Comparison of 15- Vs. 30-Day Remote Patient Monitoring for Outpatient Chimeric Antigen Receptor T-Cell Therapy (CAR-T) Across a Large Health System

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Introduction

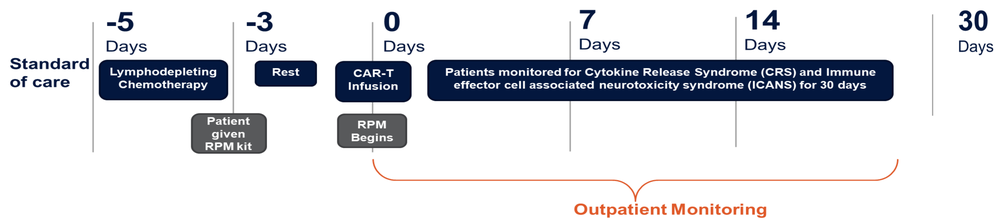
Remote patient monitoring (RPM) is a critical component of successful outpatient (OP) CAR-T, greatly reducing time in the hospital. The OP monitoring period following CAR-T is roughly four weeks to enable early intervention for toxicities such as cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). The optimal duration for RPM within the 30-day monitoring period is undefined. Previous work has shown that the incidence of new onset CRS and ICANS is low beyond the first two weeks post-infusion. Our primary objective was to compare clinical outcomes and the secondary objective to evaluate adherence metrics for 15-day versus 30-day remote pt monitoring programs (pgm) across four Sarah Cannon Transplant and Cellular Therapy Network (SCTCTN) sites.

Methods

Adults (18+ years) living <60 minutes from the treating hospital, with a 24/7 caregiver, who received non-investigational CAR-T and met OP criteria were eligible for OP administration. RPM involved enrollment into an FDA-cleared virtual care platform, virtual nurse engagement, and in-person clinic visits during the highest risk period (Days 0-14). While the overall OP duration was 30 days, **initial RPM pgm was planned for first 15 days at one site and for the full 30 days at three other sites.** The RPM kit included wearable devices that continuously transmitted vital signs (pulse, respiratory rate, and O_2 saturation), an axillary temperature patch, a tablet, and a blood pressure cuff. A multidisciplinary taskforce developed clinical pathways for remote monitoring, including parameters for alarms, virtual nurse check-ins, and escalation of care to the designated emergency department (ED) or clinic. Virtual nurses monitored vital sign trends, responded to patient concerns, and triaged according to clinical pathways, escalating as necessary.

Data from 209 patients between 2/20/23 and 6/15/2024 were analyzed. 56% had NHL, 34% myeloma, and 10% ALL. Metrics were summarized by pgm duration (15 vs. 30 days). Clinical outcomes and length of stay (LOS) were classified as occurring in the first 15 days (Day 0 - 14), or between day 15 and day 30 (Day 15 - 30). Adherence was calculated based on wear time completed versus prescribed. Wilcoxon matched-pairs signed rank test was used to compare patient adherence metrics between Day 0-14 and Day 15 – 30 in 30-day pgm.

Methods



Conclusion

OP administration using RPM and a clinical pathway driven program is safe and routinely possible with high rates of patient adherence. For patients receiving currently FDA approved CAR-T products, **RPM monitoring for the first 15 days will capture the vast majority of CRS and ICANS.**

Results

Comparative Data for 15 Day and 30 Day RPM Cohorts

	15 day (N = 97)		30 day (N = 112)	
	Day 0 – 14	**Day 15 - 30**	**Day 0 – 14**	**Day 15 - 30**
Patients requiring some level of hospital observation/admission (n)	83 (86%)	14 (14%)	92 (82%)	11 (9.8%)
Duration of inpatient admission (days) for hospitalized patients (median/IQR)	4 (3,8)	3 (2,6)	6 (3,9)	3 (2,5)
Patients requiring ICU (n) for patients who receive ICU care	13 (13%)	0 (0%)	48 (43%)	4 (3.6%)
Duration of ICU (day) (median/IQR)	2 (1,5)	--	8 (4,13)	9.5 (3,16)
Number of patients who developed CRS	77 (79%)	2 (2.1%)	79 (70%)	1 (0.9%)
Days to CRS Onset, Median (IQR)	5 (3, 7)		5 (3, 7)	
Max grade of CRS				
Grade 1:	25 (26%)	1 (1.0%)	48 (43%)	1 (0.9%)
Grade 2:	45 (47%)	1 (1.0%)	26 (23%)	0 (0%)
Grade 3:	4 (4.2%)	0 (0%)	4 (3.6%)	0 (0%)
Grade 4:	3 (3.1%)	0 (0%)	0 (0%)	0 (0%)
Grade Unspecified:	0 (0%)	0 (0%)	1 (0.9%)	0 (0%)
Number of patients who developed neurotoxicity (ICANS)	32 (33%)	5 (5.2%)	33 (29%)	1 (0.9%)
Days to ICANS Onset, Median (IQR)	7 (5, 9)		7 (5, 8)	
Max grade ICANS				
Grade 1:	12 (12%)	3 (3.1%)	10 (8.9%)	1 (3.6%)
Grade 2:	6 (6.3%)	0 (0%)	2 (1.8%)	0 (0%)
Grade 3:	2 (2.1%)	1 (1.0%)	6 (5.4%)	0 (0%)
Grade 4:	4 (4.2%)	0 (0%)	4 (3.6%)	0 (0%)
Grade Unspecified:	8 (8.3%)	1 (0%)	11 (9.8%)	0 (0%)
15 Day & 30 Day Pgm Survival*	70 (98.6%) 71 uncensored	61 (96.8%) 63 uncensored	90 (100%) 90 uncensored	82 (98.8%) 83 uncensored
	15 Day		30 Day	
Wearable adherence (%)	85.5 (75.5 – 91.4)		84.2 (77.4 – 91.1)	
Survey adherence (%)	75.0 (25.0 – 100)		68.2 (12.5 – 90.9)	
BP adherence (%)	100 (91.0 – 100)		97.7 (86.7 – 100)	
Monitoring duration days, Median (IQR)	10.5 (7.7—13.0)		25.8 (21.1—29.6)	

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