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Annual Report

2017 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), is created on the National Clinical Database (NCD) 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 EVT. In 2017, 1137 CLI limbs (male 760 limbs: 67%, female 377 limbs) were registered by 84 facilities. ASO has accounted for 98% of the pathogenesis of these limbs. In this manuscript, the background data, ischemic status, treatment and the early prognosis (within 1 month) of the registered limbs are reported. (This is a translation of Jpn J Vasc Surg 2019; 28: 415–443.)

Keywords: arterial occlusive disease, leg ischemia, peripheral arterial disease (PAD), CLI, annual report

1. Introduction

Recently, an increasing number of patients with critical limb ischemia (CLI) are undergoing medical care at clinical practice sites. Improving the outcome of treatment for these patients is an important and urgent issue. Since 2013, the Japanese Society for Vascular Surgery (JSVS) has initiated the project of a nationwide CLI registration and tracking database to obtain CLI epidemiological data that can be shared among the medical staff. The background of CLI limbs, contents of treatment, early outcome, and long-term outcome until five 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 JCLIMB project's primary objective is to clarify the current status of CLI treatment performed by vascular surgeons in Japan and inform physicians at practice sites, thus improving the quality of medical care. The initial registration data, and their tracking data one month after registration in 2013–2016, have already been published.[1–4] This article reports the basic data registered in 2017.

2. JCLIMB

Registration details, including the definition of CLI, have already been described in the 2013 annual report.[1] CLI to be registered was defined according to TASC II[5]: chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial occlusive disease. CLI diagnosis should be confirmed by ankle pressure (AP) below 50 mmHg or by toe pressure (TP) below 30 mmHg in limbs with rest pain, and done 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 five-year tracking period. When the registered limb is treated at different times or at different institutions, such data should be added only to the tracking items of each limb in JCLIMB, avoiding registration overlap. 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. Based on NCD regulations, fixing JCLIMB data is done as follows:

Initial registration data: Early April in the following year, tracking data early after treatment (one month)/six months after treatment: end of December in the following year, tracking data one year after treatment: end of December after two years.

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Tracking data two years after treatment: end of December after three years
Tracking data three years after treatment: end of December after four years
Tracking data four years after treatment: end of December after five years
Tracking data five years after treatment: end of December after six years

As a general rule, the timing of tracking data registration is accepted within a ±2-month range until 12 months after treatment, and within a ±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 is very difficult to require 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, 84 facilities, which registered CLI limbs in 2017 at the time of compiling in September 2019, are listed in the appendix.

Since JCLIMB is positioned as a registry study on NCD, patient consent to participate 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 2017

The initial registration data in 2017 were fixed in early April 2018, and the tracking data early after treatment (one month) were fixed on December 31, 2018. At that time, 1137 limbs, those of 760 males (67%) and 377 females (33%), were registered in 84 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 similar tendencies. In the comments, ASO data were presented in parentheses. In addition, because the Society for Vascular Surgery (SVS)'s WIfI classification was reported in 2014 (**Tables 1-1-1** to **1-1-3**),[6] JCLIMB made several changes and additions to the registered items, making the 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' background

Pretreatment patients' background is shown in **Tables 2-1** to **2-6**. Good blood pressure control was defined as below 140/90 mmHg, without diabetes and renal failure, or below 130/80 mmHg with these diseases. Diabetes control was considered good when hemoglobin A1c was below 7.0% (national glycohemoglobin standardization program [NGSP] value). Dyslipidemia control was considered good when low-density lipoprotein 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 heart failure based on a past history of admission due to heart failure, clinical symptoms of heart failure, a diagnosis of heart failure was confirmed by echocardiography, or reduced cardiac function on echocardiography even with no clinical heart failure symptoms. 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"[7]: Renal dysfunction was absent when the estimated glomerular filtration rate (eGFR) (mL/min/1.73 m^2) 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 5, vasculitis (Takayasu's arteritis, collagen disease, Behçet's disease, and fibromuscular dysplasia excluding TAO) in 9, and others in 9. Patients comorbidities consisted of diabetes in 62% (63%) of the limbs, hypertension in 76% (77%), dyslipidemia in 36% (36%), ischemic heart disease in 39% (40%), cerebrovascular disease in 20% (20%), dialysis for renal failure in 42% (42%), past medical history of malignant neoplasm or that being treated in 9% (9%), and arterial occlusive lesions in the contralateral limb in 78% (79%).

(2) Conditions of limb ischemia

Limb ischemia pretreatment conditions are shown in **Tables 3-1** to **3-6**. Regarding the walking function (Taylor classification),[8] patients who could 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),[9] the most severe lesion, the main treatment target, 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. To perform WIfI classification, the sites of ulcer and gangrene were registered separately. Although SPP is widely used as an objective index for evaluating 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 SPP = 0.6853 TP + 14.48 from the correlation data of SPP and TP reported in Japan,[10] and applied for WIfI ischemic grading (**Table 1-2-2**).

The lesion was considered 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, and 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 based on the size of the erythema around the ulcer, ≦ 2 or >2 cm.

Systemic inflammatory response syndrome (SIRS), indicating systemic infection, was manifested by two or more of the following signs: temperature >38°C or <36°C, heart rate >90 beats/min, respiratory rate >20 breaths/min or $PaCO_2$ <32 mmHg, white blood cell count >12,000 or <4,000 cu/mm or 10% immature (band) forms. The arteries in the ankle joint region were classified as foot arteries.

In pretreatment, 58% (58%) of the patients were ambulatory, 22% (22%) were ambulatory/homebound, and 19% (20%) were non-ambulatory. On the Rutherford classification (R),[11] limbs with categories R4, R5, and R6 accounted for 19% (19%), 66% (65%), and 15% (15%) of the limbs, respectively. The median ankle brachial index (ABI), the toe brachial index (TBI), and the SPP of the measured limbs were 0.64 (0.63), 0.32 (0.32), and 22 mmHg (22 mmHg), respectively. The occlusive legion was located in the aortoiliac artery in 21% (21%) of the limbs, in the femoropopliteal artery in 64% (64%) of the limbs, and in the crural or foot artery in 59% (59%) of the limbs. The multiple occlusive lesions were located in the aortoiliac artery and the femoropopliteal artery in 13% (13%) of limbs, in the aortoiliac artery and the crural or foot artery in 6% (6%), in the femoropopliteal artery and the crural or foot artery in 30% (31%), and in the aortoiliac artery and the femoropopliteal artery and the crural or foot artery in 5% (5%).

We were able to apply the WIfI classification with sufficient data to 875 limbs (855 limbs). On the WIfI classification, limbs with the stages 1, 2, 3, and 4 accounted for 11% (10%), 20% (20%), 27% (27%), and 42% (42%) of the limbs, respectively.

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

In **Table 3-6**, there was some dissociation between the R and Wound grades. This may be because of the R grade's obscure definition. For example, extensive gangrene involving the forefoot is classified in R5 and W3, while a shallow ulcer without exposure of the distal leg bone is classified in R6 and W1.

In **Table 3-6**, 88 limbs (86 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 56 mmHg or more in JCLIMB) or AP higher than 100 mmHg, or if arterial calcification precludes reliable AP or TP measurements, $TcPO_2$ 60 mmHg or more (**Table 1-1-2**). There should be no limb with Ischemic grade 0 since CLI registered in JCLIMB is defined according to TASC II. The limbs might be clinically judged to be CLI irrespective of the objective ischemic index, although details are unknown.

In **Table 3-6**, there were 17 limbs (17 limbs) in which infection was confirmed in R4 limbs, despite the absence of a local wound by definition of R4. This may occur because tissue loss is not always requisite for fI grade.

In **Table 3-6**, because ischemic grade data were registered in only 875 limbs (855 limbs) among 1137 limbs (1114 limbs), WIfI classification could be implemented for these 875 limbs (855 limbs). In the remaining 262 limbs (259 limbs), the data on TBI, SPP, or ABI in these limbs were registered as unmeasurable or unmeasured. The limbs clinically judged to be CLI could be registered without their objective ischemic index.

