

# 2015 JAPAN Critical Limb Ischemia Database (JCLIMB) Annual Report

The Japanese Society for Vascular Surgery JCLIMB Committee, NCD JCLIMB Analytical Team

Since 2013, the Japanese Society for Vascular Surgery has started the project of nationwide registration and tracking database for patients with critical limb ischemia (CLI) who are treated by vascular surgeons. The purpose of this project is to clarify the current status of the medical practice for the patients with CLI to contribute to the improvement of the quality of medical care. This database, called JAPAN Critical Limb Ischemia Database (JCLIMB), was created on the National Clinical Database and collects data of patients' background, therapeutic measures, early results, and long term prognosis as long as five years after the initial treatment. The limbs managed conservatively are also registered in JCLIMB, together with those treated by surgery and/or endovascular treatment. In 2015, 1138 CLI limbs (male, 796 limbs [70%]) were registered by 92 facilities. Arteriosclerosis obliterans has accounted for 98% of the pathogenesis of these limbs. In this manuscript, the background data and the early prognosis of the registered limbs are reported. (This is a translation of *Jpn J Vasc Surg* 2018; 27: 155–185.)

**Keywords:** critical limb ischemia, CLI, ASO, JCLIMB, NCD

## 1. Introduction

Recently, the number of patients with critical limb ischemia (CLI) who undergo medical care at clinical practice sites has been increasing. Approaches to improve the outcome of treatment for these patients are important and urgent issues. The Japanese Society for Vascular Surgery (JSVS) has initiated a nationwide CLI registration and tracking database project since 2013 to obtain epidemio-

logical data on CLI that can be shared among the medical staff. The background of CLI limbs, contents of treatment, early outcome, and long term outcome until 5 years after surgery, including non-surgical limbs, are registered in this database. The database was named JAPAN Critical Limb Ischemia Database (JCLIMB) and established on the National Clinical Database (NCD). The primary objective of the JCLIMB project is to clarify the current status of CLI treatment performed by vascular surgeons in Japan, and feed it back to physicians at practice sites to improve the quality of medical care. The initial registration data and their tracking data one month after registration in 2013 and in 2014 has already been published.<sup>1,2)</sup> This article reports the basic data registered in 2015.

## 2. JCLIMB

Details of the registration, including the definition of CLI, have already been described in the 2013 annual report.<sup>1)</sup> The followings are re-descriptions for confirmation.

CLI to be registered was defined according to TASC II<sup>3)</sup>: chronic ischemic rest pain, ulcers or gangrene attributable to objectively proven arterial occlusive disease. The diagnosis of CLI should be confirmed by ankle pressure (AP) below 50 mmHg or by toe pressure (TP) below 30 mmHg in limbs with rest pain, and by AP below 70 mmHg or by TP below 50 mmHg in limbs with ulcer or gangrene.

The same limb can be registered in JCLIMB only once within a 5-year tracking period. When the registered limb is treated in different periods or at different institutions, such data should be added only to the tracking items of each limb in JCLIMB, avoiding overlapping registration as a new limb with CLI. However, details of the procedure are registered each time in NCD apart from the registration in JCLIMB. On the other hand, the patient with bilateral CLI can be registered twice for each limb. Fixing JCLIMB data is done as follows, based on NCD regulations:


Initial registration data: Early April in the following year  
Tracking data early after treatment (1 month)/6 months after treatment: End of December in the following year  
Tracking data 1 year after treatment: End of December after 2 years

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Tracking data 2 years after treatment: End of December after 3 years

Tracking data 3 years after treatment: End of December after 4 years

Tracking data 4 years after treatment: End of December after 5 years

Tracking data 5 years after treatment: End of December after 6 years

As a general rule, the timing of tracking data registration is accepted within a  $\pm 2$ -month range until 12 months after treatment, and within a  $\pm 3$ -month range thereafter. Although the day for tracking data fixing is specified, it is made flexible because, in some limbs, follow-up data might be revealed later.

It was considered very difficult to make it obligatory for all the facilities participating in NCD to register CLI data since a great number of registration items in JCLIMB would put too much burden on them. Thus, facilities wishing to participate were recruited. In total, 92 facilities which registered CLI limbs in 2015 at the time of compiling in December 2016 are listed in the appendix.

Since JCLIMB is positioned as a registry study on NCD, the consent of patients for participation in the study and the ethical review of the study at the time of participation in NCD were adopted.

### 3. Comments on the Aggregated Data in 2015

The initial registration data in 2015 were fixed early April 2016, and the tracking data early after treatment (one month) were fixed on December 31, 2016. At the time of December 2016, 1138 limbs, those of 796 males (70%) and 342 females (30%), were registered by 92 facilities. All data and extracted data on arteriosclerosis obliterans (ASO) were collected according to the registered items. Since ASO accounted for 98% of all limbs, the overall and ASO data showed a similar tendency. In the comments, ASO data were presented in parentheses only when its figure was different from that of the overall data. In addition, because the Wifi classification of the Society for Vascular Surgery (SVS) was reported in 2014 (Tables 1-1-1 to 1-1-3),<sup>4)</sup> JCLIMB has made several changes and additions to the registered items to make Wifi classification possible since 2015 (Tables 1-2-1 to 1-2-3). The total figure was not always consistent mostly due to missing values, and an explanation for each inconsistency was added.

#### (1) Pretreatment patients' backgrounds

Pretreatment patients' backgrounds are shown in Tables 2-1 to 2-6. Control of blood pressure was judged as good when it was below 140/90 mmHg in the absence of diabetes and renal failure and below 130/80 mmHg in the

presence of these diseases. Control of diabetes was judged as good when hemoglobin A1c (HbA1c) was below 7.0% (national glycohemoglobin standardization program [NGSP] value). Control of dyslipidemia was judged as good when low-density lipoprotein (LDL) was below 100 and 80 mg/dL in the absence and presence of other arteriosclerotic diseases, respectively. The presence of heart failure was judged clinically. The patient was regarded as having or having had heart failure when a past history of admission due to heart failure was present, clinical symptoms of heart failure were observed and confirmed on echocardiography, or cardiac function was clearly reduced on echocardiography although no clinical symptom was present. Renal dysfunction was graded following the new chronic kidney disease severity classification of the "Clinical Practice Guidebook for Diagnosis and Treatment of Chronic Kidney Disease 2012"<sup>5)</sup>: Renal dysfunction was absent when the estimated glomerular filtration rate (eGFR) (mL/min/1.73 m<sup>2</sup>) was 60 or higher, and it was graded as G3a, G3b, G4, and G5 when eGFR was 45–59, 30–44, 15–29, and below 15, respectively. eGFR below 15 in hemodialysis patients was graded as G5D.

The causes of the arterial occlusion of the limb were ASO in 1114 (98%) limbs, thromboangiitis obliterans (TAO) in 10, vasculitis (Takayasu's arteritis, collagen disease, Behçet's disease, and fibromuscular dysplasia excluding TAO) in eight, and others in six. Comorbidities of the patients consisted of diabetes in 67% (68%) of the limbs, hypertension in 73% (74%), dyslipidemia in 38% (39%), ischemic heart disease in 43% (44%), cerebrovascular disease in 22%, dialysis for renal failure in 43% (44%), past medical history of malignant neoplasm or that being treated in 8% (9%), and arterial occlusive lesions in the opposite limb in 75% (76%).

The problems and considerations on these spreadsheets are described below. In Table 2-4, describing the medical history of malignant neoplasm, the sum of the numbers in the column with the history of malignant neoplasm ("history of cancer", "under treatment", and "unknown") is larger than that of the numbers in the column with the sites of malignant neoplasm, in the row of limbs of Rutherford 5. As there might be duplicated cancers, the total number of sites of malignant neoplasm should be the same or more than that in the column with the history of malignant neoplasm. This is due to the following reasons. When "unknown" is selected about the information of malignancy, the input screen for the part of the malignancy is not displayed. As a result, the information on the site of malignancy was not input in five "unknown" limbs. In addition, because there were four limbs with duplicated cancer, the total number of sites of malignant neoplasm decreased by one as a whole.

## (2) Conditions of limb ischemia

The pretreatment conditions of limb ischemia are shown in Tables 3-1 to 3-6. Regarding the walking function (Taylor classification),<sup>6</sup> patients with the ability to walk outdoors or indoors independently, including with a cane, were regarded as “ambulatory”, and those unable to walk but able to stand on their own legs during transfer from the bed to a wheel chair were designated as “ambulatory/homebound.”

Regarding the state of local tissue defect (Texas University Classification),<sup>7</sup> the most severe lesion being the main target of treatment was evaluated. Skin perfusion pressure (SPP) was measured on the foot (base of the toe, dorsum of the foot, or sole) and a lower value was adopted. In addition, in order to perform Wifi classification, the sites of ulcer and gangrene were registered separately. Although SPP is widely used as an objective index to evaluate ischemia in Japan, ischemic grading criteria using SPP is not shown in Wifi classification, in which TP is given top priority. Therefore, in JCLIMB, the SPP value was converted to TP using the conversion equation  $TP = 0.6853 \text{ SPP} + 14.48$  from the correlation data of SPP and TP reported in Japan,<sup>8</sup> and applied for Wifi ischemic grading (Table 1-2-2).

