

Evaluation of Clinical Lab Data from
the Tablo Hemodialysis Home IDE Trial

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BACKGROUND:

The Tablo[®] Hemodialysis System is an all-in-one system featuring:

- An Integrated Water Purification System
- On-Demand Dialysate Production
- A Simplified User Interface
- Two-way Wireless Communication

The recently published IDE trial using the Tablo system at home reported:

- Achievement of all primary and secondary efficacy endpoints.
- Achievement of all primary and secondary safety endpoints.

This study reports on the clinical lab data obtained during the Tablo Home IDE trial.

OBJECTIVE:

To assess several key clinical laboratory values for participants dialyzing 4 times per week on Tablo during the IDE trial.

The results provide insight into the stability of laboratory values of albumin, phosphorus, and hemoglobin on this treatment regimen with Tablo.

METHODS:

Participants were prescribed dialysis 4 times per week on Tablo:

- 8 weeks In-Center, 4 weeks of transition, and 8 weeks In-Home.

Prior dialysis modality, prescription and prior 3-month baseline labs were recorded.

Laboratory values were obtained no less frequently than monthly.

Results obtained during the In-Home period were compared to baseline values.



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RESULTS:

28 of 30 (93%) enrolled participants at 8 sites completed the trial per protocol.

- 15 previously In-Center participants dialyzed thrice weekly averaging 3.9 hours per treatment at baseline.
- 13 previously In-Home participants averaged 4.5 treatments per week, 3.1 hours per treatment at baseline.
- On Tablo, participants averaged 4 treatments per week and 3.4 hours per treatment.

SUMMARY:

Patients whether previously In-Center or In-Home, maintained stable values of albumin, phosphorus, and hemoglobin on Tablo 4 times per week at home.

Laboratory values between populations were similar.

There was a trend towards improved anemia and phosphorus results in the previously In-Home population both at baseline and during the In-Home phase.

