



Subsample analysis of the Vascular Complications Risk Score at two public referral centers for interventional cardiology*

Análise de subamostras do escore de risco para complicações vasculares em duas instituições públicas de referência para cardiologia intervencionista

Análisis de submuestras del score de riesgo para complicaciones vasculares en dos centros públicos de referencia para cardiología intervencionista

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ABSTRACT

Objective: Evaluate the performance of the Vascular Complications Risk Score in two public referral centers for interventional cardiology. **Method:** Subsample analysis of the Vascular Complications Risk Score, which was developed and validated in the catheterization laboratories of three cardiology referral centers (two public, one private) with a cutoff of <3 for no risk of developing vascular complications and ≥ 3 for risk. In this new analysis, we excluded data from the private facility, and only included participants from the original (validation) cohort of the two public hospitals. **Results:** Among the 629 patients studied, 11.8% had vascular complications; of these, 1.8% were major and 10% minor. Among the patients with a score <3, 310 (94.5%) presented no vascular complications; of those with a score ≥ 3 , 50 (17%) developed complications. Of those who developed vascular complications, 18 scored <3; two of these had major complications. **Conclusion:** This subanalysis confirms the ability of the Vascular Complications Risk score to predict low risk of vascular complications in patients with a score < 3.

DESCRIPTORS

Cardiac Catheterization; Percutaneous Coronary Intervention; Risk Factors; Postoperative Complications; Nursing Care.

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INTRODUCTION

Although percutaneous cardiology procedures, both diagnostic (cardiac catheterization) and therapeutic percutaneous coronary intervention (PCI), have become essential tools for the assessment and treatment of cardiovascular diseases⁽¹⁾, they are not risk-free. Complications arising during and after the procedure negatively affect clinical outcomes, resulting in increased demand for resources due to prolonged hospitalization and higher morbidity and mortality⁽²⁾.

Vascular complications are among the most prevalent complications arising from cardiac catheterization and PCI, followed by reactions to contrast, vasovagal reactions, arrhythmias, and more serious complications such as stroke, acute myocardial infarction (AMI), heart chamber perforation, and death⁽³⁾. The most frequent vascular complications are bleeding at the vascular access site and hematoma⁽⁴⁻⁶⁾. Pseudoaneurysm, arteriovenous fistula, retroperitoneal hemorrhage, thrombosis, and limb ischemia occur less frequently^(4,6).

One factor that influences increased risk of complications in these patients is the need for dual antiplatelet therapy⁽⁷⁾, as well as the combination of anticoagulants and antithrombotics, especially in PCI⁽⁷⁾. This is a notorious concern, and has prompted several studies with the purpose of ensuring safer practices and lower risk of bleeding for patients undergoing PCI⁽⁸⁻¹⁰⁾.

Other variables have been associated with risk of bleeding and of vascular complications. Among biological variables, female sex^(4,11) and older age⁽¹¹⁾ have been reported. Likewise, the choice of anatomical site for vascular access has also been investigated as a possible risk factor for vascular complications in large studies⁽¹²⁻¹³⁾, with some showing that radial access is safer than femoral access⁽¹²⁾. Another factor that has been considered is the size of the introducer; some studies have reported that, the larger the caliber, the greater the risk of complications⁽¹⁴⁾.

In this highly complex scenario, a systematic clinical evaluation by the catheterization lab nursing staff is crucial in detecting potential risks⁽¹⁵⁾. Identifying patients at risk may enable early intervention to minimize or avoid complications, thus helping ensure patient safety⁽¹⁶⁾.

It is in this context that tools validated in representative populations – e.g., risk prediction scores – are useful for stratification of patients in clinical practice⁽¹⁷⁻¹⁹⁾. From this perspective, we recently developed, validated, and published the Vascular Complications Risk (VASCOR) Score, which can predict the occurrence of vascular complications in patients undergoing interventional cardiology procedures (cardiac catheterization and PCI) with an odds ratio (OR) of 2.95 (95%CI: 2.22–3.91)⁽¹⁵⁾. The VASCOR Score was developed in three facilities: two public university-affiliated hospitals and one private, non-university-affiliated hospital. As the rates of complications were different between the three institutions, and aiming to refine the score, the present study performed a subanalysis of data from the two facilities with similar profiles (public hospitals) to evaluate VASCOR performance. In addition, we also analyzed the

cases of patients whose score identified risk but who developed no vascular complications, and the cases of patients whose score did not identify risk and who developed vascular complications. Our findings are relevant because the VASCOR Score can be immediately incorporated into the clinical practice of institutions with similar profiles.

