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Annual Report

2016 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 2016, 1,092 CLI limbs (male 755 limbs: 70%) were registered by 91 facilities. ASO has accounted for 98% of the pathogenesis of these limbs. In this manuscript, the background data, the early prognosis, and 6-months' prognosis of the registered limbs are reported. (This is a translation of Jpn J Vasc Surg 2019; 28: 1–27.)

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 a nationwide CLI registration and tracking database project 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 2013–2015, have already been published.[1–6] This article reports the basic data registered in 2016.

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[7]: 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.

Tracking data two years after treatment: End of Decem-

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ber 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, 91 facilities, which registered CLI limbs in 2016 at the time of compiling in December 2016, 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 2016

The initial registration data in 2016 were fixed in early April 2017, and the tracking data early after treatment (one month) were fixed on December 31, 2017. At that time, 1,092 limbs, those of 755 males (70%) and 337 females (30%), were registered in 91 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**),[8] 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"[9]: 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 1,070 (98%) limbs, thromboangitis obliterans (TAO) in 10, vasculitis (Takayasu's arteritis, collagen disease, Behçet's disease, and fibromuscular dysplasia excluding TAO) in nine, and others in three. Patients comorbidities consisted of diabetes in 66% (67%) of the limbs, hypertension in 76% (77%), dyslipidemia in 39% (39%), ischemic heart disease in 41% (42%), cerebrovascular disease in 21% (22%), dialysis for renal failure in 43% (44%), past medical history of malignant neoplasm or that being treated in 9% (9%), and arterial occlusive lesions in the contralateral limb in 80% (80%).

(2) Conditions of limb ischemia

Limb ischemia pretreatment conditions are shown in **Tables 3-1** to **3-6**. Regarding the walking function (Taylor's classification),[10] 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 (University of Texas classification),[11] 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 $TP = 0.6853\ SPP + 14.48$ from the correlation data of SPP and TP reported in Japan,[12] 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.

Pretreatment, 58% (58%) of the patients were ambulatory, 20% (20%) were ambulatory/homebound, and 22% (22%) were non-ambulatory. On the Rutherford classification (R),[13] limbs with categories R4, R5, and R6 accounted for 22% (22%), 65% (64%), and 14% (14%) of the limbs, respectively. The median ankle brachial index (ABI), the toe brachial index (TBI), and the SPP of the measured limbs were 0.58 (0.58), 0.32 (0.32), and 23 mmHg (24 mmHg), respectively. The occlusive legion was located in the aortoiliac artery in 22% (22%) of the limbs, in the femoropopliteal artery in 67% (68%) of the limbs, and in the crural or foot artery in 60% (60%) of the limbs. The occlusion of multiple lesions was observed in the aortoiliac artery and the femoropopliteal artery in 14% (15%) of limbs, in the aortoiliac artery and the crural or foot artery in 6% (7%), in the femoropopliteal artery and the crural or foot artery in 34% (35%), and in the aortoiliac artery and the femoropopliteal artery and the crural or foot artery in 6% (6%).

We were able to apply the WIfI classification with sufficient data to 865 limbs (848 limbs). On the WIfI classification, limbs with the stages 1, 2, 3, and 4 accounted for 14% (14%), 25% (25%), 23% (23%), and 37% (37%) 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**, 84 limbs (80 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, $TcPO_2$ 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. 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 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 865 limbs (848 limbs) among 1,092 limbs (1,070 limbs), WIfI classification could be implemented for these 865 limbs (848 limbs). When rechecking the remaining 227 limbs (222 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 94% (94%) of the registered limbs, and primary major amputations were performed in 2.5% (2.5%) of the registered limbs. Among the surgical reconstruction procedures, distal bypass, 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 49% (49%) of the total revascularization procedures. EVT applied to the crural or foot artery accounted for 37% (37%) of the total EVT.

The problems and considerations on these spreadsheets are described below. **Table 4-1**, the sum of the number of cells in treatment is larger than the number of registered limbs 1,092 (1,070) because more than one treatment method can be selected. The limbs undergoing pharmacological therapy alone accounted for 4.8% (4.7%). **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 could be because of

selecting multiple vein usage for arterial reconstruction in a limb since more than one vein usage can be selected. Two veins were used in eight limbs and three veins were used in one limb. Vascular prosthesis (−) included an endarterectomy without a patch angioplasty. **Table 4-4** shows the sum of the number of proximal anastomosis does not equal the sum of the number of distal anastomosis. This was because multiple veins in a limb were used. Two limbs had two proximal anastomoses (common femoral artery and crural artery) and one distal anastomosis (crural artery), which may be a sequential bypass, and one limb with one proximal anastomosis and two distal anastomoses was probably a duplicated bypass.

Table 4-6 summarizes the vascular grafts used for the infrainguinal arterial reconstruction. For example, the total number of femoral-above knee popliteal artery bypass was 102 (100), higher than 91 (89), 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 (TEA). Multiple procedures can be selected at the same time for lower limb arterial reconstruction. This is also the reason for "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 March 2018, follow-up data one month after treatment were obtained in 830 limbs (76%), including 813 limbs (76%) 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 3.4% (3.3%) in the whole series, and 4.5% (4.5%) and 2.5% (2.4%) treated by EVT alone and by surgical reconstruction with/without EVT, respectively. The most common cause of death was cardiac disease, accounting for 29% (30%) of all deaths. Postoperative complications were cardiac disease in 2.1% (2.1%), cerebrovascular disease in 1.9% (2.0%), pneumonia in 2.3% (2.2%), and wound complication in 5.4% (5.0%). Complications at the puncture site were noted in 1.8% (1.8%) of the limbs treated by EVT.

