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STUDY OF THE USE OF IDARUCIZUMAB IN REAL-WORLD CLINICAL PRACTICE

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Background and importance

Idarucizumab is indicated in patients treated with dabigatran who must undergo emergency surgery or who have uncontrolled bleeding.

Aim and objectives

This study seeks to analyze the effectiveness and safety of idarucizumab use in a tertiary care hospital.

Material and methods

Retrospective observational study of the use of idarucizumab from May-2016 to May-2024. Data were obtained from electronic medical records. The variables collected were: sex, age, creatinine, dabigatran indication, dabigatran treatment dose, continuation of dabigatran treatment during the year following the event studied, and idarucizumab indication. Effectiveness was measured by improvement in bleeding or possibility of surgical intervention. Safety was studied as the incidence of death during the 5 days after idarucizumab dosing and the incidence of thromboembolism and/or bleeding at 90 days.

Qualitative variables were expressed as percentages, continuous quantitative variables were expressed as median and interquartile range.

Results

A total of 30 patients were included; baseline characteristics and dabigatran dosing are summarized in Table 1. Idarucizumab was mainly used for uncontrolled bleeding and emergency surgery (Figure 1) and was administered as 5 g in all cases. Clinical effectiveness (bleeding reduction and/or feasibility of surgical intervention) was achieved in 100% of patients (Figure 2). Safety outcomes included 1 death within 5 days and 17% thromboembolism and/or bleeding at 90 days (Figure 2). After reversal, 43% of patients discontinued dabigatran, with subsequent anticoagulation pathways detailed in Figure 3.

Table 1. Baseline characteristics and dabigatran therapy (n = 30).

Variable	Value
Patients, n	**30**
Age, years (median, IQR)	**80 (68.5–91.5)**
Male sex, n (%)	**21 (70%)**
Creatinine, mg/dL (median, IQR)	**1.26 (0.11–2.41)**
Dabigatran indication	**Atrial fibrillation: 30 (100%)**
Dabigatran dose	**110 mg/12h: 20 (67%)**
	150 mg/12h: 9 (30%)
	75 mg/12h: 1 (3%)
Idarucizumab dose	**5 g: 30 (100%)**

