Patterns and trends of idarucizumab use in an Italian region: a probabilistic record-linkage approach in a real-life setting

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Background: Idarucizumab is a specific reversal agent for dabigatran, a direct oral anticoagulant. In 2015, idarucizumab was approved in Europe to quickly restore coagulation and it is currently subject to additional safety monitoring. The drug is administered only during inpatient or emergency care: in such settings, its use is poorly captured by most real-world databases.

Purpose: To retrieve individual level information on idarucizumab use from an Italian record-linkage claims database in order to describe main characteristics of users.

Methods: Italy has a regional-based, universal coverage healthcare system. Healthcare delivered to each inhabitant of Tuscany, an Italian region, is registered in a record-linkage claims database (RLCD). This information can be traced at individual level using an encrypted identification code, except in the case of medicines administered in Inpatients or Emergency Care (IEC), where only date and ward of administration are recorded. All person-years (PYs) exposed to dabigatran from January 2015 to December 2018 were calculated from RLCD, using defined daily doses (DDDs) to estimate duration of each recorded dispensation. Idarucizumab use during the study period was identified from IEC, and incidence rate was calculated over PYs of dabigatran use. To identify subjects treated with idarucizumab, emergency admissions and hospital discharge records were probabilistically linked to dabigatran users, matching date and ward of admission as retrieved from RLCD. A further selection was made by a manual check of the diagnoses compatible with the indications of use of idarucizumab. Linked users were described in terms of indication and followed-up for 30 days to assess mortality.

Results: During the study period, 26,821 PYs of dabigatran use were observed, and 112 administrations of idarucizumab were recorded, corresponding to 4.2 (95% CI: 3,4–5,0) per 1,000 PYs. Overall, 103 idarucizumab administrations (92.0%) were linked to at least one patient, while 50 (44.6%) were uniquely linked to 47 patients. Most of them were men (55.3%), aged ≥80 years (68.1%). Indications were emergency surgical procedures and life-threatening bleeding in 17 (36.1%) and in 30 subjects (63.9%), respectively. Overall, 30-days mortality was 17.0% (N=8).

Conclusions: This analysis demonstrates the potential of the Tuscany database in retrieving patient-level information on idarucizumab use and sets the stage for post-marketing surveillance on its safety profile in a real-life setting.