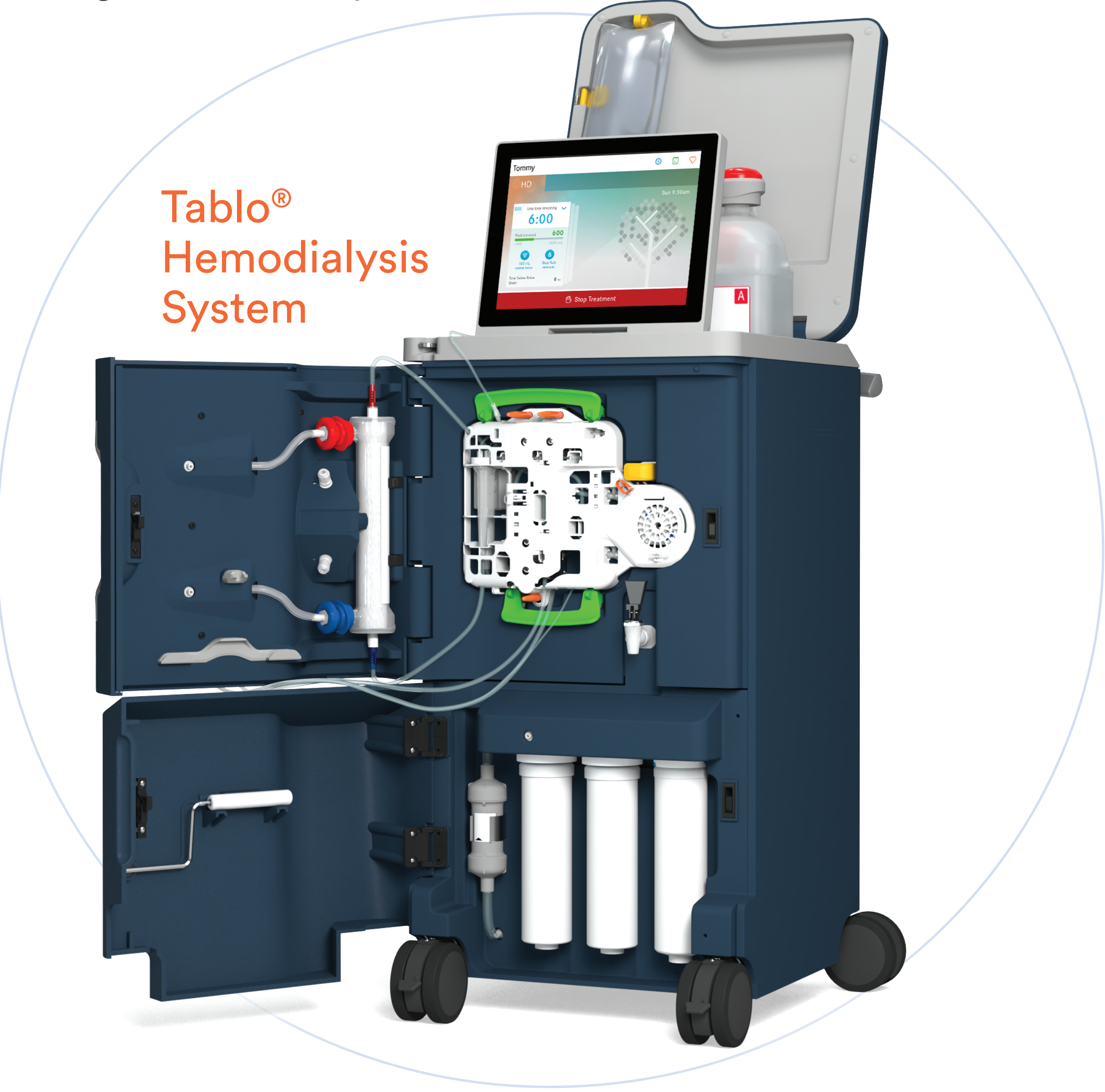


Table 1

Baseline labs compared to In-Home labs per subpopulation.

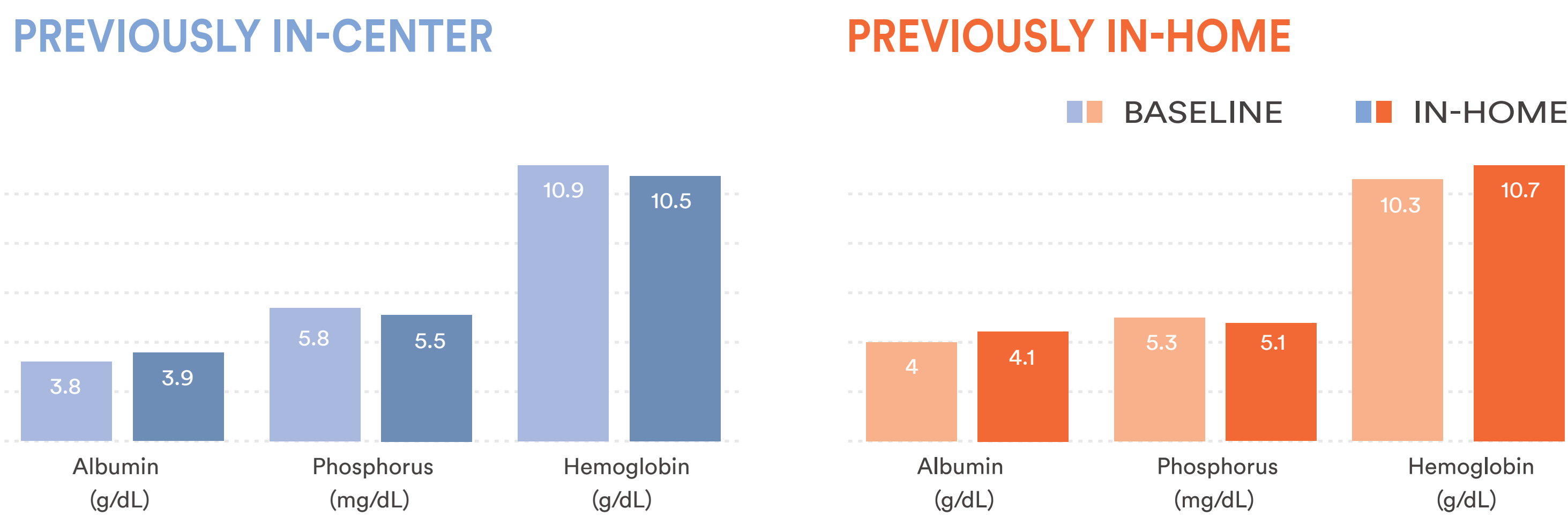


Table 2

Average Treatment Time per Week.

