Abstract

Longitudinal Assessment of Financial Toxicity in Oncology: Observational Study Protocol

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Introduction. Financial toxicity (FT) is increasingly recognized as an important determinant of oncological outcomes, affecting quality of life, treatment adherence, and survival. In universal healthcare systems such as the Italian system, the phenomenon remains poorly characterized and is likely underestimated. The recent validation of the Patient-Reported Outcome for Fighting Financial Toxicity (PROFFIT) provides a specific instrument for its assessment; however, longitudinal evidence regarding its evolution and association with clinical outcomes remains limited. The aim of this study was to evaluate changes in financial toxicity over time and analyze its association with quality of life, severe toxicity, and survival in patients with genitourinary and gastrointestinal cancers.

Methods. A prospective longitudinal observational study is being conducted at Fondazione IRCCS Istituto Nazionale dei Tumori di Milano. Adult patients (≥18 years) with metastatic genitourinary or gastrointestinal cancers eligible for first-line treatment will be enrolled. The estimated sample size is 196 patients ($\alpha = 0.05$; power = 0.80; effect size = 0.10; 20% dropout). Financial toxicity will be assessed using PROFFIT, while quality of life will be measured using the EORTC QLQ-C30 at three time points: T0, T1 (2–3 months), and T2 (5–6 months). Clinical data will include grade ≥3 adverse events, survival, and treatment persistence. Analyses will include linear mixed models, regression models, and survival analyses. The study was approved by the Ethics Committee Lombardia 4 (No. 106/25).

Results. The study is currently ongoing, with 10 patients enrolled to date. Changes in financial toxicity throughout oncological treatment are expected, together with associations between financial toxicity, quality of life, and clinical outcomes. These findings may allow the identification of clinical and socioeconomic risk profiles.

Discussion. Assessing financial toxicity in a highly specialized oncology setting will provide insight into its evolution among patients undergoing complex and prolonged treatments. The longitudinal design will enable observation of financial toxicity throughout the therapeutic pathway, while the use of PROFFIT will provide a specific measure adapted to the Italian context.

Keywords: Financial Toxicity, Patient-Reported Outcomes, Quality Of Life

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