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COMPLICATIONS AFTER PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY AND ASSOCIATED FACTORS

Gabriela Lucas CARDOSO[1], Márcia Marques dos Santos FELIX[1], Maria Beatriz Guimarães RAPONI[2], Fernando DE MARTINO[1], Patrícia da Silva PIRES[3], Maria Helena BARBOSA[1]

[1] Universidade Federal do Triângulo Mineiro, Uberaba, Minas Gerais, Brazil.
[2] Universidade Federal de Uberlândia, Uberlândia, Minas Gerais, Brazil.
[3] Universidade Federal da Bahia, Vitória da Conquista, Bahia, Brazil.

Corresponding author:
Maria Helena Barbosa
mhelena331@hotmail.com

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Abstract

This study aimed to analyze the incidence of vascular complications and associated factors in patients undergoing elective percutaneous transluminal coronary angioplasty. This study is observational, quantitative, and longitudinal, and followed 50 patients undergoing elective percutaneous transluminal coronary angioplasty. An instrument for the sociodemographic, clinical, procedure, and vascular complications characterization was used for data collection. And descriptive statistics, bivariate analysis, and multiple binomial logistic regression were used for data analysis. The level of statistical significance considered was 95%. It was detected the prevalence of male patients (70%), elderly (54%), and diagnosed with systemic arterial hypertension (72%). As for the percutaneous access route prevailed the radial approach (64%). Age and body mass index were identified as possible risk factors for vascular complications. In the 50 procedures performed, there was a prevalence of hematomas (20%) and bleeding (10%). Among the complications prevailed radial Early Discharge After Transradial Stenting of Coronary (60%), large femoral hematoma (20%), small femoral hematoma (20%), and bleeding (Bleeding Academic Research Consortium 2) (100%). The results concluded an elevated incidence of vascular complications in the first 24 hours after elective percutaneous transluminal coronary angioplasty. This study contributes to research, assistance, and training in health and nursing by identifying post-PTCA vascular complications, minimizing their progression, handling their management, and developing health care safety protocols.

Keywords: Nursing. Nursing Care. Percutaneous Coronary Intervention. Postoperative Complications. Risk Factors.

1. Introduction

In the last decades, cardiovascular diseases (CVD) have been highlighted as the leading cause of death among individuals over 45 years (Massa et al. 2019; Santos et al. 2021). Among the main CVDs, Coronary Artery Disease (CAD) stands out for its elevated incidence and mortality (Moraes et al. 2021).

CAD includes a spectrum of clinical conditions of ischemic etiology, mostly of atherosclerotic origin, and one method of treatment is the Percutaneous Transluminal Coronary Angioplasty (PTCA), which is a technique of myocardial revascularization (Feres et al. 2017).

The PTCA restores normal arterial flow to the myocardium by dilating the coronary artery with a balloon catheter and/or implanting a metallic device known as a coronary stent. It was developed in 1987

to prevent the progression of CAD and its consequences, including Acute Myocardial Infarction (AMI), the decline of ventricular function, the development of Heart Failure (HF), arrhythmias, and cardiovascular mortality (Rodrigues et al. 2021).

Because it is an invasive cardiologic procedure, patients undergoing PTCA are susceptible to potential complications. Despite being relatively safe, the percutaneous procedure is invasive and presents a diversity of minor complications without clinical repercussions and serious consequences of significant morbidity and mortality (Rodrigues et al. 2021).

Most complications arising from PTCA are related to vascular access, such as hematoma, retroperitoneal hematoma, bleeding, arteriovenous (AV) fistula, thrombosis, or pseudoaneurysm. Such complications are often associated with age, obesity, and the puncture technique (Feres et al. 2017).

In their clinical practice, identifying risk factors for possible vascular complications is a routine for nurses. Recognizing them provides early detection of signs and symptoms related to the access site of percutaneous puncture and monitoring its progression (Lima et al. 2019).

In this situation, the nurse works during the pre-procedure preparation, acts like a team in the room during the intra-procedure, and follows the patient during the immediate, mediate, and late invasive cardiologic post-procedure. The nurse must know the complications resulting from the PTCA procedure to provide health safety to these patients (Paganin et al. 2018).

