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COMPARING THE EFFICACY AND TOLERABILITY OF FONDAPARINUX WITH ENOXAPARIN FOR THE TREATMENT OF SYMPTOMATIC DEEP VEIN THROMBOSIS

Background

- Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) are the subsets of Venous Thromboembolism (VTE) and primary preventable cause of morbidity and mortality.
- For several years, the standard therapy of Low Molecular Weight Heparin (LMWH) has been in use.
- Fondaparinux is the first approved anticoagulant drug among factor 10a inhibitors, with proven effectiveness and safety in preventing deep vein thrombosis.
- However, sparse data is available supporting the benefit-risk profile of fondaparinux v/s enoxaparin in a real-world group.

Objective

The purpose of the study was to compare the effectiveness and tolerability of fondaparinux v/s enoxaparin in Indian patients with symptomatic deep vein thrombosis in a long-term real-world setting.

Study details

A retrospective, longitudinal, real-world, observational study

Involved 1008 patients diagnosed with deep vein thrombosis

Fondaparinux group (n=503)
Weight-based once-daily SC injection of
-5 mg for body weight < 50 kg
-7.5 mg for body weight between 50 and 100 kg
-10 mg for body weight > 100 kg

Enoxaparin group (n=505)
Twice-daily SC injection of 1 mg/kg of body weight

Outcome measured

Efficacy outcomes: Incidences of recurrent symptomatic thrombosis events (DVT or PE), duration of the event from the baseline, and the type of recurrence.

Safety outcomes: Major and minor bleeding events.

Results

- The recurrent incidences of DVT were lower in the fondaparinux group compared to enoxaparin (Fig. 1A).
- No significant difference was observed between both the groups in -
  - **Total episodes of clinically suspected recurrence of symptomatic VTE ($p > 0.05$).**
  - **Duration of a recurrent event (Fig. 1B).**

Results

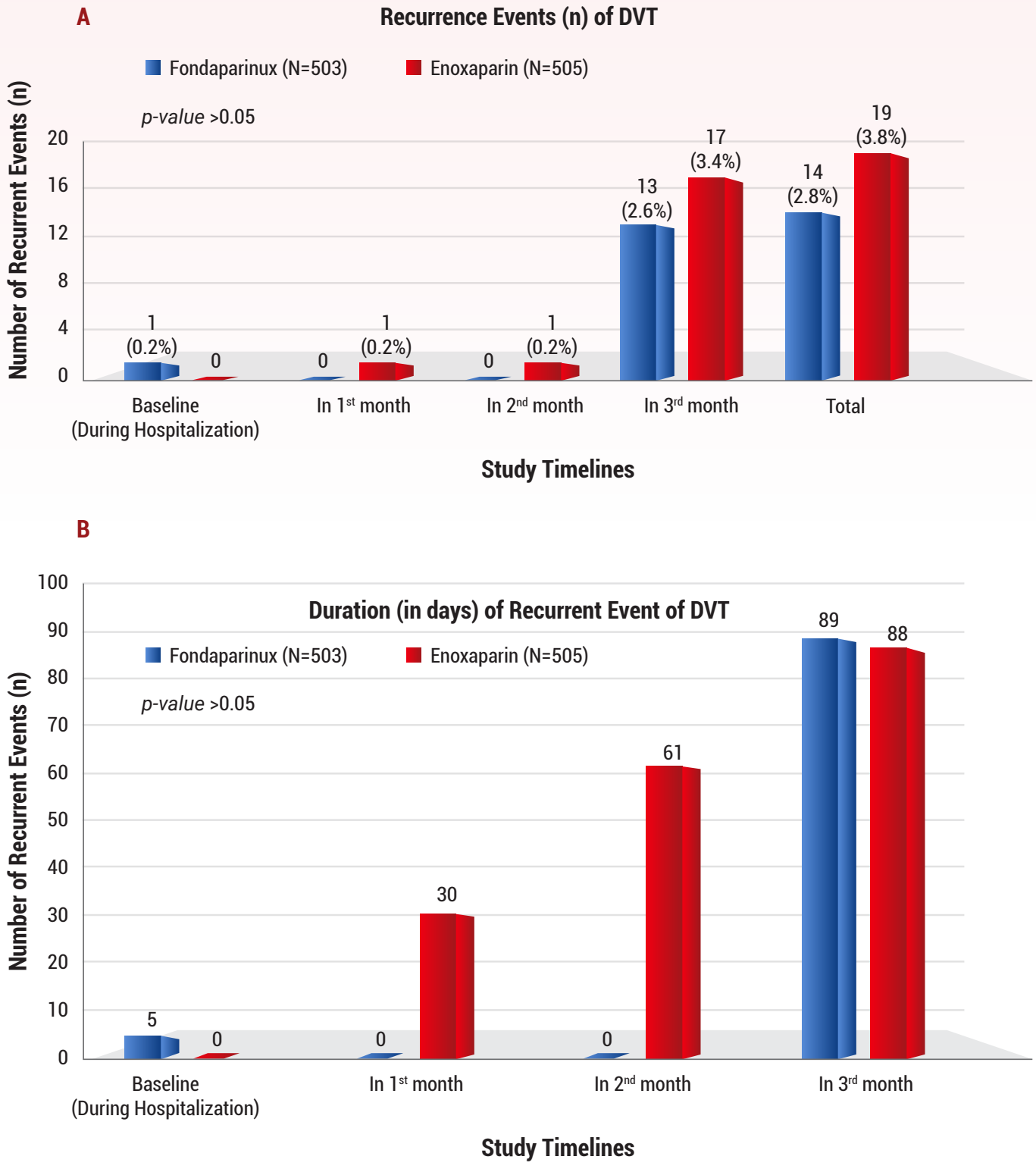

Figure 1: A) Number of deep vein thrombosis (DVT) recurrence events; B) Duration of event from baseline

- No fatal and non-fatal PE events were observed.
- Major and minor bleeding events were higher in the enoxaparin group than the fondaparinux group, though the difference was not statistically significant. (Fig. 2).
- The majority of the thromboembolism and major bleeding events occurred in the '50–100 kg' bodyweight category.

