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SHORT REPORT

Prospective Audit of "Post-Close" Haemostasis Following Large Bore Femoral Arterial Punctures: A Second Look at the Double Angio-Seal Technique

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Introduction: This study aimed to prospectively audit the efficacy of the post-close technique for the achievement of haemostasis following large bore femoral arterial punctures.
Report: Twenty-five consecutive patients (16 males, 9 females, mean age 73.3 [SD 9.6] years) underwent aortoiliac or peripheral arterial interventions via large bore femoral arterial punctures from 2017 to the present. Given previous success with closing 12F defects with a single 8F Angio-Seal, only those defects closed using a double wire set up and double Angio-Seal deployments were assessed.
Discussion: A total of 60 Angio-Seal VCDs were deployed using standard double wire preparation in 30 groins for haemostasis in 30 corresponding large bore femoral punctures. This second round audit reinforces the post-close technique using two Angio-Seal VCDs as the author's choice of femoral arterial closure up to 16F. It also provides some early insight into using this approach in redo groins.

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INTRODUCTION

This study aimed to prospectively audit the efficacy of the post-close technique for the achievement of haemostasis following large bore femoral arterial punctures. This is a second round audit following on from the first prospective audit of the "post-close" technique[1] initially applied for haemostasis after percutaneous endovascular aneurysm repair (EVAR) with the Ovation device (Endologix, Santa Rosa, USA)[2] using dual Angio-Seal VIP (Terumo Medical Corporation, Somerset, NJ, USA; hereafter designated as the Angio-Seal) vascular closure device (VCD) deployments. However, in this audit the indications have been expanded beyond EVAR alone.

REPORT

This audit prospectively examined 25 consecutive patients who underwent aortoiliac or peripheral arterial interventions via large bore femoral arterial punctures from 2017 to the present. Even though "large bore" is typically designated as >8 F, the smallest size within this series was 12F. Data were collected regarding age, gender, BMI, femoral arterial depth, and failure of haemostasis in the immediate or early post-procedure period; the latter was possible as previously, by using the standard post-procedure computed tomography (CT)/Doppler ultrasound scan (DUS) as a quality assurance tool from the imaging standpoint. Given the previous success with closing 12F defects with a single 8F Angio-Seal, this aspect was no longer analysed and only those defects closed using a double wire set up and double Angio-Seal deployments were assessed. Data were prospectively collected within Microsoft Excel and statistically analysed within Minitab 18 for Windows.

DISCUSSION

Twenty-five patients (16 males, 9 females, mean age 73.3 [SD 9.6] years) underwent procedures that involved large bore femoral access between 2017 and the present. Procedures included EVAR ($n = 17$), revision of EVAR, for example extension cuff and EndoAnchor deployment ($n = 2$) or graft limb thrombectomy and reline ($n = 1$), covered endovascular reconstruction of the aortic bifurcation (CERAB; $n = 4$), and popliteal EVAR (PEVAR, $n = 1$). Sheath sizes were 12–16F to deliver the largest bore device. Patient mean BMI was 26.8 (SD 3.95) with positive correlation with femoral arterial depth (Pearson coefficient 0.67, $p = .001$) as also previously shown. All deployments were undertaken by the author.

There was only one failure to deploy the Angio-Seal device resulting in open conversion to achieve ipsilateral

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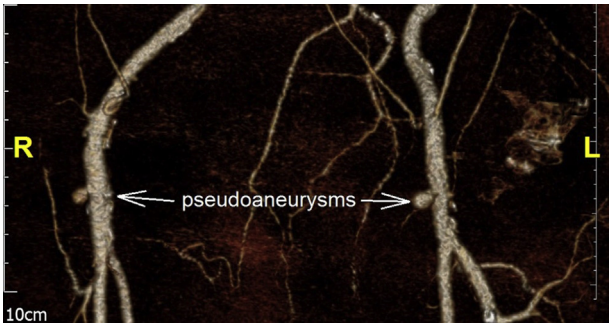

Figure 1. Representative small luminal aspects of femoral pseudoaneurysms (volume-rendered CT reconstruction).

femoral haemostasis at EVAR, caused by stretching open of the femoral puncture by the device delivery system (visually appreciated as approximately 18F). The contralateral groin was successfully post-closed with the double Angio-Seal technique but the patient is excluded from the analysis below, so as to present an analysis of fully percutaneous procedures. There was no 30 day mortality and a mean length of stay of 1.2 (SD 0.66) days.

