

Study shows value of HRQOL assessment in small cell lung cancer

28 January 2014, by John Bean, PhD



An EORTC study published in *Lancet Oncology* found that health-related quality of life (HRQOL) assessment in small-cell lung cancer randomized clinical trials provides relevant added information in studies where the treatment arms do not differ in terms of efficacy. More importantly, it provides valuable information for those treatments where better HRQOL is associated with overall survival benefit. The study also found that even though the overall standard for reporting health-related quality of life was acceptable, there is still need for improvement regarding its reporting in randomized clinical trials to optimize their value.

There were an estimated 410,000 new cases of [lung cancer](#) and 353,000 deaths in Europe in 2012. Small-cell lung cancer accounts for roughly 15% of all lung cancers, and most small-cell lung cancer patients present with advanced disease. Consequently, disease management and treatment focuses on symptom control and health-related quality of life. In randomized [clinical trials](#), health-related quality of life of small-cell lung cancer is now being evaluated more frequently.

The objective of this EORTC study was to evaluate the adequacy of health-related quality of life methodology reporting in small-cell lung cancer

[randomized clinical trials](#) and the possible impact of this on clinical decision making. The study concerned randomized clinical trials that implemented patient-reported health-related quality of life assessments and oncology treatments for adult small-cell lung cancer patients (18 years of age or older), were completed between January 1991 and December 2012, included 100 or more patients, and were published in English. Over 10,000 patients were classified as eligible for this study from 30 randomized clinical trials out of an initial pool of 79 studies found.

The EORTC study found that HRQOL was a secondary endpoint in 29 RCTs of which 53% reported no significant difference in overall survival (OS). A difference of HRQOL was reported in 77% of the positive-outcome trials, and in 50% of the negative-outcome trials. A priori hypothesis on the expected overall HRQOL outcome was defined in 27% of the RCTs. Baseline HRQOL assessment was stated as mandatory in 14% of the RCTs. Tests of statistical significance were applied in 90% of the RCTs and missing data were discussed in detail in 30% of the trials.

Dr. Andrew Bottomley, EORTC Assistant Director and an author of this study says, "The EORTC has been a leader in establishing standards for conducting systematic reviews of patient reported outcomes in oncology randomized clinical trials. Arguably, the most important point about science is if results are reproducible. We have seen, time and again in over a decade of systematic literature research, that our results are consistent. We hope our quality of life research program has been useful in obtaining robust clinical research results, that these can be interpreted with confidence, and that decision makers can accept these findings from clinical trials in oncology. We hope our research has led others to use the EORTC Patient Reported Outcomes Checklist to design and evaluate other clinical trials and ensure high quality HRQOL."

More information:

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