Assessment of Clinical Outcomes of Bivalirudin versus Heparin in Patients Undergoing Percutaneous Coronary Intervention

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BACKGROUND

- Bivalirudin (Angiomax®) is a direct thrombin inhibitor indicated for percutaneous coronary intervention (PCI), including patients with heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia and thrombosis syndrome and percutaneous coronary angioplasty[1]
- Bivalirudin is considered second-line for antithrombotic therapy in patients without HIT undergoing PCI due to lack of an established benefit over heparin[2,3,4]
- Recent studies, such as the VALIDATE-SWEDEHEART trial[5], compared heparin to bivalirudin without GP IIb/IIIa inhibitors and concluded similar incidence of thrombosis and bleeding between the two agents
- In contrast, a meta-analysis of 16 trials[6] showed an increased risk of major cardiovascular events, specifically in-stent thrombosis, with bivalirudin-based regimen
- At Baptist Health South Florida (BHSF) entities, bivalirudin is used commonly in patients undergoing PCI, which may lead to higher hospital costs without any additional benefits to the patient

OBJECTIVE

- The objective of this project to evaluate clinical and safety outcomes of bivalirudin versus heparin in patients undergoing PCI

METHODS

- **Study design**
  - Multi-site, retrospective chart review of patients who received bivalirudin or heparin at BHSF entities from January 2021 through March 2021
- **Inclusion criteria**
  - Individuals ≥ 18 years old
- **Exclusion criteria**
  - Pregnancy
- **Primary outcome**
  - Mean hospital length of stay (LOS)
  - 30-day readmission rate
- **Secondary outcome**
  - Incidence of thrombotic events defined as deep vein thrombosis, in-stent thrombosis, pulmonary embolism, myocardial infarction, transient ischemic attack (TIA), or stroke
  - Incidence of bleeding from any site defined as life-threatening bleeding, major bleeding requiring blood transfusion, or drop in hemoglobin by more than 2 g/dL

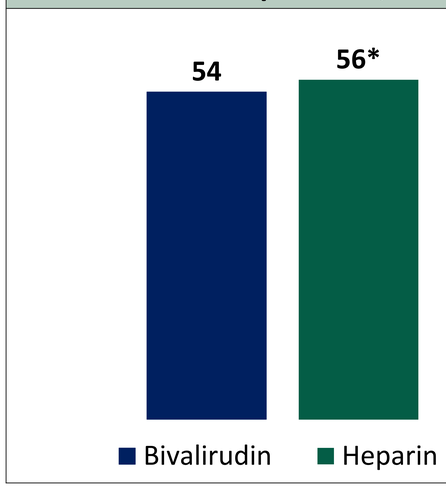
RESULTS

Baseline Demographics

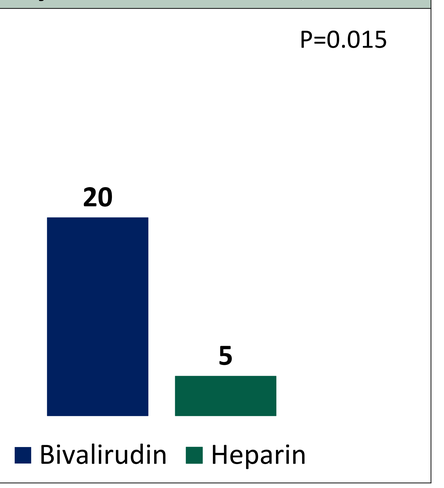
Characteristic	Bivalirudin (n=41)	Heparin (n=81)
Mean age, years	68 ± 10.7	70 ± 11.5
Gender – male, n (%)	25 (64)	62 (77)
History of heparin allergy, n (%)	0 (0)	0 (0)
Cardiac related history, n (%)		
Previous ACS	7 (17)	7 (9)
Previous PCI	8 (20)	25 (31)
Coagulopathy	0 (0)	0 (0)
Outpatient procedure, n (%)	8 (20)	31 (38)
Primary diagnosis		
Angina (stable + unstable)	25 (61)	50 (62)
NSTEMI	11 (27)	19 (23)
STEMI	5 (12)	12 (15)
Radial access site, n (%)	13 (32)	57 (70)
Median number of stents, range	1 (1-3)	1 (1-5)
Intraprocedural loading dose, n (%)		
ASA	41 (100)	81 (100)
Clopidogrel	20 (49)	36 (44)
Ticagrelor	19 (46)	45 (56)
Prasugrel	2 (5)	0 (0)
Concomitant cangrelor	0 (0)	3 (4)

Primary Outcomes

Mean Hospital LOS, hours



30-Day Readmission Rate, %



Secondary Outcomes

Outcome	Bivalirudin (n=41)	Heparin (n=81)
Thrombosis within 48 hours, n (%)	0 (0%)	1 (1%)**
Bleeding from any site within 48 hours, n (%)	0 (%)	0 (%)

* One outlier excluded (LOS= 792 hrs) due to cardiogenic shock
**Thrombosis due to occluded iliac artery

DISCUSSION

- Majority of baselines characteristics were similar between the groups
  - 15% in the bivalirudin versus 90% in the heparin group had a previous ACS
  - 49% of patients in the bivalirudin group received intraprocedural heparin 2000-4000 units
  - 31% in the bivalirudin versus 71% in the heparin group had radial access
- Mean hospital length of stay was similar between groups
  - Outpatient procedures were discharged within 6-24 hours
    - Bivalirudin cohort: mean LOS 13 hours
    - Heparin cohort: mean LOS 10 hours
  - Inpatient procedures were discharged within 24-336 hours
    - Bivalirudin cohort: mean LOS 64 hours
    - Heparin cohort: mean LOS 77 hours
- Although 30-day readmission rate was lower in the heparin cohort, reasons for readmission were not deemed to be related to bleeding, stent-related thrombosis, or ACS

LIMITATIONS

- Small sample size
- Retrospective study design
- Inconsistent documentation in regards to primary diagnosis, duration of bivalirudin infusion, dosing of heparin, purpose for co-administration of heparin in the bivalirudin cohort, and purpose for concomitant cangrelor with antiplatelet agents in the heparin cohort

CONCLUSION

- Heparin does not significantly increase hospital length of stay, risk of bleeding or thrombosis in comparison to bivalirudin
- The 30-day readmission rate results were inconclusive

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DISCLOSURES

- All authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have direct or indirect interest in the subject matter of this presentation