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Vascular complications and factors related to their occurrence after percutaneous hemodynamic procedures

Complicações vasculares e fatores relacionados a sua ocorrência após procedimentos hemodinâmicos percutâneosComplicaciones vasculares y factores asociados a su ocurrencia tras procedimientos hemodinámicos percutáneos

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Abstract: Objective: to investigate vascular complications in patients undergoing percutaneous hemodynamic procedures and identify factors related to their occurrence. **Method**: retrospective study conducted in a cardiology hospital with patients who had vascular damage between January 2015 and December 2016. Data were collected from medical records and submitted to descriptive analysis. **Results:** the study included 93 patients, most of them elderly, male and with hypertension. The rate of vascular complication was 3%, local hematoma was the most common complication (86%). Women were found to have more serious vascular injuries such as retroperitoneal hematoma and pseudoaneurysm than men did (p = 0.04). **Conclusion:** hematoma was the most frequent vascular complication, and female gender was a risk predictor associated with more serious injuries. Recognizing risk predictors contributes to the delivery of care tailored to the needs of each patient.
Descriptors: Percutaneous coronary intervention; Patient care; Hematoma; Cardiovascular nursing; Risk factors

Resumo: Objetivo: investigar as complicações vasculares em pacientes submetidos a procedimentos hemodinâmicos percutâneos e identificar fatores relacionados a sua ocorrência. **Método**: estudo retrospectivo em um hospital cardiológico, com pacientes que evoluíram com danos vasculares, entre janeiro de 2015 e dezembro de 2016. Os dados foram obtidos pela coleta em prontuários e analisados de forma descritiva e analítica. **Resultados:** foram incluídos 93 pacientes, a maioria idosos, do sexo masculino e portadores de hipertensão. A taxa de complicação vascular foi de 3%, o hematoma local foi o mais frequente (86%). O sexo feminino foi associado à ocorrência de danos vasculares mais graves como o hematoma retroperitoneal e o pseudoaneurisma (p=0,04).

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Conclusão: dentre as complicações vasculares, o hematoma foi o mais frequente e o sexo feminino foi fator preditor de risco, associado a injúrias mais graves. Reconhecer os fatores preditores de risco auxilia a assistência direcionada às necessidades individuais do paciente.
Descritores: Intervenção coronária percutânea; Assistência ao paciente; Hematoma; Enfermagem cardiovascular; Fatores de risco

Resumen: **Objetivo:** investigar las complicaciones vasculares en pacientes sometidos a procedimientos hemodinámicos percutáneos, así como identificar factores asociados a su ocurrencia. **Método**: estudio retrospectivo en hospital cardiológico, con pacientes que evolucionaron con lesiones vasculares, entre enero de 2015 y diciembre de 2016. Se obtuvieron los datos en prontuarios y se los analizaron de forma descriptiva y analítica. **Resultados:** participaron 93 pacientes, la mayor parte ancianos, del sexo masculino y portadores de hipertensión. La taja de complicación vascular fue de 3%, el hematoma local fue el más frecuente (86%). Se asoció al sexo femenino la ocurrencia de lesiones vasculares más graves como el hematoma retroperitoneal y pseudoaneurisma (p=0,04). **Conclusión:** entre las complicaciones vasculares, el hematoma fue el más frecuente y el sexo femenino fue factor predictor de riesgo, asociado a lesiones más graves. Reconocer los factores predictores de riesgo ayuda la asistencia a volverse a las necesidades individuales del paciente.
Descriptores: Intervención coronaria percutánea; Atención al paciente; Hematoma; Enfermería cardiovascular; Factores de riesgo

Introduction

There is a high incidence of cardiovascular diseases (CVD) worldwide, which can affect people of all ages. In Brazil, 20% of registered deaths are due to CVD.[1] Thus, Percutaneous Coronary Intervention (PCI), a procedure that allows visualization of coronary arteries after the administration of radio-opaque contrast, has become the most commonly performed hemodynamic intervention for the diagnosis and treatment of Coronary Artery Disease (CAD).[2] Technological advances of invasive interventions have allowed not only an increase in the number of procedures, but have also reduced costs and associated complications and ensured a more accurate treatment.[2-3]

