One Million Acute Insourced Dialysis Treatments Using Newer Technology

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BACKGROUND/INTRODUCTION

- Insourcing dialysis with newer technology has shown reduced cost, improved efficiency and similar, or improved, outcomes.
- The Tablo® Hemodialysis System enables insourcing through ease of use, integrated water purification, treatment flexibility and wireless data transmission.

OBJECTIVES

- Utilize Tablo's cloud-based data platform to report on over 1 million treatments at over 600 acute healthcare facilities insourced with Tablo.

METHODS

- Data query of the most recent 1 million acute dialysis sessions.
- Clinically significant alarms were defined as those leading to blood pump stoppage.
- Treatments were categorized as intermittent hemodialysis (IHD) or prolonged intermittent kidney replacement (PIKRT).
- Treatments either achieved prescribed time within 5 minutes or termination prior.
- Termination >5mins was subdivided into device-directed or user-initiated end treatment consistent with FDA guidance and ISO 14971 standards.[1,2]
- Alarm rates were based on events per hour.
- Alarm resolution time was determined from Tablo sensor data on duration from initiation to conclusion.

RESULTS

- Average treatment time for IHD was 3.3hrs (+/- 0.6hrs)
- Average treatment time for PIKRT was 16.7hrs (+/- 6.9hrs)
- Mean treatment time achieved for all treatment durations was over 99.5%.
- 81.2% of all treatments were completed within 5mins of prescribed
- 13.2% were terminated by the user >5mins from prescribed with no associated treatment alarm (Figure 1).
- Critical alarm resolution time averaged <16secs across all treatments with lower resolution time for IHD.
- Clinically significant alarm rates were low across all treatment times, with fewer occurring during IHD treatments.
- Average cartridge use per treatment was 1.1 across all treatment times.
- Detailed data presented in (Table 1).

FIGURE 1

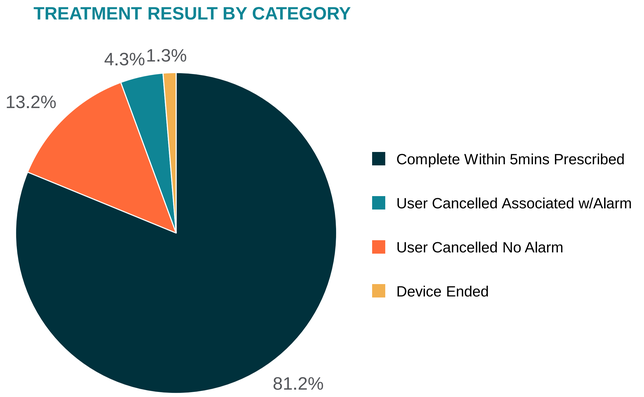

TABLE 1

Treatment Category	IHD	PIKRT	Total	Treatment Category	IHD	PIKRT	Total
Treatments (N)	969,279	30,721	1,000,000	Avg Achieved Ultrafiltration (Liters)	1.9 (+/- 1.1)	3.1 (+/- 2.2)	1.9 (+/- 1.1)
Avg Achieved Treatment Time (hrs)	3.3 (+/- 0.6)	16.7 (+/- 6.9)	3.6 (+/-2.3)	Avg Prescribed Ultrafiltration (Liters)	1.9 (+/- 1.1)	3.1 (+/- 2.1)	1.9 (+/- 1.1)
Avg Prescribed Treatment Time (hrs)	3.3 (+/- 0.6)	16.6 (+/- 7.0)	3.6 (+/- 2.3)	% UF Achieved vs Prescribed	98.7%	99.3%	98.7%
% Time Achieved vs Prescribed	99.1%	100.7%	98.7%	Avg Clinically Significant Alarms /Tx	2.1(+/- 5.6)	7.5 (+/- 17)	2.3 (+/- 6.3)
Average Alarm Resolution Time (secs)	5.6 (+/- 16)	15.3 (+/- 57)	5.9 (+/-19)	Alarm Rate per Hour	0.67	0.47	0.64

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.

DISCUSSION

- Across this 1 million treatment data set, there was a high realization of prescribed goal with a low occurrence of quickly resolved alarms.
- Fewer events and shorter resolution times observed with IHD are likely related to staffing differences for IHD vs PIKRT, dialysis access types, blood flow rates and treatment duration.
- Most user directed early terminations were not associated with device alarms and likely reflect nurse decision making (i.e. competing procedures, patient request, patient census)
- Average IHD treatment length was <3.5hrs consistent with common acute practice.
- PIKRT average treatment time of 16.7hrs may reflect a shift in practice away from 24hr therapy as a standard for critical patients.

CONCLUSION

- This large data set expands clinical evidence supporting high achievement of prescription goals in Tablo insourced facilities across a broad range of treatment durations.
- Observations suggest the continued acute practice pattern of IHD at less than 4hrs and a shift away from 24hr dialysis as a standard for prolonged renal replacement.

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

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