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Analysis of longitudinal oncology quality of life (QoL) data - are we getting it right?

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Background

Quality of Life (QoL) data from oncology trials may have missing data which cannot be assumed to be missing completely at random (MCAR) [1]. Ignoring this missing data in analysis may introduce bias. A number of statistical techniques to deal with informative missing data are available [2], but may be underutilised.

Methods

We searched MEDLINE (2002-2012) to identify oncology trials reporting longitudinal analysis of QOL data. The appropriateness of the analysis was reviewed and trials reporting QOL as primary/secondary endpoint were assessed for reporting quality using the CONSORT extension for PROs [3].

Results

69 RCTs reporting longitudinal QOL analyses were identified. 29 (42%) use an analysis to account for the nature of the missing data. Methods varied widely, eg pattern-mixture models, conditional linear models, QTWiST, joint longitudinal models, generalised estimating equations, selection models and Markov models. Fourteen papers used more than one method check the robustness of their results.

Conclusions

In order for QOL data to adequately inform clinical decision-making the correct analysis needs to be performed. Statistical methods ignoring the missing data were found to over-estimate QOL but it was rare for the significance of QOL differences between treatments to change. A strategy for appropriate analysis of QOL data will be presented using case studies to highlight where ignoring informative missing data could alter the conclusions regarding treatment differences.

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References
1. Bell ML, Fairclough DL: Practical and statistical issues in missing data for longitudinal patient reported outcomes. *Stat Methods Med Res* 2013.
2. Fairclough DL: Design and Analysis of Quality of Life Studies in Clinical Trials. CRC Press: London; 2010.
3. Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD, CONSORT PRO Group: Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. *JAMA* 2013, 309(8):814-22.

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