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Research Article

Efficacy and safety of Angio-Seal™ VIP vascular closure device compared to manual compression for access site hemostasis in patients who underwent antegrade common femoral artery puncture for popliteal and/or below the knee intervention

Angio-Seal™ VIP vasküler kapama cihazının, popliteal ve/veya diz altı müdahale için antegrad femoral arter ponksiyonu yapılan hastalarda girişim yeri hemostazı için etkililik ve güvenliği açısından manuel kompresyon ile karşılaştırılması

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Abstract

Aim: Antegrade common femoral artery puncture has become the preferred method for popliteal and below-the-knee interventions. There has been an increasing use of vascular closure devices aimed at reducing hospital stays and enhancing patient comfort. This study aimed to evaluate the efficacy and safety of the Angio-Seal™ VIP vascular closure device compared to manual compression for access site sealing in patients with popliteal and/or below-the-knee disease who underwent antegrade common femoral artery puncture.

Material and Methods: A total of 104 patients who underwent revascularization through antegrade common femoral artery puncture were randomly assigned to two groups based on the technique used for access site sealing: Angio-Seal™ VIP (n = 52) and manual compression (n = 52). The effectiveness of the two methods and the duration of hospitalization for both groups were analyzed. Complication rates were assessed during hospitalization and at a 3-month follow-up.

Results: Successful access site hemostasis without complications was achieved in 48 of 52 patients (92.30%) in the Angio-Seal™ VIP group and in 47 of 52 patients (90.38%) in the manual compression group (p = 0.42). Major complication rates did not differ between the Angio-Seal™ VIP (3.84%) and manual compression groups (3.84%, p = 1.00). However, the duration of hospitalization was significantly shorter in the Angio-Seal™ VIP group (10.4 hours vs. 28.6 hours, p = 0.03).

Conclusions: The Angio-Seal™ VIP device demonstrated safety and effectiveness comparable to manual compression for achieving hemostasis at the access site in patients undergoing antegrade common femoral artery puncture and was associated with a shorter duration of hospitalization.

Keywords: vascular closure device, antegrade, femoral, hemostasis

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Öz

Amaç: Antegrad femoral arter ponksiyonu, popliteal ve diz altı müdahaleler için tercih edilen yöntem haline gelmiştir. Hastanede kalış sürelerini azaltmayı ve hasta konforunu artırmayı amaçlayan vasküler kapatma cihazlarının kullanımı giderek artmaktadır. Bu çalışmanın amacı, popliteal ve/veya diz altı hastalığı olan ve antegrad femoral arter ponksiyonu yapılan hastalarda, girişim yeri hemostazının sağlanmasında, Angio-Seal™ VIP vasküler kapatma cihazının etkililiği ve güvenliğini manuel kompresyon ile karşılaştırmaktır.

Gereç ve Yöntemler: Antegrad femoral arter ponksiyonu ile revaskülarizasyon yapılan toplam 104 hasta, girişim yeri kapatma tekniğine dayanarak rasgele iki gruba atanmıştır: Angio-Seal™ VIP (n = 52) ve manuel kompresyon (n = 52). Her iki grup için yöntemlerin etkinlikleri ve hastaların hastanede kalış süreleri analiz edilmiştir. Komplikasyon oranları, hastanede yatış süresince ve 3 aylık takipte değerlendirilmiştir.

Bulgular: Angio-Seal™ VIP grubundaki 52 hastadan 48'inde (%92,30) komplikasyonsuz başarılı girişim yeri hemostazı sağlanmışken, manuel kompresyon grubundaki 52 hastadan 47'sinde (%90,38) bu başarı elde edilmiştir (p=0,42). Majör komplikasyon oranları Angio-Seal™ VIP (%3,84) ve manuel kompresyon grupları arasında (%3,84, p = 1,00) farklılık göstermemiştir. Ancak, hastanede kalış süresi Angio-Seal™ VIP grubunda belirgin şekilde daha kısa bulunmuştur (10,4 saate kıyasla 28,6 saat, p = 0,03).

