

Improved Quality of Sleep on Four Day per Week Home Hemodialysis with Tablo



Michael Aragon, MD¹, Yaadveer Chahal, BSc¹
¹Outset Medical, San Jose, CA

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 Investigational Device Exemption (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.

Poor sleep quality significantly impacts the quality of life (QOL) of patients with ESKD.

This study reports on participants' sleep quality using the Tablo system 4 times per week.



OBJECTIVE:

Assess sleep quality at baseline and during In-Home therapy with Tablo 4 times per week.

Provide insight into the possible impact on QOL of 4 times per week at home therapy with the Tablo Hemodialysis System.

METHODS:

Participants were prescribed dialysis 4 times per week on Tablo:

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

Modality at the time of enrollment was recorded. Participants completed a baseline sleep questionnaire which asked how many days per week they experienced any of the following symptoms:

- Difficulty falling asleep
- Difficulty with waking up several times during the night
- Difficulty staying asleep
- Feeling tired and worn out after sleep

Sleep quality was assessed weekly throughout the trial. Data obtained during In-Home phase was compared to the baseline assessment.

RESULTS:

13 previously In-Home (PIH) and 15 previously In-Center (PIC) participants completed all phases of the trial.

98.7% (221/224) of weekly surveys were completed.

Table 1 shows the data for symptoms experienced 3 or more days per week.

Table 1

Baseline assessment compared to In-Home assessment of symptoms experienced ≥ 3 symptoms per week by subpopulation.

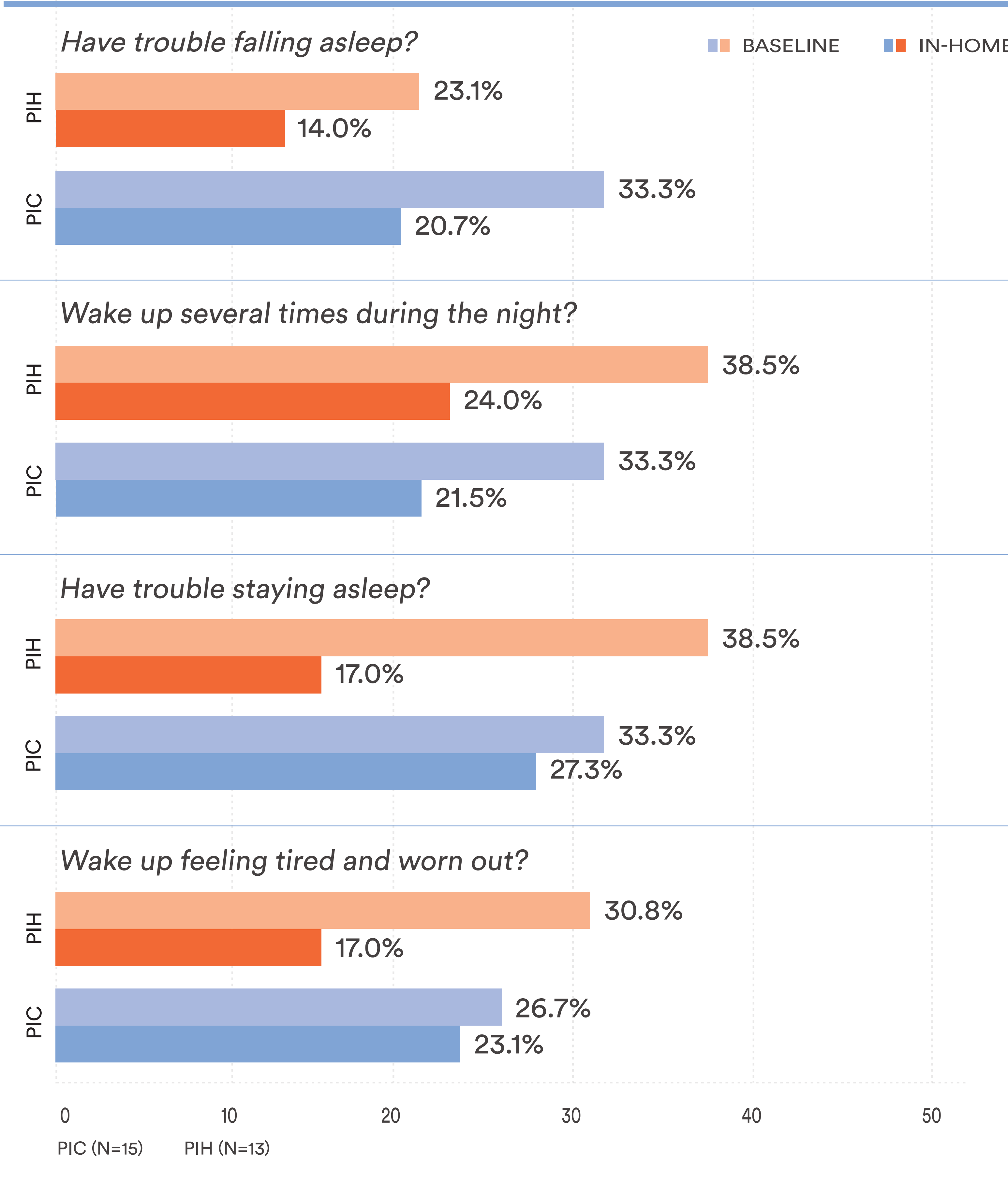


Table 2

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:

Home hemodialysis therapy with Tablo 4 times per week may improve sleep related symptoms in some patients with ESKD.



CONTACT FOR CORRESPONDENCE: Michael Aragon, MD
 maragon@outsetmedical.com