TPS12146 Poster Session

A pilot study of the ApricityCare program for early detection and management of treatment-related adverse events in patients with metastatic cancer.

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Background: Immune checkpoint therapies (ICTs) induce T cell-mediated anti-tumor immunity and can provide long-term survival benefits for cancer patients. However, ICTs may also cause life-threatening immune-related adverse events (irAEs), often requiring treatment discontinuation and high-dose steroids, leading to significant comorbidities. Early detection and intervention in irAEs can reduce steroid use, enable continuation of ICTs, and improve clinical outcomes. To address the need for earlier detection of severe irAEs, we are implementing ApricityCare, a digital health service that integrates remote symptom reporting via smartphone application, telephone, or text message, with telehealth feedback for patients on ICTs. The platform analyzes patient-reported symptoms and alerts triage nurses to intervene based on pre-specified algorithms. Hypothesis: We hypothesize that early detection and intervention in severe irAEs will improve outcomes and enable ICT continuation. **Methods:** This phase IV clinical trial evaluates ApricityCare's impact on treatment outcomes for patients receiving systemic therapies for metastatic cancer. The study includes a 50-patient run-in phase (Part I) focusing on genitourinary metastatic cancers (prostate, kidney, bladder) to assess feasibility, followed by an expansion of up to 1,000 patients (Part II) across three cohorts: investigational immunotherapies (IO), standard-of-care IO, and standard-of-care non-IO. In Part I, the primary objective is to assess patient symptom reporting via ApricityCare, defined as 80% of patients reporting symptoms for at least 80% of the study duration. Part II aims to determine the rate of therapy discontinuation due to toxicity. Exploratory objectives include associations between alerts and diagnoses, corticosteroid use (>2 weeks), and emergency visits/hospitalizations. Futility for each cohort will be evaluated using a Bayesian optimal phase 2 design, monitoring patients without therapy discontinuation over 3 months. The study is open for enrollment. ApricityCare usage will be analyzed by study phase and cohort. Symptom reporting frequency, Net Promoter Score (NPS), corticosteroid dose, and emergency visit/hospitalization rates will be summarized using frequencies, medians, and interquartile ranges. Time from symptom onset to active management will be assessed with Kaplan-Meier methods. Associations between alerts and confirmed diagnoses will be evaluated for sensitivity and specificity, with clinical diagnoses as the gold standard. The modified intention-to-treat (mITT) population includes all patients receiving at least one anticancer regimen dose. Longitudinal data will be used to identify symptom profiles associated with and preceding irAEs, informing future clinical trials. Clinical trial information: NCI-2024-09566 and MDACC 2024-0229. Research Sponsor: None.