The onset of vascular complications[4] depends on factors such as the effectiveness and type of intervention performed, vascular access type selected and the average duration of the procedure.[5] Among these complications, hematoma at the catheter insertion site is the most frequent. It is characterized by blood leakage into the interstitial space that can evolve to

swelling and compression of adjacent structures, unlike ecchymosis that is caused by minimal infiltration of red blood cells into the interstitial space.[6] In addition to the trauma resulting from catheterization and vasospasm, more serious damage may still occur, such as the pseudoaneurysm (PSA), a pulsating, encapsulated hematoma which communicates with the artery. As for the retroperitoneal hematoma (RPH) is characterized by bleeding into a more distant site, usually in the flank region;[7] and less frequently, ischemia distal to the puncture site related to embolization may occur.[8]

Although relevant, vessel injuries are not frequent (3.3%), and may be asymptomatic. However, they can make reuse of the vascular pathway impracticable.[6] Injuries are generally associated with local vascular factors such as calcification in the artery puncture site, as well as systemic factors such as obesity, age, gender, systemic arterial hypertension (SAH) and use of anticoagulants.[9] Therefore, closure of the arteriotomy site through manual compression or by vascular closure devices to achieve hemostasis must be effectively performed.[6-7,10]

Studies have found that the consequences of vascular complications in PCI can be compared to the consequences of Acute Myocardial Infarction (AMI) and are associated with increased morbidity and mortality, longer hospital stay and unfavorable clinical outcomes.[11] Thus, for the proper management of the quality of nursing care, it is important to recognize the clinical characteristics associated with the occurrence of fragility of the cardiovascular system, so that patients at higher risk are identified and preventive strategies are implemented.[7]

The present study aimed to investigate vascular complications in patients undergoing percutaneous hemodynamic procedures and identify factors related to their occurrence.

Method

Retrospective study carried out in an Interventional Cardiology Unit of a private cardiology hospital of Distrito Federal, Brazil, in 2017. The hospital has 12 intensive care beds,

30 hospital beds, outpatient unit, diagnostic imaging unit, hemodynamics service, surgical center and nuclear medicine. The study was developed according to STROBE guidelines.[12]

Patients older than 18 years who underwent percutaneous hemodynamic procedures between January 2015 and December 2016 and developed vascular complications after the procedure were included in the study. Complications were the formation of local hematoma, RPH or PSA. Patients with incomplete medical records were excluded from the study.

Secondary data were collected from electronic medical records through a semi-structured instrument developed by the researchers that included sociodemographic and clinical data for each patient, namely: patient identification (electronic record); demographic variables (age and gender); clinical variables (preexisting comorbidities, medications used, discharge status); variables associated with the hemodynamic procedure (puncture site, clinical management, imaging tests used to assess the extent of the hematoma, and/or diagnosis of PSA or RPA) and the duration of the procedure, considering the start time from anesthesia and the completion of the dressing.

Data was inserted into Microsoft Office Excel spreadsheets and then tabulated and imported into the statistical program Epinfo version 7.2.2.6. The analysis consisted of two stages: (1) descriptive - characterization of the patients included by means of calculations of mean, standard deviation (SD) for the numerical variables and of absolute and percentage values, for the categorical variables; 2) analytical - identification of the association of the studied characteristics (independent variables/exposure) with the specific types of vascular complications (dependent variables outcome). Association between complications (outcome) and the other variables analyzed (exposure) was represented by odds ratios). For comparison between the groups (hematoma, RPH or PSA) Chi-square test was used for categorical variables and Student's t-test for numerical variables. A p value below 0.05 was considered significant.

In accordance with the required ethical standards, the study was approved by the Research Ethics Committee of Oswaldo Cruz Foundation, under protocol No. 1,709,243, *Certificado de Apresentação de Certificação Ética* 58249716.0.0000.8027, on September 1, 2016.

