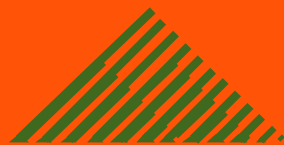


Synthesizing and Reviewing Evidence: Uncracking a Journal Article

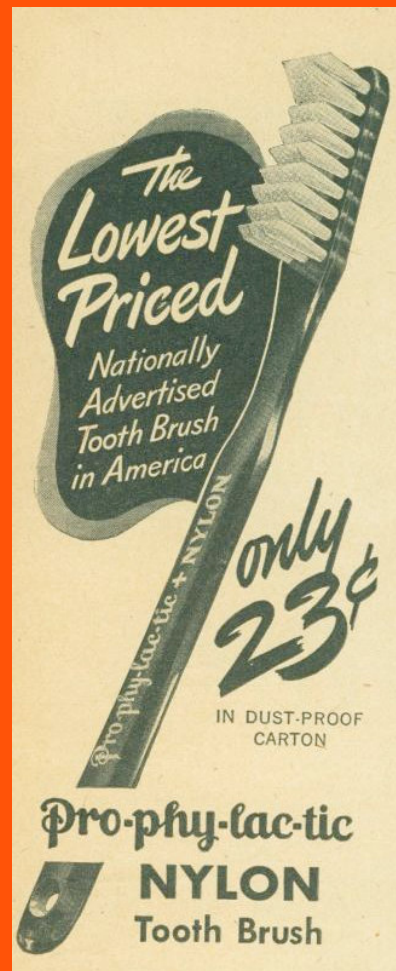


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Aim: To provide a method for reviewing journal articles



700,000
→
Versions



Abstract

Background. Bivalirudin is a short-acting direct thrombin inhibitor, with advantages over unfractionated heparin for anticoagulation in cardiac surgery. We hypothesized that bivalirudin is not associated with a clinically important increase in blood loss compared with heparin with protamine reversal in patients undergoing off pump coronary artery bypass (OPCAB) surgery. We also assessed flow with angiography at 3 months using a modified Thombolysis in Myocardial Infarction (TIMI) grade in the grafted coronary arteries.

Methods. One hundred patients were randomly assigned to receive bivalirudin (0.75 mg/kg bolus, 1.75 mg/kg/h infusion) or heparin (150 to 300 U/kg bolus) with protamine reversal.

Results. A median of 3 (range, 1 to 5) grafts were inserted per patient. Blood loss for the 12 hours after study drug initiation in the bivalirudin group (median, 793 mL; interquartile range, 532 to 1,214 mL; range, 320 to 4,909 mL; n = 50) was not significantly greater than in the heparin group (median, 805 mL; interquartile range, 517 to 1,117 mL; range, 201 to 2,567 mL; n = 50; $p = 0.165$). Median graft flow was 3.0 in the bivalirudin group (n = 40) and 2.67 in the heparin group (n = 39; $p = 0.047$). The bivalirudin group had more patients with grade 3 (ie, full) flow in at least 1 graft (100% versus 90%; $p = 0.04$), a trend toward more patients with grade 3 flow in all grafts (60% versus 38%; $p = 0.06$), and more grafts with grade 3 flow (82% versus 67%; $p = 0.03$).

Conclusions. Anticoagulation for OPCAB surgery with bivalirudin was feasible without a clinically important increase in perioperative blood loss. Graft flow was better in the bivalirudin patients; the impact of this on clinical outcomes requires a larger study.

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- * What is the assertion/study question forwarded by the author(s)?
- * If the study results are true, would you care? Why or Why not?
- * Who stands to benefit from the study's findings – patients, manufacturers, payers, clinicians?

- * What types of patients are in the study?
- * What is the setting of the study (academic vs. community-based hospital), (isolated CABG, isolated VR, CABG/VR)?
- * What type of study was conducted – cohort study, case control study, randomized trial, etc?
- * What is the intervention that the authors are focusing on? Are there important aspects of the intervention that the researchers forgot?
- * What is the outcome that the authors are interested in? Are there other outcomes that the author(s) highlighted?
- * Are the data supporting the assertion *valid*?
- * Is there a comparison group?
- * Is the comparison fair/right?
- * Is the outcome measured properly?
 - Do you agree with the definition of the main outcome?
 - How was it assessed?
 - Were subjects and/or investigators blinded to treatment, assessment
 - How complete/long was the follow-up?
- * Might the effect be due to chance?

