Cardiovascular Topics

Ultrasonographic assessment and clinical outcomes after deployment of a suture-mediated femoral vascular closure device

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Abstract

Introduction: Data regarding changes in the arterial vascular wall after the deployment of suture-mediated vascular closure devices (VCD) at the femoral site in patients undergoing percutaneous coronary angiography (CAG) or percutaneous coronary intervention (PCI) are sparse. This study investigated the occurrence of structural vascular changes or adverse vascular complications at the access site in the short term after the deployment of a suture-mediated intravascular VCD.

Methods: Ninety-three patients (72% males) with a mean age of 62 ± 11 years were enrolled. Duplex sonography was conducted at the access site at baseline, 24 hours and 30 days after femoral puncture in patients with successful VCD deployment. Vessel diameter, flow velocities, the severity of atherosclerosis, and the intravascular or perivascular tissue alterations in both the right common femoral artery (RCFA) and right external iliac artery (REILA) were assessed. Vascular complications were documented.

Results: There were no significant changes regarding the diameter of the RCFA in the transverse and longitudinal view, peak systolic velocity (PSV) of the RCFA, PSV ratio of the RCFA to REILA, the resistive index of the RFCA and the severity of arterial wall abnormalities before femoral puncture, the day following VCD deployment and 30 days after (p = NS for all) in the general population and in patients with diabetes mellitus, on oral anticoagulants or with mild peripheral artery disease (p = NS for all markers). Device failure was observed in four cases. Few (4.4%) patients had vascular complications, which included exclusively major or minor haematomas, most of which did not persist at the 30-day follow up.

Conclusion: The use of a suture-mediated VCD was safe and was not associated with adverse vascular wall changes at the femoral access site 30 days after deployment in patients undergoing CAG and/or PCI.

Keywords: vascular closure device, suture-mediated, duplex ultrasound, complications, femoral artery

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Submitted 29/5/22; accepted 30/10/23
Cardiovasc J Afr 2023; online publication www.cvja.co.za

DOI: 10.5830/CVJA-2023-054

The performance of percutaneous coronary angiography (CAG) and percutaneous coronary intervention (PCI) requires artery cannulation. Although transradial cardiac catheterisation is increasingly being adopted due to lower vascular and bleeding complications,[1,2] many interventional cardiologists persist in using the femoral approach. This preference may be partly attributed to the greater familiarity that many interventional cardiologists have with the method.[3] Importantly, observational studies show that the use of femoral vascular closure devices (VCDs) allows for comparable major bleeding rates between transradial and transfemoral arterial access in patients who underwent CAG or PCI.[4]

VCDs enable arteriotomy closure, reducing the time to achieve haemostasis, and assuring early remobilisation, ambulation and patient comfort in a safe and cost-efficient manner.[5-7] On the other hand, there is a lack of evidence regarding the superiority of VCD implementation over manual compression in terms of adverse vascular complications, such as arteriovenous fistula, pseudo-aneurysms, haematomas, occlusion, thrombosis and the incidence of major bleedings, in an all-comers population. However, VCD implementation may particularly benefit selected patient groups who receive CAG.[5,8]

The effect of VCD deployment on the properties of the vasculature at the femoral access site has been investigated by only a few researchers, who demonstrated that there was no association between VCD implantation and severe adverse vascular complications in a one- and 10-year term.[9,10] The use of Perclose Proglide™, a suture-mediated VCD, resulted in better sonographic findings than the Angio-Seal™, a VCD that delivers a suture-tethered extravascular collagen plug. However, the lack of baseline measurements prevented the precise evaluation of the VCD effect on the vascular wall, accompanied by the paradoxical observation of an increased vessel lumen on the access site compared to the non-accessed femoral artery.[9,10]

This study aimed to investigate whether the deployment of a suture-mediated intravascular VCD might result in adverse vascular complications or vascular structural changes at the vascular access site in the short term, as assessed by broadly used sonographic markers, in patients who underwent CAG and/or PCI via transfemoral access.