Results

Between January 2015 and December 2016, 3120 hemodynamic procedures were performed percutaneously. Ninety-five patients had at least one of the vascular complications proposed in the study (formation of local hematoma, RPH or PSA). However, two patients were excluded due to incomplete data in the medical records. Thus, 93 individuals were considered eligible for the study. The rate of vascular complications was 3%.

The mean age of the patients was 67.7 (SD = 10.6) years and there was a predominance of male individuals (56%). The presence of multiple comorbidities was frequent: 76.6% of the patients included had SAH and 47.3% had some type of dyslipidemia. Only one patient did not use any continuous medication (Table 1).

Table 1 – Clinical and demographic characteristics of the 93 patients with vascular complications resulting from percutaneous hemodynamic procedures. Brasília, DF, Brazil, 2017.

Characteristics	Absolute Frequency n = 93	Relative Frequency (%)
Age, Mean (SD)	67,7 (10,6)	-
Gender		
Male	52	56.0
Female	41	44.0
Comorbidities		
Systemic arterial hypertension	72	76.6
Dyslipidemias	44	47.3
Others	33	35.4
Diabetes mellitus	31	33.0
Acute myocardial infarction	10	10.8
Hypothyroidism	8	8.6
Hyperthyroidism	1	1.1
Medications used		
Antiplatelet	65	69.9

Thrombolytics	43	46.2
Antihypertensive drugs	37	39.8
Antilipidemic drugs	29	31.2
Others	29	31.2
Antidiabetic drugs	17	18.3
Antithyroid drugs	9	9.7
Anticoagulants	6	6.5

The mean duration of PCI was 67.5 (SD = 54.6) minutes. The considerable variation in the length of the procedure was due to patients' clinical conditions and the need for a new hemodynamic intervention during the procedure. The most frequent puncture site was the femoral artery, in 63.4% of cases.

In 56% of the cases, PCI was for diagnostic purposes and in 44%, for therapeutic purposes. Some patients underwent more than one hemodynamic procedure (35.3%), with catheterization being the most frequent (41%), followed by transluminal coronary angioplasty (TCA) (38.7%), angiography (4.7%) and other interventions (15.5%). The other techniques performed were heart flow reserve (FFR), implantation of endo-prosthesis, vena cava filter, placement of a shunt, electrophysiology study (EPS), rotational atherectomy and optical coherence tomography (OCT).

Regarding the vascular complications assessed, 86% of patients developed local hematoma, which is characterized as a simple complication, and 14% had more serious injuries, such as RPH or PSA (Table 2). To investigate and/or confirm the occurrence of RPH and PSA, 23 patients underwent imaging tests, 14% underwent Doppler and 10.8% computed tomography. The remaining patients did not require investigation by imaging tests. The conduct implemented for the treatment of vascular complications was predominantly conservative in 98.9% of the cases. Only one case required surgical intervention (Table 2).

As for the clinical outcome, 95.7% of the patients were discharged from the hospital, 4.3% worsened and died. However, such worsening was due to complications of the underlying disease and not associated to the hemodynamic procedure (Table 2). There were no patients with readmission records due to hemodynamic complications in this study. Data on characteristics related to hemodynamic procedures are shown in Table 2.

Table 2 – Characteristics Related to Hemodynamic Procedures of 93 patients with vascular complications. Brasília, DF, Brazil, 2017.

Type of procedure	Absolute frequency n = 93	Relative frequency (%)
Duration of the Procedure (min), Mean (SD)	67,5 (± 54,6)	-
Puncture site		
Femoral	59	63.4
Radial	30	32.3
Both	2	2.2
Jugular vein	2	2.2
Vascular Complications		
Hematoma	80	86.0
Retroperitoneal Hematoma	8	8.6
Pseudoaneurysm	5	5.4
Therapeutic Conduct		
Conservative	92	98.9
Surgery	1	1.1
Clinical Outcome		
Discharge	89	95.7
Death	4	4.3

In the second stage of the study, the presence of factors associated (exposure variables) with the vascular complications investigated (outcome variables) was assessed. Table 3 shows the distribution of the characteristics analyzed for the two groups.

