

RESULTS When compared to no GPI, administration of GPI before PCI (n=525) or in bail-out situations (n=175) did not improve the 30-day composite of death, myocardial infarction, urgent target revascularization and definite stent thrombosis (4.2% in no GPI use vs. 4.0% in routine use of GPI vs. 6.9% in bail-out use of GPI; p=0.58 in multivariate analysis). GPI in bail-out situations increased the rate of non CABG-related major PLATO bleeding compared to no GPI in univariate (odds ratio 3.40, 95% confidence interval 1.58-7.33; p<0.01) and multivariate analysis (odds ratio 2.96, 95% confidence interval 1.32-6.64; p=0.03). Though, in a univariate (odds ratio 1.60, 95% confidence interval 0.81-3.16; p=0.65) and multivariate analysis (odds ratio 1.78, 95% confidence interval 0.88-3.61; p=0.92), GPI routinely given before PCI compared to no GPI did not increase rate of bleeding.

CONCLUSION GPI administration in addition to the potent P2Y12 inhibitor ticagrelor in STEMI patients does not improve 30-days ischemic outcomes and mortality. In particular, an increase in 30-days non-CABG-related major PLATO bleeding was seen in patients who received GPI in a bail-out situation.

CATEGORIES CORONARY: Pharmacology/Pharmacotherapy

TCT-112

Patient-oriented clinical outcomes and net adverse cardiovascular event in the Global Leaders trial



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BACKGROUND Ticagrelor as a single antiplatelet therapy may be a more effective and safe long term antiplatelet strategy than dual antiplatelet therapy followed by ASA monotherapy in patients after coronary stenting. To determine in patients undergoing PCI under standardized treatment (BioMatrix DES and bivalirudin), whether 1 month of ticagrelor and ASA followed by 23 months of ticagrelor monotherapy is superior to 12 months of DAPT followed by ASA monotherapy regarding patient-oriented composite endpoint (POCE) and net adverse clinical and cerebrovascular events (NACCE).

METHODS GLOBAL LEADERS is a prospective randomized, multi-center, open label, superiority trial investigating 2 strategies of antiplatelet after PCI. Primary endpoint is a composite of all-cause mortality and new Q wave at 2 years. The experimental strategy consisted of ASA 75-100 mg once daily with ticagrelor 90 mg twice daily for 1 month followed by ticagrelor 90 mg twice daily for 23 months irrespective of presentation. Reference treatment consisted of 12-month DAPT with clopidogrel 75 mg once daily in stable CAD patients or ticagrelor 90 mg twice daily in ACS patients followed by ASA monotherapy for the remaining 12 months. From Jul 1st 2013 to Nov 9th 2015, 15991 patients were randomized before PCI stratified by center and presentation (stable vs ACS). Analysis was performed according to intention-to-treat principle. POCE (composite of all-cause death, any stroke, any MI and any revascularization) and bleeding endpoints, BARC3 and 5 were site reported. NACCE consisted of all-cause death, any stroke, any MI, any revascularization and BARC 3 bleeding.

RESULTS Patients were male in 76.7%, mean age 64.5±10.3 years. Diabetes was present in 25.3%. 53.1% of patients had stable CAD, 12.7% UA, 21.1% NSTEMI and 13.1% STEMI. 2-year vital status was available in all patients but eleven (>99.9%). At 2 years, POCE and NACCE were 13.9% and 14.5% respectively. The result of unblinded analysis will be presented at the time of presentation.

CONCLUSION This analysis will assess the impact of 23 months ticagrelor monotherapy after 1 month of DAPT on POCE and NACCE after PCI vs. a standard strategy of DAPT in real-world practice.

CATEGORIES CORONARY: Pharmacology/Pharmacotherapy

LOWER EXTREMITY INTERVENTION

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Effectiveness of Atherectomy Vs. Balloon Angioplasty for Limb Salvage in Occlusive Tibioperoneal Arterial Disease



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BACKGROUND The use of atherectomy devices for the treatment of lower extremity arterial disease has been increasing despite sparse evidence of clinical benefit. The primary goal of intervention on occlusive arterial disease of tibial and peroneal arteries (TPA) is to prevent limb loss. We sought to compare rates of ipsilateral limb amputation, long-term vessel patency, and angiographic outcomes after endovascular intervention using atherectomy and balloon angioplasty on TPA for critical limb ischemia.

METHODS Using the multicenter PVI Registry™ we identified all patients with isolated endovascular intervention on TPA for occlusive disease Rutherford category 4 to 6 using atherectomy as first treatment device or balloon angioplasty. The 2 treatment groups were matched 1:1 by clinical and angiographic characteristics.

RESULTS There were 1454 patients, with 2183 arteries treated, in the atherectomy group, and 1454 patients, with 2141 arteries treated, in the angioplasty group. Median follow-up time was 507 days. Mean age was 69 years ± 11.7 and the mean occluded length was 6.9 mm ± 6.5. The amputation rate was lower in the atherectomy group than the angioplasty group, 6.2% vs. 8.3%, p = 0.013, odds ratio 0.73 (95% confidence interval 0.57 to 0.94). This difference was driven by minor amputations. Procedural technical success was higher with atherectomy than angioplasty balloon 96.8% vs. 95%, p = 0.004. Vessel patency at 6 months was similar between atherectomy and balloon angioplasty, 66 vs. 63.5%, p = 0.35. There was no significant difference in the rates of vessel dissection, perforation, or distal embolization during the procedure. As shown in the table, contrast use and fluoroscopy time were significantly higher in the atherectomy group.

	Atherectomy	Balloon angioplasty	p value
Ipsilateral limb amputation Major	6.2% 4.5% 3% 66%	8.3% 4.6% 4.1% 63.5%	0.01 0.86 0.08
amputation Minor			
6-month patency			
Procedural outcomes			
Technical success	92.9% 1.2% 1.3% 2.3%	91% 1.1% 0.6% 2.5%	0.07 0.73 0.06 0.67
Distal embolization	4.5% 103.6 ± 65.7	6.3% 86.7 ± 58.3	0.01 <0.001 <0.001
Arterial perforation	24.9 ± 16.9	20.3 ± 15.4	
Arterial dissection			
Stent use Contrast volume in mL, mean ±SD			
Fluoroscopy time, mean ± SD			

CONCLUSION In patients with critical limb ischemia from occlusive TPA disease, the use of atherectomy was associated with a decrease in the rate of incident amputation.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention