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RESEARCH ARTICLE

Predictors of Postoperative Outcome in Patients with Lower Limb Surgical Revascularization

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Objective: In patients with critical limb ischemia who undergone revascularization procedures, the assessment of risk factors that may affect the postoperative outcome is of great importance. The main objective in this study is to assess the utility of two specific risk scores, the Finnvasc score and the modified Prevent III score. **Methods**: We evaluated the applicability of these two risk scores in 150 patients who undergone an unilateral infrainguinal surgical revascularization procedure. The receiver operating characteristic curve analysis was used to estimate the predictive value of the scoring methods. A comparison between the risk scores, determine the areas under the curve. Medium-term prediction ability was analyzed for both scoring methods. **Results**: The area under the curve of Finnvasc score for predicting amputation was 0.739 (95%CI:0.661-0.807) and of the modified PIII score 0.713 (95%CI:0.633-0.784); for restenosis we obtained 0.528 (95%CI:0.444-0.611), respectively 0.529 (95%CI:0.445-0.612) and for thrombosis 0.628 (95%CI:0.544-0.706) and 0.556 (95%CI:0.472-0.638), demonstrating that the Finnvasc score performs better in overall prediction. Heart failure is a strong independent predictor of amputation (p=0.0001, OR=26.90; 95%CI:5.81-124.2), restenosis (p=0.0003, OR=4.80; 95%CI:1.96-11.8) and mortality (p=0.01, OR=7.16; 95%CI:1.33-38.52). **Conclusions**: The accuracy of the two risk scoring methods in predicting the medium-term outcome of patients undergoing surgical infrainguinal revascularization is acceptable. The Finnvasc score is easier to be applied to the characteristics of our patients.

Keywords: limb ischemia, risk scoring methods, postoperative outcome prediction

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Introduction

Peripheral arterial disease (PAD) is a common and major manifestation of atherosclerosis, along with the coronary and cerebrovascular disease, and coexisting in about 50% of cases [1]. PAD affects about 5% of the general population aged between 55 and 74 years old and its common clinical manifestation is the intermittent claudication [2]. Despite the conservative treatment, 5-10% of patients with PAD end up undergoing revascularization interventions (reconstructive surgery, endovascular angioplasty) or amputation within the first 5 years from initial presentation and diagnosis. Estimation of the risk of adverse postoperative outcome is of paramount importance in surgery. Even more, in patients with critical limb ischemia (CLI), in whom revascularization is needed, postoperative prognosis is crucial [3,4]. The prognosis of CLI is even compared to that of some malignant diseases as the mortality reaches 20%. Moreover, studies on patients diagnosed with CLI reveal that after one year, only 50% of the patients will remain amputation-free [5]. In the last 10 years, for determining the postoperative prognosis on short term (30 days) and medium term (1 year), two specific scoring methods are being used: Finnvasc and Prevent III. Diabetes, coronary artery disease (CAD), foot gangrene, and urgent operation are the risk factors included in the Finnvasc score, 1 point being assigned to each of these four factors. For the calculation of the Prevent III score, points were assigned for the presence of dialysis (4 points), tissue loss (3 points), age >75 years (2 points), hematocrit<30% (2 points) and CAD (1 point). For a modified version of the Prevent III score (mPIII), hematocrit was no longer included and dialysis was replaced with a glomerular filtration rate (GFR)<15ml/min [6-8]. In our study, both scores (Finnvasc and mPIII) are used for the medium-term prediction.

The main objective in this study is to assess the utility of these risk scores and to determine if they should be used complementary, or the medium-term prognosis can be estimated by using only one of the two scores. We intend to establish the prediction accuracy of the two scoring methods regarding three complications: thrombosis, restenosis and amputation, leg salvage being our primary aim. Heart failure (HF) as an independent predictor of postoperative outcome is also considered.

Methods

A total number of 150 patients with PAD who underwent infrainguinal limb revascularization in Tirgu Mures Emergency County Hospital – Surgical Clinic I, from January 2012 to December 2013 were included in this study. Patients with other vascular interventions prior to 2012 and whose observation charts were not complete, or those who refused surgical interventions, were not included in this study.

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In our group we did not have patients with a GFR<15ml/min, so for calculating the mPIII score we included patients with a GFR≤30 ml/min, calculated using the MDRD equation: 186 x(Creat/88.4)$^{-1.154}$x(Age)$^{-0.203}$x(0.742 if female)x(1.210 if black), recommended by the UK chronic kidney disease eGuide [9]. Diagnosis of CAD relied on cardiological examination before surgery and prior medical documentation.

