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Prevent III score as a predictor of limb salvage and mortality after aortoiliac revascularization

Aortoiliyak revaskülarizasyon sonrası ekstremite kurtarma ve mortalitenin bir göstergesi olarak Prevent III skoru

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ABSTRACT

Background: This prospective study aimed to validate the prognostic value of Prevent III (PIII) risk score in patients undergoing aortoiliac revascularization, both in limb-related outcomes and cardiovascular risk.

Methods: The prospective cohort study included 130 consecutive patients (122 males, 8 females; mean age: 62.1±9.2 years; range, 53 to 71 years) undergoing elective aortoiliac revascularization between January 2013 and September 2022. Patients' demographic and clinical characteristics were retrieved and PIII scores were calculated. A risk category was assigned according to the total points: low-risk (score ≤3), medium-risk (score 4-7), or high-risk (score ≥8).

Results: The median follow-up period was 55 months (interquartile range, 39 to 70 months). Twenty-four (18.5%) patients had a PIII score ≥4. Regarding short-term outcomes, patients with PIII scores ≥4 exhibited lower ankle-brachial index changes at 30 days and more extended hospital stays. There were no significant associations between PIII scores and major adverse events at 30 days. However, during follow-up, a PIII score ≥4 was associated with increased major adverse limb events (p=0.036) and all-cause mortality (p=0.007).

Conclusion: The PIII score is a reliable predictor of long-term limb and mortality risk in patients undergoing aortoiliac revascularization procedures, leveraging five user-friendly clinical parameters. More research with larger cohorts and studies comparing PIII with other validated scores should be performed in the future.

Keywords: Major adverse cardiac events, peripheral arterial disease, prospective studies, risk assessment, survival analysis.

ÖZ

Amaç: Bu prospektif çalışmada, aortoiliyak revaskülarizasyon geçiren hastalarda Prevent III (PIII) risk skorunun prognostik değerinin hem ekstremite ile ilgili sonuçlar hem de kardiyovasküler risk açısından doğrulanması amaçlandı.

Çalışma planı: Prospektif kohort çalışmasına, Ocak 2013 - Eylül 2022 tarihleri arasında elektif aortoiliyak revaskülarizasyon uygulanan 130 ardışık hasta (122 erkek, 8 kadın; ort. yaş: 62.1±9.2 yıl; dağılım, 53-71 yıl) dahil edildi. Hastaların demografik ve klinik özellikleri elde edildi ve PIII skorları hesaplandı. Toplam puana göre bir risk kategorisi atandı: düşük riskli (skor ≤3), orta riskli (skor 4-7) veya yüksek riskli (skor ≥8).

Bulgular: Ortanca takip süresi 55 aydı (çeyrekler arası aralık, 39-70 ay). Yirmi dört (%18.5) hastada PIII skoru ≥4 idi. Kısa vadeli sonuçlarla ilgili olarak, PIII skoru ≥4 olan hastalar 30 günde daha düşük ayak bileği-brakiyal indeks değişiklikleri ve daha uzun hastanede kalış süreleri sergiledi. Prevent III skorları ile majör advers olaylar arasında 30 günde anlamlı bir ilişki yoktu. Bununla birlikte, takip sırasında PIII skoru ≥4, artmış majör advers ekstremite olayları (p=0.036) ve tüm nedenlere bağlı mortalite (p=0.007) ile ilişkilendirildi.

Sonuç: Prevent III skoru, aortoiliyak revaskülarizasyon işlemleri uygulanan hastalarda uzun vadeli ekstremite ve mortalite riskinin güvenilir bir belirleyicisidir ve beş kullanıcı dostu klinik parametreden yararlanır. Gelecekte daha büyük kohortlarla daha fazla araştırma ve PIII ile diğer doğrulanmış puanları karşılaştıran çalışmalar yapılmalıdır.

Anahtar sözcükler: Majör advers kardiyak olaylar, periferik arter hastalığı, prospektif çalışmalar, risk değerlendirmesi, sağkalım analizi.

