Journal of Surgery
Cornidez E, et al. J Surg 10: 11299
www.doi.org/10.29011/2575-9760.11299
www.gavinpublishers.com
Research Article

Analysis of the Presence of Clot in the Femoral Arterial Introducer During Angiography: A Randomized Clinical Trial

Carlos Alexandre de Albuquerque Maranhão[1], Laécio Leitão Batista[1], Cynthya Bezerra Tavares de Oliveira Maranhão[2], Arthur de Almeida Leitão Batista[3], Esdras Marques Lins[1]

[1]Postgraduate Program in Surgery, Medical Sciences Center , Federal University of Pernambuco, Recife, PE, Brazil

[2]Hemodynamics of the Lauro Wanderley University Hospital, Joao Pessoa, PB, Brazil

[3]Medical stdent. Center - Federal University of Pernambuco, Recife, PE, Brazil

*Corresponding author: Esdras Marques Lins, Postgraduate Program in Surgery Medical Sciences Center - Federal University of Pernambuco. Recife - PE, Av. Prof. Moraes Rego, 1235 - Cidade Universitária, Recife - PE, 5060-901, Brazil

Citation: Maranhão CAA, Batista LL, de Oliveira Maranhão CBT, Batista AAL, Lins EM (2025) Analysis of the Presence of Clot in the Femoral Arterial Introducer During Angiography: A Randomized Clinical Trial. J Surg 10: 11299 DOI: 10.29011/2575-9760.011299

Received Date: 31 March 2025; **Accepted Date:** 04 April 2025; **Published Date:** 07 April 2025

Abstract

Percutaneous angiography has been performed for decades, but it is not without complications, such as the formation of a clot within the arterial introducer, and its potential migration into the systemic circulation. However, it is not clear what the best approach is regarding the use of continuous perfusion in the introducer (pressure perfusion through the lateral port of the introducer with saline solution 0.9%) during diagnostic angiographic exams, in preventing the formation of clots inside the introducer, which is the access portal for the passage of catheters and guide wires.

Objective: To determine the frequency of clot presence in the femoral artery introducer with and without continuous perfusion in cerebral angiographic studies.

Method: A randomized clinical trial in patients undergoing cerebral angiography performed at the Hospital das Clínicas / EBSERH-UFPE and at Angiocor in João Pessoa - Paraíba, divided into two groups: Control group (GC), n=34 patients without continuous perfusion in the femoral arterial introducer during angiography. Experimental group (GE), n=34 patients with continuous perfusion in the femoral arterial introducer during angiography. Statistical analysis was performed using the *u* Mann-Whitney test, for continuous variables and the Fisher's exact test for categorical variables. The significance level was 0.05.

Results: In the GC there was the presence of a clot in all introducers at the end of the angiographic exam, while in the GE, no clot was present in any introducers at the end of the angiographic exam.

Conclusion: The use of continuous infusion prevented the formation of clots within the introducer during the angiographic exam in all cases.

Keywords: Angiography; Femoral artery; Thrombosis

Introduction

The arterial introducers are access options for percutaneous endovascular interventions. Vascular complications in the area of femoral access are relatively frequent manifestations, with an incidence ranging between 1% and 14% [1-3]. This type of complication has been considered one of the main causes of morbidity and mortality in these patients. With the development of new devices, efforts have been made to minimize damage to the arterial vascular bed, consequently determining a significant reduction in the prevalence of these complications. Local hematoma, acute arterial occlusion, pseudo aneurysm and arteriovenous fistula formation determine increased hospital stay time, discomfort and additional risks to patients as a result of possible surgical repair procedures, mechanical compression and blood transfusions [2,4].

The introducers are tubes, generally made of nylon, used to pass catheters, guidewires, balloons, etc., during procedures. These devices maintain communication between the endovascular system and the external environment, preventing blood loss through a one-way valve system, typically made of silicone. At the end of each procedure, the introducer is removed, and in some cases, the presence of a clot inside the introducer is observed. This increases the risk of clot migration into systemic circulation, which can promote arterial embolism. In interventional radiology services, there are already some ways to prevent the formation of the clot. An alternative is to fill the introducer lumen before the start of the exam with Saline Solution (SS) 0.9% and another way is to use a pressure system to maintain a constant drip of SS 0.9% into the introducer during the procedure [5,6]. It is not clear what the best approach is to prevent clots inside the introducer regarding the use or not of continuous perfusion in the introducer (perfusion under pressure through the lateral port of the introducer with 0.9% SS) during angiographic diagnostic exams. This study aims to determine the frequency of clots in the femoral arterial introducer without and under continuous perfusion in cerebral angiographic studies.

