
An industry view

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Disclosures

- Labeling
- Financial

Prologue

- “Pristine groins”

John A. Bittl. Personal communication

TREATMENT WITH BIVALIRUDIN (HIRULOG) AS COMPARED WITH HEPARIN DURING CORONARY ANGIOPLASTY FOR UNSTABLE OR POSTINFARCTION ANGINA

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Table 3. Bleeding Complications for All Treated Patients According to Treatment Group.*

COMPLICATION	BIVALIRUDIN	HEPARIN	ODDS RATIO (95% CI)	P VALUE
Entire cohort				
No. of patients	2161	2151		
	<i>no. of patients (%)</i>			
Intracranial hemorrhage	1 (0.05)	2 (0.09)	0.5 (0.0–5.5)	0.62
Retroperitoneal bleeding	4 (0.2)	14 (0.7)	0.3 (0.1–0.9)	0.02
Red-cell transfusion	80 (3.7)	186 (8.6)	0.4 (0.3–0.6)	<0.001
Major hemorrhage	82 (3.8)	210 (9.8)	0.4 (0.3–0.5)	<0.001
Patients with post-infarction angina				
No. of patients	366	369		
	<i>no. of patients (%)</i>			
Intracranial hemorrhage	0	1 (0.3)	0.3 (0.0–8.3)	1.00
Retroperitoneal bleeding	1 (0.3)	1 (0.3)	1.0 (0.1–16.1)	1.00
Red-cell transfusion	11 (3.0)	35 (9.5)	0.3 (0.2–0.6)	<0.001
Major hemorrhage	11 (3.0)	41 (11.1)	0.3 (0.1–0.5)	<0.001

Antithrombotic Strategy in Non–ST-Segment Elevation Myocardial Infarction Patients Undergoing Percutaneous Coronary Intervention

Insights From the ACTION (Acute Coronary Treatment and Intervention Outcomes Network) Registry

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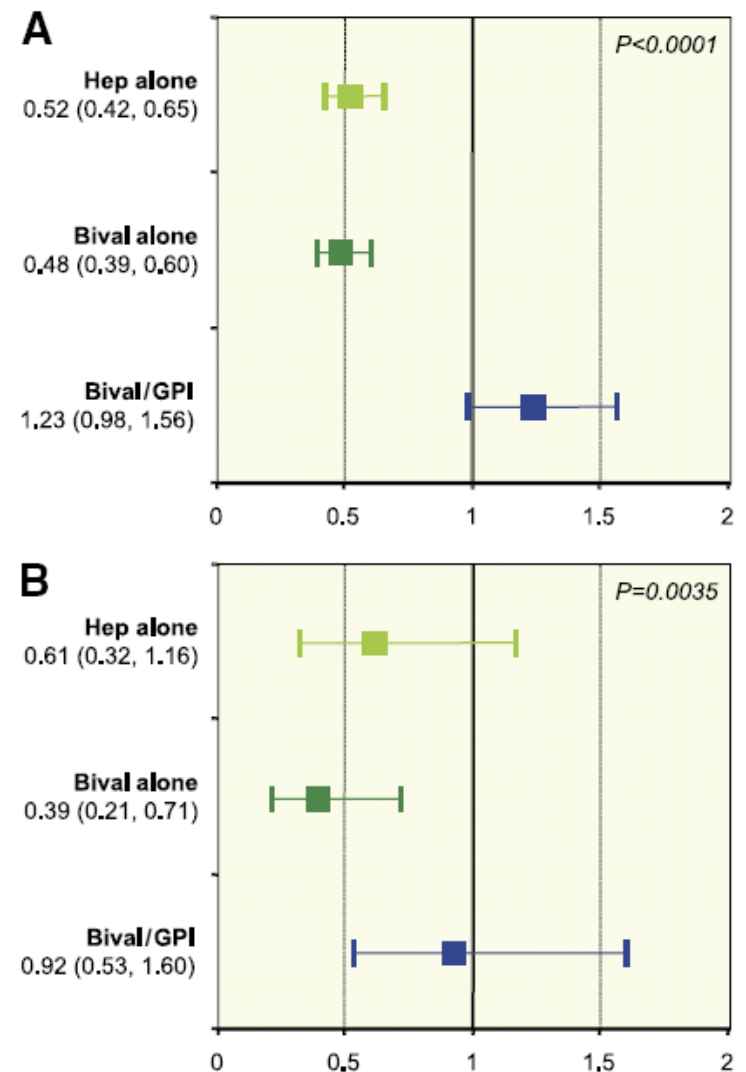