Methods

This study was a two-centre, one-arm, open-label, prospective cohort study. It included patients who had undergone a diagnostic percutaneous CAG or PCI with transfemoral access because of non-eligibility for a transradial access, based on the physician's decision and who had consented to the implementation of a VCD instead of manual compression. The participants were patients of the First Cardiology Clinic at Hippokration Hospital (65.70%) and the Second Cardiology Clinic at Attikon Hospital of the National and Kapodistrian University of Athens.

Recruitment occurred between March 2014 and July 2017. Patients under the age of 18 years, those with a history of peripheral artery disease (PAD) involving interventional or surgical treatment at the access site or reported claudication, those with ultrasonographically severe PAD and/or severe calcification of the right femoral common artery (RCFA) (n = 6), patients who had previously received an ipsilateral VCD deployment (n = 6), and those with symptoms of infection or a large haematoma (n = 1) at the end of the PCI/CAG were excluded from the study.

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and received prior approval by the Human Research Committee of Hippokration General Hospital (15/2011 as part of a greater study protocol on patients who received coronary artery angiography). All participants provided written, informed consent before entering the study.

Medical history, and clinical and laboratory results were obtained from hospital records. Arterial duplex ultrasonography was used to assess for contra-indications, as stated above, and to guide the arteriotomy of the RCFA. The RCFA was accessed with an 18-gauge needle and cannulated by means of an Arrow 6F × 11-cm introducer sheath (Medtronic, Minneapolis, MN, USA).

Ninety-three patients who received the Perclose Proglide™ closure device (Abbott Labs, Redwood City, CA, USA) were included in the study. Perclose Proglide™ is a suture-mediated VCD that delivers a non-absorbable polyester suture through the arterial wall, which is tightened to achieve haemostasis. All procedures were performed by three experienced interventional cardiologists, according to the recommendations of the manufacturer.

Device failure was defined as unsuccessful VCD deployment and led to manual compression. Complications included bleeding requiring transfusion, pseudo-aneurysms, arteriovenous fistula, access site infections, haematomas and the need for surgical or interventional vascular treatment. Haematomas were distinguished between major (≥ 5 cm) and minor (< 5 cm) with ultrasonography. Deployment of the VCD was not successful in four patients, who were consequently excluded from the follow up.

Patients were mobilised after six to eight hours, according to standard hospital protocols. Detailed information regarding mobilisation or ambulation was not recorded.

Symptoms including claudication, tenderness or pain at the access site, groin infections and haematomas were clinically assessed the day after and 30 days following femoral artery cannulation. Arterial duplex ultrasonography was performed at baseline, on the day after and 30 days after VCD deployment with an 8L-RS 4–13-MHz linear transducer (General Electric, Milwaukee, Wisconsin, USA) to assess established ultrasound markers of vascular function and structure. At baseline, ultrasound assessment was also used to obtain the appropriate access site after screening for severe PAD.

The RCFA was examined approximately 1 cm proximal to the bifurcation. At this point, vessel diameter was assessed at three sites within 1 cm in both longitudinal and transverse views at end-diastole, and mean values were estimated. In cases where a plaque was present, the thickest part of the plaque in the longitudinal view was measured.

We defined evidence of PAD as the presence of plaques or localised vascular wall thickening with a thickness ≥ 1.5 mm and characterised them as atheromas from grade 1 to 4 (grade 1 for

thickness ≤ 1.5 mm, grade 2 for 1.6–2.9 mm, grade 3 for 3–4.5 mm and grade 4 for 4.6–6 mm). Changes exceeding 6 mm were considered indicative of severe PAD, leading to exclusion from the study and/or receiving VCD treatment.

Pulsed-wave Doppler was utilised to determine the peak systolic velocity (PSV) and end-diastolic velocity (EDV) at the RCFA and at the right external iliac artery (REILA). The PSV ratio was calculated by dividing the PSV of the RCFA by the PSV of the REILA to distinguish significant vascular stenosis of > 50%. The resistive index (RI) was assessed using the formula RI = (PSV – EDV) / PSV. Additionally, hypo-echogenic changes of the arterial wall tissue and at the external side of the adventitia, such as the perivascular soft tissue of the vessels at the access site were also assessed with ultrasonography.

