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Antegrade use of a collagen based vascular closure device for day case peripheral stenting: when can we safely discharge the patients?

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ABSTRACT

Purpose: Vascular closure devices have revolutionised vascular intervention, offering early patient mobilisation after retrograde access. The purpose of this study is to assess the safety and cost saving performance of a collagen based closure device in the early mobilisation of patients that undergo antegrade peripheral stenting as day cases.

Material and Methods: We retrospectively reviewed our radiology day unit database for antegrade stenting cases in a four-year period. We included 26 patients where a collagen based closure device was used. Patients were analysed for size of sheath used, Rutherford classification, degree of calcification (score from 1-4) of the access artery, amount of inraprocedureal heparin, type of stent used, time of discharge, immediate and delayed complications. Cost analysis also followed aiming to identify potential cost benefits of the device.

Results: A 6 Fr sheath was used in all cases. 11/26 patients were Rutherford 5-6 classification. The degree of calcification was >3 in 20/26 patients. In all patients at least 3000 IU of heparin were used intraprocedurally. Two types of stents were used; the time of discharge was 4 hours. In two cases a small haematoma was detected but did not change the management of the patients. No delayed groin complications occurred. Bed turnover was 50% less than with the traditional 6-hour stay, leading to significant reduction of the healthcare costs.

Conclusions: The use of a collagen based closure device offers satisfactory day case results for patients with advanced peripheral disease that undergo antegrade stenting, with reduction of the overall procedure cost.

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KEY WORDS
Peripheral vascular intervention; Antegrade access; Vascular closure devices; Day-case angioplasty

Introduction

Effective haemostasis after peripheral vascular intervention is of paramount importance in order to achieve early patient mobilisation and limit complications. Haemostasis was historically performed with manual compression of the access site for 10-15 minutes. Manual compression however is time consuming and may lead to complications ranging between 1.5 and 9% according to the literature [1, 2]. Vascular closure devices (VCDs) have been developed in order to achieve quicker and more effective haemostasis after peripheral vascular interventions [3, 4]. Quicker mobilisation and discharge from hospital can contribute to greater patient comfort and satisfaction [4].

VCDs offer a range of results, particularly when used after antegrade puncture, due to increased technical challenge of this approach, associated with increased risk of complications [5-7].

VCDs are based on three main mechanisms: 1) Collagen plug based devices i.e. Angio-Seal (St. Jude Medical, Minnesota, USA), 2) Suture based devices i.e. PerClose (Abbott laboratories) and 3) Clip based devices i.e. StarClose (Abbott laboratories). The purpose of this study is to assess the performance of a collagen based closure device following antegrade puncture for peripheral vascular interventions.

Material and Methods

This is a single center retrospective study. Patients' medical records were analysed for a four-year period (April 2013-May 2017). Inclusion criteria were the following: a) patients that underwent peripheral vascular stenting as day case, b) access performed via an antegrade puncture and c) a collagen based closure device was used for haemostasis.

All patients were referred for endovascular treatment for signs and symptoms of peripheral vascular disease, ranging from claudication to critical limb ischaemia (rest pain, foot ulceration/gangrene). Electronic medical records (EPIC) were reviewed to identify patient demographics, clinical indications for referral, procedural details and complications.

A medical student and an interventional radiology fellow, under the supervision of a consultant interventional radiologist, collected the data. All data were collected as a part of routine clinical care, and patient treatment was not influenced by the study. No patient contact was required. An institutional review board approved the study, and informed consent was waived.

The primary end-point was to demonstrate complications (minor and major) post deployment of the collagen based VCDs, ambulatory time and the time to discharge. Secondary endpoint was the assessment of the day unit bed turnover and the impact that this metric has to the overall procedure cost.

Patients

Demographic analysis revealed that most patients included in the study were male (18/26, 69.2%); about half of the patients were diabetic (14/26, 53.8%) and with hypertension (16/26, 61.5%). Also one third of patients had previous cardiac disease (10/26, 38.5%). All these patients were considered not suitable for surgery as a primary approach during the peripheral vascular multidisplinary meeting. All clinical features are described in **Table 1**.

All lesions were chronic total occlusions and were located in the femoropopliteal segment: 10 lesions were located in the superficial femoral artery (SFA), 6 lesions were only in the popliteal artery and 10 lesions extended across the SFA and popliteal artery. Mean lesion length was 72 mm (range, 50-270 mm) and 20 lesions (76.9%) were considered as highly calcified. Calcification grade was assessed by using a previously reported circumferential degree system: we considered low-grade calcified lesion: grade 1 (90 degrees), moderately calcified lesion: grade 2 (180 degrees) and highly calcified lesions: grades 3 and 4 (>270 degrees) [8]. Access vessel calcification however was not significant in the majority of the patients. Most lesions were TASC class C and D and mean number of patent run-off vessels was 1.8 (range: 0-3) (**Table 2**).

