Accuracy of SVS-WIfI Classification in Predicting Major Amputation in Critical Limb Ischemic Patients

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Abstract

In 2014, The Society for Vascular Surgery revealed a new classification system for Critical Limb Ischemia (CLI) referred as the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System based on Wound, Ischemia, and foot Infection (SVS WIfI). This scoring system was created to stratify major amputations risk within 1 year and benefit of revascularization for the patient. This study aimed to assess the accuracy of SVS WIFi in predicting major amputations in patients with lower limb ischemia underwent revascularization at Department of Surgery, Faculty of Medicine, Universitas Padjadjaran-Dr. Hasan Sadikin General Hospital in 2016–2019. This was a retrospective observational analytic study with cohort design. Patients who fulfilled the inclusion criteria were assessed with SVS WIfI and results after 1 year of revascularization were identified. Data were analyzed statistically using the Chi-square test. 0f 56 subjects, 39 had limb salvage and 17 underwent major amputations within 1 year. In high revascularization benefit group, 31 had limb salvage and 7 underwent amputation. Meanwhile, in moderate-low revascularization benefits group, 8 had limb salvage and 10 underwent amputation. The accuracy of the SVS WIfI recommendation was 73.2%. Therefore, WIfI SVS classification accurately predicts the incidence of major amputations in patients with lower limb ischemia who underwent revascularization.

Keywords: Amputation, revascularization, SVS WIFi

Akurasi Klasifikasi SVS-WIfI dalam Memprediksi Amputasi Mayor pada Pasien Iskemik Tungkai Bawah

Abstrak

Pada tahun 2014, *The Society for Vascular Surgery* mengemukakan sistem klasifikasi baru untuk Critical Limb Ischemia (CLI), yaitu SVS-WIfI. Sistem penilaian ini dibuat untuk mengelompokkan risiko amputasi mayor dalam waktu 1 tahun dan manfaat revaskularisasi bagi pasien. Penelitian ini bertujuan untuk menilai akurasi SVS WIFi dalam memprediksi amputasi mayor pada pasien iskemia ekstremitas bawah yang menjalani revaskularisasi di Departemen Ilmu Bedah Fakultas Kedokteran Universitas Padjadjaran/Dr. Rumah Sakit Umum Hasan Sadikin tahun 2016–2019. Penelitian ini merupakan penelitian observasional analitik dengan rancangan *retrospective cohort study*. Pasien yang memenuhi kriteria inklusi dinilai dengan SVS WIfI dan hasil setelah 1 tahun revaskularisasi diidentifikasi. Data dianalisis secara statistik menggunakan uji Chi-square. Berdasar atas penelitian yang dilakukan terhadap 56 pasien yang menjalani revaskularisasi, didapatkan sebanyak 39 pasien yang tidak mengalami amputasi mayor dan 17 pasien yang mengalami amputasi mayor dalam 1 tahun. Dari penelitian ini kelompok pasien dengan manfaat revaskularisasi yang tinggi didapatkan 31 pasien tidak mengalami amputasi, sedangkan 7 pasien mengalami amputasi, pada kelompok pasien dengan manfaat revaskularisasi sedang-rendah, 8 pasien tidak mengalami amputasi, sedangkan 10 pasien mengalami amputasi. Akurasi dari rekomendasi SVS WIfI adalah 73,2%. Oleh karena itu, klasifikasi WIfI SVS secara akurat memprediksi kejadian amputasi mayor pada pasien dengan iskemia ekstremitas bawah yang menjalani revaskularisasi.

Kata kunci: Amputasi, revaskularisasi, SVS WIFi

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Introduction

Peripheral arterial disease (PAD) is the third cause of morbidity caused by atherosclerosis after coronary heart disease and stroke.[1,2] The number of people with PAD arises because of the increase in life expectancy. The number of PAD cases has increased by 25% globally from 2000 to 2010, and the mortality rate also increased by 2 to 3 times. People with PAD are widely distributed, mostly in South East Asia, with Indonesia having a PAD prevalence of 9.7%. [3,4]

