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A Vascular Complications Risk (VASCOR) score for patients undergoing invasive cardiac procedures in the catheterization laboratory setting: A prospective cohort study

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Abstract

Background: Vascular complications are still common in the catheterization laboratory setting. However, no risk scores for their prediction have been described. With a view to bridging this gap, the present study sought to develop and validate a score for prediction of vascular complications associated with arterial access in patients undergoing interventional cardiology procedures.

Methods: This prospective multicenter cohort study included adult patients who underwent cardiac catheterization via the femoral or radial route. The outcomes of interest were: access site hematoma; major and minor bleeding; and retroperitoneal hemorrhage, pseudoaneurysm, or arteriovenous fistula requiring surgical repair. Past medical history as well as pre-procedural, intra-procedural, and post-procedural variables were collected. Patients were randomly allocated to the derivation or validation cohorts at a 2:1 ratio. The following equation constituted the score: (>6F introducer sheath×4.0)+(percutaneous coronary intervention×2.5)+(history of vascular complication after prior interventional cardiology procedure×2.0)+(prior use of warfarin or phenprocoumon×2.0)+(female sex×1.5)+(age⩾60 years×1.5). The maximum score is 13.5 points.

Results: A score dichotomized at ⩾3 (best cutoff for balancing sensitivity and specificity) was moderately accurate (sensitivity=0.66 (95% confidence interval: 0.59–0.73); specificity=0.59 (95% confidence interval: 0.56–0.61)). Patients with a score ⩾3 were at increased risk of complications (odds ratio: 2.95; 95% confidence interval: 2.22–3.91).

Conclusions: This study yielded a score that is capable of predicting vascular complications and easily applied in daily practice by providers working in the catheterization laboratory setting.

Keywords

Cardiac catheterization, percutaneous coronary intervention, risk factors, postoperative complications

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Introduction

The growing number of percutaneous procedures used to support diagnosis and treatment of cardiovascular diseases pose challenges to catheterization laboratory staff.[1] The combination of more complex procedures and more potent antithrombotic regimen carries the potential for increased risk of complications in patients undergoing invasive procedures.[2]

With advancing and increasingly in-depth knowledge about complications and patient characteristics, a need has arisen to identify predictors of these events; namely, by developing specific risk scores for patients undergoing percutaneous cardiac procedures.[3–5]

Variables such as age, female sex, hemodynamic instability with shock, creatinine, ejection fraction <20%, myocardial infarction at <24 h, pre-procedural cardiogenic shock, congestive heart failure at admission, renal impairment requiring dialysis, and presence of peripheral vascular disease are associated with higher risk.[4,5] In addition to these in-hospital mortality scores, the Can Rapid risk stratification of Unstable angina patients Suppress ADverse outcomes with Early implementation of the American College of Cardiology/American Heart Association (ACC/AHA) guidelines (CRUSADE) risk score identified eight independent predictors of major bleeding (documented retroperitoneal bleed or intracranial hemorrhage): baseline hematocrit<36%, creatinine clearance, heart rate, female sex, signs of congestive heart failure, prior vascular disease, diabetes, and systolic blood pressure⩽110 or ⩾180 mm Hg.[6,7]

Although independent factors associated with development of vascular complications have been reported in the literature,[2,8] to date, these have not yet been summarized in a single, factor-weighted score for prediction of risk of access-related complications in patients undergoing interventional cardiology procedures.

Within this context, the present study was designed to develop and validate a risk score for occurrence of vascular complications in patients undergoing diagnostic or therapeutic invasive cardiac procedures in a catheterization laboratory setting. The developed risk score can contribute substantially to a targeted clinical evaluation at the time of patient admission to the catheterization laboratory, with a view to early identification of risk characteristics and implementation of safety measures to reduce the rate of complications. By enabling identification of high-risk patients who may require closer monitoring, the risk score may also provide safety benefits to patients and to care staff.

Methods

Study design

This was a prospective, multicenter cohort study.