(3) Treatment

Tables 4-1 to **4-6** show the CLI treatment data. Revascularizations of the affected limbs were performed in 95% (96%) of the registered limbs, and primary major amputations were performed in 2.3% (2.3%) of the registered limbs. Among the surgical reconstruction procedures, distal bypass accounted for 45% (44%). Endovascular treatment (EVT), including EVT alone and hybrid treatment with surgical reconstruction, accounted for 56% (57%) of the total revascularization procedures. EVT applied to the crural or foot artery accounted for 36% (36%) of the total EVT.

The problems and considerations on these spreadsheets are described below. In **Table 4-1**, the sum of the number of cells in treatment is larger than the number of registered limbs, 1137 (1114), because more than one treatment method can be selected. In **Table 4-1**, angiogenic therapy was performed in one limb. However, there was no record in detail of angiogenic therapy because of "unused." The discrepancy in the number of major amputation to the number of detail of amputation was caused by the same reason. In the column of "vein usage" of **Table 4-3**, how

the autologous veins were used were described when they were selected as vascular conduits. The sum of the number in the column of 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 could be because of selecting multiple vein usage for arterial reconstruction in a limb. Two veins were used in 16 limbs and three veins were used in one limb. Vascular prosthesis (−) included an endarterectomy without a patch angioplasty. In **Table 4-4**, the sum of the number of proximal anastomosis is not equal to the sum of the number of distal anastomosis. This was because multiple arteries could be selected in each anastomosis. The sum of the number of distal (crural/foot) bypass in **Table 4-2** is not equal to the sum of the number of distal anastomosis in **Table 4-4**. This was because multiple anastomosis sites could be selected in distal bypass in **Table 4-4**, though either femoral-crural/foot or popliteal-crural/foot was selected in bypass in **Table 4-2**. In R-5, the sum of the number of crural/foot bypass 217 (207) in **Table 4-2** is larger than that of distal anastomosis in **Table 4-4**. This was because both femoral-crural/foot and popliteal-crural/foot were recorded in **Table 4-2** and only "foot" of distal anastomosis in **Table 4-4** was recorded.

Table 4-6 summarizes the vascular grafts used for the infrainguinal arterial reconstruction. For example, the total number of vascular graft in the column of femoral-proximal popliteal artery bypass was 100 (98), which was higher than 87 (87), the number of actual applications in **Table 4-2**. This was because multiple graft materials could be selected when multiple procedures such as a bypass procedure and TEA can be performed simultaneously for arterial reconstruction in a lower limb. A composite bypass (prosthetic graft + vein) might be recorded into two grafts. When TEA without patch angioplasty was performed, "unused" was selected.

(4) Outcomes early (one month) after treatment

Tables 5-1 to **5-8** show the outcomes of early (one month) after treatment. At the time of summary count at the end of March 2019, follow-up data one month after treatment were obtained in 961 limbs (85%), including 940 limbs (94%) with ASO. Data were collected according to the severity of the local limb conditions (Rutherford classification) and treatment measures (EVT alone or surgical reconstruction with/without EVT). The mortality was 3.5% (3.6%) in the whole series, and 4.7% (4.7%) and 2.3% (2.4%) treated by EVT alone and by surgical reconstruction with/without EVT, respectively. The most common cause of death was cardiac disease and infection, both of which accounted for 24% (24%) of all deaths. Postoperative complications were cardiac disease in 2.1% (2.2%), cerebrovascular disease in 1.1% (1.1%), pneumonia in 1.6% (1.6%), and wound complication in 4.8% (4.5%). Complications at the puncture site were noted in 0.7% (0.7%) of the limbs treated by EVT alone.

The median ABI and SPP of the measured limbs, immediately after treatment and one month after treatment, were 0.87 (0.87) and 0.92 (0.92) and 42 (42) mmHg and 47 (47) mmHg, respectively. Stenosis, occlusion, infection, or other trouble occurred after revascularization by EVT alone in 9.4% (9.4%) and by surgical reconstruction with/without EVT in 6.5% (5.9%). Secondary major amputation rate was 6.8% (6.8%) in EVT alone and 2.9% (2.8%) in surgical reconstruction with/without EVT. When ambulatory function at discharge was compared to that before surgery, the rate of patients with ambulatory changed from 58% (58%) to 50% (50%), ambulatory/homebound from 22% (22%) to 22% (22%), and non-ambulatory from 19% (20%) to 27% (27%).

The problems, comments, and considerations on these spreadsheets are described below. The number of "bypass graft/EVT condition," "clinical limb symptoms," "ischemic wound," and "ambulatory function at discharge" did not match (**Table 5-5**). The total number of "ambulatory function at discharge" was 960 (939), which was equal to the number of life prognoses after exclusion of one intraoperative death (**Table 5-1**), indicating no "unused." The number of "bypass graft/EVT condition" was not equal to the number of "ambulatory function at discharge" because the objectives of "bypass graft/EVT condition" were limbs of survivors with arterial reconstruction and because more than one condition could be selected. The number of "clinical symptoms of limb" and "ischemic wound" were not identical. They must be identical because their objectives were survivor without major amputations. This is speculated to be due to the presence of "unused." The discrepancy in the total number of "life prognosis," "clinical limb symptom" and "amputation" is due to the difference of condition for aggregation of data. In **Table 5-3**, the registration of complication at puncture site in non-reconstruction and surgical reconstruction seems to be odd. The registration of complication at puncture site was required in limbs where PTA/STENT was selected in the revascularization method. Since multiple treatment methods can be selected, complications at the puncture site was registered in non-reconstruction and surgical reconstruction.

The number of limbs of survivors with EVT was 384 (382 limbs) (**Table 5-1**), which was 15 (15) limbs less than the sum of the number in the column of minor reintervention or major reintervention in the row of limbs with EVT; 399 limbs (397 limbs) (**Table 5-6**). The number of limbs of survivors with surgical reconstruction was 505 (487 limbs) (**Table 5-1**), which was 7 (7) limbs less than the sum of the number in the column of minor reintervention

or major reintervention in the row of limbs with surgical reconstruction; 512 limbs (494 limbs) (**Table 5-6**). This is speculated to be due to death after reintervention. In **Table 5-5**, the number of "clinical symptoms of limb and "ischemic wound" does not match, which was obtained regardless accurate aggregation of input data and the reason is unknown. In **Table 5-6**, the objective for input of "revision for those excluding good bypass graft/EVT condition" is limb registered in stenosis, occlusion, deterioration, anastomosis disruption (aneurysm), infection, others of "bypass graft/EVT condition." The total number of "the contralateral limb occlusive lesions" in **Table 5-7** is equal to that of "life prognosis" in **Table 5-1.** The information of contralateral limb at death was registered in a dead case. The sum of the number of "treatment for contralateral limb" is less than that of "the contralateral limb occlusive lesions" because the objectives of "treatment for contralateral limb" excluded the limbs of (-) in "the contralateral limb occlusive lesions." Since multiple registration was possible, the sum of the number of "treatment for contralateral limb" was more than that of (-) in "the contralateral limb occlusive lesions." When a patient died within one month, the information of "newly diagnosed malignant neoplasm" at death was registered in **Table 5-8**.

In addition to the above, there were some parts where the total number does not match in **Tables 5-1** to **5-8**. It might be because several items had multiple choices or missing values.

4. Conclusion

Vascular surgeons' contribution in participating facilities registered a sufficient amount of detailed data during busy clinical practice, which has been gradually clarifying the current status of CLI treatment in Japan. Data on CLI in 2017 were clarified, after annual data in 2013–2016. The JCLIMB Committee is planning to continue publishing an annual report in the future. In 2017, the new concept, "chronic limb threatening ischemia," was proposed instead of CLI[12] and a new clinical guideline, the Global Vascular Guideline, was published instead of TASC in 2019.[13] The JCLIMB Committee ought to revise the survey items according to the Global Vascular Guideline and a new registration form, which can be used in 2021, is being prepared.

The JCLIMB Committee expects these study results will be fed back to clinical situations to help develop medical care for CLI and clinical studies using these data are ongoing. Facilities can participate in JCLIMB at any time by contacting the JSVS secretariat for details.