Results

* What are the main results of the study and how big of a difference did the intervention make?

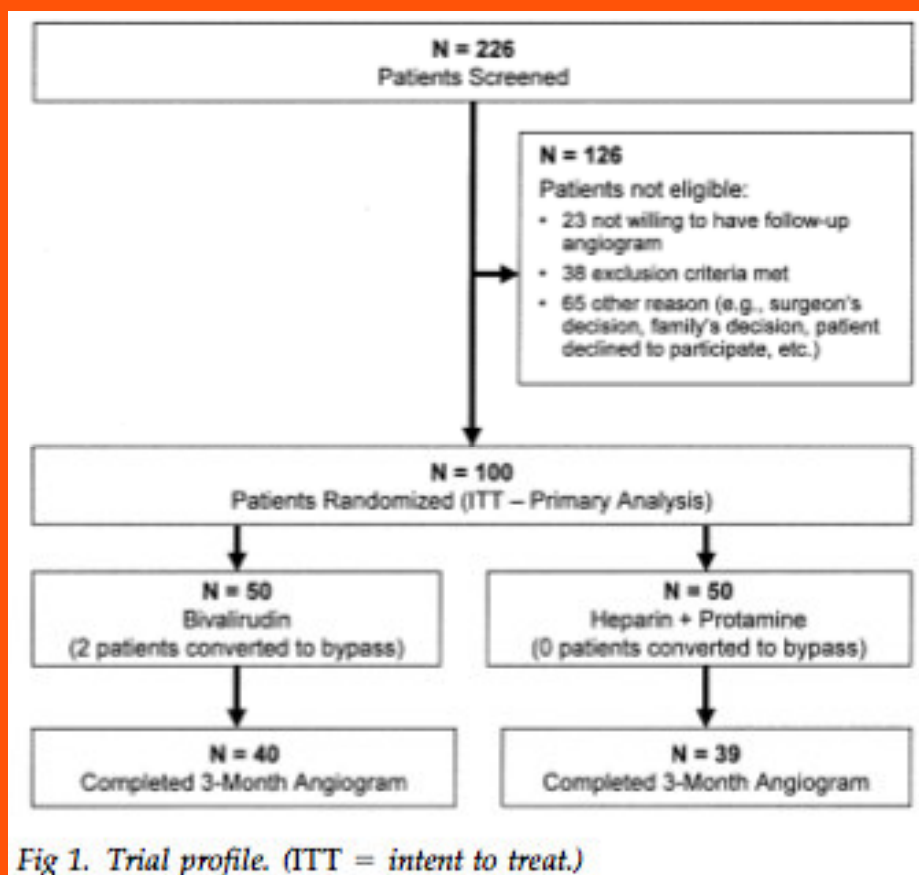


Table 1. Baseline Patient Characteristics

	Bivalirudin (n = 50)	Heparin + Protamine (n = 50)
Demographics		
Sex: female	5 (10%)	8 (16%)
Race: Caucasian	42 (84%)	46 (92%)
Age (years)	64 (11.0)	65 (9.9)
Weight (kg)	83 (14.2)	84 (13.3)
History of cardiovascular disease		
Angina (stable)	27 (54%)	28 (56%)
Angina (unstable)	22 (44%)	21 (42%)
Myocardial infarction	29 (58%)	12 (24%)
Myocardial infarction (within 7 days)	1 (2%)	1 (2%)
Angioplasty	6 (12%)	4 (8%)
CABG	0 (0%)	0 (0%)
Transient ischemic attack	1 (2%)	0 (0%)
Stroke	0 (0%)	1 (2%)
Risk factors		
Hypertension	24 (48%)	23 (46%)
Current smoker	11 (22%)	4 (8%)
Diabetes	8 (16%)	5 (10%)
Hemodynamics		
Blood Pressure:		
Systolic (mm Hg)	129 (25.1)	131 (24.1)
Diastolic (mm Hg)	63	64
Heart rate (beats/min)	64	64
Concomitant medications		
Low molecular weight heparin	0	0
Clopidogrel (<24 hours preoperatively)	2	2
Aspirin (<12 hours postoperatively)	9	9

Values are number (%) or mean (SD).

