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Clinical Evidence Summary

Vascular Closure Devices

This Clinical Evidence Summary was performed to evaluate the products available in the United States for ***Vascular Closure Devices (VCD)***.

VCDs are classified into two types of closure. Passive closure devices are used to assist in manual compression (MC) by enhancement or promotion of coagulation, by wire-stimulated track thrombosis, or by enhanced manual compression. These devices do not afford immediate closure but improve on manual compression.

Active closure devices include collagen-based devices or suture- based devices. These can achieve hemostasis within 5 minutes, with minimal or no MC.

Professional Society Statements

2013 Society of Interventional Radiology Standards of Practice Committee guidelines:

Conclusions

A. Deployment success rates for VCDs, independent of mechanism, are very high.

B. The use of VCDs, independent of mechanism, result in shorter time to hemostasis and decreased time to ambulation.

C. VCDs, independent of mechanism, are generally safe, with complication rates not significantly greater than that of manual compression, with the VasoSeal device representing a notable exception.

D. There is insufficient data to support comparative analysis of the relative efficacy and safety of different types of VCDs.

E. Although the preclosure technique represents an innovative and potentially beneficial approach to the treatment of large arteriotomies, there is at present a paucity of data to establish its noninferiority or superiority to traditional surgical approaches.

Recommendations

A. Further study of the safety and efficacy of VCDs in patients undergoing interventional radiologic procedures is needed.

Summary

- Manual compression is still the gold standard method for obtaining hemostasis at the access site.
- Hemostasis pads and gels deliver to faster hemostasis (in conjunction with manual hemostasis) but has no effect on shortening prothrombotic material that accelerate the clotting cascade that leads post hemostasis bedrest or hastening ambulation.
- In an effort to minimize patient complications, choosing a femoral artery puncture site should be facilitated by fluoroscopic landmark identification or ultrasound guidance.
- Vascular closure devices achieve faster hemostasis, which allows for earlier ambulation, improved patient satisfaction, and possibly shorter hospital length of stay.
- In the absence of a radial approach, obese patients whose body habitus may limit effective manual compression, or individuals who cannot tolerate prolonged periods in a supine position, should undergo closure using a vascular closure device.

B. Femoral angiography should be considered before deployment of a VCD.

C. The use of VCDs may be considered a safe method to reduce time to hemostasis and duration of bedrest following transarterial intervention. The potential benefits of these devices should be balanced by a careful evaluation of patient-related risk factors, vascular anatomy, body habitus, and bleeding risk. The appropriate duration of bedrest and manual compression following VCD use vary among different devices, and the individual manufacturer's recommendations should be followed.

D. Institutional complication rates for VCDs should be, at minimum, equivalent to the complication rates of manual compression.

E. VCDs should not be used for the explicit goal of reducing vascular complications.

F. There is insufficient evidence to support the routine use of VCDs in arterial grafts or stents.

G. There is insufficient evidence to support the routine use of VCDs for the explicit purpose of healthcare cost reduction.

H. Some institutions regard the use of VCDs as an independent procedure, requiring separate informed consent, repeat preparation of the sterile field, and/or use of prophylactic antibiotic agents. Discussing the unique risks and benefits of VCDs with patients before the initiation of any procedure in which such devices may be used is recommended.

2011 ACCF/AHA/SCAI Practice Guidelines for Percutaneous Coronary Intervention
Recommendations

- Class I – Patients considered for vascular closure devices should undergo a femoral angiogram to ensure their anatomic suitability for deployment (Level of Evidence: C)
- Class IIa – The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression (Level of Evidence: B)
- Class III: NO BENEFIT – The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding (Level of Evidence: B)

Clinical Evidence

The results of four meta-analyses have found that vascular closure devices decrease time to hemostasis compared with manual compression but do not decrease vascular complications, bleeding complications, or the need for blood transfusions. Future studies of vascular closure devices need to be randomized to include "high-risk" patients and "high-risk" anatomy, and be adequately powered to detect clinically important endpoints, particularly bleeding and vascular complications.[6,7,8,9] In the randomized controlled trial (ISAR-CLOSURE trial),[1] 4,524 patients undergoing coronary angiography with a 6-Fr. sheath via the common femoral artery were enrolled.

The primary outcome was the incidence of vascular site complications, including major bleeding, infection, leg ischemia, and the need for surgical repair or endovascular treatment. The study found that the access site-related complications were identified in 6.9% assigned to the VCD groups and % assigned to the manual compression group, confirming the noninferiority of VCDs.

The multicenter PEVAR trial[2] enrolled 151 patients undergoing aneurysm repair in a 2:1 ratio comparing percutaneous VCD and open femoral exposure. The primary endpoints were defined as procedural technical success, absence of major adverse events, and incidence of access-related complications. Similar to the ISAR-CLOSURE trial, noninferiority was demonstrated in VCD compared with standard open femoral exposure. A systematic review was completed to include all available RCTs comparing vascular closure device use to manual compression.

A review of 34 RCTs demonstrated that the utility of VCDs had shortened time to hemostasis, ambulation and discharge, compared to patients receiving MC. Over the last decade, with emphasis on and implementation of same-day procedures, use of VCDs has resulted in a reduction in time to discharge to half a day and a significant decrease in cost. Overall complication rates are similar, but vary between different devices on the market. Better short-term quality of life has also been described with the use of VCDs compared to MC.[3]

Physician Feedback

The Clinical Research team received feedback on vascular closure devices from interventional cardiologists, interventional radiologists, and vascular surgeons. These HealthTrust Physician Advisors felt that any of the FDA-approved vascular closure devices are acceptable, and pointed out that any device is appropriate if the implanter is comfortable with the product and it results in no complications.

The physicians who rely on large bore closure felt most comfortable with the older suture-based VCD, using two devices to safely accomplish hemostasis. They did point out that newer suture-based products only require one device, but, in their opinion, are unreasonably priced. The interventional cardiologists also felt comfortable with the collagen-based products that have been on the market reliably for some time, but had concerns about use in atheromatous arteries or the issue with scarring with the use of these devices.

The physicians felt comfortable with the VCD patch devices available on the market. The majority of our advisors rely more on collagen, suture, or plug type vascular closure.

A quality aspect that was shared repeatedly by the physicians was the need to use imaging to verify access site prior to femoral sticks. This is also a Class one recommendation from the professional society guidelines. Consideration should be taken that this adds cost and resources to the case.

The physicians also spoke of two products that are showing promise and approved for use in the EU for large bore closure: the PerQSeal and InSeal. Neither is currently FDA approved.

Considerations

For patients at high risk for difficult access or complications, ultrasound guidance can help clinicians obtain vascular access with greater accuracy, greater speed and fewer complications.

Clinical trials and meta-analyses have demonstrated that vascular closure devices do not lower bleeding or vascular complications compared with manual compression.[4] To this end, current ACC/AHA guidelines do not recommend routine use of vascular closure.[5]

No sizeable randomized trial comparing the safety and efficacy of each device has been conducted.

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Product Comparison

A product comparison chart is available for HealthTrust members in the Contract Launch Package. If further information is needed beyond this, please contact the appropriate supplier.

References

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