HD PCI

A Randomized Trial of Higher vs. Lower Dose Heparin for PCI

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Hamilton Health Sciences

McMaster University
HEALTH SCIENCES

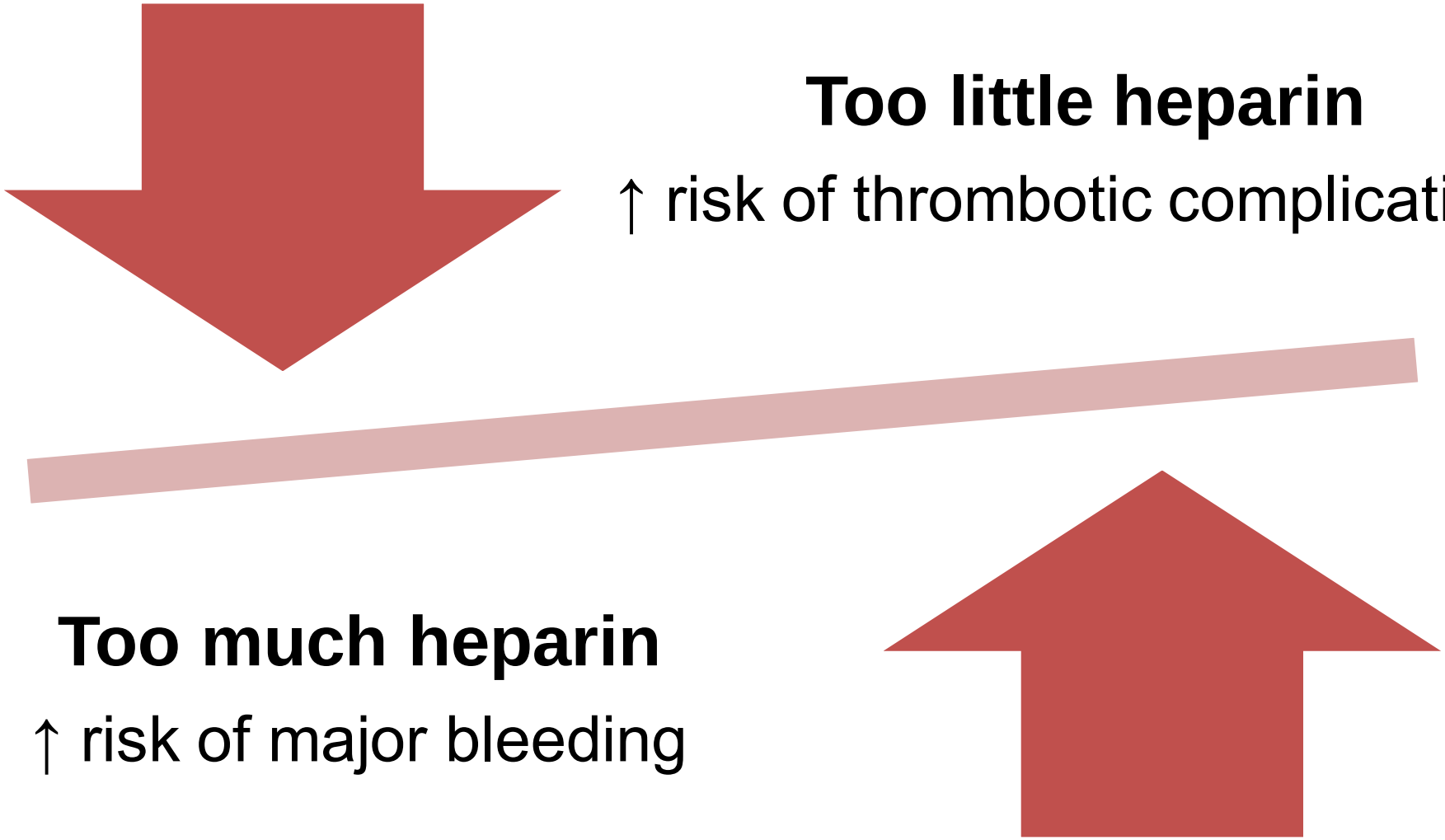
Percutaneous Coronary Intervention (PCI)