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Cardiovascular disease remains a leading global cause of morbidity and mortality.[1] It often coexists with peripheral artery disease (PAD), sharing common risk factors and underlying pathophysiology.[2] Peripheral artery disease involving aortoiliac vessels can have diverse clinical presentations, ranging from claudication to the most severe chronic limb-threatening ischemia (CLTI), defined as severe rest pain, nonhealing wounds, or tissue loss.[3] Surgical management of CLTI can involve open surgery or endovascular techniques to restore perfusion.[4]

Risk stratification is paramount when making clinical decisions related to limb and cardiovascular risk in candidates for revascularization. In CLTI management, Prevent III (PIII) risk score has been proposed as a valuable and easy-to-use tool for risk stratification.[5] Initially designed to predict amputation-free survival in a cohort of CLTI patients undergoing infrainguinal vein bypass, the PIII score assesses patient risk factors, including age, comorbidities, and clinical presentation.[5] This score includes five variables, each with different points assigned: renal replacement therapy, presence of tissue loss, age ≥75 years, hematocrit ≤30%, and a history of advanced coronary artery disease (CAD).[5] The internal and external validation of the PIII score allows the identification of patients at high risk of death and amputation one year after infrainguinal open bypass surgery with a vein conduit.[6] However, the full extent of the prognostic value of the PIII score, particularly in the aortoiliac sector, has yet to be explored.

This study sought to validate the prognostic significance of the PIII score in patients undergoing aortoiliac revascularization, focusing on both limb-related outcomes and cardiovascular and mortality risk. The authors hypothesized that a higher PIII score might indicate a higher risk of major adverse limb event (MALE), major adverse cardiovascular event (MACE), and all-cause mortality in this subgroup of patients. Therefore, the primary endpoint was the incidence of MACE, MALE, and all-cause mortality, stratified by PIII score, on the 30th day and during follow-up. Secondary outcomes included the occurrence of acute myocardial infarction (AMI), acute heart failure (AHF), and stroke during follow-up.

PATIENTS AND METHODS

One hundred thirty consecutive patients (122 males, 8 females; mean age: 62.1±9.2 years; range, 53 to 71 years) who underwent elective aortoiliac revascularization at the Department of Angiology and Vascular Surgery of Unidade Local de Saúde São João and Department of Angiology and Vascular Surgery of Unidade Local de Saúde entre o Tâmega e o Sousa between January 2013 and September 2022 were included in this prospective cohort study. All patients were selected from a tertiary and a community hospital and had atherosclerotic aortoiliac Transatlantic Inter-Society Consensus (TASC) II type D lesions, excluding those with aortoiliac aneurysmatic disease.[4] The decision between open surgery or an endovascular procedure was made between the patient and the surgeon, considering the surgeon and institution's experience and preferences. A trend towards aortoiliac stenting in cases with more comorbidities, while aortic bypass procedures were favored for younger patients with lower comorbidity burdens. Exclusion criteria included a history of inflammatory vasculitis, age below 18, and aortic aneurismatic disease.

Patients' demographic and clinical characteristics, including their cardiovascular risk factors and their procedural and lesion-specific details, were retrieved by a detailed review of their clinical records.[7] Further information regarding the type of lesion is described in the TASC II document.[4] Patients were evaluated by a vascular surgeon before the surgery and were under atorvastatin/rosuvastatin and 100 mg of acetylsalicylic acid for at least two days before surgery. Patients were assessed in the first 30 days after the procedure and during the subsequent long-term surveillance period. The outpatient clinic's clinical record was summarily reviewed for the reported outcomes, including patient-related events, such as AHF, AMI, stroke, and all-cause mortality. In addition, limb-related events, such as reintervention, acute limb ischemia, or occlusion without intervention, were considered. Points were added for each variable to calculate the PIII score for each patient, as previously described:[5] renal replacement therapy (4 points), presence of tissue loss (3 points), age ≥75 years (2 points), hematocrit ≤30% (2 points), and a history of advanced CAD (1 point). The sum of points was then associated with a risk category: low (score ≤3), medium (score 4-7), or high-risk (score ≥8) category.[5]

