



# Immediate complications of femoral vascular sheath removal: a cross-sectional study

*Complicações imediatas na retirada de introdutor vascular femoral: estudo transversal*

*Complicaciones inmediatas en la retirada del introdutor vascular femoral: estudio transversal*

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## ABSTRACT

**Objective:** to verify the prevalence of immediate complications in the removal of femoral vascular sheaths by nurses and the main factors associated with their occurrence. **Method:** this is a cross-sectional study that included 1,281 patients who underwent femoral endovascular procedures and had the vascular sheath removed by nurses at a Hemodynamics Service between January 2018 and December 2020. The factors associated with vascular complication were investigated by bivariate association and multiple linear regression with Poisson response, with a significance level of 5% ( $p < 0.05$ ). **Results:** the prevalence of vascular complications was 16.8% ( $n=215$ ). The main complication was hematoma. Removal of the femoral vascular sheath with mixed type compression ( $p=0.050$ ) and mechanical type compression ( $p < 0.001$ ), longer compression time ( $p < 0.001$ ), and the presence of psychomotor agitation ( $p=0.040$ ) were associated with the appearance of a hematoma. **Conclusion and implications for practice:** the main vascular complication in the removal of femoral vascular sheaths and associated factors were identified. The findings may help to improve the practice of removing vascular sheaths, in the search for a higher quality technique and a safer procedure for the patient, as well as enabling the implementation of appropriate preventive measures.

**Keywords:** Postoperative complications; Nursing care; Vascular access devices; Nursing; Endovascular procedures.

## RESUMO

**Objetivo:** verificar a prevalência de complicações imediatas na retirada de introdutores vasculares femorais por enfermeiros e os principais fatores associados à sua ocorrência. **Método:** estudo transversal que incluiu 1.281 pacientes submetidos aos procedimentos endovasculares por via femoral e tiveram o introdutor vascular retirado por enfermeiros de um Serviço de Hemodinâmica, no período de janeiro de 2018 a dezembro de 2020. Os fatores associados à complicação vascular foram investigados por associação bivariada e regressão linear múltipla com resposta *Poisson*, com o nível de significância de 5% ( $p < 0,05$ ). **Resultados:** a prevalência de complicações vasculares foi de 16,8% ( $n=215$ ). A principal complicação foi a ocorrência de hematoma. A retirada de introdutor vascular femoral com a compressão do tipo mista ( $p=0,050$ ) e do tipo mecânica ( $p < 0,001$ ), o maior tempo de compressão ( $p < 0,001$ ) e a presença de agitação psicomotora ( $p=0,040$ ) se associaram ao surgimento de hematoma. **Conclusão e implicações para a prática:** foi identificada a principal complicação vascular na retirada de introdutores vasculares femorais e fatores associados. Os achados podem auxiliar no aprimoramento da prática assistencial de retirada de introdutores vasculares, na busca de uma execução da técnica com maior qualidade e em um procedimento mais seguro ao paciente, além de permitir a implementação de medidas preventivas adequadas.

**Palavras-chave:** Complicações Pós-operatórias; Cuidados de Enfermagem; Dispositivos de Acesso Vascular; Enfermagem; Procedimentos Endovasculares.

## RESUMEN

**Objetivo:** verificar la prevalencia de complicaciones inmediatas en la retirada de introdutores vasculares femorales por enfermeras y los principales factores asociados a su ocurrencia. **Método:** estudio transversal que incluyó 1.281 pacientes sometidos a procedimientos endovasculares por vía femoral y a quienes se les retiró el introdutor vascular por enfermeras de un Servicio de Hemodinámica, desde enero de 2018 a diciembre de 2020. Se investigaron los factores asociados a complicaciones vasculares mediante asociación bivariada y regresión lineal múltiple con respuesta de Poisson, con un nivel de significancia del 5% ( $p < 0,05$ ). **Resultados:** la prevalencia de complicaciones vasculares fue de 16,8% ( $n=215$ ). La principal complicación fue la aparición de hematoma. La retirada del introdutor vascular femoral con compresión mixta ( $p=0,050$ ) y compresión mecánica ( $p < 0,001$ ), mayor tiempo de compresión ( $p < 0,001$ ) y la presencia de agitación psicomotora ( $p=0,040$ ) se asociaron a la aparición de hematoma. **Conclusión e implicaciones para la práctica:** se identificaron las principales complicaciones vasculares en la retirada de los introdutores vasculares femorales y los factores asociados. Los hallazgos pueden ayudar a mejorar la práctica asistencial de la retirada de introdutores vasculares, en la búsqueda de una técnica de mayor calidad y un procedimiento más seguro para el paciente, además de permitir la implementación de medidas preventivas adecuadas.