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

5. Participant Facilities (84 Facilities in the Order of the Japanese Syllabary by Prefecture, 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, Steel Memorial Muroran Hospital
Department of Cardiovascular Surgery, Nayoro City General Hospital
Department of Cardiovascular Surgery, Hirosaki University Hospital
Department of Surgery, Iwate Prefectural Iwai Hospital
Department of Surgery, Iwate Prefectural Isawa Hospital
Department of Surgery, Iwate Prefectural Chubu Hospital
Department of Vascular Surgery, Morioka Yuai Hospital
Department of Surgery, Karita General Hospital
Department of Surgery, JR Sendai Hospital
Department of Cardiovascular Surgery, Sendai City Hospital
Department of Transplantation, Reconstruction and Endoscopic Surgery, Tohoku University Hospital
Department of Cardiovascular Surgery, Saiseikai Yamagata Saisei Hospital
Department of Cardiovascular Surgery, Southern TOHOKU General Hospital
Department of Vascular and Endovascular Surgery, Ibaraki Prefectural Central 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 Vascular Surgery, Saiseikai Kawaguchi General Hospital
Department of Vascular Surgery, Saitama Medical Center, Saitama Medical University
Department of Cardiovascular Surgery, Saitama Medical Center, Jichi Medical University
Department of Cardiovascular Surgery, Jichi Medical University
Department of Cardiovascular Surgery, Tokorozawa Meisei Hospital
Department of Surgery, Saitama City Hospital
Department of Cardiac and Vascular Surgery, National Defense Medical College Hospital
Department of Cardiovascular Surgery, Shimada General Hospital

Department of Cardiovascular Surgery, Chiba Cerebral and Cardiovascular Center
Department of Cardiovascular Surgery, Itabashi Chuo Medical Center
Department of Cardiovascular Surgery, IMS Tokyo Katsushika General Hospital
Department of Surgery, Tokyo Metropolitan Health and Medical Treatment Corporation, Okubo Hospital
Department of Cardiovascular Surgery, Kyorin University
Department of Surgery, Keio University School of Medicine
Department of Vascular Surgery, International University of Health and Welfare, Mita Hospital
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, Nihon University Itabashi Hospital
Department of Surgery, Shonankamakura General Hospital
Department of Vascular Surgery, Kawasaki Municipal Hospital
Department of Cardiovascular Surgery, St. Marianna University School of Medicine
Department of Surgery, Tomei Atsugi Hospital
Department of Cardiovascular Surgery, Yokosuka General Hospital Uwamachi
Department of Cardiovascular Surgery, National Hospital Organization, Kanazawa Medical Center
Department of Vascular Surgery, Aichi Medical University Hospital
Department of Vascular Surgery, Ichinomiya Municipal Hospital
Department of Vascular Surgery, Japanese Red Cross Nagoya Daiichi Hospital
Department of Vascular Surgery, Nagoya University Hospital
Department of Vascular Surgery, Aijinkai Inoue Hospital
Department of Vascular Surgery, Kansai Medical University Medical Center
Department of Cardiovascular Surgery, Toyonaka Municipal Hospital
Department of Surgery, Shinsuma General Hospital
Department of Cardiovascular Surgery, Tsukazaki Hospital
Department of Thoracic and Cardiovascular Surgery, Wakayama Medical University Hospital
Department of Cardiovascular Surgery, Tottori Prefectural Kousei Hospital
Department of Cardiovascular Surgery, Tottori Prefectural Central Hospital
Department of Cardiovascular Surgery, Okayama University Hospital
Department of Cardiovascular Surgery, Kawasaki Medical School Hospital
Department of Cardiovascular Surgery, The Sakakibara Heart Institute of Okayama
Department of Cardiovascular and Respiratory Surgery, Hiroshima Prefectural Hospital
Department of Cardiovascular Surgery, National Hospital Organization, Higashihiroshima Medical Center
Department of Surgery, Hiroshima Red Cross Hospital & Atomic-bomb Survivors Hospital
Department of Cardiovascular Surgery, Hiroshima University Hospital
Department of Surgery, Saiseikai Yamaguchi General Hospital
Department of Surgery 1, Yamaguchi University Hospital
Department of Cardiovascular Surgery, Ehime Prefectural Central Hospital
Department of Cardiovascular Surgery, Matsuyama Shimin Hospital
Department of Vascular Surgery, Matsuyama Red Cross Hospital
Department of Cardiovascular Surgery, Kochi Health Sciences Center
Department of Surgery 2, Kochi University Hospital
Department of Vascular Surgery, National Hospital Organization, Kyushu Medical Center
Department of Vascular Surgery, Kyushu University Hospital
Department of Cardiovascular Surgery, Kurume University Hospital
Department of Vascular Surgery, Kokura Memorial Hospital
Department of Surgery, Saiseikai Fukuoka General Hospital
Department of Vascular Surgery, Fukuoka City Hospital
Department of Surgery, Saiseikai Karatsu Hospital
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6. JCLIMB Committee, NCD JCLIMB Analytical Team

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Disclosure Statement

The authors have no conflict of interest.

Additional Remarks

This report was authorized by the institutional review board of Saiseikai Yahata General Hospital (Authorization No. 140).

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Table 1-1 SVS WIfI classification original[6)]

Table 1-1-1 Wound

Grade	Ulcer	Gangrene
0	No ulcer No gangrene	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; Gangrenous changes limited to digits shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
	Clinical description: major tissue loss salvageable with multiple (3) digital amputations or standard TMA±skin coverage.	
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer±calcaneal involvement	Extensive gangrene involving forefoot and/or midfoot; full thickness heel necrosis 6 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, $TcPO_2$ (mmHg)
0	≥0.80	>100	≥60
1	0.60–0.79	70–100	40–59
2	0.40–0.59	50–70	30–39
3	≤0.39	<50	<30

ABI: ankle brachial (pressure) index, PVR: pulse volume recording, SPP: skin perfusion pressure, TP: toe pressure, $TcPO_2$: transcutaneous oximetry

Patients with diabetes should have TP measurements. If arterial calcification precludes reliable ABI or TP measurements, ischemia should be documented by $TcPO_2$, SPP, PVR. If TP and ABI measurements result or 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	IDSA/PEDIS Infection severity*
0	No symptoms or signs of infection	Uninfected
1	Infection present, as defined by the presence of at least 2 of the following items: ·Local swelling or induration ·Erythema >0.5 to 2 cm around the ulcer ·Local tenderness or pain ·Local warmth ·Purulent discharge (thick, opaque to white, or sanguineous secretion) Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). Exclude other causes of an inflammatory response of the skin (e.g., trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis)	Mild
2	Local infection (as described above) with erythema >2 cm, 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: ·Temperature >38°C or <36°C ·Heart rate >90 beats/min ·Respiratory rate >20 breaths/min or $PaCO_2$ <32 mmHg ·White blood cell count >12,000 or <4,000 cu/mm or 10% immature (band) forms	Severe

*SVS adaptation of Infectious Diseases Society of America (IDSA) and International Working Group on the Diabetic Foot (IWGDF) perfusion, extent/size, $PACO_2$: Partial pressure of arterial carbon dioxide, SIRS: systemic inflammatory response syndrome
An ischemia may complicate and increase the severity of any infection. Systemic infection may sometimes manifest with other clinical findings, such as hypo-tension, confusion, vomiting, or evidence of metabolic disturbances, such as acidosis, severe hyperglycemia, new-onset azotemia.

