

Methodological issues in economic evaluation alongside a randomized controlled trial with cross-over.

SUMMARY

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Abstract

When performing an economic evaluation alongside a randomized clinical controlled trial, analysts are often faced with methodological issues resulting from missing Health Related Quality of Life (HRQoL) data. When in addition the trial design allows for crossover between the compared treatment arms, choosing a suitable method for the economic evaluation is even more difficult. The aim of this paper is to discuss the methodological issues we encountered during the cost-utility analysis alongside the TSAR randomized controlled trial comparing Trabectedin to Best supportive care in the treatment of advanced soft tissue sarcoma. Two issues are examined: 1) the choice of the analytical method to compute QALYs in the presence of missing HRQoL data 2) the impact of the cross-over. Multiple imputation methods which assume data are missing at random could not be applied to resolve issues related to missing HRQoL data since it was suspected the missing mechanism was related to the study design and the patient health status. In addition, traditional methods for handling crossover such as the as-treated analysis, censoring crossover or inverse probability of censoring weighting proposed in the literature to address crossover were also not suitable for this analysis because of the high rate of crossover in the control arm. We explored two methods for the computation of quality adjusted life months (QALMs): the partitioned survival analysis and the quality adjusted survival analysis. Our results suggest that methodological choices may affect cost-utility results. Further investigation is needed to fully understand the behavior of each method with different datasets.