Vascular closure devices for femoral arterial puncture site haemostasis (Protocol)

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Vascular closure devices for femoral arterial puncture site haemostasis

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A B S T R A C T

This is the protocol for a review and there is no abstract. The objectives are as follows:

The aim of this review is to determine the efficacy and safety of VCD versus the traditional methods of MC or MCD, or both, to achieve haemostasis after both retrograde and antegrade percutaneous arterial puncture of the CFA. In addition, the utility of VCDs in the setting of percutaneous EVAR will also be evaluated. This review will provide an overview of existing evidence on the full utility of VCDs and other methods to achieve haemostasis in every aspect of diagnostic and interventional procedures.

B A C K G R O U N D

Description of the condition

The common femoral artery (CFA) is the most frequently used vascular access site to perform catheter-based diagnostic procedures and interventions. The standard retrograde CFA puncture is most commonly used. This refers to the placement of the needle in the CFA against the direction of arterial flow. After arterial access is established, a catheter sheath is inserted at the beginning of the procedure to provide support at the puncture site thus allowing multiple guidewire and catheter exchanges. Manual compression (MC) has been the primary method to achieve haemostasis following removal of the catheter sheath. In MC pressure is applied for

10 to 15 minutes over the puncture site, or until bleeding stops, followed by bed rest for an additional four to six hours; the most 'restrictive' practice mandates 24 hours bed rest.

Mechanical compression devices (MCDs) such as mechanical clamps, inflatable pressure devices and manual pressure aids can be used as an adjunct or alternative to manual compression in order to attain haemostasis. This may be considered less labor-intensive than applying manual compression alone. These MCDs have high technical success rates in achieving groin haemostasis; however, they do not shorten the time to ambulation or discharge compared with MC (Schwartz 2010). Although the traditional methods of MC or MCD, or both, have been successful in achieving groin haemostasis in the majority of patients, there are potential areas of shortcomings. These include the following.

1. Local anatomy (adiposity, underlying arterial calcification, etc.).

2. Medical co-morbidities (heart failure, respiratory illness, musculoskeletal ailments, etc.) that preclude patients from laying flat for a prolonged period of time.

3. Patients who are unable to follow instructions (delirium etc.) preventing a patient from lying still for a prolonged period of time.

4. Anti-platelet medications (heparin, clopidogrel, glycoprotein IIb/IIIa inhibitors) administered prior to or during the procedure, which may increase the risk of bleeding complications.

5. Limitations in human resources and physical fatigue associated with MC.

6. Time spent in angiography suite, time to ambulation and length of hospital stay, which will all have an impact on the overall financial cost.

Description of the intervention

Vascular closure devices (VCDs) have been developed to reduce the time to achieve haemostasis and reduce time to ambulation so that early outpatient discharge can be achieved. Various VCDs have been designed. They can be broadly classified according to their mechanism to achieve haemostasis with the recommended sheath size (Table 1). In addition to potential vascular access site complications, VCDs may have device specific complications. These can include arterial trauma during device deployment, embolisation of the intra-arterial anchor or the intended extra-arterial sealant, inflammation and infection of the tissue tract.

Although there are ample studies on the performance of VCDs in retrograde punctures, there is less robust evidence on the use of VCDs with the antegrade puncture (Chiu 2008). Antegrade puncture refers to the placement of an angiographic needle in the CFA in the direction of arterial flow. In infrapopliteal and infrainguinal endoluminal interventions an ipsilateral antegrade CFA puncture is often preferred as compared to a contralateral retrograde CFA puncture. This is due to anatomic or technical reasons, such as vessel occlusion, calcification or simply being unable to reaching the target from a contralateral approach (Wheatley 2011). Antegrade puncture may provide better support and easier manipulation of the catheter and wire. Antegrade puncture usually requires a much higher puncture than retrograde puncture with a longer subcutaneous tract that may be compromised by the abdominal apron (Nice 2003), thus haemostasis with manual compression may be more difficult in with overweight patients (Biondi-Zoccai 2006).

VCDs are now also utilised in the closure of a large percutaneous arteriotomy site, that is during totally percutaneous endovascular aortic aneurysm repair (EVAR). Endovascular aortic aneurysm repair mandates the use of much larger sheaths (generally 18 to 20 French) than coronary or peripheral interventional procedures

(5 to 7 French). Recent advances in stent-graft technology with development of smaller profile delivery systems have made totally percutaneous EVAR a feasible option. Perclose ProstarXL (Abbott) is the main device approved for percutaneous closure after intervention with large bore sheaths (Malkawi 2010). The Prostar XL 8 is designed for closure of 6.5 to 8 French access sites and Prostar XL 10 is for closure of 8.5 to 10 French access sites (Arslan 2009). Although the ProstarXL is the only device with formal approval for use in EVAR, several investigators have used the Proglide system (Abbott) off-label (Malkawi 2010).