Procedure

All patents were already on antiplatelet treatment with 75 mg of Aspirin due to peripheral vascular disease that was not stopped the morning of the procedure. All procedures were performed with antegrade access. Access was ob-

Table 1. Clinical characteristics of patients

Clinical feature		*Value*
Patients (n)		26
Age, mean years (range)		72.9 (56-85)
Male, n (%)		18 (69.2)
Diabetes, n (%)		14 (53.8)
High Cholesterol, n (%)		14 (53.8)
Hypertension, n (%)		16 (61.5)
Past/Current Smoker, n (%)		23 (88.4)
Obesity (BMI>35%)		29.4 (38.4)
Heredity, n (%)		3 (11.5)
Rutherford category (%)	3	8 (30.7)
	4	7 (46.8)
	5-6	11 (42.3)
Previous endovascular procedure, n (%)		11 (42.3)
Previous cardiovascular event (angina, MI, TIA, stroke)		10 (26)

Table 2. Characteristics of the treated lesions

Lesion feature		*Value*
SFA		10/26
Popliteal		6/26
Femoropopliteal		10/26
Length (mm)		72 (50-270)
TASC II Class n. of lesions (%):	A	0/26
	B	3/26
	C	21/26
	D	2/26
Access vessel calcium grade (1-2)		23/26
Access vessel calcium grade (3-4)		3/26
Lesion calcium grade (1-2)		6/26
Lesion calcium grade (3-4)		20/26
Number of run-off vessels		1.8 (0-3)

tained from the common femoral artery with a micropuncture set and ultrasound guidance. The level of calcification of the vessel was assessed with ultrasound at the time of puncture and an appropriate site was chosen. Then an angiogram was performed and the extent of disease was evaluated. In all cases the micropuncture set was replaced to an 11 cm, 6 Fr bright tip sheath when the decision to proceed was made. The lesions were crossed using suitable wires and catheters and angioplastied with plain balloons of appropriate size. In two cases a crossing device was also used (Outback ELITE, Cordis Inc). As per our standards of practice, all patients received 3000 international units (IU) of heparin intra-arterially when the 6 Fr sheath was inserted to mitigate the risk of in-situ thrombus formation. Lesions were treated with two types of stents; in 17 cases a heparin coated self-expandable stent was used (Tigris, W. L. Gore) and in 9 cases an interwoven nitinol self-expandable stent (Supera, Abbott Inc). In all patients 300 mg of Clopidogrel per os were prescribed as a stat dose immediately after the procedure, followed by double antiplatelet therapy with 75 mg of Aspirin and 75 mg of Clopidogrel per day for six months.

Vascular Closure Device

The device used in all cases was the Angio-Seal STS Plus (St Jude Medical). The device pack contains an insertion sheath, an arteriotomy locator (modified dilator) and a guidewire. The device itself is composed of an absorbable collagen sponge and a specially designed absorbable polymer anchor that are connected by an absorbable self-tightening suture (STS). The device seals and sandwiches the arteriotomy between its two primary members, the anchor and collagen sponge. Haemostasis is achieved primarily by the mechanical means of the anchor-arteriotomy-collagen sandwich, which is supplemented by the coagulation-inducing properties of the collagen. The device is contained in a delivery system that stores and then delivers the absorba-

ble components to the arterial puncture. The delivery system features a secure cap that facilitates proper technique for delivery and deployment of the absorbable unit [9].

The device was deployed at the end of every stenting procedure. The 6 Fr sheath was removed and the device was advanced over a guidewire and deployed. After successful deployment, an ultrasound scan of the area was performed in order to exclude any complications, including potential occlusion of the access vessel. The patient was then transferred from the angiographic bed to the hospital bed with the use of a patient slide. No dressing or compression bandage was applied to the arteriotomy site. The advice for the patient was to stay two hours completely flat and two hours with the head of the bed elevated at a 45 degrees angle. After two hours, the patient could eat and drink. All patients had to be accompanied by another adult at home after discharge and have someone to stay with them overnight, as per local protocol.

