Top Ten Things To Know
Arteriotomy Closure Devices for Cardiovascular Procedures

1. About 7 million invasive cardiovascular procedures are performed worldwide each year, with the vast majority of these utilizing the femoral artery approach.

2. While manual compression has been the traditional technique to achieve closure of the arteriotomy site, arteriotomy closure devices (ACDs) were developed to decrease vascular complications, reduce the time to hemostasis and ambulation, and shorten hospital stay.

3. This scientific statement provides an overview of vascular access and patient risk for vascular complications, the available evidence for ACDs, recommendations for their use, and the trials and end points needed to inform future clinical practice.

4. The rate of noncoronary vascular complications after interventional catheter-based procedures varies from 2% to 6%. Vascular complications increase with the complexity of the procedure and the intensity of anticoagulation and antiplatelet therapy.

5. Patients’ risk for vascular complications may be categorized as
   • low risk (for those undergoing diagnostic angiographic procedures) carries a <1% complication rate;
   • moderate risk (for those undergoing routine percutaneous intervention) carries a 1% to 3% complication rate; and
   • high risk, with a >3% complication rate.

6. Proposed criteria for assessment of vascular complications include
   • access-site–related bleeding,
   • vascular injury,
   • access-site–related neurological injury, and
   • access-site–related infection.

7. ACDs may be either passive-closure or active-closure devices. The risk of vascular complications is based on their mechanisms of action.

8. Nonrandomized observational registry data confirm the efficacy of ACDs but provide no definitive evidence as to their safety compared with manual compression nor of their safety and efficacy relative to each other.

9. The statement makes the following recommendations (and cites class and level of evidence) regarding ACD use:
   • patients should undergo a femoral angiogram to ensure anatomic suitability for their use;
   • facilities doing manual compression should achieve low vascular complication rates in patients undergoing angiography;
   • ACD use is reasonable after invasive cardiovascular procedures performed via the femoral artery to improve patient comfort and achieve faster hemostasis and ambulation;
   • ACDs should not be used routinely for the specific purpose of reducing complications; and
   • complications encountered should be collected systematically and reported.

10. ACDs have the potential to improve patient comfort but the available evidence is limited. Randomized studies should be done in relevant populations with varying risk to evaluate clinical outcomes. Until then, use of ACDs remains dependent on the physician’s assessment of individual patient risk/benefit analysis.