TPS11587 Poster Session

Integrating early palliative care in advanced sarcoma patients for enhanced quality of life: The SARQUALITY study.

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Background: Patients with advanced cancer may experience physical and psychological symptoms impacting health-related (HRQOL). The World Health Organization defined palliative care as "an approach that improves the quality of life of patients and their families" by identification and management of pain and other symptoms, spiritual and psychosocial assessments and interventions, facilitation of home and community-based supports, and transition to end-of-life care. Early palliative care (EPC) integration with cancer-directed treatment can enhance patient-reported outcomes (PROs). However, patients with sarcoma have been underrepresented in these studies, underscoring the need to evaluate the role and benefits of EPC in this population. This study aims to determine whether EPC alongside standard oncological care (SOC) improves PROs for patients with advanced sarcoma compared to usual care. **Methods:** This is a single program, dual institution phase 2 open-label clinical trial designed to assess whether EPC improves the HRQoL of patients with advanced sarcoma. Main eligibility criteria at enrolment include systemic treatment naïve patients over the age of 18 years with histologically proven advanced sarcoma, ECOG 0-2, English speaking and life expectancy of over 6 months. Enrolled patients are randomized 1:1 to either SOC alone or with EPC. Patients randomized to EPC will be reviewed by palliative care within 2 weeks of randomization. EPC will include routine in person (or virtual) contact integrated into their oncology visits and access to a 24-hour on-call service. Patients receiving SOC alone will be referred to palliative care upon emergence of uncontrollable symptoms or upon request by the patient. Patients on both arms will receive standard of care follow-up with their oncology teams and complete Edmonton Symptom Assessment System (ESAS) and EORTC QLQ-C30 questionnaires at baseline, weeks 6, 12 and 24. For the primary endpoint, EPC will be considered effective if ESAS score decreases at week 12 compared to baseline using T test, with one-sided significance level set to be 0.05. The secondary endpoints include EORTC QLQ-C30 score change (baseline to weeks 6, 12 and 24), number of extra clinic visits, emergency department attendance and overall survival at 6 and 12 months. Comparison between the two arms, assessing both scores, will be done using Fisher's exact or Chi-square test. Generalized linear mixed model will be carried out to examine the difference between the arms over time. To ensure this trial is powered to determine a significant statistical difference, we plan to enroll 136 patients with an estimated accrual period up to three years. This study commenced enrolment March 2024 and to date (January 2025) 27 patients have been recruited with 13 (48%) randomized to EPC. An amendment is currently ongoing to include the use of electronic wearables as part of the study evaluation. Research Sponsor: None.