PRO Reporting and Methodological Rigor in Advanced NSCLC RCTs, A Cause for Concern

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INTRODUCTION

Patient-reported outcome (PRO) endpoints have been used for at least two decades in randomized controlled trials (RCTs) involving patients with NSCLC. Despite the existing guidance on PRO reporting, which the FDA issued in 2009, most PRO studies on NSCLC used incomplete/modified checklists resulting in misinterpretation and poor reporting practices.

OBJECTIVE

To investigate the methodological quality of PRO reporting in the RCTs on first-line treatment in advanced NSCLC according to the highest quality international standards (ISOQoL), CONSORT-PRO extension, & CONSORT outcomes 2022 extension guidelines to examine factors associated with a high quality of PRO reporting.

METHODS

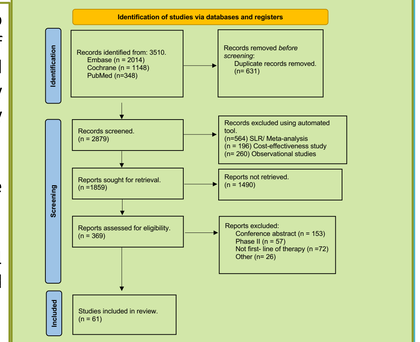
Embase, Cochrane Library, and PubMed were searched for articles published between 2014-2023. Eligible articles were RCTs of adult advanced NSCLC patients with first-line therapy with PROs in primary or subsequent publications, with a comparison of PROs among treatment groups

RESULTS PRISMA Flow chart

Studies selected for analysis were limited to randomized, controlled, phase 3 trials of untreated patients with advanced non-small cell lung cancer (NSCLC) that specifically reported PROs published between January 1st, 2014, and January 1st, 2023.

The search was restricted to English-language publications and those for

A total of 3510 studies were assessed, and 61 RCTs, enrolling 20,597 patients, were included in the review.



