with the DPD impacts outcomes.

Methods: Between 2/2000 – 3/2003, 551 pts with carotid disease had 588 procedures of CAS: All clinical variables, technical details, and results were documented prospectively. Clinical outcomes were prospectively monitored for 30 days post procedure.

Results: In 45 (7.7%) procedures the lesion was pre-dilated before DPD deployment, using 1.5-mm diameter balloon. In 40 (89%) of them, the reminder of the procedure, including DPD and stent placements, were successful. One patient had a "string" sign, so no further intervention was attempted. In one patient DPD was successfully deployed, but the stent could not be placed due to severe proximal tortuosity. In 3 cases, a filter-based DPD could not cross the stenosis despite pre-dilation. In 1 of them, distal balloon-based DPD and stent were successfully deployed. The other two had stentings without embolic protection. There were no strokes or mortality in the pre-dilation group pts.

Conclusion: 1. Balloon pre-dilation prior to DPD placement was needed in very tight and complex lesions, and enabled a DPD system to cross the lesion in 96% of these cases. 2. Balloon pre-dilatation prior to DPD placement was safe, and was not associated with any major adverse events.

**References:**

1. **Mitchell J. Silver, Darren Traub, Amy J. Tracy, Charles F. Botti, Gary M. Ansel, MidWest Cardiovascular Research Foundation, Columbus, OH**

**Background:** In order to understand the risk of carotid angiography performed by interventional cardiologists with peripheral vascular training, we undertook a retrospective study to determine the neurological complications in patients who underwent selective cerebral angiography.

**Methods:** Periprocedural and technical complications were considered related to angiography when they occurred within 24 hours of the procedure. Hospital records were reviewed to determine any in-hospital neurological complications following carotid and cerebral angiography.

**Results:** A total of 483 consecutive patients underwent aortic arch and 4-vessel cerebral angiography. Of the 23/0 of patients were symptomatic. A total of 200/483 (41%) of patients also underwent coronary angiography at the same setting. There was one transient ischemic attack. There were no minor or major strokes, or death.

**Conclusion:** Experienced interventional cardiologists can perform diagnostic aortic arch and selective carotid and vertebrobasilar angiography in the cardiac catheterization laboratory with a very low complication rate. This will be important as cardiologists begin to manage more patients with peripheral vascular disease, and carotid stenting emerges as a viable option for high-risk patients in need of carotid revascularization.

**References:**

1. **David J. Cohen, Elizabeth Mahoney, Dan Greenberg, Amy Natjarian, Tara Lavelle, Patrick Walsh, Ronna H. Berein, Jay Yadav, The SAPPHIRE Investigators, Harvard Clinical Research Institute, Boston, MA, Beth Israel Deaconess Medical Center, Boston, MA**

Recently, stenting (S) has been shown to improve outcomes compared with endarterectomy (CEA) for high risk patients undergoing carotid revascularization. The true costs and cost-effectiveness of these alternative treatment strategies are unknown.

**Methods:** We prospectively measured medical resource utilization and cost for all 334 pts who were randomized to S or CEA in the SAPPHIRE trial. Procedural costs were based on measured resource utilization and current unit costs, while all other costs were estimated from hospital charges and hospital-specific cost-to-charge ratios.

**Results:** The primary endpoint of death, MI, or stroke at 30 days was reduced by 50% with S compared with CEA (4.8% vs. 9.6%, p=0.14). Compared with CEA, S was associated with shorter initial procedures and reduced post-procedure length of stay by -1 day (see Table). As a result, S reduced hospital costs (excluding study devices) by more than $1200/patient and physician fees by ~$700/patient ($0.001 for both). Nonetheless, when the costs of study devices were included, initial treatment costs were actually $813/patient higher with S. Full year economic data and formal cost-effectiveness analysis will be available by 3/04.

**Conclusions:** Although S was associated with shorter procedures and lengths of stay than CEA, initial costs were increased modestly in this high risk population. The cost-effectiveness of S will thus depend on its ability to reduce follow-up medical care costs, to provide sustained reductions in major complications, or both.