We had 27, 65, 30, 23 and 5 patients with a Finnvasc score of 0, 1, 2, 3 and 4 points; 111 patients with a low mPIII risk (0-3 points), 39 patients with a moderate mPIII risk (4-7 points), and no patients with a high mPIII risk (Figure 1 and 2); in 47 patients (31.3%) a Ring Dissector endarterectomy was performed, a bypass using inverted autologous saphenous vein was performed in 29 patients (19.3%), and 87 patients (58%) undergone a prosthetic bypass using Goretex or Dacron grafts. Postoperative outcome was considered regardless of the surgical procedure's type. Thrombosis (in 92 patients), restenosis (in 90 patients) and amputation (in 17 patients) were the main complications followed (Table I). Thrombosis implies a clot obstruction of the vascular segment that was previously involved in a surgical procedure, and usually occurs within a month after surgery, requiring an embolectomy. Restenosis is a process of intimal hyperplasia that usually develops between a month and one year after the procedure [10,11]. To compare the predictive value of the two scores, receiver-operating characteristic (ROC) curves were constructed and the area under the curve (AUC) was determined. The optimal cutoff points were calculated considering the Finnvasc and mPIII values that maximized the weighted combination of sensibility (Se) and specificity (Sp). Based on these cutoff points, the main parameters of diagnostic validity were estimated: Se, Sp, positive predictive value (PV+), negative predictive value (PV-) and likelihood ratios (LR). All calculations were performed by using a 95 % confidence interval (95%CI). The level of statistical significance was set at 0.05 and all tests were two-tailed. A chi-square test was used in order to compare the frequencies of nominal variables (Finvasc score or mPIII