Statistical analysis

All continuous variables were tested for normal distribution before any further analysis was carried out by means of visual inspection of histograms for normal distribution, and the use of the Kolmogorov–Smirnov test for non-normal distribution. Continuous variables with a normal distribution are presented as mean ± one standard deviation (SD), whereas skewed variables are reported as median with first and third quartiles. Repeated-measures analysis of variance (ANOVA) and the Student's *t*-test or Friedman test and the Wilcoxon–Mann–Whitney test were applied for continuous variables, as appropriate. Categorical variables are reported as counts and percentages. Statistical significance was set at a *p*-value < 0.05. All statistical analyses were performed using SPSS Statistics 26 (IBM, Chicago, Illinois, USA).

Results

We enrolled 93 consecutive patients (72% males) with a mean age of 62 ± 11 years who underwent percutaneous CAG via a right femoral route and received femoral artery closure with a Perclose Proglide™ VCD. Median follow-up time was 31 (28–35) days after recruitment. In four cases, a VCD could not be delivered due to difficulties encountered during puncture, attributed to hardened tissue resulting from repeated femoral artery punctures for recent CAG procedures. The baseline demographic and clinical characteristics of the study participants are summarised in Table 1.

One asymptomatic minor dissection of the right superficial femoral artery, two cases of major local haematomas and two cases of minor local haematomas were observed on the day following the CAG, all of which were treated conservatively. At the one-month follow up after CAG, only one patient with an extensive post-interventional local haematoma was still experiencing a persistant, albeit smaller, local haematoma. No pseudo-aneurysms and no arteriovenous fistulae were observed throughout the study and the initially documented dissection of the right superficial femoral artery had healed a month later.

At baseline, a median atheroma grade of 1.50 (0.25–3) regarding vascular wall abnormalities was documented through ultrasonography. Compared to baseline values, there was an insignificant difference the day after the CAG was conducted [2.00 (1.00–2.75)] and 30 days later [2 (0.25–3.00), $p = 0.62$], regarding the severity grade of atheromatous vascular wall changes. On day 30 after CAG, one patient demonstrated the development of a small atheromatic plaque at the site of VCD deployment; 3.4% of the patients had localised arterial wall oedema and 21% had localised perivascular oedema on the day after catheterisation.

Persisting perivascular soft tissue changes 30 days after VCD deployment were present in 3.4% of the participants, while 2.2% of them continued to have arterial vessel wall thickening. The deployed polyester suture was visualised in 78% of patients on the day following CAG and in 12% of patients a month after CAG.

There was no difference between the measured diameter of the right common femoral artery in transverse view (88.85 ± 13.79 vs 86.65 ± 14.53 vs 87.42 ± 12.15 mm, $p = 0.51$) or in longitudinal view (80.83 ± 14.38 vs 78.19 ± 14.36 vs 78.73 ± 13.61 mm, $p = 0.27$) at baseline, 24 hours after puncture and after 30 days, respectively. The PSV in the RCFA estimated at baseline, on the day following CAG and after 30 days did not change significantly (90.03 ± 29.84 vs 88.82 ± 29.04 vs 86.78 ± 24.89 cm/s respectively, $p = 0.71$).

The ratio of the PSV of the RCFA to the PSV of the REILA remained unchanged compared to baseline on the day following the catheterisation and a month later (0.73 ± 0.19 vs 0.74 ± 0.19 vs 0.73 ± 0.19 respectively, $p = 0.82$). RI of the RCFA was not altered through the three time points of investigation (1.02 ± 0.11 before CAG vs 0.99 ± 0.10 on the following day vs 0.99 ± 0.11 30 days later, $p = 0.20$) (Fig. 1).

