Working Group on PROMs 2017; unpublished data). A further advantage is that the staff version of the IPOS-Renal may be helpful in situations where patients become too ill to report their problems.

The study had limitations. We chose a convenience sample of patients and their nurses; most of our participants were on hemodialysis. We could not achieve sufficient participant numbers to report sensitivity to change. While some patients completed surveys within the dialysis unit, others completed them at home or in outpatient clinics. A study powered to detect significant changes in symptom scores, and with a more deliberate sampling of patients treated with peritoneal dialysis and supportive care will address some of these limitations.

Conclusion.

In our study population, the IPOS-renal symptom survey, patient and staff versions, demonstrated good internal consistency and test-retest reliability. Convergent validity was also established by comparison to other established surveys administered concurrently. Our results recommend the use of this survey for the documentation of symptoms in patients with advanced kidney disease.

Disclosures of Conflict of Interest Statement:

Dr. R Raj, Dr. K Ahuja, Dr. M Frandsen, Dr. FEM Murtagh and Dr. M Jose declare they have nothing to disclose in terms of conflict of interest relevant to this article.

Acknowledgements

Tania Battaglini-Smith, Ruth West, Sheila Campbell (Tasmanian Health Service)

Funding:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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