A total of 60 Angio-Seal VCDs were deployed using standard double wire preparation in 30 groins in the 24 remaining patients for haemostasis in 30 corresponding large bore femoral punctures (12F, $n = 12$, 14F, $n = 12$, 15F, $n = 2$, 16F, $n = 4$) reflecting a mix of mostly ipsilateral closures ($n = 24$) and also some synchronous contralateral ($n = 6$) closures. Dual Angio-Seal closures of 12F punctures were typically undertaken if it was perceived that there was leakage around the 12F sheath or as a routine after CERAB. The "8—6" Angio-seal combination[2] was deployed in all cases, given that once the plug of the 8F Angio-Seal has been deployed, it is more convenient to deploy the lower profile 6F Angio-Seal beside it. CT/DUS was undertaken in all cases at a mean 5.6 (SD 4.2) weeks; two patients developed small bilateral pseudoaneurysms that resolved spontaneously (Fig. 1), an improvement from the previous series,[2] and one patient had a small pseudoaneurysm successfully injected, although given the small size (≅ 6mm) it may have also thrombosed spontaneously. There was no correlation between sheath size and pseudoaneurysm formation (Pearson correlation 0.041, $p = .829$). Similarly, multiple regression analysis did not show any statistical relationship among BMI, common femoral arterial depth, and incidence of pseudoaneurysms.

Of note was the use of the technique in "redo" groins in the two patients who were having re-interventions post-EVAR where scarring was noted and dual VCD deployments were noted to be effective. However, the failure to deploy in one patient has to be analysed in perspective, resulting in one maldeployment in 31 large bore femoral arterial punctures, representing an overall deployment success rate of 96.8%. Additionally, the learning curve is less than five cases, indicating that this is relatively easy. Deployment details are summarised in Table 1.

Direct comparisons of Angio-Seal versus suture mediated closure devices would be a useful study to undertake in this scenario; this has been undertaken for cardiac procedures[3] but not for aortic or peripheral vascular interventions. This

Table 1. Summary of outcomes after dual Angio-Seal deployments.

Criterion	Details	Comments
Procedure type		
EVAR	17	EVAR using ultra-low profile device
CERAB	4	Largest sheath used is 12F
Post-EVAR re-intervention/revision	3	Largest sheath used is 16F
PEVAR	1	Largest sheath used is 12F
VCD related parameters		
Total number deployed	60	All "8—6" Angio-Seal deployments
Sheath size		
12F	12	12F delivery sheath or limb sheath
14F	12	14F limb sheath
15F	2	15F sheath of Ovation aortic body
16F	4	16F delivery sheath
Haemostasis (Immediate)		
Total large bore closures attempted	31	25 patients
Success (%)	30 (96.8)	1 failure to deploy caused by non-engagement of Angio-Seal footplate
Failure (%)	1 (3.2)	
VCD failure specifics		
Early (<30 days)		
Failed to deploy	1	One patient who had failed deployment needed immediate open repair
Bleeding	0	
Haematoma	0	
Groin pain	0	
Vessel stenosis	0	
Open repair needed	1	
Late (>30 days)		
Pseudoaneurysm, treated	1	Two other patients had bilateral femoral pseudoaneurysms that resolved spontaneously
Open repair needed	0	

CERAB = covered endovascular reconstruction of the aortic bifurcation; EVAR = endovascular aneurysm repair; PEVAR = popliteal endovascular aneurysm repair; VCD = vascular closure device.

second round audit reinforces the post-close technique using two Angio-Seal VCDs as the author's choice of femoral arterial closure up to 16F, being mindful of the scope for failure (if the footplate of the Angio-Seal disengages then open conversion may become necessary). It also provides some early insight into using this approach in redo groins (although a scenario specific analysis was not possible given the small numbers), where fibrosis or increased BMI[4] may preclude use or contribute to failure of suture mediated closure devices, although this was not a factor in the current series.

CONFLICT OF INTEREST

None.

FUNDING

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