A Review of Health-Related Quality of Life Assessment in EORTC Cancer Clinical Trials

The European Organisation for Research and Treatment of Cancer (EORTC) has been important in advancing the understanding of clinical trials involving HRQOL in cancer patients. Since 1980, and especially within the last two decades, HRQOL has become a critical component of clinical practice.

Aims

1. HRQOL assessment in clinical trials: EORTC has conducted 744 RCTs in the period 1980-2012, with 369 of these in Phase II. Despite the importance of HRQOL, only 10% of these RCTs included HRQOL assessment. Of those RCTs that did include HRQOL, many did not assess all aspects of HRQOL.

Methods

1. Data extraction: The EORTC protocol database was reviewed, restricting the search to the period 1980-2012 (n=744). We investigated the number of EORTC RCTs including HRQOL, the use of HRQOL tools, and identified those RCTs that altered clinical practice.

Results

1. Of 744 RCTs assessed, 13% included HRQOL assessment, involving 71,702 patients. Of these, 32% included HRQOL assessment in the Phase II trials. Of those RCTs that included HRQOL, 88% used a larger sample size compared to RCTs that did not include HRQOL.

2. The most common selected HRQOL assessment tools were the EORTC QLC-C30 and QLC-C13 modules, which were used in 29% of the trials. The most common HRQOL assessment in the EORTC clinical trials with the most RCTs containing HRQOL assessment were the EORTC QLC-C30 and QLC-C13 modules.

Conclusions

1. The EORTC RCTs (n=744) which included HRQOL assessment and demonstrated how recent findings in EORTC RCTs have altered clinical practice and made a significant impact on patient care. The findings were based on the review of the EORTC protocol database and the analysis of the number of RCTs including HRQOL assessment.

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References


4. Van Cutsem E, Di Lorenzo S, Fassnacht M, et al. In the randomized double-blind EORTC, STBSG global network phase III study, paclitaxel and carboplatin were compared with paclitaxel and continue chemotherapy in patients with advanced non-small-cell lung cancer (EORTC 22952-26001, EORTC 62072 (PALETTE)). The EORTC protocol database was reviewed, restricting the search to the period 1980-2012 (n=744). We investigated the number of EORTC RCTs including HRQOL, the use of HRQOL tools, and identified those RCTs that altered clinical practice.