The median ABI and SPP of the measured limbs, immediately after treatment and one month after treatment, were 0.88 (0.88) and 0.92 (0.92) and 38.5 (39) mmHg and 43 (43) mmHg, respectively. Stenosis, occlusion, infection, or other trouble occurred after revascularization by EVT in 9.8% (9.6%) and by surgical reconstruction in 6.8% (6.3%). Secondary major amputation rate was 6.2% (6.3%) in EVT and 3.8% (3.9%) in surgical reconstruction. When ambulatory function at discharge was compared to that before surgery, the rate of patients with ambulatory changed from 58% (58%) to 54% (54%), ambulatory/homebound from 20% (20%) to 19% (19%), and non-ambulatory from 22% (22%) to 26% (27%).

The problems, comments, and considerations on these spreadsheets are described below. The number of "bypass graft/EVT condition," "clinical symptoms of the limb," "ischemic wound," and "ambulatory function at discharge" did not match (**Table 5-5**). The total number of "ambulatory function at discharge" was 830 (813), which was equal to the number of life prognoses (**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 the 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." **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 is required in limbs where percutaneous transluminal angioplasty/stent placement 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 322 limbs (320 limbs) (**Table 5-1**), which was 3 (3) limbs higher than the sum of the number in the column of minor reintervention or major reintervention in the row of limbs with EVT; 319 limbs (317 limbs) (**Table 5-6**). The number of limbs of survivors with surgical reconstruction was 427 limbs (415 limbs) (**Table 5-1**), which was 4 (4) limbs more than the sum of the number in the column of minor reintervention or major reintervention in the row of limbs with surgical reconstruction; 423 limbs (411 limbs) (**Table 5-6**).

Since registration in minor reinterventions and in major reinterventions cannot be performed simultaneously, and the patient may die after reintervention, the sum of the number of minor interventions or major interventions must be higher than the number of survivors. However, the sum of the number of minor interventions or major interventions was lower than the number of survivors. This is speculated to be due to "unused."

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. Conclusions

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 2016 were clarified, after those in 2013, 2014, and 2015. The JCLIMB Committee is planning to continue publishing an annual report. In 2017, the new concept, "chronic limb threatening ischemia," was proposed instead of CLI.[14] In addition, a new clinical guideline, the Global Vascular Guideline, will be published instead of TASC in the near future. The JCLIMB Committee ought to revise the survey items hereafter.

Clinical studies using these data are being started in 2018. The JCLIMB Committee expects these study results will be fed back to clinical situations to help develop medical care for CLI. 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 CLI, aiming at establishing a nationwide CLI database in Japan.

5. Participant Facilities (91 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 Thoracic and 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 Surgery, Shonai Amarume 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
Department of Cardiovascular Surgery, Saitama Medical Center, Jichi Medical University
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 Vascular Surgery, Edogawa Hospital
Department of Surgery, Tokyo Metropolitan Health and Medical Treatment Corporation, Okubo Hospital
Department of Cardiovascular Surgery, Kyorin University
Department of Surgery, Keio University Hospital
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 Hos-

pital
Department of Vascular Surgery, Kawasaki Municipal Hospital
Department of Vascular Surgery, Saiseikai Yokohamashi Tobu 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 Surgery 2, University of Yamanashi Hospital
Department of Cardiovascular Surgery, National Hospital Organization, Kanazawa Medical Center
Department of Surgery, Tsuruga City Hospital
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, Soryukai Inoue Hospital
Department of Vascular Surgery, Osaka Rosai Hospital
Department of Surgery, Kansai Medical University Medical Center
Department of Cardiovascular Surgery, Toyonaka Municipal Hospital
Department of Vascular Surgery, Suita Tokushukai Hospital
Department of Cardiovascular Surgery, Takatsuki Hospital
Department of Cardiovascular Surgery, Kobe University 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 Kosei 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, Ehime University 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
Department of Cardiovascular Surgery, Sasebo Chuo Hospital
Department of Vascular Surgery, Kumamoto Rehabilitation Hospital
Department of Cardiovascular Surgery, Oita Oka Hospital

6. JCLIMB Committee, NCD JCLIMB Analytical Team

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Disclosure Statement

The authors have no conflict of interest.

Additional Note

This report was authorized by the institutional review board of Saiseikai Yahata General Hospital. (Authorization No.126)

Additional Remarks

This Annual Report was primarily published in the Japanese Journal of Vascular Surgery Vol. 28 (2019) No. 1; however, an error in a table was detected after the publication. The errata was published in the same volume. This translation reflects that correction.

