Clinical Events within 30 days

	EPD (N=106)	GPI (N=199)	P
Neurological Death (%)	0	1.5	0.20
Non-fatal stroke (%)	0	1.0	0.55
Intracranial Hemorrhage (%)	0	2.0	0.14
Neurological Death, Non-fatal Stroke, or Intracranial Hemorrhage (%)	0	2.5	0.10
Major Bleeding (%)	0	4.6	0.03
Neurological Death, non-fatal Stroke, Intracranial Hemorrhage, or Major Bleeding (%)	0	5.1	0.02

1129-199 Predictors of Adverse Events Complicating Carotid Artery Stenting in the Era of Distal Protection Devices

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Introduction: Despite the rapid acceptance of carotid stenting(CS) as an alternative to endarterectomy, little is known about clinical and angiographic predictors of poor outcome with CS in the current era. **Methods:** Using the data from our registry of 351 consecutive patients who underwent CS between 1998 and 2001, we looked at 40 different clinical and angiographic variables to assess potential predictors of adverse events(AE). Majority of the patients in our registry had distal emboli protection devices used in conjunction with CS. Adverse events was defined as a combined endpoint of myocardial infarction, stroke, and death. Using multi-variate analysis, the predictors of AE peri-procedurally and at 6 months are shown. **Results:** The most significant predictors of peri-procedural AE were history of stroke, transient ischemic attack(TIA) and need for open heart surgery(pre-OHS). Also patients with COPD were at higher risk of events in our analysis. We found no association between patient's age, lesion characteristics (calcification, morphology or diameter), contra-lateral carotid stenosis/occlusion and AE. At 6 months, the predictors of poor outcome were low cardiac ejection fraction and diabetes. **Conclusions**: In the current era, patients who undergo CS with symptomatic lesions or are pre-OHS have higher peri-procedural AE; beyond the procedural period the traditional risk factor for cardiovascular events, diabetes and low ejection fraction become more important predictor of events.

Time-point	Predictor	P-value
Peri-procedural	History of Stroke	0.0041
	History of TIA	0.049
	Pre-OHS	0.010
	History of COPD	0.030
6-months	Diabetes	0.048
	Baseline EF<30%	0.016

1129-200 Chronic Visceral/Mesenteric Ischemia: Role of Percutaneous Angioplasty and Stenting in Celiac and Mesenteric Artery Disease

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Background: Surgical treatment for chronic mesenteric ischemia (CMI) is effective but technically demanding with operative mortality ranges from 3-14.7% (mean=7.5%) and morbidity ranges from 8-44.7% (mean=28%). Percutaneous transluminal angioplasty (PTA) alone for CMI is reported but has excessive recurrence rates (12-60%; mean=26%). Sparse data exists regarding indications, safety, feasibility, and durability of PTA/stenting for celiac and mesenteric artery disease.
Methods: Between January 1998-July 2002, 68 visceral artery stenosis [42 superior mesenteric (SMA) and 26 celiac artery (CA)] underwent PTA/stenting in 45 patients with CMI. A multivariable retrospective chart review was performed. Abdominal pain and weight loss were present in 41/45 (91%) and 39/45 (87%) respectively. An 8-French transfemoral approach was used in 30/42 (71%) SMA and 21/26 (80%) CA. A transbrachial approach was required in 12/42 (29%) SMA and 5/20 (20%) CA. All patients received balloon expandable stents. 30/68 (44%) vessels had 6 month duplex ultrasound (DU) and 25/68 (36%) angiography at median follow up of 23 months (range 7-54 months).
Results: Procedural success 67/68 (98.5%) with 6 requiring a change from femoral to brachial access. No bowel infarction, stent thrombosis, or procedural deaths occurred. Pain relief improved in 38/42 (92%) and weight gain in 35/39 (90%). 3/55 (5.4%) available for objective follow-up developed restenosis [DU 2/30 (6.6%) and angiography 1/25 (5%)] requiring repeat PTA/stenting for 100% primary assisted mid-term clinical success. There were no major complications requiring surgery and 2 minor access site hematomas (< 2 cm). 30-day mortality 0%. No late bowel related deaths. The 1-year and 2-year symptom free survival rates were 97.5% and 89.5% respectively.
Conclusion: PTA/stenting for SMA and CA disease is a safe and effective treatment option for CMI offering excellent immediate and mid-term clinical success.