Sonuçlar: Angio-Seal™ VIP cihazı, antegrad femoral arter ponksiyonu yapılan hastaların girişim yerinde hemostaz sağlamada, manuel kompresyon ile karşılaştırılabilir güvenlik ve etkinlik göstermiş ve daha kısa hastanede kalış süresi ile ilişkili bulunmuştur.

Anahtar Kelimeler: vasküler kapatma cihazı, antegrad, femoral, hemostaz

Introduction

The femoral artery is the most commonly preferred access site for popliteal and below-the-knee (BTK) endovascular interventions. While some operators favor a retrograde puncture with a crossover approach from the contralateral limb, others prefer an antegrade puncture of the common femoral artery (CFA) in appropriate cases due to several advantages, including improved pushability and support, as well as a shortened distance between the puncture site and the target lesion. The antegrade approach is particularly recommended when the operator needs to access the foot arteries for procedural success.

Manual compression and the use of vascular closure devices (VCDs) are the most commonly utilized methods for effectively sealing the arterial access site following an endovascular procedure. Several clinical trials have evaluated the effectiveness and safety of vascular closure devices for this purpose, demonstrating favorable outcomes [1-5]. The primary objectives of using these devices include reducing hospital stays, minimizing access site complications, and facilitating earlier patient mobilization. The fact that the type of anesthesia technique used can affect patients' length of hospital stay and the frequency of procedure-related complications underscores the importance of the hemostasis technique applied at the site of the intervention [6].

The Angio-Seal™ VIP is a plug-based VCD, and comprehensive data have supported its use regarding efficacy and safety in patients undergoing retrograde and antegrade CFA puncture site hemostasis. However, there is a lack of literature comparing conventional methods with Angio-Seal™ VIP for access site sealing, complications, and duration of hospitalization in patients with an antegrade CFA approach. Therefore, the aim of this study was to address this gap in the literature to some extent.

We compared the efficacy and safety of Angio-Seal™ VIP with manual compression for access site sealing in patients who underwent endovascular popliteal and/or BTK interventions through ipsilateral antegrade CFA access.

Material and Methods

Patient population

Over a 24-month period from 2022 to 2024, 93 out of 104 patients (64 male, 61.53%; age range 32-89 years) diagnosed with critical limb ischemia (n = 36) and Rutherford class 5/6 (n = 57), along with seven patients diagnosed with severe claudication unresponsive to medical/exercise therapy, underwent endovascular intervention via antegrade CFA access. Among all participants, four patients were primarily diagnosed with Buerger's disease. Seventy-eight patients (72.11%) had diabetes mellitus, and 14 patients had chronic

kidney disease (13.46%). Manual compression was performed in 52 patients, and Angio-Seal™ VIP VCD was applied in 52 patients for access site hemostasis. A total of 216 patient records were retrospectively matched by age, gender, BMI, risk factors, and Rutherford classification. We included 52 patients in each group from a total of 128 matched patients, randomly selected using a computer-based program that generates random numbers from those assigned to each patient. The sample size was calculated a priori using G-power software with 80% power and a 0.05 type I error rate. Our study received approval from the local ethics committee of Izmir City Hospital (2024/178) and was conducted in accordance with the Helsinki Declaration.

Study design and device deployment

This was a retrospective matched cohort study. Patients who underwent antegrade CFA puncture for endovascular intervention of popliteal and/or BTK disease were enrolled, and all variables associated with safety and efficacy were evaluated based on data taken from the database we carefully maintained.

All procedures were performed by a single operator with experience in over 200 cases of antegrade CFA puncture. A 6Fr vascular sheath (Terumo™) was used in all cases. Participants were evaluated using Doppler ultrasound and computed tomography angiography prior to the procedure. Fluoroscopic guidance, along with previously obtained information from CT angiography to determine the location of the bifurcation level, and Doppler ultrasound guidance were used in combination for the CFA puncture.

