

Improvement in Depressive Symptoms and Quality-of-Life in HHD Patients

Cynthia J. D'Alessandri-Silva¹, Christopher Gunter¹, Michael A. Aragon¹, David E. Henner²
1. Outset Medical, San Jose, CA 2. Berkshire Medical, Pittsfield, MA

.Outset

BACKGROUND / INTRODUCTION

- Patients with end-stage renal disease (ESRD) commonly report depressive symptoms (e.g., feeling hopeless, suicidal thoughts), significantly impacting quality-of-life (QOL) and feelings of self-worth (e.g., feeling like a failure, letting your family down).
- These symptoms can impact a patient's overall sense of well-being as well as treatment recovery time.
- The HOME Registry Study (NCT04526301) is a multi-center, prospective, study on patients receiving HHD with the Tablo® Hemodialysis System.

METHODS

- In this interim analysis of The HOME Registry Study (NCT04526301) we report results from:
 - Patient Health Questionnaire-9 (PHQ-9)
 - Time-to-Recovery (TTR)
 - Participant Net Promoter Score (NPS)
- The results were used to quantify the impact of Tablo home hemodialysis on participants' mental health and perceived QOL.

RESULTS

- 99 subjects were enrolled into the HOME Registry, with mean age of 57, 73% male, 78% non-Hispanic/Latino, and 70% married or in a domestic relationship. PHQ-9 responses from baseline to month-12 are as follows:
 - Q1: no incidence of "feeling down, depressed, or hopeless"- baseline 68%, 12 month 74%; (90% reported this feeling ≤2 times over a 2-week period at 12 months).
 - Q2: no incidence of "feeling bad about yourself-or that you are a failure"- baseline 65%, 12 months 77% (84% reported this feeling ≤2 times over a 2-week period at 12 months).
 - Q3: no incidence of "thoughts that you would be better off dead or hurting yourself"-baseline 89%, 12 months 94%; (7% reporting this feeling ≤2 times over a 2-week period).
- Over 80% of participants at month-12 reported their HHD making no/some impact on their ability to work, take care of their home and getting along with others.
- TTR of <60min trended positively over 12 months of HHD, increasing 5.5%.
- Mean NPS score for likelihood of recommending HHD with Tablo to other ESRD patients on a point scale from 1 "not likely" to 10 "extremely likely" was 9.2 at month-6 and 9.3 at month-12 visit.

DISCUSSION / CONCLUSION

- HOME Registry patients on Tablo report
 - improvement in depressive symptoms
 - low time to recovery out to 12 months.
- At both 6 and 12 months at home performing self-care, patients are extremely likely to recommend home hemodialysis via Tablo to other patients.



Important Safety Information

Tablo Indication Statement
The Tablo® Hemodialysis System and TabloCart™ is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home. Treatment types available include Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), and Isolated Ultrafiltration. This device is not indicated for continuous renal replacement therapy (CRRT) and is cleared for use for up to 24 hours. The dialysate generated by this device is not sterile and should not be used for intravenous (IV) infusion.