**Palabras clave:** Complicaciones postoperatorias; Atención de enfermería; Dispositivos de acceso vascular; Enfermería; Procedimientos endovasculares.

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## INTRODUCTION

Cardiovascular disease (CVD), especially Ischemic Heart Disease (IHD) and Cerebrovascular Disease (CbVD) is the leading cause of mortality worldwide, along with cancer.<sup>1,2</sup> The various types of approaches to diagnosing and treating CVD have evolved in tandem with technological advances. In this context, minimally invasive endovascular procedures have become the standard for diagnosing and treating heart and brain diseases.<sup>3</sup> This is an approach to the vascular system through percutaneous arterial access, usually radial or femoral, and using vascular access devices, also known as vascular sheaths, and catheters to perform them.<sup>4</sup>

The use of the femoral route for endovascular procedures is still quite common among the various interventional specialties and often remains the access of choice for certain procedures. However, post-operative vascular complications, mainly related to femoral access, should be considered an inherent risk and directly linked to the success of procedures.<sup>5</sup> Some studies<sup>5,6</sup> have demonstrated the advantages of using radial vascular access devices for endovascular procedures. In a multicenter study conducted in Turkey, which included 610 patients and compared the radial and femoral techniques for coronary angioplasty, no differences were observed in terms of the duration of the procedure, the volume of contrast used, or the dose of radiation used. However, the radial technique had fewer post-operative complications related to access.<sup>7</sup>

The occurrence of vascular complications related to femoral access may be related to certain patient characteristics, such as difficult-to-access vascular anatomy, advanced age, and the presence of comorbidities such as systemic arterial hypertension, diabetes, previous peripheral vascular disease, obesity, and coagulation disorders. In addition, factors related to the procedure, such as the experience of the endovascular surgeon, the technique used for femoral puncture, the duration of the procedure, and the use of vascular closure devices are also related to these complications.<sup>8</sup>

A systematic review,<sup>9</sup> which included 16 studies carried out in the United States, Europe, and Asia, showed that the main complications identified related to femoral access in neuroendovascular procedures were minor and more common complications, such as local hematoma and bleeding, and major and less common complications, such as retroperitoneal hematoma, pseudoaneurysm, arterial dissection, arterial occlusion, arteriovenous fistula, femoral nerve injury and puncture site infection.

The procedure for removing the femoral vascular sheath and the method to be used for hemostasis are some of the factors that are directly related to the appearance of complications. Nurses who work in hemodynamics must be trained to plan endovascular procedures, with a detailed analysis of each case and continuous monitoring, to provide safe and quality care.<sup>10</sup> In this context, the removal of the femoral sheath is a critical moment that must be properly planned by the nurse. Prior assessment, obtaining information related to the endovascular procedure performed,

together with patient information, are essential for organizing the entire care process.<sup>11</sup>

In Brazil, the removal of the femoral vascular sheath by nurses is legally supported by the normative opinion of the Federal Nursing Council (COFEN).<sup>12</sup> To carry out the procedure, the professional's technical and scientific competence must be considered throughout the process, in addition to the ability to act effectively in the event of complications.<sup>12</sup> In addition to the characteristics of the professional, the standardization of the femoral vascular sheath removal procedure through protocols is important for the quality of care provided, as it helps to make the right decisions, avoids inappropriate practices, provides legal support for professional practice and allows the incorporation of new technologies.<sup>13,14</sup> The use of scientific evidence to support nursing care has become essential. The results of research with recognized methodological rigor and its application in care practice allow for the updating of knowledge and the revision of work processes and imply changes in the attitudes of professionals.<sup>15</sup> An institutional manual prepared for the multi-professional team included relevant information for carrying out the femoral sheath removal procedure safely, as well as care and potential complications.<sup>16</sup>