The nurse's management of the patient submitted to PTCA propitiates the success of the post-procedure outcomes still in the hospital, avoiding the most common possible complications and guaranteeing humanized and safe assistance (Lima et al. 2019).

Despite the nursing relevance in the detection of PTCA complications, the literature about nursing presents a scarcity of current scientific evidence that associates the potential risk factors and vascular complications in patients undergoing PTCA (Paganin et al. 2018).

Given the above, it is necessary to analyze the incidence of vascular complications and associated factors in patients undergoing PTCA to create subsidies to establish intervention protocols that identify in clinical practice patients at higher risk of developing vascular complications, in order to guide nursing care to reduce such complications, based on scientific evidence (Lima et al. 2019).

In this context, the present study aimed to analyze the incidence of vascular complications and associated factors in patients undergoing elective PTCA.

2. Material and Methods

This study is observational, quantitative, and longitudinal, developed from September 2020 to March 2021, in the Hemodynamics Department and Coronary Intensive Care Unit (ICU) of a large public teaching hospital in Minas Gerais, certified in medium and high complexity, and reference in the city and its macro-region, composed of 27 cities.

The Hemodynamics Department has an infirmary with five beds for pre-procedure preparation and post-procedure recovery and two angiographic procedure rooms. The Coronary ICU has ten beds exclusively to care for cardiology patients and admits all patients submitted to elective PTCA, in the immediate post-procedure period, where they remain for a minimum of 24 hours.

The population of this study consisted of patients undergoing elective PTCA procedures in the Hemodynamics Department during data collection. The study included adult patients 18 years or older of both genders. It excluded patients who died during the elective PTCA procedure, subjects unable to answer the questions, and those who did not have someone responsible for them during admission to the Hemodynamics Department.

The eligible population obtained was 164 patients, and 50 completed the study, constituting this study's sample (n). There was a loss of 114 patients: 43 (37.8%) did not meet the inclusion criteria, two (1.8%) refused to participate, and 69 (60.4%) returned to the Adult Emergency Room after PTCA, where the researchers did not have access due to restrictions defined by the institution during the pandemic of the Coronavirus. The recruitment process was non-probabilistic.

To obtain the sociodemographic and clinical data inherent to the PTCA procedure and vascular complications, the researchers developed a data collection instrument consisting of four parts. They

submitted it to apparent validation and content by three judges, doctors, and specialists in the research subject.

The data collection process took place according to Figure 1.