Results

A 6 Fr sheath was used in all cases. 11/26 patients were Rutherford 5-6 classification. The degree of calcification was >3 in 20/26 patients. In all patients at least 3000 IU of heparin were used intraprocedurally.

Technical success was obtained in 26/26 patients (100%). No need for manual compression occurred in any of the patients. An ultrasound scan immediately post deployment of the device confirmed patent common femoral artery (CFA) and SFA in all cases. All patients were transferred to the Radiology Day Unit (RDU) post procedure with instructions for a four-hour stay given the presence of the closure device when it is expected to suggest a six-hour stay after the use of a 6 Fr sheath as per local protocol.

In two cases a small haematoma was detected during the first hour of the four-hour stay in the RDU. In both cases the haematoma did not raise any concern because it was there at the moment of the nursing hand-over and it was attributed to the exchange of the sheath during the procedure and not to a lack of effectiveness from the closure device. In case of haematoma expansion, a Computed Tomography would have been performed as per local protocol but it was not necessary in any of the cases. All patients were discharged after four hours. No complications occurred during the first night at home and no patient returned to the hospital. In none of the cases was there any need to interrupt the double antiplatelet treatment.

Bed turnover was 50% less than with the traditional six-hour stay leading to significant reduction of the hospital costs. In particular on a yearly basis, 200 more patients could be accommodated, given that the RDU has an operating time of 12 hours from 08:00 to 20:00 on a 5/day per week schedule. Therefore instead of accommodating two patients per day, the RDU could accommodate three.

Discussion

Endovascular arterial interventions have revolutionised the treatment of peripheral arterial disease, offering a minimal invasive solution to problems that were dealt surgically in the past. Access for peripheral interventions is obtained in the vast majority of the cases by puncturing the CFA, caudally to the level of the inguinal ligament. The puncture may be either retrograde or antegrade with the latter being considered as more technically demanding, due to the fact that the SFA needs to be catheterised simultaneously with the access to the arterial tree. When the procedure is finished, manual compression for 10-15 minutes is performed in order to compress the artery to the femoral head and achieve haemostasis.

Since their introduction, VCDs are now being increasingly used instead of traditional manual compression to seal the arteriotomy site. Studies have suggested VCD use to result in quicker haemostasis, coupled with swifter patient mobilisation and hospital discharge, thereby resulting in greater patient satisfaction.

Collagen based vascular occlusion device is now widely used for achieving haemostasis following arterial puncture. This is a bio-absorbable device that comprises of a collagen sponge and a polymer anchor that are linked by a self-tightening suture. The device seals and tightly approximates the arteriotomy access site between its two main components, the anchor positioned inside the artery lumen and the collagen sponge lying outside the arterial wall. Tightening of the suture results in compaction of collagen sponge lying outside the arterial lumen, and this creates an anchor-arteriotomy-collagen sandwich, which results in haemostasis of the vasculature access site. The device is available in 6 Fr and 8 Fr configuration. The use of the device has been associated with some risks. Some of the complications suggested by the manufacturer that may be encountered with the use of collagen plug based vascular device include access site infection, prolonged bleeding and haematoma, vascular complication e.g. arterio-venous fistula formation,

Table 3. Most salient studies

Study	Prospective/ retrospective	Patients	Antegrade/ Retrograde	Fr	Technical Success	Complications	Time to discharge
Mukhopadhyay et al [10]	Retrospective	21	Antegrade	6	100%	One minor groin haematoma and one deteriorating lower limb ischaemia	Within 24 hours
Biondi Zoccai et al [11]	Retrospective	5	Antegrade	6	100%	None	After 12 hours with manual compressive bandage over the access site
Kapoor et al [12]	Retrospective	56	Antegrade	6 (52) 8 (4)	98.2%	Two cases of minor haematoma	After overnight stay (but mobilised after 1-2 hours)
Lobby et al [13]	Retrospective	50	Antegrade	6	92%	Three patients with haematoma -one needing blood transfusion	50% discharged within 24 h
Lupatelli et al [14]	Retrospective	1626	Antegrade	6	97.9%	1.1% within 24 hours- 2.5% within 30 days (Large haematoma, bleeding requiring transfusion, pseudoaneurysm, vessel stenosis or occlusion	No data
Minko et al [15]	Prospective	120	Antegrade	6 (88) 8 (32)	81%	None	>24 hours
Chaudhuri et al [7]	Retrospective	286	Antegrade	6 (267) 8 (4)	91.1%	3.7% (haematoma, bleeding and vascular stenosis)	>24 hours

pseudo-aneurysm formation, vascular occlusion or stenosis and failure of the device to deploy [9]. The device is only used for puncture site in the CFA between the inguinal ligament and the femoral artery bifurcation. The use of collagen based vascular occlusion device is avoided in patients with evidence of severe peripheral vascular disease or if the arterial lumen is <4 mm in diameter.