Further analysis showed consistent findings among subgroups of the study. Furthermore, no significant differences were found regarding the end-diastolic diameter of the RCFA in transverse or in longitudinal view, the PSV of the RCFA, the PSV ratio, the RI of the RCFA and the sonographically estimated degree of severity of the atheromatous vascular wall abnormalities at baseline, on day 1 and on day 30 after CAG in patients with type 2 diabetes on long-term treatment with oral anticoagulants or in patients with atheromatous vascular wall changes at the site of femoral artery puncture prior to CAG (p = NS for all), as demonstrated in Table 2.

Table 1. Baseline demographic and clinical characteristics

Parameters	*Values*
Male gender, *n* (%)	67 (72)
Arterial hypertension, *n* (%)	53 (57)
Diabetes mellitus, *n* (%)	28 (30.1)
Smoking history, *n* (%)	48 (51.6
Hypercholesterolaemia, *n* (%)	57 (61.3)
Evidence of PAD, *n* (%)	66 (70)
Antiplatelet treatment, *n* (%)	55 (59.1)
Percutaneous coronary intervention, *n* (%)	66 (71)
Anticoagulation treatment, *n* (%)	16 (17.2)
End-diastolic diameter of the right common femoral artery, mean ± SD	
In transverse view (mm)	88.85 ± 13.79
In longitudinal view (mm)	80.83 ± 14.38
PSV of RCFA (cm/s), mean ± SD	90.03 ± 29.84
PSV ratio, mean ± SD*	0.73 ± 0.19
Resistive index in RCFA, mean ± SD	1.02 ± 0.11

PAD: peripheral artery disease; PSV: peak systolic velocity; RCFA: right common femoral artery; REILA: right external iliac artery.
*PSV of the RCFA to PSV of the REILA.