The Angio-Seal™ VIP device (St. Jude Medical, Minnetonka, MN, USA) consists of a polylactide/polyglycolide anchor, a collagen plug, and a suture contained within a specialized carrier system. When introduced, it achieves hemostasis by compressing the arterial puncture site between the anchor and the collagen plug. The device was deployed in accordance with the manufacturer's instructions but in an antegrade fashion. Patients with severe (>50%) proximal superficial femoral artery (SFA) disease and/or moderate to heavily calcified (graded by fluoroscopy and CT angiography) stenotic CFA, as well as those with a bypass graft at the puncture site, were excluded from the study.

The efficacy of closure with Angio-Seal™ VIP was defined by the device's ability to provide adequate hemostasis at the arterial puncture site without complications. After each successful device deployment, the access site was manually compressed for two minutes. For patients who did not receive Angio-Seal™ VIP, manual compressions were performed by the operator for a minimum of 15 minutes, starting four hours after the last intra-arterial heparin bolus, to achieve hemostasis. Patients were instructed to remain on bed rest for one hour and four hours following groin hemostasis in the Angio-Seal™ VIP and manual compression groups, respectively. An additional 2 kg sandbag was placed at the puncture site for three hours in the manual compression group. A nurse checked each patient's groin and pulses at 15 minutes, as well as at the 1st and 3rd hours after transferring them from the catheter laboratory to their beds. Patients in both the Angio-Seal™ group and the manual compression group were discharged promptly, barring any complications.

Complications were categorized as minor or major [6]. Minor complications included bleeding from the puncture site that did not require transfusion, hematomas ≤5 cm in diameter, and pseudoaneurysms that responded to ultrasound-guided manual compression. Major complications included hematomas >5 cm in diameter, bleeding requiring transfusion, pseudoaneurysms that did not respond to ultrasound-guided manual compression and required surgical intervention or percutaneous coil/thrombin embolization, arteriovenous fistula, retroperitoneal hemorrhage, plug embolism, groin infection, and vascular injury resulting in acute limb ischemia.

Patients were followed clinically and evaluated with Doppler ultrasound at one week and one month post-discharge.

Statistical Analysis

Statistical analysis was performed using SPSS 21.0 (SPSS, Chicago, IL, USA). The Kolmogorov-Smirnov test was utilized to assess the normal distribution of datasets. Categorical variables are expressed as numbers and percentages, while continuous variables are presented as mean ± standard deviation (SD) for normally distributed data and as median with interquartile ranges (25th–75th quartiles) for nonparametric data. The significance of differences between the two groups was evaluated, with two-tailed P values of <0.05 considered statistically significant.

Results

Baseline clinical characteristics of the two patient populations were similar (Table 1). The Angio-Seal™ VIP vascular closure device (VCD) was successfully deployed in all patients (100%). Successful access site hemostasis without complications was achieved in 48 of 52 patients (92.30%) in the Angio-Seal™ VIP group and in 47 of 52 patients (90.38%) in the manual compression group (p = 0.23).

Table 1. Baseline characteristics of study population. BMI; body mass index, CKD; chronic kidney disease.

Parameters		Angio-Seal™ VIP Group (n=52)	Manual Compression Group (n=52)	P value
Male (n, %)		33 (63.46%)	31 (59.61%)	0.09
Age (mean, range)		56.2 (±11.62)	57.6 (±12.08)	0.66
Diabetes mellitus (n, %)		37 (71.15%)	38 (73.07%)	0.12
Hypertension (n, %)		27 (51.92%)	23 (44.23%)	0.08
Dyslipidemia (n, %)		22 (42.30%)	24 (46.15%)	0.16
Smoking (n, %)		25 (48.07%)	27 (51.92%)	0.34
BMI (kg/m2) (mean, range)		24.2 (±3.62)	25.6 (±4.76)	0.82
CKD (n, %)		8 (15.38%)	6 (11.53%)	0.09
Rutherford classication (n, %)	3	3 (5.76%)	4 (7.69%)	0.15
	4	19 (36.53%)	17 (32.69%)	0.09
	5	16 (30.76%)	18 (34.61%)	0.22
	6	12 (23.07%)	11 (21.15%)	0.88
Buerger's disease (n, %)		2 (3.84%)	2 (3.84%)	1.00

