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Dr. Reddy's

INVESTIGATING THE EFFICACY AND SAFETY OF FONDAPARINUX IN PATIENTS WITH ACUTE CORONARY SYNDROME

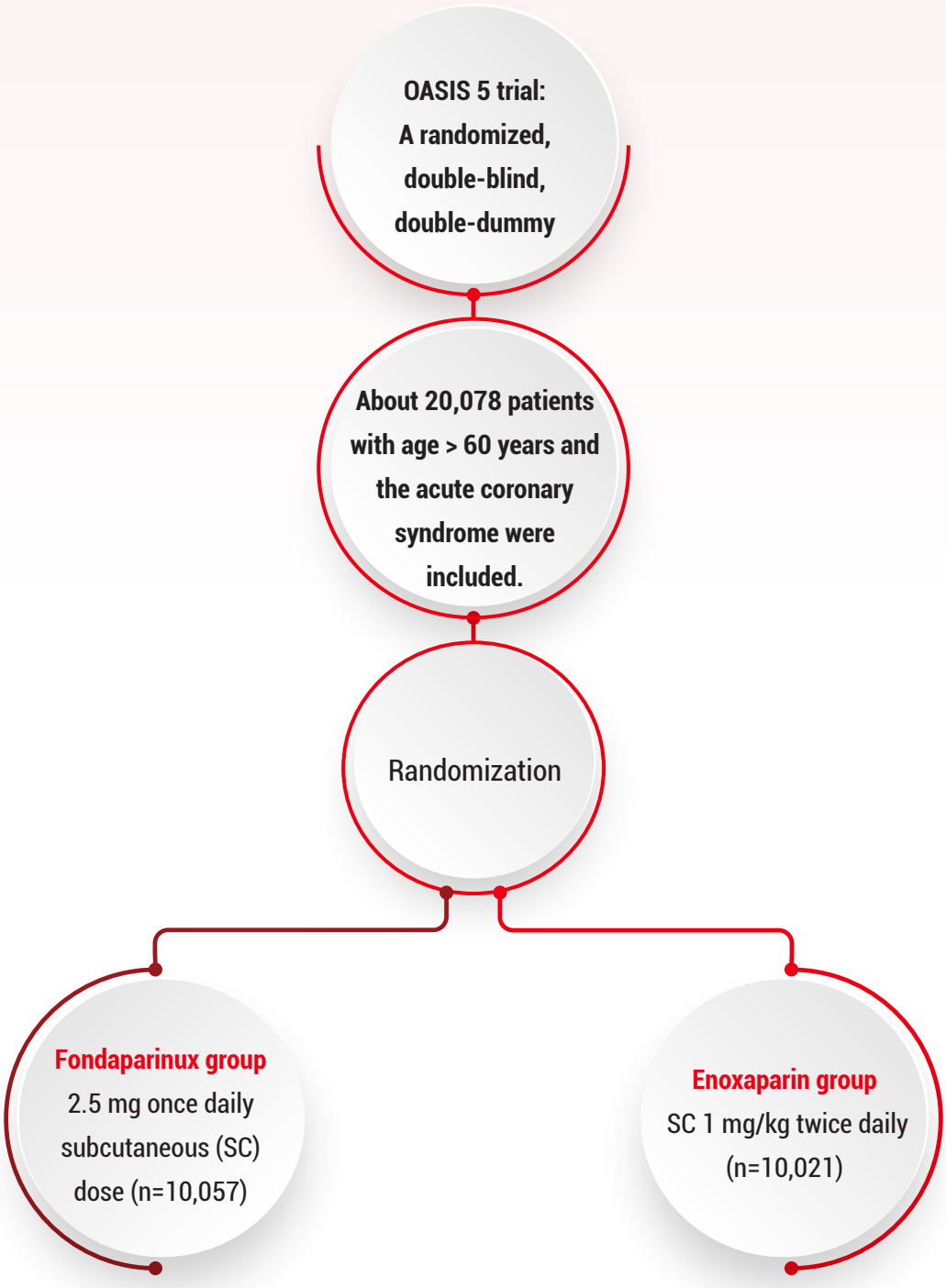
Introduction

- Although the contemporary practice of using anticoagulants, antiplatelet agents, and invasive strategy in high-risk patients may have reduced ischemic events, it has increased bleeding.
- As per the previous research fondaparinux has similar effectiveness to enoxaparin in deep vein thrombosis, pulmonary embolism, or percutaneous coronary intervention.

Objective

To compare the efficacy and safety of fondaparinux and enoxaparin in high-risk patients with unstable angina or myocardial infarction without ST-segment elevation.

Study details



Outcome measured

Primary efficacy endpoint: Non-inferiority of fondaparinux to enoxaparin in terms of death, myocardial infarction, and refractory ischemia at 9 days.

Primary safety endpoint: Prevention of major bleeding.

Secondary outcomes: Death, myocardial infarction, or refractory ischemia and the individual components of these composite outcomes at 30 days and 180 days.

