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HDx THERAPY STUDY SUMMARY

Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode

Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode Patient Related Outcome Measures 2021:12 315–321. doi: 10.2147/PROM.S325016

Patient Reported Measures Reported by Switching to **HDx** Therapy

BACKGROUND

People with end-stage renal disease on hemodialysis (HD) report a high symptom burden that impacts quality of life. Fatigue and lack of energy are common, which interfere with daily life and are associated with poor outcomes. Prolonged recovery time after each dialysis treatment is also common, with patients on conventional HD typically reporting recovery time of 2-4 hours, with approximately 25% reporting recovery time over 6 hours.

It has been proposed that the retention of large middle molecule (MM) uremic toxins in people with chronic kidney disease could influence the symptom burden. A medium cut-off membrane was recently introduced, allowing for expanded hemodialysis to achieve more effective clearance of large MMs, even when compared to HDF. Further studies are needed to assess the impact of enhanced dialytic removal of large MMs on the dialysis-related symptom burden.

OBJECTIVE

The aim of this clinical assessment was to evaluate the impact of **HDx** therapy on patient reported recovery time and symptom burden.

METHODOLOGY

This pilot retrospective analysis reports on the initial 12-month experience at an in-center renal unit after implementing **HDx** therapy, focusing on the patient-reported symptom burden during this period.

In 2018 a patient-reported outcome measures (PROM) program was implemented to capture HD patients' symptom burden as part of routine clinical care. At the same time, an evidence-based decision was made to implement **HDx** therapy, using the **MCO** membrane (**Theranova** dialyzer; Baxter Healthcare Ltd), as the preferred in-center hemodialysis therapy to achieve effective MM clearance.

PROM Data Collection

PROM data collection started in March/April 2018 and was thereafter performed quarterly. PROM assessments were typically administered to people while on dialysis at a mid-week session. Individuals were asked about their post-dialysis recovery time using the question "How long does it take to get back to normal, after dialysis?". Data on symptom prevalence and severity were collected using the 17-item version of the Palliative Care Outcome Scale–Symptom module for renal patients (POS-S Renal), which asks how 17 predefined symptoms had affected patients in the past week using a 5-point scale ("not at all"= 0, "slightly"= 1,"moderately"= 2,"severely"= 3,"overwhelmingly"= 4).

Dialysis Treatments

At the start of the PROM data collection individuals were on conventional thrice weekly hemodialysis at the in-center dialysis unit and treated with regular high-flux membranes (**Revaclear** dialyzer in HD and **Polyflux H** dialyzer in HDF; Baxter Healthcare Ltd). Following the implementation of PROM assessments, the renal team made an evidence-based decision to implement **HDx** therapy using the **MCO** membrane (**Theranova** dialyzer; Baxter Healthcare Ltd). Treatment prescription factors such as frequency, blood flow rate (median 300 mL/min), dialysate flow (500 mL/min), and treatment time (median 4 hours) were not affected by the therapy change.

RESULTS

Participants

Initially 90 patients agreed to provide PROM data. Mean age was 73 years, and 62% of participants had received hemodialysis treatments for 3 years or less, and 9% for 10 years or more. Prior to **HDx**, 25 (28%) of participants received HDF and 65 (72%) received HD.

Participant numbers providing data at 3, 6, 9, and 12 months were 80, 72, 68, and 59 respectively.

Safety of Transition to HDx therapy

The **MCO** membrane was introduced without incident over a 2-week period to all individuals on HD at the unit, and it has remained the standard of care. All individuals tolerated the new membrane well. No clinically significant changes in albumin, C-reactive protein, and hemoglobin levels were noted. No signs of increased infection rate were observed.

Post-dialysis Recovery Time

Overall, the median self-reported recovery time at baseline was 240 min (IQR: 60–720; N = 89). At follow-up, the recovery time was shorter:

- 120 min (22–435) at 3 months,
- 60 min (0–240) at 6 months ($p < 0.01$),
- 60 min (0– 240) at 9 months ($p < 0.01$), and
- 105 min (0–180) at 12 months ($p < 0.01$).

