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 II5: 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 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), 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 m²) 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), 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 wheelchair were designated as “ambulatory/homebound.”

Regarding the state of local tissue defect (Texas University Classification), 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
breaths/min or PaCO₂ > 38 indicating systemic infection, was manifested by 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 were differentiated based on the size of the lesion, an increased number of that in femoropopliteal or foot artery in 5% (5%), in the aortoiliac artery and the crural or foot artery in 30% (31%), and in the femoropopliteal 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 ischemic grading (Table 1-2-2).

The lesion was considered infected when it showed two or more of the following signs: temperature > 38°C or < 36°C, heart rate > 90 beats/min, respiratory rate > 20 breaths/min or PaCO₂ < 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 lesion 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, TcPO₂ 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 infragenual 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 improved 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 that than 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 and a new clinical guideline, the Global Vascular Guideline, was published instead of TASC in 2019. 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 Kashima 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
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Department of Vascular Surgery, Kawasaki Municipal Hospital
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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
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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^{25}

#### 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\textsubscript{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\textsubscript{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\textsubscript{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 PaCO₂ < 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, PACO₂: 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 | Depth of ulcer (University of Texas classification: grade) | Sites of ulcer | Sites of gangrene |
|-------|---------------------------|-------|----------------------------------------------------------|---------------|------------------|
| 0     | Class 4                   | No ulcer | No gangrene                              |               |
| 1     | Class 5, 6                | Any portion | No gangrene                             |               |
|       | II, III                   | Limited to digits |                                           |               |
| 2     | Class 5, 6                | Heel | Foot: distal metatarsal excluding heel | Limited to digits |
|       | II, III                   |     |                                             |               |
| 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’ background 1

#### a. Total

| Rutherford | n | Male | Female | Right | Left | Age at registration | Age at registration |
|------------|---|------|--------|-------|------|---------------------|---------------------|
| 4          | 221 | 151  | 70     | 106   | 115  | 21.6                | 71.0 (9.6)          |
| 5          | 744 | 501  | 243    | 365   | 379  | 21.1                | 74.5 (10.2)         |
| 6          | 172 | 108  | 64     | 83    | 89   | 20.4                | 72.9 (9.9)          |
| Total      | 1137| 760  | 377    | 554   | 583  | 21.1                | 74.3 (10.0)         |

#### b. ASO

| Rutherford | n | Male | Female | Right | Left | Age at registration |
|------------|---|------|--------|-------|------|---------------------|
| 4          | 216 | 148  | 68     | 104   | 112  | 21.6                | 74.9 (9.6)          |
| 5          | 727 | 491  | 236    | 359   | 368  | 21.1                | 74.5 (10.2)         |
| 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, Behçet 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' background 2

#### a. Total

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

#### b. ASO

|                  | Diabetes | Diabetes therapy | Hypertension | Dyslipidemia | Smoking |
|------------------|----------|------------------|--------------|--------------|---------|
|                  | (-)      | (+)              | (-)          | (+)          | (-)     |
|                  | Management | Diet therapy | Medication | Insulin therapy | Management | Diet therapy | Medication | Insulin therapy | Management | Diet therapy | Medication | Insulin therapy | Ex-smoker | Current smoker |
| Rutherford 4     | 94       | 93               | 29           | 15           | 149     | 28          | 128         | 79           | 9           | 73       | 107       | 36          |
| Rutherford 5     | 263      | 363              | 101          | 54           | 480     | 65          | 468         | 222          | 37          | 308      | 321       | 98          |
| Rutherford 6     | 55       | 80               | 36           | 15           | 101     | 31          | 113         | 51           | 7           | 75       | 77        | 19          |
| Total            | 412      | 536              | 166          | 84           | 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’ background 3