In this sense, it is important to analyze the vascular complications of individuals undergoing femoral endovascular procedures to support the construction of protocols and improvements in care. This study aimed to verify the prevalence of immediate complications in the removal of femoral vascular sheaths by nurses and the main factors associated with their occurrence.

## METHOD

This was a cross-sectional, retrospective study with a quantitative approach conducted under the recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).<sup>17</sup> Data was collected between May and September 2022 at a Hemodynamics Service (HS) of a public university hospital in the interior of the state of São Paulo. The HS has been accredited since 2006 as a High Complexity Cardiovascular Reference Centre for the diagnosis and specialized treatment of patients with diseases of the cardiovascular system and serves the following specialties: Interventional Cardiology, Endovascular Surgery, and Interventional Neuroradiology. In 2023, 3569 endovascular procedures were carried out at the HS.

The information was obtained from specific HS records on the removal of vascular sheaths by nurses and from the electronic medical records of the patients seen. A convenience sample was established, which included all patients who underwent femoral endovascular procedures and had their vascular sheath removed by HS nurses immediately after the end of the procedure, from January 2018 to December 2020. Records with missing data related to the variables studied were considered losses.

According to the institutional protocol,<sup>16</sup> HS nurses, who have been duly trained, are responsible for removing femoral vascular sheaths from patients treated by Interventional Cardiology and Interventional Neuroradiology. Removal at the HS is carried

out immediately after the endovascular procedure, as long as anticoagulants have not been used. If anticoagulants have been used, the vascular sheath remains in the patient and is removed from the inpatient unit. No additional tests are carried out before the femoral vascular sheaths are removed. Once the femoral sheath has been removed, local compression of the femoral artery is performed, which can be manual (when the professional compresses only with their hands), mechanical (when a mechanical compressor is used), or mixed (when there is a combination of both techniques). After 20 minutes, the arterial compression is gradually reduced until hemostasis is complete, and then a compressive dressing is applied to the area.

Immediate complications were considered to be those occurring from the moment the femoral vascular sheath was removed until the patient was discharged from the HS, either by hospital discharge or referral to an inpatient unit. The variables studied included: age (in years), gender (male and female), specialty (Interventional Cardiology and Interventional Neuroradiology), sheath caliber (in French), type of femoral compression (manual, mechanical, and mixed), and compression time (in minutes). As for immediate vascular complications, we considered the presence of hematoma at the arterial puncture site, bleeding, retroperitoneal hematoma, pseudoaneurysm, arterial dissection, arterial occlusion, and arteriovenous fistula. Conditions that could contribute to the onset of vascular complications were also assessed, such as psychomotor agitation, patients with an aproned abdomen, the presence of hypotension, and hypertension.

The factors associated with the complication were investigated by fitting a multiple linear regression model with a Poisson response, including in the deterministic component only the variables that showed  $p < 0.20$  when bivariate associated with the complication. In the final model, the variables were considered statistically significant if  $p < 0.05$ . The analyses were carried out using IBM Statistical Package of Social Science (SPSS) software - version 21.

The study was approved by the institution's Research Ethics Committee (REC) (Opinion No. 5.428.647); Certificate of Submission for Ethical Appraisal (CAAE): 56983522.4.0000.5411, in compliance with Resolution No. 466/2012<sup>18</sup> on the ethical aspects of research involving human beings in Brazil.

## RESULTS

In the period studied, 1,284 patients were identified in the HS records of vascular sheath removals. Three patients were lost due to a lack of data on the size of the vascular sheath and the femoral compression time, giving a total of 1,281 patients. The median age of the patients was 60 years (three to 104 years), and 653 (51%) were male. As for the characteristics related to the sheath removal procedure, 663 patients (51.7%) were treated by Interventional Neuroradiology. A total of 1,126 (87.9%) 5Fr femoral vascular sheaths were used, and the most common type of compression was mechanical compression in 822 (64.2%) of the cases, with a mean time of 27.47 minutes, as shown in Table 1.