Setting

This study was conducted at three facilities with catheterization laboratories located in Southern Brazil, from October 2012–March 2014. The first facility, a private hospital located in the second-largest city of the state of Rio Grande do Sul, is a regional referral center for cardiology. It has a single catheterization suite and performs approximately 110 procedures per month. The second study center is a large public teaching hospital, located in the state capital of Porto Alegre, has three catheterization suites and a procedure volume of approximately 280 per month. The third study center, a university-affiliated specialty heart hospital also located in the state capital, largely caters to patients from the publicly funded health system and performs approximately 1000 interventional cardiology procedures per month at a four-suite catheterization laboratory. As the latter two facilities host residency programs in interventional cardiology, resident physicians are also involved in procedures, although always under direct supervision.

All patients invited to take part in the study provided written informed consent for participation. All individuals involved in research aspects signed a data use agreement. The ethical and methodological aspects of the study were approved by all relevant review boards.

Participants

The sample included adults (age⩾18 years) of both sexes who underwent cardiac catheterization or percutaneous coronary intervention (PCI), electively or urgently, via the femoral or radial route. Patients who were not clinically or mentally fit to sign an informed consent form and had no legal guardian present at the time of the interview were excluded. Using a convenience sampling strategy, all potentially eligible patients were invited to take part in the study. There was no stratification; all potential patients from the three study centers were enrolled consecutively.

The study was preceded by training of all research assistants. The team comprised four nursing students, who worked under the direct supervision of specialist cardiac care nurses from each study center. All of these nurse supervisors had experience in the field of interventional cardiology.

The first step of data collection was an analysis of inter-rater agreement between the investigator nurses and the specialist cardiac care nurses, measured by means of the kappa coefficient or Prevalence and Bias Adjusted Kappa (PABAK) – ordinal scale.

After agreement had been checked, a team training activity was carried out to standardize the next steps of data collection: (a) approaching potential participants; (b) obtaining informed consent; (c) the actual data collection process; (d) outcome assessment and monitoring; and (e)

outcome recording in the research instruments. All data collection instruments were checked for proper completion by a supervising research nurse.

All patients had their arterial access site carefully inspected during their recovery suite stay for 6 h after the procedure. In patients who remained hospitalized, the access site was reinspected for complications 24 h and 48 h after the procedure. Those discharged home were instructed to inspect the access site themselves for any visible or palpable signs of complications; these instructions were provided both to patients and to their caregivers. Patients were also given a telephone number to call and a brochure explaining red flags of potential complications, and were instructed to return to the facility in case any of these complications developed. No patient contacted the study facilities to report complications. There was no follow-up after hospital discharge.

Outcomes and covariates

The same data collection instrument, designed to collect information on demographic variables, past medical history, and pre-procedural, intra-procedural, and post-procedural variables, was used for participants in all three centers. Data were obtained from patients themselves, from the care team, and from a chart review. The potential predictors of vascular complications evaluated were identified through a review of the interventional cardiology literature.[2,3,5,8,9]

The following were considered as vascular complications (study endpoints): (a) access site hematoma, graded in accordance with the ACC classification (large if $\geqslant$10 cm, small if <10 cm);[9] (b) major bleeding, based on the adapted CRUSADE criteria[6] and on generic criteria for hemodynamic instability, defined as: documented retroperitoneal bleed (not requiring surgical repair) and any red blood cell transfusion with witnessed bleed. Major bleeding also included any bleeding which caused hemodynamic instability, defined as: uncontrolled hypertension or hypotension, tachycardia, bradycardia, or oxygen desaturation from baseline. Other bleeds not causing hemodynamic instability were considered minor; and (c) retroperitoneal hemorrhage, pseudoaneurysm, or arteriovenous fistula formation requiring surgical repair.

Sample size

We followed the recommendation of Flecher et al.[10] to include 10 outcomes for each variable inserted in the multivariate model. On the basis of a historical average vascular complication rate of 3.7%,[8] we calculated that 2703 patients would have to be enrolled for 100 outcome events to occur, a number used to estimate the derivation cohort (two-thirds of patients). However, in a preliminary (interim) analysis, we observed a higher incidence of complications and thus decided to reduce the sample size without loss of sampling power.

Statistical analysis

Statistical analyses were carried out in SPSS (Statistical Package for the Social Sciences) Version 22.0 (IBM Corp., Armonk, New York, USA). Comparisons between cohorts (to establish the similarity of patients in the two cohorts) and between groups of patients with and without the events of interest were performed by means of the Pearson chi-squared (χ^2) test for categorical variables and the Student *t*-test or Mann–Whitney *U* test for continuous variables, as appropriate. Continuous variables were tested for normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. The kappa or PABAK coefficients were used to assess inter-rater agreement.