Results

- The proportion of patients with primary-outcome events was similar in both the fondaparinux and enoxaparin group (5.8% vs 5.7% respectively).
- This similarity of the primary outcome confirms the non-inferiority of fondaparinux to enoxaparin. (fig 1, p=0.007)
- The main secondary outcomes were also similar in both groups.
- However, there was a trend toward a lower rate of death, myocardial infarction, or refractory ischemia with fondaparinux than with enoxaparin at day 30 (Table).
- In comparison with enoxaparin, fondaparinux was significantly associated with: (Table)
  - **Reduction in the mortality**
  - **Extensively lower rate of major bleeding** (figure 2)
  - **The decline in the rate of stroke.**
  - **Decrease in the composite outcome of death, myocardial infarction, or stroke.**
- Fondaparinux also lowered the rates of complications after percutaneous coronary intervention including:
  - **Major bleeding after 48 hours after the procedure**
  - **Pseudoaneurysms requiring closure**
  - **Large hematoma**
  - **Complications involving the vascular access site**

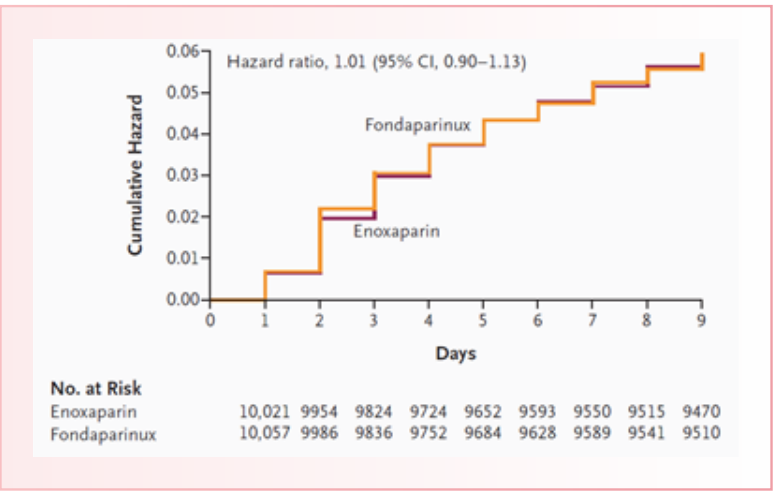


Figure 1: Deaths, myocardial infarction, or refractory ischemia through day 9

Results

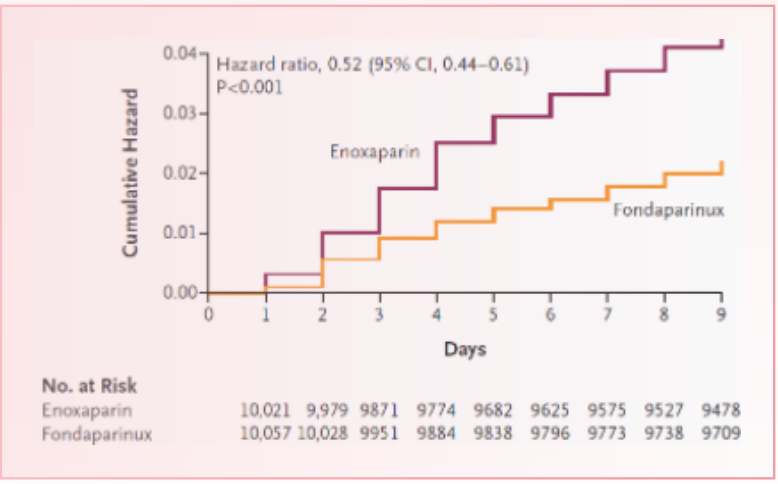


Figure 2: Major Bleeding through Day 9

Table: Main efficacy and safety outcomes

Time intervals and % outcomes	Fondaparinux	Enoxaparin	Hazard ratio	*P* value
30 days				
Death	2.9	3.5	0.83	0.02
Major bleeding	3.1	5.0	0.62	<0.001
Death, MI, refractory ischemia, or major bleeding	10.2	12.4	0.82	<0.001
Death, MI, or stroke	6.7	7.5	0.89	0.02
180 days				
Major bleeding	4.3	5.8	0.72	<0.001
Death, MI, refractory ischemia, or major bleeding	15.0	17.1	0.86	<0.001
Death, MI, or stroke	11.3	12.5	0.89	0.007

Conclusion

- The efficacy of fondaparinux in reducing the risk of ischemic events is similar to enoxaparin. However, fondaparinux provides additional benefits by reducing major bleeding events and improving long-term mortality and morbidity.
- Fondaparinux could be the choice of anticoagulant drug in the short-term care of patients with the acute coronary syndrome.

Take home points

1. The combined use of anticoagulants, antiplatelet agents, and invasive coronary procedures reduces ischemic coronary events but also increases the risk of bleeding.
2. The results of the OASIS-5 trial reported similar efficacy of short-term treatment of fondaparinux and enoxaparin in reducing the risk of ischemic events.
3. As compared to enoxaparin, fondaparinux considerably decreases bleeding events.
4. The reduction in the bleeding after fondaparinux treatment is associated with lower long-term mortality and morbidity.

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

Reference:

Fifth Organization to Assess Strategies in Acute Ischemic Syndromes Investigators, Yusuf S, Mehta SR, Chrolavicius S, Afzal R, Pogue J, et al. Comparison of fondaparinux and enoxaparin in acute coronary syndromes. N Engl J Med. 2006 Apr 6;354(14):1464-76.