This study was conducted under the framework of the 2019 STROCSS (Strengthening the Reporting of Cohort Studies in Surgery) guideline[8] and TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) guidelines.[9]

The data was retrieved and registered in agreement with the Reporting Standards of the Society for Vascular Surgery for lower extremity

ischemia.[10] The Rutherford chronic ischemia classification was used to classify the symptoms and severity of chronic lower extremity ischemia.[11]

The technical success of the operation was defined as the maintenance of patency 24 h after the procedure. Major adverse cardiovascular event was described as a composite outcome, including AMI, AHF, and all-cause mortality.[12] Major adverse limb event was defined as the combined events of reintervention, including reintervention due to primary assisted patency, secondary patency or major amputation of the revascularized artery segment, and occlusion without intervention.[13]

Statistical analysis

The sample needed for a survival test was calculated by applying WinPepi version 11.65 (Microsoft Corp., Redmond, WA, USA), aiming for a statistical power (β) of 90% and an alpha <0.05. A sample of 72 was estimated for a hazard ratio (HR) of 2 between groups and a predicted survival at the end of follow-up of 80%, although higher event rate differences are described.[14] Due to the low number of patients included in the high-risk category (one patient with a score PIII ≥8), only two groups were considered for analysis purposes to avoid a tail effect bias: PIII ≤3 (low risk) and PIII ≥4 (medium risk).

For statistical analysis, IBM SPSS version 28.0 software (IBM Corp., Armonk, NY, USA) was used. Student's t-test was favored when dealing with normally distributed continuous variables, and the Mann-Whitney U test was used when working with variables whose normal distribution could not be

Table 1. Patients' demographics and comorbidities

	Total (n=130)			Prevent III ≤3 (n=106)			Prevent III ≥4 (n=24)			
Characteristics	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			62.1±9.2			60.1±7.3			70.6±11.3	*
Sex										
Male	122	93.8		99	94.3		23	92		0.669
Hypertension	85	65.4		66	62.9		19	76		0.214
Smoking history	118	90.8		100	95.2		18	72		**0.001**
Diabetes	37	28.7		31	29.8		6	24		0.564
Dyslipidemia	87	66.9		70	66.7		17	68		0.899
CKD	17	13.1		8	7.6		9	36		*
CAD	36	27.7		19	18.1		17	68		*
COPD	15	11.5		12	11.4		3	12		0.936
CHF	16	12.3		9	8.6		7	28		0.008
ASA scores										**0.027**
II	51	39.2		48	45.3		3	12		
III	71	54.6		54	50.9		18	72		
IV	8	6.2		4	3.8		4	16		
Rutherford classification										*
III	37	28.5		34	32.4		3	12		
IV	53	40.8		48	45.7		5	20		
V	32	24.6		20	19		12	48.0		
VI	8	17.8		3	2.9		5	20.0		
Endovascular	55	42.3		41	39		14	44		0.123
Open Surgery	75	57.7		64	61		11	56		
ABI			0.31±0.13			0.33±0.13			0.26±0.12	**0.049**
Hemoglobin (g/dL)			13.11±1.94			13.56± 1.62			11.30±2.12	*
Hematocrit (%)			43.7±6.5			45.2±5.4			37.7±7%	*

SD: Standard deviation; CKD: Chronic kidney disease (creatinine ≥1.5 mg/dL); CAD: Coronary artery disease; COPD: Chronic obstructive pulmonary disease; CHF: Cardiac heart failure; ASA: American Society of Anesthesiologists; ABI: Ankle Brachial index preoperative; * Colinearity. Statistically significant values are highlighted in bold.