- **PCI is common**
  - >2 million PCIs performed annually
  - 300,000 in Canada

- **PCI can result in complications**
  - Ischemic events in 5% within 30 days
  - Bleeding complications 2-4%

- **Unfractionated Heparin (UFH) used in 90% of all PCIs**
  - Optimal dose of UFH unknown

Clinical Importance of Determining Optimal Heparin Dose



Too little heparin

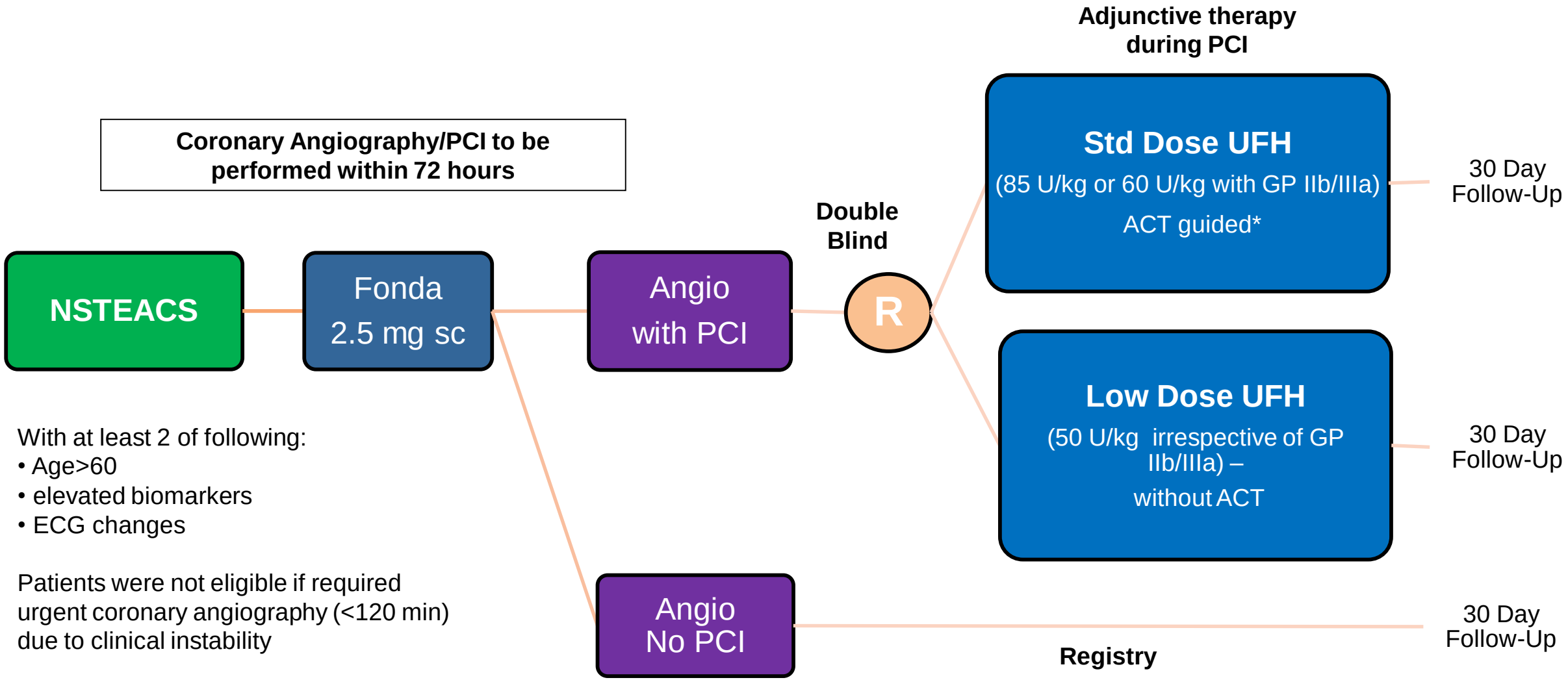
↑ risk of thrombotic complications

Too much heparin

↑ risk of major bleeding

FUTURA/OASIS-8 Trial – Study Design

Low vs. Standard Dose UFH for PCI in Acute Coronary Syndromes Patients treated with Fondaparinux

