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EVALUATING THE EFFICACY OF FONDAPARINUX FOR THE INITIAL TREATMENT OF SYMPTOMATIC DEEP VEIN THROMBOSIS

Introduction

- The current standard initial management of deep venous thrombosis includes treatment with low-molecular-weight heparin (LMWH) and unfractionated heparin.
- However, clinically important features of LMWH treatment of venous thromboembolism remain unclear, which may influence usage and recurrence or bleeding.
- Fondaparinux has shown efficacy and safety for preventing venous thromboembolism in patients undergoing orthopedic surgery.

Objective

To assess whether fondaparinux has efficacy and safety similar to enoxaparin in patients with deep venous thrombosis.

Study details

A randomized, double-blind study

About 2205 adult patients with acute symptomatic deep venous thrombosis diagnosed with noncompressible vein on ultrasonography or an intraluminal filling defect on venography were randomized into:

Fondaparinux (n=1098)
Once-daily SC injection of
- 5 mg for bodyweight < 50 kg
- 7.5 mg for bodyweight 50-100 kg
- 10 mg for bodyweight > 100 kg

Enoxaparin (n=1107)
Twice daily SC injection of 1 mg/kg of body weight.

In both groups, vitamin K antagonist therapy was started as soon as possible but within 72 hours of initiation and continued for 3 months.

Outcome measured

Primary efficacy outcome: Incidence of symptomatic recurrent venous thromboembolic complications at 3 months.

Safety outcomes: Major bleeding during initial treatment and rate of mortality.

Results

- 3-month treatment with fondaparinux demonstrated non-inferiority to enoxaparin considering incidences of recurrent venous thromboembolism. (Fig.1)
- Also, fondaparinux showed similar efficacy to enoxaparin in patients who received initial treatment partially or entirely out of the hospital (2.0% vs 4.3%, respectively).
- Comparable effect of fondaparinux and enoxaparin was observed in terms of (Table)
  - **Major bleeding events**
  - **Mortality**

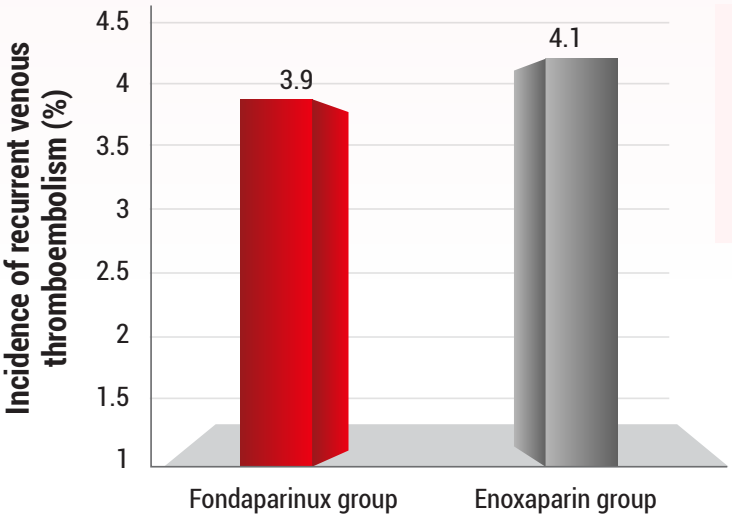

Figure 1: Incidences of recurrent venous thromboembolic at 3 months in both groups

Table: Efficacy and safety outcomes across groups

% Outcomes	Fondaparinux	Enoxaparin
Major bleeding events	1.1	1.2
Major or clinically relevant non-major bleeding	3.7	4.2
Mortality	3.8	3.0

Conclusion

Subcutaneous administration of once-daily fondaparinux was at least as effective and safe as body weight-adjusted twice-daily enoxaparin in the initial treatment of patients with symptomatic deep venous thrombosis.

Take home points

1. This randomized, double-blind study compared the efficacy of fondaparinux and enoxaparin in patients with deep vein thrombosis.

2. Results of the trial showed non-inferiority of fondaparinux for incidences of recurrent venous thromboembolism at 3 months.

3. Moreover, comparable frequencies of major bleeding events and mortality were observed in both groups.

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

Reference:

Büller HR, Davidson BL, Decousus H, Gallus A, Gent M, Piovella F, et al; Matisse Investigators. Fondaparinux or enoxaparin for the initial treatment of symptomatic deep venous thrombosis: a randomized trial. Ann Intern Med. 2004 Jun 1;140(11):867-73.