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Table 1-1 SVS WIfI classification: original[8)]

Table 1-1-1 Wound

Grade	Ulcer	Gangrene
0	No ulcer Clinical description: ischemic rest pain (requires typical symptoms + ischemia grade 3); no wound.	No gangrene
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	No gangrene
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement Clinical description: major tissue loss salvageable with multiple (≧3) digital amputations or standard TMA ± skin coverage.	Gangrenous changes limited to digits
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer ± 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	Extensive gangrene involving forefoot and/or midfoot; full thickness heel necrosis ± calcaneal involvement

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, AP: ankle pressure, 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)	Mild
	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)	
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 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
#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 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 or gangrene		
1	Class 5, 6	I	Any portion	No gangrene
		II, III	Limited to digits	No gangrene
2	Class 5, 6	I	Heel	No gangrene
		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 1-2-2 Ischemia

Grade	SPP: (mmHg; calculating from the formula*)
0	≧66
1	37–65
2	23–36
3	<23

*TP=0.6853XSPP + 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 Patients' background

Table 2-1 Patients' background 1

a. Total

	n	Sex		Laterality		BMI (median)	Pathogenesis				Age at registration			
		Male	Female	Right	Left		ASO	TAO	Vasculitis	Others	ASO mean (±SD)	TAO mean (±SD)	Vasculitis mean (±SD)	Others mean (±SD)
Rutherford 4	235	155	80	120	115	20.8	223	1	0	1	73.3 (10.2)	21.0–	0.0–	56.0–
Rutherford 5	705	496	209	372	333	21.3	688	8	8	1	73.7 (10.3)	48.4 (17.3)	65.6 (15.2)	92.0–
Rutherford 6	152	104	48	71	81	21.3	149	1	1	1	72.2 (11.4)	50.0–	68.0–	62.0–
Total	1,092	755	337	563	529	21.2	1,070	10	9	3	73.4 (10.4)	45.8 (17.5)	65.9 (14.2)	70.0 (19.3)

b. ASO

	n	Sex		Laterality		BMI (median)	Age at registration
		Male	Female	Right	Left		mean (±SD)
Rutherford 4	233	154	79	119	114	20.7	73.3 (10.2)
Rutherford 5	688	484	204	362	326	21.3	73.7 (10.3)
Rutherford 6	149	101	48	71	78	21.3	72.2 (11.4)
Total	1,070	739	331	552	518	21.2	73.4 (10.4)

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		(−)	(+)	
		Good	Poor					Good	Poor		Good	Poor		Ex-smoker	Current smoker
Rutherford 4	109	102	24	18	69	39	57	161	17	152	74	9	91	91	53
Rutherford 5	216	355	134	53	243	193	164	467	74	422	228	55	287	303	115
Rutherford 6	42	67	43	14	37	59	41	92	19	97	43	12	62	69	21
Total	367	524	201	85	349	291	262	720	110	671	345	76	440	463	189

b. ASO

	Diabetes			Diabetes therapy			Hypertension			Dyslipidemia			Smoking		
	(−)	(+) Management		Diet therapy	Medication	Insulin therapy	(−)	(+) Management		(−)	(+) Management		(−)	(+)	
		Good	Poor					Good	Poor		Good	Poor		Ex-smoker	Current smoker
Rutherford 4	107	102	24	18	69	39	55	161	17	150	74	9	90	90	53
Rutherford 5	202	353	133	53	241	192	157	458	73	411	222	55	282	295	111
Rutherford 6	40	67	42	14	37	58	39	91	19	95	42	12	62	68	19
Total	349	522	199	85	347	289	251	710	109	656	338	76	434	453	183

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

a. Total

	Ischemic heart disease				Heart failure		Cerebrovascular disease		Renal dysfunction					
	(−)	(+)			(−)	(+)	(−)	(+)	(−)	(+)				
		Medical treatment	PCI	CABG						G3a	G3b	G4	G5	G5D
Rutherford 4	153	23	35	24	211	24	191	44	100	27	15	8	0	85
Rutherford 5	410	66	144	85	593	112	550	155	209	72	62	38	4	320
Rutherford 6	78	26	27	21	121	31	117	35	46	17	10	10	1	68
Total	641	115	206	130	925	167	858	234	355	116	87	56	5	473

b. ASO

	Ischemic heart disease				Heart failure		Cerebrovascular disease		Renal dysfunction					
	(−)	(+)			(−)	(+)	(−)	(+)	(−)	(+)				
		Medical treatment	PCI	CABG						G3a	G3b	G4	G5	G5D
Rutherford 4	151	23	35	24	209	24	189	44	98	27	15	8	0	85
Rutherford 5	397	64	142	85	576	112	533	155	195	71	60	38	4	320
Rutherford 6	76	25	27	21	118	31	114	35	43	17	10	10	1	68
Total	624	112	204	130	903	167	836	234	336	115	85	56	5	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' background 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	216	12	7	0	0	0	5	4	4	7	1	1	0	1	0
Rutherford 5	636	48	21	0	1	3	6	11	4	17	4	3	0	5	18
Rutherford 6	145	6	1	0	0	1	2	0	0	2	0	2	0	0	1
Total	997	66	29	0	1	4	13	15	8	26	5	6	0	6	19

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	215	11	7	0	0	0	5	4	4	7	1	0	0	1	0
Rutherford 5	620	47	21	0	1	3	6	11	4	16	4	3	0	5	18
Rutherford 6	142	6	1	0	0	1	2	0	0	2	0	2	0	0	1
Total	977	64	29	0	1	4	13	15	8	25	5	6	0	6	19

*Including palliative therapy or recurrence.

