A Randomized Comparison of Transradial and Transfemoral Approaches for Coronary Angiography and Percutaneous Transluminal Coronary Angioplasty in Octogenarians: Final Results of the OCTO-PLUS Study

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Background: The rate of access site complications after coronary angiography (Angio) and/or PCI has been shown to be higher in older patients. This prospective randomized study was carried out to assess the potential advantages of Transradial (TRA) approach in this setting.

Methods: Patients (pts) undergoing Angio or PCI were randomized to either transfemoral approach (TFA) or TRA in 5 centers using TRA as routine. The primary end-point was the rate of access site complications leading to increased hospital stay.

Results: Study population included 371 pts, mean age 82.8 ± 2.9 years, 53.4% male, presenting with unstable angina in 35.6% of cases or AMI in 10.5%. 188 pts were randomized to TFA (174 angio followed by 87 PCI, and 9 PCI), 183 to TRA (176 angio followed by 74 PCI and 12 PCI). 51.9% of PCI pts received a femoral closure device. Main results by intention to treat are summarized below:

<table>
<thead>
<tr>
<th>Radial</th>
<th>P value</th>
<th>Femoral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-over (%)</td>
<td>9.0</td>
<td>ns</td>
</tr>
<tr>
<td>Angio duration (min)</td>
<td>18.5±10.5</td>
<td>0.069</td>
</tr>
<tr>
<td>X-ray duration (min)</td>
<td>6.0±4.4</td>
<td>0.01</td>
</tr>
<tr>
<td>PCI success (%)</td>
<td>95.3</td>
<td>ns</td>
</tr>
<tr>
<td>PCI duration (min)</td>
<td>33.9±21.6</td>
<td>ns</td>
</tr>
<tr>
<td>PCI X-ray duration (min)</td>
<td>11.8±9.5</td>
<td>ns</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>1.6</td>
<td>0.03</td>
</tr>
<tr>
<td>Hematoma&gt;3 cm (%)</td>
<td>2.2</td>
<td>0.0025</td>
</tr>
</tbody>
</table>

* p per protocol: 0.5% vs 7.6%, p=0.001

Conclusion: Combined end-point of all approach-related vascular complications leading to prolonged hospital stay is significantly lower in octogenarians randomized to transradial approach for coronary angiography and/or PCI compared to transfemoral approach. As in younger patients, for coronary angiography, X-ray exposure time is slightly but significantly longer in the tranradial group. There is no difference in X-ray exposure time for PCI; procedural time, contrast medium volume and equipment use in Angio and PCI.

Randomized Trial of Radial Versus Femoral Access for Primary and Rescue Angioplasty

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Background: Transradial access for percutaneous coronary intervention (PCI) results in fewer bleeding and vascular complications, earlier ambulation and improved patient comfort. Limited data exists for radial access in acute myocardial infarction (MI), where reperfusion must occur quickly.

Methods: In a multicentre pilot trial, 50 patients with MI requiring either primary or rescue PCI were entered. Patients were randomized to either radial or femoral access. In patients with cardiogenic shock were excluded. All patients received aspirin and heparin. All operators had previously performed at least 100 transradial cases. Procedure times were prospectively measured. All patients underwent ultrasound-Doppler of the access site, and were followed to 30 days.

Results: 143 consecutive patients referred for PCI were screened, and were eligible if a good ulnar pulse was present and if the Allen test was positive. The right ulnar artery was punctured with a 20-gauge x 2" entry needle, into which a straight 0.025" guide wire was inserted (Radifocus Introducer II, Terumo). A 4 F introducer was placed on the wire. Sodium heparin (3,000 IU) and verapamil (2.5 mg) were injected. Coronary arteries and left ventricle were catheterized with 4F JL4 and JR4 or AL2, and pig-tail catheters. Angioplasty was made using 5 or 6 F guiding catheters. Manometric measurement was done after cessation of the introducer. An Echo Doppler of the wrist vessel was done 10 ± 7 days after procedure.

Results: from 143 patients screened, access was made in 107 pts (75%), successful in 96 pts (91%). Time and number of punctons were 118 ± 135 sec and 1.6 (maximal 5).