The lesion was regarded as infected when it showed two or more of the following findings: local swelling or induration, erythema  $>0.5$  cm around the ulcer, local tenderness or pain, local warmth, purulent discharge (thick, opaque to white, or sanguineous secretion). In addition, local infections involving only the skin and the subcutaneous tissue and those involving structures deeper than the skin and subcutaneous tissues were registered separately. Local infections involving only the skin and the subcutaneous tissue were differentiated according to the size of the erythema around the ulcer,  $\leq 2$  or  $>2$  cm.

Systemic inflammatory response syndrome (SIRS), indicating systemic infection, was manifested by two or more of the following signs: temperature  $>38^{\circ}\text{C}$  or  $<36^{\circ}\text{C}$ , heart rate  $>90$  beats/min, respiratory rate  $>20$  breaths/min or  $\text{PaCO}_2 < 32$  mmHg, white blood cell count  $>12,000$  or  $<4000$  cu/mm or 10% immature (band) forms. The arteries in the ankle joint region were classified as foot arteries.

Pretreatment ambulatory function was ambulatory in 55% of the limbs, ambulatory/homebound in 24%, and non-ambulatory in 21%. On Rutherford classification (R),<sup>9</sup> limbs with categories R4, R5, and R6 accounted for 21%, 64%, and 15% of the limbs, respectively. The median ankle brachial index (ABI), the toe brachial index (TBI), and the SPP of the measured limbs was 0.61 (0.60), 0.27 (0.26), and 22 mmHg, respectively. The occlusive lesion was located in the aortoiliac artery in 16% of the limbs, in the femoropopliteal artery in 41% (42%), and in

the crural or foot artery in 43%.

We were able to apply the Wifi classification with sufficient data to 859 limbs (841 limbs). On the Wifi classification, limbs with the stages 1, 2, 3, and 4 accounted for 10%, 23%, 26% (27%), and 40% (41%) of the limbs, respectively.

The problems and considerations on these spreadsheets are described below. In Table 3-3, the total number of limbs in TASCII classification differed compared to the number in each column of the site of occlusion. In “aortoiliac” lesion, decreased number of that in TASCII classification may have been due to input omission. In “femoropopliteal” lesion, increased number of that in TASCII may have been due to inclusion of crural lesions.

In Table 3-6, there were 113 limbs (110 limbs) which classified to Wound grade 3 (W3; extensive ulcer/gangrene) in Wifi classification in the row of limbs of R5 (small-range tissue defect). Such results might have been obtained when there was a deep ulcer or gangrene in the heel, even if the wound was not extensive. In addition, any size of gangrene in parts other than toes, even if it was small, could be classified to W3.

In Table 3-6, 81 limbs (77 limbs) were registered as Ischemic grade 0 in Wifi classification. By definition, a limb with Ischemic grade 0 has a TP of 60 mmHg or more (SPP 66 mmHg or more in JCLIMB) or AP higher than 100 mmHg, or if arterial calcification precludes reliable AP or TP measurements,  $\text{TcPO}_2$  60 mmHg, or more (Table 1-1-2). There should be no limb with Ischemic grade 0 since CLI to be registered in JCLIMB is defined according to TASC II. There is a possibility that the limbs clinically judged to be CLI were registered irrespective of the objective ischemic index, although details are unknown.

In Table 3-6, there were 24 limbs (23 limbs) in which infection was confirmed in R4 limbs, despite the absence of a local wound by definition of R4. The details are unclear whether the limb showed the symptoms of cellulitis without any wound or there was a small wound somewhere (in this situation it might be better to classify the limbs in R5).

In Table 3-6, because the data on ischemic grade were registered in only 859 limbs (841 limbs) among 1138 limbs (1114 limbs), Wifi classification could be implemented for these 859 limbs (841 limbs). When rechecking the remaining 279 limbs (273 limbs), the data on TBI, SPP, or ABI in these limbs were registered as unmeasurable or unmeasured. It seems to be unlikely that these ischemic indexes could not be measured in these limbs due to the extensive gangrene because 85 limbs with R4, 138 limbs (133 limbs) with R5 and 56 limbs (55 limbs) with R6 were included in this unmeasurable or unmeasured group. There is a possibility that the limbs clinically judged to be CLI were registered without their objective ischemic index.

### (3) Treatment

Tables 4-1 to 4-6 show the data on the treatment of CLI. Revascularizations of the affected limbs were performed in 96% of the registered limbs, and primary major amputations were performed in 1.9% of the registered limbs. Among the procedures of surgical reconstruction, distal bypass, which is a bypass to the crural or foot artery, accounted for 46% (45%). Endovascular treatment (EVT), including EVT alone and hybrid treatment with surgical reconstruction, accounted for 58% (59%) of the total revascularization procedures. EVT applied to the crural or foot artery accounted for 39% of the total EVT.

The problems and considerations on these spreadsheets are described below. Table 4-3, in the column of “vein usage” described how the autologous veins were used when they were selected as vascular conduits. The sum of the number in the column with vein usage; “in-situ,” “non-reversed,” “reversed” and “spliced,” is larger than the sum of the number in the column of vein in vascular prosthesis. It is speculated to be caused by selecting multiple vein usage for arterial reconstruction of a limb since it is permitted to select more than one vein usage.

Table 4-6 summarizes the vascular grafts used for the infra-inguinal arterial reconstruction. For example, the total number of femoral-above knee popliteal artery bypass was 109 (107), higher than 102 (100), the number of actual applications in Table 4-2. It may have reflected the content of other procedures because the bypass procedure can be simultaneously applied with other procedures. Multiple procedures can be selected at the same time for lower limb arterial reconstruction. This is also the reason for the presence of “unused.”

### (4) Outcomes early (one month) after treatment

Tables 5-1 to 5-8 show the outcomes early (one month) after treatment. At the time of summary count at the end of December 2016, follow-up data one month after treatment were obtained in 837 limbs (74%) including 816 limbs (73%) with ASO. There were 36 limbs with non-arterial reconstruction. Data were collected according to the severity of the local conditions of the limb (Rutherford classification) and treatment measures (EVT alone or surgical reconstruction with/without EVT). The mortality was 2.6% (2.7%) in the whole series, and 2.3% and 3.1% (3.2%) treated by EVT alone and by surgical reconstruction with/without EVT, respectively. The most common cause of death was cardiac disease, accounting for 27% of all deaths.

Postoperative complications were cardiac disease in 2.1% (2.2%), cerebrovascular disease in 0.8%, pneumonia in 1.6% (1.7%), and wound complication in 5.0% (4.8%). Complications at the puncture site were noted in 0.5% of limbs treated by EVT. The median ABI and SPP of

the measured limbs were 0.89 and 43 mmHg, respectively.

Stenosis, occlusion, and infection occurred after revascularization by EVT in 9.9% (9.7%) and by surgical reconstruction in 8.3% (7.6%). Secondary major amputation was performed in 4.6% (4.3%) of the limbs.

When ambulatory function at discharge was compared with that before surgery, the rate of patients with ambulatory changed from 55% to 53% (52%), ambulatory/homebound from 24% to 23%, and nonambulatory from 21% to 24% (25%).

The problems, comments, and considerations on these spreadsheets are described below. Among 36 limbs of survivors with non-arterial reconstruction (Table 5-1), 4 limbs underwent primary major amputation and were counted in the column of perioperative complications in the row of limbs with non-arterial reconstruction (Table 5-2). Therefore, 36 limbs of survivors with non-arterial reconstruction comprised 4 limbs with primary major amputation and 32 limbs with conservative treatment.

The number of limbs of survivors with EVT was 344 (339 limbs) (Table 5-1), which was 5 limbs higher than the sum of the number in the column of minor reintervention or major reintervention in the row of limbs with EVT; 339 limbs (334 limbs) (Table 5-6). Four of these 5 limbs underwent major amputation after EVT, and reintervention was not performed. The information related to reintervention on the remaining one limb was missing.

The number of limbs of survivors with surgical reconstruction was 435 (419 limbs) (Table 5-1), which was one limb higher than the sum of the number in the column of minor reintervention or major reintervention in the row of limbs with surgical reconstruction; 434 limbs (418 limbs) (Table 5-6). This one limb also underwent major amputation after surgical reconstruction, and reintervention was not performed.

In Table 5-6, the sum of the number of limbs in the column of “major amputation” was expected to be 811 limbs (790 limbs); the limbs of survivors without major amputation comprised 32 limbs with conservative treatment, 344 limbs (339 limbs) with EVT, and 435 limbs (419 limbs) with surgical reconstruction. But the actual sum of the number of limbs in the column of major amputation was 808 (787), indicating 3 limbs fewer than expected. This was due to unregistered limbs with EVT; the sum of the number of limbs in the row of EVT was 341 (336), indicating that 3 limbs were unregistered.

In addition to the above, there were some parts where the total number does not match in Tables 5-1 to 5-8. It is estimated to be due to several items with multiple choice or missing values.

