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Abstract Title : Remote multi-vital sign monitoring allows earlier detection of cytokine release syndrome after bispecific T cell engager and chimeric antigen receptor T cell therapies

Category: 900s - Health Services, Quality Improvement, and Outcomes Research

Review Category: 902. Health Services and Quality Improvement: Lymphoid Malignancies

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Abstract Body

Introduction:

Cytokine release syndrome (CRS) is a systemic inflammatory condition seen in 50-80% of patients after bispecific T cell engager (BiTE) or chimeric antigen receptor (CAR) T cell therapy. As these treatments transition into the outpatient setting, reliable monitoring strategies are needed to enhance safety through earlier detection of therapy toxicities.

Methods:

This prospective clinical trial evaluates a mobile health-supported multi-vital sign monitoring platform in patients with hematologic malignancies who received a BiTE or CAR T therapy (NCT06415656). TempTraq, a wearable axillary patch, passively records body temperature every 6 minutes, integrated with a smartphone application (VitalTraq) that estimates blood pressure (BP), heart rate (HR), and respiratory rate (RR) through a 30-second facial scan on the patient's smartphone camera. BP is calculated through remote photoplethysmography (rPPG) signals using a machine learning model, while RR and HR are directly captured from observed respiration and pulse waves in facial vessels.

Patients utilized TempTraq/VitalTraq as well as standard of care (SOC) vitals monitoring for 14 days after first dose or cell infusion. SOC monitoring protocol includes nursing vitals every 4 hours while inpatient, and patient-initiated thermometer monitoring every 4 hours at home. Regardless of setting, patients wore TempTraq continuously and performed VitalTraq facial scans every 4 hours while awake. Patients and clinicians were blinded to TempTraq/VitalTraq results to allow accurate lead-time calculations. Equivalence testing was used to evaluate the bias of temperature, BP, and HR measurements from TempTraq/VitalTraq relative to SOC. Following the study, perceived user satisfaction was evaluated using the validated Post-Study System Usability Questionnaire (PSSUQ), a standardized tool for assessing system usability.

Results:

32 patients enrolled, with 31 initiating the study. The median age was 67.5 years (range, 50-79); 50% were male. 72% were white, 25% black, and 3% American Indian. 17 patients (53%) had multiple myeloma, 14 (44%) non-Hodgkin lymphoma, and 1 (3%) acute lymphoblastic leukemia. 27 (84%) received CAR T and 5 (16%) received a BiTE.

A total of 97,642 TempTraq temperature measurements and 1,602 VitalTraq scans were captured. In equivalence testing, the mean difference in concurrent temperature values between SOC monitoring and TempTraq was 0.286 degC (95% CI, 0.12, 0.46), with TempTraq temperatures being slightly lower. This

estimated difference was within the pre-specified equivalence range (-0.625, 0.625), demonstrating equivalence of TempTraq to SOC ($p < 0.0001$). The mean difference in systolic BP between VitalTraq and SOC was 6.25 mmHg (95% CI, -0.68, 13.17; $p < 0.01$), falling within the pre-specified equivalence range (-20, 20). Diastolic BP ($p = 0.9$) and HR ($p = 0.57$) fell outside the equivalence range of (-10, 10). Of note, the study was powered for equivalence testing on temperature, but not BP or HR.

Any grade CRS was observed in 22 of 31 patients (71%) via SOC monitoring. TempTraq/VitalTraq detected 19 of the 22 cases, with 3 false negatives and 1 false positive. However, 2 'false negatives' were due to TempTraq non-compliance, while the third had a TempTraq measure of 37.9 degC, slightly missing the fever threshold. In the 'false positive' case, the patient had an elevated temperature by TempTraq/VitalTraq, but did not obtain SOC measurements for comparison. The median time to detection of first CRS by TempTraq was 28.2 hours faster than SOC.

The mean overall compliance was 93.1% for TempTraq and 85.5% for VitalTraq. Specifically, when at home, the mean compliance was significantly higher for TempTraq than SOC thermometers (92.9% vs. 69.6%, $p < 0.001$). Age, race, sex, and type of therapy were not associated with compliance.

28 of 31 patients completed the PSSUQ. On a scale of 1-7 (1 indicating highest satisfaction), the TempTraq/VitalTraq platform scored an average 2.7 on usefulness, 2.5 on information quality, and 2.7 on interface quality. Additionally, patients noted that the TempTraq was easier to use than a thermometer (1.9).

Conclusion:

TempTraq temperature measurements were equivalent to SOC thermometers. Remote monitoring detected CRS 28.2 hours faster and had greater home compliance compared to SOC, potentially enabling earlier intervention and allowing institutions to ease patient proximity requirements to the treating center.

Keywords: Emerging Technologies, Adverse Events , ALL, Adult, Technology and Procedures, Lymphomas, Diseases, Clinical Trials, Lymphoid Malignancies, Study Population, Human, Research, Plasma Cell Disorders, Lymphoid Leukemias, Clinical Practice (Health Services And Quality), Aggressive Lymphoma, Non-Hodgkin Lymphoma, Clinical Research, Quality Improvement, Patient Safety, B Cell Lymphoma

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