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Vascular Function of Bioabsorbable Stented Site after Complete Absorption of the Stent

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Background: Drug eluting bioabsorbable stents (DEBSs) represent a new device based therapy for CAD. It has been reported that stented segment becomes reendothelialized after 1 mo and the segments proximal and distal to the stented site are functional at 2 years. In order to examine whether after complete degradation, the DEBS site function was similar to the unstented segments, we performed ex vivo vasomotor function studies using pig coronary arteries.
Methods: Eighteen months after implantation, 10 DEBS sites were assessed for vasomotor function using an organ chamber apparatus. They were stimulated with potassium chloride (KCl), prostaglandin$_{2\varepsilon}$ (PGF) and 3 concentrations of endothelin-1 (ET). Endothelium-dependant relaxation (EDR) to substance P (SbP; 0.01 - 100 pM) and endothelium-independent relaxation (EIDR) to sodium nitroprusside (SNP; 0.001 - 10 µM) were assessed following constriction with PGF. Remaining stent segments were fixed for histologic examination.
Results: DEBS sites showed rapid response to low and high concentrations of KCl, PGF and ET. EIDR showed concentration-dependent relaxation to SNP (13.3±4.3%, 21.3±5.6%, 52.7±7.1%, 85.5±5.4% and 100±0%). However, there was no EDR to SbP concentration-dependent stimulation. HE and VM staining showed evidence of SMCs migration across polymer struts and formation of a new abluminal layer was observed. There was complete polymer strut degradation, infiltration of inflammatory cells and minor fibrosis around some DEBS sites. Myocardial degeneration was found in the septum adjacent to the stented sites. Vessel wall within the stented segment was thicker and the lumen was narrower than in the proximal and distal segments.
Conclusion: We have demonstrated for the first time the ex vivo contraction and relaxation responses at DEBS sites to vasoactive agents after complete degradation of the stent. SMCs recovered contractile and relaxing capabilities in this segment but endothelial function was still impaired.

Hierarchical Bayesian Meta-Analysis Comparison of Transradial and Femoral Approaches for PCI

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Background: Despite lower risks of access-site related complications compared to the femoral approach (FA), the clinical benefit of transradial approach (TRA) for percutaneous coronary interventions (PCI) is uncertain. We conducted a systematic review and meta-analysis of all clinical studies comparing TRA and FA for PCI.

Methods: Randomized trials and observational studies (1993-2011) comparing TRA with FA for PCI with reports of ischemic and bleeding outcomes were included. Crude and adjusted (for age and sex) odds ratios (OR) were estimated by a hierarchical Bayesian random-effects model with prespecified stratification for observational and randomized designs. The primary outcomes were rates of death, combined incidence of death or myocardial infarction (MI), bleeding and transfusions, early (≤ 30 days) and late after PCI.

Results: We collected data from 76 studies (15 randomized, 61 observational) involving a total of 761,919 patients. Compared with FA, TRA was associated with a substantial reduction in bleeding (OR 0.22, 95% CrI 0.16-0.29) and in transfusions (OR 0.20, 95% CrI 0.11-0.32). These findings were consistent in both randomized and observational studies. There was a strong association between TRA and mortality reduction early after intervention (OR 0.56, 95% credible interval (CrI) 0.45-0.67), although the effect was mainly due to observational studies (OR 0.52, 95% CrI 0.40-0.63, adjusted OR 0.49 (95% CrI 0.37-0.60)), with an OR of 0.80 (95% CrI 0.49-1.23) in randomized trials.

Conclusion: Our results combining observational and randomized studies showed that PCI performed by TRA is associated with substantially less risks of bleeding and transfusions compared to FA. Benefit on the incidence of death or combined death or MI is found in observational studies but remains inconclusive in randomized trials.

