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Results of ISAR-CLOSURE trial reported at TCT 2014

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A new clinical trial found that vascular closure devices (VCD) are non-inferior to manual compression in patients undergoing transfemoral coronary angiography. Findings were reported today at the 26th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

Vascular closure devices help achieve more rapid hemostasis after coronary angiography, however the safety and efficacy of these devices compared to standard manual compression remains controversial. Some meta-analyses have suggested an increased risk of vascular complications with VCD compared with manual compression, while other studies have demonstrated a reduction in bleeding complications with VCD.

The ISAR-CLOSURE trial compared outcomes after arteriotomy closure with two different vascular closure devices with manual compression after diagnostic angiography performed through the femoral access route. The multicenter, open-label clinical trial randomized 4,524 patients undergoing diagnostic coronary angiography via the common femoral artery to receive either manual compression (n=1,509) or one of two vascular closure devices (Femoseal VCD n=1,509; Exoseal VCD n= 1,506).

The primary endpoint was vascular access site complications including the composite of hematoma greater than or equal to five centimeters,

arterio-venous fistula, pseudoaneurysma, access-site related bleeding, acute ipsilateral leg ischemia, the need for vascular surgical or interventional treatment, and local infection at 30 days after randomization. Secondary endpoints included time to hemostasis, repeat manual compression and device failure. A secondary comparison between the two VCDs was also performed.

After 30 days, the VCD group reported access site complications in 6.9 percent of patients compared to 7.9 percent in the manual compression group, establishing non-inferiority of VCD. The most common complication in both groups was hematoma formation, followed by pseudoaneurym formation. Time to hemostasis was shorter in the VCD group (median 1 minute [.5-2.0] vs. 10 minutes [10-15], p

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