## 4. Conclusions

The devoted contribution of vascular surgeons in the participating facilities to register a sufficient amount of detailed data during busy clinical practice has been gradually clarifying the current status of CLI treatment in Japan; data on CLI in 2015 were clarified, after those in 2013 and 2014. The JCLIMB Committee is planning to continue publishing an annual report. Facilities can newly participate in JCLIMB at any time, and clinical studies utilizing these data will also be performed under specific conditions. Please contact the secretariat of the JSVS for details.

In the future, JCLIMB is designed so as to be extended to a system which physicians in departments other than vascular surgery will be able to register, track, and analyze CLI, aiming at establishing a nationwide CLI database in Japan.

## 5. Participant Facilities (92 facilities in the order of the Japanese syllabary by area, corporate names are omitted as a rule)

Department of Vascular Surgery, Asahikawa Medical University Hospital  
Department of Cardiovascular Surgery, National Hospital Organization Obihiro Hospital  
Department of Cardiovascular Surgery, National Hospital Organization Hokkaido Medical Center  
Department of Cardiovascular Surgery, Steel Memorial Muroran Hospital  
Department of Cardiovascular Surgery, Nayoro City General Hospital  
Department of Surgery, Iwate Prefectural Iwai Hospital  
Department of Surgery, Iwate Prefectural Isawa Hospital  
Department of Cardiovascular Surgery, Iwate Prefectural Central Hospital  
Department of Surgery, Iwate Prefectural Chubu Hospital  
Department of Surgery, JR Sendai Hospital  
Department of Surgery and Cardiovascular Surgery, Sendai City Hospital  
Department of Transplantation, Reconstruction and Endoscopic Surgery, Tohoku University Hospital  
Department of Cardiovascular Surgery, Southern TOHOKU General Hospital  
Department of Thoracic and Cardiovascular Surgery, Hirosaki University Hospital  
Department of Vascular Surgery, Morioka Yuai Hospital  
Department of Cardiovascular Surgery, Akita Kouseiren Yurikumiai General Hospital  
Department of Cardiovascular Surgery, Itabashi Chuo Medical Center  
Department of Vascular Surgery, Ibaraki Prefectural Cen-

tral Hospital  
Department of Cardiovascular Surgery, IMS Tokyo Katsushika General Hospital  
Department of Vascular Surgery, Edogawa Hospital  
Department of Vascular Surgery, Kawasaki Municipal Hospital  
Department of Cardiovascular Surgery, Kyorin University Hospital  
Department of Surgery, Keio University Hospital  
Department of Surgery, Tokyo Metropolitan Health and Medical Treatment Corporation, Okubo Hospital  
Department of Vascular Surgery, International University of Health and Welfare Hospital  
Department of Vascular Surgery, International University of Health and Welfare, Mita Hospital  
Department of Vascular Surgery, Saiseikai Kawaguchi General Hospital  
Department of Vascular Surgery, Saiseikai Yokohamashi Tobu Hospital  
Department of Vascular Surgery, Saitama Medical Center  
Department of Surgery, Saitama City Hospital  
Department of Cardiovascular Surgery, Saitama Medical Center, Jichi Medical University  
Department of Surgery, Shonankamakura General Hospital  
Department of Cardiovascular Surgery, St. Marianna University School of Medicine  
Department of Cardiovascular Surgery, Shimada General Hospital  
Department of Cardiovascular Surgery, Chiba Central Medical Center  
Department of Vascular Surgery, Tokyo Medical and Dental University  
Department of Cardiovascular Surgery, Tokyo Medical University Hachioji Medical Center  
Department of Cardiovascular Surgery, Tokyo Medical University Hospital  
Department of Vascular Surgery, The Jikei University Kashiwa Hospital  
Department of Vascular Surgery, The Jikei University Hospital  
Department of Cardiovascular Surgery, Tokyo Women's Medical University Medical Center East  
Department of Vascular Surgery, The University of Tokyo Hospital  
Department of Cardiovascular Surgery, Tokyo Rinkai Hospital  
Department of Vascular Surgery, Tomei Atsugi Hospital  
Department of Cardiovascular Surgery, Tokorozawa Meisei Hospital  
Department of Cardiac and Vascular Surgery, Dokkyo Medical University Nikko Medical Center  
Department of Cardiac and Vascular Surgery, Dokkyo

Medical University Hospital  
 Department of Cardiovascular Surgery, National Defense Medical College Hospital  
 Department of Cardiovascular Surgery, Yokosuka General Hospital UWAMACHI  
 Department of Vascular Surgery, Aichi Medical University Hospital  
 Department of Vascular Surgery, Ichinomiya Municipal Hospital  
 Department of Cardiovascular Surgery, National Hospital Organization, Kanazawa Medical Center  
 Department of Vascular Surgery, Japanese Red Cross Shizuoka Hospital  
 Department of Vascular Surgery, Japanese Red Cross Nagoya Daiichi Hospital  
 Department of Vascular Surgery, Nagoya University Hospital  
 Department of Cardiovascular Surgery (Vascular Surgery), Osaka International Cancer Institute  
 Department of Vascular Surgery, Osaka Rosai Hospital  
 Department of Cardiovascular Surgery, Tsukazaki Hospital  
 Department of Vascular Surgery, Kansai Medical University Medical Center  
 Department of Cardiovascular Surgery, Kobe University Hospital  
 Department of Cardiovascular Surgery, Toyonaka Municipal Hospital  
 Department of Surgery, Shinsuma General Hospital  
 Department of Vascular Surgery, Soryukai Inoue Hospital  
 Department of Cardiovascular Surgery, Hashimoto Municipal Hospital  
 Department of Thoracic and Cardiovascular Surgery, Wakayama Medical University Hospital  
 Department of Cardiovascular Surgery, Ehime Prefectural Central Hospital  
 Department of Cardiovascular Surgery, Okayama University Hospital  
 Department of Cardiovascular Surgery, Kawasaki Medical School Hospital  
 Department of Cardiovascular Surgery, Kochi Health Sciences Center  
 Department of Cardiovascular Surgery, Kochi University Hospital  
 Department of Cardiovascular Surgery, National Hospital Organization Higashihiroshima Medical Center  
 Department of Vascular Surgery, Saiseikai Yamaguchi General Hospital  
 Department of Cardiovascular Surgery, Tottori Prefectural Central Hospital  
 Department of Cardiovascular Surgery, The Sakakibara Heart Institute of Okayama  
 Department of Cardiovascular and Respiratory Surgery,

Hiroshima Prefectural Hospital  
 Department of Surgery, Hiroshima Red Cross Hospital & Atomic-bomb Survivors Hospital  
 Department of Cardiovascular Surgery, Hiroshima University Hospital  
 Department of Cardiovascular Surgery, Matsuyama Shimin Hospital  
 Department of Vascular Surgery, Matsuyama Red Cross Hospital  
 Department of Vascular Surgery, Yamaguchi University Hospital  
 Department of Cardiovascular Surgery, Oita Oka Hospital  
 Department of Vascular Surgery, Kyushu University Hospital  
 Department of Vascular Surgery, Kumamoto Rehabilitation Hospital.  
 Cardiovascular Surgery, Kurume University Hospital  
 Department of Vascular Surgery, Kokura Memorial Hospital  
 Department of Vascular Surgery, National Hospital Organization Kyushu Medical Center  
 Department of Surgery, Saiseikai Karatsu Hospital  
 Department of Surgery, Saiseikai Fukuoka General Hospital  
 Department of Cardiovascular Surgery, Saga-ken Medical Center, Koseikan  
 Department of Cardiovascular Surgery, Sasebo Chuo Hospital  
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## 6. JCLIMB Committee, NCD JCLIMB Analytical Team

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### (3) NCD JCLIMB Analytical Team

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## Disclosure Statement

The authors have no conflict of interest.

## Additional Remarks

The original Annual Report was published in the Japanese Journal of Vascular Surgery Vol. 27 (2018) No. 3; however, errors in tables were detected after the publication. The erratum was published in the same volume. This translation reflects the corrections.

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**Table 1-1** SVS Wiffl classification: original 6)**Table 1-1-1** Wound

Grade	Ulcer	Gangrene
0	No ulcer	No gangrene
	Clinical description: ischemic rest pain (requires typical symptoms+ ischemia grade 3); no wound.	
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
	Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
	Clinical description: major tissue loss salvageable with multiple ( $\geq 3$ ) digital amputations or standard TMA $\pm$ skin coverage.	
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer $\pm$ calcaneal involvement	Extensive gangrene involving forefoot and/or midfoot; full thickness heel necrosis $\pm$ calcaneal involvement
	Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or nontraditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect	

TMA: Transmetatarsal amputation

**Table 1-1-2** Ischemia

Grade	ABI	AP (mmHg)	TP, TcPO <sub>2</sub> (mmHg)
0	$\geq 0.80$	>100	$\geq 60$
1	0.60–0.79	70–100	40–59
2	0.40–0.59	50–70	30–39
3	$\leq 0.39$	<50	<30

ABI: ankle brachial (pressure) index, AP: ankle pressure, PVR: pulse volume recording, SPP: skin perfusion pressure, TP: toe pressure, TcPO<sub>2</sub>: transcutaneous oximetry. Patients with diabetes should have TP measurements. If arterial calcification precludes reliable ABI or TP measurements, ischemia should be documented by TcPO<sub>2</sub>, SPP, PVR. If TP and ABI measurements result in different grades, TP will be the primary determinant of ischemia grade.