Methods

A total of 68 patients with suspectedintracranial aneurysms and other cerebral vascular diseases were subjected to cerebral angiography exams. The patients were from the Hemodynamics Service of the Hospital das Clínicas of the Federal University of Pernambuco (HC-UFPE) and the Paraibano Center for Invasive Cardiology and Interventional Radiology (Angiocor), located in Paraíba [2,3].

Study Type

This study was a randomized clinical trial carried out between March 2012 and October 2022. Patients aged between 18 and 65 years, who underwent diagnosticcerebral angiography with a contraindication for heparin and used a 5F introducer in the right femoral artery were included in the study. Patients were excluded if they had clotting disorders, peripheral arterial obstructive disease or were using anticoagulants, antiplatelet drugs, contraceptives, anti-inflammatory drugs, antibiotics or vitamin K. A total of 68 cards were prepared, 34 marked with perfusion and 34 without perfusion. These cards were mixed and placed in a box. As patients met the criteria, the card was randomly removed. If a patient withdrew from the study, a replacement card was added to the box to ensure consistent randomization. To determine the sample size, the equation used was the sample calculation for the study ofthe experimental average in two independent groups. Considering a confidence level of 95%, test power of 80%, expected standard deviation of the clot mass of 0.10 in the two groups evaluated, meanclot mass of 0.01 grams in the group with perfusion and 0.08 grams in the group without perfusion, the necessary sample size is 32 patients in each group. Considering the possibility of losing 10% of the sample, the number of elements for each group is 34 observations, with the total number of observations in the study equal to 68 participants.

To compare the samples, Fisher's exact test was used associated with the Relative Risk (RR) and calculating the 95% Confidence Interval (CI) for each estimated point. An electronic calculator was used, into which data was entered to calculate the sample size, and the statistical program GraphPadInstat® Version 3.06, 32 bit for Windows, was used for statistical calculations. The digital cerebral angiography was used with the patients in the study and involves the cervical and/or cranial vessels. This exam is performed under sedation, assisted by an anesthesiologist. A local anesthesia at the femoral puncture site was given to patients suspected of having hemorrhagic stroke (CVA), with contraindication to the use of heparin. The following technique was used: local anesthesia with 5mL of lidocaine 2% without vasoconstrictor at the right common femoral artery puncture site followed by femoral artery puncture with 18G Jelco. The 0.035" hydrophilic guide wire was passed, removing the Jelco and passing through the guide wire of the introducer. This introducer was filled with 0.9% SS prior to its assembly with a dilator. The group that used perfusion connected a 500mL bag of 0.9% SS under pressure of 300 mmHg to a sterile equipment after removing the dilator. Thisequipmentwas connected to the lateral route of the introducer, and 20g/m of 0.9% SS was estimated through the introducer sheath during the examination.

At the end of the exam, the presence of the clot was assessed as follows: immediately after the end of the exam, the doctor who performed the angiography removed the contents of the dead space of the introducer (3 ml) and placed the contents in a non-abrasive, clean, absorbent tissue, made from100%virgin cellulose fibers, which does not release lint. This material is specific for filtering liquid, in this case blood, leaving only the clot on the surface of the paper, when present. The clot was removed from the paper with Adson-type dissection forceps, without teeth, and was placed on an analytical scale. Its weight was measured at three different times, to get the average of the three measurements. The mass or amount of weight was expressed in kilograms. The kilogram is the amount of mass (not weight or force); it is equal to the mass of the international kilogram prototype. This international prototype in iridium platinum is kept at the International Bureau, under the conditions established by the 1st CGPM in 1889.

The sex, exam time and age (randomly in years, based on the day, month and year of the patient's birth date at the time of collection and exam time (measured in minutes and counted from the puncture until the introducer was removed).

