

R. García-Fumero¹, C. Fernández-López², J. Expósito-Hernández³, S. Portillo-Haro⁴, M.Á. Calleja-Hernández²

¹Hospital Universitario Virgen de las Nieves, Pharmacy, Granada, Spain

²Biosanitary Institute of Granada IBS. SAS-Universidad de Granada, Granada, Spain

³Hospital Universitario Virgen de las Nieves, Oncology, Granada, Spain

⁴Hospital Universitario San Cecilio, Pharmacy, Granada, Spain

Background and importance

Numerous randomized controlled trials (RCT) have been conducted over recent decades to identify the optimal therapeutic option for advanced non-small-cell lung cancer (NSCLC) patients. However, only modest clinical benefits have been achieved.

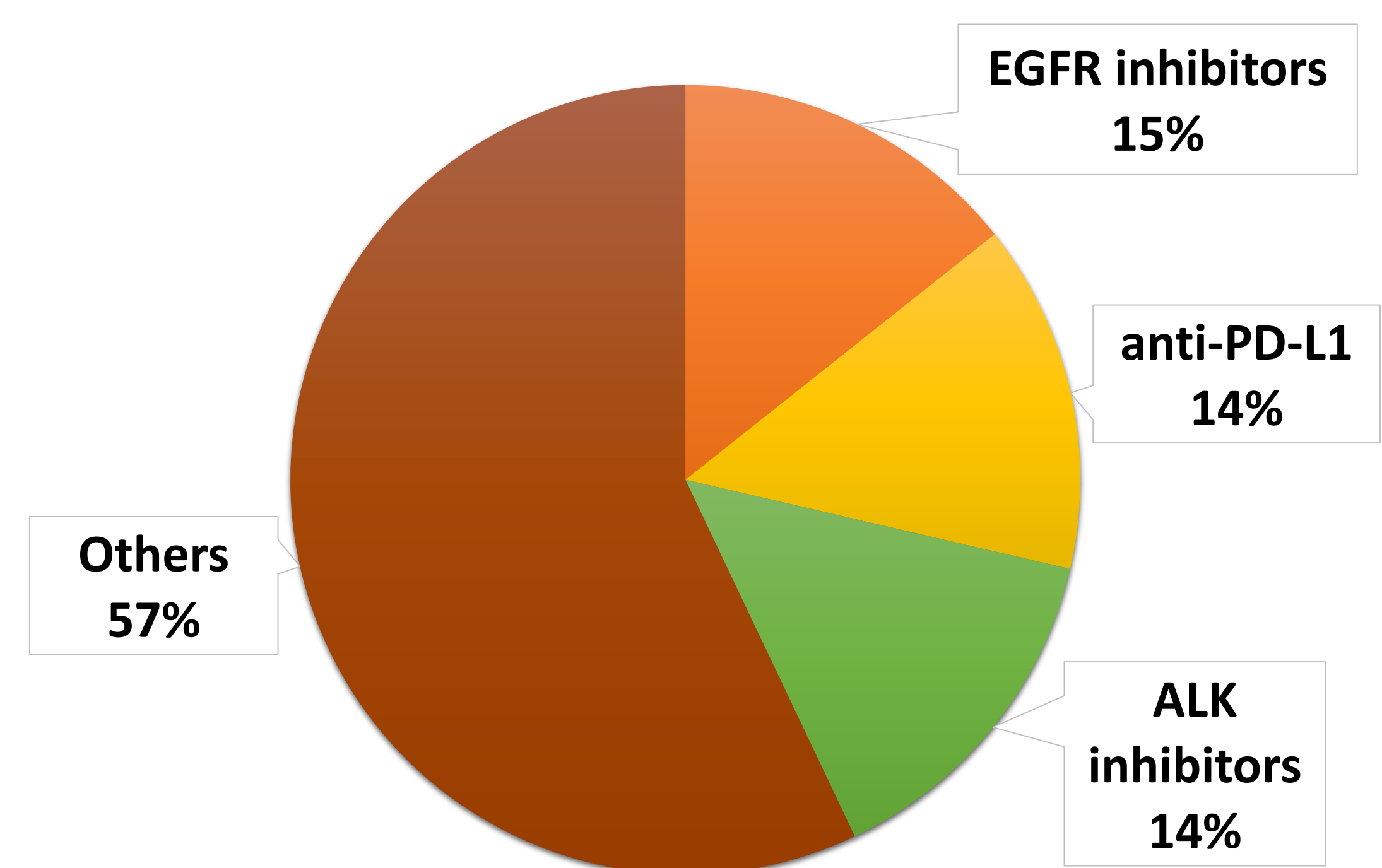
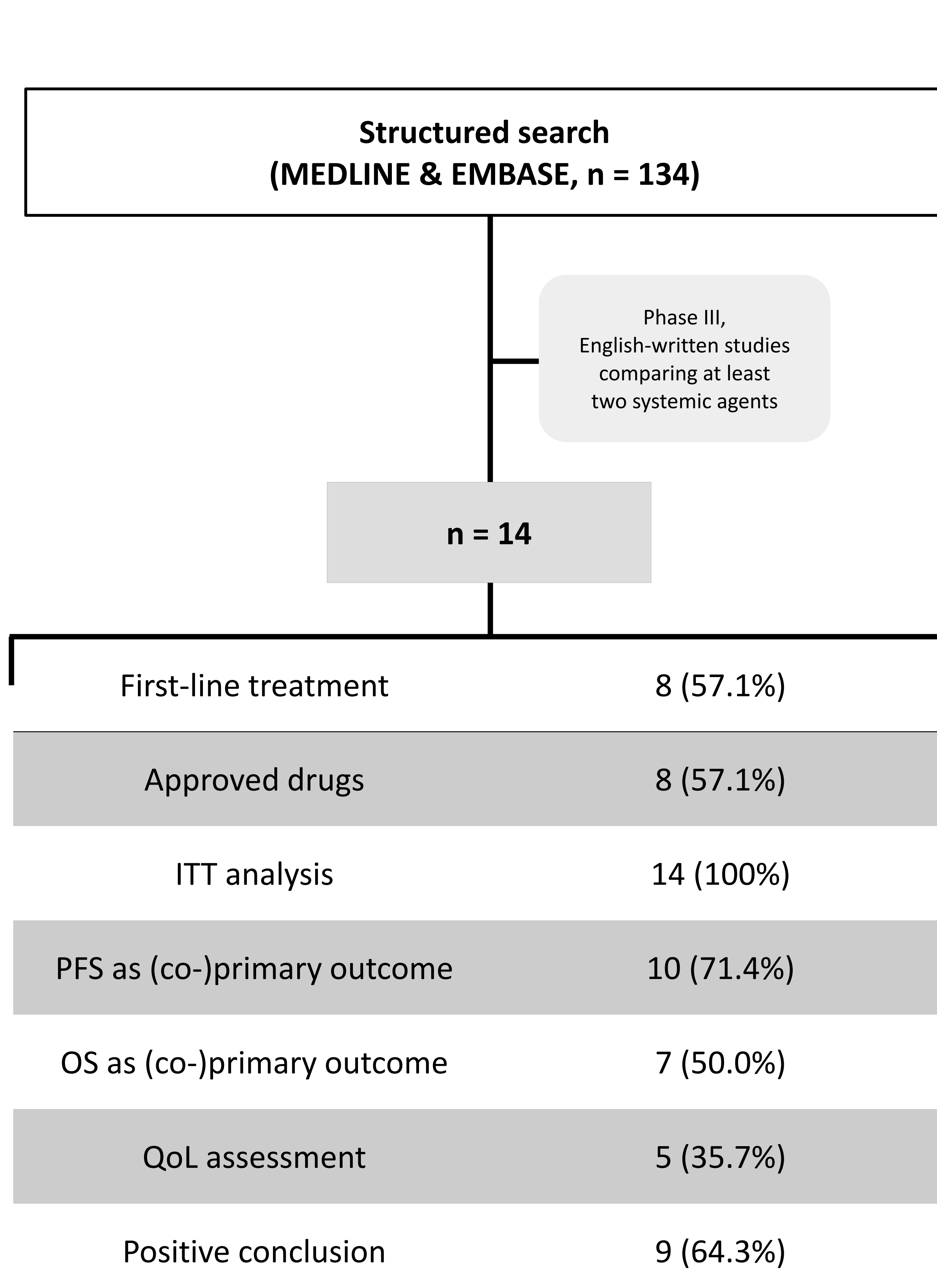
Aim and objectives

To analyze primary efficacy outcomes reported and design of phase III randomized controlled trials (RCT) on advanced NSCLC published in 2018.