METHOD

STUDY DESIGN

This study is a cross-sectional subanalysis nested in the prospective cohort that validated the VASCOR Score, conducted in the catheterization laboratories of three referral centers for interventional cardiology in the South region of Brazil⁽¹⁵⁾.

POPULATION

For this subanalysis, we included data from 629 patients from the validation cohort of the original study, in which male and female adults (aged ≥ 18) who underwent elective or emergent diagnostic or therapeutic percutaneous coronary procedures, through the transfemoral, brachial, or radial routes, were followed for up to 48 hours.

DATA COLLECTION

The data were collected from the initial database, which encompassed the period from October 2012 to March 2014. In patients who remained hospitalized, the vascular access site was inspected for complications 24h and 48h after the procedure. In patients discharged less than 24h after the procedure, the vascular access site was inspected during their recovery room stay. All notes made by the healthcare team in the patients' medical records were also reviewed. No patient was monitored after discharge.

VASCOR SCORE

The VASCOR Score was developed to predict risk of vascular complications in patients undergoing interventional cardiology procedures. The final model was composed of six variables: 1) use of a $>6F$ introducer (OR 4.17; 95%CI: 2.69–6.50); 2) PCI (OR 2.44; 95%CI: 2.03–2.92); 3) prior vascular hemodynamic complication (OR 2.02; 95%CI: 1.45–2.80); 4) prior use of warfarin or phenprocoumon (OR 1.88; 95%CI: 1.28–2.76); 5) female sex (OR 1.57; 95%CI: 1.12–2.18); and 6) age ≥ 60 years (OR 1.49; 95%CI: 1.32–1.68)⁽¹⁵⁾. The OR values obtained in the multivariate analysis, rounded to the nearest 0.5, constituted the weight of each variable in the model. Thus, patients whose procedure used $>6F$ introducers were assigned a score of 4.0 points; those undergoing PCI, 2.5 points; those with a prior complication, 2.0 points; those on warfarin and/or phenprocoumon, 2.0 points; women, 1.5 points; and those aged ≥ 60 years, an additional 1.5 points. Patients who had all variables included in the multivariate model were thus assigned a total score of 13.5 points. Taking into consideration the best balance between sensitivity and specificity and having tested different scores, the risk cutoff was defined as ≥ 3 ⁽¹⁵⁾.

OUTCOMES OF INTEREST FOR THE SUBANALYSIS

The outcomes considered in the subanalysis were the presence of vascular complications, defined in the original study as: 1) hematoma at the vascular access site, graded according to the American College of Cardiology classification (large ≥ 10 cm, small < 10 cm)⁽¹⁹⁾; 2) major bleeding, as defined in the *Can Rapid Risk Stratification of Unstable Angina Patients Suppress ADverse Outcomes with Early Implementation of the ACC/AHA Guidelines (CRUSADE)* study (documented retroperitoneal hemorrhage without surgical correction or any transfusion of red blood cells with bleeding observed)⁽²⁰⁾. Bleeding was also considered major in case of hemodynamic instability, defined by uncontrolled hypertension or hypotension, tachycardia or bradycardia, or decreased oxygen saturation from baseline. All other bleeding without hemodynamic instability was considered minor; or 3) any of the following vascular complications requiring surgical correction: retroperitoneal hemorrhage, pseudoaneurysm, or formation of arteriovenous fistula⁽²¹⁾.

The study included other variables such as the patients' clinical and demographic characteristics, prior and current health history, and data related to the pre-, inter-, and post-procedure period.