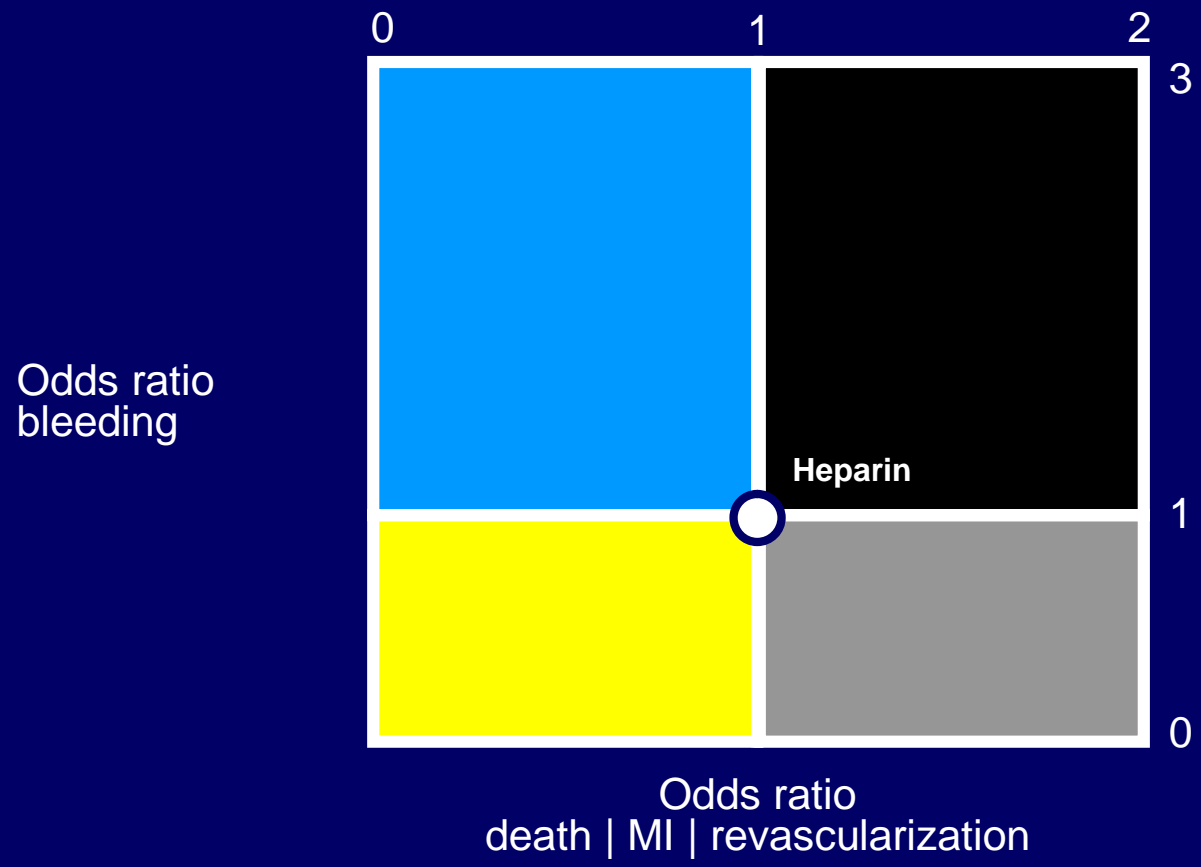
Figure 2. Adjusted Odds Ratio for Major Bleeding and In-Hospital Mortality by Antithrombotic Strategy

Adjusted odds ratio (95% confidence interval) for (A) major bleeding and (B) in-hospital mortality by antithrombotic strategy. The reference group is Hep/GPI. Abbreviations as in Figure 1.