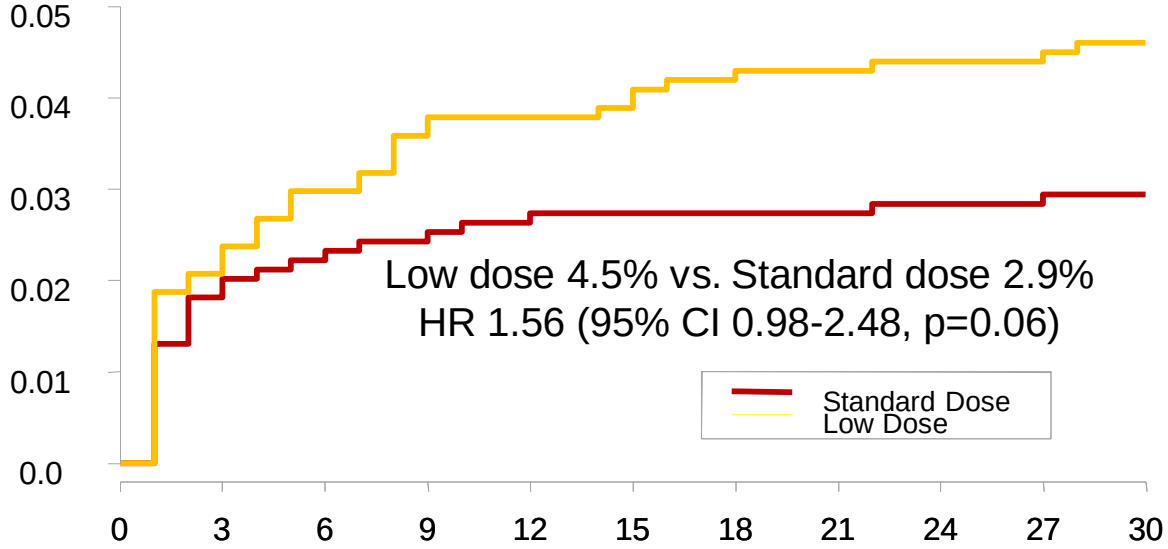


*ACT Targets consistent with current guidelines

FUTURA/OASIS-8 Trial - Results

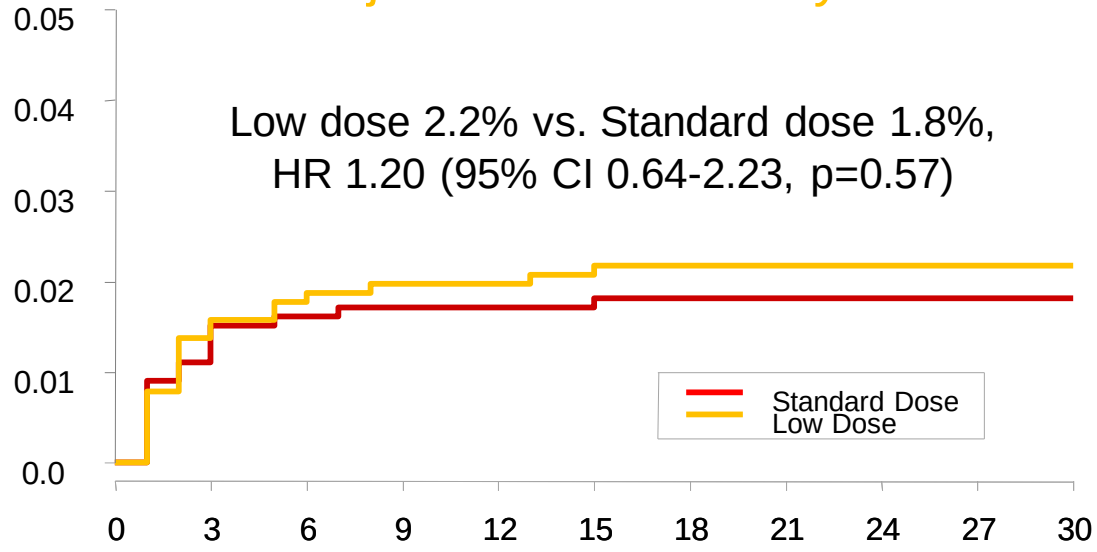
Low vs. Standard Dose UFH for PCI in Acute Coronary Syndromes Patients treated with Fondaparinux

