ADHERENCE TO CONSORT PATIENT-REPORTED OUTCOMES REPORTING GUIDELINES IN RANDOMIZED CLINICAL TRIALS EVALUATING SYSTEMIC CANCER THERAPY: A SYSTEMATIC REVIEW

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Aim: The Consolidated Standards of Reporting Trials (CONSORT) guidance was extended in 2013 to provide a set of specific recommendations regarding patient-reported outcomes (PRO) reporting in randomized clinical trials (RCTs). There is limited data regarding how well current publications of oncology RCTs report PRO if assessed using these guidelines.

Methods: The reporting of PRO was reviewed using an established database of phase III RCTs published between 2007 and 2011. Manuscripts were reviewed using an 8-point PRO reporting quality score (PRORQS) based on the 2013 CONSORT criteria. Multivariable linear regression was used to identify features associated with improved reporting quality.

Results: PRO was most frequently a measurement of the patients quality of life (n = 88, 71%), a measurement of the patients symptoms (n = 22, 18%) or both (n = 11, 9%). Unfortunately, the majority of trials did not report on PRO at all (201 of 325; 62%). Of the remaining 124 trials, the mean PRORQS score was 5.0 on an 11 points scale. Among the 11 items included in the PRORQS, none was correctly reported in more than 70% of RCTs. The only factor significantly associated with improved PRO reporting was where PRO reporting was the subject of a dedicated secondary manuscript, as was the case in 36 of the 124 (29%) of RCTs. Compared to PRO reported only in the primary manuscript (mean score 3.5, 95% confidence interval (CI): 3.1 to 3.9), a secondary PRO–specific article had a mean score of 9.0 (95%CI: 8.5 to 9.6) out of 11.0, a nearly 2.5 fold improvement (P < 0.001).

Conclusions: Despite their clinical relevance, our findings show that PRO are currently omitted completely or else poorly reported. The exceptions were where PRO were described in PRO-specific secondary publication and arguably this should be norm for all pivotal oncology RCTs. Use of the 2013 PRO CONSORT extensions should be encouraged and their effects on PRO reporting subsequently reassessed.

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