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### 732 Megadose bolus heparin as first treatment for acute myocardial infarction: results of the HEAP pilot study

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Early angiography after thrombolysis for acute myocardial infarction (AMI) shows better patency when intravenous (iv) heparin is used as adjunct. We wondered, if iv heparin alone also would induce reperfusion.

In the HEAP (Heparin in Early Patency) Pilot study 73 patients (pts) with < 6 hours (h) signs ( $\geq 2$  mm ST $\uparrow$  in  $\geq 2$  leads) and symptoms of AMI received a single iv bolus of 300 U/kg heparin, a dose usually given by cardiac surgeons prior to cardiopulmonary bypass. Doses of bolus heparin given varied from 10,000 to 40,000 U. Aspirin (160 mg chewed), but no thrombolytic agent was given. Patency was assessed by coronary angiography at 90 minutes (min) after the heparin bolus.

In 38/73 (52%) pts TIMI flow 2-3 was seen at 90 min: TIMI flow 3 in 24 (33%) pts and TIMI flow 2 in 14 (19%) pts. Pts with < 2 h symptoms (n = 34) had 68% TIMI flow 2-3 vs 39% in pts with  $\geq 2$  h symptoms (p = 0.09). Pts with TIMI flow 0-2 underwent primary angioplasty. At 90 min aPTT exceeded 120 sec in all pts. No bleeding was seen. Aspirin 80 mg daily was given, as was heparin (aPTT 2.0-2.5) for 48 h. PredischARGE angio showed TIMI flow 3 in 18/23 (78%) pts.

Thus, early therapy with high-dose front-loaded heparin alone can induce full coronary reperfusion in pts with AMI, especially in early (<2 h) pts. This simple, inexpensive and easily antagonizable strategy seems to be an attractive first AMI treatment both pre-hospital, and in-hospital prior to primary PTCA. However, high-dose bolus heparin should be compared first to the regular low-dose heparin, for which a randomized angiographic study is currently carried out.

### 733 High-dose intravenous heparin as an alternative to thrombolytics in the treatment of patients with acute myocardial infarction - The HAPI study

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**Background:** Pre-hospital chemical thrombolysis is effective in the early phase of Acute Myocardial Infarction (AMI), but has been hampered by the need for diagnosis confirmation by ECG criteria, contraindication check-list and difficult utilization of thrombolytics outside hospital. Standard Heparin (SH) has been used as an alternative or as an adjunctive for chemical, mechanical as well as endogenous thrombolysis, in patients (P) admitted to the hospital with AMI.

**Aim:** We tested the hypothesis that a high dose IV SH bolus could open occluded artery related to infarction (ARI) in an acceptable rate, being an alternative way for pre-hospital thrombolysis or as a pre-treatment before primary PTCA, at low complication level and cost.

**Methods:** Thirty-two P, mean age of  $64 \pm 10$  years, 47% male, presenting within 12 h symptoms of AMI and indication criteria for reperfusion (chest pain, ST elevation on standard ECG) were randomized (double blind fashion) to SH, 300 IU/kg IV bolus or placebo (P1). All P received 200 mg ASA before being submitted to immediate coronariography, for intended primary PTCA.

**Results:** There was no difference between the two groups in relation to time of beginning of symptoms (mean of  $4.3 \pm 3.2$  h). Coronaryography was performed with a mean delay of  $74 \pm 20$  min. SH group (n = 16) had 50% and P1 group (n = 16) 12.5% TIMI 2.3 ARI patency respectively (p = 0.05). All P with occluded ARI (TIMI 0.1) or TIMI 2.3 but critical obstruction were submitted to primary PTCA, at the discretion of the hemodynamicist.

**Conclusions:** 1) Standard heparin does have a thrombolytic action when administered in high dosage IV bolus. 2) The infrequent contraindication for its prescription, low incidence of harmful effects, no need for confirmation of diagnosis by a cardiologist neither ECG comprovation, may suggest its routine utilization in outpatients with suspected acute coronary syndromes before they get to the hospital or to inpatients waiting for intended primary PTCA.

## IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

### 739 Safety and efficacy of reduced defibrillation energies in implantable cardioverter defibrillators: results of the LEET study, a prospective, randomized multicenter trial

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For patients (pts) convenience the size of implantable cardioverter defibrillator (ICD) should be reduced. With the lowering of maximal defibrillation energy (DE) smaller capacitors can be used. A prospective, randomized study has been set up to evaluate the safety and efficacy of using ICDs at lower DE in type ICD pts.

We enrolled 142 consecutive ICD recipients with documented ventricular fibrillation (VF), polymorphic ventricular tachycardia (VT) or monomorphic VT unresponsive to antitachycardia pacing by four participating centers: 132 pts (93%) (mean age  $58 \pm 12$  years, LVEF:  $36 \pm 13\%$ , CAD: 64%, DCM: 23%) met the inclusion criteria requiring an intraoperative defibrillation threshold (DFT)  $\geq 15$  Joule (J) by using only endocardial single lead systems (Endotak) and first generation ICDs. These pts have been randomized to either a test group (63 pts, LVEF:  $38.3 \pm 14\%$ , DFT:  $9.3 \pm 3$  J) with first shock DE set at two times DFT, or a control group (63 pts, LVEF:  $35.4 \pm 13\%$ , DFT:  $10.1 \pm 4$  J) with first shock set at 34 J (maximum output (MO)). All other shocks were set on MO in both groups. The follow up period was  $9.8 \pm 6$  months.

The first shock efficacy i.e. the rate of successful termination of a sustained VT/VF episode by the first shock, amounted to 98% in the 204 episodes of ventricular tachyarrhythmias (VTA) in the test group and to 97% in the 193 episodes with VTA in the control group (p = ns). Two deaths (one sudden) occurred in each group (overall mortality 3%).

**Conclusion:** ICDs with first shock set at two times DFT appear to be safe and as efficient as ICDs set on MO in pts with malignant VT/VF. These findings suggest that pts with low intraoperative DFT may be treated with smaller, lower output devices even using the single lead alone technique.

### 740 Benefit from implanted cardioverter-defibrillators in patients with overt heart failure

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**Objective:** In the absence of prospective studies, benefit from therapy with implanted cardioverter-defibrillators (ICD) has been questioned in patients with advanced heart failure. The purpose of this study was to investigate whether implantation of an ICD is likely to improve outcome in patients with overt heart failure.

**Methods:** Between 1989 and 1995, 462 patients (62% CAD, 18% DCM) were treated with an ICD with extended memory functions (RR-interval: 300-350 bpm, 100-150 bpm) in combination with endocardial lead systems. Retrospectively, we correlated the stage of heart failure with the occurrence of fast ventricular tachyarrhythmias (VT/VF; > 240/min) and overall mortality. The potential benefit imposed by implantation of an ICD was estimated as the difference between overall mortality and the occurrence of fast and wide QRS termination by the devices presumably fatal ventricular tachyarrhythmias.

**Results:** Independent of the stage of heart failure, a significant difference between recurrences of fast ventricular tachyarrhythmias and overall mortality was observed suggesting a benefit from ICD-implantation in all groups.

3-year event rates	NYHA 1	NYHA 2	NYHA 3
n	107	221	134
Fast VT/VF (> 240 bpm)	34%	33%	43%
Overall mortality	2%	14%	24%
Estimated benefit	32%	19%	19%

In the NYHA 3-group, no differences were observed between patients with an ejection fraction above versus below 30%.

**Conclusions:** The stage of heart failure is an important determinant for survival after implantation of an ICD. However, implantation of an ICD-system is likely to improve survival significantly in all stages of heart failure. Even patients with advanced heart failure and low ejection fraction are likely to benefit from ICD-implantation.