### 🍃 Annual Report 🐔

## Vascular Surgery in Japan: 2011 Annual Report by the Japanese Society for Vascular Surgery

The Japanese Society for Vascular Surgery Database Management Committee Member, NCD Vascular Surgery Data Analysis Team

This is an annual report indicating the number and early clinical results of annual vascular treatments performed by vascular surgeons in Japan during 2011, as analyzed by database management committee (DBC) members of the Japanese Society for Vascular Surgery (JSVS).

Materials and Methods: To survey the current status of vascular treatments performed by vascular surgeons in Japan, the DBC members of the JSVS analyzed the vascular treatment data provided from National Clinical Database (NCD), including the number of treatments and early clinical results such as operative and in-hospital mortality. Given that NCD data were prospectively built by a nationwide registration, this annual report reports prospective clinical data. Results: In total 71,707 vascular treatments including open repairs and endovascular treatments were registered by 992 institutions in 2011. This database is composed of 7 fields including treatment of aneurysms, chronic arterial occlusive disease, acute arterial occlusive disease, vascular injury, complication of vascular reconstruction, venous diseases, and other vascular treatments. The number of vascular treatments in each field was 17,524, 11,278, 3,799, 1,030, 1,615, 19,371, and 17,510, respectively. In the field of aneurysm treatment, 13,218 cases with abdominal aortic aneurysms (AAA) including iliac aneurysms were registered, including 1,253 ruptured cases. Forty-five percent of AAA cases were treated by stent graft. The operative mortality of ruptured and non-ruptured AAA was 18.8% and 0.8%. respectively. Regarding chronic arterial occlusive disease, open repair was performed in 7,115 cases including 984 distal bypasses to the crural or pedal artery, whereas endovascular procedures were performed in 4,163 cases. For acute arterial occlusive disease, more than 90% of cases

were treated with open repair. Vascular injury treatment included 81 venous injury cases and 949 arterial injury cases, and 60% of arterial injuries were iatrogenic. Treatment for complication of previous vascular treatment included 445 cases of graft infections, 240 cases of anastomotic aneurysms, and 811 cases of graft revision operations. The venous treatment included 18,864 varicose vein treatments, 343 cases with lower limb deep venous thrombosis, and 67 cases with vena cava reconstructions. Regarding other vascular operations, 16,296 cases of vascular access operations and 1,037 amputation surgeries are included.

**Conclusions**: This vascular surgery database indicates not only the number of vascular treatments but also the early clinical outcomes for each treatment procedure, thereby representing a useful source for researching the clinical background of poor outcomes and for finding improvements in the quality of treatment. Continuing this work will provide information regarding changing the treatment modality in response to the changing structure of disease and societal needs. (This is a translation of Jpn J Vasc Surg 2017; 26: 45–64.)

*Keywords:* peripheral arterial disease, aneurysm, stent graft, endovascular treatment, varicose vein

### Introduction

The Japanese Society for Vascular Surgery (JSVS) has independently collated all vascular surgical procedures in Japan since 2004. Furthermore, since 2011, almost all surgical cases in Japan have been registered in the National Clinical Database (NCD), which was launched that year, when the registration of surgical cases commenced. The JSVS has used these data to publish an annual report on vascular surgery. The present report summarizes the vascular surgical procedures registered in NCD, with an analysis of these procedures by the database management committee members of the JSVS.

It must be noted that data collection methods greatly differed from those of "Vascular Surgery Case Totals" published on the JSVS website, which was conducted in 2004–2010. Until 2010, JSVS conducted an annual questionnaire survey of institutions that performed vascular surgery and published an analysis of the data. Each

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reporting institution reviewed and summarized its surgical procedures for the year and reported the summary to JSVS. In 2010, 53,821 vascular surgical cases were reported by 311 institutions. The questionnaire response rate was extremely high at 98.7%; thus, this process provided an important contribution to establishing the situation nationwide. In contrast, the 2011 annual report, which is introduced in the present report, collated data that had been prospectively registered for each individual case by each institution at the time of surgery. A disadvantage of this system is that incorrect or missing data, if not removed from the analysis, could result in inconsistencies between the total number of procedures and the summarized results. Conversely, the prospective nature of the registry is a great advantage. Furthermore, 992 institutions registered vascular surgical procedures, representing an increase to approximately three times the number of institutions that had previously completed the questionnaires; thus, a major characteristic of the new system is the extensive, comprehensive nature of the data collection. However, the different data collection methods indicate that caution is required when comparing the results of the annual reports since 2011 with those of the questionnaire surveys prior to 2010.

Caution should also be exercised regarding possible overlaps with databases for other fields, particularly those of departments of cardiovascular surgery. Most cases of surgical procedures for the major vessels, especially thoracic aorta surgery, are input into the Japan Adult Cardiovascular Surgery Database (JACVSD); for this reason, the overall vascular surgery data presented in this report do not include information about thoracic aorta surgery. Possible overlaps with departments that administer medical care other than surgery should also be considered. Many patients receive endovascular treatment for peripheral blood vessels from departments of cardiovascular medicine or radiology, but this database does not include data on the number of endovascular procedures performed at these departments. Similarly, venous and lymphatic surgical procedures performed by departments of plastic surgery and limb amputations performed by departments of orthopedics are not included.

### Methods

At the request of JSVS, a governing society of NCD, vascular surgery data for 2011 were extracted. The categories were tabulated and then checked by members of the database management committee of JSVS, and the tabulation results were analyzed, resulting in the following seven categories: 1) treatment for aneurysm, 2) revascularization for chronic arterial occlusion, 3) revascularization for acute arterial occlusion, 4) treatment for vascular trauma, 5) treatment for vascular complications after revascularization, 6) venous surgery, and 7) other vascular disease and related surgery.

The summarized results present the number of cases according to the different surgical procedures, with the underlying pathology, number of operative mortality, inhospital mortality, and the materials used. Operative mortality, which is synonymous with surgery-related death, is defined as all deaths within 30 days of surgery, irrespective of the cause or whether the patient died at the hospital. Inhospital mortality refers to patients who died at any time after the surgery during the same hospital stay.

There are discrepancies in the values given in the table; for example, the totals for the underlying pathology and materials used are inconsistent with the total number of cases. However, careful investigation by this committee and the data analysis team of NCD concluded that the discrepancies resulted from one of the following four factors: 1) input options that permitted multiple responses, 2) input options that permitted null entries, 3) omissions or incorrect input by the individual entering the data, or 4) the use of several materials or treatment of several sites during a single procedure. Since 2013, every effort has been made to implement countermeasures to avoid erroneous input and omissions as far as possible, such as programs for the provision and establishment of options and items that prevent registration of records that include null data.