Flat or minimally pulsatile forefoot PVR = grade 3.



**Table 1-1-3** Foot Infection

Grade	Clinical manifestation of infection	IDS/PEDIS Infection severity*
0	No symptoms or signs of infection	Uninfected
1	<p>Infection present, as defined by the presence of at least 2 of the following items:</p> <ul style="list-style-type: none"> <li>-Local swelling or induration</li> <li>-Erythema &gt;0.5 to ≤2cm around the ulcer</li> <li>-Local tenderness or pain</li> <li>-Local warmth</li> <li>-Purulent discharge (thick, opaque to white, or sanguineous secretion)</li> </ul> <p>Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below).</p> <p>Exclude other causes of an inflammatory response of the skin (e.g., trauma, gout, acute Charcot neuro-osteopathy, fracture, thrombosis, venous stasis)</p>	Mild
2	Local infection (as described above) with erythema >2cm, or involving structures deeper than skin and subcutaneous tissues (e.g., abscess, osteomyelitis, septic arthritis, fasciitis), and no systemic inflammatory response signs (as described below)	Moderate
3	Local infection (as described above) with the signs of SIRS, as manifested by two or more of the following: <ul style="list-style-type: none"> <li>-Temperature &gt; 38°C or &lt;36°C</li> <li>-Heart rate &gt; 90 beats/min</li> <li>-Respiratory rate &gt; 20 breaths/min or PaCO<sub>2</sub> &lt; 32 mmHg</li> <li>-White blood cell count &gt; 12,000 or &lt; 4,000 cu/mm or 10% immature (band) forms</li> </ul>	Severe#

\*SVS adaptation of Infectious Diseases Society of America (IDSA) and International Working Group on the Diabetic Foot (IWGDF) perfusion, extent/size, PaCO<sub>2</sub>: partial pressure of arterial carbon dioxide, SIRS: systemic inflammatory response syndrome

# Ischemia may complicate and increase the severity of any infection. Systemic infection may sometimes manifest with other clinical findings, such as hypotension, confusion, vomiting, or evidence of metabolic disturbances, such as acidosis, severe hyperglycemia, new-onset azotemia.

**Table 1-2** SVS Wifl classification: Correlation of Wifl and items in JCLIMB

Grade	Rutherford classification	Ulcer		
		Depth of ulcer (University of Texas classification: grade)	Sites of ulcer	Sites of gangrene
0	Class 4		No ulcer or gangrene	
1	Class 5, 6	I II, III	Any portion Limited to digits Heel	No gangrene No gangrene No gangrene
2	Class 5, 6	I II, III	Foot: distal metatarsal excluding heel	Limited to digits
3	Class 5, 6	II, III	Foot: proximal metatarsal, heel, ankle, lower leg	Extensive proximal to forefoot

**Table 1-2-3** Foot Infection

Grade	Local infection; foot	Systemic infection (SIRS)
0	(-)	(-)
1	(+)	(-)
2	Involving only the skin and the subcutaneous tissue (Erythema around the ulcer; 0.5-2cm)	(-)
3	Involving only the skin and the subcutaneous tissue (Erythema around the ulcer; >2cm), or involving structures deeper than skin and subcutaneous tissues (e.g., abscess, osteomyelitis, septic arthritis, fasciitis)	(+)

**Table 1-2-2** Ischemia

Grade	SPP: (mmHg, calculating from the formula*)
0	≥66
1	37-65
2	23-36
3	<23

\* TP=0.6853XSP+14.48

SPP: skin perfusion pressure, TP: toe pressure

**Table 2** Patients' background

**Table 2-1** Patients' background 1

n	Sex		Laterality		BMI (median)	Pathogenesis						Age at registration			
	Male	Female	Right	Left		ASO	TAO	Vasculitis	Others	ASO	TAO	Vasculitis	Others	Mean (±SD)	Mean (±SD)
Rutherford 4	241	166	75	118	123	20.9	236	3	0	2	73.7 (10.5)	51.0 (22.1)	0.0-	55.5 (7.8)	
Rutherford 5	727	500	227	371	356	20.9	710	6	7	4	73.5 (9.7)	46.0 (15.4)	64.0 (17.1)	78.5 (8.7)	
Rutherford 6	170	130	40	81	89	21.1	168	1	1	0	71.2 (10.3)	59.0-	77.0-	0.0-	
Total	1,138	796	342	570	568	20.9	1,114	10	8	6	73.2 (10.0)	48.8 (16.1)	65.6 (16.5)	70.8 (14.1)	

b. ASO

n	Sex		Laterality		BMI (median)	Age at registration	
	Male	Female	Right	Left			
							Mean (±SD)
Rutherford 4	236	163	73	114	122	20.9	73.7 (10.5)
Rutherford 5	710	490	220	361	349	20.9	73.5 (9.7)
Rutherford 6	168	129	39	80	88	21.1	71.2 (10.3)
Total	1,114	782	332	555	559	21.0	73.2 (10.0)

Vasculitis: Takayasu's arteritis, collagen disease, Behcet disease, FMD etc., excluding TAO.

Others: others (including debranch bypasses for TEVAR or EVAR).

ASO: arteriosclerosis obliterans, TAO: thromboangiitis obliterans, FMD: fibromuscular dysplasia, BMI: body mass index, TEVAR: thoracic endovascular aortic repair, EVAR: endovascular aneurysm repair

**Table 2-2** Patients' background 2

	a. Total													
	Diabetes			Diabetes therapy			Hypertension			Dyslipidemia			Smoking	
	(-)	(+) Management		Diet therapy	Medication	Insulin therapy	(-)	(+) Management		(-)	(+) Management		Ex-smoker	Current smoker
		Good	Poor					Good	Poor		Good	Poor		
Rutherford 4	119	103	19	65	38	69	150	22	153	71	17	105	45	
Rutherford 5	225	403	99	231	213	179	479	69	446	238	43	309	118	
Rutherford 6	37	95	38	48	69	64	90	16	105	54	11	76	27	
Total	381	601	156	344	320	312	719	107	704	363	71	490	190	
b. ASO														
	b. ASO													
	Diabetes			Diabetes therapy			Hypertension			Dyslipidemia			Smoking	
	(-)	(+) Management		Diet therapy	Medication	Insulin therapy	(-)	(+) Management		(-)	(+) Management		Ex-smoker	Current smoker
		Good	Poor					Good	Poor		Good	Poor		
Rutherford 4	117	100	19	64	36	65	149	22	149	70	17	103	43	
Rutherford 5	210	403	97	231	211	168	475	67	432	235	43	299	117	
Rutherford 6	35	95	38	48	69	62	90	16	104	53	11	76	26	
Total	362	598	154	343	316	295	714	105	685	358	71	478	186	

Blood pressure management good: diabetes or renal failure (-) <140/90 mmHg, (+) <130/80 mmHg. Diabetes management good: HbA1c <7.0% (NGSP).

Dyslipidemia management good: other sclerotic lesions (-) LDL <100 mg/dL, (+) LDL <80 mg/dL.

HbA1c: hemoglobin A1c, LDL: low-density lipoprotein, NGSP: national glycohemoglobin standardization program

**Table 2-3** Patients' background 3

	Ischemic heart disease				Heart failure	Cerebrovascular disease		Renal dysfunction										
	(-)	(+) (+)				(-)	(+)	(+) (+)										
		Medical treatment	PCI	CABG				G3a	G3b	G4	G5	G5D						
a. Total																		
Rutherford 4	148	33	35	25	213	28	194	47	107	33	24	12	0	65				
Rutherford 5	409	90	122	106	637	90	564	163	218	65	54	32	5	353				
Rutherford 6	87	29	33	21	141	29	130	40	59	14	7	10	5	75				
Total	644	152	190	152	991	147	888	250	384	112	85	54	10	493				
b. ASO																		
	Ischemic heart disease				Heart failure	Cerebrovascular disease		Renal dysfunction										
	(-)	(+) (+)				(-)	(+)	(+) (+)										
		Medical treatment	PCI	CABG				G3a	G3b	G4	G5	G5D						
Rutherford 4	143	33	35	25	208	28	189	47	104	32	24	12	0	64				
Rutherford 5	395	89	122	104	621	89	547	163	205	64	53	31	5	352				
Rutherford 6	85	29	33	21	139	29	128	40	57	14	7	10	5	75				
Total	623	151	190	150	968	146	864	250	366	110	84	53	10	491				

PCI: percutaneous coronary intervention, CABG: coronary arterial bypass grafting

Heart failure (+): history of admission due to heart failure, clinical symptoms due to heart failure confirmed by ultrasound examination, apparently decreased cardiac function by ultrasound examination without clinical symptoms.

Renal dysfunction: (-) (60 ≤), G3a (45-59), G3b (30-44), G4 (15-29), G5 (<15), G5D (<15 with hemodialysis).

