

*This edition flags up, again, the ever present spectre of wrong side surgery. Three cases of complications of arterial closure devices collectively highlight adverse effects of these adjuncts to vascular radiological procedures, but the cases also reveal other systematic problem areas, provoking commentary. Trainee participation in the CORESS reporting process is encouraged.*

*We are grateful to the clinicians who have provided the material for these reports. The on-line reporting form is on our website [www.cores.org.uk](http://www.cores.org.uk) which also includes all previous Feedback Reports. Published contributions will be acknowledged by a "Certificate of Contribution" which may be included in the contributor's record of continuing professional development.*

### NO SIGHT, WRONG SITE?

(Ref: 87)

A man was referred by his GP for repair of a LEFT inguinal hernia. He was seen by a Consultant during a waiting list initiative clinic. The Consultant listed the patient for LEFT inguinal hernia repair and dictated a reply to the GP, confirming the presence of a LEFT-sided hernia. The patient signed a consent form for a LEFT inguinal hernia repair, in the clinic, as part of the pre-operative paper work. On admission for surgery, the admission card and printed operation list identified the patient for LEFT inguinal hernia repair. After talking to the patient on the day of admission, the admitting nurse queried of the surgical team as to whether the side had been listed correctly. The hernia was subsequently demonstrated to be on the RIGHT side.

#### Reporter's Comments:

This episode consisted of a perpetuated series of errors. The GP's letter listed the hernia as being on the wrong side. The Consultant probably examined the patient but inadvertently confirmed the presence of the hernia on the incorrect side in his clinic letter to the GP. This error was perpetuated in the subsequent correspondence and paperwork until direct questioning by a nurse broke the cycle of misinformation. The nurse correctly drew this to the attention of the surgical team.

Despite the patient's signed informed consent, it would have been the responsibility of the operating surgeon to have examined the patient pre-operatively and marked the correct side. Hopefully this, and use of the pre-operative WHO checklist, would have prevented wrong side surgery.

#### CORESS Comments:

The potential for propagation of misinformation, particularly with respect to side of operation, should be appreciated by all surgeons. The patient cannot be relied upon to correct errors or omissions on a consent form. Nursing pre-assessment clinics may concentrate on fitness for anaesthesia rather than site of surgery. Risk of wrong side surgery is increased where the surgeon has not examined a patient pre-operatively or in the clinic, and this risk may be increased in relation to pooled lists. Marking of the correct side forms an essential part of the pre-operative assessment and a patient should not be allowed to proceed to theatre unless this has been undertaken. Anaesthetic room and WHO checklists are final fall-back positions, but the onus for confirming the correct side of surgery will always lie with the operating surgeon who must examine the patient pre-operatively.

### LIMB ISCHAEMIA AS A COMPLICATION OF VASCULAR CLOSURE DEVICE (1)

(Ref: 89)

A 64 year old man with claudication was admitted as a day-case for a proximal right superficial femoral angioplasty. Because the stenosis was very proximal, a retrograde contralateral approach was used from the left groin. Proximal and mid-superficial femoral angioplasty was successfully undertaken on the right leg. A percutaneous closure device was used to seal the arterial puncture site in the left groin. The patient presented the same night with an acutely ischaemic left leg. There was a short occlusion at the site of the puncture in the common femoral artery, due to luminal thrombosis in association with arterial wall damage caused by the closure device. The artery was explored and thrombectomy with patch repair of the common femoral artery undertaken. The patient subsequently required additional revision surgery of the common femoral artery in the groin, due to recurrent stenoses.

#### Reporter's Comments:

Patients require very careful assessment after any percutaneous procedure. Closure devices are associated with specific complications. When there is any evidence of limb ischaemia after interventional radiology using arterial closure devices, appropriate imaging should be undertaken.

#### CORESS Comments:

Most arterial puncture sites undertaken in association with peripheral angioplasty can be controlled by a period of conscientious sustained pressure on the artery. Control is more difficult where the puncture site is above the inguinal ligament, inadvertently involves the profunda femoris artery or in the obese patient. Use of large bore catheters and patient anticoagulation may also influence the decision to deploy a closure device. Numerous complications have been associated with use of closure devices including early and late thrombosis, arterial damage and infection [1]. Such devices should only be deployed after careful consideration of the individual patient's circumstances.

Records of complications should be discussed between surgeons and radiologists in multidisciplinary meetings, so that a realistic overview of potential complications associated with use of such devices can be appreciated by those who deploy them.

#### Reference:

- [1] Biancari F, D'Andrea V, Di Marco C et al. Meta-analysis of randomized trials on the efficacy of vascular closure devices after diagnostic angiography and angioplasty. *Am Heart J.* 2010 Apr;159(4):518-31.