Table 2. Patients' 30-day outcomes according to the PIII score

	Prevent III ≤3					Prevent III ≥4					
	n	%	Mean±SD	Median	IQR	n	%	Mean±SD	Median	IQR	*p*
MACE	8	7.5				3	12				0.470
Death	6	5.7				1	4				0.740
Prosthetic infection*	6	5.9				1	4.2				0.741
ABI Δ			0.45±0.24					0.35±0.21			**0.001**
Rutherford Δ			–2.48±1.42					–2.7±1.79			0.287
ICU (day)				2	0-3				2	0-4	0.752*
Infirmary stay (day)				7	3-19				14	8.5-33	**0.013***

SD: Standard deviation; IQR: Inter-quartile range; Prothesis infection (1 year of follow-up); Rutherford chronic ischemia Δ – preoperative minus postoperative; MACE: Major adverse cardiovascular event at 30 Days; ABI: Ankle-brachial index Δ - Postoperative minus preoperative; ICU: In stay on intensive care unit; * Non-parametric test; Statistically significant values are highlighted in bold.

assumed, presenting either mean and standard deviation or median and range, respectively. The chi-square test was used to analyze categorical variables. The level of statistical significance was set at $p<0.05$.

The backward and forward stepwise regression method was applied, and variables with $p<0.10$ were included. The log-rank estimator was utilized to test the effect of the score on time-dependent variables. Multivariate Cox regression analysis was performed for independent predictors of long-term MACE and all-cause mortality using the backward stepwise regression method.

RESULTS

The median follow-up was 55 months (interquartile range, 39 to 70 months). After the calculation of the PIII score, a total of 106 (81.5%) patients were included in the low-risk category (PIII ≤3) and 24 (18.5%) in the medium-risk category (PIII ≥4).

Regarding comorbidities and preoperative evaluations, PIII ≥4 patients were less likely to smoke (72% *vs*. 95.3%, p=0.001), had higher American Society of Anesthesiologists (ASA) scores, and had lower ankle-brachial index (ABI; 0.26±0.12 *vs*. 0.33±0.13, p=0.049). There were no differences between the groups regarding sex, comorbidities not included in the score, and type of revascularization procedure performed (endovascular *vs*. open; Table I).

Concerning short-term analyses, patients with PIII score ≥4 had lower ABI change at 30 days (0.35±0.21 *vs*. 0.45±0.24, p=0.001). These patients also had a more prolonged hospital stay (14 days *vs*. 7 days, p=0.013). However, no differences regarding intensive care unit stay were observed. Additionally, no differences in MACE and mortality at 30 days between PIII risk categories were identifiable (Table 2). Moreover, even on univariate regression analysis, none of the variables included in the PIII score were significant predictors of MACE or MALE at 30 days.

Nonetheless, the PIII score was influential in the discrimination of patients with a higher risk of MALE (log-rank p=0.038) and all-cause mortality (log-rank p=0.0047) during follow-up (Figures 1a, b). A higher PIII score was not associated with AMI, AHF, and stroke. MACE also was marginally associated with higher PIII scores (p=0.07) during follow-up (Figure 1c).

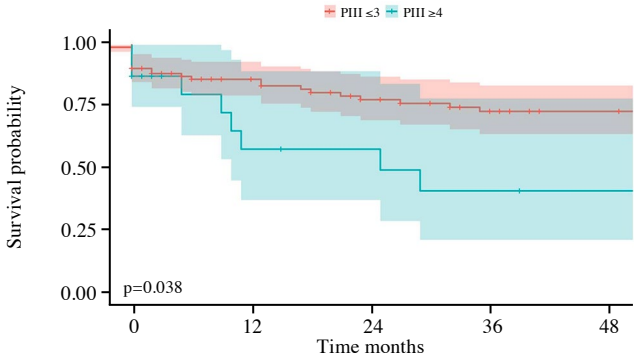
On Cox regression univariate analysis, the PIII score was significant in predicting long-term MALE (HR=2.283, 95% confidence interval [CI]: 1.057-4.927, p=0.036) and all-cause mortality (HR=2.717, 95% CI: 1.316-5.609, p=0.007). It did not reach significance when predicting long-term MACE (HR=1.915, 95% CI: 0.926-3.971, p=0.08, Figure 2; Supplemental Table 1).