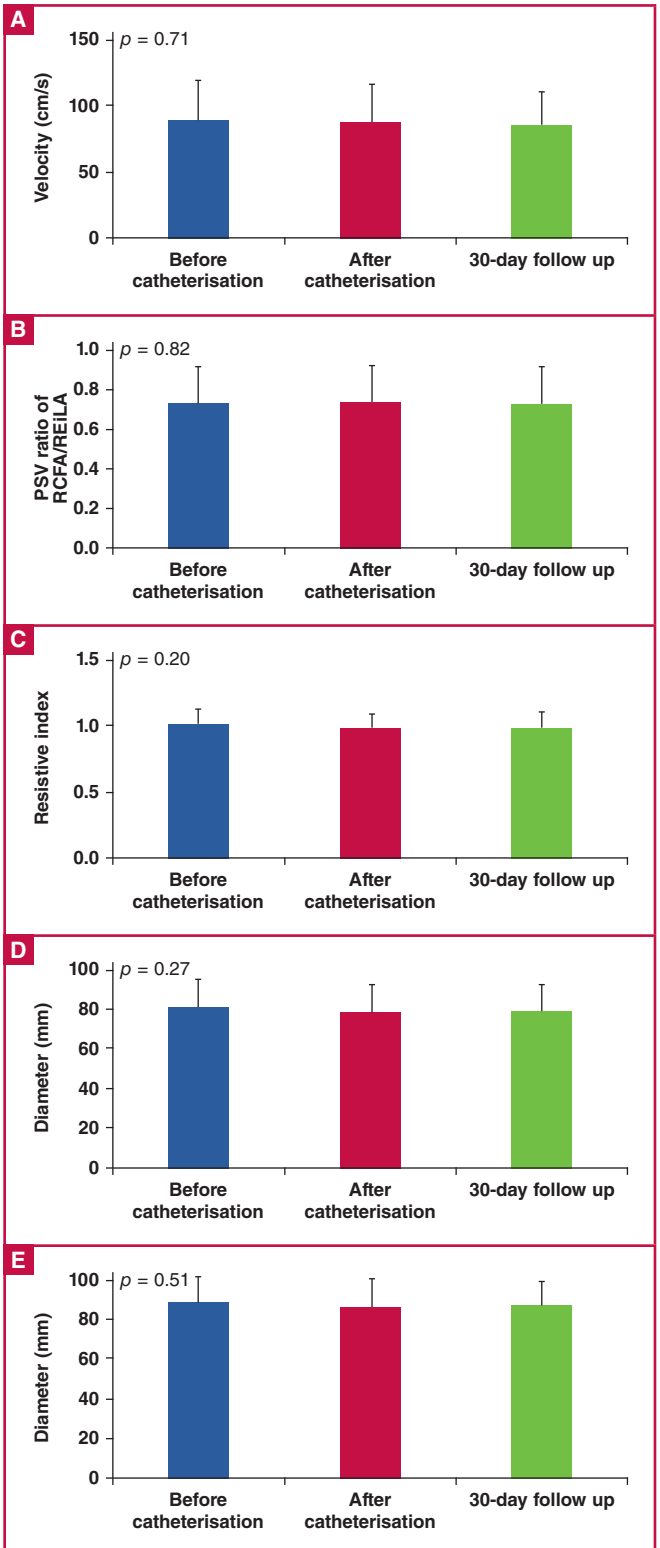

Fig. 1. Bar plots of (A) the PSV of the RCFA, (B) the PSV ratio of the RCFA/REILA, (C) the RI of the RCFA, (D) the end-diastolic diameter of the RCFA in the longitudinal view, and (E) the end-diastolic diameter of the RCFA in the transverse view at baseline before percutaneous CAG, the day following CAG and 30 days thereafter. PSV: peak systolic velocity, RCFA: right common femoral artery, REILA: right external iliac artery, CAG: percutaneous coronary angiography.

Table 2. Initial and follow-up ultrasonographic findings in selected patient subgroups

Ultrasonographic findings	*Baseline*	*24 h after catheterisation*	*1 month after catheterisation*	p-*value*
Patients on oral anticoagulants ($n = 16$)				
End-diastolic diameter of the right common femoral artery, mean ± SD				
In transverse view (mm)	84.66 ± 4.04	90.33 ± 17.38	86.00 ± 14.93	0.57
In longitudinal view (mm)	74.33 ± 11.02	76.67 ± 11.93	72.33 ± 10.50	0.20
PSV of RCFA (cm/s), mean ± SD	135.57 ± 45.61	104.33 ± 27.14	109.33 ± 1.15	0.37
PSV ratio, mean ± SD*	0.95 ± 0.16	0.80 ± 0.13	0.77 ± 0.10	0.18
Resistive index in RCFA, mean ± SD	0.97 ± 0.02	0.97 ± 0.01	0.96 ± 0.04	0.69
Severity degree of atheromatous vascular wall changes, median (min–max)**	2 (1–3.75)	2 (1–3)	2 (1–3)	0.37
Patients with diabetes mellitus ($n = 28$)				
End-diastolic diameter of the right common femoral artery, mean ± SD				
In transverse view (mm)	87.71 ± 15.43	86.57 ± 10.95	84.00 ± 10.76	0.28
In longitudinal view (mm)	81.21 ± 15.48	78.21 ± 15.02	75.00 ± 12.97	0.16
PSV of RCFA (cm/s), mean ± SD	95.28 ± 32.28	87.79 ± 20.59	81.96 ± 16.64	0.10
PSV ratio, mean ± SD*	0.68 ± 0.19	0.67 ± 0.17	0.68 ± 0.14	0.96
Resistive index in RCFA, mean ± SD	1.05 ± 0.14	1.02 ± 0.13	1.00 ± 0.13	0.24
Severity degree of atheromatous vascular wall changes, median (min–max)**	2 (1–3)	2 (1–3)	2 (1–3)	0.29
Patients with evidence of PAD ($n = 66$)				
End-diastolic diameter of the right common femoral artery, mean ± SD				
In transverse view (mm)	87.08 ± 14.20	86.53 ± 14.20	85.44 ± 12.28	0.71
In longitudinal view (mm)	78.19 ± 14.63	77.10 ± 14.18	75.80 ± 12.81	0.39
PSV of RCFA (cm/s), mean ± SD	92.16 ± 29.69	92.72 ± 28.48	88.07 ± 22.76	0.54
PSV ratio, mean ± SD*	0.73 ± 0.20	0.73 ± 0.21	0.74 ± 0.16	0.99
Resistive index in RCFA, mean ± SD	1.02 ± 0.11	0.97 ± 0.06	0.98 ± 0.08	0.12
Severity degree of atheromatous vascular wall changes, median (min–max)**	2 (1–3)	2 (1–3)	2 (1–3)	0.65