After completion of the data collection stage, two-thirds of participants were randomly allocated to constitute the derivation cohort, using the *select cases* command in SPSS. The remaining participants made up the validation cohort. Taking the multicenter design of the study into account, we performed all statistical analyses by using generalized estimation equations, with each center as cluster units. For score derivation, a univariate logistic regression was carried out, in which those variables with a p-value<0.25 (Wald's test) were selected for inclusion in the multivariate logistic regression models. Multicollinearity between variables was tested with the variance inflation factor (VIF). Starting with the highest p=value, the variables were removed one at a time until only variables with p<0.05 remained in the final models. Receiver-operating characteristic (ROC) curves were plotted and C-statistics were calculated. After selecting the model with the best performance, point values were assigned to each risk factor according to the odds ratios (ORs) obtained from logistic regression, rounding off to the nearest integer. The model was then tested in the validation cohort and the predictive properties of the score (sensitivity, specificity, positive and negative likelihood ratios, and positive and negative post-test probability), as well as OR values with 95% confidence intervals, were calculated at the selected cutoff points using the Computer Programs for Epidemiologists: WINPEPI v. 11.29 software.

Results

A total of 2696 patients were enrolled: 896 from Hospital A, 542 from Hospital B, and 1258 from Hospital C. Analysis of inter-rater agreement revealed consistency in all assessments (n=109) of vascular complications classified as small hematoma (<10 cm), large hematoma ($\geqslant$10 cm), and stable bleeding, including regarding hematoma size (kappa=1). As for the remaining vascular complications (unstable bleeding, pseudoaneurysm, retroperitoneal

hematoma, arteriovenous fistula), all nurses agreed on their absence (PABAK=1).

Of the 2696 patients enrolled, 237 developed one or more vascular complications (8.8%). The total number of such complications was 264, distributed as follows: hematoma<10 cm (n=135), stable bleeding (n=86), hematoma⩾10 cm (n=32), and unstable bleeding (n=11). There were no cases of retroperitoneal hematoma, pseudoaneurysm, or arteriovenous fistula. Only five patients (0.2%) had received a glycoprotein IIb/IIIa inhibitor (abciximab). None received tirofiban.

Access was obtained via the femoral route in 1485 patients (55%) and via the radial route in 1207 (45%). Hemostasis was achieved by manual compression in 1036 patients (38.5%), radial compression with a simple Tensoplast compression bandage dressing in 850 (31.5%), mechanical compression devices in 475 (17.6%), and radial compression devices in 335 (12.4%).

Among the demographic, clinical, pre-procedural, intra-procedural, and post-procedural variables collected in addition to the outcomes of interest, only the proportion of patients with hypertension was different between cohorts (approximately 4% greater in the validation cohort, p=0.009). All other variables were homogeneously distributed between cohorts (Table 1).

Univariate analysis of the derivation cohort (Tables 2 and 3) identified the following as potential risk factors for vascular complications (p<0.05): (a) age ⩾60 years; (b) female sex; (c) body mass index (BMI); (d) PCI procedure; (e) history of coronary artery disease; (f) prior interventional cardiology procedures; (g) history of vascular complications after prior interventional cardiology procedures; (h) peripheral artery disease; (i) dyslipidemia; (j) prior anticoagulation; (k) antiplatelet therapy; (l) heparin group antithrombotic therapy; (m) intra-procedural heparin administration; and (n) large-bore introducer sheath. However, for modeling purposes, an additional 13 variables with p<0.25 were included, for a total of 27 variables at the start of multivariate modeling.

After adjustment for confounding variables, the following were identified as independent risk factors for vascular complications: >6F introducer sheath, PCI procedure, history of vascular complication after prior interventional cardiology procedure, prior use of warfarin (Marevan) or phenprocoumon (Marcoumar) anticoagulant, female sex, and age⩾60 years (Table 4).