Death/MI/TVR at 30 days



No. at Risk						
Standard Dose	1002	980	975	975	974	971
Low Dose	1024	997	988	982	981	978

Major Bleed at 30 days



No. at Risk						
Standard Dose	1002	986	981	980	980	978
Low Dose	1024	1002	1001	998	997	994

Standard dose: 85U/kg unfractionated heparin
Low dose: 50U/kg unfractionated heparin

Meta-Analysis

Higher vs. Lower Dose Heparin for PCI

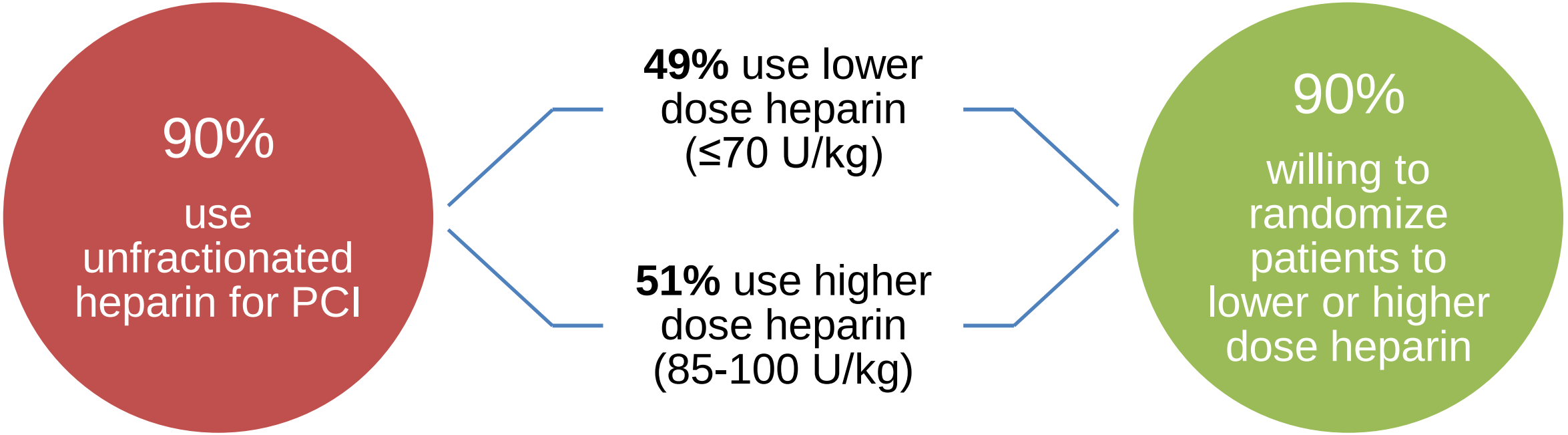
5 RCTs

N = 4822

Outcome	All		Excluding GPIIb/IIIa + Heparin trial	
	OR	95% CI	OR	95% CI
TVR	0.66	0.28-1.52	0.42	0.19-0.93
Major Bleeding	1.28	0.78-2.07	0.92	0.51-1.66

- FUTURA/OASIS-8 trial suggests that higher dose heparin may reduce death, MI and TVR with no difference in major bleeding
- Meta-analysis shows possible reduction in TVR, uncertain on major bleeding