CABG = coronary artery bypass grafting.

63 effectiveness (Real Life)
64 versus efficacy (Ideal)

0 What is the advantage of
2 having the numbers an
9 percentage?

Results

* What are the main results of the study and how big of a difference did the intervention make?

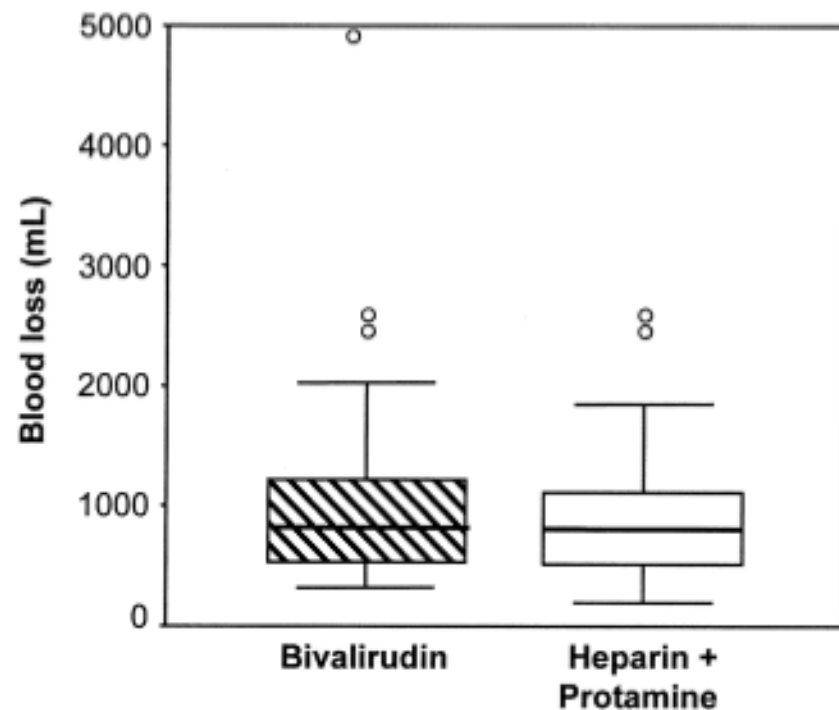


Fig 3. Perioperative blood loss: box plots showing the median, interquartile range, range, and outliers. The top two outliers in the bivalirudin group relate to patients who were converted to cardiopulmonary bypass and administered heparin.

Table 2. Transfusions and Clinical Events

	Bivalirudin (n = 50)	Heparin + Protamine (n = 50)	<i>p</i> Value
Platelets	2 (4%)	1 (2%)	
Fresh frozen plasma	4 (8%)	0 (0%)	
Cryoprecipitate	3 (6%)	0 (0%)	
Whole blood or packed red blood cells	11 (22%)	9 (18%)	
Any blood product	12 (24%)	9 (18%)	0.46
Myocardial infarction	8 (16%)	7 (14%)	
Revascularization	0 (0%)	1 (2%)	
Death	1 (2%)	0 (0%)	
Severe bleed	2 (4%)	0 (0%)	
Composite (all of the above)	9 (18%)	7 (14%)	0.59

Data are number (%). Two of the 12 patients who received a blood product in the bivalirudin arm had been converted to CPB and administered heparin.

effectiveness (Real Life)
versus efficacy (Ideal)

What is the advantage of
having the numbers an
percentage?

Conclusions /Discussion/ Comment

- * Are the data supporting the authors' conclusions *relevant to your practice*:
- Did the author(s) choose the right study population and setting?
- Are all important risk factors tracked?
- Did the author(s) choose an important main outcome? Are all the important outcomes tracked?
- Is the effect of the intervention big?
 - * How did the authors interpret their results? (briefly)
- * Do you agree with the conclusions? (why/why not?, alternative explanations?)