

Best Versus Worst Versus Core QCA

2:30 p.m.

	Immediate Stent % DS	Follow-up Stent % DS	Follow-up Binary Restenosis	Follow-up Late Loss (mm)
Stent A Best	5.2±4.8%*¥	17.6±10.9*§¥	1/13(8%)*§¥	0.43±0.81*§¥
Stent A Worst	23.8±10.2%§	61.1±11.2%§	11/13 (85%)§	2.03±0.96§
Stent A Core	11.5±4.8%	38.2±20.7%	4/13 (31%)	1.04±0.45
Stent B Best	3.8±4.5%*§¥	11.9±9%*§¥	0/13(0%)*§¥	0.24±0.68*§¥
Stent B Worst	26.7±12.7%§	57.5±18.4%§	10/13 (77%)§	1.24±0.77§
Stent B Core	8.9±6.5%	34.0±16.4%	2/13 (15%)	0.77±0.28
Stent C Best	1.6±6.5%*¥	4.6±7.8%*§¥	0/13 (0%)*§¥	-0.5±0.88*§¥
Stent C Worst	18.7±11.3%§	53.8±19.7%§	8/13 (62%)§	0.76±0.62§
Stent C Core	6.8±11.5%	22.7±15.8%	1/13 (8%)	0.24±0.71
All Stents Best	2.6±0.7%*§	11.3±10.6%*§	0/39 (0%)*§	-0.49±0.72*§
All Stents Worst	37.9±18.1%§	57.16±16.7%§	29/39 (74%)§	1.67±0.78§
All Stents Core	9.2±7%	31.6±7.4%	7/39 (18%)	0.67±0.61

ORAL CONTRIBUTIONS

818FO

Featured Oral Session...Vascular Access and Vascular Closure Devices

Monday, March 08, 2004, 2:00 p.m.-3:30 p.m.
 Morial Convention Center, Room 243

2:15 p.m.

818-2

Vascular Access and Fluoroscopy in Percutaneous Coronary Interventions: A Quality Improvement Project

Peter VerLee, Patricia Hofmaster, Theodore Silver, Paul Vom Eigen, Matthew Rowe, Carol Gallupe, Winthrop Piper, David Malenka, Eastern Maine Medical Center, Bangor, ME, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Background: In previous work by the Northern New England Cardiovascular Study Group risk factors for vascular access site complications in PCI were identified and a region-wide effort to reduce these complications was initiated. As part of this effort we considered making a regional recommendation that location of the femoral head as seen on fluoroscopy (fluoro) be used to help determine the site of femoral artery puncture. To assess the validity of such a practice guideline we assessed the use of fluoro guided vascular access to determine whether it reduced the rate of vascular complications and shortened length of stay.

Methods: Data was collected prospectively on 2,206 consecutive PCIs at Eastern Maine Medical Center from 1999-2002 including use of fluoro, vascular access site complications (bleeding, pseudoaneurysm formation, hematoma, embolic event or thrombus, A-V fistula), and length of stay.

Results: Use of fluoro among 7 interventionists was variable: 2 >20%, 3 35-45%, 2 >70%. Among all interventions, 46% were performed with fluoro to guide vascular access. The use of fluoro was associated with a significantly lower incidence of artery injury (0.59% v 1.51%, p=0.04. Among a subset of physicians (n=3) whose use of fluoro was less frequent and variable (38%, 39%, 45%), there were fewer vascular injuries among patients for whom fluoro guided vascular access (0.71% v 1.77%, p=0.14). Average length of stay was significantly lower among patients in the fluoro group (2.1 days vs. 2.6, p=0.007).

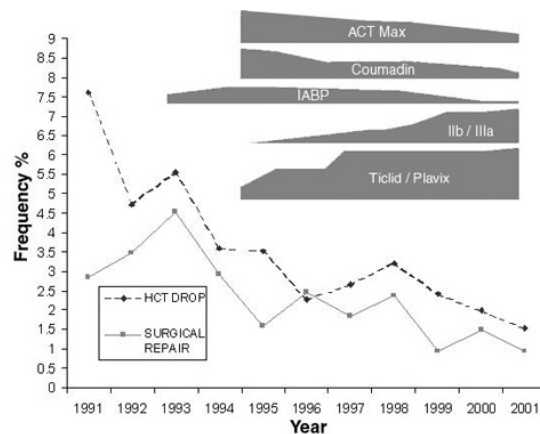
Conclusion: We conclude that using fluoro to guide vascular access leads to lower complication rates and a shorter length of stay and that this approach to femoral access might reasonably become a regional standard of care. At Eastern Maine Medical Center the current use of fluoro to guide vascular access now exceeds 70%.

