



Pre-deployment imaging

Consider using ultrasound or angiogram as these can ensure that:

- the puncture is in a location where a vascular closure device (VCD) can be used safely
- there is no significant vascular disease at the puncture site
- the VCD is appropriate for the vessel size
- there are no secondary bleeding sites.

Angle of insertion

Ensure the angle of insertion of the VCD is correct to enable optimal deployment and to avoid difficulty in removing the delivery device from the patient.

Wound healing

Ensure patients are adequately educated on the healing process, side effects, symptoms that should be reported, and instructions to modify their behaviour and activity for the first 72 hours to ensure haemostasis is maintained until full wound healing.

Existing haematomas

Use caution when deploying VCDs into existing haematomas as incorrect positioning may occur.

Instructions for use

Always follow manufacturer's instructions for use and ensure that all users are trained to use VCDs correctly.

Report device or use-related adverse incidents to the MHRA www.mhra.gov.uk

Vascular closure devices – case studies

All VCDs are different and manufacturers provide training to ensure they are used safely and appropriately. In addition, it should be noted that instructions may be revised and updated as technology evolves and adverse incidents are learned from. Ensure you are familiar with the device-specific instructions for use. Access site audit should be a core process in centres using these devices.

A 54 year old female underwent a coronary angiogram with access from the right femoral artery. Haemostasis was achieved without complication using a VCD. After discharge, the lady returned to Accident and Emergency with a cold and numb leg. Examination elicited signs consistent with peripheral vascular occlusion. A vascular surgeon removed the VCD in the emergency theatre and noted that the femoral artery contained a significant amount of plaque. He concluded that some plaque may have dislodged or prevented the VCD from sitting correctly in the artery, resulting in embolisation of the device.

A vascular surgeon who had been trained in the use of the VCD attempted femoral artery closure after a peripheral angioplasty. After deployment of the device, he was unable to remove the delivery system despite attempts to free it. The delivery system was eventually removed with one swift sharp pull and manual compression was subsequently required for 30 minutes to achieve haemostasis. Investigation of the damaged delivery system indicated it was inserted at an incorrect angle between the VCD and patient when deploying.

A 63 year old male underwent an uncomplicated aortic endovascular graft procedure and at the end a vascular closure device (VCD) was deployed and haemostasis achieved. Two hours following the procedure the patient's blood pressure dropped and he was returned to theatre for evacuation of a retroperitoneal haematoma. The surgeon noted that the femoral puncture site was high on the artery and that this may have contributed to the retroperitoneal bleed.

Following an uncomplicated removal of an inferior vena caval filter, a VCD was deployed without complications. The patient was safely discharged on the same day. 24 hours later, while out bicycling, the patient felt a pop in his leg. He was taken to Accident and Emergency and required 3 units of blood to be transfused after manual compression achieved haemostasis.

Following emergency coronary angioplasty, during which the patient developed a wound site haematoma, application of a VCD was attempted. Following deployment, bleeding continued and manual compression was applied for Two hours. An ultrasound was performed and revealed a large haematoma that was still bleeding and it was noted the device had been deployed subcutaneously, thus was not sealing the puncture site.

A 44 year old male underwent a right renal artery stenting procedure with access from the right femoral artery. A VCD was used successfully. Three hours later, immediately prior to discharge, a significant amount of bleeding from the groin access site was noted. Haemostasis was achieved through the application of manual pressure and diagnostic imaging revealed a second puncture in the posterior wall of the artery.

Reporting adverse incidents

All adverse incidents involving medical devices should be reported to the MHRA as soon as possible, even if user error (rather than a device problem) is suspected.

Use our online reporting systems on www.mhra.gov.uk

Alternatives: Email aic@mhra.gsi.gov.uk or ring on 020 3080 7080