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REFINEMENT OF THE FEMORAL PUNCTURE TECHNIQUE THE SECRET: DO NOT TRANSFIX THE ARTERY!

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ABSTRACT

Background: The femoral artery has been the standard access route for several decades. However, this access route has been associated with increased rates of vascular complications compared to the radial artery access route. The objectives of this study were to describe vascular complications at femoral access site after puncture without transfixation of the artery. **Methods**: This a was real-world registry (from January 2017 to August 2019) that enrolled 1000 patients (mean age 56±10years) with stable CAD and clinical indication of coronary angiography. All patients had their femoral arteries cannulated at the first attempt (not transfixed). After completion of the procedure the 6Fr introducer was removed and the hemostasis was done using a mechanical compressor (20 minutes), followed by a compressive bandage for 24 hours. **Results:** There were more men (656 (65.6%))than women (334 (34.4%)). The prevalence of married was 730 (73%), family income of less than 3 minimum wages 750 (75%), and elementary education, 560 (56%). At 30-day follow-up the rates of vascular complications were: hematomas < 5cm or ecchymosis = 1.8% (18 cases), hematoma ≥ 5cm = 0,9% (9 cases), and vascular surgery 0.1% (1 case). There were no death, myocardial infarction, stroke, or urgent coronary artery bypass graft surgeries related to the procedures. **Conclusions:** Vascular complications were low. The non-transfixing puncture technique associated with the use of a mechanical compressor may represent a cheap, safe, and efficient haemostasis strategy. Refinement of the puncture technique was critical to the results and should be sought.

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INTRODUCTION

The coronary Artery Disease (CAD) is the leading cause of death worldwide, with about 9 million deaths per year. CAD affects around 126 million of people (Khan, 2020). The decrease in mortality from cardiovascular disease has been a major achievement in public health, and the advances in the management of Acute Myocardial Infarction (AMI) were fundamental to reduce that rate (Smilowitz, 2016). Percutaneous Coronary Intervention (PCI) has changed the treatment of CAD. This type of treatment modality reduces mortality and morbidity, both in chronic coronary and in acute syndromes. Therefore, PCI has a positive impact on CAD treatment (Malik, 2018).

In this context, the coronary angiography for diagnostic purposes has an important role in the management of patients with CAD, especially in those considered to be at high risk for death and AMI. It is estimated that more than 1 million of these procedures are performed in the USA (Virani, 2020). Early revascularization with PCI with coronary stenting is the best technique ofreperfusion in patients with AMI with ST-segment elevation. Primary PCI improves survival and is associated with lower rates of reinfarction and intracranial hemorrhage (Singh, 2017). Percutaneous procedures can be performed via transfemoral artery access (TFA), but thisapproach has been associated with vascular complications that may affect the patient's prognosis (Tomassini, 2010). The femoral artery has been the standard access route for several decades, since it is a large caliber vessel that can accommodate large catheters and sheaths and has a

more predictable vascular anatomy as well as rapid arterial access. However, this access route has been associated with increased rates of vascular complications in some clinical settings compared to the radial artery access route (Chugh, 2020). Hemostasis after percutaneous procedures via femoral access can be performed by manual compression, mechanical compression, or vascular closure devices (Dahal, 2017). Manual compression, although effective when performed correctly, require s at least 20 minutes the puncture site and can be painful. Despite the enthusiasm of some, compression by mechanical devices has not been widely performed, and the use of vascular hemostasis devices is indicated forstage IIa (Feres, 2017). Vascular complications are related to technical issues of the puncture, type of local hemostasis, and patients' characteristics. The study was conducted to determine whether the technical standardization of the femoral artery puncture and local hemostasis could have a positive impact on the rate of vascular complications. Therefore, the objective of this study was to describe vascular complications following coronary angiography via femoral access using a protocol of puncture and mechanical compression (a metal compressor).

METHODS

Type of study and population: This is a real-world, prospective, descriptive study that has been planned to enroll 1000 patients. The study started in january 2017 and finished its enrollment in august 2019 when the sample was achieved. The inclusion criteria were patients aged over 18 years, with a clinical indication for coronary angiography due to the occurrence of symptoms despite optimal clinical treatment, or the presence of a high-risk ischemia-inducing test for myocardial infarction and/or death. The exclusion criteria were previous history of lower limb, peripheral arterial, or aortic artery disease, treatment for erectile dysfunction, active cancer, patients with severe blood dyscrasia, psychiatric disorders, inability to answer questionnaires, life expectancy of less than 1 year, or participation in another study. The patients' clinical, social, and economic data were collected through questionnaires.