818-3

Declining Entry Site Complications After Percutaneous Coronary Interventions

Joseph Lindsay, Daniel A. Canos, Ellen Pinnow, Sue Apple, Peter C. Iloanya, Augusto D. Pichard, Washington Hospital Center, Washington, DC

Background: Outcomes of percutaneous coronary intervention (PCI) have improved over the past decade. Angiographic success is now $\geq 95\%$ and urgent/emergent coronary revascularization surgery $\leq 1\%$. These advances are due to operator experience, new equipment, and the adoption of more effective antithrombotic strategies. Ineffective or dangerous devices and anticoagulation strategies have been abandoned. Little information is available about the effect of these changes on entry-site complications. **Methods:** We examined entry-site complications in 14,194 pts with PCI from 1991-2001 in our laboratory. The frequency of surgical repair (SR) and major bleeding, (drop in hematocrit of ≥ 0.15) were the outcomes of interest. **Results:** The frequency of major bleeding steadily decreased (7.6% in 1991 to 1.5% in 2001 (p for trend <0.001). This decline was paralleled by a reduction in the need for SR (4.5% in 1993 to 1.2% in 2001, p for trend <0.001). Declining use of warfarin anticoagulation, lower target ACT levels for heparin dosing, and less frequent use of an intra-aortic balloon pump (IABP) likely helped reduce the frequency of these events. The introduction of GP IIb/IIIa inhibitors (currently used in 50% of cases) and the potent antiplatelet agents (current use 96%) did not interrupt the decline. **Conclusions:** In this single center experience the improved procedural outcomes of PCI have been accompanied by a dramatic reduction in entry site complications.



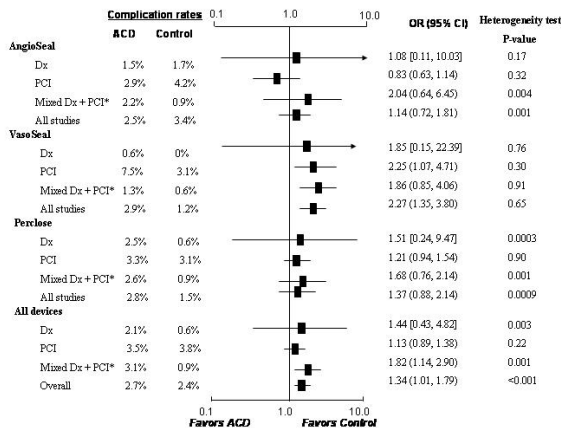
2:45 p.m.

818-4

Vascular Complications Associated With Arteriotomy Closure Devices in Patients Undergoing Percutaneous Coronary Procedures: A Meta-Analysis

Eugenia Nikolsky, Amir Halkin, Roxana Mehran, Shoshana R. Krieger, Eve A. Aymong, Zoran Lasic, Manuela Negoita, Ramez Sulaiman, Ricardo A. Costa, Jeffrey W. Moses, Gregg W. Stone, Martin B. Leon, George D. Dangas, The Cardiovascular Research Foundation and the Lenox Hill Heart and Vascular Institute, New York, NY

Background: Arteriotomy closure devices (ACD) are frequently used for hemostasis after percutaneous endovascular procedures. To evaluate overall vascular complications associated with ACD, we performed a meta-analysis of studies using ACD in pts undergoing percutaneous transfemoral coronary procedures. **Methods:** Studies considered for meta-analysis included randomized, case-control and cohort studies comparing vascular complications in pts managed with ACD (AngioSeal, VasoSeal and Perclose) vs. mechanical compression. Cumulative incidence of major vascular complications was the primary endpoint defined as pseudoaneurysm, a-v fistula, retroperitoneal hematoma, femoral artery thrombosis, surgical vascular repair, access site infection, and transfusion. Data on diagnostic catheterization (Dx) and percutaneous coronary interventions (PCI) were assessed separately and in combination. Heterogeneity between studies was assessed using Cochran's Q-statistic. **Results:** A total of 30 studies involving 42,253 pts fulfilled the inclusion criteria. Comparing complication rates with ACD vs. mechanical compression is shown in the Figure. **Conclusions:** In the setting of Dx angiography the risk of complications was similar with all 3 devices compared to mechanical compression. In the setting of PCI, risk of vascular complications using AngioSeal and Perclose was similar to that of mechanical compression while complications appeared higher with VasoSeal compared to mechanical compression.



*Mixed Dx+PCI: publications where the data were provided without separation to Dx and PCI.

POSTER SESSION

1100

Percutaneous Intervention: Pharmacologic and Biologic Adjuncts

Monday, March 08, 2004, 3:00 p.m.-5:00 p.m.
 Morial Convention Center, Hall G
 Presentation Hour: 3:00 p.m.-4:00 p.m.