Adjusted ORs were rounded to the nearest 0.5 to constitute the weight of each variable in the model. Therefore, patients in whom a >6F introducer sheath was used, for instance, were assigned 4.0 points, whereas those aged ⩾60 years were assigned 1.5 points. The highest possible score obtainable by adding each variable was 13.5 points, according to the derived equation, where:

Vascular Complication Score=(>6F introducer sheath×4.0)+(PCI procedure×2.5)+(history of vascular complication after prior interventional cardiology procedure×2.0)+(prior use of warfarin (Marevan) or phenprocoumon(Marcoumar)anticoagulant×2.0)+(female sex×1.5)+(age⩾60 years×1.5)

See Table 5.

In the derivation cohort, the score was moderately accurate for prediction of vascular complications; in the validation cohort, accuracy was slightly superior (Table 6). After testing different cutoff points, the optimal balance of sensitivity and specificity (maximizing sensitivity, in view of the intended use of the score) was achieved at ⩾3. The score was thus dichotomized at this cutoff point.

The incidence rates of complications in patients with a score <3 and in those with a score ⩾3, in both the derivation and validation cohorts, are described below (Table 7). Comparative analysis of the risk of complications in the overall sample (n=2696) identified greater risk of vascular complications in patients with a score ⩾3. Findings were similar in the derivation cohort and in the validation cohort.

Discussion

This was the first study conducted with the specific purpose of developing and validating a VAScular COmplications Risk (VASCOR) score for patients undergoing invasive cardiac procedures in a catheterization laboratory setting.

The rationale for combining complications was to facilitate applicability of the score in clinical practice in the catheterization lab setting. It bears noting that some of the outcomes of interest did not occur at all (pseudoaneurysm, retroperitoneal hematoma, arteriovenous fistula requiring surgical correction), and would thus warrant reassessment in future studies, while some occurred at very low rates (hematoma ⩾10 cm and unstable bleeding). Nevertheless, the potential for critically adverse outcomes should these complications occur justifies their inclusion in this risk prediction score.

The results suggested that the independent variables predictive of risk were age ⩾60, female sex, PCI, warfarin or phenprocoumon therapy, a history of vascular complications after a prior interventional cardiology procedure, and use of a >6F introducer sheath. The last variable (>6F introducer) was associated with greater risk than any of the other variables alone.

As in the present study, female sex has been reported as a predictor of risk in other settings. An international case-control study that sought to investigate the relationship between sex and vascular complications in patients who underwent cardiac catheterization found that, on comparison of men versus women, BMI and size of the common femoral artery were only predictive of vascular complications in women. Lower BMI correlates with smaller common femoral artery diameter, and both factors are predictive of increased risk of vascular

Table 1. Comparison of demographics, clinical characteristics, and anticoagulation regimen between the derivation and validation cohorts.

Variable	Derivation cohort (*n*=1751)	Validation cohort (*n*=945)	*p*
Age, years[a]	62.7 ± 11	63.2 ± 11	0.29
Male sex	1060 (60.5)	552 (58.4)	0.28
Body mass index,[a] (kg/m^2)	27.9 ± 4.8	28.1 ± 4.7	0.40
Facility			
Hospital A	580 (33.1)	316 (33.4)	0.76
Hospital B	346 (19.8)	196 (20.7)	
Hospital C	825 (47.1)	433 (45.8)	
Procedure			
Cardiac catheterization	1331 (76)	692 (73.2)	0.11
Percutaneous coronary intervention	420 (24)	253 (26.8)	
Access route			
Femoral	972 (55.5)	513 (54.5)	0.31
Radial	778 (44.5)	429 (45.5)	
Comorbidities			
Hypertension	1458 (83.3)	823 (87.1)	0.009
Dyslipidemia	1138 (65.2)	618 (65.5)	0.87
Diabetes mellitus	536 (30.6)	280 (29.6)	0.60
Renal failure	60 (3.4)	32 (3.4)	0.96
Renal replacement therapy	23 (1.3)	8 (0.8)	0.28
Smoking status			
Current smoker	276 (15.8)	139 (14.7)	0.69
Former smoker	729 (41.6)	390 (41.3)	
Never smoker	746 (42.6)	416 (44)	
Relevant past medical history			
Acute myocardial infarction	318 (18.2)	197 (20.8)	0.09
Coronary artery disease	930 (53.1)	486 (51.4)	0.40
Coronary artery bypass grafting	173 (9.9)	88 (9.3)	0.63
Interventional cardiology procedure	745 (42.5)	390 (41.3)	0.52
Vascular complication after interventional cardiology procedure	186 (10.6)	103 (10.9)	0.82
Peripheral artery disease	178 (10.2)	93 (9.8)	0.79
Anticoagulation regimen	1292 (73.8)	700 (74.1)	0.87
Anticoagulant therapy			
Warfarin (Marevan)	47 (2.7)	16 (1.7)	0.10
Phenprocoumon (Marcoumar)	14 (0.8)	7 (0.7)	0.87
Antiplatelet therapy			
Aspirin	1202 (68.6)	650 (68.8)	0.94
Clopidogrel	528 (30.2)	294 (31.1)	0.61
Ticagrelor	32 (1.8)	12 (1.3)	0.28
Prasugrel	1 (0.1)	0 (0)	0.46
Heparin therapy			
Enoxaparin	49 (2.8)	20 (2.1)	0.28
Heparin	47 (2.7)	34 (3.6)	0.18

