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EVALUATING THE EFFECT OF FONDAPARINUX IN PATIENTS WITH ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

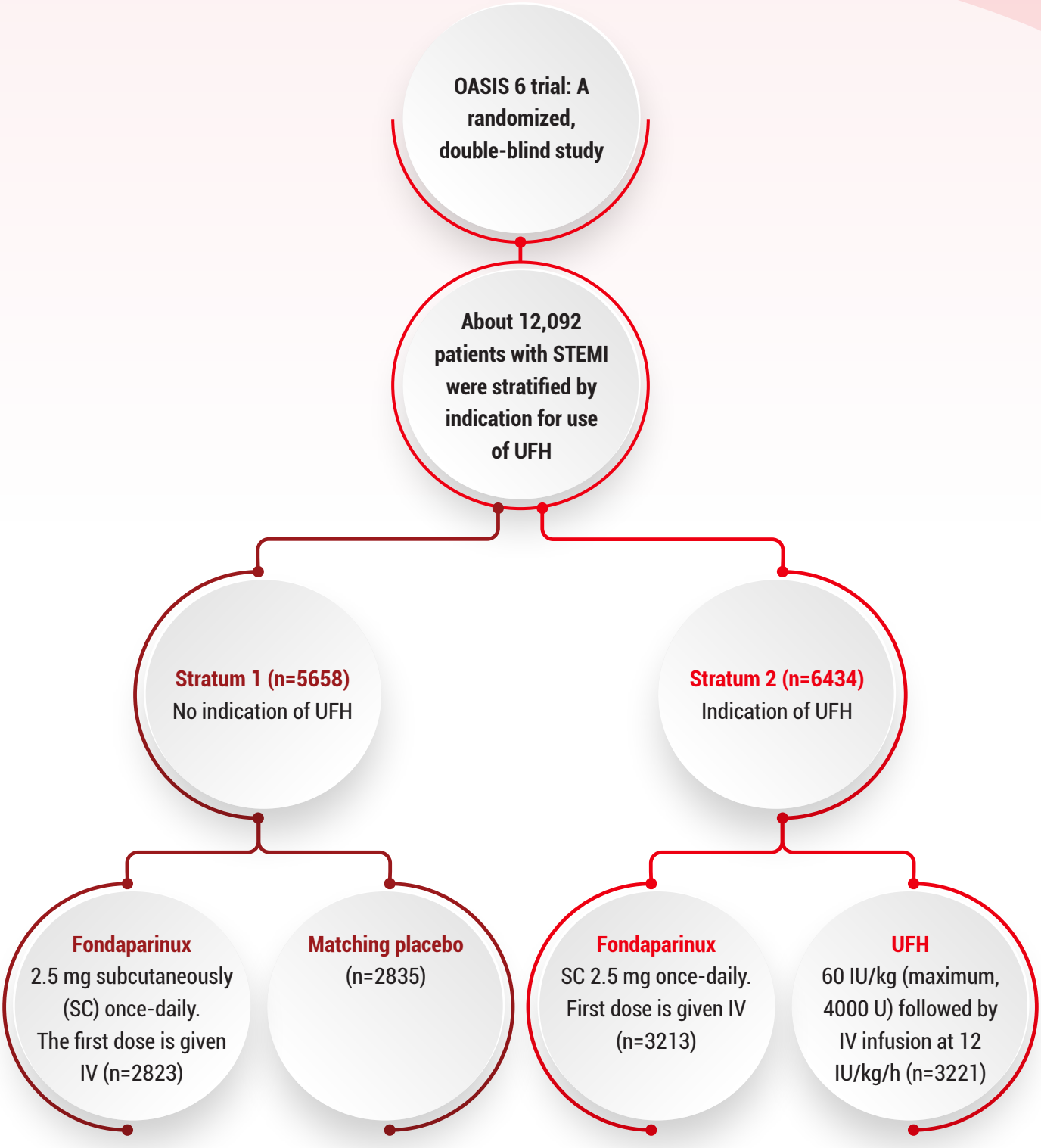
Introduction

- Cardiovascular deaths account for about 30% of total global deaths every year.
- Trials of unfractionated heparin (UFH) and enoxaparin have failed to exhibit a reduction in mortality, but also showed increased bleeding when used with aspirin and thrombolytic therapy.
- OASIS-5 trial showed the similar short-term efficacy of fondaparinux with enoxaparin in preventing ischemic events in patients without STEMI with a substantial reduction in bleeding.

Objective

To assess the effect of fondaparinux treatment on mortality and reinfarction in patients with acute ST-segment elevation myocardial infarction (STEMI).