In the Angio-Seal™ VIP group, three patients (5.76%) required extended manual compression (3 to 5 minutes) after deployment due to oozing from the puncture site; one patient (1.92%) developed a pseudoaneurysm that was treated with ultrasound-guided manual compression; one patient (1.92%) experienced a minor hematoma; one patient (1.92%) developed an arteriovenous fistula that was managed with a graft stent due to the patient's high surgical risk; and one patient (1.92%) had a major hematoma that required three units of blood transfusion and was clinically monitored, resolving within one week without surgical intervention. In the manual compression group, one patient (1.92%) had a minor hematoma; two patients (3.84%) developed pseudoaneurysms treated with thrombin embolization, while another pseudoaneurysm responded to external compression; and one patient (1.92%) experienced a major hematoma that necessitated surgery (Table 2).

The mean hospital stay was 10.4 hours for the Angio-Seal™ VIP group compared to 28.6 hours for the manual compression group (p = 0.03) (Table 2). No adverse events were reported during the 3-month follow-up period in either group.

Table 2. Main findings, complications, and duration of hospitalization of the study groups.

	Angio-SealTM VIP group (n=52)	Manual compression group (n=52)	p
Success rate of access site hemostasis (without complications) (n,%)	48 (92.30%)	47 (90.38%)	0.42
Major complications			
Hematoma >5cm or bleeding requiring blood transfusion (n,%)	1 (1.92%)	1 (1.92%)	
Pseudoaneurysm (needing for surgery) (n,%)	-	1 (1.92%)	
Arteriovenous fistula (n,%)	1 (1.92%)	-	
Total (n,%)	2 (3.84%)	2 (3.84%)	1.00
Minor complications			
Hematoma ≤5cm or bleeding not requiring blood transfusion (n,%)	1 (1.92%)	1 (2.77%)	
Pseudoaneurysm (responds to manual compression) (n,%)	1 (1.92%)	2 (3.84%)	
Total (n,%)	2 (3.84%)	3 (5.76%)	0.35
Duration of hospitalization (hours) (mean, range)	10.4 (±3.8)	0.6 (±6.7)	0.03

Discussion

Traditionally, contralateral CFA puncture with an "up and over" approach has been the preferred access for endovascular lower limb interventions. However, antegrade access has become increasingly common to mitigate the challenges associated with contralateral access, such as pushability, backup, torque control, and reaching the target site, especially in patients with popliteal and/or BTK disease [7,8]. Antegrade puncture of the ipsilateral CFA is generally preferred for popliteal and/or BTK interventions, provided the puncture site is not heavily calcified or stenotic. Nevertheless, antegrade puncture is technically more challenging than retrograde puncture and requires a longer learning curve.

VCDs have been widely adopted for access site sealing by many operators over the past two decades, providing immediate hemostasis without the need for external compression and prolonged bed rest. While vascular closure devices have been the standard for access site hemostasis in retrograde CFA punctures, their use for antegrade puncture site hemostasis has increased over the past decade [1-5].

Angio-Seal™ VIP, utilized in our study, is one of the most widely preferred VCDs due to its simple design, efficacy, and safety profile. Growing evidence in the literature encourages operators to adopt this device for antegrade CFA access site sealing. Numerous studies [9-14] have demonstrated its efficacy and safety in retrograde CFA puncture site sealing; however, several studies [1,5,7,16,17] have evaluated this VCD's use in antegrade approaches, with data primarily derived from retrospective analyses.