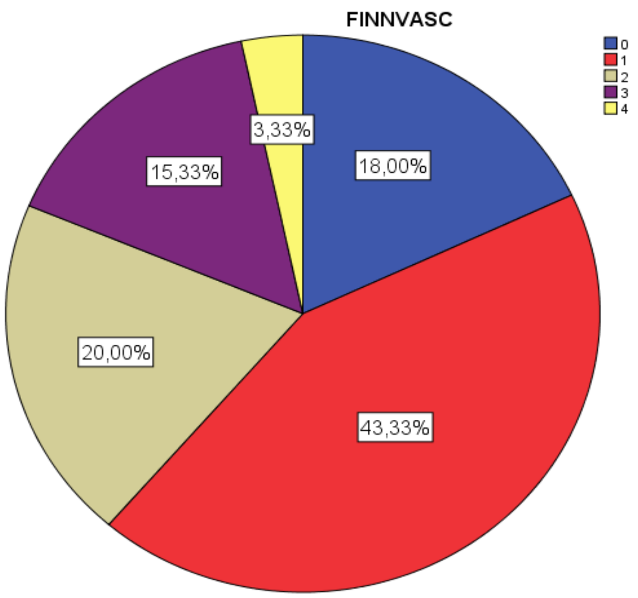


Fig. 1. Finnvasc score distribution

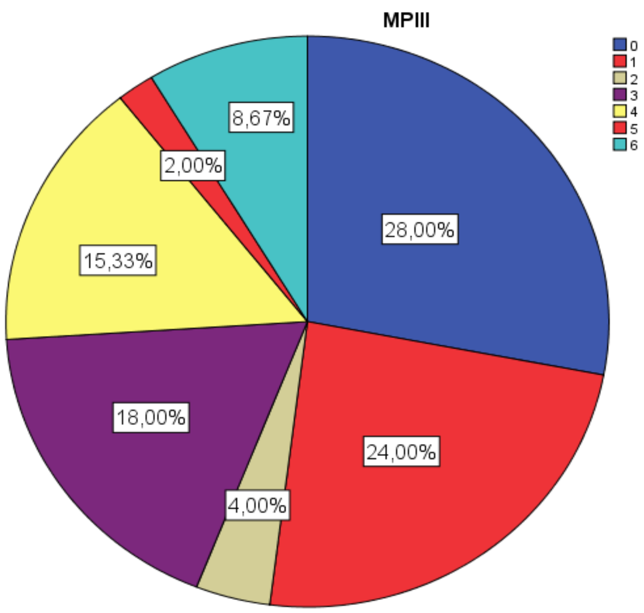


Fig. 2. mPIII score distribution

Table I. Clinical characteristics and operative data

Variabiles	No. %
Total	150(100%)
Age over 75	42(28.0%)
Female	23(15.3%)
Diabetes	52(34.6%)
Coronary artery disease	90(60.0%)
Heart failure	44(29.3%)
GFR S4	7(4.6%)
Indication for revascularization	
-rest pain	48(32.0%)
- gangrene	35(23.3%)
- ulcer	36(24.0%)
-urgent admission	31(20.6%)
Type of revascularization	
-ring dissector	47(31.3%)
-safenous vein bypass	29(19.3%)
-prosthetic bypass	87(58.0%)
Finnvasc score	
-0p	27(18.0%)
-1p	65(43.3%)
-2p	30(20.0%)
-3p	23(15.3%)
-4p	5(3.3%)
mPIII score	
-0	42(28.0%)
-1	36(24.0%)
-2	6(4.0%)
-3	27(18%)
-4	23(15.3%)
-5	3(2.0%)
-6	13(8.7%)
Complications	
-thrombosis	92(61.3%)
-retenosis	90(60.0%)
-amputation	17(11.3%)

score versus mortality, thrombosis, restenosis and amputation). We calculated the OR (odds ratio with their 95%CI) to evaluated the role of heart failure in relation with the postoperative complications. We used the SPSS statistical software package 19.0 (SPSS, Inc., Chicago, IL, USA) for all statistical analyses.

Results

Depending on each point of the risk scores, we have achieved certain values for the performance parameters. Lower values better identify the sick by an increased sensitivity, and higher values better identify the healthy by an increased specificity. By applying statistical tests to evaluate the performance of the prediction scores, cutoff points were obtained, for which we have the best level of sensitivity and specificity. Therefore, for these cutoff points, we obtained the following results for the three complications. For thrombosis: Finnvasc score (cutoff–1pt.)–Se=45.6% (95%CI:35.2-56.4), Sp=74.5% (95%CI: 61.0-85.3); mPIII score (cutoff–2pt.)–Se=47.8% (95%CI: 37.3-58.5), Sp=63.6% (95%CI: 49.6-76.2). For restenosis: Finnvasc score (cutoff–1pt.)–Se=41.1%(95%CI: 30.8-52.0), Sp=68.4% (95%CI: 54.8-80.1); mPIII score (cutoff–2pt.)–Se=46.9% (95%CI: 36.1-57.5), Sp=59.6% (95%CI: 45.8-72.4). For amputation: Finnvasc score (cutoff-1pt.)–Se=70.6% (95%CI:44.0-89.7), Sp=65.4% (95%CI: 56.7-73.4); mPIII score (cutoff –2pt.)–Se=76.4% (95%CI: 50.1-93.2), Sp=60.1% (95%CI: 51.3-68.5). A comparison between the two scores, determine the areas under the curve. The AUC of Finnvasc score for predicting thrombosis was 0.628 (CI 955: 0.544-0.706; p=0.004) and of mPIII score was 0.556 (95%CI: 0.472-0.638; p=0.25), demonstrating that the Finnvasc score performs better in prediction, the difference between the curves being 7.1%, not statistically significant (p=0.06). (Table II, Figure 3). The AUC of Finnvasc score for predicting restenosis was 0.528 (95%CI: 0.444-0.611; p=0.53) and of mPIII score was 0.529 (95%CI: 0.445-0.612; p=0.54), which shows that the scores are similar in prediction, the difference between the curves being negligible. (Table III, Figure 4). The AUC of Finnvasc score for predicting amputation was 0.739 (95%CI: 0.661-0.807; p=0.004) and of mPIII score was 0.713 (95%CI: 0.633-0.784; p=0.002), also showing that the scores are similar in prediction, the difference between the curves being negligible. (Table 4, Figure 5).

We obtained a statistically significant association between a high Finvasc score and mortality (p=0.001), thrombosis (p=0.01), restenosis (p=0.03) and amputation (p=0.0001). The association between a higher mPIII score and restenosis (p=0.02) and amputation (p=0.03) was also statistically significant. Higher mPIII scores were not statistically significant associated with mortality (p=0.1) and thrombosis (p=0.36). In all these combinations we applied the chi square test.

Age≥75 years was not statistically significantly associated with either the three postoperative complications followed in our study.

