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► **To cite this version:**

Antoine Barbieri, Christian Lavergne, Thierry Conroy, Sophie Gourgou-Bourgade, Beata Juzyna, et al.. Mixed-effects regression Models for longitudinal Analysis of Quality of Life in Oncology. 21th Annual Conference of the International Society for Quality of Life Research (ISOQOL), Oct 2014, Berlin, Germany. hal-01211826

HAL Id: hal-01211826

<https://hal.science/hal-01211826>

Submitted on 5 Oct 2015

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Mixed-effects regression Models for longitudinal Analysis of Quality of Life in Oncology

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Aims

In oncology, the Health-related Quality of Life (HRQoL) has become an essential endpoint in clinical trials. However, HRQoL longitudinal analysis remains complex and non-standardized. The development of longitudinal analysis tools adapted to this HRQoL clinical data is currently an important challenge. The aim of this work is to propose an inventory of mixed-effects regression models to process HRQoL longitudinal analysis giving advantages and drawbacks.

Methods

The observations were obtained from questionnaires filled by the patients themselves. The questionnaires are collected at different times predefined in the study protocol in order to assess the HRQoL change over time. The HRQoL data have three important characteristics: ordinal categorical, multiple responses and repeated measures. Given the characteristic of data and the aim to assess the factor influence (e.g. the treatment), the mixed-effects regression models are particularly adapted. The random effects allow taking into account the dependence from data of same patient. The first model (LMM, linear mixed model) from classical test theory is based on the HRQoL score study which is the average of the items. The two others presented models for ordinal categorical data were mixed-effects regression models and correspond precisely to adjacent-categories logit model and Cumulative logit Model (CM) (De Boeck & Wilson, 2004). From IRT view, they are respectively an extension of Partial Credit Model (LCPM) (Masters, 1982) and Graded Response Model (Samejima, 1969).

Results

The LMM which is the most used model to analyze HRQoL data in cancer clinical trials is not adapted: the score is not a really continuous variable and the model doesn't take into account the ceiling and floor effect of score. Bias estimations occurred in this case. CM is particularly known to be adapted to ordinal categorical data and have an easier interpretation. These methods were illustrated on HRQoL data from the ACCORD11 clinical trial, which recruited 342 patients treated for metastatic pancreatic cancer.

Conclusions

The inventory of mixed-effects regression models lead to a better understanding of these statistical tools for the HRQoL longitudinal analysis. The HRQoL concept is very complex, it is necessary to use the best statistical tool from methodological view.