SUBANALYSIS LOGISTICS

For the purposes of this study, we excluded data obtained at the private facility, limiting our analysis to participants from the original (validation) cohort treated at public, Unified Health System facilities (n=629). We analyzed the sociodemographic variables and clinical characteristics of this subsample, as well as procedure characteristics and vascular complications. We also evaluated medical records in search of information missing from the database; three medical records had to be assessed qualitatively to meet one of the specific objectives.

DATA ANALYSIS AND PROCESSING

All analyses were carried out in the Statistical Package for the Social Sciences (SPSS) v.20 and WinPEPI. Quantitative variables were expressed as mean \pm standard deviation if normally distributed or median and interquartile range otherwise. Categorical variables were expressed as absolute numbers and percentages. The chi-square test was used to compare the proportion of complications between the groups of patients, according to the defined cutoff point of 3 (VASCOR score < 3 , no risk of complications; ≥ 3 , risk of complications). We then identified cases of disagreement between the score and the patients' clinical condition: (1) score values ≥ 3 in patients who did not develop complications and (2) score values < 3 in patients who developed complications.

ETHICAL ASPECTS

This study was approved by the Ethics Committees of both institutions (HCPA no. 120469 and IC-FUC no. 114.772), and was conducted in compliance with Brazilian National Health Council Resolution no. 466/12 on human subject research. All researchers signed a data use agreement.

RESULTS

We evaluated data from 629 patients. The mean age was 62 ± 10 years, and there was a slight male predominance (58%). Diagnostic cardiac catheterization was the most common procedure, and hypertension and dyslipidemia were the most prevalent risk factors in the subsample (Table 1).

Table 1 – Sample characteristics – Porto Alegre, RS, Brazil, 2017.

Variables	n (%)
Age, years [†]	62 \pm 10
Sex (male)	362 (58)
Cardiac catheterization	426 (68)
Percutaneous coronary intervention Introducer sheath size, > 6 French	203 (32) 7 (1.1)
Institution	
Hospital de Clínicas de Porto Alegre	196 (31)
Instituto de Cardiologia	433 (69)
Hypertension	567 (90)
Dyslipidemia	442 (70)
Diabetes mellitus	190 (30)
Acute myocardial infarction	171 (27)
Prior vascular hemodynamic complication	90 (14)
Prior peripheral arterial disease	72 (11)
Prior anticoagulation	507 (81)
Antiplatelet drugs	
Acetylsalicylic acid	480 (77)
Clopidogrel	199 (32)
Ticagrelor	3 (0.5)
Anticoagulants	
Heparin	29 (4.6)
Enoxaparin	9 (1.4)
Warfarin	13 (2.1)
Phenprocoumon	5 (0.8)

[†] variables expressed as mean \pm standard deviation

Note: (n=629)

INCIDENCE OF VASCULAR COMPLICATIONS IN THE VALIDATION COHORT

A total of 11 (1.8%) major vascular complications occurred. Minor complications occurred in 63 (10%) of the patients.

Table 2 illustrates an analysis of the time course of post-procedural complications. Major vascular complications occurred predominantly in the first 6 hours after the procedure, as did minor vascular complications. No major vascular complications were recorded after the 6th hour of recovery. Pseudoaneurysm, retroperitoneal hematoma, and arteriovenous fistula were not observed in this sample.

Table 3 illustrates the results of analysis of the sample. Three patients were not included due to lack of information as to the size of the introducer.

Among patients with a VASCOR score < 3 , n=310 (94.5%) did not develop vascular complications; among patients with score ≥ 3 , n=50 (17%) presented vascular complications.

Table 2 – Incidence of complications from 0–6 h, 6–24 h, and 24–48 h after interventional cardiology procedures – Porto Alegre, RS, Brazil, 2017.

Vascular complications (n)	0–6 h n (%)	6–24 h n (%)	24–48 h n (%)	Total n (%)
Major (n=629)				
Major hematoma (≥ 10 cm)	10 (1.6)	0 (0)	0 (0)	10 (1.6)
Unstable bleeding	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Minor (n=629)				
Minor hematoma (<10 cm)	39 (6.2)	1 (0.2)	1 (0.2)	41 (6.5)
Stable bleeding	22 (3.5)	0 (0)	0 (0)	22 (3.5)

Table 3 – VASCOR Score and vascular complications – Porto Alegre, RS, Brazil, 2017.