1129-201 Bivalirudin as Sole Anticoagulant in Peripheral Vascular Disease: A Safety and Feasible Alternative in Renal and Iliac Interventions

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Background: Many heparin limitations are overcome by the direct thrombin inhibitor bivalirudin (Angiomax, The Medicines Company, Parsippany, NJ). Bivalirudin has shown a reduced incidence of ischemic and bleeding complications post percutaneous coronary interventions. The pharmacokinetic profile of bivalirudin appears well suited for percutaneous peripheral intervention (PPI) yet few data exist regarding safety and feasibility in this setting.
Methods: 180 renal and 75 iliac PPI's were performed (May 2001-June 2002) with bivalirudin as anticoagulation and compared to a historical heparin control (HC). Angiomax dose: 0.75 mg/kg bolus with 1.75 mg/kg/hr infusion for procedural duration. Variables: Sheath removal time (SRT), access complication (AC), time to ambulate (TA), and length of stay (LOS). Follow up: 6 month renal and iliac duplex ultrasound.
Results: No thrombotic events, intracranial bleeding, or major surgical complications occurred in bivalirudin group (BG). SRT, TA and LOS were reduced compared to HC (Table). 7/180 (3.8%) renal and 3/75 (4%) iliac required repeat PPI.
Conclusion: Bivalirudin is a safe and feasible alternative anticoagulant in renal and iliac PPI and may offer decreased SRT, TA and LOS. Larger prospective randomized trials are warranted.
Table

Variables	**BG Renal, n=180**	**HC** Renal, n=180	P-value	**BG Iliac n=75**	**HC** Iliac n=75	P-value
PPI Success, n (%)	180 (100)	179 (99)	0.3173	75 (100)	74 (98.6)	0.3173
AC (Major1), n (%)	2(1.1)	6 (3.3)	0.1532	2(2.5)	3 (4)	0.6503
AC (Minor2), n(%)	5(2.7)	8 (4.4)	0.3974	3(4)	5 (6.6)	0.4689
SRT <60 min, n (%)	152 (84)	106 (59)	<0.0001	36 (48)	21 (28)	0.0119
SRT >60 min, n (%)	28 (16)	74 (41)	<0.0001	39 (52)	54 (72)	0.0119
LOS <24 hrs, n (%)	154(85.5)	130 (72)	0.002	42(56)	32 (43)	0.1036
LOS >24 hrs, n (%)	26(14.5)	50 (28)	0.002	33(44)	43 (57)	0.1036
TA <6 hrs, n (%)	136(75.5)	105 (58)	0.0005	31(41)	19 (25)	0.0383
TA >6 hrs, n (%)	44(24.5)	75 (42)	0.0005	44(59)	56 (75)	0.0383

1="Major' = any surgery, > 5 cm hematoma, or > 2u transfusion
2="Minor' = all other non-intracranial or retroperitoneal bleeding

1129-202 Is Bivalirudin a Safe Alternative to Heparin During Carotid Stenting? A Case Matched Study

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Background: Previous studies have shown safety and feasibility of the direct thrombin inhibitor Bivalirudin (B) during percutaneous coronary interventions. However, the safety profile of this agent as an alternative to unfractionated Heparin (UFH) during carotid stenting (CS) is not known.
Methods: From December 2001 to September 2002, 59 consecutive pts (mean age = 72 ± 9 yrs, 60.4% male) underwent CS with B and compared to 83 case matched controls receiving UFH during the same timeframe. B was administered in bolus dose of 0.75mg/kg, followed by drip (1.75 mg/kg/hr) throughout the procedure. 5,000 units of UFH were administered prior to the procedure in the UFH group. No GP IIb/IIIa inhibitors were used. Neurological events, bleeding and vascular complications were recorded and adjudicated by an independent committee.
Results: Closure devices were used more often in B group than in UFH group (76.3% vs. 28.9% respectively, p< 0.0001). In-Hospital neurologic and vascular complications are shown in table.