NAPLES (Tavano) 2009

1 Treatments

Studied treatment  bivalirudin monotherapy

Control treatment  unfractionated heparin plus tirofiban

Concomittant treatments  -

Antiplatelet drugs  -

Age (mean), years  -

male (%)  -

UFH as Antithrombin during PCI (%)  -

Enoxaparin as Antithrombin during PCI  -

Bivalirudin as Antithrombin during PCI  -

stent implanted (%)  -

Drug-eluting stent implanted  -

2 Patients

Patients patients with diabetes mellitus undergoing elective percutaneous coronary intervention

Inclusion criteria  age >=18 years old, diabetes treated with insulin and/or oral agents, de novo coronary lesion in a native coronary artery, and elective PCI

Exclusion criteria  PCI performed as reperfusion therapy for acute myocardial infarction; pregnancy; recent (<1 month) PCI; restenotic lesion; saphenous venous graft and/or mammary artery lesion intervention; acute coronary syndrome with basal creatine kinase or creatine kinase-myocardial band value greater than the upper limit of local normal; recent (<=12 weeks) active internal bleeding or bleeding diathesis, surgery, trauma, or gastrointestinal or genitourinary tract bleeding; previous intracranial bleeding or structural abnormality; platelet count <=125 \(10^3\)/l; history of heparin-induced thrombocytopenia; chronic kidney disease with serum creatinine levels > 3mg/dl; dependency on renal dialysis; warfarin therapy; administration of UFH within 6 hours, low–molecular–weight heparin within 8 hours, abciximab within 7 days, or eptifibatide or tirofiban within 12 hours before PCI

Diabetes (%)  -

Previous myocardial infarction (%)  -
Previous PCI -
Previous CABG -
Weight (kg) -
Hypertension (%) -
Hyperlipidaemia -
Current smoker -
Unstable angina / ACS -
Multivessel coronary disease -

3 Methods
Blinding open
Design Parallel groups
Centers single center
Geographical area Italy
Sizes 167/168
Attempted lesions per patient (mean) -
Left main coronary artery -
Left anterior descending coronary artery -
Left circumflex coronary artery -
Right coronary artery -
## 4 Results

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
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</thead>
<tbody>
<tr>
<td>death, MI, revascularization</td>
<td>-/-9</td>
<td>-/-9</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>All cause death</td>
<td>0/167</td>
<td>0/168</td>
<td>1,01</td>
<td>[0,02; 51,00]</td>
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<tr>
<td>Ischaemic complication</td>
<td>-/-9</td>
<td>-/-9</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>MI</td>
<td>-/167</td>
<td>-/168</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>Unplanned revascularisation for ischaemia</td>
<td>0/167</td>
<td>0/168</td>
<td>1,01</td>
<td>[0,02; 51,00]</td>
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<tr>
<td>death, MI, urgent TVR, in-hospital major bleeding</td>
<td>30/167</td>
<td>53/168</td>
<td>0,57</td>
<td>[0,34; 0,95]</td>
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<tr>
<td>net benefit</td>
<td>-/167</td>
<td>-/168</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>minor bleeding</td>
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<td>31/168</td>
<td>0,43</td>
<td>[0,22; 0,85]</td>
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<td>major bleeding</td>
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<td>4/168</td>
<td>0,34</td>
<td>[0,05; 2,16]</td>
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<td>safety criteria</td>
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## 5 References