#### a. Total

| Ischemic heart disease | Heart failure | Cerebrovascular disease | Renal dysfunction |
|------------------------|--------------|------------------------|-------------------|
| (-)                    | (+)          | (-) (+)                | (-) (+)           |
| Medical treatment      | PCI          | CABG                   |                   |

| 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                   |                   |

| 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 m²) 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 |
|--------------------|-----------------------------|
| (-)                | (+)                         |
| History of cancer  | Under treatment* Unknown    |
| Head and neck      | Esophagus                   |
| Lung               | Stomach                     |
| Hepatobiliary      | Pancreas                    |
| Colon              | Breast                      |
| Uterus             | Ovarium                     |
| Prostate           | Others                      |

| 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 |
|--------------------|-----------------------------|
| (-)                | (+)                         |
| History of cancer  | Under treatment* Unknown    |
| Head and neck      | Esophagus                   |
| Lung               | Stomach                     |
| Hepatobiliary      | Pancreas                    |
| Colon              | Breast                      |
| Uterus             | Ovarium                     |
| Prostate           | Others                      |

| 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’ 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 |
| Rutherford 4   | 62                                  | 51                                  | 20                    | 37         | 5           | 0        | 46       | 176 | 0.81          | 26                          | 62                  | 74       | 35 | 0          |
| Rutherford 5   | 156                                 | 207                                 | 53                    | 23         | 143         | 7        | 155      | 525 | 0.77          | 65                          | 35                  | 334      | 37 | 0          |
| Rutherford 6   | 30                                  | 45                                  | 10                    | 3          | 15          | 30       | 39       | 83  | 0.82          | 10                          | 37                  | 53       | 42 | 0          |
| Total          | 248                                 | 303                                 | 83                    | 63         | 163         | 37       | 240      | 784 | 0.78          | 101                         | 37                  | 464      | 37 | 0          |

#### 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 |
| Rutherford 4   | 61                                  | 48                                  | 20                    | 36         | 5           | 0        | 46       | 171 | 0.81          | 26                          | 62                  | 75       | 35 | 0          |
| Rutherford 5   | 146                                 | 205                                 | 53                    | 23         | 139         | 7        | 154      | 510 | 0.76          | 65                          | 35                  | 326      | 37 | 0          |
| Rutherford 6   | 30                                  | 45                                  | 10                    | 2          | 15          | 30       | 39       | 83  | 0.82          | 10                          | 37                  | 53       | 42 | 0          |
| Total          | 237                                 | 298                                 | 83                    | 61         | 159         | 37       | 239      | 764 | 0.78          | 101                         | 37                  | 454      | 37 | 0          |

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 |
| Rutherford 4   | 6          | 162.9                  | 6                          | 59.0                       | 6      | 118.2  |
| Rutherford 5   | 22         | 168.1                  | 22                         | 42.4                       | 22     | 96.2   |
| Rutherford 6   | 4          | 158.1                  | 4                          | 83.3                       | 4      | 179.2  |
| Total          | 32         | 163.6                  | 32                         | 47.2                       | 32     | 100.0  |

#### b. ASO

|                | Fatty acid | Arachidonic acid (AA) | Eicosapentaenoic acid (EPA) | Docosahexaenoic acid (DHA) | EPA/AA |
|----------------|------------|------------------------|----------------------------|----------------------------|--------|
|                | n          | Median                 | n                          | Median                     | n      | Median |
| Rutherford 4   | 6          | 162.9                  | 6                          | 59.0                       | 6      | 118.2  |
| Rutherford 5   | 21         | 164.6                  | 21                         | 40.8                       | 21     | 95.2   |
| Rutherford 6   | 4          | 158.1                  | 4                          | 83.3                       | 4      | 179.2  |
| Total          | 31         | 162.6                  | 31                         | 44.0                       | 31     | 99.8   |
Table 3  Pretreatment condition

Table 3-1  Pretreatment condition 1

| Ambulatory function | 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            | 580              | 78                        | 25              | 57     | 17       | 13       | 67                  | 472     | 130       | 133       | 377              | 47                        | 12              | 30       | 8         | 5       | 336                  | 605     | 66        | 15        | 37       | 10       | 11       |
| Rutherford 5       | 169           | 133         | 60            | 60               | 37                        | 41              | 54     | 18       | 16       | 29                  | 45      | 49         | 78         | 60               | 44                        | 29              | 41       | 12        | 13       | 44                  | 31      | 38        | 24        | 48        | 12        | 19        |
| Rutherford 6       | 55            | 63          | 55            | 580              | 78                        | 25              | 57     | 17       | 13       | 67                  | 472     | 130       | 133       | 377              | 47                        | 12              | 30       | 8         | 5       | 336                  | 605     | 66        | 15        | 37       | 10       | 11       |
| Total              | 665           | 252         | 220           | 640              | 115                       | 66              | 111    | 35       | 29       | 96                  | 517     | 186       | 211       | 437              | 91                        | 41              | 71       | 20        | 18       | 380                  | 636     | 104       | 39        | 85        | 22        | 30        |

