Strategies for comparative analyses of registry data

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A B S T R A C T
The present paper is a description and summary of methods used in non-randomised cohort data where the comparability of the study groups usually is not granted. Such study groups are formed by a diagnostic or therapeutic intervention, or by other characteristics of the patient or the treatment environment. This is a typical situation in the analysis of registry data. The methods are presented together with an illustrative example of whole-body computed tomography in the early phase of treatment of severe trauma cases. The following approaches are considered: (i) unadjusted direct comparisons; (ii) parallelisation; (iii) subgroup analysis; (iv) matched-pairs analysis; (v) outcome adjustment; and (vi) propensity score analysis. All these approaches have in common that they try to separate, or limit, the influence of confounding variables, which are unevenly distributed among the study groups, but also influence the outcome of interest. They differ in the number of confounders being considered, as well as the number of patients regarded. The more sophisticated the approach, the more effectively such confounding factors could be reduced. However, any method used for the reduction of bias depends on the quality and completeness of recorded confounders. Factors which are difficult or even impossible to be measured could thus not be adjusted for. This is a general limitation of retrospective analyses of cohort data.

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Introduction

In recent years data from registries have become increasingly important for health services research. This is especially important in health care areas where the conduct of classical randomised trials is very difficult, or even impossible. The emergency treatment of severely injured patients is such an area because informed consent is difficult to obtain from non-responsive patients.

However, the evidence level of registry studies ranges somewhere between prospective and retrospective observational studies. The main problem with registry studies is not the sample size - there are usually much more patients documented in registries than in clinical trials. It is also a positive aspect that registries include a larger variety of patients with a certain condition while clinical trials usually consider a selected subgroup of cases only. Therefore, registry studies are most appropriate to analyse the effectiveness of routine care. But the main problem of registry studies, however, is data completeness and data correctness, which tend to be lower than in clinical trials. There are usually limited resources for monitoring and source data verification in registries, is not frequently performed. Registries also document considerably less data per case than clinical trials.

But there is a further methodological aspect of registry data analyses, which should be considered more closely here. While descriptive data (like prevalence or incidence rates) profit a lot from a large and representative sample size, problems arise with the comparability of subgroups. If a certain intervention, therapeutic or diagnostic, is analysed in registry data, then the direct comparison of cases with and without that intervention would nearly always give biased results. True comparability would only result from randomizing a sufficiently large number of patients. Registries are comparable with observational studies where treatment decisions are not influenced by an experimental design.

However, there are some analytic strategies, which would allow to reach a certain degree of comparability which sometimes comes close to that of controlled trials. The present paper intends to present and describe six of these strategies, together with their advantages and disadvantages. A summary of these strategies could be found in Table 1. In the first part some general comments on descriptive analyses, especially on the use of confidence intervals, are given.