Why it is important to do this review

VCDs are widely used to establish haemostasis after arteriotomy and the role of VCDs is ever expanding. The emergence of newer devices means there is a need to review the up-to-date evidence on efficacy and safety. Current decisions on use of VCDs are currently based on operator preference, time constraints, requirements for repeat vascular access and size of the arteriotomy. Our review will include analyses of existing evidence from randomised controlled trials on the use of VCDs to make clinically relevant recommendations.

O B J E C T I V E S

The aim of this review is to determine the efficacy and safety of VCD versus the traditional methods of MC or MCD, or both, to achieve haemostasis after both retrograde and antegrade percutaneous arterial puncture of the CFA. In addition, the utility of VCDs in the setting of percutaneous EVAR will also be evaluated. This review will provide an overview of existing evidence on the full utility of VCDs and other methods to achieve haemostasis in every aspect of diagnostic and interventional procedures.

M E T H O D S

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled clinical trials comparing vascular closure devices (VCDs) against manual compression (MC) or mechanical compression devices (MCDs), or both, for achieving common femoral artery (CFA) puncture site haemostasis. The review will also encompass comparisons between different vascular closure devices.

Types of participants

All studies involving patients of both genders undergoing a diagnostic or interventional procedure where vascular access was achieved through percutaneous puncture of the common femoral artery.

Types of interventions

1. Haemostasis after diagnostic or interventional endovascular procedures (sheath size ≤ 9 Fr):
    i) vascular closure device (VCD) versus manual compression (MC) or mechanical compression device (MCD), or both;
    ii) one type of VCD versus another.
2. Haemostasis after percutaneous EVAR (sheath size ≥ 10 Fr):
    i) one type of VCD versus another.
3. Haemostasis after EVAR with open exposure of CFA (sheath size ≥ 10 Fr):
    i) one type of VCD versus another;
    ii) surgical suture mediated closure versus VCD.

Types of outcome measures

Primary outcomes

Primary end point: efficacy

1. Time to haemostasis, measured in minutes. Haemostasis is defined as no or minimal subcutaneous oozing and the absence of expanding or developing haematoma.
2. Time to mobilisation is defined as time from removal of the introduced sheath to when the patient was able to mobilise without recurrence of bleeding.
3. Major adverse event (any time):
    i) mortality;
    ii) vascular injury requiring vascular repair by surgical or non-surgical techniques.

Secondary outcomes

1. Adverse events (30 days after arterial closure):
    i) infection;
    ii) groin haematoma;
    iii) retroperitoneal haemorrhage;
    iv) pseudoaneurysm;
    v) arterial dissection;
    vi) arteriovenous fistula;
    vii) embolisation resulting in loss of distal pulse;
    viii) deep vein thrombosis;
    ix) limb ischaemia;
    x) femoral artery thrombosis.

2. Technical failure of VCDs.
3. Time spent in angiography suite.
4. Length of hospital stay.
5. Patient satisfaction.
6. Cost of VCD and MCD.

Search methods for identification of studies

Electronic searches

The Cochrane Peripheral Vascular Diseases (PVD) Group will search their Specialised Register and the Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library* at www.thecochranelibrary.com. The Specialised Register is maintained by the Trials Search Co-ordinator and is constructed from weekly electronic searches of MEDLINE, EMBASE, CINAHL and AMED; and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used, are described in the Specialised Register section of the Cochrane PVD Group module in *The Cochrane Library*.

Searching other resources

We will search citations within identified studies and contact authors of the identified studies about unpublished studies. We will contact manufacturers of the devices for unpublished and published studies. There will be no restriction on language.

Data collection and analysis

All randomised or quasi-randomised trials that compare the safety and efficacy of vascular closure devices with manual compression or mechanical compression methods, or both, are eligible for inclusion.

Selection of studies

Two authors (CC-TH and GNCK) will independently assess studies identified for inclusion in the review using the criteria stated above. We will resolve disagreements between the two authors by discussion or by consulting a third author (MLvD).

Data extraction and management

Two authors (CC-TH and GNCK) will independently extract data from the included studies using a standard data extraction form created for the review.

Assessment of risk of bias in included studies

The authors (CC-TH, GNCK and MLvD) will assess the risk of bias for each study as described in the *Cochrane Handbook for Systematic Reviews of Interventions* 5.0.1 (Higgins 2008). The authors will assess the risk of bias for each of the following domains:

1. randomisation sequence generation;
2. allocation concealment;
3. blinding (of participants, personnel and outcome assessors);
4. completeness of data;
5. selective outcome reporting;
6. other sources of bias.