**Initial Hospital Resource Utilization and Costs**

<table>
<thead>
<tr>
<th>Procedure duration</th>
<th>Length of stay (days)</th>
<th>Device costs</th>
<th>Other hospital costs</th>
<th>Physician costs</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure duration</td>
<td>Procedure duration</td>
<td>Procedure duration</td>
<td>Procedure duration</td>
<td>Procedure duration</td>
<td>Procedure duration</td>
</tr>
<tr>
<td>1.3 ± 0.6</td>
<td>3.0 ± 1.1</td>
<td>2.8 ± 0.3</td>
<td>$2741 ± 710</td>
<td>$5949 ± 3478</td>
<td>$10,794 ± 3635</td>
</tr>
<tr>
<td>9.5 ± 2.0</td>
<td>2.8 ± 0.3</td>
<td>3.0 ± 0.7</td>
<td>$257 ± 307</td>
<td>$7175 ± 4801</td>
<td>$9980 ± 4775</td>
</tr>
</tbody>
</table>

**References:**

1. **Mohan R. Nandalur, Howard A. Cooper, Lowell Satler, Joseph Lindsay, John R. Laird, Washington Hospital Center, Washington, DC**

**Background:** Hypothesis is common following carotid artery stenting (CAS), and may be mediated by vagal stimulation and/or suppression of sympathetic outflow. Both mixed α/β agonists dopamine (DA) and more selective α-agonists (norepinephrine (NE) and phenylephrine (PE)) have been used, but the most effective treatment of post-CAS hypertension is unknown. Methods: We analyzed data for consecutive patients requiring treatment of post-CAS hypertension. Choice of vasoconstrictors may be made by the treating physician. Endpoints included infusion duration, coronary care unit (CCU) length of stay (LOS), TIA, new arrhythmia, cardiovascular, angina, and any major adverse event. Results: Over 5 years, CAS stenting was performed in 438 patients. CCU admission and/or in-hospital non-fatal stroke (2.39%), major ipsilateral non-fatal stroke (0%), total death (0.2%), myocardial infarction (0.2%), stroke (0.7%), transient ischemic attack (0.3%) were similarly low. Conclusion: Patients who undergo CAS generally respond to treatment with vasoconstrictors. The type of vasoconstrictor is not critical to the patient's treatment.

**Initial Hospital Resource Utilization and Costs**

<table>
<thead>
<tr>
<th>Stent group (n=167)</th>
<th>Endarterectomy group (n=167)</th>
<th>Difference (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure duration</td>
<td>Procedure duration</td>
<td>Procedure duration</td>
<td>Procedure duration</td>
</tr>
<tr>
<td>1.3 ± 0.6</td>
<td>3.0 ± 1.1</td>
<td>0.7 ± 1.0</td>
<td>-0.001</td>
</tr>
</tbody>
</table>

**References:**

1. **Vishal Sachar, Herbert D. Aronow, Ivan P. Casserly, Moein Sheikh, Samir Kapadia, Deepak L. Bhatt, Christopher Bajzer, Jay S. Yadav, The Cleveland Clinic Foundation, Cleveland, OH**

**Background:** Doppler ultrasonography is widely accepted as a means of non-invasively estimating internal carotid artery (ICA) stenosis. However, the utility of Doppler ultrasonography for assessing in-stent restenosis (ISR) after internal carotid stenting (CAS) has not been well studied. We examined the relationship between Doppler ultrasonography and angiographic restenosis in patients after CAS.

**Methods:** Two hundred and thirty-five patients who underwent CAS at our institution and had a follow-up Doppler study done at a minimum of 5 months after the index procedure were studied. Patients with high-grade contralateral stenosis or occlusions were excluded. Twenty-four consecutive subjects were identified who had ≥ 60% Doppler defined ISR on follow-up exam (60-79%: PSV 150 cm/sec, EDV 150 cm/sec). These patients subsequently underwent diagnostic carotid angiography. The PSV, EDV, and ICA/CCA ratio among patients who had true angiographic ISR were compared with those who did not.

**Results:** True ISR (≥ 50% by quantitative coronary angiography) was present in 8/24 patients (33.3%), while 16/24 patients (66.6%) did not have ISR by angiography. The median PSV (range: 152-427 cm/sec) and EDV (range: 34-200 cm/sec) for the entire cohort was 2850 ± 567 cm/sec and 813 ± 150 cm/sec, respectively. In patients with true angiographic ISR compared to those without angiographic ISR (PSV: 350 cm/sec vs. 201 cm/sec, p=0.004; EDV: 139 cm/sec vs. 54 cm/sec, p=0.006). Furthermore, the median ICA/common carotid artery (CCA) ratio was significantly higher among patients with true angiographic restenosis as compared to those without (0.92 ± 0.12, p=0.009).