The prevalence of vascular complications was 16.8%. A total of 215 patients had complications when the femoral sheath was removed. Of these, 60 patients had two complications and nine had three or more complications. In the sample studied, there were no cases of retroperitoneal hematoma, pseudoaneurysm, arterial dissection, arterial occlusion, or the presence of an arteriovenous fistula. The main immediate vascular complications and the conditions presented by the patients when the femoral vascular sheath was removed are described in Table 2.

**Table 1.** Distribution of demographic characteristics and femoral vascular sheath removal procedure in the sample. Botucatu (SP), Brazil. 2022. (n=1.281)

Variables	n (%)
Age in years (median)	60
Gender	
Female	628 (49.0)
Male	653 (51.0)
Specialty attended	
Interventional Neuroradiology	663 (51.8)
Interventional Cardiology	618 (48.2)
Type of compression	
Mechanical	822 (64.2)
Manual	369 (28.8)
Mixed	90 (7.0)
Compression time in minutes (mean $\pm$ SD*)	27.5 $\pm$ 9.9
Vascular sheath caliber	
4 Fr†	4 (0.3)
5 Fr†	1126 (87.9)
6 Fr†	107 (8.4)
7 Fr†	44 (3.4)

\*SD - Standard Deviation; †Fr - French.

**Table 2.** Distribution of the main immediate vascular complications and other conditions following femoral vascular sheath removal. Botucatu (SP), Brazil. 2022. (n= 215)

Variables	n (%)
Hematoma	132 (10.3)
Bleeding	58 (4.5)
Hypertension	41 (3.2)
Hypotension	11 (0.9)
Psychomotor agitation	11 (0.9)
Apron abdomen	7 (0.5)

## Complications of femoral sheath removal

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When considering patients with hematoma on removal of the femoral vascular sheath, it is worth noting that the prevalence of this complication was higher in patients whose compression was of the mixed type ( $p < 0.001$ ) and lower when the compression was of the mechanical type ( $p < 0.001$ ). Similarly, patients with an apron abdomen, psychomotor agitation, and longer compression times had a higher prevalence of hematoma (Table 3).

Table 4 shows that there was a greater association between the appearance of a hematoma and removal of the femoral vascular sheath when mixed-type compression was used, with longer compression time and in the presence of psychomotor agitation. However, although the bivariate analysis showed an association between hematoma and the presence of an aproned abdomen, this relationship was not confirmed in the multivariate analysis.

## DISCUSSION

The study investigated the prevalence of immediate complications in the removal of femoral vascular sheaths by nurses in an HS. The main complications included hematoma, bleeding, hypertension, and hypotension. A multicenter study,<sup>10</sup> carried out in three Brazilian institutions and involving 2,696 patients who underwent endovascular procedures via the radial and femoral routes, showed that the presence of hematoma and bleeding were the most prevalent complications. A study carried out in Iraq,<sup>19</sup> which looked at the earliest complications following the removal of a femoral vascular sheath, identified the occurrence of hematoma, bleeding, ecchymosis, as well as urinary retention, and back pain. In Brazil, another study,<sup>20</sup> which investigated vascular complications after percutaneous

**Table 3.** Bivariate associations of variables related to the appearance of hematoma after removal of the femoral vascular sheath. Botucatu (SP), Brazil. 2022.