Bivalirudin vs. Unfractionated Heparin during PCI in High Risk Patients for Bleeding. ACRIPAB Trial

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In low to medium risk population undergoing PCI Bivalirudin (BIV) exhibited significantly lower rate of bleeding compared to unfractionated heparin (UFH). However, clinical outcome and bleeding complications in high risk population was not established yet.
We performed randomized double blinded prospective trial comparing efficacy and safety of BIV vs. UFH on top of dual antiplatelet therapy during PCI among patients with NSTEMI or angina pectoris and with high risk for bleeding. There were 100 consecutive patients (66.6±12.3 years old, 69% males) enrolled in our study with 1:1 distribution between BIV and UFH groups. The study end points were: major, minor bleeding, port of entry complications, MACE in-hospital and after 30 days follow up. There were 87% patients with diabetes mellitus, 98% with hypertension, 22% with chronic renal failure, 30% older than 75 years, 21% with haemoglobin plasma level < 11 mg% and 58% with systolic blood pressure > 180 mm Hg. 24% of participants were catheterized due to NSTEMI. Femoral approach was used in 16% of patients. There were significantly more PCIs accomplished via radial approach in BIV group (90% vs. 78%, p=0.05). BIV group was represented with higher male's rate (78% vs. 60%, p=0.05).
Results: There was 1 case of major GI bleeding in BIV group and 7% rate of minor bleeding complications in both categories. There was twice higher rate of periprocedural AMI in BIV group compared to UFH group (20% vs.10%, p<0.16). In hospital MACE rate was higher in BIV patients too (12% vs. 2%, p=0.1). In UFH group, there was 1 case of urgent CABG and another 1 case of death 2 days after PCI. In univariate analysis, no one factor was found to be predictor of worse outcome. After follow up, there were no differences in end points between the groups.
Conclusions: In patients with high risk for bleeding undergoing PCI, BIV was found non-superior to UFH in categories of all bleeding complications, early and late clinical outcome.

The Impact of Intra-Coronary Thrombus Aspiration on STEMI Outcomes

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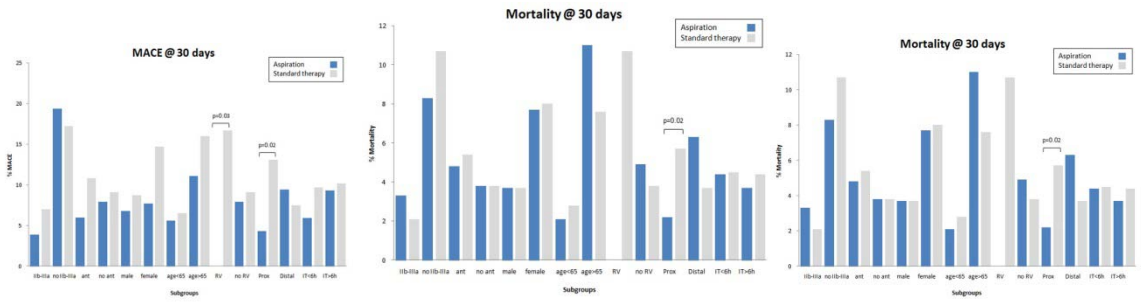
Background: Manual coronary thrombus aspiration was associated with improved outcomes of STEMI patients. We aimed to evaluate the outcome of aspiration in a "real-world" setting of primary PCI (PPCI).

Methods and Materials: We analyzed the outcome of STEMI patients who underwent PPCI (initial TIMI flow grade 0/1), comparing patients who underwent aspiration (ASP) to those who had standard (STD) therapy. Various subgroups outcomes were further analyzed. Clinical endpoints included mortality and MACE at 30 days and at one year.

Results: 1035 consecutive patients were included: 189 (18.26%) with ASP and 846 (81.74%) with STD. ASP patients were younger (58±12 vs. 61±13, p<0.05) and higher incidence of direct stenting compared to STD (34% vs. 16.7%, p<0.05). No significant differences were noted in the outcome of ASP vs. STD at 30 day (mortality rate 4.2% vs. 4.5%, p=0.9; MACE 6.9% vs. 9.8%, p=0.2) and at 1 year (mortality rate 8.0% vs. 8.3%, p=0.9; MACE 20.0% vs. 22.3%, p=0.5). A significant advantage in favour of ASP was evident in patients with proximal culprit lesions, anterior infarcts and those with right ventricular involvement (fig1-2).