b. ASO

| Ambulatory function | 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            | 565              | 77                        | 25              | 57     | 17       | 12       | 67                  | 458     | 139       | 130       | 368              | 46                        | 12              | 30       | 8         | 5       | 329                  | 590     | 65        | 15        | 37       | 10       | 10       |
| Rutherford 5       | 166           | 133         | 60            | 59               | 36                        | 40              | 53     | 17       | 15       | 29                  | 44      | 49         | 78         | 59               | 43                        | 28              | 40       | 11        | 12       | 44                  | 31      | 38        | 24        | 48        | 12        | 18        |
| Rutherford 6       | 55            | 63          | 55            | 565              | 77                        | 25              | 57     | 17       | 12       | 67                  | 458     | 139       | 130       | 368              | 46                        | 12              | 30       | 8         | 5       | 329                  | 590     | 65        | 15        | 37       | 10       | 10       |
| 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 | Local (foot) | Systemic |
|-------------------|------------|---------------|-------------|-------------|----------|
|                   | WBC | CRP | Alb | Cr | ABI | TBI | SPP | Toe pressure | Skin or subcutaneous tissue (erythema)*2 | Deep tissue*3 | SIRS*4 |
| (-) (+)           | n | Median | n | Median | n | Median | n | Median | n | Median | Uninfected | ≤ 2.0 cm | > 2.0 cm | (+) | (-) |
| 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 | Local (foot) | Systemic |
|-------------------|------------|---------------|-------------|-------------|----------|
|                   | WBC | CRP | Alb | Cr | ABI | TBI | SPP | Toe pressure | Skin or subcutaneous tissue (erythema)*2 | Deep tissue*3 | SIRS*4 |
| (-) (+)           | n | Median | n | Median | n | Median | n | Median | n | Median | Uninfected | ≤ 2.0 cm | > 2.0 cm | (+) | (-) |
| 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 | 219 |
| 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 | 9,110 | 166 | 3.765 | 154 | 2.85 | 168 | 1.56 | 75 | 0.67 | 6 | 0.17 | 75 | 24.00 | 6 | 26.0 | 75 | 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: ① Local swelling or induration, ② Erythema > 0.5 to ≤ 2 cm around the ulcer, ③ Local tenderness or pain, ④ Local warmth, ⑤ Purulent discharge (thick, opaque to white, or sanguineous secretion).

*2 Local infection at skin and subcutaneous tissue was classified by the spreading of erythema (≤ 2.0 cm or > 2 cm) 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: ① Temperature > 38°C or < 36°C, ② Heart rate > 90 beats/min, ③ Respiratory rate > 20 breaths/min or PaCO₂ < 32 mmHg, ④ White 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 |
|--------------------|--------------------|-----------------------------------|---------------------------------------|
|                    |                    | A | B | C | D | No lesion | A | B | C | D | No lesion |
| 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 |
|--------------------|--------------------|-----------------------------------|---------------------------------------|
|                    |                    | A | B | C | D | No lesion | A | B | C | D | No lesion |
| 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

| 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       | 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 |

### Table 3-6  SVS WIfI classification

| Wound | Ischemia | Foot infection | Stage |
|-------|----------|----------------|-------|
| 0     | 1        | 2             | 3     |
| Rutherford 4 | 221 | 14 | 204 | 204 |
| Rutherford 5 | 0 | 1 | 3 | 40 |
| Rutherford 6 | 0 | 1 | 75 | 0 |
| **Total** | 221 | 88 | 785 | 92 |

### Table 3-6  SVS WIfI classification (continued)

| Wound | Ischemia | Foot infection | Stage |
|-------|----------|----------------|-------|
| 0     | 1        | 2             | 3     |
| Rutherford 4 | 216 | 14 | 199 | 39 |
| Rutherford 5 | 0 | 1 | 493 | 50 |
| Rutherford 6 | 0 | 1 | 74 | 0 |
| **Total** | 216 | 86 | 766 | 89 |
### Table 4  Treatment