New CKD risk stratification by eGFR(mL/min/1.73m<sup>2</sup>) in "Clinical Practice Guidebook for Diagnosis and Treatment of Chronic Kidney Disease 2012."

eGFR: estimated glomerular filtration rate, CKD: chronic kidney disease

**Table 2-4** Patients' background 4

		Malignant neoplasm		Sites of malignant neoplasm													
		(-)	(+)	History of cancer	Under treatment*	Unknown	Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	Breast	Uterus	Ovary	Prostate	Others
a. Total																	
	Rutherford 4	212	9	20	9	0	2	0	3	2	6	2	2	2	0	2	9
	Rutherford 5	668	13	41	13	5	5	0	13	13	2	2	0	0	0	0	8
	Rutherford 6	157	4	8	4	1	1	1	1	4	0	0	1	0	1	1	3
	Total	1,037	26	69	26	6	8	1	17	19	8	4	3	0	3	3	20
b. ASO																	
		Malignant neoplasm		Sites of malignant neoplasm													
		(-)	(+)	History of cancer	Under treatment*	Unknown	Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	East	Uterus	Ovary	Prostate	Others
	Rutherford 4	207	9	20	9	0	2	0	3	2	6	2	2	0	2	2	9
	Rutherford 5	651	13	41	13	5	5	0	13	13	2	2	0	0	0	0	8
	Rutherford 6	155	4	8	4	1	1	1	1	4	0	0	1	0	1	1	3
	Total	1,013	26	69	26	6	8	1	17	19	8	4	3	0	3	3	20

\* Including palliative therapy or recurrence.

**Table 2-5** Patients' background 5

a. Total		Contralateral limb occlusive lesions (+)												Vascular lesions excluding occlusion						
		Intermittent claudication			ABI			TBI			SPP			(-)	TAA (including IAA)	Peripheral artery aneurysm	Carotid stenosis	Others		
		R4	R5	R6	n	Median	n	Median	n	Median	n	Median								
(-)	Asymptomatic	67	50	42	36	13	0	33	175	0.82	17	0.64	72	38.5	217	0	12	2	7	3
		180	182	53	29	126	6	151	493	0.78	58	0.42	309	39.0	669	4	13	9	22	10
		34	44	9	5	13	24	41	93	0.75	4	0.32	68	42.5	159	0	3	1	6	1
	Total	281	276	104	70	152	30	225	761	0.78	79	0.44	449	40.0	1,045	4	28	12	35	14
b. ASO																				
		Contralateral limb occlusive lesions (+)												Vascular lesions excluding occlusion						
		Intermittent claudication			ABI			TBI			SPP			(-)	TAA (including IAA)	Peripheral artery aneurysm	Carotid stenosis	Others		
		R4	R5	R6	n	Median	n	Median	n	Median	n	Median								
(-)	Asymptomatic	65	48	42	35	13	0	33	170	0.81	16	0.59	70	38.0	212	0	12	2	7	3
		170	181	52	29	123	6	149	480	0.78	57	0.41	305	39.0	657	3	11	7	22	10
		34	43	9	5	13	23	41	92	0.76	4	0.32	68	42.5	157	0	3	1	6	1
	Total	269	272	103	69	149	29	223	742	0.78	77	0.43	443	40.0	1,026	3	26	10	35	14

ABI: ankle brachial (pressure) index, TBI: toe brachial (pressure) index, SPP: skin perfusion pressure, CLI: critical limb ischemia, TAA: thoracic aortic aneurysm, AAA: abdominal aortic aneurysm, IAA: iliac artery aneurysm

**Table 2-6** Patients' background 6

a. Total (=ASO)		Fatty acid														
		Arachidonic acid (AA)					Eicosapentaenoic acid (EPA)					Docosahexaenoic acid (DHA)				
		n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n
	Rutherford 4	4	164.3	4	46.2	4	99.2	4	0.3							
	Rutherford 5	22	139.8	22	64.6	22	110.6	22	0.4							
	Rutherford 6	7	107.5	7	54.5	7	104.8	7	0.4							
	Total	33	138.5	33	53.3	33	110.0	33	0.4							

**Table 3** Pretreatment condition  
**Table 3-1** Pretreatment condition 1

a. Total		Depth of ulcer (University of Texas classification: grade)										Main sites of ulcer/gangrene to be treated												
Ambulatory function (Taylor's classification)		Sites of ulcer					Sites of gangrene					Foot: proximal metatarsal					Foot: distal metatarsal							
Ambulatory	Nonambulatory	Foot: proximal metatarsal	Foot: distal metatarsal	Heel	Ankle	Lower leg	Only gangrene w/o ulcer	I	II	III	Digits	Foot: proximal metatarsal	Foot: distal metatarsal	Heel	Ankle	Lower leg	Only ulcer w/o gangrene	Toe	Foot: proximal metatarsal	Foot: distal metatarsal	Heel	Ankle	Lower leg	
Rutherford 4	172	48	21	14	60	11	8	59	446	137	144	358	58	11	35	2	3	315	573	82	11	46	7	8
Rutherford 5	403	178	146	28	45	12	13	29	32	35	103	71	39	32	35	5	11	27	39	34	41	10	16	
Rutherford 6	52	52	66	42	105	23	21	88	478	172	247	429	97	43	70	7	14	342	612	116	41	87	17	24
<b>Total</b>	<b>627</b>	<b>278</b>	<b>233</b>	<b>117</b>	<b>626</b>	<b>117</b>	<b>88</b>	<b>478</b>	<b>172</b>	<b>247</b>	<b>429</b>	<b>97</b>	<b>43</b>	<b>70</b>	<b>7</b>	<b>14</b>	<b>342</b>	<b>612</b>	<b>116</b>	<b>41</b>	<b>87</b>	<b>17</b>	<b>24</b>	
b. ASO		Tissue loss (University of Texas classification: grade)										Main sites of ulcer/gangrene to be treated												
Ambulatory function (Taylor's classification)		Sites of ulcer					Sites of gangrene					Foot: proximal metatarsal					Foot: distal metatarsal							
Ambulatory	Nonambulatory	Foot: proximal metatarsal	Foot: distal metatarsal	Heel	Ankle	Lower leg	Only gangrene w/o ulcer	I	II	III	Digits	Foot: proximal metatarsal	Foot: distal metatarsal	Heel	Ankle	Lower leg	Only ulcer w/o gangrene	Toe	Foot: proximal metatarsal	Foot: distal metatarsal	Heel	Ankle	Lower leg	
Rutherford 4	168	47	21	13	59	11	8	57	437	132	141	350	56	10	35	2	3	308	561	79	10	45	7	8
Rutherford 5	393	174	143	28	44	12	13	29	32	33	103	70	38	32	35	5	11	27	39	33	40	10	16	
Rutherford 6	51	51	66	41	103	23	21	86	469	165	244	420	94	42	70	7	14	335	600	112	40	85	17	24
<b>Total</b>	<b>612</b>	<b>272</b>	<b>230</b>	<b>113</b>	<b>613</b>	<b>613</b>	<b>86</b>	<b>469</b>	<b>165</b>	<b>244</b>	<b>420</b>	<b>94</b>	<b>42</b>	<b>70</b>	<b>7</b>	<b>14</b>	<b>335</b>	<b>600</b>	<b>112</b>	<b>40</b>	<b>85</b>	<b>17</b>	<b>24</b>	

University of Texas classification: grade (I: superficial, not involving tendon, capsule, or bone; II: penetrating to tendon/capsule, III: penetrating to bone or joint).

**Table 3-2** Pretreatment condition 2

Temperature ≥38°C		Blood test						Hemodynamics						Infection <sup>§</sup>													
		WBC	CRP	Alb	Cr	ABI	TBI	SPP	Toe pressure	Local (foot)	Systemic	Local (foot)	Skin or subcutaneous tissue (erythema)*	Deep tissue <sup>#</sup>	SIRS <sup>§</sup>												
(-)	(+)	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4	232	9	230	6,725	214	0.55	215	3.6	229	1.08	121	0.56	8	0.41	86	20	8	51.5	217	12	5	7	5	237			
Rutherford 5	688	39	710	7,300	690	1.00	669	3.4	712	2.28	463	0.61	31	0.26	432	22	31	36	480	168	50	33	19	709			
Rutherford 6	143	27	169	8,600	169	4.62	161	2.9	169	1.90	79	0.66	3	0.18	92	22.5	3	27	50	31	36	54	16	154			
Total	1,063	75	1,109	7,400	1,073	1.16	1,045	3.4	1,110	1.54	663	0.61	42	0.27	610	22	42	36	747	211	91	94	40	1,100			

Temperature ≥38°C		Blood test						Hemodynamics						Infection <sup>§</sup>											
		WBC	CRP	Alb	Cr	ABI	TBI	SPP	Toe pressure	Local (foot)	Systemic	Local (foot)	Skin or subcutaneous tissue (erythema)*	Deep tissue <sup>#</sup>	SIRS <sup>§</sup>										
(-)	(+)	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4	227	9	225	6,700	209	0.54	210	3.6	224	1.09	119	0.55	8	0.41	83	20	8	51.5	213	11	5	7	5	232	
Rutherford 5	673	37	694	7,300	675	1.00	654	3.4	696	2.78	452	0.61	30	0.25	427	22	30	36	467	166	50	30	17	694	
Rutherford 6	142	26	167	8,550	167	4.62	159	2.9	167	1.94	78	0.66	3	0.18	91	22	3	27	50	31	34	54	16	152	
Total	1,042	72	1,086	7,375	1,051	1.17	1,023	3.4	1,087	1.61	649	0.60	41	0.26	601	22	41	36	730	208	89	91	38	1,078	

WBC: white blood cell, CRP: C reactive protein, Alb: albumin, Cr: creatinine, ABI: ankle brachial (pressure) index, TBI: toe brachial (pressure) index, SPP: skin perfusion pressure, SIRS: systemic inflammatory response syndrome  
<sup>§</sup> Presence of infection is defined by the presence of at least 2 of the following items: ① Local swelling or induration, ② Erythema >0.5 to ≤2 cm around the ulcer, ③ Local tenderness or pain, ④ Local warmth, ⑤ Purulent discharge (thick, opaque to white, or sanguineous secretion).  
<sup>#</sup> Local infection at skin and subcutaneous tissue was classified by the spreading of erythema (≤2.0 cm or >2 cm) around the ulcer/gangrene.  
<sup>§</sup> The signs of SIRS are manifested by two or more of the following: ① Temperature >38 or <36°C, ② Heart rate >90beats/min, ③ Respiratory rate >20 breaths/min or PaCO<sub>2</sub> <32 mmHg, ④ White blood cell count >12,000 or <4,000 cu/mm or 10% immature (band) forms.