### Results

In 2011, a total of 1,172,574 surgical procedures performed at 3,008 institutions were registered in NCD, including 71,707 (6.1%) vascular surgical procedures performed at 992 (33.0%) institutions. Of these 992 institutions, 337 (34%) were authorized training institutions for cardiovascular surgery that contributed to this data registration as of 2011. A total of 39,458 cardiovascular surgical procedures were performed at authorized institutions; a high proportion of these were procedures for aneurysms and vascular trauma, with venous surgery, surgery for other vascular diseases, and related procedures accounting for less than half of the procedures (Fig. 1). The 2011 results and analyses by category are outlined below. Statistical analyses were performed using the chisquare test, with p-values of < 0.05 considered to indicate statistical significance.

### 1. Treatment of Aneurysms (Table 1)

### 1) Aneurysms of the thoracic aorta

Most procedures for aneurysms of the thoracic aorta were registered in JACVSD through the Japan Cardiovascular

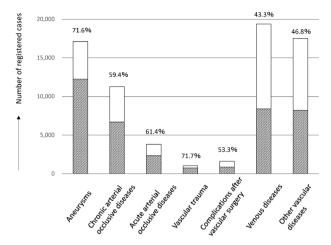


Fig. 1 The number of annual operations in each category. The percentage values and the shadow parts demonstrate the proportion of operations performed in the institutions certified by Japanese Board of Cardiovascular Surgery.

Surgery Database Organization, whereas some procedures performed by vascular surgeons were included in this vascular surgery database via NCD (Table 1). Thus, the registration of surgery for the thoracic aortic aneurysms in Japan is currently divided, making it impossible to obtain an accurate overall image of the current state. In addition to JACVSD, the Japan Association for Thoracic Surgery (JATS) conducts a questionnaire survey and presents an annual report in their journal.<sup>1)</sup> The data from this serve as a reference; however, the difference in collection method (by questionnaire rather than the reporting system used for the present report) and the lack of clarity on how many vascular surgeons who performed surgery for aneurysms of the thoracic aorta responded to the JATS questionnaire prevent the determination of the overall number of surgical procedures for aneurysms of the thoracic aorta conducted across Japan. Going forward, efforts must be made in cooperation with JACVSD to grasp an overview of surgery for aneurysms of the thoracic aorta throughout Japan.

### Aneurysms of the abdominal aorta (Tables 1-1 and 1-2)

According to NCD, in 2011, there were 13,218 surgical cases for abdominal aortic aneurysms (AAA) (including iliac aneurysms), of which 82.6% involved men. In surveys of the number of surgical procedures conducted by JSVS before 2010, there were 8,610 surgeries overall for AAA, and it is thought that this discrepancy was considerably influenced by the difference in the method of collating the questionnaire surveys up to 2010 and by the increase in stent graft placement over the year. In 2011, the number of stent grafts registered in NCD was consistent with the

number of annual stent grafts announced by the Japanese Committee for Stentgraft Management. In 2005, the total number of surgeries conducted for AAA in the USA was 41,185, which, given the population of approximately 300 million, is an incidence of 0.014%. The surgical incidence in Japan is approximately 0.011% per population calculated based on the total number of surgeries for the year, which is comparable to that of the USA. In the 2014 mortality rates ranked according to the leading causes of death announced by the Ministry of Health, Labour and Welfare of Japan, aortic aneurysm and aortic dissection were ranked as the 9th leading cause of death. Therefore, the treatment of aneurysm could affect the national death statistics.<sup>2</sup>)

The pathology of AAA was caused by so-called arteriosclerotic degenerative disease in 94.3%, followed by so-called inflammatory aneurysm in 1.6%, and infected aneurysm in 1.4%, with low rates of primary connective tissue disease such as Marfan syndrome and vasculitis at 0.27% and 0.09%, respectively.

The surgical procedure involves a replacement using a Y-graft or tube graft in 53.6%, endovascular aneurysm repair (EVAR) using stent graft in 44.5%, and exclusion bypass in 1.1%. In the USA, stent grafting was approved by the Food and Drug Administration in 1999. In 2004, the numbers of EVAR and conventional surgeries were comparable, whereas in 2005, EVAR outnumbered conventional surgeries.<sup>3)</sup> Thus, in Japan, when stent grafting became applicable for coverage by national health insurance in November 2006, it was assumed that within a few years the number of EVAR would exceed that of replacement surgery. Most artificial vascular grafts used for replacement and exclusion bypass are made of polyester (94.4%), while polytetrafluoroethylene (PTFE) accounts for 4.7% of cases.

Among 7,345 patients with AAA, excluding EVAR, 978 patients required renal artery clamping due to pararenal AAA, 244 patients required renal artery reconstruction (3.3% of open repair cases, 1.8% of AAA overall). Of these, rupture was observed in 12 patients who underwent renal artery reconstruction and 137 patients who underwent renal artery clamping. The mortality rate was 25% for inpatients with rupture and renal artery reconstruction and 29.2% for inpatients with rupture and renal artery clamping. Excluding rupture patients, the mortality rate was 4.7% for inpatients with renal artery reconstruction in elective surgery and 4.0% for those with renal artery clamping, indicating considerably inferior results compared with elective surgery with clamping below the renal artery branch. Furthermore, in Table 1-1, the items "with renal artery reconstruction," "with renal artery clamping" and "graft materials" present numerical data for patients who underwent open repair, whereas patients who under-

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Abdominal aortic aneurysm*2)							280		12,466		CN				277		÷		5,87		6,716	336	87
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Total 1,558	8 1,102	456	31	50	249	19	27	897		15	163	142	336	437	113		467 1-	142 389	212	2 156		165	5

Table 1 Treatment for aneurysm

\*4) Most likely atherosclerotic.

5) Connective tissue abnormalities such as Marfan syndrome.
 \*5) Debranch bypass surgery combined with two staged TEVAR is counted as one case of hybrid treatment.
 \*7) Only for open surgery.
 \*1) Only for open surgery.
 \*1) Intuding TAO. Takayasu anottils, collagen disease related vascuilitis, Behopt disease, fibromuscular dysplasta. Abbreviations: Y graft. T-graft: straight shape artificial graft, Polyester polyester artificial graft such as Dacron graft, ePTFE: expanded polytetrafluoroeitlylene graft

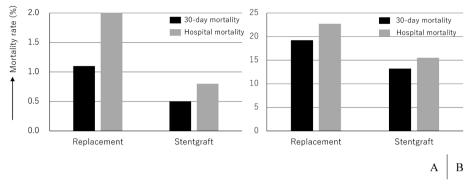


Fig. 2 Early clinical results of abdominal aortic aneurysm (AAA). The 30-day mortality and the hospital mortality of non-ruptured AAA (Fig. 2A) and the ruptured AAA (Fig. 2B). Regarding the statistical difference of mortality rates between open repair (replacement) and stent graft, see main text.

went stent grafting are not included.

