PATIENT-REPORTED OUTCOME MEASURES IN KIDNEY DISEASE

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PROMS: INTRODUCTION AND CURRENT TOOLS IN KIDNEY CARE

This section will introduce Patient-Reported Outcomes Measures (PROMs) and its role in clinical care. Furthermore, it will cover currently available PROMs tools as well as some ongoing initiatives for PROMs in patient-centered kidney disease care .

PROMS IN KIDNEY DISEASE: CURRENT MEASURES AND FUTURE PERSPECTIVES

This section will highlight the application of PROMs in CKD patients, focusing on ePROMs (electronic PROMs) to assess HRQoL (Health Related Quality of Life) and explore new tools available for PROMs in kidney care.

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PROMS: INTRODUCTION AND CURRENT TOOLS IN KIDNEY CARE

Introduction

Over the years, there has been an increased focus on patient advocacy and improving patients' QoL in clinical care. This has led to a great emphasis on collecting Patient Reported Outcomes (PROs) which include specific symptoms and overall health aspects that are not recorded by traditional laboratory data (1).

PROs are any self-reported health outcomes by patients without any interpretation by clinicians or other caregivers. These PROs are often collected using PROMs (2). PROMs are self-completed questionnaires used to assess one or multiple PROs, which collate data on patient-perceived general QoL, and HRQoL including symptoms, functional status and their healthcare experience (2,3).

Several HRQoL measures such as Medical Outcomes Study Short Form (SF-36) and Sickness Impact Profile are commonly used to collect data and compare the intervention and control groups for different purposes and estimate population norms (3).

PROMs have allowed clinicians and researchers to assess therapeutic interventions and improve patient care, best suitable and personalized to the patients. Hence, these can be used from clinicians to investigators in academia and industries to understand patients' treatment options (4).

Kidney Disease Quality of life-SF (KDQOL-SF)	Kidney Disease Quality of Life-36 (KDQOL-36)	Integrated Patient Outcome Scale-Renal (IPOS-Renal)
•An 80-item HRQoL measure designed for dialysis patients which includes the SF-36 as a generic core (physical and mental scales) supplemented with 8 kidney disease-targeted dimensions and three additional QoL dimensions. •Scores range from 0 to 100 for each dimension with higher scores indicating better HRQoL.	•A 36-item HRQoL measure designed for dialysis patients derived from the KDQOL-SF. •Three specific dimensions:(1) signs and symptoms, (2) burden of kidney disease, and (3) effects of kidney disease and a generic core derived from the SF-12 (physical and mental scales). •Overall scores range from 0 to 100, with higher scores indicating better HRQoL.	•A short measure (11 questions), combining the most common symptoms of renal patients plus additional items from IPOS on concerns beyond symptoms, such as information needs, practical issues, family anxiety.

Table 1: PROMS tools/questionnaires available for kidney patients. Adapted from BMJ Open 2018;8:e021532.

PROMs tools in Kidney care

PROMs are crucial for kidney patients and are increasingly recognized as a critical component of patient-centered care as kidney patients have high symptom burdens and comorbidities. Nair et al. identified 39 PROMs developed between 1985 and 2019 for adult kidney patients, most of which focused on physical and emotional symptom burden, social relationships, and overall HRQoL for in-center Hemodialysis (HD) patients (1).

Kidney Disease Quality of Life-36 (KDQoL-36), a kidney symptom specific questionnaire has been largely used for clinical trials (2,5) along with other validated PROMs tools available (2) (Table 1).

Furthermore, an emerging tool, PROMIS (Patient Reported Outcomes Measurement Information system), funded by National Institutes of Health (NIH) provides a collection of reliable, validated and precise measures of PROs that can be applied to ePROMs and decreases the respondent burden (5).

Moreover, an international multidisciplinary effort called Standardized Outcomes in Nephrology (SONG) initiative, between researchers, clinicians and ESKD patients, was established to identify core outcomes to be reported consistently across HD trials. Urquhart-Secord's study in 2016 on HD patients directed a core outcome for this initiative by showing that ESKD patients ranked QoL higher than long-term survival (6,7).

Patient's priorities for QoL over traditional outcomes such as mortality and adverse events in this study has raised a need of interventions that are likely to improve patients' overall well-being and measure PROs (7). Though, there is a need of a generalized PROMs to be used as a common tool for assessing impact of dialysis treatments in kidney patients.

PROMS IN KIDNEY DISEASE: CURRENT MEASURES AND FUTURE PERSPECTIVES

Patients undergoing HD need long-term care and have a negative impact on QoL as they experience pain, fatigue, and stress. With paper-based PROMs, a delay in assessing patients' QoL may lead to conflicting medical and treatment priorities. This can potentially lead to undiagnosed and untreated symptoms. ePROMs are a unique way to record the symptoms and overcome the delay in patient-centered care and treatment by improving communication (4).

A retrospective analysis by Gibbs et al compared paper vs electronic PROMs in 474 patients and reported that ePROMs had higher completion rates (57.2% vs 42.9% in paper; p=0.003), and were better at increasing PROMs retention rates (8). ePROMs, therefore provide constructive evidence on the efficacy of therapies and can help in delivering personalized care to patients (9).

ePROMS: an effective tool for patient-centered care

Several studies are now adapting ePROMs to focus on patient-centered care.

In a pilot quantitative study by Makaroff et al, 99 home HD patients completed 2 ePROs (KDQOL-36 and Edmonton Symptom assessment system revised for renal patients) and indicated that 24 issues including itchiness (n=55), appetite (n=51), sleeping problems (n=50) as well as overall patient health and general effects on QoL were more frequently reported. With this data, critical information was collected that guided future assessments toward better person-centered care (10).

Guerraoui et al conducted a multi-center study on 173 HD patients to record QoL by ePROMs. Fatigue (72% prevalence) and stress (66%) were the main symptoms reported during dialysis and indicated that identifying patients more prone to these symptoms may be helpful for better patient care (11).

In Denmark, a generic web-administered ePRO system called Ambuflex is being used to manage kidney patients as well as other chronic or malignant disease patients' follow-ups using a telePRO model (12). Additionally, some RCTs are being conducted to explore ePROMs effectiveness in kidney care. The Australian SWIFT study and Canada's EMPATHY study are investigating the effect of using ePROMs in HD patients (9). The primary outcome for SWIFT is monitoring the changes in patients' HRQoL (13), while EMPATHY focuses on patient-provider communication (14). However, optimized usage of ePROMs in kidney care still requires more efforts for effective implementation (9).

Novel measurement tool: PROMIS

PROMs are now commonly used in nephrology care. However, there is no consensus on the preferred tool due to unawareness about psychometric properties. PROMIS is an ePRO survey toolbox that utilizes computerized adaptive testing (CAT). It is proposed to assess generic HRQoL in CKD patients by a consensus group of the International Consortium of Health Outcomes Measurement (ICHOM) (15).

A study showed that 7 PROMIS CATs (physical function, pain interference, fatigue, sleep disturbance, anxiety, depression, ability to participate in social roles and activities) have sufficient construct validity and test-retest reliability in patient with advanced CKD. The patients completed 7 PROMIS CATs and SF-12. PROMIS CATs had a lower variation compared to Short form survey SF-12, and hence were more reliable (Table 2). Nevertheless, more evidence is needed to establish the use of PROMIS CATs in routine kidney care (15).

Population: CKD patients: eGFR<30 N=207, age:66, 60% male	
PROMIS CATs	**12-item Short form (SF-12)**
Validity √All seven sufficient validity	**Validity** Reference
Reliability √All seven sufficient reliability	**Reliability** √Most domains sufficient reliability

Table 2. Validity and reliability of PROMIS using CAT in patients with advanced chronic kidney disease. (adapted from Nephrol Dial Transplant 2023;38:1158–69.)

PROMs in CONVINCE study

Recently published CONVINCE study, including over 1300 kidney patients in EU reported a 23% mortality reduction in patients receiving high dose hemodiafiltration (HDF) compared to those on high-flux hemodialysis (HD) (16). Besides, the effect of HDF vs HD on PROs, particularly HRQoL were assessed by validated tools such as PROMIS and SF-12. The health domains and symptoms were determined in due consideration of SONG and ICHOM initiatives. These results (yet to be published) are being evaluated and will assist in determining the aspects that positively influence health perception (17).

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