Table 2-5 Patients' background 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	60	53	27	42	6	0	47	169	0.75	13	0.4	74	37	212	0	7	1	7	8
Rutherford 5	129	243	32	18	154	8	121	521	0.75	55	0.38	320	37	623	8	25	2	35	12
Rutherford 6	34	45	5	1	14	22	31	84	0.75	4	0.28	70	34	139	0	3	0	2	8
Total	223	341	64	61	174	30	199	774	0.75	72	0.39	464	37	974	8	35	3	44	28

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	59	53	27	41	6	0	47	169	0.75	13	0.4	74	37	211	0	7	1	7	7
Rutherford 5	123	241	32	18	149	8	117	510	0.75	54	0.38	316	37	608	8	25	1	35	11
Rutherford 6	32	45	5	1	14	22	30	83	0.75	4	0.28	68	34	136	0	3	0	2	8
Total	214	339	64	60	169	30	194	762	0.75	71	0.39	458	37	955	8	35	2	44	26

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

	Fatty acid							
	Arachidonic acid (AA)		Eicosapentaenoic acid (EPA)		Docosahexaenoic acid (DHA)		EPA/AA	
	n	Median	n	Median	n	Median	n	Median
Rutherford 4	6	156.3	6	105.6	6	89.5	6	0.7
Rutherford 5	23	162	23	50.2	23	100.4	23	0.3
Rutherford 6	6	161.1	6	31.8	6	89.7	6	0.2
Total	35	157.6	35	50.2	35	94.6	35	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	156.3	6	105.6	6	89.5	6	0.7
Rutherford 5	23	162	23	50.2	23	100.4	23	0.3
Rutherford 6	5	161.1	5	34.3	5	89.1	5	0.3
Total	34	157	34	50.7	34	95.8	34	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	162	37	36																							
Rutherford 5	422	146	137	528	101	16	60	10	17	49	448	128	129	321	48	6	24	4	4	357	545	85	15	42	7	11
Rutherford 6	49	39	64	51	41	37	49	11	22	21	32	35	85	53	44	40	30	10	15	36	31	35	25	38	4	19
Total	633	222	237	579	142	53	109	21	39	70	480	163	214	374	92	46	54	14	19	393	576	120	40	80	11	30

b. ASO

	Ambulatory function (Taylor's classification)			Sites of ulcer							Tissue loss (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	161	36	36																							
Rutherford 5	407	144	137	515	97	16	59	10	17	49	435	126	127	311	48	6	24	4	4	350	532	81	15	42	7	11
Rutherford 6	48	37	64	49	41	37	49	11	21	21	32	35	82	51	43	40	30	10	15	36	29	34	25	38	4	19
Total	616	217	237	564	138	53	108	21	38	70	467	161	209	362	91	46	54	14	19	386	561	115	40	80	11	30

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°C		Blood test								Hemodynamics								Infection[&]					
			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)*		Deep tissue#	SIRS[$]	
																				≦2.0 cm	>2.0 cm		(+)	(−)
Rutherford 4	230	5	232	6,300	217	0.31	213	3.6	232	1.13	133	0.51	9	0.38	90	24.5	9	43	218	10	5	2	0	235
Rutherford 5	671	34	690	7,250	672	1.12	659	3.4	694	1.81	476	0.6	38	0.33	447	24	38	44	465	157	44	39	14	691
Rutherford 6	133	19	149	9,400	148	4.42	140	2.85	148	1.62	70	0.55	3	0.17	90	20	3	21	53	31	17	51	13	139
Total	1,034	58	1,071	7,300	1,037	1.08	1,012	3.4	1,074	1.51	679	0.58	50	0.32	627	23	50	42	736	198	66	92	27	1,065

b. ASO

	Temperature ≧38°C		Blood test								Hemodynamics								Infection[&]					
			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)*		Deep tissue#	SIRS[$]	
																				≦2.0 cm	>2.0 cm		(+)	(−)
Rutherford 4	229	4	230	6,300	215	0.31	211	3.6	230	1.13	132	0.51	9	0.38	90	24.5	9	43	216	10	5	2	0	233
Rutherford 5	655	33	673	7,210	656	1.13	644	3.4	677	1.94	466	0.6	38	0.33	438	24	38	44	456	151	43	38	12	676
Rutherford 6	130	19	146	9,385	145	4.4	137	2.8	145	1.76	69	0.56	3	0.17	88	20.5	3	21	52	31	17	49	13	136
Total	1,014	56	1,049	7,240	1,016	1.1	992	3.4	1,052	1.56	667	0.58	50	0.32	616	24	50	42	724	192	65	89	25	1,045

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

[&]Presence of infection is defined by the presence of at least 2 of the following items: ①Local swelling or induration, ②Erythema >0.5 to ≦2.0 cm around the ulcer, ③Local tenderness or pain, ④Local warmth, ⑤Purulent discharge (thick, opaque to white, or sanguineous secretion).