There were 1,253 surgeries for rupture, for which the operative mortality rate was 18.8% and the inhospital mortality rate was 22.3%. Meanwhile, excluding rupture cases, operative death in elective surgery occurred in 96 out of 11,965 patients (0.8%), with inhospital death occurring in 174 out of 11,965 patients (1.5%). Although the year differs, in the USA in 2005, the mortality rate for rupture surgery was 40.5%, twice that of Japan. The mortality rate for elective surgery was 2.7%, indicating a better rate in Japan.<sup>3</sup> Among long-term dialysis patients, the operative mortality rate was 3.0% and the inhospital mortality rate was 4.8%. Although the proportion accounting for rupture cases is unclear, the mortality rate is inferior to that of non-dialysis patients.

A differential analysis of the early outcomes of surgical replacement and stent grafting was performed according to the presence or absence of rupture (Table 1-2). For replacement surgery in patients without rupture, operative mortality was 1.1%, and inhospital mortality was 2.0%, whereas for stent grafting, the corresponding rates were 0.5% and 0.8%, respectively, indicating better mortality rates for the latter (Fig. 2A). Meanwhile, for replacement surgery in patients with rupture, operative mortality was 19.2%, and inhospital mortality was 22.7%. For stent grafting, the rates were better, at 13.2% and 15.5%, respectively (Fig. 2A). Upon performing statistical tests, the postoperative mortality rate was found to be lower for stent graft placement than for replacement surgery, with p-values of <0.001 and <0.0001 for operative mortality and inhospital mortality in patients without rupture, respectively. For operative mortality and inhospital mortality in patients with rupture, the p-values were 0.0586 and <0.05. However, as patient and anatomical background differed among the candidate patients with ruptured aneurysms, due care should be paid to the fact that comparison of unmatched data between the two groups poses a problem. In patients with rupture, replacement is selected for patients with unstable hemodynamics and anatomic difficulties, whereas stent grafting can be selected for patients with stable hemodynamics and anatomically simple cases.

### 3) Peripheral aneurysms (Table 1-3)

There were 1,558 registered patients with peripheral aneurysms, with a male-to-female ratio of 1,102:456. This ratio indicates that peripheral aneurysms were more common among men. A breakdown of the regions in descending order indicated that the aneurysm affected arteries of the lower limbs in 652 patients, abdominal splanchnic arteries in 502 patients, arteries of the upper limbs in 371 patients, and aortic arch branches in 58 patients, while according to artery, femoral artery aneurysms were most common at 25.4%, followed by "other" (Table 1-3). The large number of aneurysms observed in "other" may have been because this category mainly included internal iliac artery aneurysms. Based on this result, we decided to revise the registration method for internal iliac artery aneurysms. There were 249 patients with rupture (16.0%), which was most commonly observed in the femoral, brachial, and hepatic arteries. This tendency was similar to that prior to 2010. The selection of surgical procedures included ligature, resection, replacement, exclusion, and bypass surgery, with stent grafting selected in 9.1%. The surgical procedure named "other" was inferred to include procedures such as coil embolization.

### 2. Revascularization for Chronic Arterial Occlusion (Table 2)

Chronic arterial occlusion registered in NCD, as shown in **Table 2**, is divided into five fields including aortic arch branches/upper limbs/abdominal splanchnic arteries, aorta-lower limb arteries, extra-anatomical bypass, thromboendarterectomy of the lower limb arterial system, and endovascular treatment for the lower limb arteries. In this report, we will discuss the results according to different anatomical areas.

## 1) Aortic arch branches/upper limbs/abdominal splanchnic arteries

This region includes the carotid artery, vertebral artery, subclavian artery, multiple lesions of the aortic arch branches, axillary artery-brachial artery, celiac artery/ superior mesenteric artery, renal artery, and other items. For the carotid artery, revascularization was performed in 118 patients, approximately 80% of whom underwent carotid endarterectomy (CEA) and 10% underwent carotid artery stenting (CAS). In the field of neurosurgery, given that CAS is performed in more than 6,000 cases per year and CEA in more than 3,000 cases per year, the number of patients can be understood based on the historical background, whereby unlike in Europe and the USA, in Japan, surgery for carotid artery stenosis has primarily been performed by the department of neurosurgery. The medical standard for implementing CAS requesting 30 cases experiences of cerebral angiography as the minimum requirement in Japan, which is a kind of barrier for vascular surgeons, is a possible reason for the small number of CAS in this registry.

For the subclavian artery, percutaneous transluminal angioplasty (PTA/stent) with or without stent insertion was performed in half of the patients, followed by axillary-axillary arterial bypass in 35%. For the axillary artery-brachial artery, 50% of the patients were dialysis patients, and PTA/stent was performed in approximately 40%, among which endovascular treatment for vascular access might have been registered in this category by misunderstanding. For the celiac artery/superior mesenteric artery, the underlying disease was arteriosclerosis in 90% of patients; in 50% of patients, PTA/stent was performed, whereas in 30% of patients, other treatment by replacement/bypass was performed. It is inferred that endovascular treatment is the first option in these regions. For the renal artery, revasularization was performed by percutaneous transluminal renal angioplasty in 90% of patients. As devices for renal artery lesions are covered by national health insurance, endovascular treatment had been considered the first-line treatment.

### 2) Anatomical bypass, extra-anatomical bypass, and endovascular surgery in the field of the aorto– lower limb arteries

In the field of the aortoiliac artery, anatomical surgical revascularization was performed in 782 patients, most of whom had obstructive arteriosclerosis. At present, for bypass surgery in this field, Dacron artificial grafts were commonly used; however, in aortofemoral artery bypass, ePTFE (expanded polytetrafluoroethylene) artificial grafts were used in >20% of patients, possibly reflecting the inclusion of ilio-femoral artery bypass in this item. Furthermore, there were 34 patients in whom an autogenous vein was used as the vascular graft, and it was inferred that the femoral vein was mainly used in cases with infection. Extra-anatomical bypass includes axillofemoral artery bypass and femoro-femoral crossover bypass, which were performed in 397 patients and 961 patients, respectively. In these procedures, ePTFE vascular grafts have come to be used in >50% of patients. Overall, surgical bypass was performed in 2,000 patients, while endovascular treatment (primarily for the iliac artery) was performed in 2,569 patients. In recent years, although endovascular treatment is often indicated to be the first-line treatment for lesions in this region, it appears to be used less commonly than shown in reports from Europe and the USA. This discrepancy is likely attributable to the fact that many patients who receive endovascular treatment in other medical departments (cardiology, radiology) are not registered in NCD and that vascular surgeons do not necessarily adhere to endovascular treatment for TASC D lesions, such as long obstructive lesions of the iliac artery, and perform relatively minimally invasive extraanatomical bypass surgery for the treatment of such TASC D lesions with or without common femoral artery lesions involving the non-stent zone.

