TCT-531

Use of SpiderFX™ Embolic Protection Device vs. Distal Embolic Event: Hospital Length of Stay, Operating Room Time, Costs and Mortality

Eric J. Dippel[1], Niraj Parikh[2], Katrine L. Wallace[2]
[1]Midwest Cardiovascular Research Foundation, Davenport, IA, [2]Covidien, Mansfield, MA

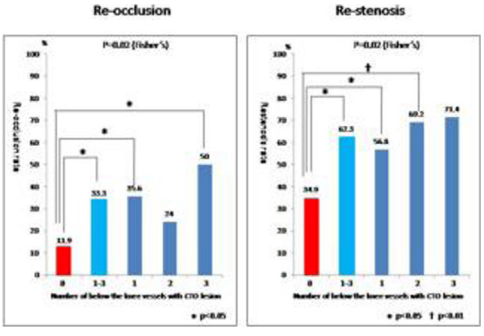
Background: Distal embolization (DE) is a potential complication of percutaneous atherectomy and other endovascular procedures that can lead to poor outcomes for the patient and escalated costs for hospitals. Embolic protection (EP) devices have been shown in several studies to have a low failure rate, and thus reduce the incidence of these events. This study compared inpatient hospital costs and resource utilization in two non-coronary (presumed lower extremity) atherectomy patient populations: (1) a DE event group, and (2) a SpiderFX™ Embolic Protection Device (Covidien, Plymouth, MN) group.
Methods: All inpatient discharges for atherectomy of non-coronary vessels (ICD-9-CM procedure code 39.50) were selected from a comprehensive hospital admissions database (Premier Perspective CY2006-Q3 of CY2012). Of these, DE patients were identified using ICD-9-CM diagnosis codes (444.xx, 434.0, and 434.1). Patients using a SpiderFX™ Device were identified using a product keyword search. Discharges in both the groups were matched 1:1 using propensity score methodology, adjusting for age, gender, race, region and severity. Hospital length of stay, operating room (OR) time, costs and inpatient mortality were compared between the groups.
Results: A total of 624 matched pairs were identified for the final analysis. Hospital stay averaged 1.4 days longer in the DE patients ($p<0.0001$) compared to the SpiderFX™ Device patients. OR time was 38 minutes longer for DE patients ($p=0.02$). Total costs were higher but not statistically significant for the DE group ($21,709 vs. $19,948, $p=0.10$). Room and board, pharmacy, laboratory and diagnostic costs were all significantly higher for DE than for the SpiderFX™ Device ($p<0.05$). The inpatient mortality rate was higher in the DE group but not statistically significant (1.8% vs. 0.80%, $p=0.13$).
Conclusions: The use of the SpiderFX™ Device is strongly associated with shorter hospital stays and shorter OR times. Cumulatively, these findings demonstrate embolic protection devices such as the SpiderFX™ Device may significantly reduce consumption of hospital resources.

TCT-532

Impact of below the knee lesions to outcome in patients implanted stent for superficial femoral artery chronic total occlusion lesion.

Maoto Habara[1], Yoshihisa Kinoshita[1], Tetsuo Matsubara[2], Kenya Nasu[2], Takahiko Suzuki[1], Mitsuyasu Terashima[1]
[1]Toyohashi Heart Center, Toyohashi, Japan, [2]Toyohashi Heart Center, Toyohashi, Aichi

Background: The purpose of this study was to identify the relationship between below the knee (BTK) lesions and outcomes after endovascular treatment (EVT) of chronic total occlusion (CTO) lesion in the superficial femoral artery (SFA).
Methods: From June 2001 to November 20011, 209 atherosclerosis obliterans patients underwent endovascular therapy for only SFA CTO lesions with self-expanding stents. After the EVT, final angiography was performed to evaluate the blow the knee lesions and number of vessels (0 - 3) in BTK with CTO lesions were counted. Within them, 120 limbs in 120 patients were performed 9 months follow up angiography.
Results: In total, 31 patients (25.8%) were showed in-stent occlusion and 63 patients (52.5%) were revealed in-stent restenosis including stent occlusion. The patients with stent occlusion were more frequently observed BTK lesions at stent implantation compared to the patients without stent occlusion (83.9% vs 58.4%; $p=0.02$). Similarly, the patients with in-stent restenosis were aloso more frequently observed BTK lesions (76.2% vs 45.6%; $p<0.001$). The re-occlusion rate was significantly higher in the patients with 1 or 3 BTK lesions than patients without BTK CTO lesion. In addition, the restenosis rate was also higher in the patients with 1 or 2 BTK CTO lesions than patients without BTK lesions.
Conclusions: Re-occlusion and restenosis rate of the patients treated SFA CTO lesions may be associated to the distal run-off vessel disease.



TCT-533

Drug-Eluting Balloon for treatment of superficial femoral artery in-stent restenosis. Two years results from an Italian registry.