All data expressed as *n* (%) unless otherwise noted. [a]Expressed as mean±standard deviation.

complications; this may explain the greater predisposition of women to these events.[11]

More recently, a study that evaluated the impact of sex on clinical outcomes and hemorrhagic complications after radial PCI reported the following factors as predictors on multivariate analysis: female sex (OR 7.7; 1.8–13.4), age ⩾ 75 years (OR 5.8; 2.1–16.2), and chronic kidney disease (OR 7.3; 2.4–12.3).[12]

Anticoagulant therapy, represented in the present study by use of warfarin (Marevan) or phenprocoumon (Marcoumar), was also associated with twofold risk of vascular complications, which is consistent with the

Table 2. Univariate analysis of characteristics associated with vascular complications in the derivation cohort.

Variable	Vascular complication (%)	*p*
Age, years		
<60	7.0	<0.0001
⩾60	10.5	
Sex		
Male	7.7	0.034
Female	11.3	
Body mass index, kg/m²		
<25	11.5	
⩾25	8.2	<0.0001
Procedure		
Cardiac catheterization	6.7	<0.0001
Percutaneous coronary intervention	16.9	
Diabetes mellitus		
No	8.8	0.118
Yes	9.9	
Hypertension		
No	7.2	0.169
Yes	9.5	
Renal failure		
No	9	0.058
Yes	13.3	
History of acute myocardial infarction		
No	9.0	0.245
Yes	9.7	
History of coronary artery disease		
No	6.8	<0.0001
Yes	11.2	
History of coronary artery bypass grafting		
No	8.9	0.100
Yes	11	
History of interventional cardiology procedures		
No	7.8	<0.0001
Yes	11	
History of vascular complications after interventional cardiology procedure		
No	8.1	<0.0001
Yes	18.3	
Peripheral arterial disease		
No	8.6	0.027
Yes	13.5	
Current or former smoker		
No	8.8	0.607
Yes	9.4	
Dyslipidemia		
No	7.7	0.027
Yes	9.8	
Anticoagulant therapy (warfarin (Marevan) or phenprocoumon ((Marcoumar))		
No	8.9	0.001
Yes	15	
Antiplatelet therapy (aspirin, clopidogrel, ticagrelor, prasugrel)		
No	6.9	<0.0001
Yes	10	
Heparin therapy (heparin, enoxaparin, fondaparinux)		
No	9	0.045
Yes	12	

Table 3. Univariate analysis of pre-procedural, intra-procedural, and post-procedural characteristics related to vascular complications in the derivation cohort.

Variable	Vascular complication (%)	*p*
Pre-procedural systolic blood pressure, mm Hg		
<130	11.1	
130–179	7.8	<0.0001
⩾180	9.7	0.318
Pre-procedural diastolic blood pressure, mm Hg		
<100	9.4	0.491
⩾100	6.6	
Pre-procedural heart rate, bpm		
<60	6.8	0.083
⩾60	9.7	
Duration of procedure, min		
⩽60	8.9	0.139
>60	12.5	
Arterial access site		
Femoral	11	0.198
Radial	6.8	
Intra-procedural heparin, IU		
⩽5000	8.6	<0.0001
>5000	17.5	
Introducer sheath size, French (F)		
⩽6F	8.7	<0.0001
>6F	33.3	
Number of vascular access attempts		
One attempt	9.1	
Two attempts	8	0.715
Three attempts	33.3	0.207
Concomitant venous access		
No	9.1	0.087
Yes	18.2	
Timing of introducer sheath withdrawal		
Immediate	7.4	0.139
Delayed (⩾2 min)	11.9	
Post-procedural systolic blood pressure, mm Hg		
<130	8.1	
130–179	10.5	<0.0001
⩾180	10.3	0.29
Post-procedural diastolic blood pressure, mm Hg		
<100	9.1	0.285
⩾100	13.4	
Post-procedural heart rate, bpm		
<60	7.7	0.317
⩾60	9.7	