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

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

[$]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 $PaCO_2$ <32 mmHg, ④White 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	147	135	15	76	169	103	11	15	10	27	2	17	27	29	111	10
Rutherford 5	500	363	21	140	457	445	47	32	13	39	3	68	96	86	294	90
Rutherford 6	111	74	6	25	106	106	6	11	2	5	0	14	21	22	53	20
Total	758	572	42	241	732	654	64	58	25	71	5	99	144	137	458	120

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	146	134	15	75	168	103	11	15	9	27	2	17	26	29	111	10
Rutherford 5	484	356	21	140	451	432	47	32	13	39	3	67	96	85	286	85
Rutherford 6	108	72	6	25	104	105	6	11	2	5	0	14	21	22	51	19
Total	738	562	42	240	723	640	64	58	24	71	5	98	143	136	448	114

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	128	2	128	1	128	5	128	5	129	3	129	3	127	3
Rutherford 5	423	1	424	1	423	4	422	5	422	3	422	2	416	3
Rutherford 6	93	1	93	1	94	4	95	5	94	3	94	2	94	3
Total	644	1	645	1	645	4	645	5	645	3	645	2	637	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	127	2	127	1	127	5	127	5	128	3	128	3	126	3
Rutherford 5	415	1	416	1	415	4	414	5	414	3	414	2	408	3
Rutherford 6	92	1	92	1	93	4	94	5.5	93	3	93	2	93	3
Total	634	1	635	1	635	4	635	5	635	3	635	2	627	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	125	13	124	7.5	124	13	121	13	125	4	120	5	99	4
Rutherford 5	414	13	404	13	417	13	409	13	414	6	401	6	352	6
Rutherford 6	94	13	94	13	94	13	95	13	94	10	93	6	78	13
Total	633	13	622	13	635	13	625	13	633	6	614	6	529	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	124	13	123	9	123	13	120	13	124	4	119	5	98	4
Rutherford 5	406	13	396	13	409	13	401	13	406	6	393	6	344	6
Rutherford 6	93	13	93	13	93	13	94	13	93	13	92	6	77	13
Total	623	13	612	13	625	13	615	13	623	6	604	6	519	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	235	0	0	0	18	33	53	62	218	10	7	0	50	107	9	0
Rutherford 5	0	279	329	97	58	113	178	238	465	151	76	13	69	104	178	236
Rutherford 6	0	11	34	107	8	17	31	56	53	30	57	12	3	6	15	88
Total	235	290	363	204	84	163	262	356	736	191	140	25	122	217	202	324

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	233	0	0	0	18	33	52	62	216	10	7	0	50	106	9	0
Rutherford 5	0	273	318	97	54	113	174	233	456	146	75	11	67	102	175	230
Rutherford 6	0	11	32	106	8	17	30	54	52	30	55	12	3	6	15	85
Total	233	284	350	203	80	163	256	349	724	186	137	23	120	214	199	315

Table 4 Treatment

Table 4-1 Treatment 1

a. Total

	Treatment					Angiogenic therapy			Reoperation				
	Pharmacological therapy	Angiogenic therapy	Arterial reconstruction	Major amputation	Lumber sympathectomy	Bone marrow	Peripheral blood	Others	Unknown	(−)	(+)		
											1X	2X	3X≦
Rutherford 4	74	0	220	2	0	0	0	0	1	168	41	14	11
Rutherford 5	227	1	668	10	0	0	0	1	8	542	106	24	25
Rutherford 6	46	0	135	15	1	0	0	0	3	115	24	3	7
Total	347	1	1023	27	1	0	0	1	12	825	171	41	43

b. ASO

	Treatment					Angiogenic therapy			Reoperation				
	Pharmacological therapy	Angiogenic therapy	Arterial reconstruction	Major amputation	Lumber sympathectomy	Bone marrow	Peripheral blood	Others	Unknown	(−)	(+)		
											1X	2X	3X≦
Rutherford 4	74	0	218	2	0	0	0	0	1	166	41	14	11
Rutherford 5	220	1	653	10	0	0	0	1	8	528	103	24	25
Rutherford 6	46	0	132	15	1	0	0	0	3	113	24	3	6
Total	340	1	1003	27	1	0	0	1	12	807	168	41	42

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	Femoral/popliteal	Others	
Rutherford 4	1	1	5	24	12	34	14	2	3	10	1	2	22	3	118
Rutherford 5	0	0	9	56	39	89	109	4	8	16	3	6	61	6	381
Rutherford 6	0	0	0	11	6	18	19	1	2	3	1	0	8	3	80
Total	1	1	14	91	57	141	142	7	13	29	5	8	91	12	579

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	Femoral/popliteal	Others	
Rutherford 4	1	1	5	24	12	34	13	2	3	9	1	2	22	3	118
Rutherford 5	0	0	9	54	38	88	102	4	8	16	3	6	61	6	376
Rutherford 6	0	0	0	11	6	17	17	1	2	3	1	0	8	3	80
Total	1	1	14	89	56	139	132	7	13	29	5	8	91	12	574