818-5

Percutaneous Transfemoral Coronary and Peripheral Procedures via Aortofemoral Synthetic Vascular Grafts: A Review of 123 Diagnostic and Interventional Cases

Michael J. Gallagher, Simon R. Dixon, Mohan C. Madala, Renny Abraham, Steven D. Rimar, William W. O'Neill, Joel K. Kahn, William Beaumont Hospital, Royal Oak, MI

Background: Few data exist regarding the incidence of vascular complications associated with transfemoral catheterization and sheath placement into synthetic vascular grafts.

Methods: We performed a retrospective analysis of all patients who underwent aortofemoral bypass surgery at our institution between January, 1991 and July, 2003. Those patients who underwent subsequent transfemoral catheterization were selected. A total of 123 procedures were performed in 70 patients between February, 1994 and April, 2003.

Results: One hundred and thirteen coronary (91.9%) and 10 peripheral (8.1%) procedures were performed, including sixty-four (52.0%) interventional (angioplasty and/or stent), and 59 (48%) diagnostic procedures. Two of the interventional procedures included placement of an intraaortic balloon pump via the graft. The interval between graft implantation and sheath placement was 2.9 ± 2.1 years (range 4 days to 10.3 years). Four procedures (3.3%) required concomitant brachial or radial access due to inability to access the ascending aorta via the femoral approach. Pre-procedural anticoagulation included aspirin (91.9%), clopidogrel (28.5%), warfarin (10.6%), and intravenous heparin (39.0%). The peak activated clotting time was 313 ± 89 seconds. The procedure time was 53.2 ± 34.1 minutes, and sheaths were pulled an average of 5.2 hours after catheterization. Adverse events related to vascular access occurred in 8/123 (6.5%) procedures. Complications included blood transfusion (4.1%), thrombotic occlusion (1.6%), and retroperitoneal bleed (0.8%). The two cases of thrombotic occlusion were associated with early clinical signs of diminished perfusion. One patient required surgical thrombectomy and the other was treated with intraarterial local thrombolysis. There were no cases of graft infection or pseudoaneurysm formation, nor any deaths attributable to vascular access complications.

Conclusion: Transfemoral sheath entry into a synthetic aortofemoral bypass graft is associated with a low incidence of adverse vascular events. However, careful observation and follow up during the 24-hour post catheterization period is critical.

3:15 p.m.

818-6

Women Remain at Higher Risk for Retroperitoneal Hematoma After Percutaneous Coronary Intervention in the Era of Glycoprotein IIb/IIIa Inhibitors and Vascular Closure Devices

H.M. Omar Farouque, Jennifer A. Tremmel, Meenakshi Aggarwal, Farshad Raissi Shabari, William F. Fearon, Mehrdad Rezaee, Alan C. Yeung, David P. Lee, Stanford University Medical Center, Stanford, CA

Background: The incidence, clinical features, and determinants of retroperitoneal hematoma (RPH) after percutaneous coronary intervention (PCI) have been previously described. We examined these variables in the current era of widespread glycoprotein (GP) IIb/IIIa inhibitors and vascular closure devices (VCDs).

Methods: 3,230 PCI procedures were performed from January 2000 to August 2003. There were 22 cases of radiographically documented RPH. Cases were compared to a random sample of 50 controls using chi-square and logistic regression.

Results: The incidence of RPH was 6.8/1000 cases. Mean age \pm SD was 67 ± 12 years in both groups. Cases and controls did not differ in prevalence of hypertension, diabetes, or hyperlipidemia. Median time from procedure end to onset of clinical signs was 126 minutes (range 15-840). Symptoms included lower abdominal pain (59%), diaphoresis (59%), groin pain (45%), and back pain (18%). Groin hematoma was evident in 32%. Hypertension occurred in 91%, with a mean BP nadir of 78/40 mmHg. Bradycardia requiring atropine occurred in 36%. Hematocrit dropped from $37.5 \pm 3.4\%$ to $27.1 \pm 3.8\%$

($p=0.007$). All cases had blood loss anemia and at least two of the above clinical features. Mean hospital stay was longer in RPH cases (2.2 ± 1.3 vs. 1.7 ± 1.5 days, $p=0.06$). The use of GP IIb/IIIa inhibitors and the method of vascular closure had no effect on the risk of RPH. There was also no association between RPH and acuity of PCI (elective vs. emergent), duration of procedure, heparin dose, ACT level, arterial sheath size, insertion of a venous sheath, or prior femoral artery puncture. Female sex was most strongly associated with RPH (OR 5.0, 95% CI 1.7-14.5). Angiographic analysis revealed that a higher femoral artery puncture in relation to the femoral head (superior third of the femoral head and higher vs. mid third and lower) was also associated with RPH (OR 4.2, 95% CI 1.3-14.0).