Table 4. Univariate and multivariate data results of derivation cohort (*n*=1751). Expressed as odds ratio (OR) (95% confidence interval (CI)).

Variables	OR crude (95% CI)	OR adjusted (95% CI)
>6 French introducer sheath	5.25 (3.15–8.76)	4.17 (2.69–6.50)
Percutaneous coronary intervention procedure	2.84 (2.35–3.43)	2.44 (2.03–2.92)
History of vascular complications after prior interventional cardiology procedure	2.55 (1.63–4.00)	2.02 (1.45–2.80)
Anticoagulant therapy (Warfarin (Marevan) or phenprocoumon (Marcoumar))	1.80 (1.27–2.54)	1.88 (1.28–2.76)
Female sex	1.52 (1.03–2.23)	1.57 (1.12–2.18)
Age⩾60 years	1.55 (1.42–1.71)	1.49 (1.32–1.68)

Table 5. Risk score for prediction of vascular complications.

Characteristic	Weight (points)
>6 French introducer sheath	4
Percutaneous coronary intervention procedure	2.5
History of vascular complication after prior interventional cardiology procedure	2
Prior use of Warfarin (Marevan) or phenprocoumon (Marcoumar) anticoagulant	2
Female sex	1.5
Age⩾60 years	1.5

Table 6. Diagnostic properties of the risk score for prediction of vascular complications, in the derivation and validation cohorts.

	Derivation cohort *n*=1751 (95% CI)	Validation cohort *n*=945 (95% CI)
Sensitivity	0.66 (0.59–0.73)	0.71 (0.60–0.80)
Specificity	0.59 (0.56–0.61)	0.58 (0.54–0.61)
Positive likelihood ratio	1.61 (1.42–1.82)	1.67 (1.42–1.97)
Negative likelihood ratio	0.57 (0.46–0.72)	0.50 (0.35–0.72)
Positive post-test probability	0.14 (0.13–0.16)	0.13 (0.11–0.15)
Negative post-test probability	0.60 (0.40–0.70)	0.40 (0.30–0.60)
C-statistic	0.68 (0.63–0.72)	0.72 (0.70–0.80)

CI: confidence interval.

existing literature.[8] Early identification of drugs being taken by patients and their washout time, whether by means of a thorough history or through voluntary disclosure, is increasingly important. In addition, it is mandatory that providers pay closer attention to the occurrence of these potential events, as longer manual compression time is indicated to ensure hemostasis.

Among the predictors included in this score, that associated with the greatest risk of vascular complications was introducer sheath size >6F. A previous study of 4595 patients undergoing PCI in Southern Brazil found that the only independent predictor of vascular complications was use of a 7F introducer sheath (OR 3.0; 1.2–7.8). The sole outcome of interest in this study was major complications, defined as hematoma >10 cm, major bleeding, or need for surgical repair.[13] Several studies have reported this factor as an important predictor to be considered when performing interventional cardiology procedures. In clinical practice, there is a trend toward use of ever-smaller introducer sheaths, both to improve patient comfort and to reduce complication rates.

Several initiatives have sought to establish risk prediction criteria, including scores to predict in-hospital mortality,[3–5] major bleeding,[6] and increased risk of readmission within 30 days of PCI;[14] however, we are not aware of any risk scores designed to identify predictors of vascular complications in patients undergoing invasive cardiac procedures in the catheterization laboratory setting.

Variables such as age and female sex are consistent with prior scores described in the literature, which suggest that these factors are predictive of the risk of mortality, major bleeding, and 30-day readmission.[3–6,14] The variables anticoagulation, PCI procedure, and large-bore introducer sheath have also been described in the literature as independent predictors of vascular complication risk,[8,9,11–13,15] even though these factors have not been included in any risk scores to date. During development and validation of the present score, we identified an additional independent predictor of vascular complications: a history of complications after prior interventional procedures, which was associated with twofold risk.