The subgroup of participants who provided recovery time data throughout the 12-month period (N = 58) reported a similarly decreased recovery time (See Figure 1). In this subgroup, the percentage of people reporting a recovery time greater than 360 minutes decreased from 36% at baseline to 26%, 14%, 14%, and 9% at 3, 6, 9, and 12 months, respectively.

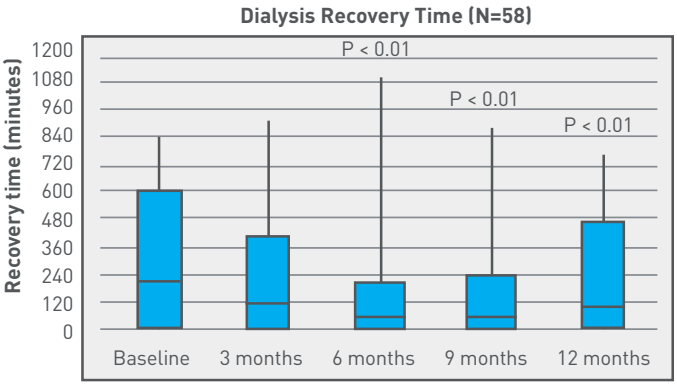

FIGURE 1. Reported post-dialysis recovery times for individuals who completed the 12-months observation period (N = 58). Notes: Boxes show medians and 25th/75th percentiles and whiskers show 95th percentiles #Denotes *P* < 0.01 vs baseline.

Symptom Burden

In the overall population, at baseline the median number of symptoms per participant was 7 (IQR 4–10; N = 90) and the total symptom score varied between individuals from 1 to 42, with a median value of 13 (IQR 7–18.8). At the 3- and 6-month follow-ups, the total symptom score showed a decrease to 11 (5–16) at 3 months (p = 0.03) and 10.5 (5–19) at 6 months (p = 0.005), while subsequent follow-ups were not different from baseline.

The subgroup of the population who completed the 12-month observation period showed a baseline total score of 12 (7–17.3; N = 56), with a significant decrease at 6 months (See Table 1).

TABLE 1. POS-S Renal Total Symptom Scores (Median, IQR for Participants Who Provided Ratings Up to 12 Months (N = 56)

Baseline	3 Months	6 Months	9 Months	12 Months
12 (7-17.3)	10 (4.5-16) P = 0.06	8 (5-19) P = 0.003	11 (5.8-20.3) P = 0.8	12 (5-22) P = 0.8

Notes: P-values are in comparison to baseline.

"Weakness or lack of energy" and "Poor mobility" were reported as the most bothersome symptoms. The percentage of patients reporting that "Weakness or lack of energy" affected them "severely" or "overwhelmingly" in the past week decreased from 28% at baseline to 16%, 15%, 20%, and 16% at 3, 6, 9, and 12 months, respectively.

Limitations

As this was not a formal study with a control group, we cannot exclude that improvements seen in recovery time and fatigue were unrelated to the membrane and therapy change. It should be considered that PROM data were not returned anonymously so the identification of specific symptoms at the initial assessment could have led to improved symptom management resulting in reduced symptom severity at later stages. These findings reflect a real-life assessment of PROMs in about 80% of the in-center HD population, however, being a single-center experience, these results may not necessarily be applicable to populations in other dialysis centers with other dialysis practices.

CONCLUSION

Sustained improvements in patient-reported post-dialysis recovery time and POS-S Renal fatigue score were observed over a 12-month period after a switch from regular HD/HDF using high-flux membranes to **HDx** therapy using the **MCO** membrane. Quarterly application of PROM tools to an in-center HD population was feasible and well accepted by patients. These results provide indications that enhanced clearance of large middle molecules, as achieved by **HDx**, may have a positive impact on HD individuals' symptom burden.

Switching to HDx therapy with MCO membrane led to a sustained, clinically relevant decrease in patient-reported recovery time after dialysis and a decrease in fatigue levels.

The **Theranova** Dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 kDa) that may play a pathologic role in the uremic clinical syndrome. The **Theranova** Dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for the **Theranova** Dialyzer and the set should represent less than 10% of the patient's blood volume.

For single use only.

Rx Only. For the safe and proper use of this device, refer to the Instructions for Use.

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