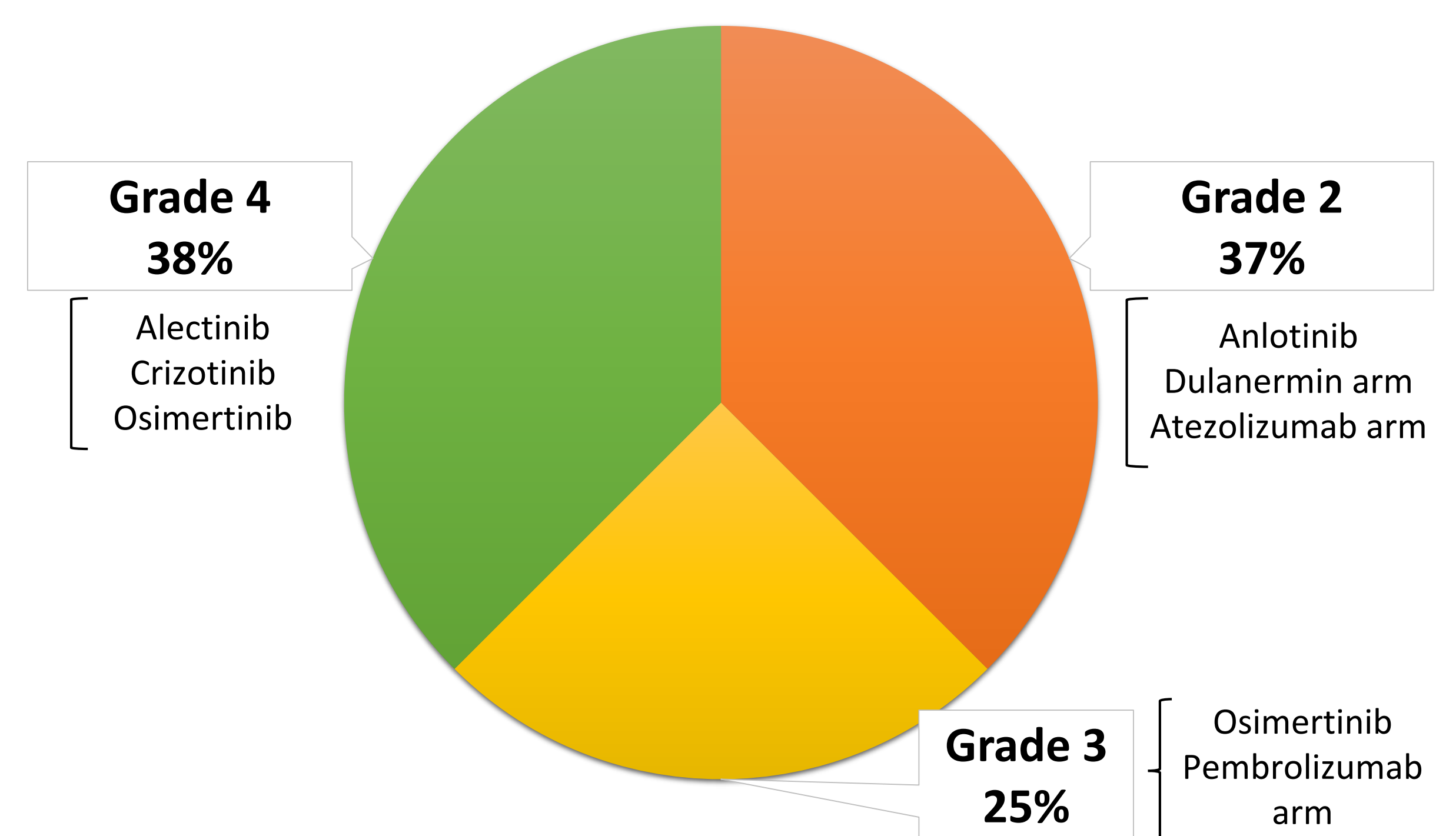
Material and methods

A structured search using MEDLINE and EMBASE was conducted for phase III RCT reported within 2018 for treating advanced NSCLC. Any English-written study comparing at least two systemic agents was included. Selected trials were scrutinized to identify potential duplications. The following information was recorded: sample size, treatment line, pharmacological agents, intention to treat (ITT) analysis, ESMO Magnitude of Clinical Benefit Scale (MCBS) v1.1, assessment of: quality of life (QoL) and primary efficacy outcomes (overall survival; OS, or progression-free survival; PFS), and the investigators' conclusion on the experimental arm (positive or negative result).

Results



Drug distribution by pharmacological group



ESMO MCBS scale (applicable to 8 out of 14 studies)

Conclusion and relevance

QoL, which has been found to be a strong predictor of survival and toxicity outcomes, was evaluated in only 35.7% of the selected trials. It was also disturbing that only 50% of the trials considered OS as the primary/co-primary efficacy outcome. Despite of that, results seemed to be positive in 64.3% of the trials.