The authors will evaluate each criterion as 'Low risk' of bias or 'High risk' of bias. If these criteria are not discussed in the publication, the authors will assess the risk of bias as 'Unclear'.

Measures of treatment effect

When dealing with dichotomous outcome measures, we aim to calculate a pooled estimate of the treatment effect for each outcome across trials using the odds ratio (OR) (the odds of an outcome among treatment-allocated participants to the corresponding odds among participants in the control group) and estimate the 95% confidence interval (CI). For continuous outcomes, we plan to record either mean change from baseline for each group or mean post-intervention values and standard deviation (SD) for each group. Then, where appropriate, we will calculate a pooled estimate of treatment effect by calculating the mean difference and SD.

Unit of analysis issues

We will not include cross-over trials in the review because there is only a single treatment designated to each group. In the case of cluster-randomised trials, where the unit of randomisation is not the same as the unit of analysis, we will perform appropriate adjustment for clustering as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009).

Dealing with missing data

The review authors will request any missing data from the original investigators, if appropriate. If these cannot be obtained we will carry out an intention-to-treat (ITT) analysis. For the ITT analysis we will use data on the number of participants with each outcome event by allocated treatment group irrespective of compliance and whether or not the participant was later thought to be ineligible or otherwise excluded from the treatment or follow up.

Assessment of heterogeneity

We will assess heterogeneity using a two-staged approach. Firstly, we will assess face value heterogeneity (for example population, setting, risk of complications). Secondly, we plan to assess statistical heterogeneity in the meta-analysis using the I^2 statistic (Higgins 2009). Reasons for heterogeneity will also be explored. A guide to interpretation of the I^2 statistic is described in the Cochrane Handbook (Higgins 2009) as: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; 75% to 100% represents considerable heterogeneity. The observed importance of the I^2 statistic depends on factors including: (i) magnitude and direction of effects, and (ii) strength of evidence for heterogeneity determined by the P value from the Chi^2 test or a confidence interval for the I^2 statistic (Higgins 2009).

Assessment of reporting biases

We will investigate publication bias using funnel plots if we are able to include a sufficient number of studies (at least 10), as recommended by the Cochrane Handbook (Higgins 2009; Sterne 2001). If we detect asymmetry, we will explore causes other than publication bias. Asymmetrical funnel plots can indicate outcome reporting bias (ORB) or heterogeneity. If ORB is suspected, trialists will be contacted. Outcome reporting bias can be assessed by comparing the methods section of a published trial to the results section, where the original protocol is not available.

Data synthesis

We plan to use a fixed-effect model in our analysis (Higgins 2009). If we detect moderate heterogeneity ($I^2 > 40\%$) we plan to reassess the significance of the treatment effect by using a random-effects model.

Subgroup analysis and investigation of heterogeneity

We will perform the following subgroup analyses.

1. VCD for the conventional interventional vascular procedure using either 5F or 6F introducer sheaths versus VCD requiring larger introducer sheath, i.e. for EVAR.
2. Comparision between antegrade and retrograde punctures.
3. Comparison between diagnostic procedures, interventional procedures and EVAR.

In the presence of heterogeneity, we will explore the impact of each of the trials on heterogeneity by pooling the trials one by one in a sensitivity analysis.

Sensitivity analysis

If possible, we plan to perform a sensitivity analysis to assess the impact of trials with high risk of bias on the overall outcome of the pooling of data. This will be done by gradually adding the trials assessed as having a high risk of bias to the pooled results of trials with a low risk of bias.

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Type of vascular closure devices

Type of vascular closure devices (VCD) classified according to their mechanism to achieve haemostasis	Name	Recommended Sheath size (Fr)	Extravascular Haemostatic agent	Intravascular component
Balloon-based device	The Epiclose-T	6	Temporary extravascular haemostatic balloon which is withdrawn at end of procedure	Temporary anchor balloon which is withdrawn at end of procedure
Disc-based device	Cardiva Catalyst II	4-10		Temporary nitinol-based wire with a nitinol braided mesh disc, which is removed at end of procedure
Collagen-based device	Angio-Seal VIP, Angio-Seal STS Plus, Angio-Seal Evolution	6, 8	Bovine collagen plug, and an absorbable traction suture	Absorbable intraarterial anchor (copolymers of polylactic and polyglycolic acids, are absorbed within 30 days)
	VasoSeal VHD, ED, Elite	5-8	Purified bovine collagen based plug	-
	VasoSeal Low Profile	4, 5	Purified bovine collagen based plug	-
	Duett Pro, Duet	5-9	Thrombin with the platelet activation of collagen	Temporary anchor balloon which is withdrawn at end of procedure
	The 6/7F Mynx, Mynx M5	5-7	Water-soluble, freeze-dried polyethylene glycol (PEG) material	Temporary anchor balloon which is withdrawn at end of procedure
	ExoSeal		PGA (Polyglycolic Acid) , a trusted non-collagen plug material	-
Metal clip-based device	StarClose	5, 6	Nitinol clip	-
	StarClose SE	5, 6	Nitinol clip	-

