

A DATABASE REVIEW OF PATIENT REPORTED OUTCOME STUDIES IN EORTC CANCER CLINICAL TRIALS

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Purpose

For the last two decades, QL has been increasingly assessed in the EORTC. A detailed database review of all completed and ongoing EORTC QL studies has been undertaken.

Methods

A database of all EORTC QL clinical trial protocols was established in 2000. This regularly updated database comprises all trials where QL has been included as an endpoint. It summarizes details of closed and ongoing trials, QL tools used, assessment timing, disease and treatment types, compliance and published outcomes. These were examined and reported.

Results

The database contains over 128 EORTC clinical trial protocols over a 15 year period between 1995 and 2010 which included a QL component. This is an average of eight new clinical trials with QL per year with only two having QL as a primary endpoint. The QLQ-C30 was the instrument of choice in 85% of trials. In the last decade, 15 EORTC clinical groups have been recruiting patients. The majority of trials were conducted by the radiotherapy, brain and breast groups. Over 20,000 patients, mostly from Belgium, France, Germany and the Netherlands, have been entered into closed and ongoing multinational trials. Typically, EORTC trials are conducted across an average of 12 countries which include over 85 centers and often involve only a single trial. Several early EORTC trials experienced lower than ideal compliance. This presents a major challenge for the EORTC, but trials in the last 6 years have demonstrated significantly improved compliance. Most QL studies were published as separate papers from the main clinical paper, and over 80% were published in high impact factor journals (IF>12).

Conclusion

QL is now a major component of cancer clinical trials, an almost standard secondary endpoint. This suggests that researchers in the European context increasingly acknowledge the importance of patient reported outcome assessments for evaluating cancer therapeutic modalities.