THE ANGIO-SEAL EVOLUTION MULTICENTER REGISTRY: THE LEARNING CURVE ASSOCIATED WITH A NEW CLOSURE DEVICE

i2 Poster Contributions
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Background: The use of vascular closure devices (VCDs) has been subject to a significant learning curve. The Angio-Seal Evolution vascular closure device was developed to automate the compaction of the anchor-collagen sandwich, potentially reducing the dependence of device efficacy and safety on operator experience.

Methods: The Angio-Seal Evolution closure device (EVCD) was placed in 1,004 patients by 44 investigators at 10 sites undergoing cardiac catheterization (CATH) or intervention (PCI) from retrograde femoral artery access. Prior VCD and registry EVCD experience were assessed for each investigator. In-hospital and 30-day clinical follow-up including device deployment success, and major and minor vascular complications (VC) were obtained in all patients. The registry was approved by the Institutional Review Board of each site.

Results: The EVCD was successfully deployed in 1,001/1,004 (99.7%), and hemostasis was achieved by device in 983/1,004 (97.9%). Any VC occurred in 28/1,004 (2.8%) of all pts., 4/575 (0.7%) of CATH, and 24/429 (5.6%) of PCI. EVCD deployment success and VC were similar with prior VCD experience of <500 and >500, p>0.05. Any VC occurred in 3.5% of the first half of each investigator's EVCD registry use vs. 2.0% in the last half, p=0.18. EVCD deployment success was 99.6% in the first half of each investigator's EVCD registry use vs. 99.8% in the last half, p=1.00.

Conclusions: Successful Angio-Seal Evolution device deployment success and the rate of any vascular complications were similar in regards to both prior VCD experience and Evolution registry use. Thus, the Angio-Seal Evolution device was adopted without evidence of a significant learning curve.