Table 1. Type of vascular closure devices *(Continued)*

	Angiolink EVS	6-8	Titanium staple	-
Suture-based device	Perclose AT	5-8	Braided polyester suture	-
	Perclose ProGlide	5-8	Monofilament polypropylene suture	-
	Prostar XL	8.5-10	Braided polyester suture	-
	X-Site	5, 6	Braided polyester suture	-
	SuperStitch	6-12	Polypropylene suture	-

• Balloon-based device (Epiclose-T) (Karaklis ju 2008): a temporary balloon-positioning catheters is inflated inside the arterial puncture site while a larger haemostasis balloon is inflated directly on the outer surface of the arteriotomy. The balloon applies direct pressure on the arteriotomy site thus allowing natural coagulation to occur. After a few minutes of device deployment, the anchor balloon is pulled back into the distal end of the shaft while the haemostasis balloon remains pressing against the arteriotomy site. At the end of the haemostasis-waiting period, the haemostasis balloon is deflated and the device is removed, leaving no foreign body in either the intraluminal or extraluminal space.

• Disc-based closure device (Cardiva Catalyst II) (Schwartz 2010): conformable nitinol-based wire with a temporary nitinol braided mesh disc on a tether which is deployed inside the artery to achieve haemostasis. The temporary placement of low-profile, conformable disc against the intima creates a site-specific compression of both the arteriotomy and tract. The haemostatic mechanism is based on the natural elastic recoil of the arteriotomy site back to its pre-dilated state, around the wire. In addition a biocompatible coating on the Catalyst II Wire aides the body's natural haemostatic process and promotes ease of removal. After a few minutes of device deployment, the nitinol mesh disc and wire are then removed, thus leaving no foreign body in either the intraluminal or extraluminal space.

• Collagen-based device consisting of an extraluminal sealant with or without an intraluminal anchor (VasoSeal VHD, ED, Elite, VasoSeal Low Profile) (Bechara 2010). The intra-arterial anchor can be either a temporary balloon-positioning catheter that is removed at the end of the procedure (Duett Pro, Duet,The 6/7F Mynx, Mynx M5) (Bechara 2010; Scheinert 2007) or an absorbable intra-arterial anchor which is absorbed by the body in 30 days (Angio-Seal VIP, Angio-Seal STS Plus, Angio-Seal Evolution). Collagen-based devices without an intra-arterial anchor can undergo repeated puncture for angiography. A commonly used extra-arterial sealant is a bovine biodegradable product which triggers a haemostatic cascade and physical expansion to tamponade the puncture site and tissue tract .

• Metal clip-based device (StarClose, StarClose SE, Angiolink EVS) (Bechara 2010): devices, which utilize metal clip-based technology, deploy either metal staple or clip that penetrates the vessel wall to achieve haemostasis. Upon deployment, the metal clip or staple remains in situ over the vessel wall and forms a geometric configuration that approximates adventitial vessel layers to close the arterial hole. The metallic clips or staples do not undergo a bioresorption reaction, which therefore does not trigger significant soft tissue inflammatory response. Repeat puncture or surgical exploration of the artery can be done safely.

• Suture-based device (Perclose AT, Perclose ProGlide, Prostar XL, X-Site, SuperStitch) (Bechara 2010): arterial haemostasis is achieved by deploying sutures to form a knot to close the arteriotomy. The knot is tied by a built-in mechanism within the closure device or tied manually. No proteinaceous biomaterial is left behind in the puncture tract, therefore no inflammatory soft tissue reaction is associated with this closure technology. Consequently, repeat arterial access or surgical exploration of the same artery can be performed safely.

CONTRIBUTIONS OF AUTHORS

Charlie Chia-Tsong Hsu (CC-TH), Gigi Nga Chi Kwan (GNCK) and John A Rophael (JAR) drafted the protocol. Mieke L van Driel (MLvD) provided support with the methodological aspects of the protocol. All authors contributed to drafting of the protocol and agreed on the final version.

DECLARATIONS OF INTEREST

None known