

DEM Journal Club Report

1. **Host/Presenter/Date:** Dr. Lohoar/Allyson Cornelis/October 25, 2017

2. **Title of paper/citation:**

Pollack et al. Idarucizumab for Dabigatran reversal—full cohort analysis.

New England Journal of Medicine. 2017. 377(5): 431-441.

3. **Research question/PICOD**

- a. **Question:** Does 5g of IV idarucizumab reverse the anticoagulant effect of dabigatran in patients with uncontrolled bleeding or requiring urgent surgery
- b. **Population:** patients on dabigatran who either had uncontrolled bleeding or required urgent surgery
- c. **Intervention:** 5g IV idarucizumab
- d. **Comparison:** none
- e. **Outcome:**
 - i. Primary: percent reversal of anticoagulation or severity of bleeding during surgery (normal, mildly abnormal, moderately abnormal, severe/ abnormal)
- f. **Design**
 - i. Prospective open label cohort study

4. Results

- a. 100% of patients with elevated DTI and ecarin clotting time at baseline had normal clotting time within minutes
- b. In those where it was measurable (only about 45% of patients in the bleeding group), all patients had bleeding cessation within 24 hours with median time to cessation of 2.5 hours
- c. Among those needing surgery 94% of patients had normal hemostasis and no patients had severely abnormal hemostasis

5. Authors conclusions

Idaricizumab is effective, fast, and safe for reversing the anticoagulant effect of dabigatran

6. Discussion at Journal Club

- a. Strengths
 - i. Design was generalizable to real life ED (lab results not always known prior to decision to intervene with bleeding; repeat imaging not always a possibility)
 - ii. Laboratory effect of idaricizumab was shown objectively
- b. Weakness
 - i. No control group
 - ii. Inability to control other treatments patients were given during the study (anticoagulation, blood transfusions)
 - iii. We described the secondary outcome data as “soft”, with extrapolation of lab significance to clinical significance

- iv. No inclusion of quality of life/morbidity data
- v. Large majority of patients were on anticoagulation for Afib and had multiple comorbidities which cannot be controlled for and may impact overall prognosis despite the therapy
- vi. Paper was funded by Boehringer Ingellheim (the producer of both dabigatran and Idaracizumab)

7. Bottom line/suggested change to practice/actions

- a. If in acute onset severe/life threatening bleeding or acute injury in patients with fair prognosis if bleeding is stopped it can be used
- b. Not for patients who are bleeding but otherwise stable
- c. Indication in severe brain hemorrhage less convincing.