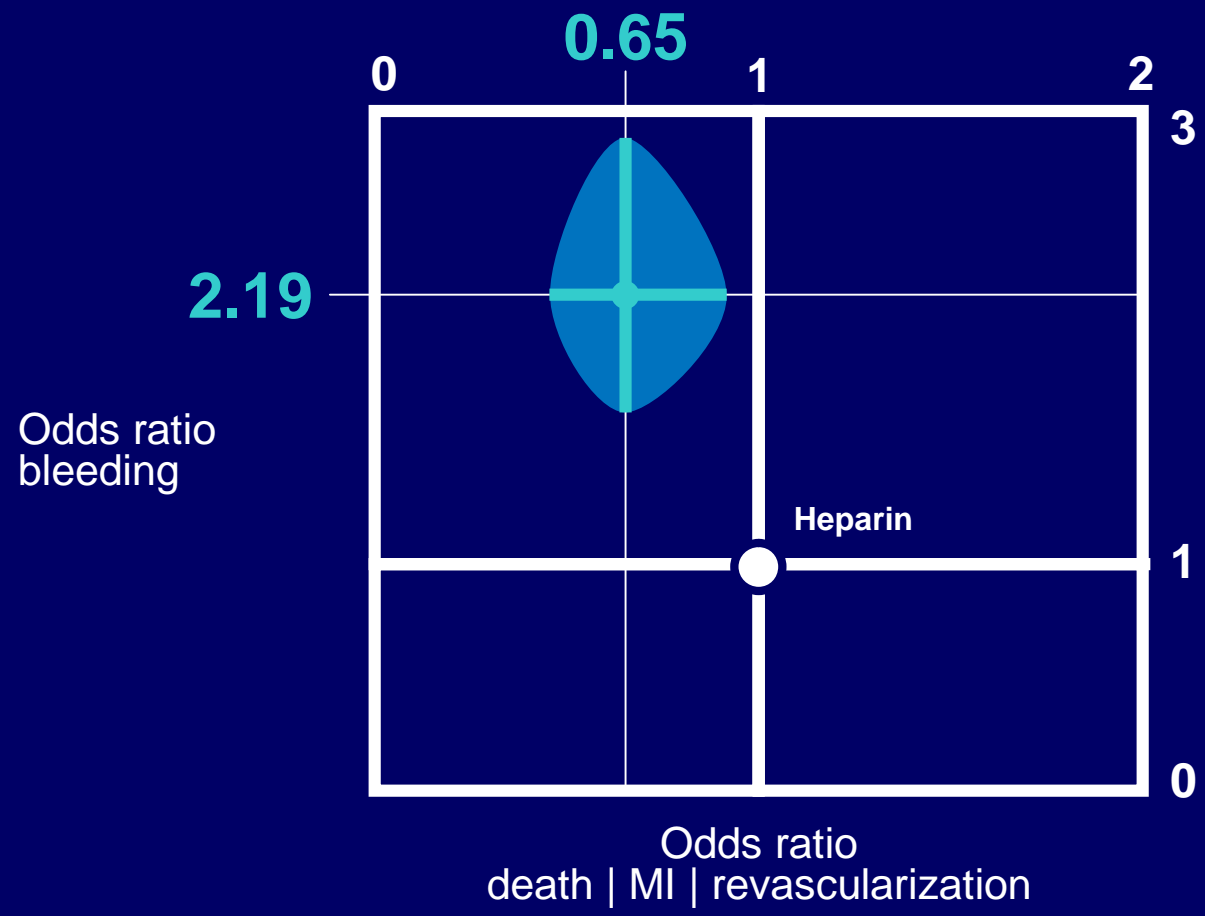
Topics

1. Framework
2. Associations
3. Sources
4. Approaches
5. Observations

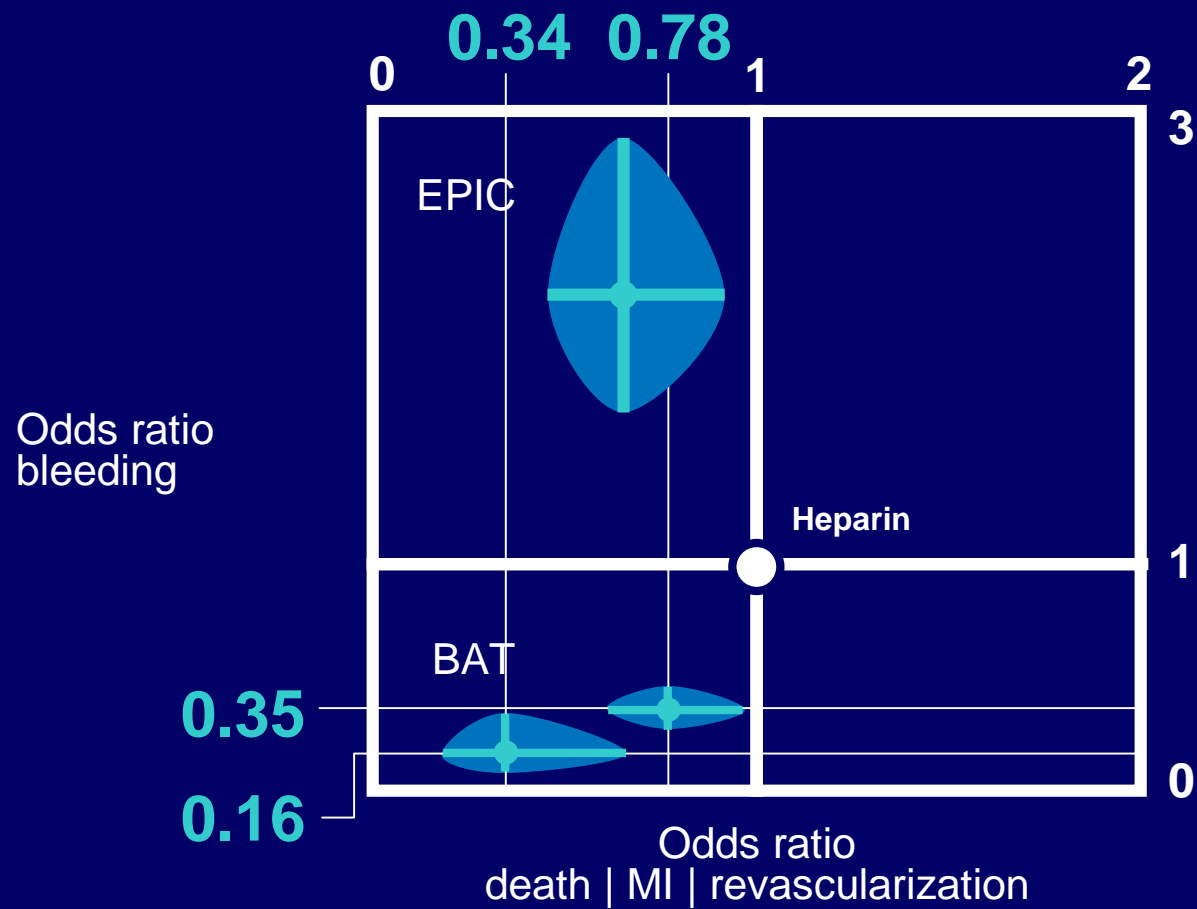
1. Framework



1. Framework

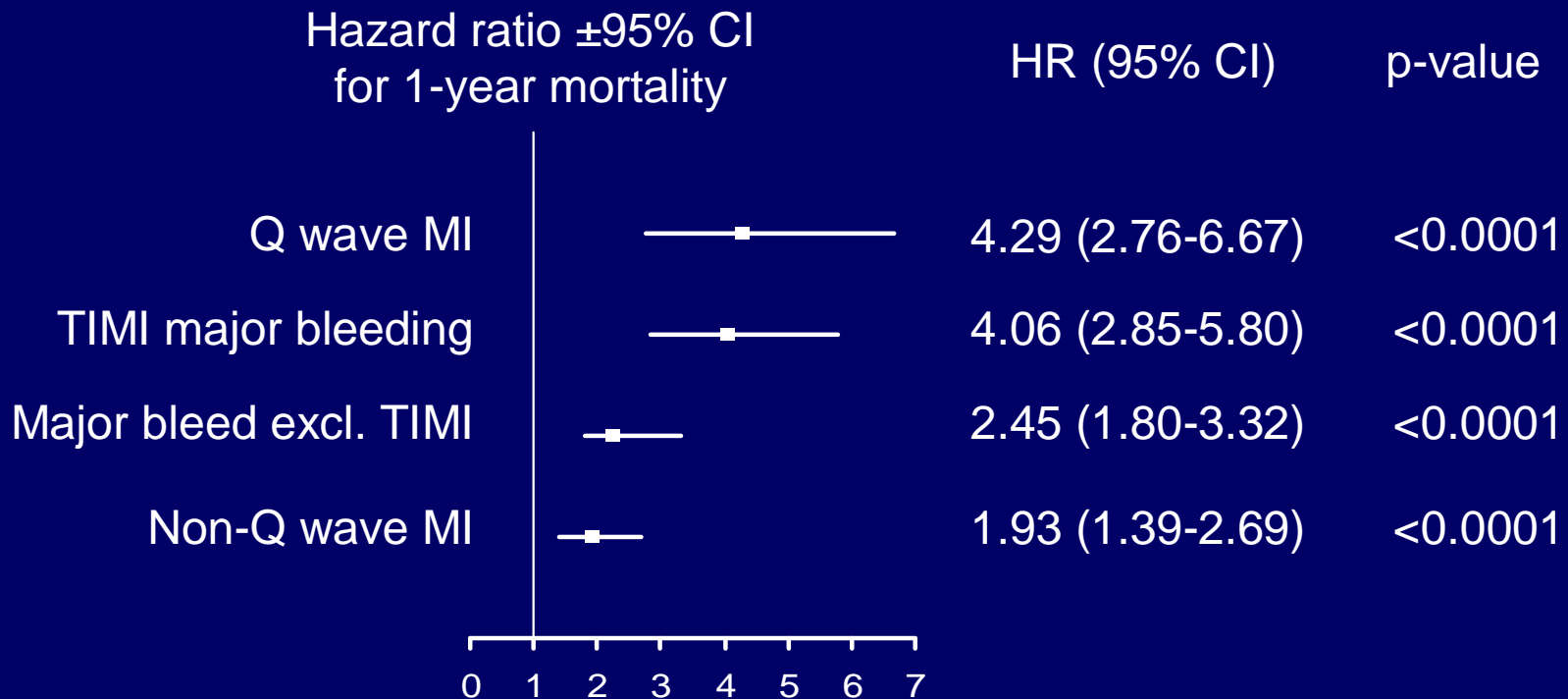


1. Framework



2. Associations

- Several outcome events associate with 1-year mortality



Cox model adjusted for baseline predictors, with time-updated covariates
ACUTY Trial: N = 13,819

3. Sources

- Access site and non-access site bleeds both influenced by antithrombotic treatment

