Angio-Seal™ Evolution™
Vascular Closure Device

Angio-Seal Evolution Vascular Closure Device
Registry Subset Analysis

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Angio-Seal Evolution Device Registry Subset Analysis of Obese and Prior Catheterization Subsets

Background

Obesity and scar tissue at the vascular access site can impact the performance of vascular closure devices. Body Mass Index (BMI) is frequently used as a measure for obesity. Previous catheterization has been associated with an increased risk for scar tissue formation at the vascular access site. St. Jude Medical's Angio-Seal Evolution vascular closure device was clinically evaluated in patients with obesity and scar tissue overlying the vascular closure site to observe its performance when faced with variables that might negatively impact device performance.

Methods

- Prospective observational registry of 1,004 patients (6 patients had two devices deployed, one in each leg)
- 10 U.S. centers; 44 U.S. physicians
- Primary outcomes: 30 day rate of major vascular complications
- Secondary outcomes: device deployment success, time to hemostasis, and 30 day rate of minor vascular complications

Baseline Patient Characteristics

- 575 catheterization procedures
- 435 percutaneous coronary interventions (PCI)
- Average BMI, kg/m^2 was 30.6 ± 6.4

BMI Subset Analysis

Procedure Characteristics	**All** (N = 1,010)	**BMI < 30** (n = 519)	**BMI ≥ 30** (n = 491)	**P-Value**
Successful device deployment	1,007 (99.7%)	519 (100%)	488 (99.4%)	0.1145
Hemostasis by device	988 (97.8%)	512 (98.7%)	476 (96.9%)	0.0634

All Major Adverse Events (AE)	**Analysis Population** (N = 1,010)	**BMI < 30** (n = 519)	**BMI ≥ 30** (n = 491)	**P-Value**
Vascular injury requiring repair	2 (0.2%)	0 (0.0%)	2 (0.4%)	0.2361
Permanent access site-related nerve injury	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Access site-related bleeding requiring transfusion	1 (0.1%)	1 (0.2%)	0 (0.0%)	1.0000
New ipsilateral lower extremity ischemia requiring surgical intervention	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Retroperitoneal bleeding	1 (0.1%)	1 (0.2%)	0 (0.0%)	1.0000
Infection requiring hospitalization and/or IV antibiotics	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Had any major AE(s) (not including death)	4 (0.4%)	2 (0.4%)	2 (0.4%)	1.0000

All Minor Adverse Events (AE)	**Analysis Population** (N = 1,010)	**BMI < 30** (n = 519)	**BMI ≥ 30** (n = 491)	**P-Value**
Bleeding requiring 30+ minutes of manual compression	14 (1.4%)	8 (1.5%)	6 (1.2%)	0.6643
Ipsilateral hematoma > 10 cm	10 (1.0%)	4 (0.8%)	6 (1.2%)	0.5370
Ipsilateral pseudoaneurysm without intervention	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Ipsilateral A-V fistulae	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Ipsilateral deep vein thrombosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Access site infection without prolonged hospitalization	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Had any minor AE(s) (not including death)	24 (2.4%)	12 (2.3%)	12 (2.4%)	0.8906

- 48.6% of patients had a BMI > 30 kg/m^2
- 51.5% had previous ipsilateral percutaneous femoral access
- 19.8% had previously used arterial puncture closure device

Outcomes

- **No significant difference in deployment success or hemostasis in obese patients.** Device deployment success was 100% vs. 99.4% and hemostasis by device was 98.7% vs. 96.9% for patients with BMI < 30 vs. BMI ≥ 30, respectively.
- **No significant difference in major or minor adverse events in obese patients.** Major adverse events were 0.4% vs. 0.4% and minor adverse events were 2.3% vs. 2.4% for patients with BMI < 30 vs. BMI ≥ 30, respectively.
- **No significant difference in deployment success or hemostasis in patients with previous catheterization.** Device deployment success was 99.4% vs. 100% and hemostasis by device was 97.7% vs. 97.9% for patients with no previous catheterization vs. patients with previous catheterizations, respectively.
- **No significant difference in major or minor adverse events in patients with previous catheterization.** Major adverse events were 0.8% vs. 0.0% and minor adverse events were 2.3% vs. 2.5% for patients with no previous catheterization vs. patients with previous catheterizations, respectively.

Conclusions

Obesity and previous catheterization did not significantly affect deployment success or hemostasis provided by Angio-Seal Evolution vascular closure device and were not associated with an increase of major or minor complications after deployment.

Previous Catheterization Subset Analysis

Procedure Characteristics	All (N = 1,010)	No Previous Catherization (n = 488)	Previous Catherization (n = 522)	P-Value
Successful device deployment	1,007 (99.7%)	485 (99.4%)	522 (100%)	0.1124
Hemostasis by device	988 (97.8%)	477 (97.7%)	511 (97.9%)	0.8731

All Major Adverse Events	Analysis Population (N = 1,010)	No Previous Catherization (n = 488)	Previous Catherization (n = 522)	P-Value
Vascular injury requiring repair	2 (0.2%)	2 (0.4%)	0 (0.0%)	0.2332
Permanent access site-related nerve injury	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Access site-related bleeding requiring transfusion	1 (0.1%)	1 (0.2%)	0 (0.0%)	0.4832
New ipsilateral lower extremity ischemia requiring surgical intervention	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Retroperitoneal bleeding	1 (0.1%)	1 (0.2%)	0 (0.0%)	0.4832
Infection requiring hospitalization and/or IV antibiotics	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Had any major AE(s) (not including death)	4 (0.4%)	4 (0.8%)	0 (0.0%)	0.0542

All Minor Adverse Events	Analysis Population (N = 1,010)	No Previous Catherization (n = 488)	Previous Catherization (n = 522)	P-Value
Bleeding requiring 30+ minutes of manual compression	14 (1.4%)	5 (1.0%)	9 (1.7%)	0.3420
Ipsilateral hematoma > 10 cm	10 (1.0%)	6 (1.2%)	4 (0.8%)	0.5352
Ipsilateral pseudoaneurysm without Intervention	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Ipsilateral A-V fistulae	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Ipsilateral deep vein thrombosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Access site infection without prolonged hospitalization	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Had any minor AE(s) (not including death)	24 (2.4%)	11 (2.3%)	13 (2.5%)	0.8054

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Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

St. Jude Medical Angio-Seal Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8 F Angio-Seal device and a 6 French or smaller procedural sheath for the 6 F Angio-Seal device. The Angio-Seal STS Plus, VIP and Evolution platform devices are also indicated for use to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to safely ambulate after sheath removal and device placement. Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation, or edema.

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