	Risk Score	Vascular complication		Total n
		No n (%)	Yes n (%)	
	< 3	310 (94.5)	18 (5.5)	328
	≥ 3	248 (83)	50 (17)	298
	Total	558 (89.1)	68 (10.9)	626

ACCURACY OF THE RISK SCORE

Table 4 describes the performance, sensitivity, and specificity of the VASCOR Score in the subsample, with odds ratios and C-statistics (accuracy, 0.70; 95%CI 0.63–0.77).

Table 4 – Ability of VASCOR Score to predict vascular complications – Porto Alegre, RS, Brazil, 2017.

	Validation Cohort
Sensitivity	0.73 (95%CI 0.61–0.83)
Specificity	0.55 (95%CI 0.51–0.59)
Odds ratio +	1.65 (95%CI 1.39–1.96)
Odds ratio -	0.47 (95%CI 0.32–0.71)
Positive predictive value	0.17 (95%CI 0.14–0.19)
Negative predictive value	0.95 (95%CI 0.92–0.96)
C-statistic	0.70 (95%CI 0.63–0.77)

CI: confidence interval.

Note: (n=629)

ANALYSIS OF PATIENTS WITH RISK SCORE ≥ 3 AND NO SUBSEQUENT COMPLICATION

The majority of patients with a score ≥ 3 (n=248) nevertheless developed no complications. On bivariate analysis, some variables were significantly associated with this phenomenon: diagnostic procedure (p=0.03), absence of prior vascular complication (p=0.029), radial access (p=0.008), duration of procedure ≤ 60 min (p=0.012), and systolic blood pressure at the end of the procedure <130 mmHg (p=0.001).

ANALYSIS OF PATIENTS WITH RISK SCORE <3 AND SUBSEQUENT COMPLICATION

Of the 18 patients who developed vascular complications despite a score <3, two had major vascular complications (major hematoma). Both were aged >60 years, overweight, hypertensive, and taking acetylsalicylic acid. One of these

patients had undergone coronary artery bypass graft surgery in the same year with double vascular access (radial and femoral); the subsequent catheterization procedure was transfemoral. Hematoma developed within the first 6 hours after mobilization in this case. The other patient developed major hematoma after removal of the introducer, which was also placed in the femoral artery.

DISCUSSION

This subgroup analysis of the VASCOR Score validation cohort, now limited to public hospitals, confirmed its original performance. The score was capable of accurately predicting the absence of these outcomes, with 94.5% of patients below the risk threshold (<3) developing no such complications. Its performance in predicting the occurrence of complications in patients with score ≥ 3 was similar to that found in the original study, proving it is an inclusive score⁽¹⁵⁾.

Among patients with a VASCOR Score <3 (that is, no risk), 18 developed vascular complications. However, in only two were the complications were considered major. Qualitative analysis of these patients' characteristics showed four shared variables: age over 60 years, male sex, hypertension, and overweight. Age is a component variable of the VASCOR Score; however, the other variables did not compose the model that originated the score after regression analysis. An association of hypertension with vascular complications after interventional cardiology procedures has often been reported in other studies^(4,6,14). In one of these studies, hypertension was a significant predictor of such complications, but was not included in the final model after logistic regression⁽⁴⁾, just as in the analyses that originated the VASCOR Score.

Male sex is not usually associated with the occurrence of vascular complications; conversely, female sex has been included as a predictor of these outcomes in various studies^(2,4,19). Reasons for the greater risk of vascular complications in women include anatomic issues (such as a shorter common femoral artery in women than in men) and the hypothesis that women undergoing PCI have a worse cardiovascular risk profile than men selected for the same procedures⁽²⁾. As only two patients developed major complications in our qualitative analysis, we cannot extrapolate that sex might be considered a risk factor for occurrence of vascular events.