In the superficial femoral artery region, above-knee femoro-popliteal artery (FPAK) bypass was performed in 2,014 patients. The bypass conduit used was ePTFE, Dacron, and autogenous vein in 65%, 20%, and 12% of limbs, respectively. Most current guidelines recommend the use of an autogenous vein<sup>4</sup>); and the results have shown that Dacron is superior to ePTFE when using artificial grafts.<sup>5)</sup> Therefore, actual circumstances in Japan is different from the guidelines in the USA and Europe. Although the guidelines will possibly change the rate of artificial graft use in Japan, new artificial grafts have become commercially available for which an observation period of several years is probably needed for the selection of the most appropriate material, taking into account the outcomes. Endovascular treatment was performed in 1,894 patients and similar to the aforementioned aortoiliac region, is speculated to be performed less frequently than presumed, based on reports from the USA and Europe. In addition to the fact that many patients who underwent endovascular treatment in other medical departments (medical departments not involved in NCD including cardiology and radiology) were not registered, these results indicate that vascular surgeons were suggested to perform FPAK bypass at the same time as the treatment for common femoral artery lesions involving the non-stent zone and deep femoral artery lesions.

occlusive diseases*1)	
for chronic arterial	
Revascularization for	
Table 2	

branches
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Table

		Gender		Mortality Backgrounds	grounds			Etiology					Reva	scularizatior	Revascularization procedures					U	Graft materials*6)	rials <sup>*6)</sup>	
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Vertebral artery	2	-	1	0	0	0	0	0	-	0	0	0	0	-	0	0	0	-	0	0	-	0	0
Subclavian artery	113	83 30	0 (	4	8	88	0 0	0	2	25 0	0	0	0	56	2	ŝ	9	40	8	16	32	-	0
Multiple lesions of arch branches	15	8 7	7 0	0	2	7	0			5 0	0	0	0	ę	2	8	0	0	2	7	0	e	-
Upper limb including axillar artery	84	47 37	7 0	42	21	59	1	0	2	22				31	2	19	0	7	27	9	6	13	2
Celiac/superior mesenteric artery	69	46 23	5	7	10	60	0	0	~	80				33	10	10	0	-	17	11	ę	2	0
Renal artery	116	92 24	+	2	5	66	0	. 1	£.	15				104	-	9	0	0	4	2	-	2	0
Others	49	37 12	2	19	2	38	2 0	0	6	0 6	0	0	0	29	с	С	2	-	10	4	2	2	2
Total	554 4	405 149	9	06	53	451	е С	2 2		92 13	-	92	e	255	21	49	10	51	67	45	49	27	5

# Table 2-2 Arterial reconstruction for chronic lower limb ischemia

		Ge	Gender	Mortality	Backgrounds	spun			Etiology				Graft ma	Graft materials <sup>*6)</sup>	
From aorta to lower limb arterial system	Cases	Male	Female	30-day mortality	Dialysis cases	Redo ope.	ASO	TAO	Vasculitis	Takayasu arteritis	Others	Polyester	ePTFE	Autogenous vein	Others
Aorto-aorto bypass	20	54	16	0	3	2	62	0	0	3	5	48	18	£	0
Infrarenal aortic reconstruction (suprarenal clamp)	32	29	ę	-	ę	0	32	0	0	0	0	30	с	0	0
Aorto-femoral bypass*7)	680	578	102	7	39	51	661	2	2	0	14	509	195	29	5
Femoro-popliteal (above knee) bypass	2,014	1,554	460	12	231	251	1,998	5	-	-	7	391	1,305	253	21
Infrapopliteal arterial bypass	1,616	1,210	406	35	460	394	1,559	6	8	-	31	135	316	1,129	63
Femoro-popliteal (below the knee) bypass	658	494	164	12	131	149	638	e	з	0	8	84	215	341	25
Femoro-crural/pedal bypass*s	984	734	250	23	338	253	946	7	5	-	23	53	113	810	38
Others	173	132	41	e	25	23	165	0	0	0	7	61	72	26	4
Total	4,327	3,351	976	54	733	705	4,221	15	11	5	63	1,032	1,771	1,360	85

# Table 2-3 Extra-anatomic bypass\*9)

		5	Gender	in or carried									
Extra-anatomical pypass	Cases	Male	Female	30-day mortality Dialysis cases Redo ope. ASO	Dialysis cases	Redo ope.	ASO	TAO	Others	Polyester	ePTFE	Autogenous vein	Others
Carotid-subclavian bypass	10	9	4	0	-	2	ø	0	2	5	с	2	0
Axillo-axillary bypass	51	38	13	0	2	2	39	0	12	17	32	<del></del>	-
Axillo–femoral bypass* <sup>10)</sup>	397	280	117	10	55	55	377	0	20	151	239	15	5
Femoro-femoral cross-over bypass	961	819	142	9	79	114	934	0	26	269	577	56	9
Others	139	103	36	2	18	25	129	7	80	43	46	20	0
Total	1,532	1,223	309	17	155	193	1,462	2	67	479	877	91	12

\*\*) Including redo operation only. Revision surgery cases should be counted in vascular complication part (see Table 8).
\*3) Including collagen disease related vasculitis, Behçet disease, fibromuscular dysplasia.

\*4) Postoperative irreversible brain complication.

\*5) Including percutaneous transluminal angioplasty (PTA), stent, and other endovascular means such as catheter atherectomy.

\*6) Only for open surgery.

\*7) Including aorto-iliac bypass or ilio-femoral bypasses

\*8) Including popliteal-crural (or pedal) bypass.

<sup>+1</sup>0) A case underwent axillo-femoral crossover bypass is counted as one case. A case combined with additional contralateral side of axillilo-femoral bypass as second staged surgery is counted as 2 cases. \*b) Cases undervent extraanatomic bypass because of graft infection should not be included this category. Those cases are listed in vascular complication (Table 5).

Abbreviations; ASO: arteriosciencesis obriterance, TAO: thromboangitits obliterans (Buerger's cleases), CAS: carotid artery stertling, CEA: carotid endarterectomy, PTA: percutaneous transluminal angioplasty, EVT: endovascular treatment.

 Table 2
 Revascularization for chronic arterial occlusive diseases<sup>\*1</sup> (continued)

Thromboendarterectomy	Cases	Ge	ender	Mortality	- Dialysis cases		Etiology	
monboendarterectomy	Cases	Male	Female	30-day mortality	Dialysis cases	ASO	TAO	Others
Aorto-iliac lesion	50	36	14	0	7	49	0	1
Femoro-popliteal lesion	568	432	136	11	122	553	3	7
Others	90	57	33	0	19	85	1	4
Total	702	521	181	11	146	682	4	11

Table 2-4	Thromboendarterectomy	(*11) for chronic lower limb ischemia
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Table 2-5 E	Endovascular treatmen	t for chronic lower	limb ischemia*5)
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Endovascular treatment	Cases	G	ender	Mor	tality	Dialysis cases		Etiology	
Endovascular treatment	Cases	Male	Female	30-day mortality	Hospital mortality	Dialysis cases	ASO	TAO	Others
Aorto-iliac lesion*12)	2,569	2,122	447	12	23	285	2,548	3	17
Femoro-popliteal lesion*12)	1,834	1,300	534	7	29	498	1,824	5	4
Infrapopliteal-ankle lesion*12)	961	651	310	25	48	460	950	1	8
Others	46	30	16	2	1	22	43	2	1
Total (number of regions underwent $EVT)^{*12)}$	4,768	3,636	1,132	39	83	1,026	4,727	9	28
Total (number of limbs underwent $EVT)^{*_{13)}}$	4,153	3,191	962	32	65	804	4,116	7	26

\*11) Including patch plasty.

