The added value of Patient Reported Outcomes in oncology clinical trials. The PROBE experience.


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ABSTRACT

Introduction
The Patient Reported Outcomes and Behavioural Evidence (PROBE) project brings together investigators from a variety of disciplines in oncology to conduct retrospective quantitative analysis of data pooled from closed randomized clinical trials (RCTs).

Its aim was to better understand the burden of cancer on patients’ lives from the patient’s perspective and to create better interpretive tools to guide clinicians in their decision making for improving patients’ Health-Related Quality of Life (HRQOL).

Matériel et Méthodes Material and Methods
All analyses were based on 30 closed EORTC RCTs that were merged for this project. Among many research topics, researchers explored cancer survival prognosis, internal relationships among indicators and Minimal Important Differences (MID) for HRQOL Scores for the European Organisation for Research and Treatment of Cancer (EORTC) quality of life questionnaire (EORTC QLQ-C30).

Résultats Results
Since 2008, over 20 meta-analyses have been conducted, 25 abstracts presented at major conferences (e.g. ASCO, ESMO), five papers published and five submitted to high impact factor oncology journals. Our study of symptom clusters revealed that symptoms tend to appear in clusters for cancer types and treatments. The study of baseline HRQOL as a prognostic indicator of survival strongly suggests that patient-reported data on their HRQOL increases predictive accuracy when compared to clinical data alone. The meta analysis study of clinical MID estimated the smallest HRQOL score on the EORTC...
QLQ-C30 considered important (>10) which can guide clinicians to evaluate changes in HRQOL over time, to assess the value of a health care intervention, or to compare treatments.

While these analyses provided valuable insights, major constraints, such as data access, data ownership, transfer of data across member states, the need to standardise databases to facilitate meta-analysis, and funding are possible long term barriers that need to be addressed by PROBE investigators.

**Conclusions**

Using closed international clinical trials holds great promise towards understanding the patient’s unmet psychosocial and QOL needs. Despite the challenges, we believe the PROBE initiative is something invaluable that can maximize the use of patient-reported data, which otherwise might have limited further use in closed RCTs.

Our multi-disciplinary research project suggests that PROs, alongside clinical data, can be used by health care professionals to predict survival more accurately, evaluate changes in HRQOL and to better understand their patients’ needs. Such results would not have been possible without conducting retrospective HRQOL analysis in closed RCTs.

**Key Words:** Oncology, EORTC, QLQ-C30, Patient Reported Outcomes, Randomized Controlled Trials

**BIBLIOGRAPHY (including published papers and papers in progress)**

- Maringwa et al. Minimal Important Differences for Interpreting Health Related Quality of Life Scores from the EORTC QLQ-C30 in Lung Cancer Patients Participating in Randomized Controlled Trials
- Maringwa et al. Minimal Clinically Meaningful Differences for the EORTC QLQ-C30 and EORTC QLQ-BN20 Scales in Brain Cancer Patients
- Quinten et al. Is patient self-reporting more accurate than clinician reporting of symptoms for predicting survival in patients with cancer? A pooled retrospective EORTC analysis
- Maringwa et al. Effect of Time Windows in Analysis of Health-Related Quality of Life (HRQOL) Outcomes Based on the EORTC QLQ-C30
- Martinelli et al. Examining the relationships among Health-Related Quality of Life indicators in cancer patients: a pooled study of baseline EORTC QLQ-C30 data
- Quinten et al. Understanding the age-dependent cancer burden on pretreated Health Related Quality of Life of cancer patients: a pooled study by the EORTC Quality of Life Department

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