In the analysis of patients who had risk predicted by the VASCOR (i.e., those with a score ≥ 3) but did not develop vascular complications, we determined five statistically significant variables. Two were included in the final VASCOR model⁽¹⁵⁾: PCI and prior hemodynamic complication, with scores of 2.5 and 2 respectively. Naturally, their opposites – i.e., diagnostic rather than therapeutic catheterization and absence of prior vascular complications – appeared as protective factors in this group of patients with score ≥ 3 who had no subsequent complication.

Radial access is a variable that was not included in the VASCOR Score, but was significant in this subgroup analysis. Several comparative studies^(12–13,22) have found that radial access is safer than femoral access and has lower rates of

vascular complications. One of the reasons that contribute to the greater safety of radial access is the comfort it provides to the patient, due to the possibility of early mobilization out of bed, whereas femoral access requires at least 3 hours of bed rest^(5,21).

Procedure duration less than 60 minutes was also a protective factor in this subsample. The duration of the procedure was reported as an independent factor for complications in a study that assessed immediate vascular complications after cardiac catheterization; in this study, the procedure duration was 7–131 minutes⁽²³⁾. The relationship between extended duration of the procedure and increased risk of vascular complications can be explained by the fact that longer procedure time is associated with greater manipulation at the vascular access site, in addition to the need for higher doses of anticoagulant.

The fact that systolic blood pressure <130 mmHg at the end of the procedure was a significant protective variable in patients who had VASCOR scores consistent with risk but developed no subsequent complication is consistent with previous studies^(4,6,14). This is explained by the fact that high blood pressure increases arterial pulsatility and thus makes hemostasis more difficult to achieve, thereby increasing the risk of bleeding and hematoma at the puncture site.

Risk scores have guiding therapeutic decision-making for decades^(17–18,20). Validated scores are generally easy to use and can be applied at bedside. Reviews of the literature show no reports of available scores to evaluate the risk of vascular complications in patients undergoing endovascular procedures, except for in-hospital^(18–19) and out-of-hospital⁽¹⁷⁾ mortality risk scores and a major bleeding risk score⁽²⁰⁾. The VASCOR Score is easily applied by nurses at the bedside and can be incorporated immediately into clinical practice.

Systematization of care in the catheterization laboratory involves a variety of processes, ranging from the direct care provided to patients undergoing endovascular procedures to the management of material resources, high-tech equipment, and daily contact with a multidisciplinary team. This dynamic milieu, and especially the limited time patients remain in this unit, poses a challenge for excellence in care. Within this context, patient safety has become a growing concern⁽¹⁶⁾.

A recent integrative review of the literature aimed to analyze the nurse's role in the catheterization laboratory. The most commonly covered topics concerned the health of nursing professionals and the materials used in the catheterization laboratory⁽²⁴⁾. Of 11 studies included, only two addressed the role of nurses in pre- and post-procedure evaluation of patients⁽²⁴⁾. This suggests that scientific output related to clinical evaluation of patients in the catheterization laboratory, especially regarding the use of risk scores, is still scarce.

Other studies conducted at international centers have investigated changes in patients' lifestyle after PCI, or alterations after intervention⁽²⁵⁾, or simply patients' recognition of

or perceptions about their modifiable cardiovascular risk factors⁽²⁶⁾. Regarding the prevention of vascular complications, a group in Turkey sought to determine the approaches used for prevention of complications of femoral arteriotomy and contrast-induced nephropathy in patients undergoing cardiac catheterization⁽²⁷⁾. Thirty-six university-affiliated hospitals were sent a questionnaire which addressed hemostasis-related care and prevention of contrast use; 29 responded. The authors found that manual compression followed by pressure dressing and sandbag placement were the most common methods used to achieve hemostasis, while for prevention of contrast-induced nephropathy, intravenous saline solution is given before and after the procedure⁽²⁷⁾. A review study that included four randomized clinical trials sought to assess pain control after introducer sheath removal in patients undergoing PCI and determine if pain relief had any influence on complication rates⁽²⁸⁾. This study found no association between pain relief and complications arising from the procedure⁽²⁸⁾.