We also evaluated the role of heart failure in relation with the postoperative complications and have obtained a statistically significant association between HF and restenosis (p=0.0003, OR=4.80; 95%CI: 1.96-11.8), amputation (p=0.0001, OR= 26.90; 95%CI: 5.81-124.2) and mortality (p=0.01, OR=7.16; 95%CI: 1.33-38.52). Association between HF and thrombosis was not statistically signifiant (p=0.40, OR=1.3; 95%CI: 0.65-2.90).

Table II. The comparison between the AUC values obtained for both scores in predicting thrombosis

	AUC	SE	95%CI
FINNVASC	0.628	0.0463	0.544-0.706
MPIII	0.556	0.0485	0.472-0.638

Table III. The comparison between the AUC values obtained for both scores in predicting restenosis

	AUC	SE	95%CI
FINNVASC	0.528	0.0487	0.444-0.611
MPIII	0.529	0.0487	0.445-0.612

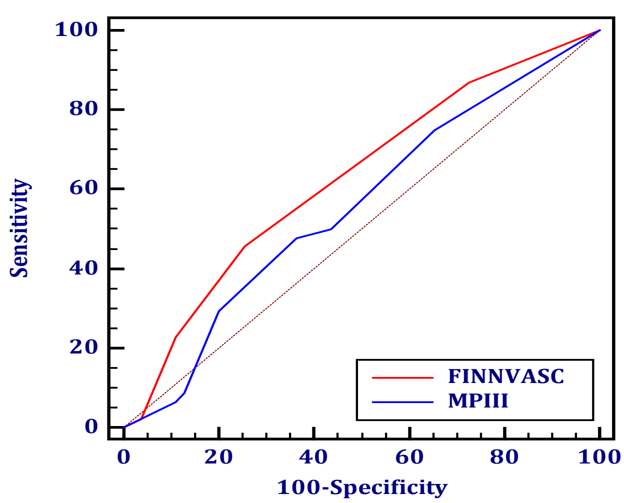


Fig. 3. AUC obtained for both scores in thrombosis prediction

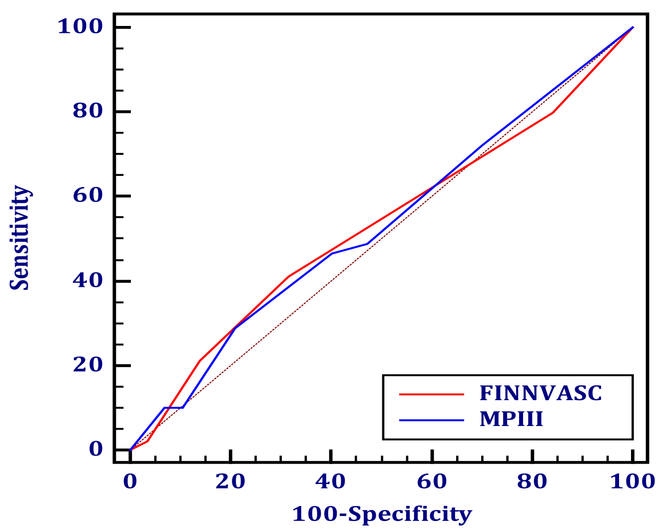
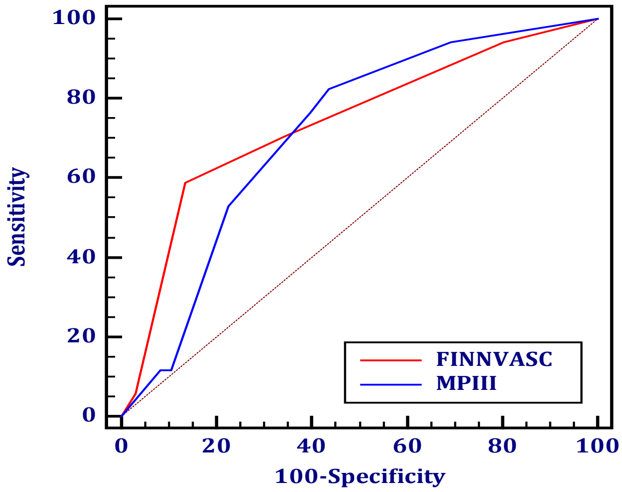


Fig. 4. AUC obtained for both scores in restenosis prediction

Table IV. The comparison between the AUC values obtained for both scores in predicting amputation