Conclusion: With the widespread use of GP IIb/IIIa inhibitors and VCDs, being a woman remains a significant risk factor for RPH, as does a more superior femoral artery puncture. Awareness of the determinants and clinical features of RPH may aid in prevention, early recognition, and prompt treatment.

1100-55

Intravenous Mesenchymal Stem Cell Therapy Early After Reperfused Acute Myocardial Infarction Improves Left Ventricular Function and Alters Ventricular Electrophysiologic Properties

Matthew J. Price, Chung-Chuan Chou, Malka Frantzen, Takashi Miyamoto, Saibal Kar, Dougal McClean, Suzhen Guo, Steve Lee, Prediman K. Shah, Bradley J. Martin, Michael Lill, James S. Forrester, Peng-Sheng Chen, Raj R. Makkar, Cedars Sinai Medical Center, Los Angeles, CA

Background: Direct intramyocardial injection of stem cells improves LV function. However, the injection of immature cells has been associated with an increased risk of ventricular arrhythmia. We hypothesized that the IV infusion of allogeneic mesenchymal stem cells (MSCs) without immunosuppression after acute MI would improve LV function but might be accompanied by pro-arrhythmic electrical remodeling.

Methods: An apical MI was induced in swine by balloon occlusion-reperfusion of the mid-LAD. Animals received either no treatment, or, 30 minutes after reperfusion, Dil-labeled allogeneic bone marrow derived MSCs ($3.2 \pm 0.4 \times 10^8$ cells) were infused IV. LV function was evaluated by LV cineangiography and wall thickness by echocardiography. Epicardial effective refractory periods (ERPs) were determined at 3 month sacrifice. Spectral imaging by confocal microscopy was used to identify Di-I in tissue specimens.

Results: At 3 months, MSC treated pigs ($n=7$) had significantly higher LVEF than controls ($n=8$) ($50 \pm 1\%$ vs $44 \pm 1\%$, $p=0.015$), as well as significantly higher LV systolic pressure (144 ± 5 mmHg vs. 119 ± 5 mmHg, $p=0.01$). The mean increase in LVEDV over time tended to be greater in the control group (48 ± 6 cm³ vs. 32 ± 6 cm³, $p=0.09$). The wall thickness of normal, non-infarcted myocardium increased significantly more in controls than in treated animals. ERPs of the MSC group were significantly shorter than controls at all pacing cycle lengths in LV peri-infarct, LV free wall (FW), and right ventricular (RV) FW (225 ± 6 , 227 ± 5 , 225 ± 6 ms, vs 251 ± 6 , 251 ± 6 , 247 ± 7 ms, all $p < 0.002$). The mean slope of the ERP restitution curves was steeper in the MSC group than in controls (1.6 ± 0.8 vs 1.0 ± 0.4 , $p=0.02$). Dil was identified in the lungs and myocardium of treated animals.

Conclusions: IV infusion of MSCs soon after reperfused acute MI in swine improves LV function, lessens compensatory hypertrophy of non-infarcted myocardium, shortens ERP, and steepens the ERP restitution curve. Clinical trials assessing the efficacy of IV MSC therapy after MI in humans should include arrhythmia monitoring.

1100-56

Comparison Between Intracoronary Infusion and Direct Transendocardial Injection of Mesenchymal Stem Cells in a Dog Acute Ischemia Model

Emerson C. Perin, Joao A. Assad, Guilherme V. Silva, Stephanie Coulter, Judy Ober, Jing Lin, Andre L. Sousa, Silvio Litowski, Yong Geng, Bradley J. Martin, William K. Vaughn, James T. Willerson, Texas Heart Institute, Houston, TX

Background: Experimental data suggest that mesenchymal stem cell (MSC) therapy contributes to healing after acute myocardial infarction (AMI). The ideal route of administration is still controversial.

Methods: A total of 10 dogs were divided in three groups: a) Control $n=3$; b) Intracoronary (IC) $n=3$ and c) NOGA guided transendocardial injections (TEI) $n=4$. All animals had an anterior wall AMI induced by ligation of LAD artery for three hours and then reperfused. The animals received cell therapy (100 million MSC's (Osiris)) 1 wk after AMI and were sacrificed 2 wks after cell therapy. 2D-echo was performed immediately before AMI, cell therapy and sacrifice. NOGA mapping was performed immediately before cell therapy and sacrifice. Ischemic area was measured by NOGA. ANOVA was performed.

Results: The 2D-echo findings concerning ejection fraction (EF), end-diastolic dimension (EDD), end-systolic dimension (ESD), and ischemic area are presented in table 1. The TEI group had a statistically significant increase in EF ($p=0.006$), a reduction in EDD ($p=0.04$), a reduction in ESD ($p=0.02$), and more importantly a reduction in ischemic area ($p=0.006$) when compared to the control group. All the other comparisons did not reach statistical significance ($p>0.05$).