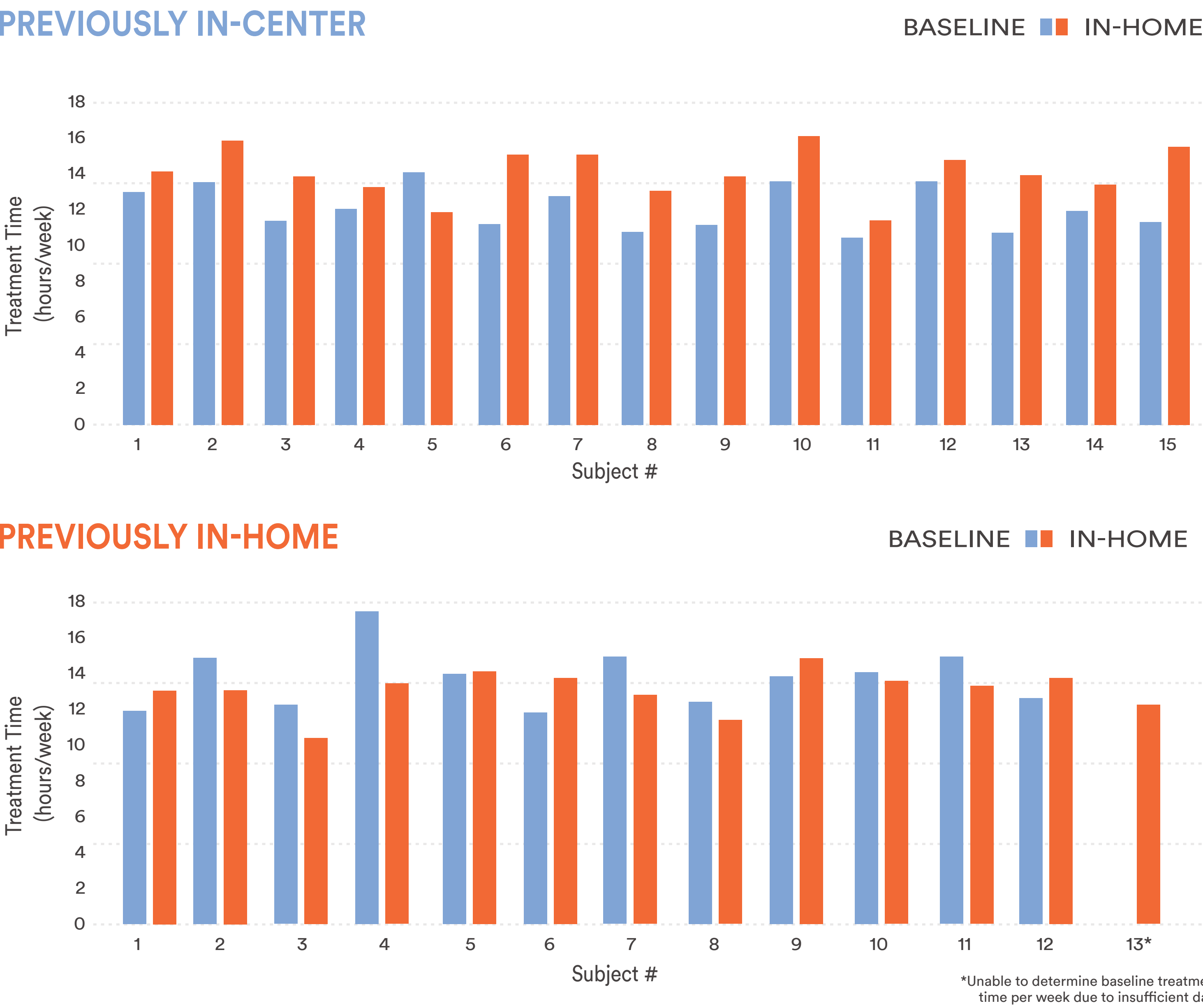


Table 3

PATIENT CHARACTERISTICS	PIH n (%)	PIC n (%)
Total	13	15
GENDER		
Male	8 (62)	10 (67)
ETHNICITY		
Not Hispanic or Latino	9 (69)	11 (73)
Hispanic or Latino	3 (23)	4 (27)
Not Reported	1 (8)	0 (0)
RACE		
White	8 (62)	8 (53)
Black or African American	5 (38)	7 (47)
AGE		
Avg ± SD	50 ± 13	55 ± 11
WEIGHT		
Avg ± SD	92 ± 17	97 ± 17
ACCESS		
Fistula	9 (69)	12 (80)
Catheter	2 (15)	2 (13)
Graft	2 (15)	1 (7)
PRIMARY CAUSE OF ESKD		
Diabetes	4 (31)	9 (60)
Polycystic Kidney Disease	2 (15)	0 (0)
Glomerulonephritis	1 (8)	1 (7)
Hypertension	1 (8)	0 (0)
Other	5 (38)	5 (33)

CONCLUSION:

At home, patients can maintain adequate control of anemia, phosphorus and albumin on 4 times per week therapy with the Tablo Hemodialysis System.