Estimation of pregnancy outcome probabilities in the presence of heavy left-truncation

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Estimating the risk of spontaneous abortion after drug use during pregnancy is complicated by two issues: First, the analysis takes place in a competing risks setting since a pregnancy may end in a live birth, a spontaneous or an induced abortion. Second, the data are left-truncated since women enter observational studies at different time points after conception. This leads to small risk sets at the beginning of a study, causing unreliable estimates. In our pregnancy data analysis, standard estimation methods showed a protective effect of statin use during pregnancy on the risk of induced abortion, which is medically implausible. We present a modified version of the Nelson-Aalen estimator for the cumulative hazard of spontaneous abortion. The idea of the modification is to only estimate increments of the pregnancy outcome intensities, when the risk sets are large enough to allow for reliable estimation. Making use of martingale arguments, uniform strong consistency and weak convergence against a Gaussian martingale are obtained for the new estimator, and a variance estimator is derived. Results are also generalized to the Aalen-Johansen estimator. Extensive simulation studies and a real data analysis illustrate the merits of the new approach. Reanalyzing the pregnancy data with the modified estimator leads to plausible results concerning the effect of statin use on the risk of abortion.