## LIMB ISCHAEMIA AS A COMPLICATION OF VASCULAR CLOSURE DEVICE (2) (Ref: 90)

A 66 year old lady was admitted for day-case right superficial femoral angioplasty for intermittent claudication. The lesion in the superficial femoral artery was proximal and a retrograde contra-lateral approach was used, from the left groin. Because the intended procedure was undertaken as a day case, a percutaneous closure device was placed in the left femoral artery. Immediately after this, the left leg appeared pale. A CT arteriogram was undertaken and demonstrated a slightly narrowed, but patent common femoral artery. The patient was admitted overnight for observation. The following day the limb was not thought to be at threat, although the resting ankle brachial pressure index (ABPI) in the left leg had dropped to 0.50, compared to a pre-intervention ABPI of 0.9. The patient was allowed home. She presented 14 days later with rest pain in the left leg. In the interim she had attended A & E twice, had seen her GP once and had contacted NHS Direct. On all occasions her symptoms had been dismissed. She was admitted directly from the vascular clinic with left common iliac artery thrombosis secondary to femoral artery occlusion and an ischaemic ulcer on the back of the left calf. Her common femoral artery was explored, thrombectomy of the iliac artery undertaken and the femoral artery, which had an extensive dissection

flap at the site of the percutaneous closure device, was repaired with an interposition graft. Following debridement, the ischaemic ulcer was skin grafted.

### Reporter's Comments:

Use of a percutaneous closure device was associated with arterial injury. Clues suggesting significant post-interventional arterial flow impairment were ignored. A system for appropriate follow-up in the case of post-procedural complications must exist. This might have been achieved by improved discharge communications between surgeon and GP.

### CORESS Comments:

Several factors merit discussion here. Appropriate follow-up imaging should be undertaken urgently when there is deterioration following radiological arterial intervention. Indications for re-intervention will be dependent on the case in question, but the decision to discharge a patient in the event of deterioration should be made by someone with appropriate seniority and experience. Avenues for urgent re-referral should be discussed explicitly with the patient prior to discharge and the GP should be provided with an early summary of the patient's treatment episode. Early planned follow-up in a case such as this is advisable.

## LIMB ISCHAEMIA AS A COMPLICATION OF VASCULAR CLOSURE DEVICE (3) (Ref: 91)

A 72 year old lady presented with established gangrene of her left forefoot. She was warfarinised for a prosthetic mitral valve replacement, with a current INR of 7.5. CT angiography confirmed a calcified and stenosed (60%) left common iliac artery, a good external iliac artery and a 2cm stenosis of the distal left superficial femoral artery. Angioplasty had to be delayed until 3.00pm on a Friday afternoon to allow reversal of anticoagulation. The iliac stenosis was dilated and a stent inserted. Following intervention, there was some bleeding from the groin (anticoagulation not having been fully reversed) and, to avoid a second downstream puncture, it was felt that, having dealt with the proximal stenosis, the more distal stenosis could wait until after the weekend. Due to the bleeding from the groin, a percutaneous closure device was inserted in the left common femoral artery. In the recovery area, the limb appeared cool and pale, but a duplex ultrasound was undertaken, which showed the closure device to be in a good position with flow below this.

The patient was transferred back to the ward for observation and commenced on heparin. One hour post-procedure the limb was still cool, although the patient denied pain and had full movement and sensation. The vascular Consultant took the locum Consultant covering for the weekend to see the patient and explained that he thought that further intervention may eventually be required but that it was too early to see if the limb was going to improve. The vascular Consultant returned on Monday morning. The locum stated that the patient had remained comfortable although the limb still looked slightly "blotchy".

When the vascular Consultant reviewed the limb, it was instantly apparent that the leg was irreversibly ischaemic with fixed contractures of the calf muscles and mottling to the groin. Imaging showed that the common femoral

artery was occluded. The closure device had caused dissection of an atherosclerotic plaque, occluding the artery. The common femoral artery was reconstructed with a graft to the profunda femoris artery, to salvage an above-knee amputation which was performed at the same time. The original bleeding in the groin was found to have been from a transected vein at the puncture site.

### Reporter's Comments:

The percutaneous closure device was associated with arterial injury. Inadequate follow-up cover by someone inexperienced in assessment of vascular deterioration was arranged, despite a formal handover. Where specialist assessment is required, this must be formally arranged, ideally between the responsible surgeon and the Consultant surgeon on-call.

### CORESS Comments:

Having accepted the points made with respect to percutaneous closure devices in the previous two cases, the essence of this case revolves around the responsibility for continued and appropriate care. It is essential, in cases such as this, that a named and appropriately qualified clinician assumes responsibility for clinical care. Whilst the onus here may appear to rest with the vascular surgeon, in the modern health service appropriate provision should be made for continuity of specialist care. Rotas for emergency vascular cover should be in place if an institute is to undertake vascular intervention. In this case, formal reassessment by an on-call vascular surgeon, as part of a covering on-call vascular rota, recommended by Vascular Society guidelines [1], should have been put in place.

### Reference:

[1] [http://www.vascularsociety.org.uk/library/vascular-society-publications/doc\\_download/65-the-provision-of-services-for-patients-with-vascular-disease-2009.html](http://www.vascularsociety.org.uk/library/vascular-society-publications/doc_download/65-the-provision-of-services-for-patients-with-vascular-disease-2009.html)

## FINALLY...Slip on down!

The MHRA is aware of a number of falling accidents that have occurred when patients wearing anti-embolism hosiery have been allowed to walk around with no other foot covering, owing to the slippery nature of this material. Always ensure that patients wearing compression hosiery are encouraged to wear slippers or non-slip footwear when mobilising.

### Trying it on?

The MHRA has been made aware of a number of instruments, such as ophthalmic surgical lasers and surgical diathermy, which have failed to function but only discovered after the patient was anaesthetised.

All surgical equipment, particularly if infrequently used, should be tested at the beginning of an operating list and prior to any patient being prepped and anaesthetised.

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