JACC March 3, 2004

### 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 outcomeswere prospectively monitored for 30 days post procedure.

**Results:** In 45 (7.7%) procedures the lesion was pre-dilated before DPD deployment, using 1.5-2mm 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 tortuousity. In 3 cases, a filter-based DPD could not cross the stenosis despite pre-dilatation. In 1 of them, distal balloon-based DPD and stent were successfully deployed. The other two had stenting without embolic protection. There were no strokes or mortality in the pre-dilatation group pts. **Conclusion:** 1. Balloon pre-dilatation 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.

## 1156-61 The Safety of Carotid and Cerebral Angiography Performed by Cardiologists in the Cardiac Catheterization Laboratory

Mitchell J. Silver, Darren Traub, Amy J. Tracy, Charles F. Botti, Gary M. Ansel, MidWest Cardiology 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: Neurological 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. Almost 2/3 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 vertebral 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.

# 1156-62 Economic Outcomes of Carotid Stenting Versus Endarterectomy for High Risk Patients: Preliminary Results From the SAPPHIRE Trial

David J. Cohen, Elizabeth Mahoney, Dan Greenberg, Amy Natjarian, Tara Lavelle, Patrick Walsh, Ronna H. Berezin, 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/pt and physician fees by ~\$750/pt (p<0.001 for both). Nonetheless, when the costs of study devices were included, initial treatment costs were actually \$813/pt higher with S. Full 1-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

	Stent group (n=167)	Endarterectomy group (n=167)	Difference (95% CI)	P- value
Procedure duration (hours)	1.3 ± 0.6	3.0 ± 1.1	-1.6 (-1.8, -1.4)	<0.001
Length of stay (days)	1.9 ± 2.0	2.8 ± 3.6	-0.9 (-1.6, -0.3)	<0.001
Device costs	\$2741 ± 710	\$35 ± 307	\$2706 (2583, 2829)	<0.001
Other hospital costs	\$5949 ± 3475	\$7175 ± 4801	-\$1226 (-2155, -297)	<0.001
Physician costs	\$2104 ± 294	\$2850 ± 567	-\$746 (-845, -646)	<0.001
Total Cost	\$10,794±3635	\$9980 ± 4775	\$813 (-128, 1755)	0.09

## ABSTRACTS - Anglography & Interventional Cardiology 91A

### 1156-63 Inaccuracy of Doppler Ultrasonography for Assessing Restenosis After Internal Carotid Artery Stenting

Ravish Sachar, Herbert D. Aronow, Ivan P. Casserly, Mobeen 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 (CS) has not been well studied. We examined the relationship between Doppler ultrasound criteria and angiographic restenosis in patients after CS.

**Methods:** Two hundred and thirty-five patients who underwent CS 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 patients were identified who had  $\geq 60\%$  Doppler-defined ISR on follow-up exam (60-79%: PSV $\geq$ 150 cm/sec, EDV<cm/sec; 80-99%:  $\geq$ 150 cm/sec, EDV $\geq$ 135 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 ( $\geq$ 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 were 231 cm/sec and 65 cm/sec, respectively. The median PSV and EDV were significantly higher among patients with true angiographic ISR as 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 restensis as compared to those without (3.92 vs 1.62, 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 CS.

## 1156-64 Carotid Angioplasty and Stenting: Early and Late Follow-Up Results

Raffaella Manetti, Castriota Fausto, Enrico Ricci, Armando Liso, Kareem Oshoala, Alberto Cremonesi, Villa Maria Cecilia Hospital, Cotignola (RA), Italy

**Purpose.** Our objective was to evaluate immediate and long-term results of carotid angioplasty and stenting and the clinical impact of cerebral protection systems. **Materials/Methods.** From June 1997 to June 2003 a total of 674 patients (mean age 71  $\pm$ 7,6) underwent carotid stenting for carotid stenosis.

**Results.** Primary technical success achieved in 672/674 (99,70%). Procedure failures were two. One for entrapment of Angioguard wire in the proximal edge of a Planza stent treated by surgical cut-down without complications and the second one due to a spiral dissection of internal carotid caused by Percusurge occlusive balloon. Twenty-eight (4,17%) patients had symptomatic complications : 1 (0,15%) death, 2 (0,30%) major stroke, 9 (1,34%) minor stroke, 8 (1,19%) intracranial hemorrhage, 7 (1,04%) TIA and 1 (0,15%) arterial wall perforation. In hospital and 30-days complications in protected group (547 patients) was: 1 (0,18%)death, 2 (0,37%) major stroke, 6 (1,10%) minor stroke, 7 (1,28%) intracranial hemorrhage, 6 (1,10%) TIA and 1 (0,18%) arterial wall perforation. Embolic complications rate in protected group was 15 (2,75%). We used : Angioguard 236 (43,14%), Mednova Neuroshield 95 (17,37%), Trap-filter 67 (12,25%), Percusurge 26 (4,75%), MOMA 20 (3,66%), Accunet 15 (2,74%), Parodi System 7 (1,28%) complications reated to the use of embolic protection devices were: two (0,37%) dissection treated with an additional stent, one (0,18%) vessel occlusion by spiral dissection, one (0,18%) "trapped" guidewire.

Long-term outcome (range 3 months-72 months) was concluded in 510 patients. Patients free for major and minor neurologic events was 471 (92,35%). Complications: neurological death 4 (0,78%), major ipsi-lateral non-fatal stroke 2 (0,39%), minor ipsi-lateral non-fatal stroke 0 (0%), stent crush 1 (0,20%), stent migration 2 (0,39%), death (other causes) 17 (3,33%). Color-Doppler follow up examination showed 13 (2,55%) asymptomatic restenosis ( $\supset$  50%).

**Conclusion.** our results suggested that carotid angioplasty and stenting is a safe in term of early and long term results. Cerebral protection devices appears effective.

#### 1156-65 Post-Carotid Artery Stent Hypotension and Optimal Pressor Use

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

Background: Hypotension is common following carotid artery stenting (CAS), and may be mediated by vagal stimulation and/or suppression of spinal sympathetic outflow. Both mixed  $\alpha/\beta$  agonists dopamine (DA) and more selective  $\alpha$ -agonists (norepinephrine (NE) and phenylephrine (PE)) have been used, but the most effective treatment of post-CAS hypotension is unknown. Methods: We analyzed data for consecutive patients requiring vasopressor treatment of post-CAS hypotension. Choice of vasopressor was made by the treating physician. Endpoints included infusion duration, coronary care unit (CCU) length of stay (LOS), TIA, new arrhythmia, cardioversion, angina, and any major adverse event. Results: Over 5 years, CAS stenting was performed in 438 patients. CCU admission, in atropine non-responders, for vasopressor treatment was required in 42 patients (9.6%): DA in 20 patients (48%), NE in 13 patients (31%), and PE in 9 patients (21%). Vasopressor infusion time was 31.8 ± 10.6 h for DA, compared with 23.8 ± 8.1 h for NE (p=0.052) and 22.2 ± 6.1 h for PE (p=0.028). CCU LOS was 46.5 ± 14.1 h for DA compared with 36.9 ± 9.1 h for the NE and PE groups combined (p=0.056). Adverse events were more common among patients receiv-