The evidence presented herein suggests that implementation of the VASCOR Score can be useful in the clinical practice of catheterization laboratory nurses. The score is a useful tool for identifying patients at potential risk of developing vascular complications. Despite being more inclusive (that is, it classifies more patients as being at risk of developing complications), this is actually an advantage, as it ensures that a larger number of patients will receive more attentive care. Additional measures can be adopted for patients identified as being at risk (score ≥ 3), specifically: close, frequent observation of hemostasis at the vascular access site; monitoring for changes in vital signs; prevention of patient movement before the recommended period; and keeping patients classified as at-risk physically closer to the team.

As limitations of this study, we identified the non-inclusion of other procedures performed in the catheterization laboratory, i.e., patients who underwent non-cardiac procedures were not included in the sample.

CONCLUSION

The VASCOR Score can be readily used by nurses to prevent vascular complications after interventional cardiology procedures. In this sub-analysis, the score's performance confirmed its ability to predict low risk of complications for patients below the 3-point cutoff.

The findings of this study provide important contributions to the clinical practice of catheterization laboratory nursing staff. The VASCOR Score is an easily applicable, low-cost instrument. Its use enables the team to plan the organization of care in advance, enhancing safety during patient recovery. Furthermore, it is relevant for research and teaching activities, as it can be used by nurses and students as a basis for development of quantitative tools to measure risk of vascular complications and plan more effective interventions.

RESUMO

Objetivo: Avaliar o desempenho do Escore de Risco para Complicações Vasculares em duas instituições públicas de referência para cardiologia intervencionista. **Método:** Análise de subamostras do Escore de Risco para Complicações Vasculares, que foi desenvolvida e validada nos laboratórios de cateterização de três instituições de referência em cardiologia (duas públicas, uma particular) com um valor de corte de <3 para nenhum risco de desenvolver complicações vasculares e ≥3 para risco. Nesta nova análise, excluímos dados do centro particular e apenas incluímos participantes da coorte original (validação) dos dois hospitais públicos. **Resultados:** Entre os 629 participantes estudados, 11,8% tiveram complicações vasculares; destas, 1,8% foram maiores e 10%, menores. Entre os pacientes com um escore <3, 310 (94,5%) não apresentaram nenhuma complicação vascular; daqueles com um escore ≥3, 50 (17%) desenvolveram complicações. Daqueles que desenvolveram complicações vasculares, 18 pontuaram <3; dois destes tiveram complicações maiores. **Conclusão:** Esta subanálise confirma a habilidade do Escore de Risco para Complicações Vasculares de prever baixo risco de complicações vasculares em pacientes com um escore <3.

DESCRITORES

Cateterismo Cardíaco; Intervenção Coronária Percutânea; Fatores de Risco; Complicações Pós-Operatórias; Cuidados de Enfermagem.

RESUMEN

Objetivo: Evaluar el desempeño del Score de Riesgo para Complicaciones Vasculares en dos centros públicos de referencia para cardiología intervencionista. **Método:** Análisis de submuestras del Score de Riesgo para Complicaciones Vasculares, que fue desarrollado y validado en los laboratorios de cateterización de tres centros de referencia en cardiología (dos públicos, uno privado) con punto de corte <3 para ningún riesgo de desarrollar complicaciones vasculares y ≥3 para riesgo. En este nuevo análisis, excluímos datos de la institución privada y solo incluímos a participantes de la cohorte original (validación) de dos hospitales públicos. **Resultados:** Entre los 629 participantes estudiados, el 11,8% tuvieron complicaciones vasculares; de estas, el 1,8% fueron mayores y el 10%, menores. Entre los pacientes con un score <3, 310 (94,5%) no presentaron ninguna complicación vascular; de aquellos con un score ≥3, 50 (17%) desarrollaron complicaciones. De los que desarrollaron complicaciones vasculares, 18 tuvieron un puntaje <3; dos de estos tuvieron complicaciones mayores. **Conclusión:** Este subanálisis confirma la habilidad del Score de Riesgo para Complicaciones Vasculares de predecir bajo riesgo de complicaciones vasculares en pacientes con un score <3.

DESCRIPTORES

Cateterismo Cardíaco; Intervención Coronaria Percutánea; Factores de Riesgo; Complicaciones Posoperatorias; Atención de Enfermería.

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