Background:

There is little data about long term results of unprotected left main stenting. In a multicenter randomized trial we compared percutaneous coronary intervention (PCI) using Sirolimus eluting stent to bypass revascularization (CABG) for patients with significant left main stenosis. We present the cumulative 5-years results and therefore the longest available results of a randomized left main study at all.

Methods: Between 8/2003 and 9/2008 a total of 201 pts with hemodynamically significant stenosis of the unprotected left main coronary artery were recruited in 4 german centers. The primary endpoint of the study was death, myocardial infarction, stroke and target vessel re-intervention. Hundred patients were randomized within the PCI-group and 101 patients within the CABG-group. There were no differences in the baseline characteristics. The left main lesion was located at the ostium in 22%, mid-shaft in 8% and at the bifurcation in 70%. Nearly half of the CABG patients were operated on using an off-pump technique (46%) and with total arterial revascularization in 65%.

Complete revascularization was achieved in both groups.

Results: Over a cumulative period of 5 years, 14 pts (11.1%) within the PCI group died. Myocardial infarction occurred in 2 patients after CABG and in 4 PCI patients after PCI. One patient had a stroke in the PCI group and 2 patients in the CABG group. The incidence of stroke was found to be low (1 vs 2 within the PCI and CABG group, respectively). Reintervention within the PCI group was required in 20 patients (3/20 underwent CABG) vs 9 patients within the CABG group. Cumulative MACCE rate after 5 years was 36.4% for the PCI group vs 27.3% for the CABG group (p = 0.16 for non-inferiority).

Conclusion: In patients with unprotected left main stenosis mortality during a 5-year follow-up was found to be low. There were no significant differences in the primary endpoints death, myocardial infarction and stroke between the 2 treatments groups. However, for overall MACCE rate, non-inferiority for PCI could not be demonstrated. This was a result of a higher rates of target vessel re-intervention during the PCI group during follow-up.

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Prolonged Bivalirudin Infusion is Associated with Enhanced ST Segment Resolution Following Primary Percutaneous Coronary Intervention

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Background: Bivalirudin use during primary percutaneous coronary intervention (PCI) is nowadays a cornerstone for the management of ST elevation myocardial infarction (STEMI). However, an increased acute stent thrombosis rate has been found in patients treated with bivalirudin in the Horizons-AMi trial. A prolonged infusion after PCI has already been shown to be a safe and effective tool in patients undergoing complex urgent or elective PCI in the Probi Viri study. We examined the effects of a prolonged drug infusion after primary PCI.

Methods: From the database of five high-volume italian centers, we compared a group of patients treated with a 4-hour prolong bivalirudin infusion after PCI with two groups treated with a normal, peri-PCI infusion and heparin+abciximab for 12 hours. Primary study endpoint was >70% ST segment resolution (STR) within 90 minutes after PCI. Secondary endpoints were partial (>50%) STR within 90 min and intra-hospital TIMI major and minor bleedings.

Results: Study population consisted of 264 patients undergoing primary PCI, all pre-treated with aspirin and clopidogrel (600 mg). The three study groups did not differ significantly for baseline characteristics. Primary endpoint in prolonged bivalirudin, normal bivalirudin and heparin+abciximab groups was achieved respectively in 69.8%, 48.8% and 69.6% of patients (p between prolonged and standard infusion = 0.048, between prolonged infusion and abciximab = 0.98). Major bleedings and other secondary study endpoints were not significantly different between the study groups.

Conclusion: A strategy of prolonged bivalirudin infusion after primary PCI seems equivalent to a strategy with heparin+abciximab and better than a standard infusion in obtaining improved early microvascular reperfusion. Further studies with a bigger population are needed to clarify if this strategy exerts clinical benefits.