Conclusions: Although this was largely a negative study, when STEMI involved a large jeopardized myocardium, aspiration was associated with sustained improved clinical outcomes.



Figures 1-2: Prevalence of mortality and MACE (all-cause mortality, re-infarction, TVR and unplanned CABG) in subgroups of patients undergoing standard therapy vs. aspiration thrombectomy at 30d. Only significant p is presented. (RV-right ventricle involvement, Prox-proximal culprit lesion, IT-ischemic time)

Unprotected Left Main Coronary Artery (LMCA) Stenting: In Hospital and Long Term Outcomes

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Background: Coronary bypass graft surgery (CABG) has been recommended for left main stenosis. Improvements in angioplasty and stent techniques have resulted in wider applicability of a percutaneous approach, resulting in a recent updating of the revascularization guidelines.
Objectives: This study served to present the in-hospital and long term clinical and angiographic outcomes and survival data of consecutive patients undergoing unprotected stenting for LMCA stenosis.
Methods: A total of 288 patients underwent LMCA stenting between January 2001 and August 2010. The majority of patients presented with acute coronary syndromes (72%), while the remainder (28%) had stable angina. Patients were followed routinely in outpatient clinics at 1, 3, 6, and 12 months. Clinical and angiographic follow up was obtained either from out-patient records or by telephone interview. Follow-up angiography was recommended to all patients and was performed in 80% of them at 6 months.
Results: The clinical presentation of the patients was ST elevation MI in 7.9%, non ST elevation MI 13.6% , unstable angina 50.5% and stable angina 28%. The average left ventricular ejection fraction was preserved (50±11%). The majority (82%) of the patients were in Killip class I. The procedural success rate was 100%. The in-hospital overall mortality was 2.85%. Only one death occurred in patients that were in stable hemodynamic state at the procedure's onset. None of the patients needed emergent CABG. At long term follow-up (average 3 years) there were 20 deaths (7.1%), 7 patients required CABG and 30 patients required repeat target vessel revascularization.
Conclusions: Coronary stenting for LM stenosis can be performed safely with acceptable in-hospital and long -term outcomes. Our results confirm that LM PCI (especially using a single drug eluting stent) is a viable alternative to surgery.

Anemia and Inflammation Predict Adverse Outcomes Following Percutaneous Coronary Interventions

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Background: Anemia and Inflammation are both associated with an unfavorable outcomes in ischemic heart disease patients. In a previous report we showed that Inflammation was associated with lower hemoglobin concentrations in myocardial infarction (MI) patients undergoing percutaneous coronary intervention (PCI). We now analyze the additive value of each variable on patient's outcomes.

Methods: We performed an analysis on prospectively collected data at a tertiary hospital catheterization laboratory. Cox regression models were fitted for hemoglobin and C-reactive protein (CRP) cut-offs (hemoglobin above and below lower limit of norm and CRP above and below 3mg/l) and performed separately for MI (ST and non ST segment elevation) and angina pectoris (AP) patients(stable and unstable). Major adverse cardiovascular events were defined as all cause mortality, myocardial infarction and stroke. Follow up time was defined as the time form PCI to either MACE or November 20, 2011.

Results: Included were 1976 patients (825 with angina pectoris [AP] and 1151 with myocardial infarction [MI]). The median follow up in the MI and the AP were 14 and 13 months, respectively (maximal follow up of 4 years). In the myocardial infarction group, the risk of MACE during follow-up was increased with the presence of either anemia (HR=2.1, p=0.07) or of elevated CRP (HR=1.9, p=0.04), while the presence of both increased the risk even further (HR=3.4, $p<0.01$). In the AP group, the risk of MACE was increased only in patients who had both anemia and elevated CRP (HR=2.9, $p<0.01$). In general, traditional risk factors as well as coronary disease severity did not predict adverse outcomes during the follow-up period.