Peripheral arterial disease is stenosis, occlusion, and aneurysm of the aorta and its branches, other than the coronary arteries. The most common PAD at lower extremities takes the form of stenosis and occlusion.[5] Peripheral arterial disease causes decreasing blood flow to the distal of the limb, which will lead to symptoms of ischemia such as intermittent claudication. Furthermore, if the arteries are blocked, it will cause Critical Limb Ischemia (CLI). The term CLI was first published in 1982 and, as science developed, it is subsequently defined as a clinical condition that describes limb pain when resting and injury or gangrene in the extremity caused by a prolonged arterial insufficiency process. Critical limb ischemia itself is a terminal condition of PAD.[6]

Patients with CLI have a higher amputation rate, approximately 25% in one year. Patients diagnosed with CLI are often associated with loss of limbs and revascularization.[6] Several studies show that 50% of wounds on CLI can heal without revascularization. The challenge for these cases rests in making decisions to determine whether a patient can heal with normal wound treatment or should undergo revascularization. Revascularization itself must be decided carefully based on clinical conditions and the benefits after revascularization.[6,7]

In 2014, The Society for Vascular Surgery revealed a new classification system for CLI, the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System based on Wound, Ischemia, and foot Infection (SVS WIfI).[6] The SVS WIfI scoring system was created to stratify the risk of major amputations within a year and benefit from patients' revascularization. This classification assessment is based on the injury to the extremities, the presence of arterial insufficiency, and the presence of leg infection.

The challenges to determine proper management for CLI and the issuance of the new classification, which is still not widely used, have encouraged the authors to conduct this study.

Methods

This study was conducted at the Department of Surgery, Dr. Hasan Sadikin General Hospital, Universitas Padjadjaran, in 2016–2019. The subjects were patients with CLI who underwent revascularization at Dr. Hasan Sadikin General Hospital and data on these subjects were retrieved from their medical records. The inclusion criteria for the subject were CLI patients underwent revascularization with complete medical records. Patients whose data were incomplete or those who died less than one year after revascularization were excluded. Data were then grouped according to the SVS WIfI classification and revascularization results were assessed to see whether the patient had an amputation within one year after the procedur. Statistical analysis was then conducted.

The sample size calculation was carried out using a formula to determine the categorical analysis sample size. A sample size 2.0 program from Holmer and Lemeshow was used. A sample of 26 subjects per group was required and written consent was obtained from these subjects before the study. Data were collected electronically, stored in Microsoft Excel, and analyzed with SPSS version 24.0 for windows. The analysis was planned by the intent-to-treat principle using the parametric and nonparametric tests. Continuous variables were analyzed with the Shapiro-Wilk test to test data normality. The P-value for categorical data was calculated based on the Chi-Square test with Kolmogorov Smirnov test and Exact Fisher as the alternatives when the requirements of Chi-Square were not met. Statistical significance was defined as a p-value of 0.05 and 95% CI and 90% power test were applied. This research received ethical approval from the Medical Ethics Committee of Dr. Hasan Sadikin General Hospital (LB.02.01/X.6.5/301/2019).

Results

There were 87 CLI patients who underwent revascularization during the study period. Of these, only 56 cases met the inclusion criteria. Sixteen cases had incomplete data, 8 cases died less than one year after revascularization, and 7 subjects could not be contacted after the revascularization treatment.

The mean age of subjects was 52.60±14.033 years old. There were 39 male patients (69.6%) and 17 female patients (30.4%) and

Table 1 Subject Characteristics

Variable	(n=56)
Age	
Mean±Std	52.60±14.033
Median	56.00
Range (min-max)	25.00–83.00
Sex	
Male	39 (69.6%)
Female	17 (30.4%)
Diabetes mellitus	
No	36 (64.3%)
Yes	20 (35.7%)
Heart disease	
No	40 (71.4%)
Yes	16 (28.6%)
Hypertension	
No	30 (53.6%)
Yes	26 (46.4%)
Hypercholesterolemia	
No	46 (82.1%)
Yes	10 (17.9%)
Smoking	
No	15 (26.8%)
Yes	41 (73.2%)
Type of Revascularization	
Angioplasty Ballooning	2 (3.6%)
Aortofemoral Bypass	8 (14.3%)
Femorofemoral Bypass	7 (12.5%)
Femoroperoneus Bypass	1 (1.8%)
Femoropopliteal Bypass	6 (10.7%)
Femorotibial Bypass	30 (53.6%)
Ileofemoral Bypass	1 (1.8%)
Ileopolitea Bypass	1 (1.8%)
Major Amputation	
No	39 (69.6%)
Yes	17 (30.4%)