Endpoint ¹	Heparin + GPIIb/IIIa	Bivalirudin + GPIIb/IIIa	Bivalirudin alone
	n=4603	n=4604	n=4612
Non-access site bleeding	5.4%	5.7%	3.9%
Access site bleeding	18.4%	18.0%	10.2%

1. Includes ACUITY major + minor bleeding, excluding CABG related bleeds

4. Approaches

- Access route does not appear to impact organ bleeds

	Heparin + GPIIb/IIIa	Bivalirudin + GPIIb/IIIa	Bivalirudin alone
	n=4603	n=4604	n=4612
All patients	7.9%	7.8%	4.2%
Radial access (n=826)	7.4%	9.7%	4.7%
Femoral access (n=11,988)	7.3%	7.1%	4.1%

Includes ACUTY major + minor bleeding, excluding CABG related bleeds:
Intracranial, intraocular, GI tract, genitourinary, pulmonary, ENT & pericardial)

5. Observations: what counts...

- We don't know why all this happens
- Patient experience counts
- The finance department counts

Summary

1. Choice of drugs or of access approach should consider both potential ischemic and bleeding impact
2. Both are associated with long-term mortality
3. Drug choice impacts access and non-access site bleeds
4. Access choice does not appear to impact organ bleeds
5. Patient experience and costs count