Conclusions: Inflammation and anemia are independently and additively associated with MACE in MI patients.

Neutrophil Lymphocyte Ratio is Related to Coronary Artery Disease Extent and Clinical Outcome

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Background: Neutrophils play an important part in the progression of Atherothrombosis. The Neutrophil/Lymphocyte (N/L) ratio has been shown to be effective predictor for future cardiovascular events. We evaluated the relationship between N/L ratio, Coronary Artery Disease (CAD) extent and cardiovascular outcomes in different clinical groups.
Methods: We enrolled 3005 consecutive patients referred for coronary angiography. Arterial blood was obtained from all participants via their arterial access puncture sites as a part of the coronary angiography procedure. N/L ratio was computed according to absolute values of Neutrophils and lymphocytes. We followed up the patients up to 3 years using telephone interviews periodically.
Results: Mean age was 66.6 ± 11.9 (range: 18-97 years), 71% were males. By multivariable analysis adjusting for potential clinical, metabolic, and inflammatory confounders, N/L ratio was independently associated with Coronary Artery Disease (CAD) extent (HR=2.07, CI 95% 1.7-2.6, $p<0.001$) for each point increase in N/L ratio and in different clinical subgroups (diabetes status, statin therapy, stable or unstable clinical presentation). Furthermore, N/L was a significant predictor of cardiovascular events (MI, stroke and death) in up to 3 years follow up, in the entire cohort and in different subpopulations (HR=1.44, CI 95% 1.19-1.75, $p<0.001$) for each point increase in the N/L ratio.
Conclusion: N/L ratio is an independent predictor of CAD extent and adverse clinical events. These results give further evidence for the potential usage of this simple, cheap and readily available biomarker in different clinical scenarios.

Mean Platelet Volume as a Predictor for Long-Term Outcome after Percutaneous Coronary Intervention

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Background: Mean platelet volume (MPV) is a value that is readily available from standard blood count. Increased MPV reflects larger platelets and is associated with increased platelet reactivity. In patients with acute coronary syndromes (ACS), increased MPV has been correlated with adverse cardiac outcomes. However, there is limited information about the prognostic value of baseline MPV in a large heterogenous patient population which undergoes percutaneous coronary intervention (PCI). We, therefore, aimed to examine whether baseline MPV is predictive of clinical outcomes in patients who undergo PCI.
Methods: Included were consecutive patients who underwent PCI during 2004-2010 (n=7585, mean age 67.5±12.0 years, 5761 males) and were followed for a median period of 4 years. Baseline MPV before angiography and long-term clinical outcomes were assessed.
Results: The mean MPV was higher in women compared to men (8.6±1.2 vs. 8.5±1.1 fL, p=0.02), in diabetic vs. non-diabetic patients (8.6±1.2 vs. 8.4±1.1 fL, p<0.001) and in patients who were admitted with ACS (n=4961) compared to patients who underwent an elective PCI (8.6±1.1 vs. 8.5±1.1 fL, p=0.001). On univariate analysis MPV level was associated with mortality with an hazard ratio of 1.23 (95% CI 1.17-1.28, p<0.001). On multivariate analysis adjusted for age, gender, type of stent, diabetes, prior heart failure, myocardial infarction and ACS, MPV was associated with mortality (HR 1.18, 95% CI 1.12-1.23, p<0.001) and with a composite end-point of death, MI and target vessel revascularization (HR 1.09, 95% CI 1.04-1.13, p<0.001). Baseline MPV was associated with mortality in patients undergoing an elective PCI as well as in urgent PCI (HR 1.30 ,95% CI 1.20-1.40, p<0.001 and HR 1.13, 95% CI 1.07-1.20, p<0.001, respectively).
Conclusion: In patients undergoing either an elective or urgent PCI, an elevated MPV is a significant predictor of cardiovascular adverse events including death.