\*12) When endovascular treatment performed for multiple region, the case should be counted in each region (If a case underwent endovascular treatment in both aorto-iliac and femoro-popliteal region, this case can be counted one in aorto-iliac, and one in femoro-popliteal region).

\*13) When a case underwent endovascular treatment in multiple regions, the case is counted as one case.

Abbreviations; ASO: arteriosclerosis obriterance, TAO: thromboangiitis obliterans (Buerger's disease), CAS: carotid artery stenting, CEA: carotid endarterectomy, PTA: percutaneous transluminal angioplasty, EVT: endovascular treatment.

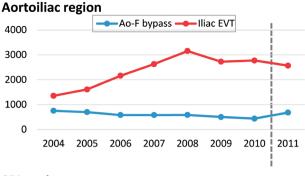
Revascularization below the knee was achieved by femoropopliteal below-knee (FPBK) bypass and distal bypass to infrapopliteal or more distal region in 658 and 984 patients, respectively, whereas patients on dialysis accounted for 20% and 33%, respectively, indicating increasing number of patients including the majority of those with crural arterial lesions reflecting underlying illnesses, such as diabetes and chronic renal failure (maintenance dialysis). An artificial graft was used in 40% and 15% of patients who underwent FPBK and distal bypass, respectively, suggesting that there might be many patients for whom it is considered that an autogenous vein will be inappropriate for bypass conduit due to poor quality or that many institutions have not fully adopted the guideline to thoroughly use an autogenous vein. Endovascular treatment in this area was performed in 961 patients, of which 50% were dialysis patients. It is inferred that endovascular treatment was selected in many dialysis patients because of their poor physical condition which did not suit to bypass surgery.

Thromboendarterectomy was performed in the iliac and femoropopliteal artery regions in only 50 and 568 patients, respectively. This finding suggests that many lesions are well-suited for endovascular treatment in the iliac artery region, whereas the femoropopliteal artery region was speculated to be affected by areas with bends, such as of the common femoral and popliteal arteries, i.e., non-stent zone, and the presence of lesions that are anatomically unsuited for endovascular treatment, such as the deep femoral artery. Other reasons include the fact that thromboendarterectomy is an established procedure in the common femoral arterial region, and its major clinical usefulness is maintained.

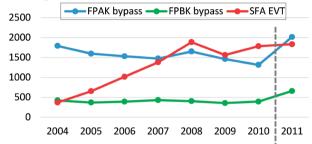
We have hereby reported on the current state of revascularization for chronic arterial obstruction in Japan. Our results indicate that endovascular treatment is performed less often in Japan than in the USA and Europe. In terms of investigations of chronic arterial obstruction based on national databases, a report summarizing peripheral vascular disease over 3 years in Germany (2005, 2007, and 2009), reported that the ratio of endovascular treatment-to-bypass surgery was 2:1.6) A report based on the national database of Sweden in 2009 found that the choice of treatment for intermittent claudication under the inguinal ligament in the above-knee popliteal artery region is endovascular treatment, with a ratio of 2:1 for endovascular treatment-to-surgery.7) Thus, when viewed overall, endovascular treatment appears to be performed more commonly than bypass surgery. In Japan, although the results of a questionnaire survey conducted from 2004 to 2010 cannot be simply compared with those of the present registration, it is clear that an increasing number of vascular surgeons are performing endovascular treatment (Fig. 3), and the incidence of endovascular surgery is expected to increase further in the future.

# 3. Revascularization for Acute Arterial Occlusion (Table 3)

Excluding cases of vascular trauma, 3,799 cases of acute arterial obstruction were registered, and the incidence was approximately 20% and 80% in the upper limb region and lower body region including arteries in abdomen



SFA region



Crural / pedal region

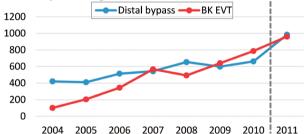


Fig. 3 The annual trends of the number arterial reconstructions in aortoiliac, superficial femoral (SFA), and crural/pedal region, comparing open repair and endovascular treatment. The broken line lying between year 2010 and 2011 means the timing of alteration regarding data collection methods. Data has been prospectively registered since January 2011, while the data had been retrospectively collected annually from 2004 until 2010. AK: above the knee, BK: below the knee.

and lower limbs, respectively. Acute arterial obstruction was caused by thrombosis and embolism, which each accounted for approximately half of the cases. This result is consistent with recent reports from the USA.<sup>8)</sup>

With regard to incidence, in a prospective study conducted in the UK, 93 (10/100,000/year) and 78 cases (8/100,000/year) of acute limb ischemia (ALI) and acute visceral ischemia (AVI), respectively, were reported in a population of 92,728 individuals over a 10-year period.<sup>9)</sup> The incidence of AVI accounted for 44% of ALI + AVI in the UK, whereas the proportion of AVI per acute arterial obstruction was extremely low in Japan at approximately 2%. This discrepancy is likely attributable to the fact that the British study included patients who did not receive therapeutic intervention, whereas the present data included only patients who underwent revascularization. The 30-day mortality for AVI was 72% in the British report, in contrast to 20% in the present data for revascularization. Therefore, it can be inferred that many AVI patients die without attaining revascularization.

The 30-day mortality rate for ALI in the British prospective study, was 25%; however, the present data showed that the mortality rate for ALI distal to the abdominal aorta was 9.2%. The present data indicate the results for patients who underwent revascularization, which is believed to have led to better outcomes than those reported in the British study.

With respect to the revascularization procedure, approximately 90% of ALI was treated via open surgery. In the future, endovascular treatment is expected to increase (thrombolytic therapy and thrombus aspiration). The conduit used for revascularization at proximal to the popliteal artery was commonly artificial graft. A questionable situation has arisen in which more than half of cases involving crural arteries, for which autogenous vessel graft is recommended, are actually undergoing treatment with artificial grafts.

Furthermore, in the present data, the total number of each region was inconsistent with the total in the lower row of the table, which may have been due to the existence of several cases in which the same patient had obstruction at multiple sites.