The data was collected on a standardized form (appendix A) and stored in an electronic data spreadsheet (Microsoft Excel® 2007. Redmond, WA, USA). Data entries were performed independently. For data analysis, a database was built in Microsoft Excel, which was exported to the SPSS software, version 17, where the analysis was completed. To evaluate the sex distribution of the patients, age group and examination time, percentage frequencies were calculated and the respective distributions were constructed. When comparing the distribution of factors between the group of patients who underwent perfusion and those who did not, the Chi-square test was applied for homogeneity. In cases where the test assumptions were not met, Fisher's Exact test was applied. Furthermore, the mass (in grams) of the clot formed during the procedure was calculated. For the quantitative variables of the study, statistics were calculated: mean and standard deviation. In addition the normality of the measurement was assessed using the Kolmogorov-Smirnov test. Mass comparison was made using the Mann-Whitney test. For the comparison of this study, variables with statistical significance ($p<0.05$) were used.

This study was approved by the Research Ethics Committee of the State University of Health Sciences of Alagoas (UNCISAL), Maceió, on July 25, 2012 at CEP N. 1946. It was a prospective, randomized, 1:1 study, with a recruitment period between March 2012 and October 2022, in which it was determined that all patients who met the criteria during this period would be recruited. A total of 251 patients were recruited, with 68 entering the study. These patients were divided into two groups: Group 1 (control) - No Perfusion (NP) and Group 2 (experimental - with perfusion (WP), each group containing 34 patients.

In Table 1, the distribution of sex, age range, procedure time and the calculated clot mass during the procedure are shown. Table 1 also shows that most patients were female (55.9%), aged between 41 and 60 years (50.0%) and underwent the procedure for 16-20 minutes (51.5%). The distribution of these factors was identical between patients who received perfusion and those who did not. This similarity in the distribution was confirmed by the Chi-square test for homogeneity, which showed no significant differences between the groups.

Regarding the clot mass, the average was0.05 grams. For the perfusion group, the mean was 0 grams, while in the non-perfusion group the average was 0.11 grams with a standard deviation also of 0.11 grams. The comparison of mass distribution between the two groups was significant (p-value < 0.001), indicating that non-perfusion was a determining factor for the formation of clot mass.

			Perfusion		
			Yes (n = 34)	No (n = 34)	
Evaluated factor	**n**	**%**			**p-value**
Sex					
Male	30	44.1	15 (44.1%)	15 (44.1%)	1.000[1]
Female	38	55.9	19 (55.9%)	19 (55.9%)	
Age range					
Under 21 years old	5	7.4	2 (5.9%)	3 (8.8%)	0.897[2]
22 to 40 years old	12	17.6	5 (14.7%)	7 (20.6%)	
41 to 60 years old	34	50.0	18 (52.9%)	16 (47.1%)	
61 years or older	17	25.0	9 (26.5%)	8 (23.5%)	
Exam time					
13 a 15	22	32.4	10 (29.4%)	12 (35.3%)	0.420[2]
16 a 20	35	51.5	16 (47.1%)	19 (55.9%)	
21 a 25	9	13.2	6 (17.6%)	3 (8.8%)	
26 a 40	2	2.9	2 (5.9%)	0 (0.0%)	
Mass					
Mean+Standard deviation	0.05±0.9		0.00±0.00	0.11±0.11	<0.00[3]

[1]p-value of the Chi-square test for homogeneity; [2]p-value of Fisher's Exact test; [3]p-value of the Mann-Whitney test.

Table 1: Distribution of sex, age group, exam time and calculated mass.

Table 2 showsthe descriptive analysis of the mass according to the sex of the patients, age group, and the procedure time. The mean mass was higher in female patients (mean = 0.06 grams), aged 41 to 60 years (average = 0.06 grams) and who spent between 21 and 25 minutes of treatment (average = 0.10 grams). Furthermore, even though a higher mean mass was found in these groups described, the distribution comparison test was not significant in any of the factors evaluated (p-value = 0.812; 0.902 and 0.503, respectively), indicating that the mass is not significantly altered due to the sex of the patients, the patient's age group or the duration of the procedure.