Femoral artery puncture and hemostasis with a mechanical compressor: The target site for femoral artery puncture was 2 cm below the inguinal ligament, and only the anterior wall of the vessel was punctured using a puncture needle entering the skin at a 45 º angle (IT COULD NOT BE TRANSFIXED). After completing the procedure, the 6 French (6Fr) introducer was removed, and a 3-cm (square) gauze pad was placed 0.5 cm above the skin puncture hole. Next, the acrylic disk (3 cm) of the compressor was positioned on the gauze pad and compression was placed using the standard technique (the skin was depressed by 1 cm). The compression was maintained for 20 mins, followed by the placement of a compressive dressing for 24 h. The patients were in bed for 4 h after removing the introducer, then they were discharged. The patients returned for outpatient follow-up 7 and30 days after the procedure.

Statistical analysis: The descriptive statistical analysis was performed by an independent statistician using SPSS v21. The categorical variables are expressed as absolute and percentage frequencies. The Shapiro-Wilk test was applied to numerical variables and, since they had a normal distribution, are expressed as mean and standard deviation.

Ethical considerations: The study was conducted in accordance with the principles of the Declaration of Helsinki and approved by a Research Ethics Committee.

RESULTS

Tables 1 and 2 show the results related to the sample profile of the 1,000 patients with average age of 56±10 years. There were 656 (65.6%), 730 (73%), and750 (75%) patients who were male, married, and with a family income of less than 3 minimum wages, respectively.As for past medical history the rate of systemic arterial hypertension was 80%and Diabetes Mellitus was 37%.

Table 1. Demographic and social data of the patients

Variable	n (%)
Gender	
Male	656 (65.6)
Female	344 (34.4)
Marital Status	
Single	112 (11.2)
Married	730 (73)
Widower	71 (7.1)
Divorced	60 (6)
Family income	
<3 minimumwage	750 (75)
Scholarity	
Elementary	560 (56)
High school	360 (36)
First degree	73 (7.3)
Illiterate	7 (0.7)

Table 2. Clinical characteristics of the patients

Variable	n (%)
Past medical history Hypertension	800 (80)
Diabetes Mellitus	370 (37)
Dyslipidemia	210 (21)
Smoking	160 (16)
Alcoholism	96 (9.6)
Stroke	140 (14)
Family medical history	
Hypertension	750 (75)
Diabetes Mellitus	530 (53)
Dyslipidemia	70 (7)
MyocardialInfarction	270 (27)
Stroke	150 (15)
ChronicKidneyDisease	40 (4)

All procedures were performed using a 6 Fr introducer in the femoral artery, and all catheters were also 6Fr. A 0.035" Teflon guidewire was used in 92.1% of patients, and a left ventriculography was performed in 8.4%. The most frequently used catheters were Judkins Right in 92.3% of patients and Judkins Left in 89.5% of patients. The following complications occurred at the vascular access site at the end of 30 days of clinical follow-up: hematoma <5 cm or ecchymosis in 18 patients (1.8%), hematoma ≥5 cm in 9 patients (0.9%), and vascular thrombosis requiring surgical repair in 1 patient (0.1%). This patient started presentingwith pain in the right lower limb after 2 h of dressing application on right inguinal region. After a physical examination and imaging exams, an arterial obstruction was diagnosed and corrected with surgery, and the patient was subsequently discharged asymptomatic. There were no deaths, AMI, strokes, or emergency coronary artery bypass surgery in this group.

DISCUSSION

The occurrence of vascular complications was very low in this study. A relevant complication occurred in 0.1% of patients but was resolved with a surgical approach, and the patient was discharged asymptomatic. The puncture of only one wall of the vessel (accepted as anterior wall since there was blood reflux during the introduction of the needle), the absence of transfixation,andinexistence of multiple perforations of the artery were the main factors for the low rate of vascular complications. The standard placement of the compressor, so that the force required for hemostasis of the vessel was exerted but did not compromise the flow leading to cyanosis or altered lower limb perfusion, also contributed to the satisfactory results of the study. Our findings demonstrate the importance of an adequate arterial puncture when it is not guided by ultrasonography. Although the ultrasound-guided puncture technique presents excellent results (Feres, 2017), most hemodynamic laboratories in the world for coronary artery procedures do not routinely use this technique. The femoral access route contributed to the advancement in the percutaneous procedures between the 70s and the 2000s (Basua, 2017).

A series of publications have demonstrated a reduction in clinical events when using the radial route as compared to the femoral route, especially in patients undergoing PCI or those with acute coronary syndromes (Ferrante, 2011; Manly, 2021; Fischman, 2021). A meta-analysis that included 22,843 patients revealed that the radial route reduced all-cause death (OR=0.71 (95% CI: 0.59 - 0.87), p=0.001), the occurrence of major cardiovascular events (OR=0.84 (95% CI: 0.75 - 0.94), p=0.002), major bleeding rates (OR=0.53 (95% CI: 0.42 - 0.65), p<0.001), and major vascular complications (OR=0.23 (95% CI: 0.16 - 0.35), p<0.001) when compared to the femoral route in patients who underwent coronary angiography followed by PCI, when indicated (Ferrante, 2016). The analysis of 1,279,058 angiographic proceduresfor coronary arteries and vascular grafts in patients with a previous history of myocardial surgical revascularization revealed that the radial route was associated with lower mortality rates (OR=0.83 (95% CI: 0.75 - 0.91)), lower bleeding rates (OR=0.57 (95% CI: 0.51 - 0.63)), less vascular complications (OR=0.38 (95% CI: 0.30 - 0.47)), and a higher chance of a successful PCI (OR=1.11 (95% CI: 1.06 - 1.16), p=0.001) (Manly, 2021). The radial route was more rapidly incorporated in Europe, Asia, and Canada, while its use started later in the United States and has yet to increase (2007=1.2% and 2016=16.1%) (Fischman, 2021).