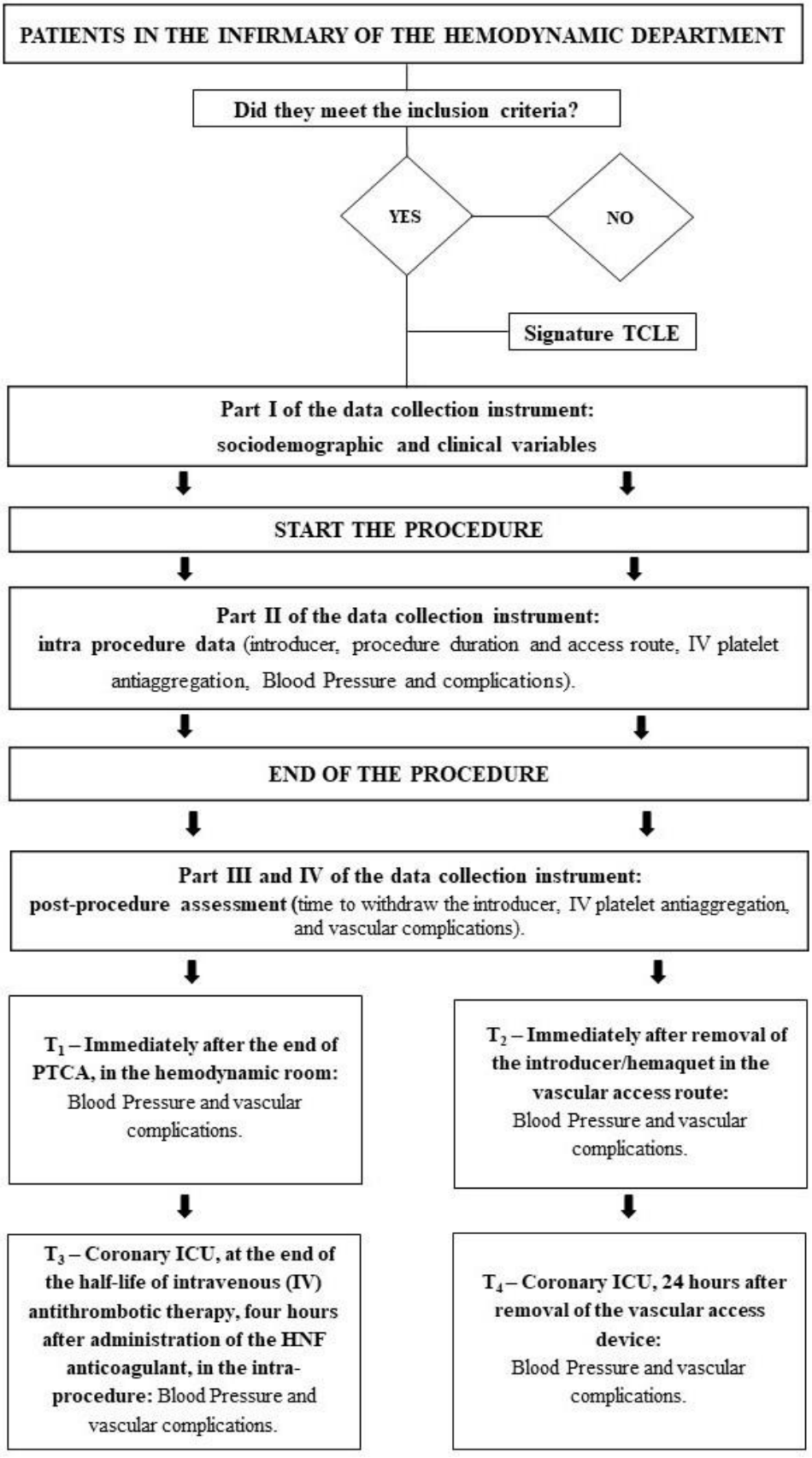

Figure 1. Data collection procedure flowchart (n=50).

The data collected were double entered and analyzed using the Statistical Package for the Social Sciences (SPSS 22.0). Categorical variables were analyzed according to descriptive statistics with absolute

and relative frequency distribution, while measures of centrality (mean and median) and variability (range and standard deviation) were employed for quantitative variables. The next formula defined the incidence of patients who presented post-PTCA vascular complications. (Pereira 2008):

$$\frac{\text{number of "new cases" in a particular period}}{\text{number of people exposed to risk in the same period}} \times \text{constant}$$

The “new cases" include the number of people affected or episodes of a health problem (Pereira, 2008). In this research, the "new cases" exemplified the number of patients who develop vascular complications, and the constant will be the number 100.

A bivariate analysis was initially performed with association measures in contingency tables (chi-square, relative risk, and odds ratio) to evaluate possible predictors for the occurrence of vascular complications. The simultaneous contribution of associated factors or relevant predictors included multiple binomial logistic regression analysis. It was considered a statistical significance level of 95%, i.e., p=0,05.

Researchers conducted this study following resolution 466/12 of the National Health Council. The Research Ethics Committee (CEP) approved this research under opinion Nº. 3.790.857/2019.

3. Results

The final sample of this study consisted of 50 patients submitted to PTCA procedures during the data collection period. Most of the participants, 35 (70%), were male, with a mean age of 64.82 (minimum 39 and maximum 88 years; SD=10.46).

About the clinical variables, mean weight was 75.28 kilograms (minimum of 38 and maximum of 127 kilograms; SD=15.08), mean height was 1.66 meters (minimum of 1.45 and maximum of 1.80 meters; SD=0.08), mean Body Mass Index (BMI) was 22.31 Kg/m2 with a variation of 15.22 to 60.40 Kg/m2 (SD=6.42).

Regarding comorbidities, 36 (72%) had Systemic Arterial Hypertension (SAH), 8 (16%) had Diabetes Mellitus (DM), 2 (4%) suffered from Chronic Renal Failure (CRF), 5 (10%) had stroke (CVA), and 4 (8%) had Peripheral Arterial Disease (PAD).