1004-46 The Risk of Bleeding in Renal Failure Patients Undergoing Glycoprotein IIb/IIIa Receptor Inhibition: A Report From the American College of Cardiology-National Cardiovascular Data Registry

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Background: Renal dysfunction is present in a substantial number of patients undergoing percutaneous coronary intervention (PCI). Few studies have investigated the effect of Glycoprotein (Gp) IIb/IIIa inhibition in these patients. The purpose of this study was to evaluate bleeding complications with Gp IIb/IIIa inhibitors in patients with renal failure.

Methods: Between January 1, 2001 and March 31, 2003 data from 278,105 consecutive PCI procedures were submitted to the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR). Vascular bleeding events with and without IIb/IIIa inhibitors were compared in patients with renal dysfunction using chi-square analysis.

Results: Out of 278,105 patients in the ACC-NCDR registry, 12,059 patients had renal failure. Renal failure was defined as a documented history of renal failure that was treated with medication, low protein diet, or dialysis by a physician. In the absence of Gp IIb/IIIa inhibition, patients with renal failure had more bleeding complications than those without renal failure (2.8% vs. 1.9%; p-value <0.0001). However, in the renal failure group there was no significant increase in bleeding complications with or without the addition of Gp IIb/IIIa inhibitors (2.4% vs. 2.8% p-value = ns).

Conclusion: The presence of renal dysfunction during PCI predisposes patients to bleeding complications. This risk is not significantly increased with the addition of Gp IIb/IIIa inhibitors. Therefore, Gp IIb/IIIa inhibition in the setting of renal dysfunction, does not appear to be an independent risk factor for bleeding.

1004-S1 Percutaneous Ulnar Artery Approach for Coronary Diagnostic and Therapeutic Interventions

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Background: While the transradial approach is now a well established alternative to femoral approach, the use of the ulnar artery has rarely been intended for percutaneous coronary interventions (PCI).

Aim of the study: to ascertain the feasibility and security of the transulnar approach for PCI.

Methods: 143 consecutive patients referred for PCI were screened, and were eligible if a good ulnar pulse was present and if the Allen test was positive. The right ulnar artery was punctured with a 20-gauge x 2" entry needle, into which a straight 0.025" guide wire was inserted (Radifocus Introducer II, Terumo). A 4 F introducer was placed on the wire. Sodium heparin (3,000 IU) and verapamil (2.5 mg) were injected. Coronary arteries and left ventricle were catheterized with 4F JL4 and JR4 or AL2, and pig-tail catheters. Angioplasty was made using 5 or 6 F guiding catheters. Manometric measurement was done after cessation of the introducer. An Echo Doppler of the wrist vessel was done 10 ± 7 days after procedure.

Results: from 143 patients screened, access was made in 107 pts (75%), successful in 96 pts (91%). Time and number of punctons were 118 ± 135 sec and 1.6 (maximal 5).

Assessment of the Feasibility, Safety, and Success of Transradial Access for Percutaneous Coronary Intervention: A Report From the American College of Cardiology-National Cardiovascular Data Registry


Background: Previous studies have shown that transradial access (TRA) appears to be safe, with an acceptable success rate, but these studies were limited by small sample size. The purpose of this study was to evaluate the feasibility, safety and success rate of the TRA for percutaneous coronary intervention (PCI) in contemporary practice.

Methods: PCI procedures were submitted between March 1, 2001 and March 31, 2003 on data from 278,105 PCI procedures submitted from 304 institutions to the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR). Of these, valid data on access site entry were available for 275,290 PCI procedures. TRA was used in 3,237 (1.2%) of these procedures. There were no procedural complications. Echo Doppler was obtained in 91 pts (94%). Access site complications were: 0 occlusion, 1 pseudo-aneurysm, 3 slight hematomas.

Conclusion: ulnar artery approach is a feasible and safe alternative to radial approach for percutaneous coronary interventions.

1004-ST Assessment of the Feasibility, Safety, and Success of Transradial Access for Percutaneous Coronary Intervention: A Report From the American College of Cardiology-National Cardiovascular Data Registry


Background: Previous studies have shown that transradial access (TRA) appears to be safe, with an acceptable success rate, but these studies were limited by small sample size. The purpose of this study was to evaluate the feasibility, safety and success rate of the TRA for percutaneous coronary intervention (PCI) in contemporary practice.