**Table 3-3** Pretreatment condition 3

a. Total	Diagnostic imaging				Sites of occlusion				TASC II classification aortoiliac				TASC II classification femoropopliteal			
	IADSA	CTA	Others	Aortoiliac	Femoropop	Lower leg/foot	A	B	C	D	No lesion	A	B	C	D	No lesion
Rutherford 4	165	121	18	79	161	105	20	8	6	36	3	19	35	24	106	13
Rutherford 5	531	328	28	137	435	489	44	28	15	49	0	112	103	94	244	107
Rutherford 6	136	51	11	41	81	113	11	13	5	9	1	15	10	13	67	37
Total	832	500	57	257	677	707	75	49	26	94	4	146	148	131	417	157

b. ASO

b. ASO	Diagnostic imaging				Sites of occlusion				TASC II classification aortoiliac				TASC II classification femoropopliteal			
	IADSA	CTA	Others	Aortoiliac	Femoropop	Lower leg/foot	A	B	C	D	No lesion	A	B	C	D	No lesion
Rutherford 4	162	118	18	79	158	100	20	8	6	36	3	19	35	24	101	13
Rutherford 5	517	323	26	134	429	475	44	27	15	47	0	112	103	92	237	101
Rutherford 6	134	50	11	41	80	111	11	13	5	9	1	15	10	13	65	37
Total	813	491	55	254	667	686	75	48	26	92	4	146	148	129	403	151

IADSA: intra-arterial digital subtraction angiography, CTA: computed tomography angiography

**Table 3-4** Pretreatment condition 4

a. Total	Bollinger score																				
	Common femoral			Deep femoral			Superficial femoral: proximal			Superficial femoral: distal			Popliteal: proximal			Popliteal: distal			Tibioperoneal trunk		
n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4	115	3	115	2	115	5	12	115	12	114	5	114	3	112	3	112	3	112	3	112	3
Rutherford 5	461	1	457	1	463	3	4	461	4	464	3	466	2	463	3	463	3	463	3	463	3
Rutherford 6	105	1	103	1	106	3	4	105	4	105	2	106	2	106	3	106	3	106	3	106	3
Total	681	1	675	1	684	3	4	681	4	683	3	686	2	681	3	681	3	681	3	681	3

b. ASO

b. ASO	Bollinger score																				
	Common femoral			Deep femoral			Superficial femoral: proximal			Superficial femoral: distal			Popliteal: proximal			Popliteal: distal			Tibioperoneal trunk		
n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4	112	3	112	2	112	5	10.5	112	10.5	111	5	111	3	109	3	109	3	109	3	109	3
Rutherford 5	451	1	447	1	453	3	4	451	4	454	3	456	2	454	3	454	3	454	3	454	3
Rutherford 6	104	1	102	1	105	3	4	104	4	104	2	105	2	105	3	105	3	105	3	105	3
Total	667	1	661	1	670	3	4	667	4	669	3	672	2	668	3	668	3	668	3	668	3

**Table 3-5** Pretreatment condition 5

		Bollinger score													
		Posterior tibial: proximal		Posterior tibial: distal		Anterior tibial: proximal		Anterior tibial: distal		Peroneal: proximal		Peroneal: distal		Foot	
a. Total		n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4		112	13	108	6	112	13	106	12.5	111	6	105	5	93	6
Rutherford 5		462	15	456	13	461	13	456	13	458	6	454	6	409	13
Rutherford 6		106	13	104	13	105	13	103	13	105	6	104	6	97	13
Total		680	13.5	668	13	678	13	665	13	674	6	663	6	599	13
b. ASO															
		Bollinger score													
		Posterior tibial: proximal		Posterior tibial: distal		Anterior tibial: proximal		Anterior tibial: distal		Peroneal: proximal		Peroneal: distal		Foot	
a. Total		n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4		109	13	106	6	109	12	103	12	108	6	103	5	91	5
Rutherford 5		452	15	446	13	451	13	446	13	448	6	444	6	401	13
Rutherford 6		105	13	103	13	104	13	102	13	104	6	103	6	96	13
Total		666	13	655	13	664	13	651	13	660	6	650	6	588	13

**Table 3-6** SVS Wifl classification

		Wound						Ischemia						Foot infection						Stage											
		1		2		3		1		2		3		1		2		3		1		2		3		1		2		3	
Rutherford 4		241	0	0	0	16	31	46	63	217	10	11	44	103	7	2															
Rutherford 5		263	351	113	52	107	173	257	478	161	71	71	42	93	204	250															
Rutherford 6		0	10	43	117	13	19	30	52	50	30	74	16	2	3	14															
Total		241	273	394	230	81	157	249	372	745	201	156	88	199	225	347															
b. ASO																															
		Wound						Ischemia						Foot infection						Stage											
		1		2		3		1		2		3		1		2		3		1		2		3		1		2		3	
Rutherford 4		236	0	0	0	16	31	44	60	213	9	11	44	99	6	2															
Rutherford 5		257	343	110	48	106	170	253	465	160	70	70	40	89	203	245															
Rutherford 6		0	10	43	115	13	19	29	52	50	30	72	16	2	3	14															
Total		236	267	386	225	77	156	243	365	728	199	153	86	191	223	341															

Table 4 Treatment

Table 4-1 Treatment 1

	Treatment										Reoperation		
	Angiogenic therapy					Angiogenic therapy					Reoperation		
	Pharmacological therapy	Angiogenic therapy	Arterial reconstruction	Major amputation	Lumber sympathectomy	Bone marrow	Peripheral blood	Others	Unknown	(-)	1X	2X	3X $\leq$
Rutherford 4	61	1	228	2	0	0	0	0	0	177	44	9	11
Rutherford 5	185	3	704	5	0	0	0	1	2	555	114	24	32
Rutherford 6	39	2	158	14	0	0	0	0	0	127	21	9	13
Total	285	6	1,090	21	0	0	0	1	2	859	179	42	56

b. ASO

	Treatment										Reoperation		
	Angiogenic therapy					Angiogenic therapy					Reoperation		
	Pharmacological therapy	Angiogenic therapy	Arterial reconstruction	Major amputation	Lumber sympathectomy	Bone marrow	Peripheral blood	Others	Unknown	(-)	1X	2X	3X $\leq$
Rutherford 4	61	1	223	2	0	0	0	0	0	173	44	9	10
Rutherford 5	181	3	687	5	0	0	0	1	2	541	112	23	32
Rutherford 6	39	2	156	14	0	0	0	0	0	125	21	9	13
Total	281	6	1,066	21	0	0	0	1	2	839	177	41	55

Table 4-2 Treatment 2

	Bypass										TEA					
	Angiogenic therapy					Angiogenic therapy					TEA					
	Aorta-aorta	Aorta (with suprarenal clamp)	Aorta-femoral	Femoral-proximal popliteal	Femoral-distal popliteal	Femoral-crural/foot	Femoral-crural/foot	Popliteal-crural/foot	Anatomical others	Axillary-femoral	Femoral-femoral	Extra-anatomical others	Aorta/iliac	Femoral/popliteal	Others	EVT
Rutherford 4	0	0	6	27	18	37	12	0	0	10	9	2	1	22	1	111
Rutherford 5	0	0	13	62	41	93	103	3	3	16	21	1	2	47	5	365
Rutherford 6	0	0	1	13	9	24	30	0	0	3	2	1	0	15	1	74
Total	0	0	20	102	68	154	145	3	3	29	32	4	3	84	7	550

b. ASO

	Bypass										TEA					
	Angiogenic therapy					Angiogenic therapy					TEA					
	Aorta-aorta	Aorta (with suprarenal clamp)	Aorta-femoral	Femoral-proximal popliteal	Femoral-distal popliteal	Femoral-crural/foot	Femoral-crural/foot	Popliteal-crural/foot	Anatomical others	Axillary-femoral	Femoral-femoral	Extra-anatomical others	Aorta/iliac	Femoral/popliteal	Others	EVT
Rutherford 4	0	0	6	27	17	34	11	0	0	10	9	2	1	22	1	110
Rutherford 5	0	0	13	61	39	90	98	2	2	16	20	1	2	47	5	360
Rutherford 6	0	0	1	12	9	23	30	0	0	3	2	1	0	15	1	74
Total	0	0	20	100	65	147	139	2	2	29	31	4	3	84	7	544