DISCUSSION

This study found that a preoperative PIII score ≥4 predicts long-term outcomes such as MALE and all-cause mortality in patients undergoing aortoiliac revascularization for TASC II type D lesions, with a marginal association with MACE. Additionally, these patients exhibited lower ABI change at 30 days and longer hospital stays.

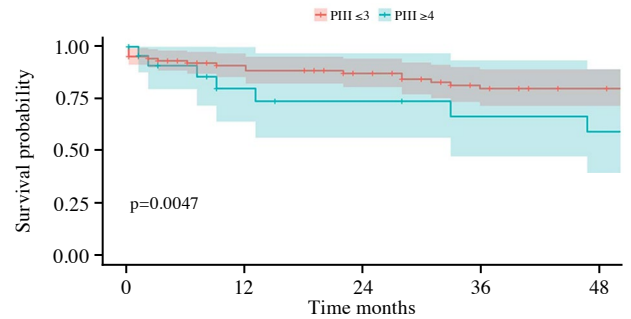
In this study population, apart from variables included in the score, patients with PIII ≥4 had

(a)



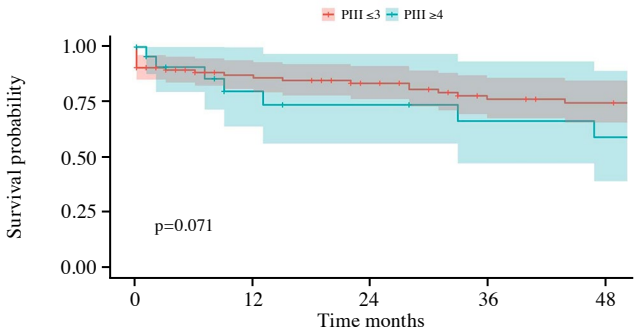
MALE		30d	12	24	36	48
Prevent III ≤3	Survival (%)	90.6	86.2	78.1	73.4	73.4
	SE (%)	2.8	3.4	4.4	4.9	4.9
	n	90	67	54	45	36
	Events	10	4	6	3	0
Prevent III ≥4	Survival (%)	87.5	58.3	58.3	41.7	41.7
	SE (%)	6.8	12.7	12.7	13.5	13.5
	n	18	8	7	5	4
	Events	3	4	0	2	0

(b)



All-cause mortality		30d	12	24	36	48
Prevent III ≤3	Survival (%)	95.3	88.4	87.1	79.8	79.8
	SE (%)	2.1	3.3	3.5	4.5	4.5
	n	96	74	65	52	44
	Events	5	6	1	5	0
Prevent III ≥4	Survival (%)	95.7	79.8	73.7	66.3	58.9
	SE (%)	4.3	9.1	10.3	11.6	12.4
	n	23	13	11	9	8
	Events	1	3	1	1	1

(c)



MACE		30d	12	24	36	48
Prevent III ≤3	Survival (%)	90.6	86.0	83.5	76.3	74.6
	SE (%)	2.8	3.5	3.8	4.7	4.8
	n	91	72	63	51	44
	Events	10	4	2	5	1
Prevent III ≥4	Survival (%)	95.7	79.8	73.3	66.3	58.9
	SE (%)	4.3	9.1	10.3	11.6	12.4
	n	23	13	11	9	8
	Events	1	3	1	1	1

Figure 1. Kaplan-Meyer survival curves and number-at-risk table stratified according to Prevent III (PIII) risk scores (low-risk ≤3 and medium-risk ≥4). **(a)** Major adverse limb events (MALE); **(b)** All-cause mortality; **(c)** Major adverse cardiac events (MACE).

lower preoperative ABI than low-risk counterparts. The observed phenomenon could be attributed to the influence of comorbidities considered in the PIII score, indicative of an elevated severity of peripheral vascular disease, such as tissue loss and chronic kidney disease, which have consistently been identified as high-risk comorbidities in PAD patients.[15,16] Notably, the lower prevalence of smoking in patients with a higher PIII category may be a consequence of other comorbidities having a higher impact on the increased severity of PAD, once again, in particular regard to advanced chronic kidney disease.