Evaluated factor	Minimum	Maximum	Mass	Standard deviation	p-value
Sex					
Male	0.00	0.22	0.04	0.06	0.812
Female	0.00	0.56	0.06	0.11	
Age range					
Under 21 years old	0.00	0.03	0.01	0.01	0.902
22 to 40 years old	0.00	0.15	0.05	0.05	
41 to 60 years old	0.00	0.56	0.06	0.11	
61 years or older	0.00	0.30	0.05	0.08	
Exam time					
13 a 15	0.00	0.30	0.05	0.07	0.503
16 a 20	0.00	0.22	0.05	0.06	
21 a 25	0.00	0.56	0.10	0.20	
26 a 40	0.00	0.00	0.00	0.00	

[1]p-value of the Kruskal-Wallis test (if p-value < 0.05, the mean mass differs between the levels of the factor evaluated).

Table 2: Descriptive analysis of the mass according to the patient's sex, patient's age group and procedure time.

Discussion

In this research, the use of continuous saline perfusion during arterial angiography prevented clot formation in the introducer in all patients studied. This may have contributed to the absences of femoral arterial thrombosis or embolism to the distal arteries of the lower limbs in the studied sample. In the literature, the vascular complication rate in angiography varies from 1% to 14% [7]. A multicenter study conducted in southern Brazil with 2,696 patients undergoing hemodynamic procedures reported an overall vascular complication rate of 8.8%.The most common complication was local hematoma. Aless frequent complication was distal ischemia due to arterial embolization. However, the causes of these complications were not specifically addressed in the study [8]. Arterial thrombosis was rare in lower limb access sites and occurred more often when the brachial artery approach was used. Predisposing factors for femoral artery thrombosis include: small-caliber vessels, the presence of peripheral obstructive arterial disease and/or diabetes mellitus, female sex, the use of large-diameter catheters or sheaths (e.g., for intra-aortic balloon pumps or aortic endoprostheses), or prolonged retention of the catheter within the artery [7-10].

Regarding arterial embolism, several causes have been identified, including atheroembolism secondary to the use of rigid guidewires and large-caliber guiding catheters, which can traumatize the aortic endothelium, leading to the detachment of atheromatous debris from the vessel wall [7-9].

Distal arterial microembolization was reported in a prospective study involving 1,786 patients, which examined the incidence and risk factors of cholesterol embolization syndrome, a complication of cardiac catheterization. Investigators of the Cholesterol Embolism Study (CHEST) made the following observations: 25 patients (1.4%) were diagnosed with atheroembolism, of whom four (16%) died during hospitalization. The same study reported a significantly lower mortality rate (0.5%) among patients who did not develop atheroembolism [11]. The present studywas prompted by the observation of clot formation in the femoral artery introducer in some patients at the time of its removal, increasing the risk of distal embolization during this procedure. The issue is exacerbated by the fact that, in many cases, patients are discharged from the hospital just a few hours after angiography, which may lead to delayed recognition of early signs and symptoms of distal lower limb ischemia. Consequently, this complication may be underdiagnosed, with only the most severe cases returning to the hospital for appropriate treatment.

Distal arterial embolism or thrombosis at the puncture site poses a significant risk to the lower limb, often necessitating urgent open thrombectomy or endovascular intervention to salvage the limb. These procedures are associated with increased mortality rates and higher healthcare costs [10,11]. A comprehensive review of the literature did not identify any studies linking the arterial introducer used in angiography to distal artery embolism. Similarly, no research was found regarding the use of sheath perfusion during this procedure or its potential role in clot prevention. Another important issueis the lack of a standardized protocol in the literature regarding the use of continuous perfusion during arterial angiography. Even within interventional cardiology services, physicians who use introducer perfusion with saline solution do so empirically, without a solid scientific basis. This study could contribute to the development of a standardized protocol for the use of saline solution perfusion in the introducer during all angiographic procedures, whether diagnostic or therapeutic. Such a protocol could be particularly beneficial for patients with an absolute contraindication to anticoagulants during angiography. Thus, this research offers a simple and cost-effective approach to preventing arterial embolism and its complications.

A limitation of this study is that it did not evaluate the use of introducer perfusion in alternative access sites, such as brachial and radial arterial access or venous access. Additionally, introducers of different diameters were not assessed, nor were patients on antiplatelet therapy, which could have provided further insight into the presence of clots in the introducer under these conditions. This study provides an objective perspective on the prevention of arterial embolism and its complications through the use of introducer perfusion at the time of removal, effectively eliminating the presence of clots within the sheath.

Conclusion

It is concluded that the use of continuous perfusion with 0.9% saline solutionin the introducer during cerebral angiography prevented clot formation inside the femoral artery introducer in all cases.

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