BAT (BITTL) 1995

A randomised clinical trial investigating the effect ofbivalirudin versus UFH in patients undergoing urgent angioplasty for unstable or postinfarction angina

1 Treatments

Studied treatment	bivalirudin immediately before angioplasty. bivalirudin bolus dose of 1.0 mg per kilogram of body weight, followed by a 4-hour infusion at a rate of 2.5 mg per kilogram per hour and a 14-to-20-hour infusion at a rate of 0.2 mg per kilogram per hour. If the clotting time was less than 350 seconds, saline was given
Control treatment	heparin immediately before angioplasty bolus dose of 175 units per kilogram followed by an 18-to-24-hour infusion at a rate of 15 units per kilogram per hour. If the clotting time was less than 350 seconds a bolus dose of 60 units of heparin per kilogram to those treated with heparin
Concomittant treatments	Aspirin (300 to 325 mg),

[2]0pt

2 Patients

Patients	patients undergoing urgent angioplasty for unstable or postinfarction angina
Inclusion criteria	patients urgently scheduled to undergo angioplasty for unstable angina defined as crescendo angina, angina of new onset, or angina at rest or for postinfarction angina less than two weeks after myocardial infarction;
Exclusion criteria	serum creatinine concentrations exceeded 3.0 mg per deciliter (265µmol per liter); thrombolytic therapy within the previous 24 hours; coronary atherectomy, stenting, or laser angioplasty; staged angioplasty procedure; possibly pregnant; intolerance to aspirin or heparin

[2]0pt

3 Methods

Blinding	double blind
Design	Parallel groups
Centers	121
Geographical area	US
Sample size	4098 (2059 / 2039)
ArretTrt1	-
ArretTrt0	-
PeriodeInclusion	Mar 1993 - Jul 1994
Hypothese	Superiority

[2]0pt

4 Results

Endpoint	T1	T0	d	95% CI
death, MI, revascularization	-/2059	-/2039	NA	-
All cause death	9/2059	4/2039	2,23	[0,69; 7,25]
Ischaemic complication	235/2059	249/2039	0,93	[0,77; 1,13]
MI	65/2059	80/2039	0,80	[0,58; 1,12]
Unplanned revascularisation for ischaemia	35/2059	35/2039	0,99	[0,62; 1,59]
death, MI, urgent TVR, in-hospital major bleeding	-/2059	-/2039	NA	-
net benefit	-/2059	-/2039	NA	-
minor bleeding	-/2059	-/2039	NA	-
major bleeding	82/2059	210/2039	0,39	[0,30; 0,50]
safety criteria	-/2059	-/2039	NA	-

5 References

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Bittl JA, Strony J, Brinker JA, Ahmed WH, Meckel CR, Chaitman BR, Maraganore J, Deutsch E, Adelman B, Treatment with bivalirudin (Hirulog) as compared with heparin during coronary angioplasty for unstable or postinfarction angina. Hirulog Angioplasty Study Investigators. N Engl J Med 1995;333:764-9. [7643883]
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6 Comments

Bivalirudin Angioplasty Trial (BAT) is the post hoc reanalyzed of this trial using contemporary definitions of adjudicated end points