The femoral arterial access can be either via retrograde or antegrade approach. Antegrade femoral artery puncture is known to be a bit more challenging than the retrograde

one [5-7]. There are a limited number of studies assessing the use of collagen based closure devices to achieve haemostasis of the access site following antegrade femoral arterial puncture. The most salient studies are demonstrated in Table 3.

Mukhopadhyay et al [10] in a retrospective study assessed 21 patients who underwent antegrade femoral arterial puncture, and 6 Fr Angio-Seal device was subsequently used to seal the arteriotomy site. This study reported satisfactory haemostasis post procedure in all patients, with no manual compression use post procedure. Of 21 patients, two patients developed complication post procedure. One patient was noted to have minor groin haematoma not necessitating intervention and one patient reported to have deteriorating lower limb ischaemia. The majority of patients (80%) were discharged within 24 hours post procedure. Besides suggesting Angio-Seal device to be safe and effective for achieving haemostasis, this study suggested the outcome of device deployment is unaffected with the status of arterial disease of the access site. Biondi Zoccai et al [11] reported immediate haemostasis of the antegrade femoral arterial puncture site with Angio-Seal deployment and with no complications in five patients, despite intense antithrombotic regime. All the patients were ambulated after 12 hours with manual compressive bandage over the access site.

Kapoor et al [12] in another retrospective review reported a success rate of 98.2% with the use of Angio-Seal for antegrade CFA access site and furthermore demonstrated early mobilisation post procedure. Fifty-five patients underwent 56 antegrade CFA puncture either for diagnostic lower limb angiography or lower limb re-vascularisation. Successful haemostasis was achieved with Angio-Seal deployment in 55 CFA punctures, with no additional interventions needed post procedure. The only unsuccessful procedure was attributed to device failure due to likely extra-vascular placement of the device, warranting manual compression of the arteriotomy access site. Complication rate was reported as 3.6%, with only two cases developing minor haematoma (<5 cm) post procedure, with no major complications observed. All the patients reviewed by the study were mobilised one to two hours post procedure.

Similar findings of high success and low complication rate with the use of collagen based VCDs were put forward by another retrospective study conduced by Lobby et al [13]. This study reviewed 60 patients, of which there were 58 ante-grade arterial puncture for either SFA or popliteal artery angioplasty. Angio-Seal was successfully deployed in 46 patients. For the remaining 12 patients manual compression was used to seal the access site, owing to several factors which included significant arterial occlusive disease (n=7), device failure (n=4) and vasculature wall dissection (n=1). Of the Angio-Seal group three patients (6.5%) experienced complications post procedure, all of them being haematoma, with two patients requiring only manual compression and one patient additionally needing blood transfusion along with manual compression of the access site post procedure. No further procedure related complications were reported, although three patients were noted to have deteriorating lower limb ischaemia necessitating vascular surgery, but this was attributed to underlying significant peripheral vascular disease rather than a result of device deployment.

In the largest reported series, Lupatelli et al [14] compared Angio-Seal use for sealing either antegrade or retrograde femoral arterial puncture and manual compression. This study reported a success rate of 97.9% with use of antegrade Angio-Seal deployment. Out of the 1889 patients in whom Angio-Seal device was used to seal antegrade femoral arterial access site, 1849 patients attained successful haemostasis. Lack of success was attributed to failure of device deployment and due to complications that had arisen post procedure. Major complications (n=20) encountered include haematoma formation, which was either >10 cm in size or necessitated transfusion, and vascular complications e.g. lumen stenosis or occlusion and pseudoaneurysm formation which failed to respond to manual compression. Vascular stenosis and occlusion were a result of either collagen plug displacement or, less commonly, a result of femoral artery intimal dissection. Minor complications (n=27) encountered included haematoma of smaller size (<10 cm) not needing any intervention, pseudoaneurysms that resolved with prolonged manual compression and prolonged bleeding from the access site post procedure. Similar success rate (97.8%) was found with the use of retrograde Angio-Seal deployment, although there was a considerably smaller number of subjects in this group (n=278). Overall complication rate was noted to be lowest in the group where the device was used for antegrade access site haemostasis with an overall complication rate of 2.5%, as compared to the retrograde Angio-Seal group and manual compression group where overall complication rates were 4% and 4.9% respectively. However, Minko et al [15] argued that exclusion of patients for Angio-Seal deployment based

on certain high risk factors, e.g. vessel calcification, prior surgical interventions and obesity may have biased the findings obtained of the study from Lupatelli et al [14].