PAD: peripheral artery disease; PSV: peak systolic velocity; RCFA: right common femoral artery; REILA: right external iliac artery.
*PSV of the RCFA to PSV of the REILA; **Friedman test.

Discussion

Data from a series of observational and randomised studies show that the implementation of a femoral VCD is safe and has been proven beneficial for selected patient groups, contributing to better haemostasis, early remobilisation, and prompt ambulation and patient comfort, which explains their increasing use after diagnostic CAG or PCI.[5,7,11]

The primary goal of this study was to assess structural changes on the access femoral site after VCD implantation in patients who had undergone CAG or PCI. It was demonstrated that VCD deployment did not lead to a deteriorating impact on vascular wall properties in the short term, as assessed with well-established and broadly used sonographic indices. Moreover, no

significant changes were observed regarding the diameter of the RCFA in transverse and longitudinal view, PSV of the RCFA, ratio of the PSV of the RCFA to REILA, and RI of the RCFA. Notably, the degree of atheromatous vascular wall abnormalities at the puncture site remained unchanged in the short-term follow-up time at 30 days after CAG/PCI.

Only a few studies have systematically assessed ultrasound indices and intra-, endo- and perivascular complications after the deployment of a VCD. Lee *et al.* observed no flow abnormalities and no increased incidence of critical peripheral vascular disease after serial ultrasound and clinical assessment of the puncture site compared to the contralateral, non-puncture site in 205 patients treated with Perclose Proglide™ VCD at a one- and 10-year follow up.[9,10] It is noticeable that these studies lacked baseline measurements.

Data from non-comparative studies showed a 2% incidence of severe vessel stenosis or occlusion. However, this was associated with the inadvertent cannulation of the superficial femoral artery.[12] Another study demonstrated a numerical, but not statistically significant, higher incidence of bleeding complications when the puncture site was located lower than the femoral bifurcation, compared to other puncture sites.[13]

Our study assessed ultrasound markers of vascular function and structure at baseline and within a 30-day time range after puncturing the RCFA, which provided better means to ultrasonographically identify the optimal access site to the RCFA and to set a better context for comparisons between baseline and post-cannulation measurements than previous studies.

Our study demonstrated that the use of the Perclose Proglide™, a femoral VCD that delivers percutaneous suture to the access site, was safe and not associated with adverse vascular sequelae. This safety profile is in agreement with data in the literature regarding acute vascular complications. Moreover, 4.4% of the patients who eventually received Perclose Proglide™ experienced acute vascular complications, and 2.2% developed a large groin haematoma. This is in comparison to 6.9 and 4.8%, respectively, in the Instrumental Sealing of ARterial Puncture Site – CLOSURE Device vs Manual Compression (ISAR-CLOSURE) trial,[7] which is the largest randomised trial on the matter.

Data from randomised studies have demonstrated that the use of a VCD was not inferior to manual compression in terms of the incidence of pseudo-aneurysms and arteriovenous fistulae (2.2%), while it was associated with a reduced incidence in large groin haematomas (ranging from 2.2 to 4.8%).[7,14] Findings from two network meta-analyses of femoral VCDs revealed a relatively similar safety profile among various VCDs compared to manual compression. One of the meta-analyses found that Angio-Seal™ and FemoSeal™ were advantageous over other VCDs in terms of major adverse vascular complications and haematomas,[15] while a more recent meta-analysis demonstrated that StarClose™ outperformed other VCDs regarding the occurrence of major complications.[16]

It should be noted that the implementation of a VCD provides the opportunity for prompt remobilisation and ambulation with safety, which can be particularly beneficial for selected patient groups, such as those on oral anticoagulation, who have a higher bleeding risk after femoral artery puncture.