Table 3 –Factors associated with vascular complications in 93 patients, Brasília, DF, Brazil, 2017.

Characteristics (n)	**Hematoma**		**RPH[*] and PSA[†]**		**OR[‡] (CI)**	**P value**
	Absolute Frequency (n =80)	Relative Frequency (%)	Absolute Frequency (n =13)	Relative Frequency (%)		
Age (years ± SD	67.7 ±10.35	-	67.8 ±12.3	-	-	0.46[§]
Gender (%)						
Female	32	40.0	9	69.3		
Gender	48	60.0	4	30.7	0.29 (0.08-1.04)	**0.04**[‖]
Presence of Comorbidities (%)						
Diabetes *mellitus* (yes)	27	33.8	4	30.8	0.87 (0.24-3.09)	0.83[‖]
(no)	53	66.2	9	69.2		
SAH (yes)	63	78.8	9	69.2	0.60 (1,16-2.21)	0.44[‖]
(no)	17	21.2	4	30.8		
Use of Medications						
Anticoagulant (yes)	4	5.0	2	15.4	3.45 (0.56-1.13)	0.15[‖]
(no)	76	95.0	11	84.6		
Antiplatelet (yes)	57	71.2	8	61.6	0.64 (0.19-2.18)	0.47[‖]
(no)	23	28.8	5	38.4		
Thrombolytic (yes)	37	46.3	6	46.2	0.99 (0.3-3.22)	0.99[‖]
(no)	43	53.7	7	53.8		
Length (mean min)	68.6 ±55.6	-	60.8±49.5	-	-	0.10[‖]
Outcome						
Discharge	78	97.5	11	84.6		
Death	2	2.5	2	15.4	0.14 (0.01-1.10)	**0.03**[§]

[*] retroperitoneal hematoma, [†] pseudoaneurysm, [‡]odds ratio, [§] t *student* test, *Chi-square* test

Age, Diabetes Mellitus (DM) and SAH, length of the procedure, as well as use of drugs that affect hemostasis (anticoagulants, antiplatelet and thrombolytic agents) were not significantly associated with the occurrence of more severe vascular damage (RPH and PSA) (p> 0.05), according to Table 3. Women were more likely to suffer serious injuries (HRP and PSA) than men were (p = 0.04). Also, the most serious complications (RPH and PSA) were associated with a worse clinical outcome (death) (p = 0.03).

Discussion

The present study analyzed patients who had vascular complications after PCI, in order to describe its occurrence and the factors associated with this outcome. The complication rate (3%) was lower than that described in the literature[9,13-14]

The rate of vascular injuries found in the literature ranges from 1% to 14%. This variation can be explained by the different clinical characteristics (predictors of complications) of each group evaluated.[13] A multicenter study carried out in southern Brazil with 2,696 patients undergoing hemodynamic procedures reported an overall vascular damage rate of 8.8%.[9]

Among the vascular complications assessed in this study, local hematoma was the most frequent condition, corroborating other studies.[9,15-16] The occurrence of hematoma may be associated with patients' risk factors, but can also be influenced by post-procedure care, such as removal of the introducer and mechanical compression of the artery[9,15-16,] which reinforces the importance of a nursing team trained in specialized hemodynamic care.[17]

RPH and PSA are considered more complex vascular complications,[16-17] and were reported less frequently in this study. The occurrence of PSA (5.4%) was higher when compared to another study that found a rate of 2.6%.[14] Likewise, HRP had a higher incidence than that observed in another report.[18] RPH can be caused by a difficult mechanical compression, while PSA, due to its direct communication with the artery, can be associated with age, gender, presence of comorbidities, obesity, length of the procedure, excessive manipulation of the vessel, as well as calcification of the artery.[9,16-17]

It is known that the femoral artery route increases the risk of bleeding and vascular complications compared to the radial artery route. A study carried out in southern Brazil reported the use of the femoral artery in PCI in 95% of the cases. In this study, the femoral route was used in 60% of the procedures. The frequent choice of the femoral artery route can be explained by the high incidence of arteriosclerosis and calcification of small and medium

caliber vessels in old patients, since the use of the radial route would lead to failures in vascular access, prolonging the duration of the procedure, which may increase the need to use nephrotoxic contrast in the patients, exposing them to higher doses of radiation and pharmacological toxicity.[19]