20 (35.7%) patients suffered from diabetes mellitus. Sixteen patients suffered from heart disease (28.6%), while 26 (46.4%) patients and 10 (17.9%) suffered from hypertension and hypercholesterolemia, respectively. Of all patients, 41 patients (73.2%) were smokers. The most frequent revascularization was the femorotibial open bypass (n-30, 53.6%).

Patients who had major amputations after revascularization were 17 people (30.4%). Information on the characteristics of the subjects is listed in Table 1.

Study subjects were further classified into groups based on the WIfI classification as presented in Table 2. For the wound category, most patients who underwent revascularization most were in grade 3 (n=21, 37.5%). When observed from the ischemic status, most subjects were grade 2 (n=29, 51.8%) and 21 patietns (37.5%) experienced grade 1 foot infection. Subsequently, each sample was grouped based on the risk of amputation and the benefits of revascularization as described in the SVS WIfI. The majority of subjects were in the high-risk category for amputation (n=44, 78.6%) while the remaining 12 subjects (21/4$) were in the moderate-low risk.

In terms of revascularization benefits, the category of high benefits was seen in 38 patients (67.9%), and moderate-low benefits were seen in 18 patients (32.1%).

Table 3 explains the results of the statistical calculations between the wound, ischemic, foot infection, and major amputations. Statistical test results demonstrated that the P-value for the wound, ischemic, and foot infection was less than 0.05 (P-value <0.05), thus statistically significant. Therefore, it can be explained that statistically, the wound, ischemic, and foot infection variables have significant relationships major amputations.

Table 4 explains the comparison between the benefits of revascularization and the major amputation group. In the group without major amputations, 31 patients (79.5%) were in the high category for the revascularization benefits while the remaining eight (20.5%) were in the moderate-low category. In the group with major amputations, the high category of revascularization benefits was seen in seven patients (41.2%), and the moderate-low was observed in ten patients (58.8%). Statistical test results from the Chi-Square gave a p-value of less than 0.05 (P-value <0.05), which means significant or statistically significant. Therefore, there was a statistically significant relationship between the benefits of vascularity variables in the group without major amputations and with major amputations.

From the results of Table 4, the accuracy value of the WIfI SVS recommendation was 73.2%, meaning that it has a moderate accuracy value statistically.

Table 2 Subject Characteristics by SVS WIFi Classification

Variable	(n=56)
Wound	
(No ulcer, ischemic rest pain)	8 (14.3%)
(Small, shallow ulcer on distal leg or foot without gangrene)	8 (14.3%)
(Deeper ulcer with exposed bone, joint or tendon, gangrene on toes)	19 (33.9%)
(Extensive deeper ulcer, full thickness heel ulcer, extensive gangren)	21 (37.5%)
Ischemic	
(ABI ≥ 0.80)	0 (0%)
(ABI 0.60–0.79)	11 (19.6%)
(ABI 0.40–0.59)	29 (51.8%)
(ABI < 40)	16 (28.6%)
Foot infection	
(No symptoms/signs of infection)	11 (19.6%)
(Local infection involving only skin and subcutaneous tissue)	21 (37.5%)
(Local infection involving deeper than skin and subcutaneous tissue)	14 (25.0%)
(Systemic inflamatory response syndrome)	10 (17.9%)
Amputation risk	
High	44 (78.6%)
Moderate-low	12 (21.4%)
Revascularization benefit	
High	38 (67.9%)
Moderat-low	18 (32.1%)

Discussion

Patients with CLI will have to undergo limb amputation if not treated properly. This study shows the results of revascularization as an intervention to prevent major amputations in one year according to the recommendation of SVS WIfI. [11]

Findings in this study demonstrated that 56 CLI patients who have undergone revascularization at Dr. Hasan Sadikin General Hospital Bandung are 52.6 years old on average with most of them are men. This finding is consistent with the literature stating that PAD rarely occurs in patients under the age of 40 and that the risk of PAD occurrence will increase depending on age. Previous studies also declare that the PAD presents more signs and symptoms in men.[4,12] This study also discovered that most patients with CLI were smokers and smoking has been mentioned as one of the risk factors that can cause atherosclerosis in peripheral arteries,

which is the cause of PAD.

