Background

The cohort method is one of the most common methods in comparative effectiveness and safety studies. In a cohort study, we compare rates of events during time-at-risk in target and comparator groups. Such rates are, therefore, dependent on the choice of starting point for time-at-risk or, as we call it, anchoring. Choice of anchoring may influence both the rates of observed outcomes and baseline patient characteristics, which are subsequently used in propensity score models or outcome models.

Methods

We investigated the influence of anchoring on population incidence rates of 15 adverse events occurring during different time-at-risk windows (A). Additionally, we investigated its impact on baseline patient characteristics in unvaccinated and vaccinated populations (B).

Results

When the cohort method is applied in vaccine safety studies, a vaccinated population is compared to an unvaccinated population. The latter cohort does not have a clear index date, which is left up to researchers’ judgment.

In this study, we investigated how the choice of the index date (anchor) influences patient baseline characteristics and baseline incidence rates.

Conclusions

1. Anchoring influences both baseline patient characteristics and incidence rates observed after the index date.
2. It is crucial to select an anchoring that represents the target index date best based on the knowledge of the target (e.g., vaccination settings) or empirical comparison of multiple options.
3. Balance on visit on day 0 should be assessed in any cohort study.