**Conclusions:** Among patients with carotid stents, current Doppler criteria for defining restenosis are not accurate. Modified Doppler criteria with higher thresholds for PSV and EDV, as well as the use of ICA/CCA ratios are more appropriate for assessing ISR after CAS.

**References:**

1. **Filippo Ravani, Tatiana M. Javid, Mohammad K. Fattah, Joseph W. Corson-Tobias, Jr., Richard M. Zaret, Jeffrey Goldsmith, Michael J. Caputo, Medical College of Wisconsin, Milwaukee, WI**

Conclusions: Based on these data, it appears that carotid angioplasty and stenting is a safe and effective option for high-risk patients in need of carotid revascularization.
Carotid Artery Stenting in African Americans

Paul A. Jones, Jeffrey Kramer, Okuyamowaki Aonde, Sharon Holloway, Florence Molinaro, Mercy Hospital and Medical Center, Chicago, IL

Background: Strokes are particularly devastating to the African American community and extracranial carotid artery disease is a significant etiologic factor. The benefits of surgical intervention with carotid endarterectomy are well documented, but African Americans are underrepresented in most of these trials and there is evidence that their post surgical short-term mortality is increased. Carotid artery stenting (CAS) is rapidly becoming an accepted treatment strategy for certain high risk patient groups and this study examines the safety and efficacy of CAS in African Americans.

Methods: Between December 1999 and August 2003, a total of 172 consecutive patients underwent CAS. Patients were objectively evaluated pre- and post procedure by a board certified neurologist and NIH stroke scores were recorded. All cases were performed by a single operator in a single institution. All patients received periprocedural intravenous heparin and fractionated heparin to maintain activated clotting time (ACT) 200-250 secs. All cases were performed without distal protection. All patients received oral antplatelet therapy for at least 4 weeks post procedure.

Results: In a retrospective review of the 172 patients, 66(38%) were African Americans. Of this group, there was a 100% procedural success rate. There were no periprocedural major or minor strokes. There were no TIAs. There were no significant change in pre and post procedural NIH stroke scores. There were no deaths. At 30 days there were no new neurovascular events or deaths.

Conclusion: CAS is a safe and efficacious procedure in the management of extracranial carotid disease in African Americans.

POSTER SESSION

1157 Physiologic Assessment of Coronary Lesions

Tuesday, March 09, 2004, 3:00 p.m.-5:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 3:00 p.m.-4:00 p.m.

1157-41 Lesion Severity Index, a New Non-hyperemic Physiologic Parameter for the Assessment of Coronary Stenosis: A Comparison to Fractional Flow Reserve

David Brosh, Stuart T. Higano, Ryan J. Lennon, Stephan Carlier, Morton J. Kern, Rafi Beyar, Luis Gruberg, Mayo Clinic Foundation, Rochester, MN

Fractional flow reserve (FFR) is the gold standard for physiologic assessment of coronary stenoses. It can be determined during maximal hyperemia. We recently introduced a non-hyperemic parameter for lesion severity assessment, pulse transmission coefficient (PTC), which is derived from pressure waveform analysis. The functional severity of coronary lesions may be affected by the transstenotic baseline hemodynamics. Therefore, we investigated an improved new non-hyperemic parameter, Lesion Severity Index (LSI), which is calculated based on PTC corrected for baseline pressure gradient.

Methods: Pressure signals were obtained by pressure wire in 59 lesions (49 pts.) at baseline and in hyperemic state. LSI value was calculated as the ratio between the distal and proximal high-frequency components of the pressure waveform normalized to the baseline pressure gradient. FFR measurements were assessed with intracoronary adenosine.

Results: Mean age was 62 ± 11 years. Most patients were men (73%). The results shown in figure 1 indicate a significant high correlation between LSI and FFR (R=0.90, P <0.001) with 65% sensitivity, 85% specificity, positive predictive value of 85%, and negative predictive value of 87% for predicting an FFR cutoff value of 0.75. Results: LSI is highly correlated with FFR, and may predict FFR <0.75 with high accuracy. It may represent a simple and less expensive method for accurate assessment of the functional severity of coronary stenoses, without the need for vasoactive agents.

