	Number of anti-hypertensive MEDS						
	0 MEDS (N=2)	*1 MED (N=11)*	*2 MEDS (N=26)*	*3 MEDS (N=52)*	*4 MEDS (N=31)*	*5 MEDS (N=20)*	*6 MEDS (N=6)*
BP Response Rate (%)	0%	0%	7.7%	19.2%	51.6%	80.0%	66.7%

Conclusions: These data suggest that patient selection for RAS may be guided by the number of MEDS, diastolic BP, and CR.

Author Disclosures: J. Modrall, None; **C.H. Timaran,** None; **B.L. Dolmatch,** Bard; Bard, Endovascular Forum; Bard; **G. Clagett,** None; **C. Trimmer,** None.

Carotid Stenting

PP11.

Prevalence and Clinical Significance of Stent Fracture and Deformation Following Carotid Artery Stenting

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Objective: Carotid artery stenting (CAS) is a developing intervention for carotid artery stenosis, and the long-term outcomes remain unclear. The purpose of this study was to determine the prevalence of carotid stent fractures or deformations following CAS and the clinical significance of these stent changes.

Methods: This is a retrospective analysis of 276 consecutive CAS performed in 250 patients at a single academic institution between 8/2000 and 10/2008. 100 stents were evaluated with multi-planar plain films of the neck to assess for stent fracture or significant deformation. Deformation was defined as an increase in stent cell area due to stent strut deformation. A subjective assessment was made by 2 independent observers (kappa = 1.0). Rate of stent fracture & deformation was determined using Kaplan-Meier life table analysis and compared using the log rank test. Study endpoints also included recurrent carotid artery stenosis of >70% requiring re-intervention and post-operative stroke.

Results: Of the 100 stents evaluated with neck films, there were 50 closed cell stents (Wallstent 11, Xact 37, other 2) and 50 open cell stents (Acculink 22, ViVexx 15, Precise 13). Overall, there were 3 stent fractures and 24 deformed stents. All stent fractures occurred in closed cell Xact stents placed > 1 year prior to examination (3 of 25 or 12%). 0 of 10 Wallstents with follow up > 1 year were fractured. No open cell stents fractured. 2 of the 3 stent fractures were associated with the presence of calcified plaque noted on plain films. Stent deformation was significantly associated with both open cell stent type (HR 15.9, P=.007) and the presence of calcified plaque on plain film (HR 16.3, P=.007). Overall at a median follow up of 22.5 months (IQR 0.9 to 63.5 months), in-stent restenosis requiring treatment occurred in 6% and late stroke in 1%. Neither stent fracture nor deformation was significantly associated with the occurrence of late stroke or re-intervention.

Conclusions: Stent fracture and deformation is not uncommon following CAS and is strongly associated with the presence of heavily calcified carotid vessels. Whether a carotid stent fractures or deforms correlates with stent cell design. Larger studies will be necessary to determine the possible clinical significance of carotid stent fracture and deformation.

Author Disclosures: C.K. Chang, None; **C.P. Huded,** None; **R.J. Powell,** AnGes.

PP12.

The Impact of Diabetes Mellitus on Results and Neointimal Progression of Carotid Artery Stenting

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Background: Diabetes mellitus (DM) increases the risk of cerebrovascular disease (CVD) in the general population and its influence in carotid artery revascularization is debated, however its impact in carotid artery stenting (CAS) has been scarcely investigated. We evaluated the impact of DM on CAS results and on the progression of the neointimal layer over the stent.

Methods: Patients with symptomatic and asymptomatic CVD undergoing CAS with distal protection were divided in GI (DM) and GII (no DM) and evaluated in term of epidemiology, percent of carotid stenosis, type of carotid plaque, contralateral carotid disease, aortic arch atherosclerosis, type of stent, technical success and early neurological outcome. Follow-up was at 3, 6, 12 months and yearly thereafter by clinical and duplex examination. Results were analyzed by Fisher's and Wilcoxon tests, logistic regression and life table analysis. A subgroup of consecutive patients was also examined by high resolution duplex scanning with 3d reconstruction at the same intervals to identify possible stent coverage by a neointimal layer, assessing the percentage of stent surface coverage.

Results: In 427 CAS, 112 pts (26%) were in GI and 315 (74%) in GII. The only significant differences in the two groups were found in age (>80 years: 26% vs. 74%, OR 0.95 for 1-year increment) and coronary artery disease (48% vs. 35% P=0.011, OR 1.74). No deaths occurred in this series. Technical success (92% vs. 89 %, P=0.4) and major complication rate (3% vs. 2% P=0.2) were similar. Cerebral haemorrhage occurred in 2 patients after few weeks (one in each group); one patient in GII developed a significant asymptomatic restenosis at 1 year. In the 110 pts (40 in GI, 40 in GII) analyzed for stent coverage a complete neointimal layer over the stent in 16 GI patients (40%) vs. 18 in GII (46%, P=NS). The progression of this new layer was independently and inversely associated with age (1-year increment OR 1.06).

Conclusions: Although patients with DM and CVD are significantly younger and with higher incidence of CAD compared with other pts, they show early and long term results after of CAS similar to those of patients without DM. Stent coverage by neo-intimal layer is similar in the two groups. CAS indication in patients with DM should follow accepted guidelines for carotid revascularization.

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PP13.

Prior Cervical Radiation Predicts Reduced Durability of CAS

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Background: Carotid endarterectomy (CEA) in the setting of prior cervical radiation is technically challenging with increased periprocedural complications. As a result, cervical radiation is considered an indication for carotid artery stenting (CAS). Recent small analyses of CAS in these patients report higher primary thrombosis, stroke and restenosis rates. We assessed whether prior radiation was a predictor of poor outcome after CAS and investigated possible reasons for this interaction.

Method: Demographic, clinical, lesion, procedural, and outcome data were collected prospectively in patients undergoing CAS from 1996-2008. Univariate comparisons were made between patients with and without a history of prior radiation. The endpoints were rates of stroke/death/MI, in-stent restenosis (ISR)>50%, and target lesion revascularization (TLR). Multivariate logistic regression was used to assess if RT was an independent predictor of adverse outcomes.

Result: 364 patients underwent CAS; 37 (10.1%) had a history of cervical radiation (RT). They did not differ from those without radiation (NRT) with respect to age, gender, smoking, symptoms, or prior CEA. RT patients had a lower incidence of hypertension, diabetes, and CAD vs. NRT. Primary thrombosis did not occur in either group. 30-day stroke/death/MI occurred in 5.4% of RT vs. 5.8% of NRT (p=ns). The ISR rate was 21.6% for RT vs. 7.6% for NRT (p=.01). 18.9% of RT required TLR vs. 4.7% for NRT (p=.002). Multivariate analysis showed that radiation (OR=2.3) and prior CEA (OR=2.1) were independent risk factors for ISR. Radiation remained a predictor of ISR despite controlling for prior CEA. Radiation (OR=4.4), prior CEA (OR=2.1), and >1 stent placed (OR=8.8) predicted the need for TLR. Radiation was still a predictor of TLR despite controlling for the other factors.

Conclusion: Peri-procedural complications are not increased for CAS in patients with prior cervical radiation. Radiation reduces the durability of CAS, increasing ISR and TLR rates. It predicts ISR and TLR despite correction for other patient and technical factors. Radiation-associated carotid lesions can be long and multifocal, requiring longer and multiple stents. History of radiation and the use of multiple stents contribute additively to increased luminal narrowing and therefore TLR in these patients.

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