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	45	53	43	5	9	35	68	1	16	16	31	20	7	59	9
Rutherford 5	99	188	181	5	21	68	250	0	34	49	81	106	17	215	35
Rutherford 6	13	44	45	2	3	12	46	0	16	5	21	18	3	41	5
Total	157	285	269	12	33	115	364	1	66	70	133	144	27	315	49

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	45	53	43	5	9	34	67	1	16	16	31	19	7	58	9
Rutherford 5	99	188	176	5	20	68	241	0	34	49	77	101	17	207	34
Rutherford 6	13	44	45	2	3	12	44	0	16	5	19	18	2	39	5
Total	157	285	264	12	32	114	352	1	66	70	127	138	26	304	48

ePTFE: expanded polytetrafluoroethylene, EVT: endovascular treatment

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	19	3	11	5	9	1	0	35	13	2	22	5	7	4	0	1	8	1
Rutherford 5	1	47	6	37	20	74	10	3	84	114	2	48	26	9	20	11	1	55	28
Rutherford 6	0	10	0	8	8	8	4	0	19	18	0	9	9	3	3	4	0	7	5
Total	1	76	9	56	33	91	15	3	138	145	4	79	40	19	27	15	2	70	34

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	19	3	11	4	9	1	0	34	13	2	21	5	7	4	0	1	8	1
Rutherford 5	1	47	6	36	20	67	10	3	84	106	2	48	26	9	19	11	0	54	23
Rutherford 6	0	9	0	8	7	7	4	0	17	17	0	8	8	3	3	4	0	7	4
Total	1	75	9	55	31	83	15	3	135	136	4	77	39	19	26	15	1	69	28

Table 4-5 Treatment 5

a. Total

	Pharmacological therapy					
	Antiplatelet	ATA	Prostaglandin	Heparin	Statin	Others
Rutherford 4	110	11	5	2	12	9
Rutherford 5	348	32	50	37	31	15
Rutherford 6	71	7	9	11	6	4
Total	529	50	64	50	49	28

b. ASO

	Pharmacological therapy					
	Antiplatelet	ATA	Prostaglandin	Heparin	Statin	Others
Rutherford 4	110	11	5	2	12	9
Rutherford 5	336	30	47	35	30	14
Rutherford 6	71	7	9	11	6	4
Total	517	48	61	48	48	27

Antiplatelet: aspirin, cilostazol, beraprost, sarpogrelate, ticlopidine, clopidogrel, ethyl icosapentate.
ATA: antithrombotic agent

Table 4-6 Treatment 6

a. Total

	Femoral–proximal popliteal bypass	Femoral–distal popliteal bypass	Femoral–crural/foot bypass	Popliteal–crural/foot bypass
Polyester	11	1	2	1
ePTFE	56	21	4	12
Vein	34	40	134	131
Artery	1	0	6	10
Others	0	0	0	0
(−)	0	3	2	1
Total	102	65	148	155

b. ASO

	Femoral–proximal popliteal bypass	Femoral–distal popliteal bypass	Femoral–crural/foot bypass	Popliteal–crural/foot bypass
Polyester	10	1	2	1
ePTFE	56	21	4	12
Vein	33	39	132	123
Artery	1	0	5	8
Others	0	0	0	0
(−)	0	0	2	1
Total	100	64	145	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

a. Total

		Life prognosis			Causes of death											
						Cerebrovascular disease					Infection					
		Alive	Dead	Unknown	Cardiac disease	Hemorrhage	Infarction	Unknown	Malignant neoplasm	Aortic aneurysm/ dissection	Diseased limb	Others	Ischemic enteritis	Gastrointestinal bleeding	Others	Unknown
Local condition	Rutherford 4	160	4	0	1	0	0	0	1	0	0	0	0	0	1	1
	Rutherford 5	532	18	0	4	0	3	0	1	0	3	0	1	0	4	2
	Rutherford 6	110	6	0	3	1	0	0	0	0	1	0	0	0	0	1
Therapeutic measures	Non-reconstruction	53	2	0	1	1	0	0	0	0	0	0	0	0	0	0
	EVT	322	15	0	6	0	0	0	1	0	3	0	0	0	4	1
	Surgical reconstruction	427	11	0	1	0	3	0	1	0	1	0	1	0	1	3
	Total	802	28	0	8	1	3	0	2	0	4	0	1	0	5	4

b. ASO

		Life prognosis			Causes of death											
						Cerebrovascular disease					Infection					
		Alive	Dead	Unknown	Cardiac disease	Hemorrhage	Infarction	Unknown	Malignant neoplasm	Aortic aneurysm/ dissection	Diseased limb	Others	Ischemic enteritis	Gastrointestinal bleeding	Others	Unknown
Local condition	Rutherford 4	159	3	0	1	0	0	0	0	0	0	0	0	0	1	1
	Rutherford 5	520	18	0	4	0	3	0	1	0	3	0	1	0	4	2
	Rutherford 6	107	6	0	3	1	0	0	0	0	1	0	0	0	0	1
Therapeutic measures	Non-reconstruction	51	2	0	1	1	0	0	0	0	0	0	0	0	0	0
	EVT	320	15	0	6	0	0	0	1	0	3	0	0	0	4	1
	Surgical reconstruction	415	10	0	1	0	3	0	0	0	1	0	1	0	1	3
	Total	786	27	0	8	1	3	0	1	0	4	0	1	0	5	4