Minko et al [15] in their prospective study assessed 120 patients who underwent ante-grade CFA access for lower limb interventions. This study reported a lower success rate of 81%, with prompt haemostasis achieved in 97 patients with the use of Angio-Seal. No exclusion criteria were applied for patients, when selected for Angio-Seal use. Twelve patients (10%) had persistent bleeding without any obvious reason. For nine patients there was device failure, owing to kink in the vascular sheath, which prevented the collagen plug advancement. In two patients (2%), the anchor of the collagen device was dislodged out of the vessel. No significant difference was detected between coagulation status between the successful and unsuccessful group. This study reported no major or minor vascular complications following Angio-Seal use even in the group where the device failed to achieve haemostasis. This study attributed absence of these complications to its protocol of immobilising patient for six hours post procedure and applying manual bandage over the wound site 24 hours post procedure. Owing to higher Body Mass Index reported by the study in the unsuccessful group, the authors suggested obesity to be an independent risk factor compromising successful haemostasis attained with Angio-Seal collagen device deployment.

Chaudhuri et al [7] in their study retrospectively compared the results of antegrade and retrograde Angio-Seal deployment following femoral arterial puncture. Of 271 cases of antegrade femoral puncture, there were 247 patients (91.1%) with successful haemostasis following Angio-Seal deployment and 24 patients (8.9%) who failed to obtain haemostasis following the procedure. The commonest factor resulting in unsuccessful haemostasis of antegrade puncture was failure of the device to deploy but other complications encountered included haematoma, bleeding and vascular stenosis. Of 237 retrograde femoral arterial punctures, successful haemostasis with collagen plug device was obtained for 229 patients, with device failing to deploy in eight patients. Based on high success rate observed in attaining haemostasis, this study suggested Angio-Seal device to be effective for sealing the access site. However contrary to Lupatelli et al [14], this study reported antegrade Angio-Seal deployment to be linked to higher failure rate as compared to retrograde device deployment.

Even though the safety features of the device have been extensively illustrated in the literature, the assessment of an exclusive group of patients that are treated in the setting of a day unit has not been reported yet. The impact that the device has in the management of these patients is clearly linked to the fact that in case of failure a hospital bed has to be requested for overnight stay. This event changes the status of the patient causing pressure for hospital beds but also distress to the patient and the family. Our study confirmed that patients with complex vascular disease due to extensive calcification that will be treated with the use of a stent might be safely treated in the setup of a RDU as the limiting factor, which is the haemostasis, is safely controlled with the use of this specific device.

The choice behind this specific device lays on the fact that hemostasis does not depend on clotting parameters like i.e with other VCDs. Therefore even patients that will receive double antiplatelet therapy with a loading dose of Clopidogrel may be safely treated with this device, as demonstrated from our study where all the patients received 300 mg of Clopidogrel immediately after stenting.

Another positive aspect of the use of the device that has not been extensively investigated previously is the fact that the turnover of the day unit may increase significantly, reducing the pressure for hospital beds, which is truly beneficial for a busy tertiary care center.

The main point of attention from the use of this device, apart from the immediate effectiveness in terms of haemostasis, consists in the assessment of the flow of the CFA post deployment. There is a small risk that the contralateral intima layer may be caught when the device is retracted and this causes immediate blockage of the access vessel. For this reason it is recommended -based also on our experience- that an ultrasound scan of the CFA and the proximal SFA artery is performed after deployment to confirm flow. In the case of accidental vessel blockage, contralateral access and recanalisation of the blocked segment is required. Luckily we did not encounter this complication is our series.

The limitations of our study are mainly the retrospective nature and the relatively limited number of patients. However, we consider that a prospective design may have hindered the risk of treating patients that may not have been suitable for deployment of such device. Furthermore, we selected a specific group of patients with advanced disease that were treated in a very specific way (antegrade puncture). Therefore, even for a large scale tertiary care center like ours, the

number of patients could not be significantly larger.

We may conclude that with the use of collagen based closure devices we can safely achieve quick haemostasis and quick mobilisation for patients with advanced peripheral vascular disease. Those patients can be offered a day unit treatment without hesitation, reducing hospital time and pressure for hospital beds. **R**

Conflict of interest

The authors declared no conflicts of interest.

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