

# ARNO TRIAL

*(Antithrombotic Regimens aNd Outcome)*

A RANDOMIZED TRIAL COMPARING  
BIVALIRUDIN WITH UNFRACTIONED  
HEPARIN IN PATIENTS UNDERGOING  
ELECTIVE PCI

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# ARNO TRIAL

- The aim of this randomized study is to determine if bivalirudin is still superior to unfractionated heparin plus protamine in patients undergoing elective PCI.
- All patients undergoing PCI and pretreated with aspirin (325 mg), and a 600 mg loading dose of clopidogrel at least 6 hours before PCI were considered eligible for enrolment.

# TREATMENTS

- Aspirin (325 mg) and clopidogrel (600 mg loading) at least 6 hours before PCI in all patients. Abciximab on a provisional basis.
- Heparin group: 100 IU per kg of body weight with or without additional boluses to achieve an ACT of 250 to 300 seconds. Protamine 0.5 mg per 100 IU of heparin utilized.
- Bivalirudin group: bolus of 0.75 mg/kg followed by infusion of 1.75 mg/kg per hour for the duration of the procedure.
- Immediate post-PCI sheath removal and routine use of closure devices in all patients.

# ONE-MONTH OUTCOME - BLEEDING

	<i>Bivalirudin</i> (n=425)	<i>Heparin</i> (n=425)	<i>p</i>
➤ <b>Major bleeding</b>			
in-hospital	2 (0.5%)	9 (2.1%)	0.033
one-month	4 (0.9%)	12 (2.8%)	0.043
≥ 3gr/dL overt source, n	2	3	
≥ 4gr/dL, n	0	3	
blood transfusion, n	2	6	
➤ <b>Minor bleeding</b>	2.4%	2.4%	NS

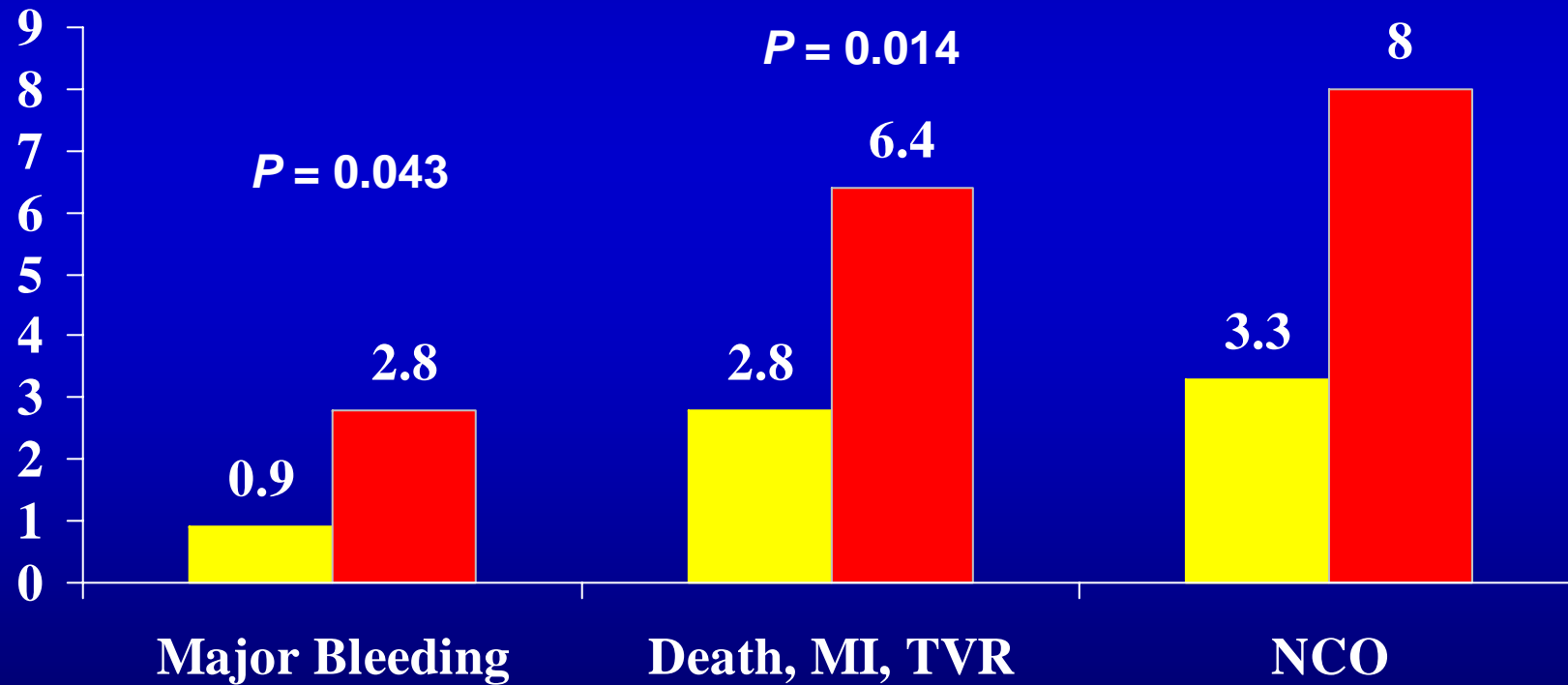
# ONE-MONTH OUTCOME

	<i>Bivalirudin</i> (n = 425)	<i>Heparin</i> (n = 425)	<i>p</i> <i>value</i>
<b>Death/MI/TVR</b>	<b>12 (2.8%)</b>	<b>27 (6.4%)</b>	<b>0.014</b>
Death	1 (0.2%)	6 (1.4%)	0.057
MI	11 (2.4%)	20 (4.5%)	0.098
Q-wave	1	1	
TVR	2 (0.4%)	3 (0.7%)	0.411
<b>NCO</b>	<b>14 (3.3%)</b>	<b>33 (8.0%)</b>	<b>0.004</b>
<b><i>Definite stent thrombosis</i></b>	<b>2 (0.5%)</b>	<b>1 (0.3%)</b>	
<i>acute</i>	1	0	
<i>subacute</i>	1	1	

# Study 30-Day End Points

■ Bivalirudin  
■ UFH

Incidence (%)



# CONCLUSIONS

In this randomized trial of patients undergoing elective PCI and pre-treated with aspirin and clopidogrel, bivalirudin compared to unfractionated heparin plus protamine resulted in a significant reduction of major bleeding, of the composite of death, MI, TVR, and in a better net clinical outcome.