TCT-844

Active Versus Passive Anchoring Vascular Closure Devices: A Safety and Efficacy Comparative Analysis

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Background: We evaluate the prevalence of complications and failure rates between the most commonly used "active" anchoring vascular closure device (VCD), AngioSeal™ and the "passive" anchoring VCD, Mynx,™ in all-comers undergoing percutaneous coronary intervention (PCI).
Methods: A total of 4,074 patients between 2008-2014, representing an era when both devices were available, were included. 32% were acute coronary syndromes (37% STEMI). VCD choice was at the operator's discretion and included AngioSeal (n=2910) or Mynx (1,164). Cardiogenic shock or patients receiving intra-aortic balloon pumps were excluded. Safety was assessed by vascular complications defined as either vascular injury (perforation, dissection, acute limb ischemia, arteriovenous fistula, pseudoaneurysm with thrombin injection, or surgical repair) or access-site bleed (hemoglobin drop >3 g/dL requiring transfusion, retroperitoneal bleed, or hematoma >5cm, or the composite of both. Efficacy was evaluated by device failure defined as inability to achieve immediate hemostasis, or additional hemostatic mechanisms require. Outcomes at 30-days were evaluated.
Results: Groups (AngioSeal vs. Mynx) were fairly balanced with regards to bleeding risk factors of gender (male, 65% vs. 66%), body mass index (30±6 vs. 30±7), heart failure class III/IV (5% vs. 6%), chronic kidney disease (15% vs. 17%), use of glycoprotein IIb/IIIa inhibitor (5% vs. 4%) or bivalirudin (86% vs. 88%), all p >0.5. The AngioSeal group was slightly younger (64±12 vs. 65±12, p < 0.001) with less peripheral arterial disease (11.3% vs. 13.9%, p =0.03), and increased 7F sheath use compared with Mynx (59% vs. 22%, p < 0.001). Safety and efficacy outcomes were similar between groups (table).
Conclusions: AngioSeal and Mynx appear to be equally safe and efficacious VCDs following PCI. The passive anchoring system may prove desirable as no intra-arterial anchor remains upon device removal.

	Outcomes		
	AngioSeal (n=2,910)	Mynx (n=1,164)	p value
Safety			
Vascular injury	0.30%	0.80%	0.09
Access-site bleed	1.90%	1.40%	0.8
Composite safety	2.30%	1.50%	0.6
Efficacy			
Device failure	7.50%	8.70%	0.4

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Femoral Approach with Systematic Use of FemoSeal™ Closure Device Compared to Radial Approach in Primary Angioplasty: a Propensity-matched Comparison

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Background: Radial approach (RA) has been shown to reduce access-related bleedings as compared to femoral approach (FA). However, although the risk of femoral bleeding can be reduced with the adoption of vascular closure devices (VCD), there are few data about the comparison of RA and FA with VCD, particularly in patients at high risk of bleeding such as those undergoing primary percutaneous coronary intervention (pPCI). The FemoSeal™ (St.Jude Medical,MN,USA) is a sandwich type, fully resorbable VCD that has been associated with a low rate of access-site bleeding and vascular complications. Aim of this study was to compare the incidence of bleedings, defined according to the Thrombolysis in Myocardial Infarction (TIMI) criteria, and of major adverse cardiac and cerebrovascular events (MACCE) in a population of patients undergoing primary angioplasty through RA or FA with systematic closure by FemoSeal™.
Methods: We included in this retrospective registry 777 patients who underwent pPCI at two high-volume Centers from years 2010 to 2013. Exclusion criteria were the implantation of intra-aortic balloon pump and the achievement of femoral hemostasis by other means than the FemoSeal™. The study population was divided in RA patients, enrolled in Center A (Group 1, n=511) and FA patients, enrolled in Center B (Group 2, n=266). We performed multivariate analysis and propensity-score matching in order to adjust for clinical and procedural confounders.
Results: Main results of the study are provided in the Table. At multivariate analysis, the following predictors of bleeding were identified: FA (OR 3.2, 95% C.I. 1.3-7.5), use of Gp IIb/IIIa blockers (OR 3.6, 95% C.I. 1.5-8.7) and heart rate at presentation (OR 1.04, 95% C.I. 1.02-1.07).
Conclusions: In primary PCI the rate of TIMI major bleedings was higher in FA with closure by FemoSeal™ as compared to RA, whereas the rates of minor bleedings and of MACCE were similar.

	Group 1	Group 2	p
General population (n)	511	266	
TIMI major (%)	0.2	2.3	<0.01
TIMI minor (%)	2.0	3.4	0.22
MACCE (%)	3.5	3.4	0.9
Propensity-matched population (n)	229	229	
TIMI major (%)	0	2.6	<0.05
TIMI minor (%)	1.3	3.9	0.79
MACCE (%)	4.4	2.6	0.44

TCT-846

Radial-to-femoral access crossover is not associated with adverse outcomes in the setting of primary percutaneous coronary intervention

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Background: We aimed to describe the impact of the vascular access used when patients are treated with primary percutaneous coronary intervention (PPCI) and to assess whether this translates into differences in angiographic outcomes.
Methods: ST-elevation myocardial infarction (STEMI) patients undergoing PPCI were divided into three groups: successful radial access (RA), successful femoral access (FA) and Crossover (failed RA with need for bailout FA) groups. Vascular access-related time (VART) was defined as the delay in PPCI that can be attributed to vascular access-related issues. Study endpoint was the final corrected TIMI frame count (CTFC). Multivariable analysis was used to identify predictors of RA failure (RAF: FA+Crossover).
Results: We included 241 patients (RA n=172, FA n=49, Crossover n=20). Mean VART was longer in Crossover (10.3 (8.8-12.4) min), relative to RA (4.1 (3.2-5.5) min) and FA (4.6 (3.4-8.4) min, p< 0.001). A similar situation was found for time-to-first-device (Crossover: 22.5 (20.3-32.0) min; RA: 15.0 (12.0-19.8) min; FA: 17.9 (13.5-22.3) min; p< 0.001) and total procedure time (Crossover: 60.3 (51.6-71.5) min; RA: 46.8 (38.1-59.7) min; FA: 52.3 (41.9-74.7) min; p< 0.001). No differences in CTFC were observed (Crossover: 26 (18-32) frames; RA: 24 (18-32) frames; FA: 25 (16-34) frames; p=0.625). Killip class IV (OR 3.628, 95% CI: 1.098-11.981, p=0.035), cardiopulmonary resuscitation prior to arrival (OR 3.572, 95% CI: 1.028-12.407, p=0.045) and glomerular filtration rate (OR 0.861, 95% CI: 0.758-0.978, p=0.021) were independent predictors of RAF.
Conclusions: In the setting of PPCI, radial-to-femoral access crossover can lead to VART delays that do not impact angiographic outcomes, in comparison with successful RA. Killip class IV, cardiopulmonary resuscitation prior to arrival and impaired renal function are independent predictors of RAF in STEMI patients undergoing PPCI.

TCT-847

Safety And Efficacy Of Angio-Seal® Vs. Exo-Seal® In Patients Undergoing Primary Percutaneous Coronary Intervention For ST-elevation Myocardial Infarction

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Background: Patients undergoing primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) are at high risk of femoral vascular complications (VC). In spite of the growing use of radial approach, femoral remains the most common in primary PCI. The use of femoral vascular closure devices (VCDs) has expanded in recent years despite previous controversial trials. Angio-Seal® is a collagen-based plug/anchor intravascular device and Exo-Seal® is an extravascular polyglykolacid plug. Objective: to evaluate safety and efficacy, and to compare these VCDs in primary PCI.