

Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes (PROs): COREXH Registry

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BACKGROUND

Health-related quality of life (HRQoL) is a patient reported outcome (PRO) that considers the subjective point of view of the patient and supports the evaluation of outcomes and healthcare quality. Patients on dialysis experience poor HRQoL due to the symptoms of end-stage renal disease (ESRD) and the physical and psychosocial burdens of their treatments.

The impact of contemporary renal replacement therapies on a patient's perceived HRQoL is critical to treatment success. While hemodialysis (HD) therapy removes small solutes, the removal of larger molecules >25 kDa (often termed large middle molecules) is limited. Hemodiafiltration (HDF) therapy can remove middle molecules more effectively than HD. However, the effect of an improved uremic environment resulting from the clearance of middle molecules remains unclear based on randomized studies.

Advances in membrane technology have led to the development of novel medium cut-off membranes that have enhanced selectivity and increased permeability to conventional and large middle molecules. This results in a steep sieving curve in which the molecular weight retention onset and molecular weight cut-off are very close to each other while remaining lower than that of albumin, mimicking the filtration profile of the native kidney. The application of these membranes in clinical dialysis is known as expanded hemodialysis therapy due to the enhanced clearance of large middle molecules, which are associated with cardiovascular disease, immune modulation, and protein-energy wasting. Initial studies have demonstrated that the **MCO** membrane removes toxins at least as effectively as a hemofilter used in HDF mode. The goal is that this enhanced removal will improve PROs and QoL for dialysis patients.

OBJECTIVE

The goal of this study was to determine the impact of the **MCO** membranes on PROs, including HRQoL, presence and severity of symptoms, as well as diagnostic criteria of restless legs syndrome (RLS) in a large multicentric cohort of patients in the Expanded Hemodialysis Registry Protocol in Colombia (COREXH).

METHODOLOGY

Study Design and Patients

The study was a prospective, multicenter, observational cohort study of 992 patients undergoing dialysis from 12 renal clinics in Colombia who were switched from high-flux HD to **HDx** therapy with **MCO** membrane and observed for 12 months. Patients with chronic kidney disease (CKD) aged 18 or older who had been undergoing HD therapy for more than 90 days at a **Renal Therapy Services** network clinic were invited to participate. Patients received HD therapy using the **MCO** dialyzer (**Theranova**, Baxter, Deerfield, IL, USA) three times a week for a minimum of 4 hours. Patients diagnosed with an active infection within the last 4 weeks or had a life expectancy less than 6 months were excluded. Eligible patients were prospectively followed for 12 months from enrollment.

Assessments

Baseline (before switching to therapy with the **MCO** dialyzer) demographic and disease characteristics were collected. HD treatment parameters, including session duration, number of sessions per week, blood flow, dialysate flow, and type of vascular access were recorded. Baseline values of Kidney Disease Quality of Life 36-Item Short Form Survey (KDQoL-SF36), Dialysis Symptom Index (DSI), and diagnostic criteria for RLS were captured and repeated at 6 and 12 months.

RESULTS

Patient Profile

A total of 992 patients from 12 clinics were included in the baseline, with 638 remaining at 12-month follow-up. Patients had been receiving high-flux HD for a median of 3.7 years at the time of enrollment.

Kidney Disease Quality of Life 36-Item Short Form Survey

After 12 months of therapy with the **MCO** dialyzer, three of five KDQoL domains improved compared with baseline, with the most pronounced improvements found in the kidney disease effects domain. Significant increases in KDQoL-36 mean scores from baseline were also observed for symptoms/problems and burden of kidney disease. No significant changes in scores for mental and physical domains were found (see Table 1). The effect size was modest but consistent across the full 12-month follow up period, suggesting that the expanded clearance of large molecules may be associated with improvements in QoL. In addition, contrary to the expected outcomes for patients receiving chronic dialysis, QoL trended towards improvement over the course of follow-up.

Decreases in the physical and kidney disease components of KDQoL-36 had been associated with increased adjusted mortality risk. The Convective Transport Study (CONTRAST) demonstrated that decreases in physical function, emotional health, and social functioning were significantly associated with mortality over 2 years and were independent of age. Thus, the positive impact of the expanded removal of large middle molecules on QoL measures observed in this study is encouraging.

KDQoL-36 Domain	Statistic	Baseline	6 months	12 months	P value*
		n = 971	n = 808	n = 642	
Symptoms/problems	Mean	78.6	81.0	81.5	<0.0001
	SD	15.8	15.4	14.9	
Effects of kidney disease	Mean	69.7	72.8	75.1	<0.0001
	SD	22.3	22.0	21.0	
Burden of kidney disease	Mean	46.2	48.9	50.2	<0.0001
	SD	27.5	29.9	32.3	
SF-12 Physical	Mean	41.1	41.0	41.7	0.3
	SD	11.1	11.2	10.5	
SF-Mental	Mean	51.1	51.9	52.3	0.02
	SD	11.6	11.3	11.1	

TABLE 1. Change of Kidney Disease Quality of Life 36-Item Short Form Survey (KDQoL-36) Score Over 12 Months of Follow Up. *For hypothesis testing, type-1 error/p value significance was set at p=0.01. Abbreviation: SD, standard deviation. Adapted from Alarcon et al.