Variable	PR*	IC <sup>†</sup> 95%	p-value <sup>‡</sup>	
Age	1.00	0.99	1.01	.425
Female	1.15	0.88	1.51	.300
Specialty Neuroradiology	1.05	0.80	1.38	.710
<b>Mixed compression</b>	2.10	1.45	3.03	<b>p&lt;0.001</b>
<b>Mechanical compression</b>	0.47	0.35	0.63	<b>p&lt;0.001</b>
Manual compression <sup>§</sup>	1.00			
Sheath gauge - 7 Fr	0.55	0.07	4.53	.575
Sheath gauge - 6 Fr	0.93	0.13	6.90	.947
Sheath gauge - 5 Fr	0.65	0.09	4.64	.668
Sheath gauge - 4 Fr**	1.00			
<b>Compression time (minutes)</b>	1.03	1.02	1.04	<b>p&lt;0.001</b>
<b>Apron abdomen</b>	3.45	1.28	9.28	<b>.014</b>
<b>Psychomotor agitation</b>	3.31	1.47	7.46	<b>.004</b>

\*PR: Prevalence Ratio; †IC: Confidence Interval; ‡Bivariate analysis by simple linear regression with Poisson response; §reference for the type of compression; \*\*reference for sheath caliber.

**Table 4.** Multivariate analysis to verify the factors associated with the appearance of hematoma after removal of the femoral vascular sheath. Botucatu (SP), Brazil. 2022.

Variable	PR*	IC <sup>†</sup> 95%	p-value <sup>‡</sup>	
Intercept	0.11	0.08	0.150	<b>p&lt;0.001</b>
Mixed compression	1.16	0.76	1.77	<b>.050</b>
Mechanical compression	0.39	0.29	0.53	<b>p&lt;0.001</b>
Manual compression	1.00			
Compression time (minutes)	1.03	1.02	1.04	<b>p&lt;0.001</b>
Apron abdomen	1.89	0.70	5.13	.210
Shaking	2.33	1.03	5.29	<b>.040</b>

\*PR: Prevalence Ratio; †IC: Confidence Interval; ‡Multiple linear regression with Poisson response; §reference for type of compression.

endovascular procedures, revealed local hematoma as the main complication and indicated few cases of retroperitoneal hematoma and pseudoaneurysm.

In general, post-operative complications related to femoral vascular access are observed up to 48 hours after the endovascular procedure. In this study, complications were identified immediately after the removal of the femoral vascular sheath by nurses, while still assisting in the HS. The occurrence of complications in the immediate period can influence the continuity of care after the endovascular procedure and therefore requires a critical evaluation by nurses to assess potential complications. In addition, the development of competencies and the experience of nurses who work with endovascular procedures allow them to act more safely and effectively in the face of vascular complications.<sup>21</sup> Current legislation does not require nurses to be specifically qualified to remove femoral vascular sheaths.<sup>12</sup> Therefore, to develop these competencies, continuous training and qualification are necessary to provide individualized, quality nursing care.

The type of compression performed after removal of the femoral sheath in this study was associated with the occurrence of hematomas. The use of mechanical and mixed compression, when mechanical compression alone is not sufficient for hemostasis, was related to an increase in the prevalence of hematomas when compared to manual compression. Another method for hemostasis after the removal of vascular sheaths is the use of arterial closure devices. This method achieves hemostasis by applying a plug, suture, or clip to the arterial access used for the endovascular procedure via the femoral route. A systematic review,<sup>22</sup> which evaluated the effectiveness of different vascular closure devices for controlling hemostasis compared to extrinsic compression (manual or mechanical), found that the use of these devices reduced the risk of hematoma. However, the need for manual compression after the use of vascular closure devices, considered to be a failure of the device, also favored the appearance of complications, especially hematoma.<sup>22</sup> In this study, vascular closure devices were not used due to the unavailability of resources in the institution.

As for the compression time required for hemostasis, the average time identified in the study was 27.5 minutes. The increase in compression time was associated with an increase in the prevalence of hematoma ( $p < 0.001$ ). According to the institutional protocol used<sup>16</sup>, the hemostasis time after removal of the femoral sheath is 20 minutes. This is an important factor to consider when planning the procedure, along with the characteristics of the patient and the endovascular procedure to be performed. In a study carried out in Iran,<sup>23</sup> the compression time varied between five and ten minutes, but the caliber of the vascular sheath used was not specified. For sheaths with calibers larger than 7 Fr, the use of an arterial closure device is recommended.<sup>24</sup> In Brazil, the time determined for femoral compression after removal of vascular sheaths is not described in specific guidelines on endovascular procedures. Therefore, this study used the institutional protocol 16 for data collection and analysis of associations.