Lupattelli et al. [18] conducted a retrospective analysis of their data and found no statistically significant differences in overall complications between antegrade and retrograde CFA puncture site sealing using Angio-Seal™ VCD and manual compression (2.5%, 4.0%, and 4.5%, respectively). Lobby et al. [16] also reported no major complications associated with the use of Angio-Seal™ VCD in 58 patients undergoing antegrade CFA puncture. They performed manual compression instead of VCD in 7 patients due to severe CFA calcification at the puncture site, failure of device deployment in 4 patients, and one patient with superficial femoral artery dissection. In our study, we excluded patients with moderate to severe calcification at the puncture site, making this a non-determinant factor for access site hemostasis success or failure.

In a prospective trial, Minko et al. [15] identified obesity (BMI: 26.6 vs 28.8 kg/m^2, p = 0.04) as an independent risk factor for inadequate sealing with Angio-Seal™ VCD. Although this parameter was not analyzed in our study, the mean BMI was similar across both groups (Table 1). However, they [15] did not compare the efficacy and safety of this VCD with extrinsic compression as the conventional method in their investigation.

A meta-analysis [19] indicated that Angio-Seal™ VCD was non-inferior (and possibly favored) compared to manual compression concerning complications. Odds ratios (ORs) for hematoma events were 0.86 (95% CI 0.51–1.45, p = 0.78), for pseudoaneurysms 0.30 (95% CI 0.04–2.07, p = 0.93), for ischemic complications 0.80 (95% CI 0.22–2.94, p = 0.58), and for the need for surgery 0.83 (95% CI 0.18–3.85, p = 0.53). The analysis of total complications using Angio-Seal™ compared with manual compression also revealed no significant differences between the two groups (OR 0.84, 95% CI 0.53–1.34, p = 0.49). This meta-analysis [19] included a prospective randomized trial [20] which also determined that Angio-Seal™ was safe and effective compared to manual compression in terms of complications, additionally allowing for shorter hemostasis times. However, the trial [20] only included procedures involving retrograde femoral puncture.

A recent retrospective single-center study [21] reported a complication rate of 0.47% (46 of 9,754 cases) after VCD implantation, with complications ranging from claudication (n = 24) to acute limb ischemia (n = 19) and major bleeding (n = 3). They [21] found that female gender and diabetes mellitus were associated with major vascular complications. In our study, no major vascular complications such as acute limb ischemia, subsequent limb loss, or retroperitoneal hemorrhage were observed.

Limitations of the study

We did not analyze the cost-effectiveness of using Angio-Seal™ VIP; however, the shorter hospital stay demonstrated in both the literature and our study represents a significant factor in reducing costs [22]. Our sample size was relatively small due to the study being conducted at a single center over a limited time period, highlighting the need for further investigation into this device's efficacy and safety in larger cohorts. Additionally, patients with CKD and those classified as Rutherford class 6 were statistically different between the two groups. However, we believe this discrepancy may have resulted from simple randomization in our relatively small sample size and is unlikely to have influenced our results.

In conclusion the Angio-Seal™ VIP device proved to be a safe and effective method for access site hemostasis compared to manual compression in patients undergoing antegrade CFA puncture for endovascular popliteal and/or below-the-knee interventions, resulting in a significantly shorter duration of hospitalization in the Angio-Seal™ VIP group.

Declaration of conflicting interests

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Ethics approval

This study was approved by Izmir City Hospital Ethics Committee with protocol number 2024/178.

Authors' contribution

GÇ: developed the study concept, collected patient data, conducted the literature review, and performed the statistical analyses. AÇ: carried out all procedures and reviewed the final version of the manuscript. Both authors contributed to all stages of the study and share joint responsibility for the final manuscript.

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