Health-Related Quality of Life in Small-Cell Lung Cancer: A Systematic Review on Reporting of Methodological and Clinical Issues in Randomized Controlled Trials


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Small-cell lung cancer (SCLC) is a fast-growing type of lung cancer and accounts for 15% of all lung cancers [1]. SCLC is slightly more common in men than women and almost all cases of SCLC are concentrated in patients under the age of 70 years. SCLC has a high mortality rate, with 90% of patients dying within 5 years of diagnosis. SCLC is characterized by a high incidence of distant metastases at diagnosis, rapid disease progression, and frequent relapse and the most common metastatic disease. In general, survival varies with the stage of disease, with the most prominent ones being stage I/II (30% of the trials). Quam pero te

**METHODS**

A MEDLINE systematic review was performed in RCTs. Eligible RCTs were identified by searching the MEDLINE database for all SCLC patients. Included studies were published in English between January 1991 and December 2012, with sample size ≥100 and patient follow-up ≥18.

A checklist of evaluation criteria [4] was used for three independent reviewers who evaluated 29 topics in each of the eligible RCTs. The checklist included 27 topics (47% of which were related to HRQOL) and 28 topics (53% of which were related to the RCTs); trial design aspects relevant to HRQOL endpoints; study quality data; the quality of the HRQOL measurement; and all statistical analysis and presentation of results.

**RESULTS**

The current review included 10 SCLC RCTs [4]. HRQOL was a secondary endpoint in 29 of 40 reported no significant difference in OS. For example, HRQOL was reported in RCTs of the positive-outcome trials and in 44% of the negative-outcome trials. Significant improvements in HRQOL were seen when standard platinum-based regimens were compared with at least one combination and carboplatin, etoposide, and vincristine. Improvements in HRQOL were also seen for a combination of HRQOL assessment tools, with the most prominent ones being EORTC QLQ-C30 plus QLQ-LC13.

**DISCUSSION**

A large number of SCLC trials globally incorporate HRQOL assessment and while the overall reporting of HRQOL seems acceptable, some improvement in methodology should be considered.

**OBJECTIVES**

The objective was to evaluate the adequacy of HRQOL methodology in SCLC RCTs over the last two decades and its possible impact on clinical decision making.

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A checklist of evaluation criteria [4] was used for three independent reviewers who evaluated 29 topics in each of the eligible RCTs: (a) key characteristics identified in the HRQOL tools; (b) trial design aspects relevant to HRQOL endpoints; (c) study quality data; the quality of the HRQOL measurement; and all statistical analysis and presentation of results.

**RESULTS**

The current review included 10 SCLC RCTs. HRQOL was a secondary endpoint in 29 of 40 RCTs, while no significant difference in OS was reported in 27 of the RCTs of the positive-outcome trials and in 44% of the negative-outcome trials. Significant improvements in HRQOL were seen when standard platinum-based regimens were compared with at least one combination and carboplatin, etoposide, and vincristine. Improvements in HRQOL were also seen for a combination of HRQOL assessment tools, with the most prominent ones being EORTC QLQ-C30 plus QLQ-LC13.

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