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

Table 1-2-1 Wound

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

Table 1-2-2 Ischemia

Grade	SPP: (mmHg; calculating from the formula*)
0	>55
1	42–55
2	35–41
3	<35

*SPP=0.6853XTP+14.48
SPP: skin perfusion pressure, TP: toe pressure

Table 1-2-3 Foot infection

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

Table 2-1 Patients' back ground 1

a. Total

	n	Sex		Laterality		BMI (Median)	Pathogenesis				Age at registration				Age at registration			
		Male	Female	Right	Left		ASO	TAO	Vasculitis	Others	ASO Mean (±SD)	TAO Mean (±SD)	Vasculitis Mean (±SD)	Others Mean (±SD)	ASO Mean (±SD)	TAO Mean (±SD)	Vasculitis Mean (±SD)	Others Mean (±SD)
Rutherford 4	221	151	70	106	115	21.6	216	0	2	3	74.9	(9.6)	—	—	69.0	(4.2)	65.3	(14.4)
Rutherford 5	744	501	243	365	379	21.1	727	5	7	5	74.5	(10.2)	48.8	(7.6)	57.6	(9.5)	71.2	(8.7)
Rutherford 6	172	108	64	83	89	20.4	171	0	0	1	72.9	(9.9)	—	—	—	—	84.0	—
Total	1137	760	377	554	583	21.1	1114	5	9	9	74.3	(10.0)	48.8	(7.6)	60.1	(9.8)	70.7	(11.1)

b. ASO

	n	Sex		Laterality		BMI (Median)	Age at registration
		Male	Female	Right	Left		Mean (±SD)
Rutherford 4	216	148	68	104	112	21.6	74.9 (9.6)
Rutherford 5	727	491	236	359	368	21.1	74.5 (10.2)
Rutherford 6	171	107	64	83	88	20.4	72.9 (9.9)
Total	1114	746	368	546	568	21.1	74.3 (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, BM: body mass index, TEVAR: thoracic endovascular aortic/aneurysm repair, EVAR: endovascular aortic/aneurysm repair

Table 2-2 Patients' back ground 2

a. Total

	Diabetes			Diabetes therapy			Hypertension			Dyslipidemia			Smoking		
	(−)	(+)		Diet therapy	Medication	Insulin therapy	(−)	(+)		(−)	(+)		(−)	(+)	
		Management						Management			Management			Ex-smoker	Current smoker
		Good	Poor					Good	Poor		Good	Poor			
Rutherford 4	99	93	29	15	72	35	41	151	29	132	79	10	75	110	36
Rutherford 5	276	367	101	57	237	174	193	485	66	482	225	37	314	328	102
Rutherford 6	56	80	36	15	58	43	39	102	31	114	51	7	75	77	20
Total	431	540	166	87	367	252	273	738	126	728	355	54	464	515	158

b. ASO

	Diabetes			Diabetes therapy			Hypertension			Dyslipidemia			Smoking		
	(−)	(+)		Diet therapy	Medication	Insulin therapy	(−)	(+)		(−)	(+)		(−)	(+)	
		Management						Management			Management			Ex-smoker	Current smoker
		Good	Poor					Good	Poor		Good	Poor			
Rutherford 4	94	93	29	15	72	35	39	149	28	128	79	9	73	107	36
Rutherford 5	263	363	101	54	237	173	182	480	65	468	222	37	308	321	98
Rutherford 6	55	80	36	15	58	43	39	101	31	113	51	7	75	77	19
Total	412	536	166	84	367	251	260	730	124	709	352	53	456	505	153

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' back ground 3

a. Total

	Ischemic heart disease				Heart failure		Cerebrovascular disease		Renal dysfunction					
	(−)	(+)			(−)	(+)	(−)	(+)	(−)	(+)				
		Medical treatment	PCI	CABG						G3a	G3b	G4	G5	G5D
Rutherford 4	142	23	33	23	192	29	187	34	108	17	16	10	1	69
Rutherford 5	458	73	127	86	636	108	594	150	259	61	68	25	6	325
Rutherford 6	88	26	32	26	133	39	129	43	54	18	15	3	2	80
Total	688	122	192	135	961	176	910	227	421	96	99	38	9	474

b. ASO

	Ischemic heart disease				Heart failure		Cerebrovascular disease		Renal dysfunction					
	(−)	(+)			(−)	(+)	(−)	(+)	(−)	(+)				
		Medical treatment	PCI	CABG						G3a	G3b	G4	G5	G5D
Rutherford 4	137	23	33	23	187	29	182	34	106	15	15	10	1	69
Rutherford 5	444	72	125	86	619	108	577	150	246	59	67	25	6	324
Rutherford 6	88	25	32	26	133	38	128	43	53	18	15	3	2	80
Total	669	120	190	135	939	175	887	227	405	92	97	38	9	473

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/1.73 m^2) 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' back ground 4

a. Total

	Malignant neoplasm				Sites of malignant neoplasm										
	(−)	(+)			Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	Breast	Uterus	Ovarium	Prostate	Others
		History of cancer	Under treatment*	Unknown											
Rutherford 4	197	15	7	2	1	1	2	2	2	9	3	1	0	1	5
Rutherford 5	674	51	17	2	2	3	11	9	6	14	4	1	0	14	13
Rutherford 6	162	8	2	0	0	0	1	0	2	4	0	0	0	0	3
Total	1033	74	26	4	3	4	14	11	10	27	7	2	0	15	21

b. ASO

	Malignant neoplasm				Sites of malignant neoplasm										
	(−)	(+)			Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	Breast	Uterus	Ovarium	Prostate	Others
		History of cancer	Under treatment*	Unknown											
Rutherford 4	193	14	7	2	1	1	2	2	2	8	3	1	0	1	5
Rutherford 5	658	51	16	2	2	3	11	9	5	14	4	1	0	14	13
Rutherford 6	161	8	2	0	0	0	1	0	2	4	0	0	0	0	3
Total	1012	73	25	4	3	4	14	11	9	26	7	2	0	15	21

*Including palliative therapy or recurrence.

Table 2-5 Patients' back ground 5

a. Total

	Contralateral limb occlusive lesions												Vascular lesions excluding occlusion					
	(−)	(+)																
		Asymptomatic	Intermittent claudication	CLI			Post-treatment	ABI		TBI		SPP		(−)	TAA	AAA (including IAA)	Peripheral artery aneurysm	Carotid stenosis	Others
				R4	R5	R6		n	Median	n	Median	n	Median						
Rutherford 4	62	51	20	37	5	0	46	176	0.81	26	0.62	77	35.0	200	0	8	1	11	1
Rutherford 5	156	207	53	23	143	7	155	525	0.77	65	0.35	334	37.0	684	8	13	2	19	18
Rutherford 6	30	45	10	3	15	30	39	83	0.82	10	0.37	53	42.0	162	1	6	0	3	0
Total	248	303	83	63	163	37	240	784	0.78	101	0.39	464	37.0	1046	9	27	3	33	19

b. ASO

	Contralateral limb occlusive lesions												Vascular lesions excluding occlusion					
	(−)	(+)																
		Asymptomatic	Intermittent claudication	CLI			Post-treatment	ABI		TBI		SPP		(−)	TAA	AAA (including IAA)	Peripheral artery aneurysm	Carotid stenosis	Others
				R4	R5	R6		n	Median	n	Median	n	Median						
Rutherford 4	61	48	20	36	5	0	46	171	0.81	26	0.62	75	35.0	196	0	7	1	11	1
Rutherford 5	146	205	53	23	139	7	154	510	0.76	65	0.35	326	37.0	669	7	13	1	19	18
Rutherford 6	30	45	10	2	15	30	39	83	0.82	10	0.37	53	42.0	162	1	5	0	3	0
Total	237	298	83	61	159	37	239	764	0.78	101	0.39	454	37.0	1027	8	25	2	33	19

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

Table 2-6 Patients' back ground 6

a. Total

	Fatty acid							
	Arachidonic acid (AA)		Eicosapentaenoic acid (EPA)		Docosahexaenoic acid (DHA)		EPA/AA	
	n	Median	n	Median	n	Median	n	Median
Rutherford 4	6	162.9	6	59.0	6	118.2	6	0.4
Rutherford 5	22	168.1	22	42.4	22	96.2	22	0.3
Rutherford 6	4	158.1	4	83.3	4	179.2	4	0.5
Total	32	163.6	32	47.2	32	100.0	32	0.3

b. ASO

	Fatty acid							
	Arachidonic acid (AA)		Eicosapentaenoic acid (EPA)		Docosahexaenoic acid (DHA)		EPA/AA	
	n	Median	n	Median	n	Median	n	Median
Rutherford 4	6	162.9	6	59.0	6	118.2	6	0.4
Rutherford 5	21	164.6	21	40.8	21	95.2	21	0.2
Rutherford 6	4	158.1	4	83.3	4	179.2	4	0.5
Total	31	162.6	31	44.0	31	99.8	31	0.3

