Robust tests for trials with recurrent events occurring over multiple treatment periods

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Abstract: Robust methods for the analysis of recurrent events have been developed based on Poisson estimating equations (Andersen and Gill, 1982; Lawless and Nadeau, 1995). We describe alternative robust methods of analysis based on binomial or multinomial models, motivated by suitably conditioning within the class of mixed Poisson models. Such methods can be used when trials are designed with baseline periods of observation, or when patients’ undergo different kinds of therapies in successive treatment periods. Here the relative efficiency of the robust conditional analyses versus a marginal analysis is examined and related tests are illustrated by application.

Key Words: baseline data, conditioning, recurrent events, robust tests