In terms of blood pressure (BP) measurement before PTCA, the participants' mean detected was 126 x 75 mmHg with a variation of 86 x 51 mmHg to 175 x 100 mmHg. As for the performance of a previous hemodynamic procedure, more than half, 29 (58%) of the participants reported having already done it, and as for the use of dual platelet anti-aggregation, most of them, 46 (92%) had used it.

Regarding the intra-procedural evaluation, none of the participants made use of intravenous anti-aggregation platelet. The mean blood pressure was 125 x 72 mmHg varying from 90 x 50 mmHg to 210 x 103 mmHg. The prevalent introducer/hemaquet diameter in 46 patients (92%) was 6F, followed by 3 (6%) 7F and 1 (2%) 5F. The predominant vascular access route 32 (64%) was right radial, 14 (28%) right femoral, 3 (6%) right brachial, and 1 (2%) left femoral. The procedures had a mean time of 49.28 minutes (SD=22.33, range 15 to 120 minutes).

Concerning the immediate post-procedure evaluation, most participants, 48 (96%), removed the introducer at the scheduled time, and 2 (4%) took it out prematurely. The mean BP in time 1 was 133 x 76 mmHg ranging between 80 x 50 mmHg and 192 x 108 mmHg; the mean in time 2 was 130 x 75 mmHg with a range between 80 x 50 mmHg and 192 x 108 mmHg; the mean in time 3 was 126 x 76 mmHg ranging between 83 x 47 mmHg and 182 x 105 mmHg, and the mean in time 4 was 122 x 74 mmHg ranging between 75 x 49 mmHg and 181 x 106 mmHg.

As for vascular complications, 10 (20%) participants presented hematomas, and 5 (10%) had bleeding. As for the number of complications, 11 (22%) participants exhibit one complication, and 2 (4%) participants got two complications. The incidence of post-PTCA vascular complications in the six-month period was 30 per 100 procedures performed.

The post-PTCA hematoma was detected in six patients with the radial access approach. According to the Early Discharge After Transradial Stenting of Coronary (EASY) scale, all were classified as a type I hematoma with a diameter less than or equal to 5 cm (Bertrand et al., 2006). There was no hematoma in patients with brachial route approach. Femoral hematoma appeared in four patients, all percutaneous

punctures to the right: two were presented as large hematomas and two as small hematomas, according to the classification by the American College of Cardiology (ACC 2003). A large hematoma presents a diameter larger than or equal to 10 cm, and a small hematoma has a diameter less than 10 cm (American College of Cardiology, 2003). In one patient with a large hematoma, it was used a 7F introducer sheath.

The five patients with bleeding were submitted to different percutaneous puncture access routes. One patient underwent a femoral approach, another the brachial technique, and three patients the radial approach. According to the Bleeding Academic Research Consortium (BARC), all patients with bleeding were classified as type 2 (Mehran et al. 2011). Of these patients, two presented bleeding and hematomas simultaneously, and those hematomas were located in the femoral and radial route. In the patients with bleeding, hemoglobin and hematocrit were requested to analyze the values, but there was no percentage decrease in the samples.

Another complication observed in two post-PTCA patients, but not considered a vascular complication, was the vasovagal reaction while removing the introducer sheath and manual compression by the femoral access approach. These were the patients with a femoral hematoma larger than or equal to 10 cm in diameter.

While investigating the association between sociodemographic and clinical variables and the occurrence of vascular complications in patients undergoing elective PTCA, the bivariate analysis showed that patients with altered BMI presented a higher incidence of complications when compared to eutrophic patients. They were also 1.4 times more likely to develop vascular complications than patients with adequate BMI, with a marginally statistical significance (p=0.07) (Table 1).

Table 1. Bivariate analysis including the occurrence of vascular complications and clinical and sociodemographic variables in patients undergoing elective PTCA (n=50).