Table 3 Pretreatment condition

Table 3-1 Pretreatment condition 1

a. Total

	Ambulatory function (Taylor's classification)			Sites of ulcer							Depth of ulcer (University of Texas classification: grade)			Sites of gangrene							Main sites of ulcer/gangrene to be treated					
	Ambulatory	Ambulatory/homebound	Nonambulatory	Digits	Foot: distal metatarsal	Foot: proximal metatarsal	Heel	Ankle	Lower leg	Only gangrene w/o ulcer	I	II	III	Digits	Foot: distal metatarsal	Foot: proximal metatarsal	Heel	Ankle	Lower leg	Only ulcer w/o gangrene	Toe	Foot: distal metatarsal	Foot: proximal metatarsal	Heel	Ankle	Lower leg
Rutherford 4	168	29	24																							
Rutherford 5	442	169	133	580	78	25	57	17	13	67	472	139	133	377	47	12	30	8	5	336	605	66	15	37	10	11
Rutherford 6	55	54	63	60	37	41	54	18	16	29	45	49	78	60	44	29	41	12	13	44	31	38	24	48	12	19
Total	665	252	220	640	115	66	111	35	29	96	517	188	211	437	91	41	71	20	18	380	636	104	39	85	22	30

b. ASO

	Ambulatory function (Taylor's classification)			Sites of ulcer							Depth of ulcer (University of Texas classification: grade)			Sites of gangrene							Main sites of ulcer/gangrene to be treated					
	Ambulatory	Ambulatory/homebound	Nonambulatory	Digits	Foot: distal metatarsal	Foot: proximal metatarsal	Heel	Ankle	Lower leg	Only gangrene w/o ulcer	I	II	III	Digits	Foot: distal metatarsal	Foot: proximal metatarsal	Heel	Ankle	Lower leg	Only ulcer w/o gangrene	Toe	Foot: distal metatarsal	Foot: proximal metatarsal	Heel	Ankle	Lower leg
Rutherford 4	164	28	24																							
Rutherford 5	428	166	133	565	77	25	57	17	12	67	458	139	130	368	46	12	30	8	5	329	590	65	15	37	10	10
Rutherford 6	55	53	63	59	36	40	53	17	15	29	44	49	78	59	43	28	40	11	12	44	31	38	24	48	12	18
Total	647	247	220	624	113	65	110	34	27	96	502	188	208	427	89	40	70	19	17	373	621	103	39	85	22	28

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

a. Total

	Temperature ≧38°		Blood test								Hemodynamics								Infection*1)					
			WBC		CRP		Alb		Cr		ABI		TBI		SPP		Toe pressure		Local (foot)				Systemic	
	(−)	(+)	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	Uninfected	Skin or subcutaneous tissue (erythema)*2)		Deep tissue*3)	SIRS*4)	
																				≦2.0cm	>2.0cm		(+)	(−)
Rutherford 4	218	3	213	6,670	209	0.39	183	3.60	213	1.13	121	0.57	14	0.50	94	20.00	13	66.0	204	13	4	0	2	219
Rutherford 5	722	22	734	7,100	717	1.07	682	3.40	734	1.50	460	0.65	30	0.24	460	23.00	29	35.0	506	167	26	45	13	731
Rutherford 6	152	20	168	9,115	167	3.74	155	2.90	169	1.50	75	0.67	6	0.17	75	24.00	6	26.0	75	31	20	46	19	153
Total	1092	45	1115	7,200	1093	1.08	1020	3.40	1116	1.36	656	0.64	50	0.32	629	22.00	48	39.0	785	211	50	91	34	1103

b. ASO

	Temperature ≧38°		Blood test								Hemodynamics								Infection*1)					
			WBC		CRP		Alb		Cr		ABI		TBI		SPP		Toe pressure		Local (foot)				Systemic	
	(−)	(+)	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	Uninfected	Skin or subcutaneous tissue (erythema)*2)		Deep tissue*3)	SIRS*4)	
																				≦2.0cm	>2.0cm		(+)	(−)
Rutherford 4	213	3	208	6,685	204	0.4	178	3.7	208	1.17	117	0.57	14	0.50	90	20.00	13	66.0	199	13	4	0	2	214
Rutherford 5	705	22	717	7,100	700	1.055	666	3.4	717	1.60	446	0.64	30	0.24	448	23.00	29	35.0	493	164	26	44	13	714
Rutherford 6	152	19	167	9,100	166	3.765	154	2.85	168	1.56	75	0.67	6	0.17	75	24.00	6	26.0	74	31	20	46	19	152
Total	1070	44	1092	7,200	1070	1.075	998	3.4	1093	1.41	638	0.63	50	0.32	613	22.00	48	39.0	766	208	50	90	34	1080

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

*1) Presence of infection is defined by the presence of at least 2 of the following items: ①Local swelling or induration, ②Erythema >0.5 to ≦2cm around the ulcer, ③Local tenderness or pain, ④Local warmth, ⑤Purulent discharge (thick, opaque to white, or sanguineous secretion).

*2) Local infection at skin and subcutaneous tissue was classified by the spreading of erythema (≦2.0cm or >2cm) around the ulcer/gangrene.

*3) Local infection involving structures deeper than skin and subcutaneous tissues (e.g., abscess, osteomyelitis, septic arthritis, fasciitis).

*4) The signs of SIRS are manifested by two or more of the following: ①Temperature >38 or <36°C, ②Heart rate >90 beats/min, ③Respiratory rate >20 breaths/min or $PaCO_2$<32mmHg, ④White blood cell count >12,000 or <4000 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	134	118	20	57	159	91	11	9	7	25	2	11	32	40	88	16
Rutherford 5	528	323	28	151	469	452	42	27	23	48	6	85	94	105	263	126
Rutherford 6	123	66	12	33	99	130	11	5	2	14	0	22	24	26	54	27
Total	785	507	60	241	727	673	64	41	32	87	8	118	150	171	405	169

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	131	114	20	55	156	88	11	9	7	23	2	10	32	39	86	15
Rutherford 5	515	316	28	150	461	442	42	27	23	47	6	84	94	104	256	120
Rutherford 6	122	66	12	33	98	129	11	5	2	14	0	22	24	26	53	27
Total	768	496	60	238	715	659	64	41	32	84	8	116	150	169	395	162

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
Rutherford 4	114	1.5	113	2	115	6	114	13	113	3	113	3	109	3
Rutherford 5	440	1	441	1	448	3	448	4	443	3	447	2	440	3
Rutherford 6	100	1	100	1	103	3	103	4	104	3	106	2	105	3
Total	654	1	654	1	666	4	665	5	660	3	666	2	654	3

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
Rutherford 4	113	2	112	2	114	6	113	13	112	3.5	112	3	108	3
Rutherford 5	430	1	431	1	438	3	438	5	433	3	437	2	430	3
Rutherford 6	100	1	100	1	103	3	103	4	104	3	106	2	105	3
Total	643	1	643	1	655	4	654	5	649	3	655	2	643	3

Table 3-5 Pretreatment condition 5

a. Total

	Bollinger Score													
	Posterior tibial: proximal		Posterior tibial: distal		Anterior tibial: proximal		Anterior tibial: distal		Peroneal: proximal		Peroneal: distal		Foot	
	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4	110	9	109	6	111	13	108	12	110	5	108	6	91	5
Rutherford 5	439	13	437	13	440	13	431	13	438	6	429	6	360	9
Rutherford 6	106	13	101	13	106	13	100	13	105	5	100	5	82	13
Total	655	13	647	13	657	13	639	13	653	5	637	5	533	6

b. ASO

	Bollinger Score													
	Posterior tibial: proximal		Posterior tibial: distal		Anterior tibial: proximal		Anterior tibial: distal		Peroneal: proximal		Peroneal: distal		Foot	
	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median	n	Median
Rutherford 4	109	8	108	6	110	13	107	12	109	5	107	6	90	4.5
Rutherford 5	429	13	427	13	430	13	421	13	428	5	419	5	351	8
Rutherford 6	106	13	101	13	106	13	100	13	105	5	100	5	82	13
Total	644	13	636	13	646	13	628	13	642	5	626	5	523	6

