EFFICACY AND LONG TERM SAFETY OF STARCLOSE™, AN EXTRA LUMINAL CLIP VASCULAR CLOSURE SYSTEM, FOR HEMOSTASIS OF ARTERIAL PUNCTURES DISTAL TO COMMON FEMORAL ARTERY BIFURCATION AFTER PERCUTANEOUS CORONARY INTERVENTIONS

i2 Poster Contributions
Georgia World Congress Center, Hall B5
Monday, March 16, 2009, 9:30 a.m.-10:30 a.m.

Session Title: Endovascular and New Technologies
Abstract Category: Vascular Access, Closure Devices and Complications
Presentation Number: 2505-489

Authors: Payam Dehghani, Atif Mohammad, Daniel Marcuzzi, Tony Hong, Melma Evangelista, Howard Leong-Poi, Asim N. Cheema, St. Michael’s Hospital, Toronto, ON, Canada

Background: Currently approved vascular closure devices (VCD) are recommended for use in common femoral artery (CFA) only. StarClose™ vascular system (SC) is a unique VCD that utilizes an extra luminal nitinol clip without an intravascular component, a feature that may allow safe use in small caliber vessels distal to CFA bifurcation.

Objective: To determine immediate efficacy and long term safety of SC for hemostasis of arterial punctures distal to CFA bifurcation.

Methods: Consecutive patients with arterial puncture distal to CFA bifurcation received SC after PCI. Baseline characteristics, procedural details and clinical outcomes were prospectively collected. Patients were ambulated 4-6 hours post PCI and adequacy of groin hemostasis and presence of vascular complication determined before hospital discharge. Clinical follow up and duplex ultrasound examination (DUS) of SC site was completed at 6-8 months to assess long term safety.

Results: A total of 106 patients undergoing PCI were included in the study. Mean age was 66±12 years and 63% were male. 93 (88%) patients received adjunctive glycoprotein IIb/IIIa platelet receptor antagonist or bivalirudin and 103 (97%) received a stent. The arterial puncture was located in superficial femoral artery (SFA) in 76 (72%), profunda femoris artery (PFA) in 22 (21%) and was undetermined in 8 (7%) patients. The mean diameter of CFA was significantly greater than its distal branch with SC (6.2±1.5 vs 4.5±1.0 mm for CFA and SC branch respectively, p<0.0001). SC was successful in 102 (96%) patients. At 24 hours, hematoma ≥5 cm was reported for 13 (12%) patients. No other major vascular event including access site bleeding, clinical evidence of pseudoaneurysm (PSA), arteriovenous fistula (AVF), local infection and neurological or vascular injury were observed. At a mean follow up of 9±2.5 months, there was no clinical evidence of arterial insufficiency or vascular complications by DUS and/or clinical assessment.

Conclusion: In patients undergoing PCI, placement of SC distal to CFA bifurcation results in effective immediate hemostasis and does not adversely affect arterial morphology or blood flow on long term follow up.