A New Procedure to Assess When Estimates from the Cumulative Link Model Can Be Interpreted as Differences for Ordinal Scales in Quality of Life Studies

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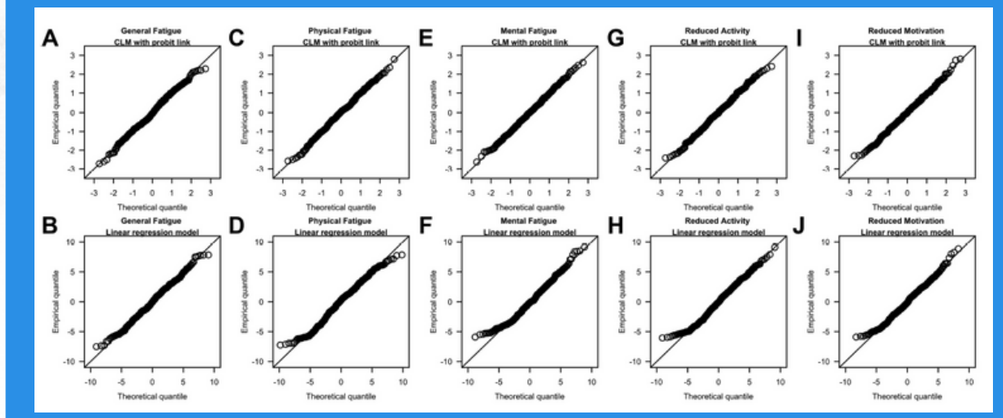
Purpose:

Assessing the clinical importance of an exposure effect on a quality of life (QoL) score often requires quantifying the effect in terms of a difference in scores.

Using the linear regression model (LRM) for this purpose assumes the ordinal score is a proxy for an underlying continuous variable, but the analysis offers no assessment for the validity of the assumption.

We propose an approach that assesses the proxy assumption and estimates the exposure effect by using the cumulative link model (CLM)

CLM offers a valid test for the presence of an association, a method for assessing the proxy assumption, and when the assumption is adequate, an assessment for clinical significance using the difference in means.



"Figure 5 qq-plots of surrogate residuals from the cumulative link model (CLM) with probit link (A, C, E, G and I) and residuals from the linear regression model (B, D, F, H and J) when analyzing the five subscales of the Multidimensional Fatigue Inventory.
Notes: The last three categories (ie, 15th to 17th categories) of the original subscale scores were grouped into a new category and assigned a score of 18."

Patients and methods:

CLM is a well-established regression model that assumes an ordinal score is an ordered category generated from applying thresholds to a latent continuous variable.

The proxy assumption was assessed by testing whether these thresholds are equidistant. We compared the performance of CLM and LRM using simulated ordinal data and illustrated their application to the effect of time since diagnosis on five subscales of fatigue among breast cancer survivors measured using the Multidimensional Fatigue Inventory.

Results:

CLM had good performance in estimating the difference in means with simulated ordinal data satisfying the proxy assumption, even when the outcome had only a few categories. When the proxy assumption was inadequate, both the CLM and LRM had biased estimates with poor coverage. The proxy assumption was appropriate for four of the five subscales in our real data application to fatigue scores.

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