TEA: thromboendarterectomy, EVT: endovascular treatment

**Table 4-3 Treatment 3**

a. Total	EVT										Vascular prosthesis						Vein usage				Vein quality							
	Aorta/iliac		Femoral/ popliteal		Tibioperoneal/ foot		Others		Polyester		ePTFE		Vein		Others (-)		In-situ		Non-reversed		Reversed		Spliced		Good		Poor	
Rutherford 4	39	53	37	5	8	36	71	6	13	13	13	22	31	7	64	7												
Rutherford 5	85	176	197	5	32	81	246	2	24	53	68	104	26	211	35													
Rutherford 6	24	26	35	2	4	10	66	1	12	13	29	24	3	61	5													
Total	148	255	269	12	44	127	383	9	49	79	119	159	36	336	47													
b. ASO																												
a. Total	EVT										Vascular prosthesis						Vein usage				Vein quality							
	Aorta/iliac		Femoral/ popliteal		Tibioperoneal/ foot		Others		Polyester		ePTFE		Vein		Others (-)		In-situ		Non-reversed		Reversed		Spliced		Good		Poor	
Rutherford 4	39	53	36	5	8	36	67	6	13	11	22	29	7	60	7													
Rutherford 5	84	176	193	5	32	78	238	2	23	52	64	100	26	204	34													
Rutherford 6	24	26	35	2	4	10	64	1	12	13	28	23	3	59	5													
Total	147	255	264	12	44	124	369	9	48	76	114	152	36	323	46													

ePTFE: expanded polytetrafluoroethylene, EVT: endovascular treatment

**Table 4-4 Treatment 4**

a. Total	Distal bypass																Distal anastomosis: sites of foot artery																				
	Proximal anastomosis								Distal anas-tomosis								Distal anastomosis: sites of crural artery				Distal anastomosis: sites of foot artery																
	External iliac		Common femoral		Deep femoral		Super-ficial femoral		Proximal popliteal		Distal popliteal		Crural		Others		Crural		Foot		Tibio-peroneal trunk		Posterior tibial		Anterior tibial		Peroneal		Posterior tibial		Anterior tibial		Peroneal		Dorsalis pedis		Plantar
Rutherford 4	1	21	2	11	8	4	1	1	26	23	3	14	3	3	6	10	3	0	8	2																	
Rutherford 5	2	41	7	45	21	69	8	3	63	133	3	27	28	5	39	11	0	66	17																		
Rutherford 6	0	10	1	9	4	24	6	0	21	33	3	6	9	3	12	3	0	16	2																		
Total	3	72	10	65	33	97	15	4	110	189	9	47	40	14	61	17	0	90	21																		
b. ASO																																					
a. Total	Distal bypass																Distal anas-tomosis				Distal anastomosis: sites of crural artery				Distal anastomosis: sites of foot artery												
	Proximal anastomosis								Distal anas-tomosis								Distal anastomosis: sites of crural artery				Distal anastomosis: sites of foot artery																
	External iliac		Common femoral		Deep femoral		Super-ficial femoral		Proximal popliteal		Distal popliteal		Crural		Others		Crural		Foot		Tibio-peroneal trunk		Posterior tibial		Anterior tibial		Peroneal		Posterior tibial		Anterior tibial		Peroneal		Dorsalis pedis		Plantar
Rutherford 4	1	18	2	11	8	3	1	1	24	21	3	13	2	6	8	3	0	8	2																		
Rutherford 5	2	41	6	41	20	67	8	3	58	130	3	27	24	4	39	11	0	65	15																		
Rutherford 6	0	10	1	8	4	24	6	0	20	33	3	6	8	3	12	3	0	16	2																		
Total	3	69	9	60	32	94	15	4	102	184	9	46	34	13	59	17	0	89	19																		

**Table 4-5 Treatment 5**

	Pharmacological therapy					
	Antiplatelet	ATA	Prostaglandin	Heparin	Statin	Others
a. Total						
Rutherford 4	107	8	2	3	13	6
Rutherford 5	341	35	38	20	31	16
Rutherford 6	70	8	5	3	8	5
Total	518	51	45	26	52	27
b. ASO						
Rutherford 4	107	8	2	3	13	6
Rutherford 5	335	34	36	19	30	13
Rutherford 6	70	8	5	3	8	5
Total	512	50	43	25	51	24

Antiplatelet: aspirin, clostazol, beraprost, sarpgrelate, ticlopidine, dlopidogrel, ethyl icosapentate.  
ATA: antithrombotic agent

**Table 4-6 Treatment 6**

	Pharmacological therapy					
	Antiplatelet	ATA	Prostaglandin	Heparin	Statin	Others
a. Total						
Femoral-proximal popliteal bypass	9	5		1		2
Femoral-distal popliteal bypass	57	14		9		7
Femoral-crural/foot bypass	39	52		139		135
Femoral-crural/foot bypass	1	0		7		5
Others	2	0		1		1
(-)	1	0		0		1
Total	109	71		157		151
b. ASO						
Femoral-proximal popliteal bypass	9	5		1		2
Femoral-distal popliteal bypass	57	13		8		7
Femoral-crural/foot bypass	37	50		134		129
Femoral-crural/foot bypass	1	0		6		5
Others	2	0		1		1
(-)	1	0		0		1
Total	107	68		150		145

ePTFE: expanded polytetrafluoroethylene

**Table 5** Outcomes early (one month) after treatment therapeutic measures: EVT (only EVT without surgical reconstruction), Surgical reconstruction (surgical reconstruction with or without EVT)

**Table 5-1** Life prognosis/causes of death

	Life prognosis													
	Alive						Causes of death							
	Dead	Unknown	Cardiac disease	Cerebrovascular disease	Malignant neoplasm	Aortic aneurysm/dissection	Infection	Ischemic enteritis	Gastrointestinal bleeding	Others	Unknown			
Local condition	162	5	0	1	0	0	0	0	0	0	0	3	1	
	538	14	0	4	0	0	1	0	2	1	2	0	3	1
	115	3	0	1	0	0	0	0	0	1	0	0	0	1
Therapeutic measures	36	0	0	0	0	0	0	0	0	0	0	0	0	0
EVT	344	8	0	3	0	0	1	0	1	0	0	0	3	0
Surgical reconstruction	435	14	0	3	0	0	0	0	1	2	2	0	3	3
Total	815	22	0	6	0	0	1	0	2	2	2	0	6	3

b. ASO

	Life prognosis													
	Alive						Causes of death							
	Dead	Unknown	Cardiac disease	Cerebrovascular disease	Malignant neoplasm	Aortic aneurysm/dissection	Infection	Ischemic enteritis	Gastrointestinal bleeding	Others	Unknown			
Local condition	157	5	0	1	0	0	0	0	0	0	0	0	3	1
	523	14	0	4	0	0	1	0	2	1	2	0	3	1
	114	3	0	1	0	0	0	0	0	1	0	0	0	1
Therapeutic measures	36	0	0	0	0	0	0	0	0	0	0	0	0	0
EVT	339	8	0	3	0	0	1	0	1	0	0	0	3	0
Surgical reconstruction	419	14	0	3	0	0	0	0	1	2	2	0	3	3
Total	794	22	0	6	0	0	1	0	2	2	2	0	6	3

EVT: endovascular treatment

**Table 5-2** Perioperative complications 1

	a. Total													
	Cardiac disease			Cerebrovascular disease			Pneumonia		Wound complication		Peripheral embolism			
	(-) Angina	Serious arrhythmia	Myocardial infarction	(-) TIA	Functional loss (-)	Functional loss (+)	(-) (+)	(-) (+)	(-) (+)	(-) (+)	Minor (including blue toe)	Major		
Local condition	Rutherford 4	0	0	3	156	0	0	154	2	149	7	155	0	1
	Rutherford 5	4	4	4	518	2	1	516	8	492	32	519	3	2
	Rutherford 6	1	0	1	113	0	0	110	3	112	1	113	0	0
	Non-reconstruction	4	0	0	4	0	0	4	0	4	0	4	0	0
	EVT	339	2	2	346	0	1	1	341	7	346	2	345	1
Therapeutic measures	Surgical reconstruction	433	2	6	437	2	0	435	6	403	38	438	2	1
	Total	776	4	8	787	2	1	780	13	753	40	787	3	3
b. ASO														
	b. ASO													
	Cardiac disease			Cerebrovascular disease			Pneumonia		Wound complication		Peripheral embolism			
	(-) Angina	Serious arrhythmia	Myocardial infarction	(-) TIA	Functional loss (-)	Functional loss (+)	(-) (+)	(-) (+)	(-) (+)	(-) (+)	Minor (including blue toe)	Major		
Local condition	Rutherford 4	0	0	3	151	0	0	149	2	145	6	150	0	1
	Rutherford 5	4	4	4	503	2	1	501	8	479	30	504	3	2
	Rutherford 6	1	0	1	112	0	0	109	3	111	1	112	0	0
	Non-reconstruction	4	0	0	4	0	0	4	0	4	0	4	0	0
	EVT	334	2	2	341	0	1	1	336	7	341	2	340	1
Therapeutic measures	Surgical reconstruction	417	2	6	421	2	0	419	6	390	35	422	2	1
	Total	755	4	8	766	2	1	759	13	735	37	766	3	3