Variables	Vascular Complication		RR†(CI)‡	OR^A§ (IC) ‡	p
	Yes	No			
	n (%)	n (%)			
Gender					
Female	6 (40.0%)	9 (60.0%)	2.00 (0.807 – 4.955)	2.66 (0.709 – 10.023)	0.17
Male	7 (20.0%)	28 (80.0%)			
Platelet antiaggregation					
Yes	12 (26.1%)	34 (73.9%)	1.04 (0.179 – 6.100)	1.059 (0.100 – 11.179	1.00
No	1 (25.0%)	3 (75.0%)			
PAD*					
Yes	1 (25.0%)	3 (75.0%)	0.95 (0.164 – 5.602)	0.944 (0.089 – 9.972)	1.00
No	12 (26.1%)	34 (73.9%)			
BMI**					
Altered	10 (27.8%)	26 (72.2%)	1.29 (0.418 – 4.025)	1.41 (0.324 – 6.135)	0.07
Eutrophic	3 (21.4%)	11 (78.6%)			

Note: †relative risk; ‡ confidence interval; § crude odds ratio; ¶ level of significance (p <0,05); * peripheral arterial disease; ** body mass index.

Regarding univariate logistic regression, only the age variable showed a statistically significant association (p=0.03), demonstrating that the risk of complications increases by 8.2% with each additional year in age (Table 2).

Table 2. Univariate logistic regression of factors associated with the occurrence of vascular complications in patients undergoing elective PTCA (n = 50).

	Vascular Complications	
Variables	OR* (IC)˟	p▪
Age	1.082 (1.007 – 1.162)	0.03
Time of procedure	0.999 (0.969 – 1.027)	0.87
BMI#	1.025 (0.934 – 1.125)	0.60
Introducer diameter	1.841 (0.208 – 16.307)	0.58
DBP§	1.025 (0.979 – 1.073)	0.29
SBP+	1.016 (0.992 – 1.040)	0.19

Note: * odds ratio; ˟confidence interval; ▪ probability; # body mass index; § diastolic blood pressure; + systolic blood pressure.

4. Discussion

Most patients in this study were male, aged over 60 years. That fact corroborates the literature, which identifies CAD as a multifactorial condition that affects more males (Paganin et al. 2018). A variety of research pointed out that cardiovascular events in women have a lower incidence, probably due to the hormonal protective function of estradiol (Mertins et al. 2016; Global Burden of Disease 2020). Regarding the age over 60 years, it reflects the pattern of global population aging (Global Burden of Disease 2020).

Regarding the BMI of the participants in the present sample, they were considered healthy, in contrast to studies with a prevalence of BMI above 25.0 kg/m2 (Paganin et al. 2017). It is noteworthy that BMI is a well-known risk factor for developing cardiovascular diseases (Lu et al. 2014).

About comorbidities, most participants had SAH, contributing to the increased cardiovascular risk. A study corroborates the current premise by establishing the evidence of the association of SAH with increased cardiovascular risk (Précoma and Oliveira 2019). One multicenter research confirms the present study by showing the prevalence of SAH among the comorbidities identified in their participants. That research aimed to assess vascular complications in patients undergoing endovascular cardiologic procedures (Paganin et al. 2018).

Studies point out that increased BP values are related to the risk of developing CVD in both genders, wide age range, and different ethnicities, explaining the high prevalence of hypertensive individuals, being these values applied in cardiovascular risk stratification scores (Arnett et al. 2019; Barroso et al. 2021).

This study used an introducer sheath with a hemostatic valve with 6F and 7F diameters through the femoral approach. The 7F sheath caused an extensive hematoma in one of the individuals. The usage of an introducer sheath larger than 6F was recognized as an independent risk factor for vascular complications in the literature (Paganin et al. 2017).

The incidence rate of complications observed in this study was 30%, which is considered high compared to other studies with the prevalence of vascular events. A multicenter cohort study with 2,696 patients showed an incidence of 8.8% in vascular complications, totaling 264 complications distributed in hematomas <10 cm, stabilized bleeding, hematomas ≥10 cm, and irregular bleeding; There were no complications such as retroperitoneal hematoma, pseudoaneurysm, and arteriovenous (AV) fistula (Paganin et al. 2017).

Among the complications, it was observed the prevalence of hematoma and bleeding. In the present study, the incidence of bleeding in the studied individuals was 10%, and all these events classified as BARC type 2. That incidence is high when compared to a study that refers to BARC 2 classification with an incidence of 5.4% (Ndrepepa et al. 2012).

