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ASSESSING THE EFFICACY OF 2 UNFRACTIONATED HEPARIN REGIMENS IN PATIENTS UNDERGOING PCI AND INITIALLY TREATED WITH FONDAPARINUX

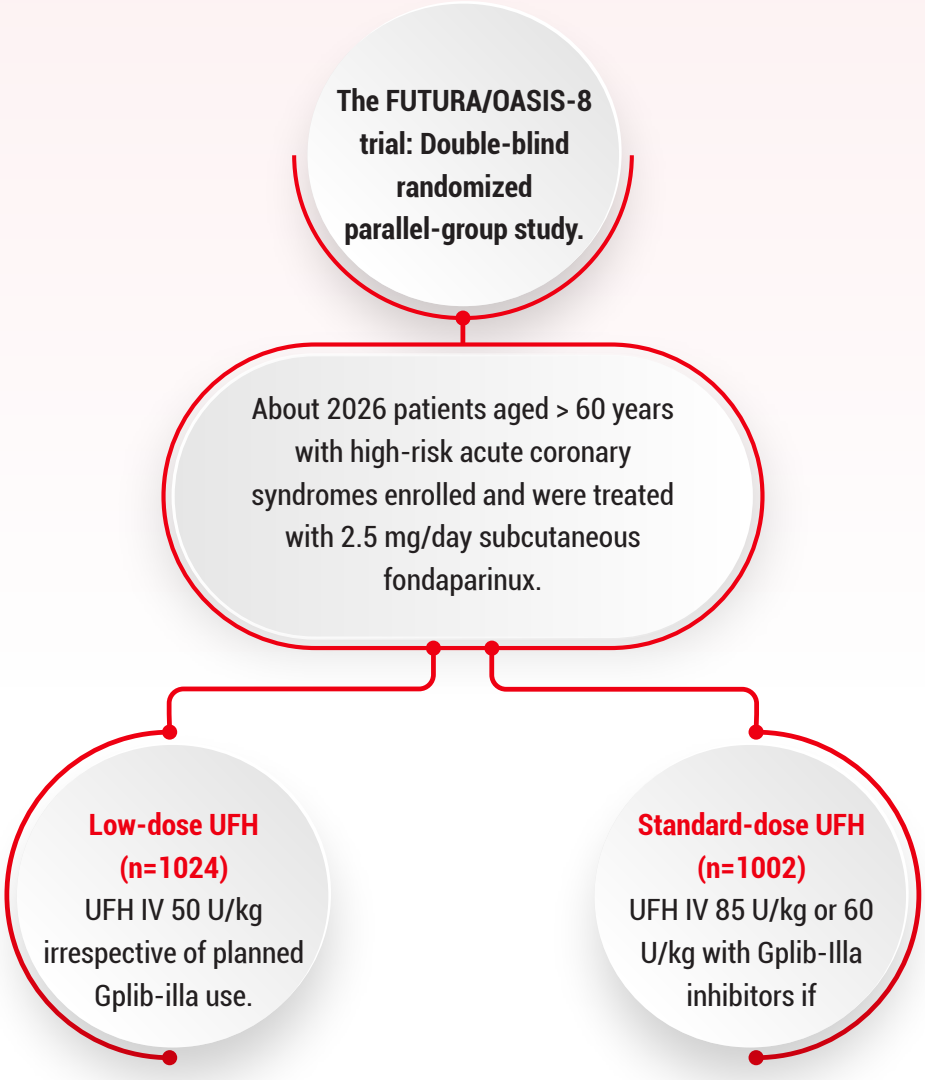
Introduction

- OASIS-5 trial reported noninferiority of fondaparinux to enoxaparin for primary efficacy outcomes, but it was associated with catheter-related thrombosis.
- The combined analysis of OASIS-5 and 6 showed a 0.3% rate of catheter thrombus in patients who received Unfractionated Heparin (UFH) and fondaparinux.
- This finding led to the recommendation of additional UFH therapy during PCI in patients treated with fondaparinux.

Objective

To compare the safety of 2 UFH regimens during PCI in high-risk patients with non-ST-segment elevation acute coronary syndromes initially treated with fondaparinux.

Study details



Outcome measured

- **Primary outcomes:** Composite of major bleeding, minor bleeding, or major vascular access-site complications up to 48 hours after PCI.
- **Secondary outcomes:** Composite of major bleeding at 48 hours with death, myocardial infarction, or target vessel revascularization within day 30.