EVT: endovascular treatment

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	145	3	2	2	152	0	0	0	150	2	145	7	151	1	0
	Rutherford 5	509	3	0	2	500	1	3	10	506	8	487	27	506	6	2
	Rutherford 6	104	1	2	1	107	0	0	1	100	8	100	8	106	0	2
Therapeutic measures	Non-reconstruction	7	1	0	1	9	0	0	0	9	0	9	0	9	0	0
	EVT	329	3	1	4	333	0	0	4	333	4	330	7	333	2	2
	Surgical reconstruction	422	3	3	0	417	1	3	7	414	14	393	35	421	5	2
	Total	758	7	4	5	759	1	3	11	756	18	732	42	763	7	4

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	143	3	2	2	150	0	0	0	148	2	143	7	149	1	0
	Rutherford 5	499	3	0	2	490	1	3	10	496	8	479	25	497	5	2
	Rutherford 6	101	1	2	1	104	0	0	1	98	7	99	6	104	0	1
Therapeutic measures	Non-reconstruction	7	1	0	1	9	0	0	0	9	0	9	0	9	0	0
	EVT	327	3	1	4	331	0	0	4	331	4	328	7	331	2	2
	Surgical reconstruction	409	3	3	0	404	1	3	7	402	13	384	31	410	4	1
	Total	743	7	4	5	744	1	3	11	742	17	721	38	750	6	3

TIA: transient ischemic attack, EVT: endovascular treatment

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	149	3	0	0	1	2	3	0	0	0	151	1	79	3
	Rutherford 5	507	6	1	0	1	5	5	1	0	0	513	1	281	3
	Rutherford 6	106	2	0	0	2	0	0	2	0	0	107	1	58	0
Therapeutic measures	Non-reconstruction	9	0	0	0	0	0	0	0	0	0	9	0	13	0
	EVT	333	4	0	0	0	4	4	0	0	0	337	0	331	6
	Surgical reconstruction	420	7	1	0	4	3	4	3	0	0	425	3	74	0
	Total	762	11	1	0	4	7	8	3	0	0	771	3	418	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	147	3	0	0	1	2	3	0	0	0	149	1	79	3
	Rutherford 5	497	6	1	0	1	5	5	1	0	0	503	1	279	3
	Rutherford 6	103	2	0	0	2	0	0	2	0	0	104	1	58	0
Therapeutic measures	Non-reconstruction	9	0	0	0	0	0	0	0	0	0	9	0	13	0
	EVT	331	4	0	0	0	4	4	0	0	0	335	0	329	6
	Surgical reconstruction	407	7	1	0	4	3	4	3	0	0	412	3	74	0
	Total	747	11	1	0	4	7	8	3	0	0	756	3	416	6

GI: gastrointestinal, EVT: endovascular treatment

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	87	0.87	77	110	39	35	66	0.89	57	109	14	39
	Rutherford 5	253	0.87	245	116	213	40	170	0.92	161	124	92	43
	Rutherford 6	34	0.94	30	124.5	32	36.5	25	1.02	24	124	17	49
Therapeutic measures	Non-reconstruction	22	0.93	16	119.5	14	34	11	0.96	6	133	7	32
	EVT	171	0.89	166	120.5	137	38	132	0.9	127	120	79	44
	Surgical reconstruction	181	0.87	170	112.5	133	40	118	0.96	109	121	38	44.5
	Total	374	0.88	352	116	284	38.5	261	0.92	242	120	123	43

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	86	0.87	76	110.5	38	35	66	0.89	57	109	14	39
	Rutherford 5	249	0.87	241	116	206	40	169	0.92	161	124	91	44
	Rutherford 6	33	0.93	29	125	30	36.5	24	0.98	23	126	16	52
Therapeutic measures	Non-reconstruction	21	0.92	15	115	13	33	10	0.97	6	133	6	32.5
	EVT	170	0.9	165	120	137	38	132	0.9	127	120	79	44
	Surgical reconstruction	177	0.87	166	112.5	124	40.5	117	0.96	108	121	36	44.5
	Total	368	0.88	346	116	274	39	259	0.92	241	120	121	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	Uncured		Unknown	Ambulatory	Ambulatory/ homebound	Nonambulatory
													Improved	Deteriorated				
Local condition	Rutherford 4	140	3	2	0	0	1	2	144	13	3	111	31	12	4	112	27	25
	Rutherford 5	461	8	20	0	1	6	6	432	60	23	133	301	77	4	310	109	131
	Rutherford 6	90	4	5	0	0	0	3	76	12	4	9	69	13	0	30	25	61
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	24	8	1	10	16	3	1	31	7	17
	EVT	294	9	11	0	0	3	9	247	50	19	89	161	61	5	157	67	113
	Surgical reconstruction	397	6	16	0	1	4	2	381	27	10	154	224	38	2	264	87	87
Total		691	15	27	0	1	7	11	652	85	30	253	401	102	8	452	161	217

