Alert generation using the case-population approach in the French claims databases: Alcapone

Abstract

Background: France has a nationalised health insurance system database – the SNIIRAM (National system of information on the use of medicines) – that covers almost 99% of the French population. A 17th sample – the EGB (SNIIRAM generation of ambulatory medical data) – is now available. For each drug-outcome pair, detailed registration data on both the treated patient and the controls is available. Case-population exposure window, exclusion period, Case-control: number of controls per case, matching strategy. The identification of the optimal design for a health outcome of interest will enable the calibration of the selected design variant based on the CTR.

Objectives

- To present the methodology of the Alcapone project.
- To assess the feasibility of the project through preliminary results from the EGB database.

Methods

- **Study design**
  - OMOP reference set
    - 4 health outcomes of interest
      - Acute liver injury (ALI)
      - Myocardial infarction (MI)
      - Upper gastrointestinal bleeding (UGIB)
    - Drug controls
      - Positive controls (CTR+): have been associated with the outcome of interest (RR>1)
      - Negative controls (CTR-): have not been associated with the outcome of interest (RR<1)
    - According to a narrow definition
    - According to a broad definition.
  - Case-based extractions between 01/01/2009 and 12/31/2014
  - Based on the broad outcome definitions, 40 ALI, 6,334 MI, and 26,233 UGIB cases were identified between 01/01/2009 and 12/31/2014 according to hospitalization primary diagnoses. A narrow and a broad definition of the outcomes were identified:
    - ALI: Acute Liver Injury
    - MI: Myocardial infarction
    - UGIB: Upper gastrointestinal bleeding
  - Selection of the drug-outcomes pairs
    - Selection of the drug-outcome pairs
      - Selection of the drug-outcomes pairs
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  - Power calculations are in process to estimate the number of detectable drug controls.
  - By extrapolation, the SNIIRAM would be powerful enough to detect an association ≥0.05 with a power of 0.80 for each drug-outcome pair.
  - Generation of 4 sub-study databases composed of the cases extracted for a health outcome of interest and the corresponding reference containing the detectable drug controls.

Results

- **Project stages**
  - Case-based patients extraction and selection of the detectable drug controls
    - Selection of the drug-outcomes pairs
      - Selection of the drug-outcomes pairs
        - Selection of the drug-outcomes pairs
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        - Selection of the drug-outcomes pairs
      - EGB / SNIIRAM
    - Stages of the Figure 1
    - Table 2: Outcomes included in the Alcapone project and corresponding number of patients by health outcome of interest definition

Conclusion

- The feasibility study shows that the EGB is not powerful enough, especially when the event and/or the exposure is rare. The SNIIRAM seems to have a sufficient size to implement the Alcapone project.
- The step 1b) Selection of detectable controls must be repeated after SNIIRAM extraction to confirm the number of detectable drug controls. If necessary, additional ones could be added to enhance the French market Reference set.
- The elimination of the optimal design for a health outcome of interest will enable the generation and the validation of drug safety alerts.