Table 3-6 SVS WIfI classification

a. Total

	Wound				Ischemia				Foot infection				Stage			
	0	1	2	3	0	1	2	3	0	1	2	3	1	2	3	4
Rutherford 4	221	0	0	0	14	29	28	90	204	13	4	0	40	112	9	0
Rutherford 5	0	278	369	97	63	84	71	389	506	163	67	8	52	64	206	285
Rutherford 6	0	17	29	126	11	17	12	67	75	29	49	19	0	2	19	86
Total	221	295	398	223	88	130	111	546	785	205	120	27	92	178	234	371

b. ASO

	Wound				Ischemia				Foot infection				Stage			
	0	1	2	3	0	1	2	3	0	1	2	3	1	2	3	4
Rutherford 4	216	0	0	0	14	28	28	86	199	13	4	0	39	108	9	0
Rutherford 5	0	271	360	96	61	83	69	379	493	160	66	8	50	62	204	276
Rutherford 6	0	17	29	125	11	17	12	67	74	29	49	19	0	2	19	86
Total	216	288	389	221	86	128	109	532	766	202	119	27	89	172	232	362

Table 4 Treatment

Table 4-1 Treatment 1

a. Total

	Treatment					Angiogenic therapy			Amputation							Reoperation				
	Pharmacological therapy	Angiogenic therapy	Arterial reconstruction	Major amputation	Lumber sympathectomy	Bone marrow	Peripheral blood	Others	Toe	Metatarsal	Chopart· Lisfranc	Syme	Below knee	Above knee· knee disarticulation	Hip disarticulation	Unknown	(−)	(+)		
																		:1X	2X	3X≦
Rutherford 4	90	1	203	2	0	0	0	0	0	0	0	0	0	0	0	0	158	42	7	14
Rutherford 5	259	0	719	8	1	0	0	0	17	3	0	0	1	2	0	3	569	98	34	40
Rutherford 6	60	0	160	16	1	0	0	0	0	1	0	0	4	4	0	1	144	15	5	7
Total	409	1	1082	26	2	0	0	0	17	4	0	0	5	6	0	4	871	155	46	61

b. ASO

	Treatment					Angiogenic therapy			Amputation							Reoperation				
	Pharmacological therapy	Angiogenic therapy	Arterial reconstruction	Major amputation	Lumber sympathectomy	Bone marrow	Peripheral blood	Others	Toe	Metatarsal	Chopart· Lisfranc	Syme	Below knee	Above knee· knee disarticulation	Hip disarticulation	Unknown	(−)	(+)		
																		:1X	2X	3X≦
Rutherford 4	88	1	201	2	0	0	0	0	0	0	0	0	0	0	0	0	155	40	7	14
Rutherford 5	252	0	708	8	1	0	0	0	17	3	0	0	1	2	0	3	556	96	34	38
Rutherford 6	60	0	159	16	1	0	0	0	0	1	0	0	4	4	0	1	143	15	5	7
Total	400	1	1068	26	2	0	0	0	17	4	0	0	5	6	0	4	854	151	46	59

Table 4-2 Treatment 2

a. Total

	Bypass											TEA			EVT
	Aorta-aorta	Aorta (with suprarenal clamp)	Aorta-femoral	Femoral-proximal popliteal	Femoral-distal popliteal	Femoral-crural/foot	Popliteal-crural/foot	Anatomical others	Axillary-femoral	Femoral-femoral	Extra-anatomical others	Aorta/iliac	Fomoral/popliteal	Others	
Rutherford 4	1	0	3	23	23	22	13	3	5	11	1	2	27	0	103
Rutherford 5	0	1	10	55	40	87	130	5	6	15	4	2	79	0	403
Rutherford 6	0	0	2	9	10	18	23	0	3	6	1	0	10	0	104
Total	1	1	15	87	73	127	166	8	14	32	6	4	116	0	610

b. ASO

	Bypass											TEA			EVT
	Aorta-aorta	Aorta (with suprarenal clamp)	Aorta-femoral	Femoral-proximal popliteal	Femoral-distal popliteal	Femoral-crural/foot	Popliteal-crural/foot	Anatomical others	Axillary-femoral	Femoral-femoral	Extra-anatomical others	Aorta/iliac	Fomoral/popliteal	Others	
Rutherford 4	1	0	3	23	22	22	12	3	5	10	1	2	27	0	103
Rutherford 5	0	1	10	55	39	84	123	4	6	15	4	2	78	0	401
Rutherford 6	0	0	2	9	10	17	23	0	3	6	1	0	10	0	104
Total	1	1	15	87	71	123	158	7	14	31	6	4	115	0	608

TEA: thromboendarterectomy, EVT: endovascular treatment/therapy

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	35	63	34	3	8	36	67	1	20	14	28	19	11	63	4
Rutherford 5	110	228	199	2	29	63	275	4	30	39	120	106	19	256	19
Rutherford 6	23	59	62	1	3	11	49	0	10	9	22	19	3	46	3
Total	168	350	295	6	40	110	391	5	60	62	170	144	33	365	26

b. ASO

	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	35	63	34	3	8	34	63	1	20	14	28	16	9	60	3
Rutherford 5	109	227	198	2	28	63	263	4	29	39	114	101	18	244	19
Rutherford 6	23	59	62	1	3	11	48	0	10	9	21	19	3	45	3
Total	167	349	294	6	39	108	374	5	59	62	163	136	30	349	25

Table 4-4 Treatment 4

a. Total

	Distal bypass																		
	Proximal anastomosis								Distal anastomosis		Distal anastomosis: sites of crural artery				Distal anastomosis: sites of foot artery				
	External iliac	Common femoral	Deep femoral	Superficial femoral	Proximal popliteal	Distal popliteal	Crural	Others	Crural	Foot	Tibioperoneal trunk	Posterior tibial	Anterior tibial	Peroneal	Posterior tibial	Anterior tibial	Peroneal	Dorsalis pedis	Plantar
Rutherford 4	0	14	2	8	6	4	2	1	17	19	2	12	1	2	7	2	1	9	0
Rutherford 5	5	46	6	36	25	89	5	7	79	137	6	34	31	10	22	20	5	78	15
Rutherford 6	0	6	3	6	4	18	3	1	13	28	0	7	4	2	8	2	0	16	3
Total	5	66	11	50	35	111	10	9	109	184	8	53	36	14	37	24	6	103	18

b. ASO

	Distal bypass																		
	Proximal anastomosis								Distal anastomosis		Distal anastomosis: sites of crural artery				Distal anastomosis: sites of foot artery				
	External iliac	Common femoral	Deep femoral	Superficial femoral	Proximal popliteal	Distal popliteal	Crural	Others	Crural	Foot	Tibioperoneal trunk	Posterior tibial	Anterior tibial	Peroneal	Posterior tibial	Anterior tibial	Peroneal	Dorsalis pedis	Plantar
Rutherford 4	0	14	2	8	6	3	2	1	17	18	2	12	1	2	6	2	1	9	0
Rutherford 5	5	44	6	35	25	82	5	7	75	131	5	32	31	9	20	20	5	77	12
Rutherford 6	0	6	3	6	4	18	2	1	13	27	0	7	4	2	7	2	0	16	3
Total	5	64	11	49	35	103	9	9	105	176	7	51	36	13	33	24	6	102	15

Table 4-5 Treatment 5

a. Total

	Pharmacological therapy					
	Antiplatelet	VKA	Prostaglandin	Heparin	Statin	Others
Rutherford 4	137	17	13	16	21	15
Rutherford 5	414	36	44	40	41	21
Rutherford 6	99	10	12	10	11	2
Total	650	63	69	66	73	38

b. ASO

	Pharmacological therapy					
	Antiplatelet	VKA	Prostaglandin	Heparin	Statin	Others
Rutherford 4	135	16	13	16	20	14
Rutherford 5	403	34	44	39	41	18
Rutherford 6	99	10	12	10	11	2
Total	637	60	69	65	72	34

Antiplatelet: aspirin, cilostazol, Beraprost, sarpogrelate, ticlopidine, clopidogrel, ethyl icosapentate.

