Closure devices for femoral punctures

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Although the use of radial arterial access is slowly increasing, the majority of percutaneous coronary and non-coronary interventions use the femoral artery as the site of entry. I will ignore the use of the brachial artery since cut-down techniques are a dying art form, and percutaneous brachial puncture has an unacceptable complication rate. Apart from reasons of familiarity and training, there are several good reasons to maintain the "old" skill of femoral access. The ability to upscale to larger catheter sizes for more complex interventions such as carotid and thoracic stenting, and the use of some types of thrombus extraction devices needing 7F and 8F sheaths, maintain the need for femoral access for the present. Imaging of venous and arterial bypasses to the coronary arteries is also often more easily done from the leg than the arm. In the future, device implantation for paravalvular leaks and percutaneous valves, both needing large access sites, may gain favour, and are unlikely to be achievable from smaller arteries such as the radial.

However, the reason for the growth of radial access is its twofold ability to allow mobilisation of patients more rapidly and reduction of the risk of access-site complications. Have devices that close the hole in the femoral artery matched either of these benefits?

The three main types of devices used are a suture (Perclose; Abbott Vascular, Illinois, USA), an intravascular plug (Angioseal; St Jude Medical, Minnesota, USA) or a metal clip external to the lumen (Starclose; Abbott Vascular). In our centre nearly all femoral punctures are closed with a device, unless the puncture is not "clean" (the artery may have been hit twice) or the femoral angiogram shows severe disease and there are concerns about vessel patency.

ASSISTING MOBILISATION OF THE PATIENT

After removal of an arterial sheath, haemostasis can be achieved by manual compression, followed by a period of 4-hour bed rest, and slow ambulation 2 hours later. Manual compression and prolonged bed occupancy is uncomfortable and has cost implications.[1 2] Few studies, however, have looked from the patient perspective. Efficacy of devices can be assessed by looking at time to haemostasis, time to ambulation and time to discharge.

Data suggesting a 15-minute shorter time to haemostasis appear robust. Time in bed is often driven by protocols and so is harder to assess in studies, but again favours device closure by several hours. The same is true of length of stay in hospital. Although shorter by 0.6 days (95% confidence interval (CI) 0.1 to 1.1 days) in a meta-analysis, there was evidence of publication bias in favour of device closure.[3] Proving that this reduction provides a cost saving is even more difficult.[4 5]

REDUCING COMPLICATIONS

Manual compression can be associated with vaso-vagal reactions due to the pain of pressing hard, while most closure devices are associated with a degree of discomfort during deployment. Well-recognised complications of arterial (and venous) puncture are haematoma, bleeding, pseudoaneurysm formation, arteriovenous fistula formation with surgical intervention being needed. One observational study of over 5000 patients using manual compression compared with the Angioseal device suggested that complication rates are increased, with rates of up to 9.3% with device closure versus 5.1% with manual compression ($p<0.001$).[6] In addition, the need for surgical intervention was increased from 1.5% to 2.5% ($p<0.001$) in the device group.

However, a meta-analysis of 30 studies with 3000 patients provided no evidence that complication rates were decreased or increased. Most confidence intervals were wide, and embraced equivalence. The relative risk ratio of leg ischaemia (mentioned in seven studies) was closest to showing harm with devices (hazard ratio = 2.10, 95% CI 0.97 to –4.58).[3] A second meta-analysis totalling over 37 000 patients, that included cohort and case–control studies, including the one mentioned above, as well as randomised trials, concluded similarly that there was no evidence of increased risk with the Angioseal or Perclose devices for diagnostic or interventional procedures.[6 7] In fact, the Angioseal device had a trend towards reduced complications during interventional procedures (odds ratio = 0.46, 95% CI 0.20 to 1.04, $p = 0.062$). However, these authors detected an increased risk after interventional procedures using the Vasoseal device (odds ratio = 2.25, 95% CI 1.07 to 4.71). When all data from all device types, in all types of studies were pooled, there was a small benefit from manual compression over device closure, but with considerable heterogeneity within the studies.[7] Since only 10% of the data came from randomised patients, information to date suggests that, overall, closure devices are probably safe, but does not prove it.

CLOSING VENOUS PUNCTURES

Femoral venous puncture does not carry the same risk of complications as arterial puncture, despite the large sheath sizes (up to 14F) used for electrophysiological procedures and percutaneous atrial septal defect and patent foramen ovale closure. Despite full heparinisation, immediate haemostasis is achieved with 10 minutes of manual compression in most cases. Is there a merit then in device closure?

In this issue of *Heart*, Mahadevan and colleagues show a consecutive series of 146 patients in whom venous punctures as large as 14F have been closed with suture devices (***see article on page 571***).[8] They confirm that it is safe to do so, with a 1.4% major complication rate. No patient needed radiological or surgical intervention. They also present acceptable duplex findings of the femoral veins in their initial cohort to confirm this. In addition, all patients were discharged home on the same day. However, 4% of patients did develop a late ooze >60 minutes after the closure, requiring manual compression. A single device was placed even in large holes, unlike the device that would be required for such a hole in the femoral artery. There was no control group, however, and Mahadevan *et al* do not show data on complications, or more importantly, discharge times for patients treated with manual compression alone. Theoretically, mobilisation may be quicker with a closure device, but this needs to be proved before routine use of

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such devices in veins can be recommended.

FUTURE TRIALS

In future trials, clear definitions of end points such as haematoma and bleeding are needed. An end point at hospital discharge is also probably not adequate as some complications, such as arteriovenous fistulae, infection, or pseudoaneurysm, may not present till later.[9–12] Given the varying sheath sizes and anticoagulation regimens, separate trials in a diagnostic and interventional setting should be arranged, since combining them may lead to confusion.[13]

CONCLUSION

In real life, in centres that regularly use devices, manual compression probably carries higher risks than predicted, as it requires a meticulous technique that can only come from regular practice. In addition, those cases that then have manual compression, do so for reasons such as difficult access, poor vessels, known peripheral vascular disease, etc, all features that predispose to complications. This is balanced against the learning curve for any new closure device. A change in device must be preceded by adequate training in its use and the management of complications.[14]

The use of arterial closure devices in a time-strapped setting is likely to increase further, but it should be realised that they are used to save time, but probably not money, and certainly not complications. Their use in veins is even less evidence based.

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Notes