Study details



Outcome measured

Primary efficacy endpoint: Death or reinfarction at 30 days.

Primary safety endpoint: Deaths and reinfarction at day 9, 3 months, and 6 months.

Secondary outcomes: Severe bleeding.

Results

- Among the components of the composite at 30 days, fondaparinux demonstrated a significant decrease in:
  - **Mortality (Fig. 1)**
  - **Reinfarction (Fig. 2)**

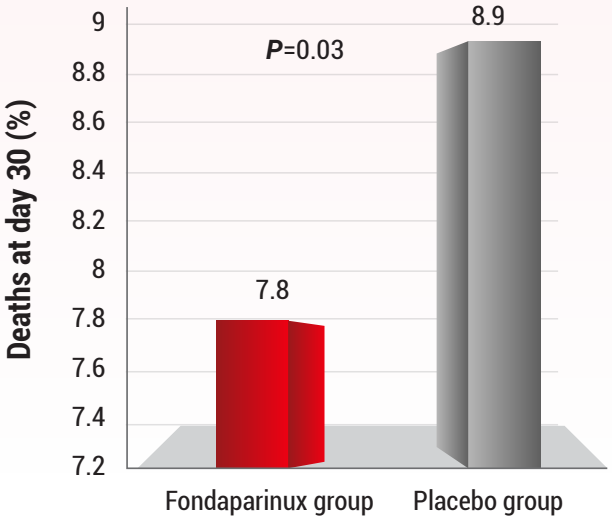


Figure 1: Deaths at 30 days

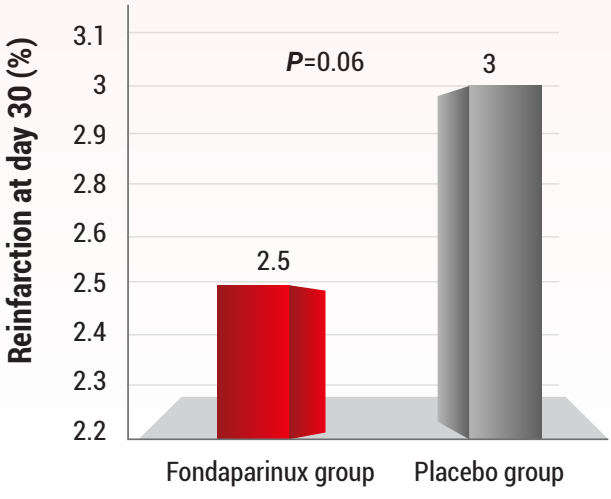


Figure 2: Reinfarctions at 30 days

- The reduction in the deaths and reinfarction in the fondaparinux group was driven by stratum 1 without significant difference.
- Fondaparinux was superior to UFH in preventing death or reinfarction in patients not undergoing primary percutaneous intervention (PCI) at: (Table)
  - **Day 30**
  - **Study end**
- Fondaparinux also showed benefits in patients receiving thrombolytic therapy at 30 days by:
  - **Reducing death and reinfarction by 21%**
  - **Decreasing deaths by 19%**
- As compared to the control group, the fondaparinux group in stratum 1 reported lower rates of:
  - **Severe hemorrhage (44 vs. 28; *p*=0.06)**
  - **Major bleeds (57 vs. 39; *p*=0.07)**

Table: Death or reinfarction in patients without primary PCI

Duration	Fondaparinux	UFH	Hazard ratio	*P* value
30 days	11.5	13.8	0.82	0.08
Study end (90-180 days)	14.9	19.0	0.77	0.008

Conclusion

Treatment with fondaparinux effectively reduced mortality and reinfarction without increasing the bleeding and stroke in patients with STEMI, particularly those not undergoing PCI.

Take home points

1. OASIS-6 trial evaluated the effect of fondaparinux treatment in patients with STEMI.
2. Initial management of fondaparinux followed by standard UFH is an attractive choice for patients who may need rescue PCI or PCI after admission.
3. Fondaparinux reduced death and reinfarction in those receiving thrombolytic therapy and not receiving reperfusion therapy by 21% and death by 19% at 30 days.
4. There is a trend toward fewer severe bleeds with a significant reduction in cardiac tamponade with fondaparinux.
5. Fondaparinux demonstrated a moderate reduction in mortality and reinfarction compared with usual care.

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

Reference:

Yusuf S, Mehta SR, Chrolavicius S, Afzal R, Pogue J, Granger CB, et al; OASIS-6 Trial Group. Effects of fondaparinux on mortality and reinfarction in patients with acute ST-segment elevation myocardial infarction: the OASIS-6 randomized trial. JAMA. 2006 Apr 5;295(13):1519-30.