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**Does Cox analysis of a randomized survival study yield a causal treatment effect?**

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Abstract

Statistical methods for survival analysis play a central role in the assessment of treatment effects in randomized clinical trials in cardiovascular disease, cancer, and many other fields. The most common approach to analysis involves fitting a Cox regression model including a treatment indicator, and basing inference on the large sample properties of the regression coefficient estimator. Despite the fact that treatment assignment is randomized, the hazard ratio is not a quantity which admits a causal interpretation in the case of unmodelled heterogeneity. This problem arises because the risk sets beyond the first event time are comprised of the subset of individuals who have not previously failed. The balance in the distribution of potential confounders between treatment arms is lost by this implicit conditioning, whether or not censoring is present. Thus while the Cox model may be used as a basis for valid tests of the null hypotheses of no treatment effect if robust variance estimates are used, modeling frameworks more compatible with causal reasoning may be preferrable in general for estimation.