Survey of Canadian Interventional Cardiologists (August 2017)
N=61



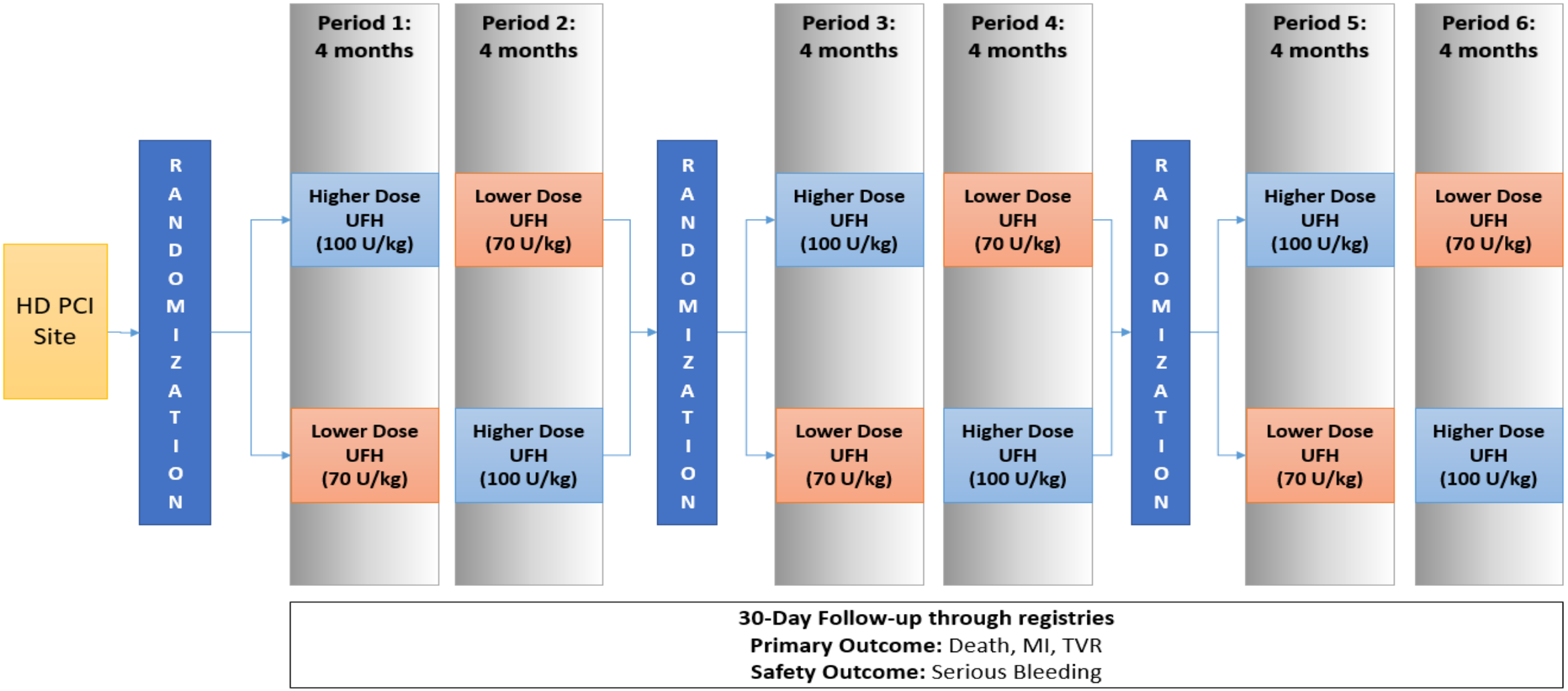
Demonstrates equipoise for the optimal dose of heparin for PCI

Study Question

In patients undergoing elective PCI, does a policy of ***higher dose heparin*** use compared with ***lower dose heparin*** use during PCI reduce composite incidence of death, MI and TVR within 30 days after PCI?

HD PCI Study Design: Cluster Crossover Registry Based Trial

N = 16,152



Eligibility Criteria

Hospital Criteria

- Submit PCI procedure data to a compatible registry
- Site (all operators) agrees to manage patients as per policy in place during the given crossover period

Patient Criteria

- **Inclusion Criteria**
  - Patients undergoing elective PCI
- **Exclusion Criteria**
  - Age <18 years
  - Planned chronic total occlusion PCI
  - Non-resident precluding follow up through registry

Study Interventions

Higher Dose UFH Treatment Period	Lower Dose UFH Treatment Period
•100 U/kg bolus of intravenous UFH	• 70 U/kg bolus of intravenous UFH

Prolonged procedure (≥60 minutes) in either group

- Operators allowed to administer additional UFH guided by activated clotting time (ACT) per standard practice.

Study Outcomes

Primary Outcomes

Efficacy

Death, MI or TVR up to 30 days after PCI

Safety

Major bleeding within 30 days after PCI

Key Net Benefit

Death, MI, TVR or major bleeding within 30 days after PCI

Secondary Outcomes

Death or MI

Components of the primary outcome evaluated separately