### 4. Treatment for Vascular Trauma (Table 4)

The site of registered vascular trauma, cause of injury, classification based on the surgical procedure, and type of prosthesis used are presented in **Table 4**. Overall, 1,030 cases had a combination of arterial and venous trauma. In the NCD database, the cause of vascular trauma was classified into 1) traffic accident, 2) work-related, 3) iatrogenic, and 4) others, among which iatrogenic vascular trauma was the most common, accounting for approximately 64%, followed by traffic accidents (~11%), and work-related trauma (~9%). Although graft materials were used in a few cases because most were managed by direct suture and ligature, approximately 40% of graft materials were autogenous vessels. In trauma, as the injured site is often contaminated, autogenous vessel grafting is selected as much as possible in peripheral vascular reconstruction.

### 1) latrogenic vascular trauma

The underlying mechanism of iatrogenic vascular trauma is speculated to include catheter-related trauma and accidental vascular injury during surgery. Catheter-related trauma includes hematoma arising at the vascular punc-

 Table 3
 Revascularization for acute arterial occlusive disease

 Non-trainmatic acute limb ischemia

		ē	Gender	Mortality	canty		Ellology							Ciall III	aterials for d	Graft materials for open surgery	Ž
Obstructive artery* <sup>*1)</sup>	Cases	Male	Female	30-day mortality	Hospital mortality	Embolism	Thrombosis*2)	Others	Thrombectomy ± patch	Bypass	Replacement	PTA ± stent	Others	Autogenous vessel	Polyester	ePTFE	Others
Carotid artery	9	4	2	-	-	0	e	e	e	7	0	-	-	-	-	0	0
Subclavian artery	75	43	32	4	5	38	27	6	26	17	29	ო	2	2	10	34	0
Axillar artery	51	29	22	5	9	19	28	4	38	8	0	9	5	S	4	ę	-
Brachial artery	567	270	297	18	20	322	243	2	489	14	2	16	58	7	7	15	С
Celiac/superior mesenteric artery	82	58	24	16	25	32	22	28	34	31	ę	9	10	16	9	12	7
Renal artery	14	10	4	2	ę	9	0	9	-	5	-	7	0	2	-	4	0
Abdominal aorta-iliac artery	644	462	182	83	98	196	338	108	382	227	18	86	25	13	137	112	5
Femoro-popliteal artery	2,004	1,265	739	157	213	886	1,044	69	1,667	246	12	150	91	93	110	145	7
Crural artery	616	420	196	60	70	293	311	12	487	59	7	74	42	38	29	48	5
Pedal artery	25	15	10	e	ę	11	12	2	16	4	0	5	e	S	-	-	-
Others	280	193	87	14	20	44	176	60	158	94	15	29	19	79	14	16	ю
Total	3,799	3,799 2,394	1,405	292	381	1,615	1,889	288	2,830	617	81	321	231	228	276	343	24

		Ğ	Gender	Mortality	ality		Cause of trauma	f trauma					Procedure	lure				Graft materials	(0	
Injured artery	Cases	1	Male Female	30-day mortality	Hospital mortality	Traffic accident	Labor accident	latrogenic	Others	Direct closure	Patch plasty	Replace	Bypass	Endovascular	Ligation	Others	Autogenous vessel	Polyester	ePTFE	Others
Carotid artery	£	80	3	-	2	2	2	4	e	5	-	0	-	2	ю	0	-	-	0	0
Subclavian artery	12	80	4	<del></del>	2	-	-	8	2	7	0	0	-	-	2	<del></del>	0	-	0	0
Axillar artery	12	9	9	0	0	ę	4	4	<del>.</del>	ę	0	2	4	-	2	0	4	0	2	0
Brachial artery	181	116	65	2	4	с	14	150	4	133	-	7	6	0	20	14	13	0	4	0
Descending aorta (thoracic/thoracoabdominal)	37	23	14	14	4	15	4	9	12	ę	0	10	0	12	2	10	0	8	2	0
Celiac/superior mesenteric artery	17	17	0	2	с	9	-	7	e	2	0	0	0	9	9	4	0	0	0	0
Renal artery	4	4	0	2	2	-	2	-	0	0	0	-	0	-	-	-	0	-	0	0
Abdominal aorta-iliac artery	95	48	46	12	15	13	5	60	15	34	ო	5	17	20	14	7	-	13	Ø	2
Femoro-popliteal artery	398	258	140	55	76	27	28	300	42	293	14	19	34	7	18	18	42	8	15	0
Crural artery	27	20	7	0	0	5	80	6	5	7	0	ę	10	0	2	9	11	-	0	0
Others	166	111	55	35	37	35	15	62	25	60	ę	ю	2	1	63	25	2	2	-	<del></del>
Total	949	610	339	123	154	105	83	609	150	547	22	48	78	60	131	84	75	34	30	e

-
*
trauma*1
Venous
4-2
Table

Injured vein Cases		Cause of	Cause of trauma					Procedure	lure				Graft materials	2	
	Traffic accident	Labor accident	latrogenic	Others	Direct Patch closure plasty	Patch plasty	Replace	Bypass	Endovascular Ligation	Ligation	Others	Autogenous vessel	Polyester	ePTFE	Others
Superior vena cava	-	0	0	0	0	0	0	0	0	-	0	0	0	0	0
Inferior vena cava	-	2	7	ę	4	0	0	0	0	-	ę	0	0	0	0
Brachiocephalic-subclavian vein 6	0	~	ы	2	ю	0	۰	0	0	-	2	0	0	-	0
lliac-femoral-popliteal vein 39	e	ę	32	-	8	-	0	-	4	е	ы	0	-	-	0
Others 27	4	3	11	6	80	-	7	2	0	13	ю	4	0	0	-
Total 81	6	6	48	15	49	2	e	3	-	19	7	4	-	5	-

\*1) Cases with vessel injury involving both vein and accompanying artery are listed in Table 4-1.

ture site, false aneurysm, arteriovenous fistula, dissection, obstructive thrombus, infection, and abscess, i.e., access site complications, as well as puncture, hemorrhage, dissection, obstruction, and migration of foreign body such as guidewire and catheter tip. The type of catheters causing the abovementioned trauma include those used for angiography and endovascular treatment, as well as those used in visceral artery embolization for malignant tumor, arterial injection chemotherapy, and transvenous catheter feeding.<sup>10,11)</sup> Upon examining different sites of iatrogenic vascular trauma in the present study, the arteries of the lower limbs were most commonly affected (47%), followed by the upper limb arteries (25%), most of which were speculated to be complications of the catheter puncture site. Based on a factual survey conducted by the National Cerebral and Cardiovascular Center in Japan in 2012, the number of cardiac catheterizations exceeded 500,000 cases.<sup>12)</sup> Furthermore, the incidence of complications of the catheter puncture site is generally reported to be 2.1%-6.6%.<sup>13)</sup> Among which, only those requiring surgical repair were speculated to be registered in NCD; however, there were few registrations, and thus, we cannot conclude that these data reflect the actual state. Intraoperative accidental vascular injury was also included in iatrogenic vascular trauma, in which injury can occur in the carotid artery during head and neck surgery, in the thoracic aorta and associated branches during respiratory and esophageal surgeries, in the abdominal aorta, iliac vessels, and visceral blood vessels during gastrointestinal surgery, and in the vessels of the upper and lower limbs during orthopedic surgery. As these are included under the category of iatrogenic in NCD, the injury mechanisms noted above are unclear.