#### Table 4-1  Treatment 1

|                | Treatment | Angiogenic therapy | Amputation | Reoperation |
|----------------|-----------|--------------------|------------|-------------|
|                |           | Bone marrow | Peripheral blood | Others | Toe | Metatarsal | Chopart | Lisfranc | Syme | Below knee | Above knee | Disarticulation | Hip | Disarticulation | Unknown | (−) | (+) |
| Rutherford 4   | 90        | 203       | 2          | 0       | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 4   | 42 | 14 |
| Rutherford 5   | 259       | 719       | 8          | 1       | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 1   | 2   | 0   | 0   | 3   | 569| 34 |
| Rutherford 6   | 60        | 160       | 16         | 1       | 0   | 0   | 0   | 0   | 0   | 1   | 0   | 0   | 4   | 4   | 0   | 0   | 1   | 144| 15 |
| Total          | 409       | 1082      | 26         | 2       | 0   | 0   | 0   | 0   | 17  | 4   | 0   | 5   | 6   | 0   | 0   | 4   | 671| 155 | 61 |

#### Table 4-2  Treatment 2

|                | Treatment | Angiogenic therapy | Amputation | Reoperation |
|----------------|-----------|--------------------|------------|-------------|
|                |           | Bone marrow | Peripheral blood | Others | Toe | Metatarsal | Chopart | Lisfranc | Syme | Below knee | Above knee | Disarticulation | Hip | Disarticulation | Unknown | (−) | (+) |
| Rutherford 4   | 88        | 201       | 2          | 0       | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 155| 15 | 7 |
| Rutherford 5   | 252       | 708       | 8          | 1       | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 4   | 2   | 0   | 3   | 556| 96 | 38 |
| Rutherford 6   | 60        | 159       | 16         | 1       | 0   | 0   | 0   | 0   | 0   | 1   | 0   | 0   | 4   | 4   | 0   | 0   | 1   | 143| 15 | 7 |
| Total          | 400       | 1068      | 26         | 2       | 0   | 0   | 0   | 0   | 17  | 4   | 0   | 5   | 6   | 0   | 0   | 4   | 854| 151 | 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-crunal/foot | Popliteal-crunal/foot | Anatomical others | Axillary-femoral | Femoral-femoral | Extra-anatomical others | Aorta/iliac | Femoral/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-crunal/foot | Popliteal-crunal/foot | Anatomical others | Axillary-femoral | Femoral-femoral | Extra-anatomical others | Aorta/iliac | Femoral/popliteal | Others |
| Rutherford 4     | 1 | 0 | 3 | 23 | 23 | 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 | 385 | 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: 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                               |
|               |                      |                                           | Anterior                               |
|               |                      |                                           | Peroneal                               |
|               |                      |                                           | Dorsalis pedis                         |
|               |                      |                                           | Plantar                                |
| Rutherford 4 | 0                    | 14                                       | 2                                      |
|               | 8                    | 6                                        | 4                                      |
|               | 2                    | 1                                        | 1                                      |
|               |                      |                                           | Rutherford 5                           |
|               | 5                    | 46                                       | 6                                      |
|               | 36                   | 25                                       | 89                                     |
|               | 5                    | 7                                        | 17                                     |
|               |                      |                                           | Rutherford 6                           |
|               | 0                    | 6                                        | 3                                      |
|               | 6                    | 4                                        | 18                                     |
|               | 3                    | 1                                        | 13                                     |
|               |                      |                                           | Total                                   |
|               | 5                    | 66                                       | 11                                     |
|               | 50                   | 35                                       | 111                                    |
|               | 10                   | 9                                        | 109                                    |
|               |                      |                                           | 184                                    |
|               |                      |                                           | 8                                      |
|               |                      |                                           | 53                                     |
|               |                      |                                           | 36                                     |
|               |                      |                                           | 14                                     |
|               |                      |                                           | 37                                     |
|               |                      |                                           | 24                                     |
|               |                      |                                           | 6                                      |
|               |                      |                                           | 103                                    |
|               |                      |                                           | 18                                     |
| Rutherford 5 | 5                    | 44                                       | 6                                      |
|               | 35                   | 25                                       | 82                                     |
|               | 5                    | 7                                        | 79                                     |
|               |                      |                                           | Rutherford 6                           |
|               | 0                    | 6                                        | 3                                      |
|               | 6                    | 4                                        | 18                                     |
|               | 2                    | 1                                        | 13                                     |
|               |                      |                                           | Total                                   |
|               | 5                    | 64                                       | 11                                     |
|               | 49                   | 35                                       | 103                                    |
|               | 9                    | 9                                        | 105                                    |
|               |                      |                                           | 176                                    |
|               |                      |                                           | 7                                      |
|               |                      |                                           | 51                                     |
|               |                      |                                           | 36                                     |
|               |                      |                                           | 13                                     |
|               |                      |                                           | 33                                     |
|               |                      |                                           | 24                                     |
|               |                      |                                           | 6                                      |
|               |                      |                                           | 102                                    |
|               |                      |                                           | 15                                     |
| Rutherford 6 | 0                    | 6                                        | 3                                      |
|               | 4                    | 18                                       | 2                                      |
|               | 1                    | 2                                        | 1                                      |
|               |                      |                                           | 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

