The Tablo Hemodialysis System at Home: Comparing Real World to the IDE Trial

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BACKGROUND

- The Tablo® Hemodialysis System ("Tablo") obtained FDA clearance for home hemodialysis (HHD) in March 2020.
- Approval was based on a prospective, crossover trial, where 30 patients were followed for 8 weeks during each study phase (in-center and home).
- Tablo met all safety and effectiveness endpoints, reported high rates of treatment adherence, patient retention, and included a diverse patient population (Home IDE; NCT02460263).

OBJECTIVE

To report on the first 30 patients in the HOME Registry (NCT04526301), which is an ongoing study of real-world patients utilizing Tablo for HHD.

METHODS

Utilizing the same eligibility criteria as the Tablo IDE:

- Incident and prevalent patients were initiated on Tablo at participating study sites.
- Treatment data were obtained wirelessly via the Tablo data platform.
- All other data were reported by site staff into the study database.
- Data collected from the first 30 patients on the HOME Registry over the first 8 weeks was compared to the 30 patients who participated in the IDE.

RESULTS

- Mean patient age was 55.2 years, with the majority being male (66.7%), white (73.3%) and with an AV fistula (60.0%).
- Mean prescribed treatment time was 3.3 hours, with a mean prescribed frequency of 3.8 treatments per week.
- Treatment adherence was 95%, with 92% of treatments completing at least 90% of prescribed time.
- The mean number of clinically significant alarms per treatment was 1.3 (±2.9), with an average time to resolution of 10.8 (±23.1) seconds.
- The mean weekly standard Kt/V at the 4-week visit was 2.3±0.5.
- Patient retention was 100%, with no patients opting out of HHD with Tablo.
- One serious adverse event (SAE) was reported, a seizure and subsequent hospitalization, that was deemed not related to Tablo or to the HD treatment by the site investigator.

Table 1. Comparison of Patient Demographics: IDE & Registry

Characteristic	IDE (n=30)	Registry (N=30)
Age, y	52.3± 11.6	55.2 ± 16.3
Weight, kg	93.8± 17.0	90.4 ± 34.3
Male	63% (19)	67% (20)
Race		
White	57% (17)	73% (22)
Black or African American	43% (13)	17% (5)
Asian	-	7% (2)
Not Reported	-	3% (1)
Ethnicity		
Hispanic or Latino	27% (8)	13% (4)
No Hispanic or Latino	73% (22)	87% (26)
Vascular Access Type		
Fistula	77% (23)	60% (18)
Catheter	13% (4)	30% (9)
Graft	10% (3)	10% (3)

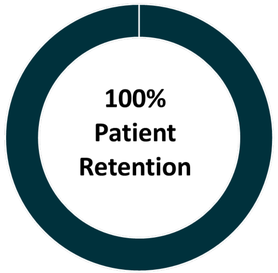

Table 2. Comparison of Treatment Parameters: IDE & Registry

Parameter	IDE	Registry
Prescribed treatment time (min)	207 ± 24	195.9 ± 35.3
Actual treatment time (min)	203 ± 31	190.0 ± 45.2
Prescribed UF volume (ml/tx)	2232 ± 1118	1250.8 ± 987.7
Actual UF volume (ml /tx)	2223 ± 1119	1088.8 ± 1064.9
Prescribed UF rate (ml/min)	10.6 ± 4.8	6.5 ± 5.1
Actual UF rate (ml/min)	10.7 ± 4.9	6.7 ± 9.7
Avg Standard Weekly Kt/V	2.8 ± 0.3	2.3 ± 0.5
Avg Clinically Significant Alarms (tx)	1.3 ± 3.0	1.3 ± 2.9
Avg time to Alarm Resolution (s)	11.7 ± 28.5	10.8± 23.1

CONCLUSION

- Tablo achieves standard adequacy goals and provides more flexibility in dialysis schedules than current HHD options.
- Results from the Tablo IDE are reproducible with high treatment adherence, patient retention, and low rates of alarms and SAEs.