Results

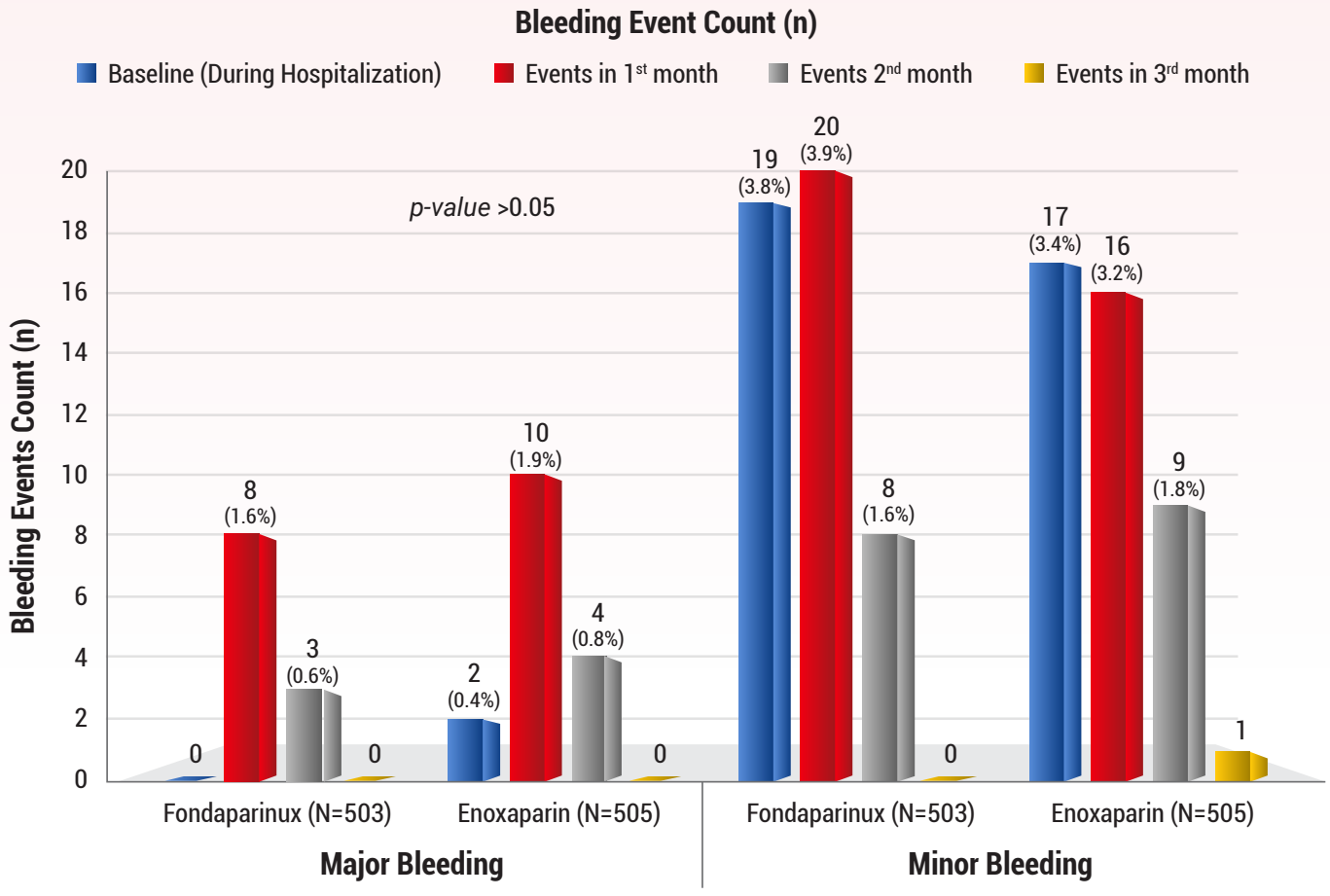

Figure 2: Count of bleeding events is shown from baseline to the end of the study duration

Conclusion

Fondaparinux showed non-inferior effectiveness and a comparable tolerability profile with enoxaparin for the management of symptomatic deep vein thrombosis.

Take home points

1. Fondaparinux, a pentasaccharide, is the first of a new class of synthetic antithrombotic drugs that acts through specific inhibitionof factor Xa.

2. Significantly lower incidence of VTE and DVT was observed with fondaparinux compared to enoxaparin in other studies.

3. Between the two drugs, there was a significant relationship between the onset of symptoms and the initiation of DVT therapy.

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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

Reference:

Ramakrishna P, Gupta PC, Pai P, Rai K, Rajkumar M, Sahu T, et al. Effectiveness and Tolerability of Fondaparinux vs Enoxaparin in a Population of Indian Patients with Symptomatic Deep Vein Thrombosis: A Retrospective Real-World Study. Drugs Real World Outcomes. 2021 Aug 25.