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Tipping point for survival analyses

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Background: Traditionally, tipping point analysis explores the influence of missingness on the overall conclusion of the treatment difference by shifting the imputed missing values in the treatment group towards the reference group until the result becomes non-significant. Over the past years, tremendous efforts have been made to develop statistically rigorous methods for tipping point analysis in clinical trials for continuous and for binary or categorical endpoints. However, less attention has been paid to studies with time-to-event outcomes.
Methods: The objective of this research project is to investigate how methods that are widely used for time-to-event outcomes can be extended in a clinically meaningful and interpretable way to test the censor-at-random assumption.Several approaches for conducting such analyses based on multiple imputation using parametric, semi-parametric, and non-parametric imputation models are investigated and their operating characteristics via simulation are evaluated.
Results: It appeared that the piecewise exponential multiple imputation (PCEMI) has a smaller bias compared with other methods when estimating treatment effect while preserving the Type I error rates, but this might be explained by the fact the data were simulated following a piecewise exponential hazard. The range of methods that we studied allows the analyst to match a method with the analysis planned for
a particular clinical trial, whether this analysis be parametric, semi-parametric, or non-parametric.

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