



Medium Cut-Off Dialyzers in a Large Population of Hemodialysis Patients in Colombia: COREXH Registry

Bunch A, Sanchez R, Nilsson LG, et al. Medium cut-off dialyzers in a large population of hemodialysis patients in Colombia: COREXH Registry. *Ther Apher Dial*. 2020; 1-11. [doi: 10.1111/1744-9987.13506](https://doi.org/10.1111/1744-9987.13506).

BACKGROUND

Recent advances in technology have introduced expanded hemodialysis utilizing medium cut-off membranes with high retention onset membranes. The **MCO** membrane easily clears conventional and large middle molecules with acceptable levels of albumin removal (2-4 g/session), which maintains serum albumin levels within the normal range.

Middle molecules, which accumulate during hemodialysis (HD) are considered to be inflammatory mediators. Inflammation also contributes to decreased serum albumin levels. Importantly, a lower serum albumin level is associated with increased mortality. The higher mortality rate associated with low serum albumin levels has been reported to be dependent on inflammation as assessed by high sensitivity C-reactive protein (hsCRP) levels.

Renal Therapy Services (RTS) is a nationwide provider in Colombia partially owned by Baxter that serves over 9000 patients who are undergoing HD or peritoneal dialysis. RTS dialysis units provide HD to over 5500 patients, accounting for approximately 29% of patients receiving HD in Colombia.

There is a paucity of longitudinal data regarding the clinical outcomes and safety of the **MCO** membrane, especially in the current practice setting.

OBJECTIVE

To describe the outcomes and trends in serum albumin levels among a large cohort of patients switched from conventional high-flux HD to **HDx** therapy utilizing an **MCO** membrane and document the long-term safety.

METHODOLOGY

Expanded Hemodialysis Registry Protocol in Colombia (COREXH) is a prospective, observational, multicenter cohort study of patients undergoing **HDx** therapy in Colombia. Between September 4, 2017 to November 30, 2017 prevalent HD patients (receiving HD therapy for at least 90 days at an RTS renal clinic) were invited to participate in the registry. Patients were required to be at least 18 years of age and receiving **HDx** therapy for a minimum of 4 hours, 3 times per week using an **MCO** membrane (**Theranova** dialyzer, Baxter, Deerfield, IL). Patients with life expectancy less than 6 months or those with an active infection diagnosed within the previous 4 weeks were not invited to participate. Baseline data were obtained of the last seven days before switching to **HDx** therapy and represent the initial state of the patient's health, serum albumin levels, and other laboratory parameters. Patients were prospectively followed for one year from enrollment into the registry.

RESULTS

Patients

One thousand (1000) patients at 12 clinics across Colombia were invited to participate. A total of 992 patients met the participation criteria and were included in the intention to treat (ITT) group. The majority (62%) of the patients were men, and at enrollment the mean age was 60 years. Over 90% of the patients had a history of hypertension and nearly 50% had a history of diabetes. Two-thirds (67%) of patients had chronic kidney disease (CKD) attributed to hypertension (28%) or diabetes (39%). A total of 638 patients were eligible for the 1-year follow up assessment.

Albumin Levels

The cumulative change in serum albumin levels in the ITT population during the follow-up was -1.8%. See Table 1. A total of 468 patients in the per protocol (PP) population had all six serum albumin measurements taken during **HDx** therapy. The changes in serum albumin levels was less pronounced, with an accumulated change of -1.2%. See Table 2.

While a slight decrease in albumin over 12 months of observation was statistically significant in the large cohort study, this should be considered clinically insignificant. At all times, the observed variability of serum levels was within 5% from baseline and the mean serum albumin concentration remained within the normal ranges (3.5-5.5 g/dL).

Follow-up	n	Marginal mean* (g/dL)	Change from baseline (%)	Change from previous ^b (%)	Cumulative change(%)
Baseline	992	4.05 (4.04-4.07)	–	–	–
15 days	938	3.98 (3.97-4.00)	-1.7	-1.7	-1.7
1 month	951	4.00 (3.98-4.01)	-1.2	0.3	-1.4
3 months	883	3.91 (3.90-3.93)	-3.5	-2.0	-3.5
6 months	728	3.94 (3.92-3.96)	-2.7	0.7	-2.8
9 months	735	3.94 (3.92-3.96)	-2.7	0	-2.8
12 months	587	3.98 (3.96-4.00)	-1.7	1.0	-1.8

TABLE 1. Change in serum albumin levels over time (ITT population). Abbreviation: ITT, intention to treat. *Marginal mean is the means estimation based on the fitted model in repeated measures and are presented as 95% confidence interval. ^bThe percentual change from the last measurement value Table adapted from Bunch, et al.