

Abstract

Intensive Longitudinal Monitoring of Symptom Patterns in Patients With Melanoma Treated With BRAF/MEK Inhibitors: A Pilot Study

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Introduction. Melanoma represents a major public health challenge. Despite significant therapeutic advances associated with BRAF and MEK inhibitors, patients may experience a complex and dynamic symptom burden. Conventional clinical assessments provide a static perspective and may fail to capture intra- and inter-daily symptom fluctuations. Patient-reported outcomes, particularly the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), enable the patient's perspective to be incorporated into symptom assessment. However, their application within intensive longitudinal designs remains limited. This pilot study aims to characterise temporal symptom patterns among patients with melanoma receiving BRAF/MEK inhibitors and explore their associations with daily activity interference and self-care behaviours.

Methods. This intensive longitudinal pilot study will be conducted at the Oncology Day Hospital of IDI-IRCCS. Approximately 165 patients with melanoma receiving BRAF/MEK inhibitors will be enrolled and stratified into three cohorts according to treatment phase: treatment initiation, consolidation phase of at least three months, and advanced phase of at least six months. Participants will complete a PRO-CTCAE-based symptom diary twice daily, in the morning and evening, for three weeks. Sociodemographic, clinical, and symptom-related data will be collected. Descriptive and exploratory

analyses will focus on intra-individual variability and temporal symptom patterns.

Results. The study is expected to characterise intra- and inter-daily symptom fluctuations and identify dynamic and recurrent symptom patterns across treatment phases. Symptom interference with daily activities and its association with self-care behaviours will also be explored, with potential implications for treatment adherence and early symptom management.

Discussion. Intensive symptom monitoring represents an innovative and patient-centred approach to understanding the symptom experience of patients with melanoma. Findings from this pilot study may inform the development of targeted nursing interventions, facilitate the early identification of clinically relevant changes, and support personalised symptom management throughout the treatment pathway.

Keywords: Melanoma, BRAF/MEK Inhibitors, Patient-Reported Outcomes, PRO-CTCAE, Intensive Longitudinal Study

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