### 2) Traffic accidents

Examination of vascular trauma caused by traffic accidents based on different sites revealed that the arteries of the lower limbs were most commonly affected, accounting for approximately 27% of cases. In trauma caused by accidents, such as the collision of a car with a pedestrian, or accidents that occur while driving a motorcycle, blunt force trauma can occur in the blood vessels near the body surface of the four limbs where direct force is easily applied. Furthermore, bone fracture and bone fragments can cause penetrating trauma to nearby blood vessels. The second most common site of trauma was the descending and thoracoabdominal aortas (12%), followed by the abdominal aorta and iliac artery (11%). In car collisions, wearing a seatbelt and improved safety and technology of the vehicle have resulted in less direct force being applied to the major blood vessels. However, in high-speed collisions, the sudden decrease in speed causes mediastinal movement, and the stress is concentrated on the branches of the cervical region and arm and associated ramifications attached to the thorax, in particular dissection and laceration/transection of the thoracic descending aorta occurs in the left subclavian artery branching site. Compared with other causes described below, the high rate of injury to the thoracic aorta is attributed to the characteristics of traffic injury. The steering wheel, dashboard, and seatbelt can also cause blunt force trauma to the large vessels of the abdomen.

### 3) Work-related trauma

When strong force is sustained by falling from hight or from a heavy falling object, it can cause blunt force trauma to the major blood vessels. Furthermore, sharp objects, such as glass fragments, can fly in all directions from an explosion, and sharp penetrative vascular trauma and vascular compression trauma can occur in the event of being caught in a machine. These injury mechanisms are speculated to be common to occupations associated with risk, such as workers in construction sites, and trauma classified as "work-related" in this database is assumed to be such accidents during occupation work. The database registered 92 cases, and the arteries that are close to the body surface of the four limbs where direct force is easily applied accounted for 60%.

### 4) Other vascular trauma

Excluding iatrogenic and traffic accident-related traumas, other injury mechanisms for vascular trauma include accidents, deliberate harm, and acts of self-harm. Furthermore, damage to blood vessel walls caused by illness, such as vascular invasion of a tumor, can be considered another type of vascular trauma. (1) Accidents: Natural disasters, sports injury, and falls other than at work can cause injury. 2 Deliberate harmful acts/acts of self-harm: Harmful acts using a blunt or sharp instrument. In the event of blood vessels, sharp injuries are often speculated to be acquired with a cutting instrument. Although rare in Japan, gunshot wounds are included here. (3) Damage to the blood vessel wall by other illnesses, such as tumor invasion: When direct tumor invasion and abscesses causes vascular wall destruction and when false aneurysm and thrombi form, surgical treatment of the affected blood vessel is required. These injuries are not caused by medical treatment and are thus not classified as iatrogenic but currently classified as "vascular trauma from other causes."

As noted above, we analyzed vascular trauma; however, generally, few cases were registered, and the actual state may not be reflected by these data. In departments of radiology, many patients are treated with embolization, and in departments of orthopedics, a considerable number of patients undergo amputation when vascular repair is deemed difficult; moreover, some vascular traumas in the departments of general surgery and trauma surgery are treated by ligation and suture hemostasis and might not be registered as vascular surgery. Therefore, we believe that information should be shared with emergency medical care services.

# 5. Surgery for Vascular Complications after Revascularization (Table 5)

There were 1,615 surgical cases of revascularizationrelated complications, including artificial graft infection in 445 patients, anastomotic aneurysm in 240 patients, autogenous graft aneurysm in 86 patients, artificial graft degradation in 33 patients, and repair for restenosis and acute obstruction of the prostheses in 811 patients. The incidence of complications is of great interest; however, we were unable to calculate the incidence because the total number of surgeries conducted to date could not be ascertained.

### 1) Artificial graft infection

Based on different regions, artificial graft infection affected the descending thoracic aorta-abdominal aorta region in 11 patients, the abdominal aorta-iliac/femoral artery region in 77 patients, and the femoral-peripheral artery region in 123 patients. In the aorta-iliac/femoral artery region, repair of infection was performed with orthotopic replacement and extra-anatomical bypass (EAB) in 21 and 29 patients, respectively, with EAB being performed more commonly. In contrast, at sites peripheral to the femoral artery, the number of patients who underwent orthotopic replacement and EAB were comparable; however, "other" surgical procedures were the most common in this region. The underlying reason could be the treatment of many patients by infected graft removal alone, suggesting poor prognosis for the limbs. The graft material used for infection was ePTFE, polyester, and autogenous vessel in 138, 72, and 41 patients, respectively. The operative and inhospital mortality rates were 6.3% and 17.1%, respectively, indicating poor prognosis. With regard to underlying factors of artificial graft infection, although not examined in the present study, Siracuse et al. reported that the incidence of artificial graft infection of the femoral artery was 3.8%, and risk factors included repeat surgery, the presence of active infection at the time of the initial surgery, diabetes, and female sex.14)

### 2) Anastomotic aneurysms

The most common underlying pathological cause of anastomotic aneurysm was arteriosclerosis in 109 patients, followed by infection in 30 patients. Based on the database, the abdominal aorta followed by the femoral artery were most often affected. Although anastomotic aneurysms were common in the arteries of the arms, affecting 44 patients, many of these anastomotic aneurysms were highly likely included from vascular access for dialysis. For the repair procedure, repair by stent grafting was often performed for anastomotic aneurysms central to the iliac artery, whereas replacement or exclusion and bypass surgery were often performed for anastomotic aneurysms peripheral to the femoral artery. Thirteen mortalities were noted (5.4%), among which the iliac artery was affected in five patients.

### 3) Autogenous graft aneurysm

Among the 86 patients who underwent autogenous vessel grafting, aneurysm most commonly affected the arteries of the upper limbs in 44 patients, which was attributed to the relationship with vascular access. For this reason, the surgical procedure was more often possibly considered "other" than "exclusion or bypass," and simple ligation or aneurysm resection with end-to-end anastomosis was performed for vascular access related aneurysms. Vascular access related aneurysms, including aneurysms at the site of vascular access anastomosis, should be registered as vascular access repair by nature. Therefore, with respect to the type of vascular surgery, upon selecting "other vascular diseases and related surgery" rather than "surgery for revascularization-related complications" and when selecting "vascular access surgery for dialysis" in that division, an option appears for "vascular shunt aneurysm repair." In the future, awareness of these registration methods needs to be raised.

