Insourced 24-Hour Prolonged Intermittent Kidney Replacement Therapy (PIKRT) in Critically Ill Patients: Multisite Outcomes from 10,000 Treatments

Co-authors: Elise Edson[1], Michael Aragon MD[1]

BACKGROUND/INTRODUCTION

- PIKRT reduces nursing burden and cost while demonstrating reproducible effectiveness and safety.
- PIKRT provides operational advantages over other ICU modalities.
- The Tablo Hemodialysis System simplifies traditional PIKRT delivery and expands the modality up to 24hrs.

OBJECTIVES

- Utilizing Tablo's cloud-based data platform, evaluate and report on prescription achievement, cartridge utilization and user experience on PIKRT treatments prescribed >23hrs with a maximum of 24hrs.

METHODS

- Transmitted data from Tablo's cloud-based platform was reviewed for acute treatments prescribed >23hrs.
- Cartridge usage, prescribed and achieved time and ultrafiltration (UF), alarms, and alarm resolution times were collected.
- Treatments were classified as achieving treatment time within 5mins or >5mins of prescribed time and subclassified by sensor data as device- or user-directed (with or without an alarm), consistent with FDA benefit-risk guidance and ISO 14971 standards.
- Critical alarms were defined as those leading to blood pump stoppage.
- Alarm resolution time was obtained from device sensor data.

RESULTS

- A total of 10,000 consecutive PIKRT treatments prescribed for >23hrs were analyzed across 148 hospitals.
- 88.5% were completed within 5mins of prescribed time
- 11.0% were terminated >5mins by the user (Fig. 1).
- Prescribed time averaged 23.6±2.2hrs vs Actual delivered time of 23.8±1.4hrs.
- Average UF achieved versus prescribed was over 99% (4.0±2.6L vs 4.0±2.6L).
- 82% of treatments experienced one or fewer cartridge changes
- 62% of treatments had one or fewer critical alarms with an average resolution time of 14.3±42.8secs (Table 1).

FIGURE 1

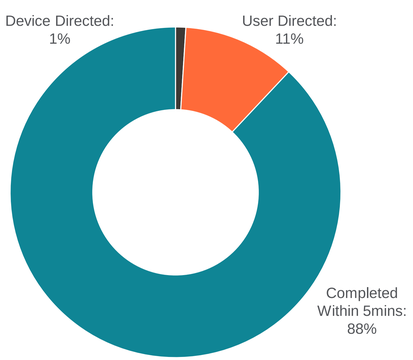

TABLE 1

Treatments (N)	10,000			Average Alarm Resolution (sec)	14.3 ±42.8
Average Achieved Time (h)	23.8±1.4	Average Prescribed Time (h)	23.6 ±2.2	% Time Achieved vs Prescribed	100%
Average Achieved UF (L)	3.99 ±2.6	Average Prescribed UF (L)	4.03 ±2.6	% UF Achieved vs Prescribed	99.10%

DISCUSSION

- Across 10,000 treatments, Tablo PIKRT prescribed >23hrs demonstrated over 89% achievement of prescribed time and 99% ultrafiltration achievement with infrequent cartridge changes and rapid alarm resolution.
- In critically ill patients, achievement of prescribed treatment duration and target ultrafiltration are foundational to optimal renal replacement.
- Minimizing treatment interruptions and cartridge changes enhance treatment efficiency and reduce potential for cartridge associated blood loss.

CONCLUSION

- PIKRT treatments >23hrs with Tablo were associated with high achievement of prescription goals with minimal workflow interruption. These findings support Tablo utilization for up to 24 hours in critically ill patients.

References:

1) U.S. Food and Drug Administration. Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions. 2016.

2) International Organization for Standardization (ISO). ISO 14971:2019 Medical devices — Application of risk management to medical devices. Geneva: ISO; 2019.

1. Outset Medical Inc, San Jose, CA, United States.

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