|                | 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     |

#### a. 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

|                | 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/cause of death

| Life prognosis | Causes of death | Infection | Ischemic | Gastrointestinal bleeding | Others | Unknown |
|----------------|-----------------|-----------|----------|---------------------------|--------|---------|
| Alive | Dead | Intraoperative death | Cardiac disease | Cerebrovascular disease | Malignant neoplasm | Aortic aneurysm/dissection | Diseased limb | Others | |
| Intraoperative death | Cardiac disease | Cerebrovascular disease | Malignant neoplasm | Aortic aneurysm/dissection | Diseased limb | Others | |
| Intraoperative death | Cardiac disease | Cerebrovascular disease | Malignant neoplasm | Aortic aneurysm/dissection | Diseased limb | Others | |
| Intraoperative death | Cardiac disease | Cerebrovascular disease | Malignant neoplasm | Aortic aneurysm/dissection | Diseased limb | Others | |
| Rutherford 4 | 178 | 5 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 2 |
| Rutherford 5 | 600 | 21 | 1 | 7 | 0 | 1 | 0 | 0 | 1 | 2 | 1 | 1 | 6 | 2 |
| Rutherford 6 | 140 | 7 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 1 | 0 |
| Total | 927 | 33 | 1 | 8 | 0 | 1 | 0 | 0 | 2 | 4 | 4 | 1 | 2 | 6 | 5 |
| Local condition | Rutherford 4 | 173 | 5 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 2 |
| Rutherford 5 | 594 | 21 | 0 | 7 | 0 | 1 | 0 | 0 | 1 | 2 | 1 | 1 | 6 | 2 |
| Rutherford 6 | 139 | 7 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 1 | 0 |
| Total | 906 | 33 | 1 | 8 | 0 | 1 | 0 | 0 | 2 | 4 | 4 | 1 | 2 | 6 | 5 |

b. ASO
Table 5-2  Perioperative complications 1

a. Total

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

b. ASO

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

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 | 170 2 | 84 0 |
| Rutherford 5 | 604 13 1 | 2 2 | 9 11 0 | 0 2 0 613 5 | 319 6 |
| Rutherford 6 | 139 2 1 | 0 1 | 1 2 0 2 | 0 0 1 141 1 | 83 0 |
| Therapeutic measures | | | | |
| Non-reconstruction | 12 0 | 1 0 0 | 0 0 0 | 13 0 | 8 1 |
| EVT | 396 6 1 | 1 2 | 3 5 0 1 | 0 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 | 165 2 | 83 0 |
| Rutherford 5 | 590 13 1 | 2 2 | 9 11 0 | 2 0 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 | 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

| Local condition | ABI | Ankle pressure | SPP | ABI | Ankle pressure | SPP |
|-----------------|-----|----------------|-----|-----|----------------|-----|
|                 | n   | Median         | n   | Median | n   | Median         | n   | Median |
| 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 | ABI | Ankle pressure | SPP | ABI | Ankle pressure | SPP |
|----------------------|-----|----------------|-----|-----|----------------|-----|
| 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

| Local condition | ABI | Ankle pressure | SPP | ABI | Ankle pressure | SPP |
|-----------------|-----|----------------|-----|-----|----------------|-----|
|                 | n   | Median         | n   | Median | n   | Median         | n   | Median |
| 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 | ABI | Ankle pressure | SPP | ABI | Ankle pressure | SPP |
|----------------------|-----|----------------|-----|-----|----------------|-----|
| 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          | 164 | 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