Results

- The low dose of UFH was not superior to standard UFH in terms of preventing peri-PCI major bleeding or major vascular access-site complications at 48 hours. (Fig. 1)
- The rates of major bleeding were not different, but the rates of minor bleeding were lower with the low-dose group v/s the standard-dose group. (Fig. 2)

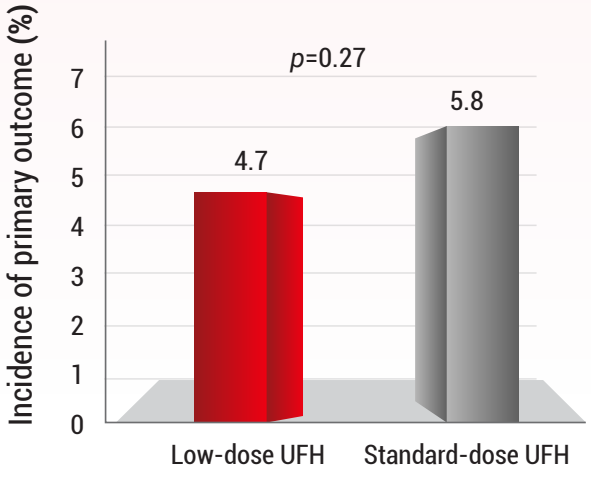


Figure 1: Incidence of primary outcome events in both groups.

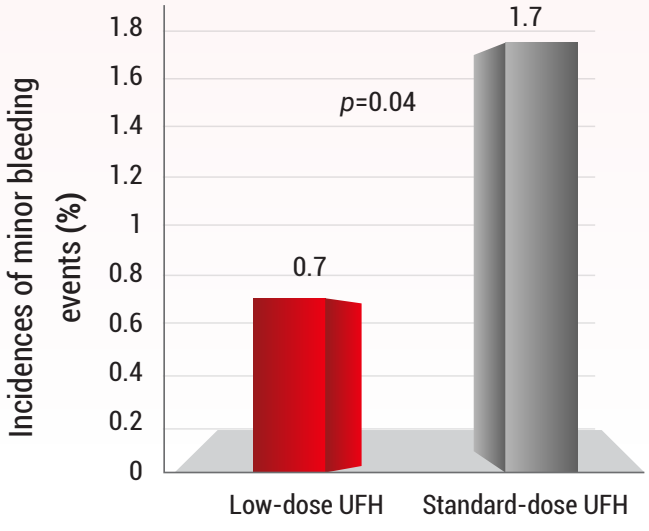


Figure 2: Incidences of minor bleeding events in both groups.

- The secondary outcomes were insignificantly higher in the low-dose UFH group than standard dose UFH. (Table)
- Catheter thrombosis was rare (0.5%) in the low-dose heparin group and very rare (0.1 %) in the standard-dose heparin group.

Table: Secondary outcomes in both groups

Outcome	Low-dose heparin (%)	Standard-dose heparin (%)	OR	*P*-value
Peri-PCI major bleeding, death, MI, and target vessel revascularization at 30 days	5.8	3.9	1.51	0.05
Death/MI/TVR at 30 days	4.5	2.9	1.58	0.06

Conclusion

Catheter-associated thrombosis are rare when using standard unfractionated heparin for PCI in patients with non-ST segment elevation acute coronary syndrome treated with fondaparinux.

Take home points

1. The FUTURA/OASIS-8 trial was conducted to deal with the issue of catheter thrombosis associated with the use of fondaparinux alone in ACS patients undergoing PCI.
2. Low-dose compared with standard-dose UFH did not reduce major peri-PCI bleeding and vascular access site complications.
3. Low-dose UFH therapy was associated with a marginally significant increase in ischemic events.
4. Catheter thrombosis is rare when using UFH for PCI in patients with non-ST-segment elevation acute coronary syndromes treated with fondaparinux.
5. Patients with acute cornory syndromes treated with fondaparinux and undergoing PCI should receive guideline recommended ACT-guided standard dose of UFH.

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

Reference:

FUTURA/OASIS-8 Trial Group, Steg PG, Jolly SS, Mehta SR, Afzal R, Xavier D, Rupprecht HJ, et al. Low-dose vs standard-dose unfractionated heparin for percutaneous coronary intervention in acute coronary syndromes treated with fondaparinux: the FUTURA/OASIS-8 randomized trial. JAMA. 2010 Sep 22;304(12):1339-49.