TIA: transient ischemic attack, EVT: endovascular treatment





**Table 5-4** Hemodynamics

	Immediate after the treatment						One month after the treatment					
	ABI		Ankle pressure		SPP		ABI		Ankle pressure		SPP	
	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Local condition	76	0.83	73	114	41	30	73	0.90	72	115	18	41.5
	234	0.87	220	115.5	190	40	186	0.88	175	123	85	43
Rutherford 6	31	0.98	30	130	34	33	28	0.99	27	122	17	44
Therapeutic measures	8	0.675	6	97.5	7	19	12	0.90	12	118.5	8	27
Non-reconstruction EVT	173	0.79	161	112	133	36	133	0.86	123	116	70	41.5
Surgical reconstruction	160	0.91	156	120.5	125	41	142	0.92	139	121	46	45
Total	341	0.87	323	117	265	38	287	0.89	274	119	120	43
<b>b. ASO</b>												
	Immediate after the treatment						One month after the treatment					
	ABI		Ankle pressure		SPP		ABI		Ankle pressure		SPP	
	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Local condition	73	0.81	70	109	40	29	70	0.90	69	114	18	41.5
	230	0.86	216	115.5	188	40	184	0.88	173	123	84	43
Rutherford 6	31	0.98	30	130	33	33	28	0.99	27	122	17	44
Therapeutic measures	8	0.675	6	97.5	7	19	12	0.90	12	118.5	8	27
Non-reconstruction EVT	172	0.79	160	111.5	133	36	132	0.86	122	116	70	41.5
Surgical reconstruction	154	0.905	150	120.5	121	41	138	0.92	135	122	45	45
Total	334	0.865	316	116.5	261	38	282	0.89	269	119	119	43

ABI: ankle brachial (pressure) index, SPP: skin perfusion pressure, EVT: endovascular treatment

**Table 5-5** Condition of the limbs

a. Total

	Bypass graft/EVT condition										Clinical symptoms of the limb			Ischemic wound			Ambulatory function at discharge (Taylor's classification)		
	Good	Stenosis	Occlusion	Deterioration	Anastomosis disruption (aneurysm)	Infection	Others	Improved	No change	Deteriorated	Cured	Improved	Deteriorated	Un-known	Ambulatory	Ambulatory/homebound	Nonambulatory		
																		Un-known	Ambulatory/homebound
Local condition	142	3	5	0	0	2	0	137	19	2	105	38	8	7	115	32	20		
	477	10	27	0	2	2	4	445	62	18	97	329	92	7	295	123	134		
Rutherford 6	91	5	8	0	1	0	1	82	12	4	11	69	18	0	31	38	49		
Therapeutic measures	0	0	0	0	0	0	0	16	2	3	8	9	2	2	24	7	5		
	310	12	19	0	0	0	3	256	58	15	79	183	62	5	179	83	90		
EVT	400	6	21	0	3	4	2	392	33	6	126	244	54	7	238	103	108		
Surgical reconstruction	710	18	40	0	3	4	5	664	93	24	213	436	118	14	441	193	203		
Total																			

b. ASO

	Bypass graft/EVT condition										Clinical symptoms of the limb			Ischemic wound			Ambulatory function at discharge (Taylor's classification)		
	Good	Stenosis	Occlusion	Deterioration	Anastomosis disruption (aneurysm)	Infection	Others	Improved	No change	Deteriorated	Cured	Improved	Deteriorated	Un-known	Ambulatory	Ambulatory/homebound	Nonambulatory		
																		Un-known	Ambulatory/homebound
Local condition	138	3	5	0	0	1	0	133	19	2	103	36	8	7	111	31	20		
	466	10	23	0	2	2	4	435	62	15	95	322	88	7	286	119	132		
Rutherford 6	90	5	8	0	1	0	1	81	12	4	11	68	18	0	31	37	49		
Therapeutic measures	0	0	0	0	0	0	0	16	2	3	8	9	2	2	24	7	5		
	306	12	18	0	0	0	3	254	58	12	78	182	59	5	176	82	89		
EVT	388	6	18	0	3	3	2	379	33	6	123	235	53	7	228	98	107		
Surgical reconstruction	694	18	36	0	3	3	5	649	93	21	209	426	114	14	428	187	201		
Total																			

EVT: endovascular treatment

**Table 5-6** Revision of treatment

	Revision for those excluding good bypass graft/EVT condition										Major reintervention (revision for occlusion)										Major amputation						
	Revision for those excluding good bypass graft/EVT condition					Minor reintervention (revision for stenosis)					Thrombectomy (±patch plasty)					Thrombolysis					EVT					Major amputation	
	(+)	(-)	(-)	(-)	(-)	Patch plasty	EVT	Others	(-)	(±patch plasty)	Thrombolysis	EVT	Re-bypass	Jump bypass	Interposition	Others	(-)	Due to preoperative wound	Due to new wound								
<b>a. Total</b>																											
Local condition	7	6	150	0	2	0	0	146	1	0	0	5	0	0	0	0	157	4	1								
Rutherford 4	34	14	498	2	16	4	490	6	0	2	12	7	1	2	517	18	3										
Rutherford 5	14	2	96	0	4	1	89	4	0	2	4	1	0	1	97	10	1										
Rutherford 6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	30	2	0								
Therapeutic measures	23	14	325	1	12	1	316	0	0	3	13	4	1	2	322	18	1										
Non-reconstruction	32	8	419	1	10	4	409	11	0	1	8	4	0	1	419	12	4										
EVT	55	22	744	2	22	5	725	11	0	4	21	8	1	3	771	32	5										
Surgical reconstruction																											
Total																											
<b>b. ASO</b>																											
Revision for those excluding good bypass graft/EVT condition										Major reintervention (revision for occlusion)										Major amputation							
Revision for those excluding good bypass graft/EVT condition					Minor reintervention (revision for stenosis)					Thrombectomy (±patch plasty)					Thrombolysis					EVT					Major amputation		
(+)	(-)	(-)	(-)	(-)	Patch plasty	EVT	Others	(-)	(±patch plasty)	Thrombolysis	EVT	Re-bypass	Jump bypass	Interposition	Others	(-)	Due to preoperative wound	Due to new wound									
<b>a. Total</b>																											
Local condition	6	6	145	0	2	0	141	1	0	0	5	0	0	0	0	153	4	0									
Rutherford 4	31	13	483	2	16	4	477	5	0	2	11	7	1	2	504	17	2										
Rutherford 5	14	2	95	0	4	1	88	4	0	2	4	1	0	1	96	10	1										
Rutherford 6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	30	2	0									
Therapeutic measures	22	14	320	1	12	1	312	0	0	3	12	4	1	2	317	18	1										
Non-reconstruction	29	7	403	1	10	4	394	10	0	1	8	4	0	1	406	11	2										
EVT	51	21	723	2	22	5	706	10	0	4	20	8	1	3	753	31	3										
Surgical reconstruction																											
Total																											
<b>EVT: endovascular treatment</b>																											



**Table 5-8 Malignant neoplasm**

		Newly diagnosed malignant neoplasm													
		Sites of newly diagnosed malignant neoplasm													
Local condition	Therapeutic measures	Newly diagnosed malignant neoplasm		Unknown	Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	Breast	Uterus	Ovarium	Prostate	Others
		(-)	(+)												
Rutherford 4		165	1	1	0	0	1	0	0	0	0	0	0	0	0
Rutherford 5		546	4	2	1	0	0	1	0	0	1	0	0	0	1
Rutherford 6		118	0	0	0	0	0	0	0	0	0	0	0	0	0
Non-reconstruction		33	0	3	0	0	0	0	0	0	0	0	0	0	0
EVT		349	3	0	1	0	0	1	0	0	1	0	0	0	0
Surgical reconstruction		447	2	0	0	0	1	0	0	0	0	0	0	0	1
Total		829	5	3	1	0	1	1	0	0	1	0	0	0	1
b. ASC															
		Newly diagnosed malignant neoplasm													
		Sites of newly diagnosed malignant neoplasm													
Local condition	Therapeutic measures	Newly diagnosed malignant neoplasm		Unknown	Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	Breast	Uterus	Ovarium	Prostate	Others
		(-)	(+)												
Rutherford 4		160	1	1	0	0	1	0	0	0	0	0	0	0	0
Rutherford 5		531	4	2	1	0	0	1	0	0	1	0	0	0	1
Rutherford 6		117	0	0	0	0	0	0	0	0	0	0	0	0	0
Non-reconstruction		33	0	3	0	0	1	0	0	0	0	0	0	0	0
EVT		344	3	0	1	0	0	1	0	0	1	0	0	0	1
Surgical reconstruction		431	2	0	0	0	0	0	0	0	0	0	0	0	0
Total		808	5	3	1	0	1	1	0	0	1	0	0	0	1
EVT: endovascular treatment															