The C-statistic of the score developed in the present study was indicative of moderate discriminative capacity, as in the CRUSADE study (C-statistic: 0.72 and 0.71 in the derivation and validation cohorts respectively).[6] However, existing risk scores for mortality prediction have higher C-statistics, such as 0.87[3] and 0.88.[5] In the present study, we chose to set a cutoff point for score dichotomization that privileged sensitivity to the detriment of specificity, as the implementation of supplemental measures (such

Table 7. Incidence of complications in patients with score <3 vs score ⩾3 in the derivation and validation cohorts.

	Derivation (*n*=1751)	Validation (*n*=945)	Overall (*n*=2696)
Incidence of complications in patients with score<3	5.5	4.2	5.5
Incidence of complications in patients with score⩾3	13.9	12.8	13.5
OR (95% CI)	2.80; (1.99–5.55)	3.3; (1.99–5.94)	2.95; (2.22–3.91)

CI: confidence interval; OR: odds ratio.

as monitoring and nursing care) in direct patient care is not associated with any additional risk. This yielded an inclusive score, which identifies the majority of patients with the potential for development of vascular complications. Strategies can be designed to optimize the use of human resources, equipment, and physical space when caring for these patients, such as: (a) devoting greater attention to access site compression; (b) increasing access site surveillance; (c) monitoring vital signs and peripheral perfusion; and (d) improving physical allocation of gurneys or chairs to enable enhanced patient monitoring in the recovery suite.

Use and interpretation of this score should allow providers involved in the aftercare of patients who have undergone interventional cardiology procedures to recognize that patients with a score ⩾3 have threefold odds of developing a vascular complication (OR: 2.95). This alone may prompt implementation of measures such as those suggested above.

Development of risk scores has an essential role to play in targeting care and planning best practices. In addition, communication skills and evidence-based knowledge can improve the care provided to patients at all levels, and especially in the secondary prevention setting.[16] Knowledge of the risks involved directly in the development of vascular complications can help guide the provision of care, improving patient safety and care quality.

Study limitations

Some limitations of the present study must be noted, including that collection of some variables, such as number of arterial access attempts and venous puncture (intentional or otherwise), was limited by the fact that investigators were not present for all procedures. Nevertheless, this will not have affected our results, because these variables were found to be underpowered on multivariate analysis and were not retained for the final model. Furthermore, we did not include non-cardiac interventional procedures performed in the catheterization laboratory. Another potential limitation is the fact that there was no follow-up for outcome monitoring after hospital discharge; however, only 13% of the study sample remained hospitalized.

The sensitivity and specificity of this score was only moderate. However, the diagnostic performance of a score must be evaluated from the perspective not only of its statistical properties (sensitivity, specificity, predictive values), but also taking into account its accuracy and intended use. Adopting this score as a screening measure to identify patients at higher risk of complications would select a greater number of patients to receive preventive measures (specifically, closer monitoring by the nursing team), which are interventions that do not pose any additional risk or hazard.

Conclusion

The risk score described herein combines six factors that predict vascular complications in patients undergoing cardiac procedures in the catheterization laboratory setting. The cutoff point was established as ⩾3, on the basis of the optimal balance between sensitivity and specificity. The maximum score is 13.5 points. The component variables are: >6F introducer sheath (four points); PCI procedure (2.5 points); history of vascular complications after prior interventional cardiology procedures (two points); prior use of warfarin (Marevan) or phenprocoumon (Marcoumar) anticoagulant (two points); female sex (1.5 points); and age⩾60 years (1.5 points).

Although this study only identified one novel independent risk factor for vascular events, it was the first to assign weights to each factor according to the magnitude of the risk conferred simultaneously.

Implications for practice

- Availability to the scientific community of a risk score for occurrence of vascular complications.
- Can be administered immediately by nurses to all patients who have undergone invasive cardiology procedures.
- Its application enables advance planning and organization of the care team, with a view to enhanced prevention and safety during patient recovery.
- Future studies should consider differences in the type of device or method used to achieve hemostasis after interventional cardiology procedures.

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Conflict of interest

The authors declare that there is no conflict of interest.

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