1157-42 Fractional Flow Reserve Versus Intravascular Ultrasound for Decision-Making in Equivocal Left Main Coronary Stenosis

Venu Jasti, Venkata Yalamanchili, Eugene Ivan, Barry Merrill, Mukul Chandra, Massoud A. Leesar, University of Louisville, Louisville, KY

Background: Intravascular ultrasound (IVUS) is frequently used to determine significance of left main stenosis (LMS) in patients with angiographically ambiguous LMS. A fractional flow reserve (FFR) above 0.75 is associated with excellent 3-year outcomes. However, the use of IVUS parameters to determine the physiological significance of LMS is unknown. Methods: In 55 patients with angiographically ambiguous LMS, a 0.014" pressure guidewire was used to calculate the FFR by dividing distal coronary pressure by aortic pressure during hyperemia. IVUS images were obtained during automatic pull-back. Results: FFR averaged 0.86 ± 0.1 (range 0.64 to 1.0). The following parameters were assessed by IVUS: minimal luminal diameter (MLD) was 3.08 ± 0.61 mm; minimal luminal area (MLA) was 7.65 ± 2.9 mm²; percent cross sectional narrowing (%CSN) was 59 ± 13%; and percent area stenosis (%AS) was 47 ± 19%. Linear regression analysis demonstrated a strong positive correlation between an FFR cut-point of 0.75 and MLD (R² = 0.79, P<0.0001) and between FFR and MLA (R² = 0.74, P<0.0001). There were inverse moderate correlations between FFR and %CSN (R² = 0.69, P<0.0001) and between FFR and %AS (R² = 0.44, P<0.0001). An MLD cut-point of 2.8 mm had the highest sensitivity and specificity to determine the significance of the LMS (93% and 98%, respectively) followed by an MLA of 5.9 mm² (sensitivity and specificity of 93% and 95%, respectively). Based on FFR measurement of the LMS, coronary artery bypass surgery (CABG) was performed in 14 patients (25.5%). During a follow-up period of 16 ± 10 months, there was one non-cardiac death; a total of 7 patients (12%) were admitted with chest pain, 2 patients underwent stenting of the LCX artery, and 2 patients underwent CABG. Conclusions: 1) A combination of the MLD and MLA cut-points of 2.8 mm and 5.9 mm², respectively, highly predicts physiological significance of LMS; 2) FFR can be used as a surrogate for an IVUS to determine the significance of LMS; and 3) Recommending CABG based on physiological data is safe and results in a low event rate during clinical follow-up.

1157-43 Coronary Flow Velocity Pattern Immediately After Percutaneous Coronary Intervention as a Predictor of Complications After Acute Myocardial Infarction in Patients Achieving Thrombolysis in Myocardial Infarction Grade 3 Flow

Atsushi Yamamuro, Takashi Asakasa, Koichi Tamita, Minako Katayama, Shuichiro Kaji, Kunihiko Nogai, Tomokazu Tanabe, Shigeru Morioka, Kobe General Hospital, Kobe, Japan, Kawasaki Medical School, Kurashiki, Japan

Background: Reperfusion therapy for acute myocardial infarction (AMI) aims to achieve prompt re-occlusion-related coronary artery and thrombolysis in myocardial infarction (TIMI) 3 flow. However, it has been reported that even if TIMI 3 flow is achieved in epicardial coronary arteries, microvascular injury results in insufficient reperfusion of the infarcted myocardium, leading to complications. Our recent studies have shown that microvascular injury can be assessed by coronary flow velocity (CFV) patterns. The purpose of this study was to investigate whether CFV patterns serve as predictors of complications in patients who have achieved TIMI grade 3 flow after reperfusion.

Methods: One hundred and forty consecutive patients with first anterior AMI were studied after successful percutaneous coronary intervention (PCI) (angiographically p<0.05 residual stenosis with TIMI grade 3). CFV patterns were recorded using a Doppler guidewire immediately after successful PCI. We defined severe microvascular injury as a diastolic deceleration time (DdT) >600 ms. Patients were divided into those without severe microvascular injury (Group 1, n=114) and those with severe microvascular injury (Group 2, n=26).

<table>
<thead>
<tr>
<th>Lesion</th>
<th>Dopamine (n=20)</th>
<th>Nonopinephrine (n=13)</th>
<th>Phenylephrine (n=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amyothymia, n(%)</td>
<td>5 (25.0)</td>
<td>1 (7.6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Cardioversion, n(%)</td>
<td>3 (15.0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Angina, n(%)</td>
<td>2 (10.0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>TIA, n(%)</td>
<td>2 (10.0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
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<tr>
<td>Any major adverse event, n(%)</td>
<td>7 (35.0)</td>
<td>1 (7.6)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>