Table 4-6 Treatment 6

a. Total

	Femoral-proximal popliteal bypass	Femoral-distal popliteal bypass	Femoral-crural/foot bypass	Popliteal-crural/foot bypass
Polyester	7	5	2	4
ePTFE	52	20	6	9
Vein	34	49	118	156
Artery	1	3	6	5
Others	3	0	1	0
(−)	3	1	0	1
Total	100	78	133	175

b. ASO

	Femoral-proximal popliteal bypass	Femoral-distal popliteal bypass	Femoral-crural/foot bypass	Popliteal-crural/foot bypass
Polyester	7	5	2	4
ePTFE	51	20	6	8
Vein	33	47	114	147
Artery	1	3	6	5
Others	3	0	1	0
(−)	3	1	0	1
Total	98	76	129	165

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

a. Total

		Life prognosis			Causes of death											
		Alive	Dead	Intraoperative death	Cardiac disease	Cerebrovascular disease			Malignant neoplasm	Aortic aneurysm/dissection	Infection		Ischemic enteritis	Gastrointestinal bleeding	Others	Unknown
						Hemorrhage	Infarction	Unknown			Diseased limb	Others				
Local condition	Rutherford 4	178	5	0	0	0	0	0	0	1	0	2	0	0	0	2
	Rutherford 5	609	21	1	7	0	1	0	0	1	0	2	1	1	6	2
	Rutherford 6	140	7	0	1	0	0	0	0	0	4	0	0	1	0	1
Therapeutic measures	Non-reconstruction	38	3	0	0	0	0	0	0	0	1	1	0	0	1	0
	EVT	384	19	0	4	0	0	0	0	1	3	0	0	2	4	5
	Surgical reconstruction	505	11	1	4	0	1	0	0	1	0	3	1	0	1	0
	Total	927	33	1	8	0	1	0	0	2	4	4	1	2	6	5

b. ASO

		Life prognosis			Causes of death											
		Alive	Dead	Intraoperative death	Cardiac disease	Cerebrovascular disease			Malignant neoplasm	Aortic aneurysm/dissection	Infection		Ischemic enteritis	Gastrointestinal bleeding	Others	Unknown
						Hemorrhage	Infarction	Unknown			Diseased limb	Others				
Local condition	Rutherford 4	173	5	0	0	0	0	0	0	1	0	2	0	0	0	2
	Rutherford 5	594	21	0	7	0	1	0	0	1	0	2	1	1	6	2
	Rutherford 6	139	7	0	1	0	0	0	0	0	4	0	0	1	0	1
Therapeutic measures	Non-reconstruction	37	3	0	0	0	0	0	0	0	1	1	0	0	1	0
	EVT	382	19	0	4	0	0	0	0	1	3	0	0	2	4	5
	Surgical reconstruction	487	11	1	4	0	1	0	0	1	0	3	1	0	1	0
	Total	906	33	1	8	0	1	0	0	2	4	4	1	2	6	5

Table 5-2 Perioperative complications 1

a. Total

		Cardiac disease				Cerebrovascular disease				Pneumonia		Wound complication		Peripheral embolism		
								Cerebral infarction							(+)	
		(−)	Angina	Serious arrhysmia	Myocardial infarction	(−)	TIA	Functional loss (−)	Functional loss (+)	(−)	(+)	(−)	(+)	(−)	Minor (including blue toe)	Major
Local condition	Rutherford 4	168	2	0	2	171	0	1	0	166	6	166	6	172	0	0
	Rutherford 5	606	7	2	3	611	1	4	2	612	6	583	35	608	8	2
	Rutherford 6	138	2	2	0	140	0	0	2	139	3	138	4	141	1	0
Therapeutic measures	Non-reconstruction	13	0	0	0	13	0	0	0	12	1	11	2	13	0	0
	EVT	392	9	2	0	398	1	1	3	398	5	397	6	397	5	1
	Surgical reconstruction	507	2	2	5	511	0	4	1	507	9	479	37	511	4	1
Total		912	11	4	5	922	1	5	4	917	15	887	45	921	9	2

b. ASO

		Cardiac disease				Cerebrovascular disease				Pneumonia		Wound complication		Peripheral embolism		
								Cerebral infarction							(+)	
		(−)	Angina	Serious arrhysmia	Myocardial infarction	(−)	TIA	Functional loss (−)	Functional loss (+)	(−)	(+)	(−)	(+)	(−)	Minor (including blue toe)	Major
Local condition	Rutherford 4	163	2	0	2	166	0	1	0	161	6	162	5	167	0	0
	Rutherford 5	592	7	2	3	597	1	4	2	598	6	572	32	594	8	2
	Rutherford 6	137	2	2	0	139	0	0	2	138	3	137	4	140	1	0
Therapeutic measures	Non-reconstruction	13	0	0	0	13	0	0	0	12	1	11	2	13	0	0
	EVT	390	9	2	0	396	1	1	3	396	5	395	6	395	5	1
	Surgical reconstruction	489	2	2	5	493	0	4	1	489	9	465	33	493	4	1
Total		892	11	4	5	902	1	5	4	897	15	871	41	901	9	2

TIA: transient ischemic attack

Table 5-3 Perioperative complications 2

a. Total

		Hemorrhage			Sites of bleeding			Outcome of bleeding				Complication due to contrast medium		Complication at puncture site	
		(−)	(+)	Unknown	Brain	GI tract	Others	Cured	Uncured	Dead	Others	(−)	(+)	(−)	(+)
Local condition	Rutherford 4	172	0	0	0	0	0	0	0	0	0	170	2	84	0
	Rutherford 5	604	13	1	2	2	9	11	0	2	0	613	5	319	6
	Rutherford 6	139	2	1	0	1	1	2	0	0	0	141	1	83	0
Therapeutic measures	Non-reconstruction	12	0	1	0	0	0	0	0	0	0	13	0	8	1
	EVT	396	6	1	1	2	3	5	0	1	0	400	3	400	3
	Surgical reconstruction	507	9	0	1	1	7	8	0	1	0	511	5	78	2
Total		915	15	2	2	3	10	13	0	2	0	924	8	486	6

b. ASO

		Hemorrhage			Sites of bleeding			Outcome of bleeding				Complication due to contrast medium		Complication at puncture site	
		(−)	(+)	Unknown	Brain	GI tract	Others	Cured	Uncured	Dead	Others	(−)	(+)	(−)	(+)
Local condition	Rutherford 4	167	0	0	0	0	0	0	0	0	0	165	2	83	0
	Rutherford 5	590	13	1	2	2	9	11	0	2	0	599	5	317	6
	Rutherford 6	138	2	1	0	1	1	2	0	0	0	140	1	83	0
Therapeutic measures	Non-reconstruction	12	0	1	0	0	0	0	0	0	0	13	0	8	1
	EVT	394	6	1	1	2	3	5	0	1	0	398	3	398	3
	Surgical reconstruction	489	9	0	1	1	7	8	0	1	0	493	5	77	2
Total		895	15	2	2	3	10	13	0	2	0	904	8	483	6

GI: gastrointestinal

Table 5-4 Hemodynamics

a. Total

		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	Rutherford 4	102	0.83	99	104	36	36	81	0.90	75	120	14	36
	Rutherford 5	243	0.89	237	118	210	42.5	172	0.93	167	123	88	47
	Rutherford 6	38	0.90	35	114	33	42	25	0.94	25	132	18	49
Therapeutic measures	Non-reconstruction	12	0.815	9	127	6	49.5	7	0.86	2	114.5	1	66
	EVT	176	0.865	173	114	133	41	136	0.91	133	120	68	43
	Surgical reconstruction	195	0.89	189	112	140	43	135	0.94	132	126	51	50
Total		383	0.87	371	113	279	42	278	0.92	267	123	120	47

b. ASO

		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	Rutherford 4	100	0.82	97	103	35	36	79	0.89	73	120	13	36
	Rutherford 5	239	0.89	233	118	208	42.5	166	0.92	162	123.5	88	47
	Rutherford 6	38	0.9	35	114	33	42	25	0.94	25	132	18	49
Therapeutic measures	Non-reconstruction	12	0.815	9	127	6	49.5	6	0.82	2	114.5	2	48
	EVT	175	0.86	172	113.5	133	41	136	0.91	133	120	68	43
	Surgical reconstruction	190	0.89	184	111.5	137	43	128	0.94	125	126	50	50
Total		377	0.87	365	112	276	42	270	0.92	260	123.5	119	47