Our subgroup analysis revealed no differences in sonographic indices in patients on oral anticoagulation, with type 2 diabetes or with subclinical PAD during the study follow-up period. Notably, patients with diabetes mellitus demonstrated a trend for a decreasing PSV of the RCFA, and patients with evidence of PAD displayed a trend towards a lower RI in the RCFA throughout the study. However, these observations did not reach statistical significance at the level of ≤ 10%. This suggests the potential advantageous use of a VCD in high-risk patients, not only concerning vascular and bleeding complications, allowing for a shorter time to haemostasis and early discharge, as observed in other studies,[17] but also for better functional vascular properties.

Participants in the current study were treated exclusively with Perclose Proglide™, which is a suture-mediated closure system. The suture appeared as a subtle perivascular hyper-echogenicity in ultrasonography just after deployment, but this finding did not persist in the short-term follow up. In line with previous findings, the deployed suture was visible in only 12% of the participants at the 30-day follow up.

Other VCD types correlate with partial absorption, perivascular and intravascular changes.[18] These changes could be attributed to traumatic and inflammatory triggers resulting from the intra-arterial anchor plate, a characteristic feature of other VCDs.[19,20] However, the characteristic feature of Perclose Proglide™ was reflected on the sustained integrity of the arterial wall and unobstructed deployment site observed in the current study and may explain the low incidence of intra- and perivascular adverse changes, found in only one case of minimal atheromatous changes at the 30-day follow up.

Recent guidelines recommend the transradial approach regardless of the clinical setting (acute or chronic disease) due to the lower rate of complications at the access site, quicker ambulation and comparable clinical outcomes.[21,22] However, femoral access remains an option in patients with anatomical limitations or in cases in which a coronary artery bypass graft surgery is highly likely, and the radial artery needs to be preserved as a bypass conduit vessel.[21,22] Our findings suggest that the use of a VCD in patients ineligible for transradial access does not result in femoral arterial wall alterations and is safe.

The deployment of Perclose Proglide™ is known to be technically demanding. Data from a large single-centre registry reported a 6.1% rate of device failure in 2 996 patients treated with a suture-type VCD after CAG.[23] Four device failures (4.3%) were observed in our study, which were associated with repeated femoral artery puncture in the recent past. Other investigators reported higher rates of Perclose Proglide™ device failure, suggesting the association with a learning curve and familiarity with the device usage.[24] It is important to note that interventionalists must be familiar with a VCD, its limitations and deployment specifics to effectively use it and prevent post-procedural complications.

Limitations

This study has limitations. First, this was a two-centre, one-arm, open-label study with a prospective, short-term follow-up design. Implementing ultrasonographic assessment prior to femoral puncture excluded patients with PAD or abnormalities that could result in vascular complications. However, it may have improved femoral artery localisation and optimised cannulation by preventing higher or lower punctures or punctures at bifurcation.

The participants in the current study underwent CAG and PCI with the use of 6F sheaths. Our results should not be extrapolated in subjects with femoral cannulation in other conditions, such as transcatheter aortic valve replacement.

The power of the study was limited by the sample size, although most studies on clinical outcomes after the implantation of the suture-mediated VCD, used in our study, included similar numbers of participants.[16,24] Previous investigations regarding ultrasonographic assessment of femoral access site included more patients and followed up patients for a longer duration, but they did not obtain baseline values.[9] Our findings should, therefore, be confirmed in prospective studies with long-term follow up, conducted in a randomised manner, with a comparative arm of patients treated with manual compression.

Conclusion

The use of a suture-mediated VCD was safe and was not associated with adverse vascular complications or structural vascular wall changes at the femoral access site 30 days after deployment in patients undergoing percutaneous CAG and/or PCI.

The first two authors (DP and KM) contributed equally to the study.

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