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Systematic literature review of health-related quality of life in locally-advanced non-small cell lung cancer: Has it yet become state-of-the-art?

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ABSTRACT

Lung cancer and its treatment have an important impact on the patients' health-related quality-of-life (HRQoL). A systematic literature review of prospective clinical studies published since 2005 and measuring HRQoL in patients with locally-advanced non-small cell lung cancer (LA- NSCLC) was performed. Besides reviewing the HRQoL impact of LA-NSCLC treatment, it critically examined the frequency, methodology and quality of HRQoL data collection and analysis in LA-NSCLC clinical studies. Out of 814 potentially eligible publications, only 27 (representing 19 individual studies) met the inclusion criteria. Eight studies documented an impact on HRQoL. Large variability in use of HRQoL instruments, statistical analysis and methodological quality was observed. Reporting of HRQoL data lacks standardization, but recent initiatives establishing recommendations to standardize the analysis and reporting of HRQoL in cancer trials are expected to address these issues. Overall, more research is needed to evaluate the treatment impact on HRQoL in both clinical trials and daily care.

1. Introduction

Lung cancer is the most common cause of cancer death globally (Ferlay et al., 2015). Currently, non-small cell lung cancer accounts for more than 80% of all lung cancers, of which the vast majority presents with advanced disease stages and 30–35% has locally-advanced disease (LA-NSCLC) at diagnosis. Choosing the optimal treatment for these patients is difficult because of the large heterogeneity in disease extent and pathology, as well as in co-morbidity and general condition of each individual patient (Stinchcombe and Socinski, 2009). To date no single therapeutic approach can be recommended for all patients, hence the need for personalized care.

The prognosis of LA-NSCLC is poor (Aupérin et al., 2010). Regardless of the unceasing efforts made to improve outcome by optimizing multimodality treatment – often consisting of novel combinations of radiotherapy and systemic therapy – the impact on survival remains typically limited to the order of magnitude of months (Stinchcombe and Socinski, 2009; Tanvetyanon et al., 2007). In this context, measuring health-related quality-of-life (HRQoL), in addition to traditional outcome measurements, is considered to be of added value (Damm et al., 2013; Osoba, 2011). In randomized controlled trials (RCT), HRQoL may offer an additional tool to forecast and assess the relative risks and benefits of a new treatment. Moreover, being identified as a prognostic

factor for survival (Efficace et al., 2006; Langendijk et al., 2000; Lemonnier et al., 2014; Movsas et al., 2009), pretreatment HRQoL measurement has the potential to aid daily clinical decision-making and choosing the optimal treatment for the individual patient (Damm et al., 2013).

Whereas quality-of-life (QoL) tools measure all facets of life, including non-health related aspects, HRQoL measurement instruments quantify only the degree to which a disease and the therapy chosen impacts the patient's life. Yet, the terms QoL and HRQoL are frequently used interchangeably. Although the definition of HRQoL may differ from study to study, it generally refers to a multidimensional concept covering physical, role, emotional, social, cognitive, sexual and spiritual functioning (Fayers and Machin, 2000; McKenna, 2011). We define HRQoL measurements in lung cancer as measurements evaluating the relation between lung cancer and its treatment and the various aspects of functioning and of lung cancer-related symptoms, such as pain, appetite-loss and nausea. If these measurements are performed directly by the patient, they are referred to as patient-reported outcomes, PRO (Frost et al., 2007).

The aim of this systematic literature review is to provide an overview of prospective clinical studies in LA-NSCLC published over the last decade using HRQoL as an endpoint. In particular, this review wants to shed light on how often and how HRQoL is included in LA-NSCLC

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studies and whether HRQoL has an additional value to determine outcome in this critical patient population. Moreover, the statistical approach and methodological quality of HRQoL assessment and reporting in these studies is reviewed.

2. Materials and methods

2.1. Literature search

A literature search, conducted according to the PRISMA principles (Moher et al., 2009) was performed in Medline, Web of Science, Embase and Cochrane database with both systematic and free text terms concerning HRQoL, locally advanced and NSCLC. The last search was performed on March 31st, 2017. In addition, hand-searching the references of the eligible publications was undertaken to identify more potentially relevant papers.

2.2. Study selection

All prospective clinical studies, both clinical trials and observational studies, published in English between January 2005 and December 2016, focusing on the treatment of LA-NSCLC and reporting repeated assessments of HRQoL, were included. In case the HRQoL concept was briefly mentioned without comprehensive details, an attempt was made to search for companion papers that addressed HRQoL data in more detail. Studies measuring symptom scores assessed by HRQoL measurements were also included. Review articles, conference presentations, short reports, study protocols, editorials and letters were excluded, as well as publications without full-text availability. HRQoL analyses published independently from the clinical studies, identified by screening the bibliography of the selected papers, were reviewed along with the original publication. In case a study was presented in more than one publication, all relevant publications were included in this review, but were counted as one study.