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

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	Uncured		Unknown	Ambulatory	Ambulatory/ homebound	Nonambulatory
													Improved	Unchanged/ deteriorated				
Local condition	Rutherford 4	159	2	2	1	0	0	3	159	13	4	113	49	13	1	133	26	24
	Rutherford 5	546	20	21	2	2	3	4	522	74	27	139	366	111	7	312	155	163
	Rutherford 6	120	4	1	0	0	0	4	101	22	8	14	80	36	1	42	33	72
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	14	3	2	8	6	5	0	19	6	16
	EVT	349	15	12	1	0	1	7	306	72	21	100	202	90	7	196	75	132
	Surgical reconstruction	476	11	12	2	2	2	4	462	34	16	158	287	65	2	272	133	111
Total		825	26	24	3	2	3	11	782	109	39	266	495	160	9	487	214	259

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	Uncured		Unknown	Ambulatory	Ambulatory/ homebound	Nonambulatory
													Improved	Unchanged/ deteriorated				
Local condition	Rutherford 4	155	2	2	1	0	0	2	155	12	4	109	49	13	0	128	26	24
	Rutherford 5	535	20	18	2	2	3	4	511	70	27	138	357	106	7	302	153	160
	Rutherford 6	119	4	1	0	0	0	4	100	22	8	13	80	36	1	42	32	72
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	14	2	2	8	6	4	0	18	6	16
	EVT	347	15	12	1	0	1	7	304	72	21	99	202	89	7	195	74	132
	Surgical reconstruction	462	11	9	2	2	2	3	448	30	16	153	278	62	1	259	131	108
Total		809	26	21	3	2	3	10	766	104	39	260	486	155	8	472	211	256

Table 5-6 Revision of treatment

a. Total

		Revision for those excluding good bypass graft/EVT condition		Minor reintervention (revision for stenosis)				Major reintervention (revision for occlusion)								Major amputation		
		(+)	(−)	(−)	Patch plasty	EVT	Others	(−)	Thrombectomy (±patch plasty)	Thrombolysis	EVT	Re-bypass	Jump bypass	Interposition	Others	(−)	(+)	
																	Due to preoperative wound	Due to new wound
Local condition	Rutherford 4	3	5	166	0	3	2	167	1	0	1	0	0	1	1	174	7	1
	Rutherford 5	27	25	580	1	28	3	592	5	0	3	5	3	2	2	603	20	1
	Rutherford 6	6	3	123	0	5	0	123	0	0	1	2	2	0	0	117	16	0
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	25	3	0
	EVT	16	22	377	0	18	4	382	1	0	5	6	2	2	1	372	27	0
	Surgical reconstruction	17	14	492	1	18	1	500	5	0	0	1	3	1	2	497	13	2
Total		33	36	869	1	36	5	882	6	0	5	7	5	3	3	894	43	2

b. ASO

		Revision for those excluding good bypass graft/EVT condition		Minor reintervention (revision for stenosis)				Major reintervention (revision for occlusion)								Major amputation		
		(+)	(−)	(−)	Patch plasty	EVT	Others	(−)	Thrombectomy (±patch plasty)	Thrombolysis	EVT	Re-bypass	Jump bypass	Interposition	Others	(−)	(+)	
																	Due to preoperative wound	Due to new wound
Local condition	Rutherford 4	2	5	161	0	3	2	162	1	0	1	0	0	1	1	169	7	1
	Rutherford 5	26	23	566	1	28	3	580	4	0	3	5	2	2	2	589	19	1
	Rutherford 6	6	3	122	0	5	0	122	0	0	1	2	2	0	0	116	16	0
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	24	3	0
	EVT	16	22	375	0	18	4	380	1	0	5	6	2	2	1	370	27	0
	Surgical reconstruction	15	12	474	1	18	1	484	4	0	0	1	2	1	2	480	12	2
Total		31	34	849	1	36	5	864	5	0	5	7	4	3	3	874	42	2

Table 5-7 Condition of contralateral limbs

a. Total

		Contralateral limb occlusive lesions							Treatment for contralateral limb									
		(−)	(+)						Unnecessary	(+)								
			Asymptomatic	Intermittent claudication	CLI			Post-treatment		Pharmacological therapy	Angiogenic therapy	EVT	Surgical bypass	Minor amputation	Major amputation	Lumber sympathectomy	Necessary but no treatment	Others
					R4	R5	R6											
Local condition	Rutherford 4	55	65	16	6	2	0	39	11	91	0	23	14	1	4	0	1	0
	Rutherford 5	163	235	32	8	48	6	138	47	299	1	68	67	8	17	0	8	1
	Rutherford 6	32	48	5	0	11	8	43	9	73	0	20	11	5	11	0	3	0
Therapeutic measures	Non-reconstruction	14	13	1	1	3	2	7	2	16	0	2	4	1	1	0	1	0
	EVT	91	159	19	3	27	9	95	31	206	0	76	18	5	20	0	6	0
	Surgical reconstruction	145	176	33	10	31	3	118	34	241	1	33	69	8	11	0	5	1
Total		250	348	53	14	61	14	220	67	463	1	111	91	14	32	0	12	1

b. ASO

		Contralateral limb occlusive lesions							Treatment for contralateral limb									
		(−)	(+)						Unnecessary	(+)								
			Asymptomatic	Intermittent claudication	CLI			Post-treatment		Pharmacological therapy	Angiogenic therapy	EVT	Surgical bypass	Minor amputation	Major amputation	Lumber sympathectomy	Necessary but no treatment	Others
					R4	R5	R6											
Local condition	Rutherford 4	54	62	15	6	2	0	39	11	87	0	23	14	1	4	0	1	0
	Rutherford 5	153	234	32	8	46	6	136	47	296	1	68	65	8	16	0	8	1
	Rutherford 6	32	47	5	0	11	8	43	9	72	0	20	11	5	11	0	3	0
Therapeutic measures	Non-reconstruction	13	13	1	1	3	2	7	2	16	0	2	4	1	1	0	1	0
	EVT	91	159	19	3	26	9	94	31	205	0	76	18	5	19	0	6	0
	Surgical reconstruction	135	171	32	10	30	3	117	34	234	1	33	68	8	11	0	5	1
Total		239	343	52	14	59	14	218	67	455	1	111	90	14	31	0	12	1

CLI: critical limb ischemia

Table 5-8 Malignant neoplasm

a. Total

		Newly diagnosed malignant neoplasm			Sites of newly diagnosed malignant neoplasm										
		(−)	(+)	Unknown	Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	Breast	Uterus	Ovarium	Prostate	Others
Local condition	Rutherford 4	181	2	0	0	0	0	0	1	1	0	0	0	0	0
	Rutherford 5	625	2	3	0	0	0	2	0	0	0	0	0	0	0
	Rutherford 6	145	1	1	0	0	0	1	0	0	0	0	0	0	0
Therapeutic measures	Non-reconstruction	40	0	1	0	0	0	0	1	1	0	0	0	0	0
	EVT	397	4	2	0	0	0	2	0	0	0	0	0	0	0
	Surgical reconstruction	514	1	1	0	0	0	1	0	0	0	0	0	0	0
Total		951	5	4	0	0	0	3	1	1	0	0	0	0	0

b. ASO

		Newly diagnosed malignant neoplasm			Sites of newly diagnosed malignant neoplasm										
		(−)	(+)	Unknown	Head and neck	Esophagus	Lung	Stomach	Hepatobiliary pancreas	Colon	Breast	Uterus	Ovarium	Prostate	Others
Local condition	Rutherford 4	176	2	0	0	0	0	0	1	1	0	0	0	0	0
	Rutherford 5	610	2	3	0	0	0	2	0	0	0	0	0	0	0
	Rutherford 6	144	1	1	0	0	0	1	0	0	0	0	0	0	0
Therapeutic measures	Non-reconstruction	39	0	1	0	0	0	0	1	1	0	0	0	0	0
	EVT	395	4	2	0	0	0	2	0	0	0	0	0	0	0
	Surgical reconstruction	496	1	1	0	0	0	1	0	0	0	0	0	0	0
Total		930	5	4	0	0	0	3	1	1	0	0	0	0	0