RESULTS

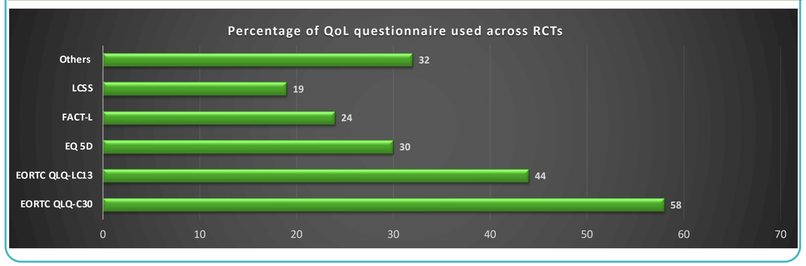
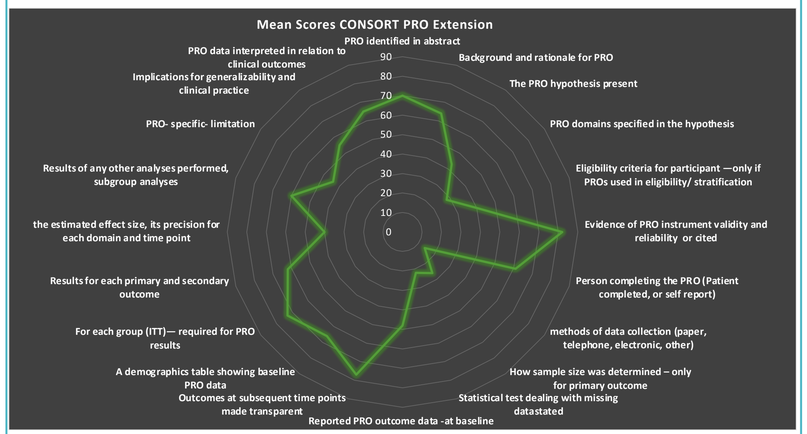
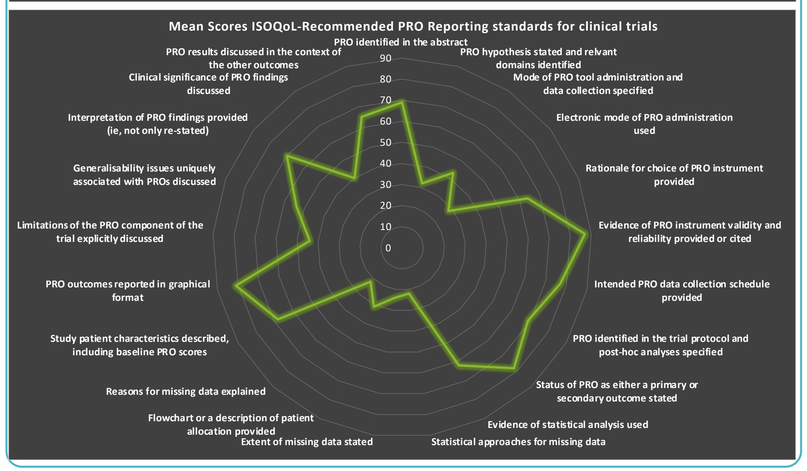
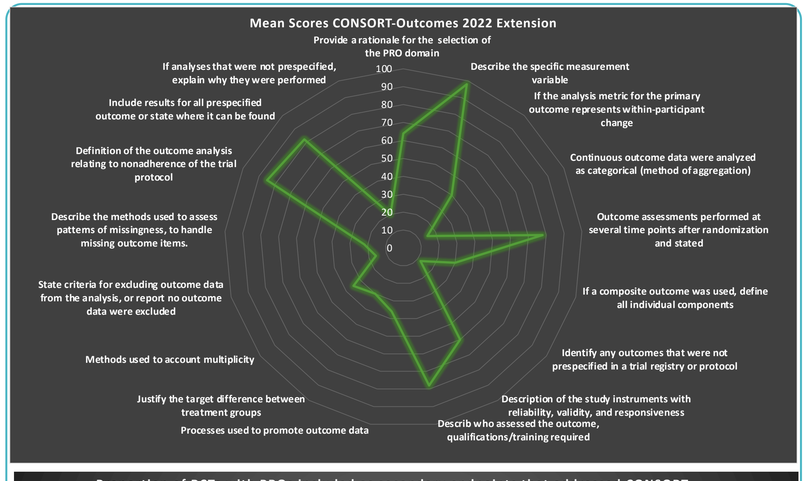


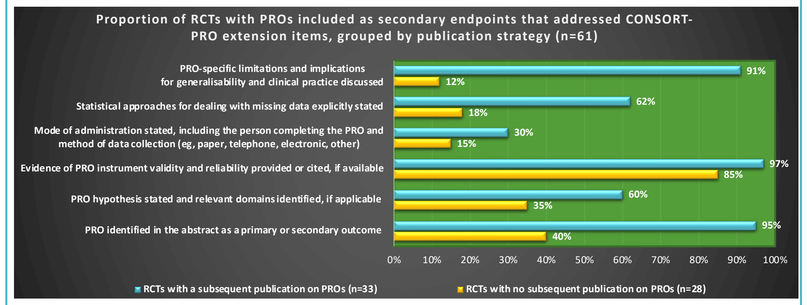
Table 1: Characteristics of Randomized control trials

	Randomized controlled trials (n=61)	
Industry -Supported	Yes - 46 (75%)	No - 15 (25%)
Trial site	Multinational - 49 (80%)	Single Country - 12 (20%)
PRO endpoint	Primary - 7 (11%)	Secondary or exploratory - 54 (89%)
PRO publication strategy	Reported in primary manuscript	Reported in the subsequent manuscript









CONCLUSION

International guidelines for designing, reporting, and analyzing PRO data are available to improve overall study quality, but PRO reporting in clinical trials still needs to be more consistent. Tailored efforts to measure QoL for different subsets of the NSCLC patient are required. The findings can help investigators to focus on critical aspects most in need of attention when reporting PROs in NSCLC trials—further assisting in understanding lung cancer patients' real-life experiences in the era of personalized medicine.

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