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i2 SUMMIT

SAFETY AND EFFICACY OF ANGIO-SEAL™ VASCULAR CLOSURE DEVICE FOLLOWING PERCUTANEOUS CORONARY INTERVENTION

i2 Poster Contributions
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Background: Although Angio-Seal™ vascular closure device (VCD) (St. Jude Medical, St. Paul, MN) is effective in reducing time to hemostasis following percutaneous coronary intervention (PCI), there are safety concerns.

Methods: From March 2005 to June 2009, 13,379 consecutive patients underwent PCI using femoral artery approach. We retrospectively evaluated length of hospital stay, rate of local vascular complications and all-cause mortality in 2 groups: Angio-Seal VCD (1,103 patients, 8%) and manual compression or mechanical compression devices (12,276 patients, 92%).

Results: Length of hospital stay was shorter with Angio-Seal VCD (1.8 days vs. 2.3 days, p<0.001). Incidence of any vascular complication was not different between the 2 groups (1.1% vs. 1.9%, p=0.053). After adjusting for baseline differences, multivariate logistic regression analysis showed no difference in rate of vascular complications or 1-year all-cause mortality between the 2 groups. Conclusions Following PCI, Angio-Seal VCD may shorten length of hospital stay, but doesn't increase vascular complications or 1-year all-cause mortality when compared to manual compression or mechanical compression devices.

Angio-Seal VCD Versus Manual Compression or Mechanical Compression Devices				
		Type of Closure		P-value
Characteristic	Overall	Seal	Manual/Mechanical	
No of Patients	13,379	1,103 (8.2%)	12,276 (91.8%)	
Baseline Characteristics				
Age - mean ± SD years	66.1±12.30	65.3±12.48	66.1±12.28	0.019
Age ≥70 years - no. (%)	5,609 (41.9%)	434 (39.4%)	5,175 (42.2%)	0.070
Women - no. (%)	4,964 (37.1%)	401 (36.4%)	4,563 (37.2%)	0.592
Renal failure - no. (%)	603 (4.5%)	53 (4.8%)	550 (4.5%)	0.618
PVD - no. (%)	1,736 (13.0%)	94 (8.5%)	1,642 (13.4%)	<0.001
BMI - mean ± SD kg/m2	30.0±6.57	30.4±6.96	30.0±6.53	0.087
GP IIbIIIa - no. (%)	3,318 (24.8%)	104 (9.4%)	3,214 (26.2%)	<0.001
Endpoint				
Length of hospital stay - mean ± SD days	2.2 ± 3.72	1.8 ± 2.83	2.3 ± 3.78	<0.001
Any vascular complication - no (%)	246 (1.8%)	12 (1.1%)	234 (1.9%)	0.053
All-cause one-year mortality - no. (%)	581 (4.3%)	35 (3.2%)	546 (4.5%)	0.047
Endpoint	Adjusted OR (95%CI) for Manual/Mechanical vs. Seal			
Any vascular complication	0.67 (0.35-1.16)			0.183
All-cause one-year mortality	0.75 (0.51-1.06)			0.115

Differences in patients' demographic and clinical characteristics were compared across the two closure groups with Wilcoxon rank sum test for continuous variables and chi-square test for categorical variables.
Abbreviations: BMI=body mass index; OR=odds ratio; PCI=percutaneous coronary intervention; PVD=peripheral vascular disease.