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	Deteriorated				
Local condition	Rutherford 4	139	3	2	0	0	1	2	142	13	3	109	31	12	4	110	27	25
	Rutherford 5	453	8	19	0	1	6	5	423	59	22	131	295	74	4	301	107	130
	Rutherford 6	89	4	3	0	0	0	3	75	10	4	8	67	13	0	28	24	61
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	22	8	1	10	14	3	1	30	7	16
	EVT	293	9	11	0	0	3	8	246	50	19	88	161	61	5	156	66	113
	Surgical reconstruction	388	6	13	0	1	4	2	372	24	9	150	218	35	2	253	85	87
Total		681	15	24	0	1	7	10	640	82	29	248	393	99	8	439	158	216

EVT: endovascular treatment

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	5	4	143	2	2	1	142	2	0	2	1	1	0	0	158	1	0
	Rutherford 5	21	22	486	0	11	0	468	2	0	8	9	6	1	3	503	22	1
	Rutherford 6	8	6	94	0	2	1	92	1	0	0	2	0	0	2	89	15	0
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	40	3	0
	EVT	16	17	309	0	9	1	297	2	0	5	8	3	1	3	301	19	1
	Surgical reconstruction	18	15	414	2	6	1	405	3	0	5	4	4	0	2	409	16	0
Total		34	32	723	2	15	2	702	5	0	10	12	7	1	5	750	38	1

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	5	4	142	2	2	1	141	2	0	2	1	1	0	0	157	1	0
	Rutherford 5	21	20	476	0	11	0	459	2	0	8	8	6	1	3	492	21	1
	Rutherford 6	6	6	92	0	2	0	91	0	0	0	2	0	0	1	86	15	0
Therapeutic measures	Non-reconstruction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	38	3	0
	EVT	16	16	307	0	9	1	295	2	0	5	8	3	1	3	300	18	1
	Surgical reconstruction	16	14	403	2	6	0	396	2	0	5	3	4	0	1	397	16	0
Total		32	30	710	2	15	1	691	4	0	10	11	7	1	4	735	37	1

EVT: endovascular treatment

Table 5-7 Condition of contralateral limbs

a. Total

		Contralateral limb occlusive lesions							Treatment for contralateral limb									
			(+)							(+)								
		(−)	Asymptomatic	Intermittent claudication	CLI			Post-treatment	Unnecessary	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	47	16	10	1	1	35	7	76	0	19	13	1	2	0	3	0
	Rutherford 5	147	193	31	9	49	1	120	32	270	2	64	56	9	21	0	11	3
	Rutherford 6	41	37	1	1	4	6	26	11	50	0	12	9	4	3	0	2	1
Therapeutic measures	Non-reconstruction	25	13	5	2	1	2	7	0	20	0	5	4	0	1	0	1	0
	EVT	101	97	16	6	29	3	85	22	159	2	62	14	6	17	0	5	3
	Surgical reconstruction	116	167	27	12	24	3	89	28	217	0	28	60	8	8	0	10	1
	Total	242	277	48	20	54	8	181	50	396	2	95	78	14	26	0	16	4

b. ASO

		Contralateral limb occlusive lesions							Treatment for contralateral limb									
			(+)							(+)								
		(−)	Asymptomatic	Intermittent claudication	CLI			Post-treatment	Unnecessary	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	53	47	16	10	1	1	34	7	75	0	19	13	1	2	0	3	0
	Rutherford 5	144	191	31	9	47	1	115	31	266	2	64	54	9	19	0	11	3
	Rutherford 6	39	37	1	1	4	6	25	10	50	0	12	9	4	3	0	2	1
Therapeutic measures	Non-reconstruction	23	13	5	2	1	2	7	0	20	0	5	4	0	1	0	1	0
	EVT	101	97	16	6	28	3	84	22	158	2	62	14	6	16	0	5	3
	Surgical reconstruction	112	165	27	12	23	3	83	26	213	0	28	58	8	7	0	10	1
	Total	236	275	48	20	52	8	174	48	391	2	95	76	14	24	0	16	4

CLI: critical limb ischemia, EVT: endovascular treatment

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	161	1	2	0	0	0	0	0	0	0	0	0	0	1
	Rutherford 5	546	1	3	0	0	0	0	0	1	0	0	0	0	0
	Rutherford 6	116	0	0	0	0	0	0	0	0	0	0	0	0	0
Therapeutic measures	Non-reconstruction	55	0	0	0	0	0	0	0	0	0	0	0	0	0
	EVT	332	2	3	0	0	0	0	0	1	0	0	0	0	1
	Surgical reconstruction	436	0	2	0	0	0	0	0	0	0	0	0	0	0
	Total	823	2	5	0	0	0	0	0	1	0	0	0	0	1

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	159	1	2	0	0	0	0	0	0	0	0	0	0	1
	Rutherford 5	534	1	3	0	0	0	0	0	1	0	0	0	0	0
	Rutherford 6	113	0	0	0	0	0	0	0	0	0	0	0	0	0
Therapeutic measures	Non-reconstruction	53	0	0	0	0	0	0	0	0	0	0	0	0	0
	EVT	330	2	3	0	0	0	0	0	1	0	0	0	0	1
	Surgical reconstruction	423	0	2	0	0	0	0	0	0	0	0	0	0	0
	Total	806	2	5	0	0	0	0	0	1	0	0	0	0	1

EVT: endovascular treatment