Variables in the score, while originally proposed for patients submitted to infrainguinal vein bypass, also have been related to worse outcomes in patients with aortoiliac disease. Tissue loss was associated with increased reintervention in aortoiliac disease.[17] Older age has also been linked with loss of patency in the endovascular reconstruction of the aortic bifurcation.[18] Renal replacement therapy was connected with a higher risk of MALE and death in patients with aortoiliac disease undergoing aortofemoral bypass.[19] A relationship between lower levels of hemoglobin and a higher risk of MALE and death at one year after aortofemoral bypass was also reported,[19,20] while lower hematocrit values were related to higher mortality at 30 days and MALE after bypass surgery for aortoiliac occlusive disease.[21] Coronary artery disease has been described as a predictive factor of postoperative myocardial infarction in patients with aortoiliac occlusive disease undergoing open revascularization.[22]

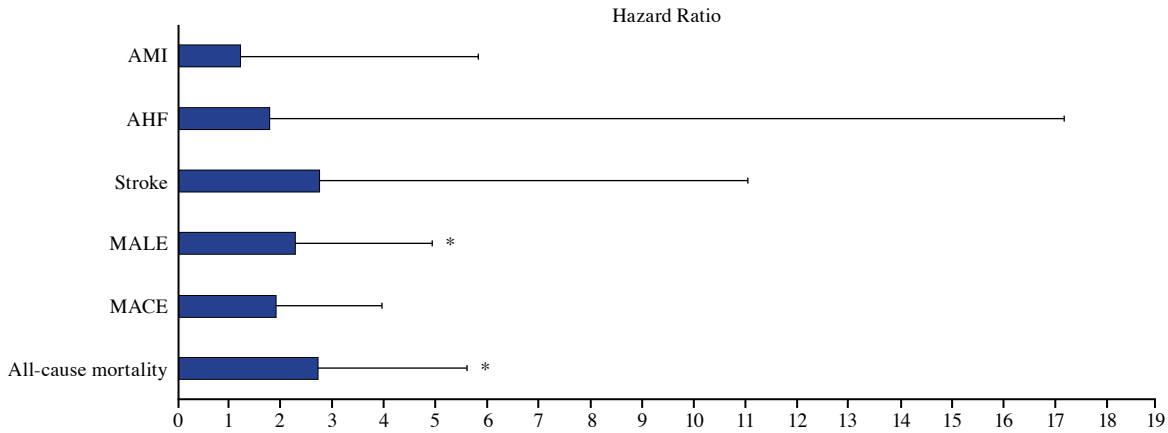


Figure 2. Cox multivariate regression proportional hazard ratio for each outcome.

AMI: Acute myocardial infarction; AHF: Acute heart failure; MALE: Major adverse limb events; MACE: Major adverse cardiac events; * Statistically significant values ($p<0.05$).

No significant associations between the PIII score and short-term outcomes, such as MACE and all-cause mortality, were observed at 30 days, which differs from the original study where PIII predicted perioperative MACE and mortality.[5] This finding may be due to the low number of events registered in these categories in the short term. It can also be related to the fact that the 30-day outcomes may be derived primarily from other factors, such as technical or initial presentation, and not exclusively from patient comorbidities and selection. Another study analyzed 30-day outcomes and found that steroid use and low serum albumin at the time of intervention, which are not included in the PIII score, were associated with 30-day mortality.[23] Patients with scores ≥4 in PIII also exhibited lower ABI changes at 30 days, potentially indicating a polyvascular and multisectorial disease in these patients. Age, renal failure, and a higher Rutherford category have been associated with lower ABI change after revascularization procedures.[11,24] Furthermore, in our study, these higher-risk patients had longer hospital stays, which may be a reflex of increased complexity in these patients, not only concerning comorbidities but also anatomic complexity, as shown by the lower variance of ABI, leading to more complications in this subgroup and the need for secondary procedures. Both dialysis and anemia have been associated with increased length of hospital stay after revascularization,[25,26] which goes in line with the variables in the PIII score.