Vittorio Virga[1], Eugenio Stabile[2], Luigi Salemme[3], Angelo Cioppa[4], Giuseppe Giugliano[5], Tullio Tesorio[6], Linda Cota[7], Grigore Popusoi[8], Armando Pucciarelli[8], Linda Brevetti[5], Anna Sannino[5], Vittorio Schiano[9], Giancarlo Biamino[10], Giovanni Esposito[5], Paolo Rubino[8]
[1]Clinica Montevergine, Mercogliano, Avellino, Italy, [2]Clinica Montevergine, Mercogliano, Italy, [3]Clinica Montevergine, Mercogliano (AV), Naples, Italy, [4]Montevergine Clinic, Avellino, Italy, [5]University of Naples Federico II, Naples, Italy, [6]clinica montevergine, mercogliano, Italy, [7]clinica montevergine, mercogliano, avellino, [8]Montevergine Clinic, mercogliano, Italy, [9]University of Naples Federico II, Napes, Italy, [10]Clinica Montevergine (Mercogliano, AV Italy), Mercogliano, Italy

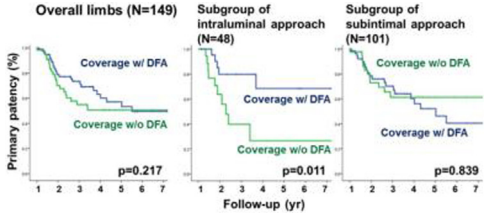
Background: The patency rate of treated SFA has been improved through use of the self-expanding nitinol stents. As the population with SFA stenting continues to increase, occurrence of in-stent restenosis (ISR) has become a thoughtful problem. The use of DEB has showed promising results in reducing restenosis recurrence in coronary stents. Accordingly, the purpose of this prospective registry was to evaluate the safety and efficacy, at 2 years, of the use of drug-eluting balloons (DEB) for the treatment of superficial femoral artery (SFA) in-stent restenosis (ISR).
Methods: From December 2009 to December 2010, 39 consecutive patients underwent PTA of SFA-ISR in our institution. All patients underwent conventional SFA PTA and final post-dilation with paclitaxel-eluting balloons (IN.PACT, Medtronic, Minneapolis, Minnesota). Clinical follow-up and duplex ultrasonography scan were performed at 30 days, and at 3, 6, 12, 18 and 24 months post-procedure. Repeat angiography was performed when proximal flow velocity ratio (PVR) was between 2.4 and 5.0 (intermediate restenosis) and when the patient had clinical symptoms or > 5.0 (severe restenosis) regardless clinical symptoms and in case of stent occlusion.
Results: Technical and procedural success was achieved in every patient. No in-hospital major adverse cardiac and cerebrovascular events occurred. At 2 years, 2 patient died (1 due to heart failure and 1 due to myocardial infarction). Primary endpoint, primary patency rate at 24 months, was obtained in 70.3% (26 patients). The presence of an occlusive restenosis at the time of treatment was not associated with an increased restenosis rate, when compared with non-occlusive restenosis, at 2 years.
Conclusions: The data suggest that adjunctive use of DEB for the treatment of SFA-ISR represents a potentially safe and effective therapeutic strategy. These data should be considered hypothesis-generating to design a randomized trial.

TCT-534

To cover or not to cover deep femoral arteries in stenting for bifurcation lesions of superficial femoral artery

Sung-Jin Hong[1], Young-Guk Ko[1], Jung-Sun Kim[1], Myeong-Ki Hong[1], Yang soo Jang[1], Donghoon Choi[1]
[1]Severance Cardiovascular Hospital, Yonsei University, Seoul, Korea, Republic of

Background: We evaluated the clinical impact of different stenting strategies, to cover or not to cover deep femoral arteries (DFA) in proximal superficial femoral artery (SFA) stenting, on the patency of SFA and to identify subgroups of patients for whom these different stenting strategies have stronger association with better patency for SFA bifurcation.
Methods: Between 2005 and 2012, 149 limbs stented at proximal SFA were retrospectively enrolled and classified into 2 groups according to stenting strategies; 85 limbs (57%) with coverage of DFA, group 1 and 64 limbs (43%) stented without coverage of DFA, group 2. The fate of DFA and primary patency of SFA were compared.
Results: Flow-limitation of DFA after stenting were observed in 14 limbs (9%) for overall, 10 limbs (12%) in group 1 and 4 limbs (6%) in group 2 ($p=0.25$). 85 limbs had follow-up CT angiography within 2 yrs and no stenosis of DFA were observed in both groups. Primary patency of SFA at 1 yr and 3 yr for overall limbs was 75% and 56%. Primary patency was not significantly different between 2 groups ($p=0.22$), although there was a trend of higher patency in group 1 up to 2 yrs. In subgroup analysis, there was a significant interaction between stenting strategy and approach method ($p=0.03$). Group 1 had significantly higher patency in subgroup of intraluminal approach ($p=0.01$), whereas there were no difference in patency between 2 groups in subgroup of subintimal approach ($p=0.84$).



POSTERS