Methods: PCI procedures were submitted between March 1, 2001 and March 31, 2003, on data from 278,105 PCI procedures submitted from 304 institutions to the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR). Of these, valid data on access site entry were available for 275,290 PCI procedures. TRA was used in 3,237 (1.2%) of these procedures.
dure. Results: Compared to Non-TRA, TRA was used more commonly in males (70.5% vs. 65.7%; p<0.001), but less often in hypertensives (65.7% vs. 69.2%; p<0.001), patients with a history of renal failure (3.0% vs. 4.3%; p<0.001), patients with a history of diabetes (25.8% vs. 28.6%; p<0.001) or prior coronary artery bypass graft surgery (11.6% vs. 19.1%). TRA patients were significantly younger (61±12 vs. 63±12 years; p<0.001) and more likely to have BMI >35 (20.1% vs. 16.1%; p<0.001). Mortality risk was significantly lower in the TRA patients (0.6% vs. 1.2%; p<0.0001) compared to Non-TRA patients. Adjusted mortality (observed/expected X observed) was similar between the groups, as was PCI success. Patients with TRA had a length of hospital stay 0.5 days shorter than Non-TRA patients (p<0.001). Bleeding was less common with TRA (0.7% vs. 1.7%; p<0.001) and 1-2 doses females and males had similarly less bleeding (0.4% vs. 1.1% for males, and 1.4% vs. 2.8% for females; both p<0.001). Multivariate analysis demonstrated that TRA was independently associated with less bleeding complications. Conclusions: The transradial access is more likely to be used in less severely ill patients, but outcomes are comparable and there does appear to be less bleeding, both for males and females.

1004-52 Impact of Abciximab on Distal Embolization Induced by Primary Angioplasty

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Background. Distal embolization during primary angioplasty (PA) may affect myocardial reperfusion. We evaluated the impact of Abciximab pre-treatment on the entity and qualitative composition of PA-induced distal embolization. Methods. Forty-two consecutive patients with acute myocardial infarction underwent PA using the non-occlusive distal protection device FilterWire Ex (Boston Scientific Corp., USA). Abciximab pre-treatment was performed in 22 patients (52%). The embolic fragments retrieved from the filters underwent morphometric and histopathological analysis. Serial histological sections (5 micron intervals) were stained with hematoxylin-eosin. Additional histochimical stains were used: Von-Guericke for collagen fibers, Oil Red-O for lipid droplets, and Alcian blue for mucopolisaccharides. Anti-platelet drugs such as eptifibatide that block the glycoprotein IIb/IIIa receptor have been shown in-vitro to prevent both platelet aggregation and thrombin generation. We therefore hypothesized that, for higher risk PCI, eptifibatide-based anti-platelet therapy accompanied by only limited, specific anti-thrombin therapy would be efficacious and safe. Results. In this observational study, we retrospectively assessed the outcomes of 786 consecutive inpatients (pts) undergoing urgent, higher risk PCI. We reviewed our database for patients that underwent percutaneous revascularization for chronic total occlusions (CTO) >5cm (TASC Type D lesions). We report our experience on the technical feasibility and impact on quality of life using standard stenting techniques to treat “surgical disease” of the lower extremities. Methods: We reviewed our database for patients that underwent percutaneous revascularization for CTO. Primary traditional stenting techniques were employed utilizing the self-expanding, nitinol SMART® stent (CORDIS, Miami, FL). The Walling Impairment Questionnaire[2] (WIQ range: 0 to 14,080) was used to assess quality of life pre and post procedure. Ankle-brachial index (ABI) was obtained pre and post procedure. Results: 44 patients (51 legs) underwent attempted percutaneous revascularization for CTO. Patients with a significant improvement in their quality of life, and objective improvement on serial non-invasive testing. Repeat revascularization rates are reasonably low, and parallel historical data. A minimally invasive percutaneous approach should become the initial preferred method of revascularization for lower extremity TASC lesion type.