| Local condition | 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) | Infected | Others | Improved | No change | Deteriorated | Cured | Improved | Unchanged | Deteriorated | Unknown | Ambulatory | Ambulatory/ homebound | Nonambulatory |
| 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 EVT | 0 | 0 | 0 | 0 | 0 | 0 | 14 | 3 | 2 | 8 | 6 | 5 | 0 | 19 | 6 | 16 |
| Surgical reconstruction | 476 | 11 | 12 | 2 | 2 | 2 | 2 | 148 | 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       |

| Therapeutic measures | Bypass graft/EVT condition | Clinical symptoms of the limb | Ischemic wound | Ambulatory function at discharge (Taylor’s classification) |
|----------------------|-----------------------------|------------------------------|----------------|----------------------------------------------------------|
| Local condition      | Good | Stenosis | Occlusion | Deterioration | Anastomosis disruption (aneurysm) | Infected | Others | Improved | No change | Deteriorated | Cured | Improved | Unchanged | Deteriorated | Unknown | Ambulatory | Ambulatory/ homebound | Nonambulatory |
| 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          | 139   | 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 EVT | 0 | 0 | 0 | 0 | 0 | 0 | 14 | 2 | 2 | 8 | 6 | 4 | 0 | 18 | 6 | 16 |
| 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

| Local condition | 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 |
| 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 |       |      |        |             |             |       | 25 3              | 0               |
|                  | EVT     | 377          | 0   | 18 4   | 382 1     | 0 5 6 2 2 2 |       |      |        |             |             |       | 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

| Local condition | 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 |
| 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 |       |      |        |             |             |       | 24 3              | 0               |
|                  | EVT     | 375          | 0   | 18 4   | 380 1     | 0 5 6 2 2 2 |       |      |        |             |             |       | 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 | (+) | Pharmacological therapy | Angiogenic therapy | EVT | Surgical bypass | Minor amputation | Major amputation | Lumber sympathectomy | Necessary but no treatment | Others |
| Local condition | Rutherford 4 | 55 | 65 | 16 | 6 | 2 | 0 | 39 | 11 | 91 | 0 | 23 | 14 | 1 | 4 | 0 | 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 | 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 | (+) | Pharmacological therapy | Angiogenic therapy | EVT | Surgical bypass | Minor amputation | Major amputation | Lumber sympathectomy | Necessary but no treatment | Others |
| 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 | 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

| Local condition | 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 |
| Rutherford 4    | 181 2 0                             | 0 0 0 0 1 1 1 0 0 0 0 0 0 0 |
| Rutherford 5    | 625 2 3                             | 0 0 0 2 0 0 0 0 0 0 0 0 0 0 |
| Rutherford 6    | 145 1 1                             | 0 0 0 1 0 0 0 0 0 0 0 0 0 0 |
| Therapeutic measures | 40 0 1 | 0 0 0 0 1 1 0 0 0 0 0 0 0 0 |
| EVT             | 397 4 2                             | 0 0 0 2 0 0 0 0 0 0 0 0 0 0 |
| Surgical reconstruction | 514 1 1 | 0 0 0 1 0 0 0 0 0 0 0 0 0 0 |
| Total           | 951 5 4                             | 0 0 0 3 1 1 0 0 0 0 0 0 0 0 |

### b. ASO

| Local condition | 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 |
| Rutherford 4    | 176 2 0                             | 0 0 0 0 1 1 1 0 0 0 0 0 0 0 |
| Rutherford 5    | 610 2 3                             | 0 0 0 2 0 0 0 0 0 0 0 0 0 0 |
| Rutherford 6    | 144 1 1                             | 0 0 0 1 0 0 0 0 0 0 0 0 0 0 |
| Therapeutic measures | 39 0 1 | 0 0 0 0 1 1 0 0 0 0 0 0 0 0 |
| EVT             | 395 4 2                             | 0 0 0 2 0 0 0 0 0 0 0 0 0 0 |
| Surgical reconstruction | 496 1 1 | 0 0 0 1 0 0 0 0 0 0 0 0 0 0 |
| Total           | 930 5 4                             | 0 0 0 3 1 1 0 0 0 0 0 0 0 0 |