2.3. Data extraction

Abstract screening was performed by three investigators (LVDW, VS, YL). For each included study, general characteristics and data on HRQoL parameters were abstracted. Data extraction of articles was performed by one investigator (LVDW) in close collaboration with two others (VS, YL). Reviewers met early in the reviewing process to ascertain consensus and avoid discrepancies.

2.4. Evaluating the methodological quality of HRQoL assessment

The methodological quality of each primary study was assessed by the 2013 CONSORT (Consolidated Standards of Reporting Trials) PRO (patient-reported outcome) extension checklist. This checklist provides guidance on reporting PROs in RCTs with PROs as primary or secondary endpoints. The CONSORT-PRO extension checklist added 5 items to the CONSORT 2010 checklist to aid optimal reporting of PRO data (Calvert et al., 2013). As certain items in the checklist are not applicable for some of the included studies, such as those concerning blinding and randomization, analysis in these studies was restricted to the applicable items.

3. Results

Eight hundred fourteen articles were extracted, in addition, 12 publications were found through hand search the references. After abstract review, 68 articles were submitted to full text analysis. As a result, 27 publications (representing 19 studies) were submitted to qualitative synthesis. The stages of the review process are summarized in Fig. 1. Details of the general characteristics of the included studies and of the HRQoL evaluation are presented in Table 1, respectively 2.

3.1. General characteristics

Of the 19 studies in this review, 11 were RCTs, (6 phase II; 5 phase III), 7 were single arm studies (1 phase I, 2 phase II, and 4 phase I–II) and one was a pilot study.

The impact of a variety of therapeutic options was evaluated. Of interest is that all studies included radiotherapy, either in combination with systemic cancer therapy, surgery or with medication aiming to reduce adverse effects.

Different radiotherapy approaches were studied including external beam radiotherapy and brachytherapy, curative and palliative radiotherapy schedules, loco-regional radiotherapy and prophylactic cranial irradiation, various fractionation schedules. One study lacked specification on the radiotherapy treatment (Whitney et al., 2010, 2008).

3.2. HRQoL measurement

The way in which HRQoL parameters were evaluated differed amongst the studies. In only two studies, HRQoL was a co-primary endpoint (Goldberg et al., 2015; Van der Meij et al., 2012a, 2012b, 2010). In the remaining 17 studies, HRQoL was a secondary endpoint. One study looked into confounders possibly influencing the relation between cognitive functioning and chemotherapy (Whitney et al., 2010, 2008).

Overall, four different HRQoL measurement instruments were identified within the included studies: the European Organization for Research and Treatment of Cancer (EORTC QLQ-C30) questionnaire along with its brain (QLQ-BN20) and lung cancer supplement (QLQ-LC13/LC14) (Koller et al., 2015), Lung Cancer Symptom Scale (LCSS), the 36-Item Short Form Survey (SF-36) and Functional Assessment of Cancer Therapy Lung (FACT-L) version II, of which one study used a validated component (FACT-TOI) (Movsas et al., 2016).

Compliance rate to follow-up varied greatly among the studies and typically decreased over time, from almost 100% at baseline in most studies to as low as 20% at 30 months follow-up in one trial (Li et al., 2015). Seven studies did not report compliance rates, one of these did not provide details on follow-up time points (De Ruyscher et al., 2007).

3.3. HRQoL outcome

Only four of the 11 RCTs reported a significant difference in HRQoL between treatment arms. Two showed an improvement in HRQoL. One following the addition of oral nutritional supplements with fatty acids (Van der Meij et al., 2012a, 2012b, 2010); another after concurrent chemo-radiotherapy over chemotherapy alone (Strøm et al., 2014a, 2014b, 2013). Another study evaluating accelerated hypofractionated radiotherapy delivered concurrently with chemotherapy showed a mixed response with better emotional, social and cognitive functioning and less chest pain while worsening alopecia in this arm compared with neoadjuvant chemotherapy followed by standard radiotherapy (Roy et al., 2016). The RTOG 0617 study reversely reported a clinically meaningful decline in HRQoL after 74 Gy compared to 60 Gy at 3 months (Movsas et al., 2016). Additionally, two RCTs reported no significant difference between therapy arms, but reported an overall HRQoL decline in both arms (Shehata et al., 2013; Stephens et al., 2005).

In 7 single arm studies HRQoL was monitored over time. In only three of these, a significant difference in HRQoL was reported. A radiotherapy dose-escalation study found decreased global health status and worsened functional parameters and symptoms at the end of treatment compared to baseline (Bral et al., 2010). In another study, HRQoL remained stable during induction therapy, but decreased significantly after surgery and concurrent chemo-radiotherapy. During adjuvant therapy and follow-up HRQoL recovered to baseline (Kocher et al., 2014). At last, one showed patients receiving brachytherapy experienced improved HRQoL at one month after therapy (Mallick

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