Although psychomotor agitation occurred in only 11 patients (0.9%), it was associated with the appearance of a hematoma. In healthcare practice, agitation is more common in patients undergoing endovascular procedures by Interventional Neuroradiology, which performs many procedures with sedation. In a review and meta-analysis,<sup>25</sup> the occurrence of agitation was observed in stroke patients during endovascular procedures that began with sedation and required conversion to general anesthesia. Longer endovascular procedures using specific technologies, such as thrombus extraction, can cause discomfort and intense headaches in patients.<sup>25</sup> Although sedation is recommended due to its safety and fewer complications in certain cases, there is a need for a multidisciplinary approach for more individualized care.<sup>26</sup>

Even though it was not confirmed in the multivariate analysis as a factor associated with the appearance of a hematoma, the presence of an apron-shaped abdomen is considerable when assisting in the removal of the femoral vascular sheath. In addition to the technical difficulties involved in femoral puncture and subsequent removal of the vascular sheath, increased abdominal circumference is directly linked to obesity or overweight and to increased cardiovascular risk.<sup>27</sup>

The prevention of vascular complications related to femoral vascular access, which includes the procedure for removing vascular sheaths, should be started before the proposed endovascular procedure is performed. One of the main measures to be considered is a pre-procedure nursing consultation. This is an important tool for nurses in identifying problems and risks that may influence the performance of endovascular procedures. Information on previous illnesses, medications in use, current state of health, as well as the application of bleeding risk scores, are important for all care planning during and after endovascular procedures.<sup>28,29</sup> At the time of the procedure, ultrasound-guided femoral arterial puncture is a strategy that can reduce the risk of complications.<sup>30</sup>

This points to the importance of continuing education actions that promote knowledge and, consequently, changes in the attitudes of the nursing team. In addition, it is important to consider the importance of standardizing the procedure for removing vascular sheaths and the need for new studies on this subject, to disseminate evidence for qualified practice. We should also point out the need for new studies to be carried out aimed at evaluating new technologies, such as mechanical compression.

## CONCLUSION AND IMPLICATIONS FOR PRACTICE

The prevalence of immediate vascular complications following the removal of femoral sheaths by nurses was 16.8% ( $n=215$ ). The main complication was the appearance of a hematoma, which was associated with the time and type of compression performed, as well as patient agitation.

The specific characteristics of endovascular procedures and their increasing use in the diagnosis and treatment of CVD show that prior assessment of patients to identify potential risk factors for vascular complications is very important, as the success of the

procedure is also related to the absence of complications. The findings can help to improve the practice of removing vascular sheaths, in the search for a higher quality and safer procedure for the patient, as well as allow for the implementation of appropriate preventative measures, such as structuring pre-procedure nursing consultations and monitoring these patients for later assessment.

The limitations of this study are related to the evaluation of only manual, mechanical and mixed compressions, since the use of vascular closure devices is still very limited in public services in Brazil, despite the known contributions of using these devices, including reducing hospital costs. In addition, as this was retrospective data, some information about the patients that was considered important was not included in the specific HS records, such as previous comorbidities and medications in use that could contribute to an increased risk of complications. This limitation led to the restructuring of the records on the removal of femoral sheaths by HS nurses and contributed to readjustments in work processes and clinical practice. Likewise, the institutional protocol was revised due to the need to include relevant items, such as specific tests before removing femoral vascular sheaths.

## AUTHOR'S CONTRIBUTIONS

Study design. Carolina Galli da Silveira. Fernanda Maria Alves Lima.

Data collection. Carolina Galli da Silveira. Fernanda Maria Alves Lima.

Data analysis and interpretation of results. Carolina Galli da Silveira. Fernanda Maria Alves Lima. Graziela Maria Ferraz de Almeida. Marla Andréia Garcia de Avila.

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## DATA AVAILABILITY

The contents underlying the research text are contained in the article.

## ASSOCIATED EDITOR

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