Therefore, the studies demonstrate the superiority of the radial access route over the femoral access route when performing percutaneous coronary procedures, especially when there wasPCI (Ferrante, 2016; Manly, 2021; Fischman, 2021). On the other hand, comparative studies of ultrasound-guided femoral artery puncture to the modified Seldinger technique have demonstrated a higher success rate in the first cannulation attempt, a decrease in the number of attempts to cannulate the artery, decreased risk of venous puncture, less time for vascular access, and reduced vascular complications favoring ultrasound guided puncture (Seto, 2010; Stone, 2020; Sobolev, 2015; Gedikoglu, 2013). Only one wall of the femoral artery is punctured when a patient undergoes an ultrasound-guided puncture, while the artery is often transfixed in an unguided puncture (Seto, 2010; Stone, 2020). Ultrasound-guided vascular puncture is the gold standard central venous punctures, and only one wall of the vessel is punctured in these cases. Therefore, puncturing only one wall of the vessel in ultrasound-guided venous puncture has been considered as a potential beneficial factor for reducing complications (Shin *et al*., 2019; Shinde *et al*., 2019; Brass, 2015). Most studies comparing radial and femoral access routes do not discuss that systematically only one wall of the femoral artery was punctured and that there was no transfixation of the vessel (Ferrante, 2016; Fischman, 2021). If a femoral artery is transfixed and a patient who was already receiving dual antiplatelet therapy is given full anticoagulation for PCI a few minutes later, bleeding related to a potential iatrogenic perforation may occur. The optimal puncture site in the femoral artery is 2-3 cm below the inguinal ligament, but most studies comparing femoral and radial access routesdo not report on the percentage of cases in which this was done. The complication rate increases when the puncture is not performed at that location (Deepak, 2011). Finally, it is well known that an inadequate hemostasis of the femoral artery increases the complication rate[22], but most studies comparing the complication rate with radial and femoral access routes do not provide hemostasis protocols when puncturing the femoral artery (Ferrante, 2016; Fischman, 2021). In the context of coronary artery disease management, femoral artery closure devices have not demonstrated superiority regardingimportant complications compared to manual compression or the use of mechanical compressors, but are associated with shorter walking time, less time to hemostasis, and greater patient satisfaction and comfort (Noori, 2018; Yi, 2020). On the other hand, there is an increase in costs in some countries when using such devices, and the cost-effectiveness of their routine use is unclear. Therefore, there is limited detailed information on femoral artery puncture and hemostasis techniques in many studies that compared this technique to the radial artery puncture (Ferrante, 2016; Manly, 2021; Fischman, 2021). From a technical and clinical perspective, such lack of information represents an unstated bias of these studies.

Puncture by palpation method is an imprecise term as has been described, because it does not describe the technique that evolved when compared to the beginnings of femoral puncture, as for example in the current days it is unacceptable to transfix the artery, the pull the needle until the blood flows back and cannulate the artery. Thesuccess of such puncture can greatly depend on who is in charge. It has been shown that the femoral artery puncture by palpation technique performed by trainees or residents has had more adverse outcomes (Stone, 2020). In this regard, our study reveals that a femoral vascular access accomplished by a single puncture without transfixation of the vessel, and a standardized mechanical compression protocol were associated with extremely low complication rates. It should be noted that such results were expected when the study was planned. Therefore, when only one wall of the femoral artery is punctured to perform coronary angiography with a standard technique on the first attempt, associated with standard compression, the risk of vascular complications is minimal. Our findings reinforce the need for accuracy in puncturing the common femoral artery, which does not represent a major challenge for its location, route, and diameter, but requires training and has a learning curve. Further studies comparing the outcomes of the radial and common femoral access techniques as described in this study may change the current paradigm that the femoral route is inferior to the radial route for coronary artery procedures. Our study has limitations, and the most significant is that it included only patients undergoing diagnostic procedure. However, our study hypothesizes that the puncture of a single wall of the femoral artery, the lack of transfixation, and the systematic use of a compression protocol reduce the complication rate after percutaneous coronary procedures via femoral route and that these are not inferior to those via the radial route.

CONCLUSION

The occurrence of vascular complications were low The non-transfixing puncture technique associated with the use of a mechanical compressor may represent a cheap, safe, and efficient haemostasis strategy, especially in developing countries. Haemostasis without compromising limb perfusion is possible with this compressor technique, and further refinement of the puncture technique is critical to the results and should be sought.

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