	AUC	SE	95%CI
FINNVASC	0.739	0.0718	0.661-0.807
MPIII	0.713	0.0734	0.633-0.784



Fig, 5. AUC obtained for both scores in amputation prediction

Discussion

Chronic critical limb ischemia, defined as more than 2 weeks of rest pain, ulcers, or tissue loss attributed to arterial occlusive disease, is associated with high rates of amputation and mortality. Therapeutic goals in treating patients with CLI include reducing cardiovascular risk factors, relieving ischemic pain, healing ulcers, preventing major amputation, improving quality of life and increasing survival. These aims may be achieved through medical therapy, revascularization, or amputation [3,12]. Revascularization offers the best option for limb salvage. In recent years, many studies were carried out to identify conditions that influence the unfavorable evolution of patients with lower limb revascularization, knowing that failure is multi-factorial. Some factors are patient-releted (e.g. multiple or severe comorbidites, noncompliance) and other are technical (e.g. suboptimal graft material and poor run-off status) [13,14]. The extent and severity of ischemia, associated with gangrene, ulcer and infection are major determinants of prognosis [15]. In our study, age over 75 years (28% of cases) was not an independent predictor for mortality and amputation, not being a ground for refusal of surgical revascularization; results are consistent with data from literature [15]. Predictive scores were conceived due to the many individual risk factors which condition the postoperative outcome. Of these, Finnvasc and Prevent III are the most frequently used [6,7,16], closely followed by the modified PIII [8]. In our study data needed to asses Finnvasc score was easier to obtain from the medical charts, and risk stratification was more balanced, as we had patients of all risk categories. By applying statistical analysis we obtained a highly significant association between high scores and amputation, respectively mortality, but also for thrombosis and restenosis. According to the mPIII score, most of our patients had a low risk score (74%) and the rest of them a moderate one (26%); we did not have patients with a high mPIII risk score. This may explain why the association between higher mPIII scores and restenosis and amputation is less significant than in Finnvasc score, and the the fact that mPIII scores were not statistically significant associated with mortality and thrombosis. The area under the ROC curve suggests a good amputation prediction capability for both scores, which is very important, and a satisfactory ability to predict the risk of thrombosis for the Finnvasc score. Both scores poorly predicted restenosis. These results show that postoperative prediction is difficult, as it is conditioned by many factors. Including other risk factors in the predictive scores, could hinder the evaluation process. There are most certainly also, some other factors that influence the postoperative success: patient related, drug therapy related and surgical procedure related factors. It is certain that one of the undeniable risk factors is severe renal function impairment which is not present in our group and which increases the risk of amputation [17,18]. On the other hand, Finnvasc score separates foot gangrene as one risk factor, but in the modified P III score, gangrene and ulcer are considered as one equivalent factor. Yet, there are data suggesting that gangrene is a stronger independent risk factor for a poor outcome than stable ulcer [19]. These two considerations may explain, at least in part, why Finnvasc score had in our study a better predictive ability for one year than the mPIII score which is considered an indicator for the medium/long term evaluation. Coronary artery disease is a risk factor included in both scores, but heart failure is not. In our study, CAD occurred in 60% of the patients and 50% of them had HF. Statistical analysis shows that HF acts as a strong independent risk factor that increases the risk of amputation 25 times, the risk of mortality 7 times, and the risk of restenosis almost 5 times. There are other studies suggesting that a low left ventricular ejection fraction should be considered an independent risk factor and included in the Prevent III score, along with the cerebrovascular disease [19]. Although the number of patients with high Finnvasc risk score is small (3.3%), this category shows a high rate of complications after revascularization and suggests that conservative therapy may be more appropriate. Furthermore, as noticed in previous studies, when trying to predict postoperative outcome from preoperative data, it is easier to predict the patients with good outcome [8,20].

Limitations: the number of enrolled patients was relatively small and postoperative follow-up was made during just one year. Our group did not include patients with high mPIII score (≥8points) and for assigning 4 points we replaced GFR<15ml/min with GFR<30ml/min. Information related to mortality was partially collected by phone.

Conclusions

Finnvasc and mPIII risk scoring methods predict the medium-term outcome of patients undergoing surgical infrainguinal revascularization for critical limb ischemia, and the accuracy of these risk scores is acceptable. The Finnvasc score was easier to apply to the characteristics of our patients and we believe it can stand alone in assessing prognosis after surgery. Conservative therapy should be considered in patients with high Finnvasc scores**.** Heart failure acts like an important independent predictor of negative outcome.

Conflicts of interest

The authors report no conflicts of interest.

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