

Impact of Early Surveillance on Safety Signal Identification in the CathPCI DELTA Study**Supplemental Appendix**

Supplemental Appendix Table 1: VCD models produced by the same manufacturer were grouped together into “Device Families” if they shared mechanisms and common implant materials. Only VCD which delivered an implanted component to the level of the artery were included as “active VCD”.

Device	Manufacturer	Family
Angiolink EVS	Angiolink	AngioLink
Angio-Seal Angio-Seal Millenium Angio-Seal STS Angio-Seal STS PLUS Angio-Seal VIP Angio-seal Evolution	St. Jude Medical	AngioSeal
Arstasis	Arstasis Inc	Axera
Duett Pro Sealing-2210 Duett Sealing Device	Vascular Solutions	Duett
Femoral Introducer Sheath and Hemostasis Device	MIR	MIR
Mynx Mynx-M5 Mynx Cadence MynxGrip	Access	Mynx
Closer S Perclose A-T Perclose ProGlide Prostar XL 8 Suture	Abbott Laboratories	Perclose
Starclose Vascular Clo Sys Starclose SE	Abbott Laboratories	Starclose
Sutura Superstitch device	Sutura	Sutura
Techstar Techstar XL	Abbott Laboratories	Techstar
Vasoseal Vasoseal Elite VasoSeal ES VasoSeal Low Profile VasoSeal VHD	Datascope Corp.	Vasoseal
X-Press	X-site Medical	X-site

Covariates Included in Propensity Score Model and Definitions

Age (years)

Female Gender

Diabetes: Diabetes mellitus is diagnosed by a physician or can be defined as a fasting blood sugar greater than 7 mmol/l or 126 mg/dL. It does not include gestational diabetes.

Chronic Lung Disease: A history of chronic inhalation reactive disease (asbestosis, mesothelioma, black lung disease or pneumoconiosis) qualifies as chronic lung disease. Radiation induced pneumonitis or radiation fibrosis also qualifies as chronic lung disease. A history of atelectasis is a transient condition and does not qualify.

Hypertension: Hypertension is defined by any one of the following: 1. History of hypertension diagnosed and treated with medication, diet and/or exercise 2. Prior documentation of blood pressure greater than 140 mm Hg systolic and/or 90 mm Hg diastolic for patients without diabetes or chronic kidney disease, or prior documentation of blood pressure greater than 130 mm Hg systolic and/or 80 mm Hg diastolic on at least two occasions for patients with diabetes or chronic kidney disease 3. Currently on pharmacologic therapy for treatment of hypertension.

Creatinine pre-procedure (mg/dL)

Peripheral Artery Disease: Peripheral arterial disease can include: 1. Claudication, either with exertion or at rest. 2. Amputation for arterial vascular insufficiency. 3. Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (excluding dialysis fistulas and vein stripping). 4. Documented aortic aneurysm with or without repair. 5. Positive non-invasive test (e.g., ankle brachial index ≤ 0.9); ultrasound, magnetic resonance, computed tomography, or angiographic imaging of $> 50\%$ diameter stenosis in any peripheral artery (e.g., renal, subclavian, femoral, iliac). For purposes of the Registry, periph

Emergent Procedure

NSTEMI on Presentation: The patient was hospitalized for a non-ST elevation myocardial infarction (STEMI) as documented in the medical record. Non-STEMIs are characterized by the presence of both criteria: a. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I) exceed the upper limit of normal according to the individual hospital's laboratory parameters with a clinical presentation which is consistent or suggestive of ischemia. ECG changes and/or ischemic symptoms may or may not be present. b. Absence of ECG changes diagnostic of a STEMI

Bivalirudin exposure

Left main coronary artery PCI

Number of vessels treated during index PCI

Fluoroscopy time (minutes)**Total number of PCI during admission****Adverse Outcome Definitions**

All covariates and adverse clinical events were defined according to the CathPCI Registry version 4.4 data definitions.

Any Vascular Complication denotes the composite of bleeding at access site, hematoma at access site, retroperitoneal bleeding, and other vascular complications requiring treatment.

Other vascular complications requiring treatment could include, but were not limited to, access site occlusions, peripheral embolizations, dissections, pseudoaneurysms and/or AV fistulas. Any noted vascular complication must have had an intervention such as a fibrin injection, angioplasty, or surgical repair to qualify. Prolonged pressure did not qualify as an intervention, but ultrasonic guided compression after making a diagnosis of pseudoaneurysm did qualify. A retroperitoneal bleed or hematoma requiring transfusion is not a vascular complication under this data element.