The most frequent revascularization procedure experienced by the subjects in this study isthe Femorotibial bypass. This statement is in line with the literature, stating that PADs occur at the femoral artery and popliteal.[4,13]

As depicted in this study, the higher the wound and foot infection levels are, the higher the amputation rate. Revascularization can only be performed when the foot infection is already under control.[6] If the infection cannot be controlled, we should perform amputation for saving the life of the patient.

In this study, the variables used in the WIFi classification (Wound, Ischemic, and Foot Infection) have statistically significant relationships with major amputation, which is in line with the findings of Joseph et al. from the Society for Vascular Surgery.[6,14]

This study also discovered a statistically significant relationship between the benefits of revascularization and major amputations (Table

Table 3 Comparison between WIfI SVS Classification Variables and Major Amputation

Variable	Mayor Amputation		P-Value
	No	Yes	
	n=39	n=17	
Wound			0,047*
(No ulcer, ischemic rest pain)	5 (12.8%)	3 (17.6%)	
(Small, shallow ulcer on distal leg or foot without gangrene)	6 (15.4%)	2 (11.8%)	
(Deeper ulcer with exposed bone, oint or tendon, gangrene on toes)	19 (48.7%)	0 (0.0%)	
(Extensive deeper ulcer, full thickness heel ulcer, extensive gangren)	9 (23.1%)	12 (70.6%)	
Ischemic			0,025*
(ABI ≥ 0.80)	0 (0%)	0 (0%)	
(ABI 0.60 – 0.79)	4 (10.3%)	7 (41.2%)	
(ABI 0.40 – 0. 59)	22 (56.4%)	7 (41.2%)	
(ABI < 40)	13 (33.3%)	3 (17.6%)	
Foot Infection			0,000*
(No symptoms/signs of infection)	10 (25.6%)	1 (5.9%)	
(Local infection involving only skin and subcutaneous tissue)	19 (48.7%)	2 (11.8%)	
(Local infection involving deeper than skin and subcutaneous tissue)	7 (17.9%)	7 (41.2%)	
(Systemic inflamatory response syndrome)	3 (7.7%)	7 (41.2%)	

Note: P-value is calculated based on the Chi-Square test with alternative Kolmogorov Smirnov test and Exact Fisher if the requirements of Chi-Square are not met. The significance value is based on a p-value of <0.05. The sign * indicates a p-value of <0.05, meaning that it is significant or statistically significant.

Table 4 Comparison between Revascularization Benefit and Major Amputation

Variable	No	Yes	P-Value
	n=39	n=17	
Revascularization Benefit			0.005*
High	31 (79.5%)	7 (41.2%)	
Moderate-low	8 (20.5%)	10 (58.8%)	

Note: P-value is calculated based on the Chi-Square. The significance value is based on a p-value of <0.05. The sign * indicates a p-value of <0.05, meaning that it is significant or statistically significant.

4) with a P-value of 0.005, and this complies with the WIfI classification.[6,8,15]

From this study, it is observed that the vascular status is not the only consideration in the CLI treatment. There are also wound and foot infection that affect the result of revascularization. The SVS WIfI recommendation can be used as a guide for deciding whether a patient should undergo revascularisation or amputation. If the revascularization benefits are low, it will be better to perform the amputation to lower mortality and morbidity.

This study has a limitation in that the classification into groups based on WifI was only done by a researcher, which may lead to bias. This study can be further developed with a better research design, such as the prospective cohort design, and by involving more experts to assess the initial wound condition to reduce bias. Thus, WIfI SVS classification accurately predicts the incidence of major amputations in critical limb ischemic patients that have undergone revascularization, making it suitable to be used as a guideline to treat these patients.

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