The PIII score proved to be useful in identifying patients at a heightened risk of MALE and all-cause mortality during the follow-up period, aligning with findings from the original study where PIII predicted one-year amputation-free survival and all-cause mortality.[5] This relationship can be substantiated by considering specific components of the score. Not only are there described associations between the different components of the score and MALE and all-cause mortality, as explained above, but also a relationship between its components and the pathophysiology of PAD.[27,28] Dialysis and advanced age are known risk factors for PAD.[27,28] As mentioned before, CAD shares a common underlying pathophysiology with PAD, and when associated, presents poorer cardiovascular outcomes.[2,29,30]

Despite its marginal nature, this weak association suggests a meaningful link between the PIII score and the occurrence of MACE. This finding highlights the importance of delving deeper into this association through additional studies. Previous research has already established a connection between PIII and an elevated risk of MACE in patients with infrainguinal disease,[6] and thus, this study might have been underpowered to reach statistical significance for MACE.

There are some limitations to this study. Since it included a surgical cohort, there was a possible selection bias since patients with more comorbidities and worse clinical conditions might have been excluded from revascularization. This might explain, at least partially, the low number of patients in the high-risk group with PIII scores ≥8, which led the authors to its exclusion from the analysis as a separate category, limiting the ability to draw

conclusions about this specific group. The small sample size and the inclusion of only TASC II type D lesions, excluding those with aortoiliac aneurysmatic disease, can limit its general applicability as well as the overrepresentation of male sex and low number of perioperative events. It should be noted that while the study utilized established definitions for outcomes such as MACE and MALE, there may be variations in how these events are defined across other studies.[15] To minimize these variations, the Society for Vascular Surgery definition was used,[10] but some differences can potentially impact the comparability of the results with other studies. On the other hand, the prospective design and the extended follow-up are some of the strengths of the current study. Including patients from a large academic institution and a community referral hospital increases the results' external validity and more accurately reflects real-world practice.

In conclusion, the PIII score can be a reliable tool for predicting long-term MALE and mortality after aortoiliac revascularization procedures by analyzing five easy-to-obtain clinical parameters. The multitude of outcomes predicted by this score reveals its clinical utility, although more studies are needed to validate it. Future directions involve validating PIII in larger prospective cohorts with surgical and nonsurgical aortoiliac disease and comparing it with other validated scores.

Ethics Committee Approval: The study protocol was approved by the Centro Hospitalar Universitário de São João / Faculdade de Medicina da Universidade do Porto Ethics Committee (date: 10.10.2018, no: 246-18). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, processing, materials: J.R.N., A.N.; Design: J.R.N., L.R.D., D.A.; Control/supervision: A.N., J.P.A., J.V.; Data collection and/or: A.N., D.A., J.R.N.; Analysis and/or interpretation: L.R.; J.R.N., A.N.; Literature review: L.R.D., A.N., D.A.; Writing the article: J.R.N., A.N., J.V., J.P.A., L.R.D., D.A.; Critical review: J.P.A., J.V., A.N.; References and fundings: J.P.A., J.R.N.

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Supplemental Table 1. Cox multivariate regression proportional HR for each outcome

	Non-adjusted HR	95% CI	*p*
AMI	1.227	0.259-5.821	0.797
AHF	1.785	0.185-17.223	0.617
Stroke	2.750	0.682-11.087	0.155
MALE	2.283	1.057-4.927	**0.036**
MACE	1.915	0.926-3.961	0.080
All-cause mortality	2.717	1.316-5.609	**0.007**

HR: Hazard ratios; CI: Confidence interval; AMI: Acute myocardial infarction; AHF: Acute heart failure; MALE: Major adverse limb events; MACE: Major adverse cardiovascular events. Statistically significant values are highlighted in bold.