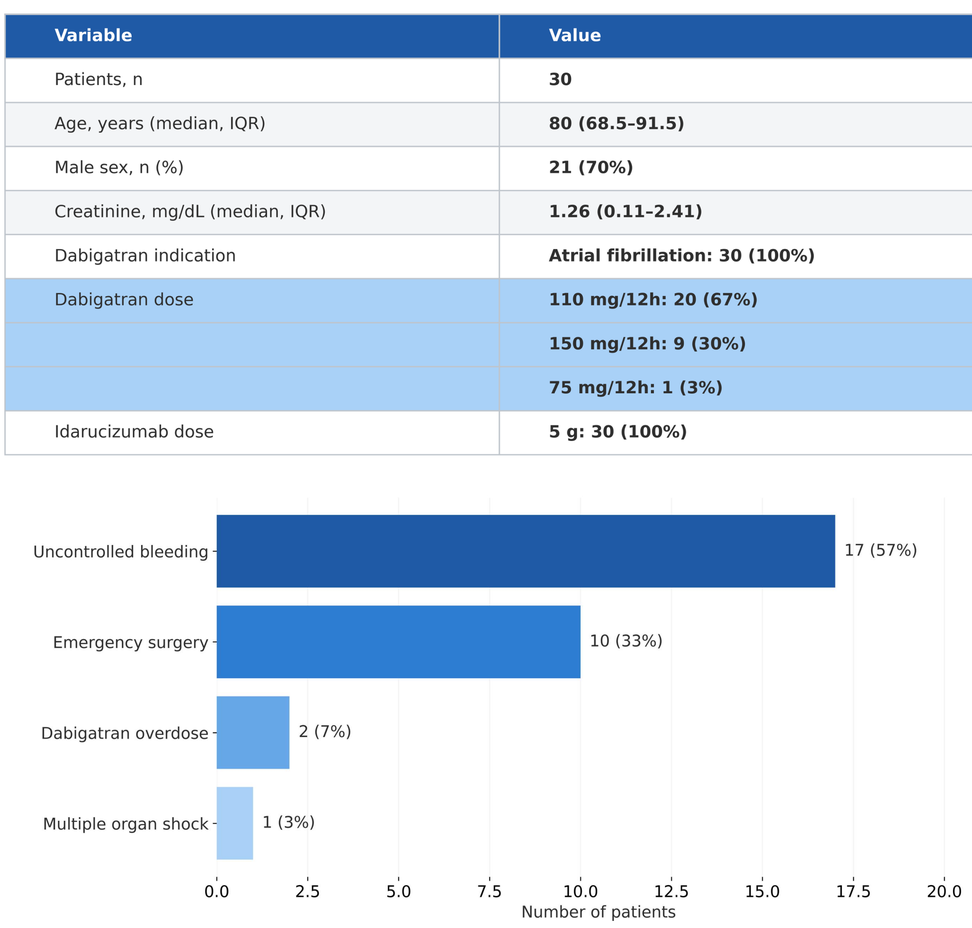

Figure 1. Indication for idarucizumab use (n = 30).

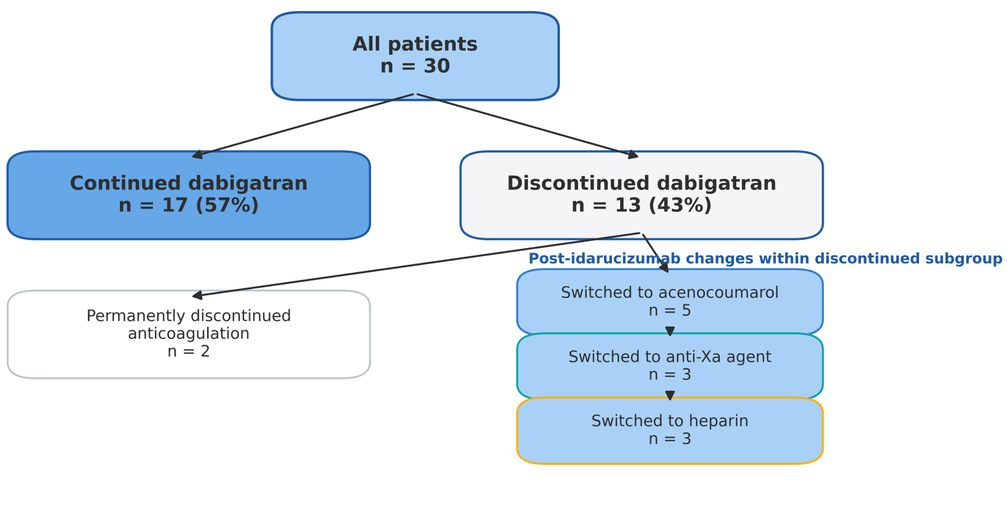

Figure 3. Anticoagulant therapy after idarucizumab (n = 30).

Note. Post-idarucizumab changes are within the discontinued dabigatran subgroup.

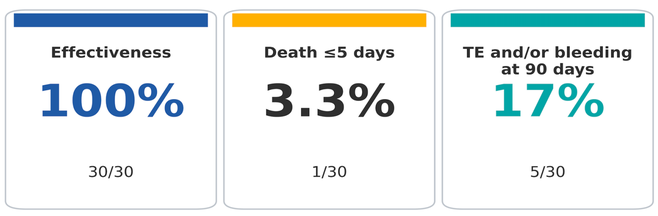

Figure 2. Effectiveness and safety outcomes.

Note. Effectiveness defined as bleeding reduction and/or possibility of surgical intervention.

Conclusion and relevance

Idarucizumab was used in 90% of patients under indications approved in the summary of product characteristics. Its effectiveness in these patients was 100%. One death was reported in the first 5 days after administration of idarucizumab and 17% of thromboembolic events and/or bleeding at 90 days. Two out of five patients treated with idarucizumab changed or discontinued anticoagulant therapy.