The most elevated incidence of vascular complications described in the literature is related to the hematoma event. The incidence rate observed in this study is considered high (20%) compared to other studies with the prevalence of this event (Matte et al. 2016; Paganin et al. 2017).

In this study, the hematoma by radial technique occurred in a large number of femoral artery approach, and all were classified as EASY type I hematoma, contradicting data from studies comparing radial and femoral percutaneous access routes of other centers performing a higher quantity of radial technique, which reported an incidence of 2.5% and 4.2% in EASY type I hematoma (Jolly et al. 2011; Garg et al. 2019; Shafiq et al. 2020).

The results of this study showed that the large hematoma was identified in PTCA procedures by femoral artery puncture and did not occur in radial puncture, corroborating the decrease of major adverse events by radial access route (Ferrante et al. 2016; Bhat et al. 2017; Kolkailah et al. 2018).

The post-PTCA hemorrhagic complications are enhanced with a potent platelet anti-aggregation regimen, with a 5% to 10% bleeding rate, constituting the main non-cardiac complication observed in PCI patients. The bleeding event appears when a fast-acting thienopyridine drug is administered, having age over 75 years, weight less than 60 kg, and previous stroke as predictors (Feres et al. 2017).

This study discovered that age and BMI as predisposing factors for hematomas and bleeding complications in patients undergoing the PTCA procedure. A prospective study confirms this premise, in which age, BMI, multiple puncture attempts, and potent antiplatelet therapy were identified as

independent predictors for the development of hematoma through the radial access route (Subherwal et al. 2009).

A few research in Western countries reported that the extremes between lean and obese patients have a higher risk of adverse events after Percutaneous Coronary Intervention (PCI), correlating vascular complications to reduced BMI values and overweight and obesity (Ndrepepa et al. 2012; Ahmed et al. 2013). One study highlights that obesity correlates with the following high levels of coagulation factors: factor VII, VIII, fibrinogen, and plasminogen activator inhibitor-1 (Yui et al. 2010).

Individuals with lower BMI have been identified in studies in Western and Asian populations as being at higher risk for events such as bleeding and major cardiac complications post-PCI (Yui et al. 2010). Another inferred justification for the increased incidence of post-PCI events in low BMI individuals would be the antithrombotic therapy determining vascular complications in lower weight patients (Lorga Filho et al. 2013).

The data associating age with vascular complications conform with the literature, indicating a higher prevalence of these events in individuals older than 75 years. A meta-analysis with 349 studies that included the elderly population over 75 years identified seven clinical trials reporting major bleeding, besides comparing the groups considering the radial and femoral access route, in which there was a lower incidence in the radial group (Basu et al. 2017).

Given the above, the importance of nurses in the Hemodynamic Unit stands out, as they work in the post-invasive cardiology invasive procedure, in the detection of events, and non-invasive intervention with a conservative approach. The nurse's clinical evaluation is guided by their knowledge of the main post-PTCA vascular complications and associated factors in the interventional cardiology setting. They monitor patients at higher risk and implement specific health safety protocols to follow up on vascular complications and evaluate the results of nursing interventions (Paganin et al. 2018; Lima et al. 2019).

A limitation of this study is the small number of patients due to the current pandemic scenario of the SARS-CoV-2 virus, which causes COVID-19 disease. Data should be cautiously evaluated in healthcare and nursing clinical practice through other prospective studies with supervision and extended follow up until the period of hospital discharge needed for an adequate definition of vascular complications and associated factors in patients undergoing PTCA procedure.

5. Conclusions

The results allow us to infer an elevated incidence of vascular complications in the first 24 hours after elective PTCA, compared to that described in other reference centers with experience in the adopted prevalent puncture technique. These complications occurred in the first 4 hours after the invasive cardiologic procedure. The planning of specific care for patients undergoing invasive cardiologic procedures in the Hemodynamic Unit allows for optimizing the time for the team to work and quality of care, reducing harm and risks to patient safety. The findings of this study contribute to research, assistance, and teaching in health and nursing by identifying the existence of post-PTCA vascular complications, minimizing their progression, and handling their management, as well as the development of health care safety protocols.

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