Age is a predisposing factor for the occurrence of vascular damage.[20] Studies have found that the age group between 40 and 70 years is a risk factor for vascular injuries, including bleeding, hematoma, RPH and PSA.[20-22] The mean age of the participants in this study was 67.7 (± 10.58) years, characterizing an elderly population. However, it had no significant association with the severity of vascular injuries (p = 0.46). The referred mean age was consistent with the current context of the population pyramids, which shows quick aging and higher life expectancy, a higher incidence of CVD and a greater use of therapeutic technological advances.[21]

Vascular complications associated with PCI are more incident and severe in females,[22] which can be explained by the cardiovascular fragility resulting from hormonal disorders related to climacteric and menopause.[23] Corroborating the findings in the literature, the frequency of less serious complications was higher among men, with males being associated with a lower risk of serious complications (OR = 0.29; 95% CI = 0.08-1.04; p = 0.04).

Regarding the presence of comorbidities, SAH and DM were the most frequent clinical comorbidities. However, they were not factors associated with the worsening of vascular injuries (p = 0.44 and p = 0.83 respectively). However, it is known that comorbidities can be related to damage, as they are responsible for triggering and/or aggravating the patients' conditions, requiring the use of drugs such as antiplatelet and thrombolytic agents, which can increase the risk of bleeding.[21,24-26]

Regarding medications for continuous use, Acetyl Salicylic Acid (ASA) was the most widely used antiplatelet, and during PCI the use of thrombolytic agents was frequent. These drugs are recommended by the Brazilian Guideline for Antiplatelet and Anticoagulants in

Cardiology. However, it is known that the dose-response varies according to the patient's risk of bleeding. Dual antiplatelet therapy is required for PCI. Its use is associated with a higher risk of bleeding after the procedure. Therefore, when it cannot be avoided, specific patient care measures must be taken in patient care.[27] The use of these drugs was not significantly associated with the worsening of vascular complications ($p > 0.05$).

Thus, when signs and symptoms suggestive of vascular complications after PCI are identified, rapid medical evaluation and clinical investigation using imaging tests, if applicable, to establish the therapeutic approach, is recommended.[17] Doppler was the most commonly used test to identify and monitor the complication in this study. It is an efficient, low-cost test that can be used as a bedside tool without the need for anesthesia or nephrotoxic contrast. Thus, it is a valuable tool for diagnosis and evaluation of serious vascular complications.[28]

Regarding the final outcome, most patients were discharged after treatment, which is consistent with a study on the prognosis of vascular complications when identified and treated quickly. However, the deaths recorded in the survey cannot be attributed to the occurrence of vascular injuries ($p = 0.03$), but to factors such as the underlying disease and worsening of the patient's clinical condition. Such data are corroborated by findings in the literature, since death is often not an outcome related to vascular damage, but rather the fact that the patient is refractory to the treatment of the underlying CVD.[20,29] he data presented and discussed in this study reinforce the importance of evaluating the nursing team in the pre-procedure in order to list existing or potential risk factors,[28-29] and thus provide qualified and safe care plan and assistance.

The limitations of this study were the lack of data that allowed the analysis of clinical characteristics relevant to the topic, namely: data related to the introducer (gauge), length of compression after removal and the device used (manual or mechanical), as well as the absence of risk stratification for bleeding.

Conclusion

Vascular complications after PCI occurred in 3% of the patients, with a higher frequency of hematomas (86%). Female gender was associated with more serious injuries ($p = 0.04$) and the injuries were associated with a worse outcome ($p = 0.03$).

The data presented here draw attention to the need to recognize the risk predictors for the development of vascular complications of each patient, in order to assist the multidisciplinary team, especially the nursing team, to provide care tailored to best meet the needs of each patient. Although the data of this study reflects characteristics of a specific population, it can contribute to further research.

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