### 4) Artificial graft deterioration

Surgery was needed in 33 patients including polyester grafts in 14 patients and ePTFE in 16 patients due to deterioration of their artificial grafts. As the total number of implanted artificial grafts for each material are unknown, we were unable to determine the difference in the deterioration rate between different types of artificial grafts.

### 5) Surgical repair of restenosis and acute obstruction of prostheses

Surgical repair of prostheses was most commonly performed for the arteries of the lower limbs in 486 patients, and the surgical procedure in descending order was patch/ thrombectomy, bypass surgery, and endovascular treatment. By contrast, endovascular treatment most commonly performed surgical repair of the prostheses of the aorta and its primary branches. Surgical repair of prostheses using the arteries of the upper limbs was performed in 219 cases; however, as expected, it is inferred that a considerable number of cases of vascular access surgery were intermixed. As per number 4) above, we would prefer that stenosis and obstruction of vascular access to be

		Mort	Mortality	Proced	Procedure for graft infection	fection	2	laterial	for revision o	Material for revision or redo surgery	
Position of infected graft	Cases	30-day mortality	Hospital mortality	In-situ replace	Extra- anatomic bypass	Others	Polyester e	PTFE	Autogenous vessel	Others Polyester ePTFE vessel homograft	Others
Thoracic descending aorta	2	0	~	0	0	0	-	0	0	0	0
Thoracoabdominal aorta	6	-	2	с	0	9	с	0	0	0	-
Abdominal aorta-iliac artery	46	7	12	14	22	10	20	16	ę	0	<del>.</del>
Abdominal aorta-femoral artery	31	-	ę	7	7	17	4	7	9	0	0
Femoro-popliteal artery	123	7	22	18	17	88	13	40	17	٢	-
Others*1)	234	12	36	24	32	177	31	75	15	0	1
Total	445	28	76	66	78	300	72	138	41	~	14

Table 5 Revascularization for vascular complication after revascularization Table 5-1 Graft infection

\*1) Cases with graft infection involving aortic arch branch or upper limb artery are listed on this column.

# Table 5-2 Anastomotic aneurysm\*2)

		Mortality	Cause of a	neurysm treat	aneurysm treated at the primary operation	operation			Repair procedure	ure		4	Material for I	Material for repair surgery	
Location of anastomotic aneurysm	Cases	30-day mortality	Degenerative* <sup>3)</sup>	Takayasu arteritis	Other vasculitis <sup>*4)</sup>	Infection	Others	Replacement	Exclusion and bypass	Stentgraft	Others	Polyester	ePTFE	Autogenous vessel	Others
Aortic arch branch	9	-	4	0	0	-	-	-	0	-	5	e	-	0	-
Upper limb artery including axillar artery	44	<del>.</del>	4	0	0	13	27	-	7	0	40	0	5	сı	~
Thoracic aorta	28	2	6	0	0	0	19	0	0	24	9	8	4	0	16
Splanchnic artery	4	<del>.</del>	-	0	0	<del>.</del>	2	0	-	-	ო	с	0	0	0
Renal artery	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Abdominal aorta	69	<del>.</del>	42	-	0	С	23	9	-	30	34	23	6	0	16
lliac artery	34	5	12	0	0	4	18	7	0	20	14	4	5	+	13
Femoral artery	56	-	27	0	0	7	20	15	ი	0	38	16	12	8	-
Popliteal or more distal lower limb artery	17	<del></del>	11	0	-	<del></del>	4	Q	с	-	œ	ę	ы	Ð	0
Total	240	13	109	-	З	30	97	30	6	99	142	58	39	19	32
<sup>*</sup> 2) Cases with infectious pseudoaneurysms located at the anastomotic site to the artificial graft are listed in Table 5-1	ms locate	ed at the anas	stomotic site to the arti	ficial graft are	listed in Table 5-	-									

\*3) Including the atherosclerotic aneurysm.
\*4) Including TAO, collagen disease, Behçet disease, and fibromuscular dysplasia.

lable 2-3 Autogenous gran aneurysm	gran aneur	iysm			
		Mortality	Repair	Repair procedure	
		30-day mortality	Replacement	Bypass	Others
Visceral artery	-	0	0	-	0
Upper limb artery	4	0	7	10	29
Lower limb artery	28	-	9	ŝ	19
Others	13	4	<del>.</del>	ю	6
Total	86	2	41	17	57

 Table 5
 Revascularization for vascular complication after revascularization (continued)

 Table 5
 Automatic and another complication

# Table 5-4 Graft degeneration

		Mortality	Initie	al revascular	Initial revascularization procedure	ure	Degen	Degenerated material	srial		Re	Repair procedure	0		Material t	Material for repair surgery	ırgery
Revascularization area	Cases	30-day mortality	Replace	Replace Bypass	Stentgraft	Others	Polyester ePTFE	ePTFE	Others	Others Replacement Bypass Stentgraft Patch plasty Others	Bypass	Stentgraft	Patch plasty	Others	Polyester	ePTFE	Others
Descending thoracic aorta	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Thoracoabdominal aorta	<del>.</del>	0	-	0	0	0	0	0	-	-	0	0	0	0	-	0	0
Abdominal aorta-femoral artery	9	0	2	e	-	0	4	-	<del>.</del>	4	0	-	0	<del></del>	2	e	0
Femoro-popliteal artery	5	0	2	c	0	0	c	2	0	7	-	0	0	2	ę	0	-
Others	23	0	5	9	0	11	80	13	-	7	£	0	0	1	5	10	-
Total	33	0	6	7	-	11	14	16	0	13	9	-	0	13	10	13	5

# Table 5-5 Repair operation for graft stenosis or acute thrombosis\*5)

-											
		Mortality		Repair	Repair procedure				Material for r	Material for repair surgery	
Initial procedure	Cases	30-day mortality	Patch ± thrombectomy	Replacement	Bypass	PTA±stent	Others	Polyester	ePTFE	Autogenous vessel	Others
Reconstruction of aorta or its primary branches	117	5	29	10	35	43	16	45	32	4	4
Revascularization of upper limb	219	8	76	25	38	65	41	18	71	39	13
Revascularization of lower limb	486	15	224	31	141	108	50	61	129	135	10
Total	811	26	319	65	210	214	106	122	227	178	27
*5) Including stenosis such as the anastomotic stenosis,	tenosis, graft	stenosis or oc	graft stenosis or occlusion, and restenosis at the site of endarterectomy.	sis at the site of end	larterectomy.						

registered as "other vascular disease and related surgery" rather than "surgery for vascular complications after revascularization."

### 6. Venous Surgery (Table 6)

### 1) Varicose veins

Surgery for varicose veins was performed in 18,864 patients, with a male-to-female ratio of approximately 1:2. Compared with 2010, the number of surgeries increased by approximately 70%; however, the advent of new surgical procedures, such as venous ablation, as mentioned below, appeared to have influenced this increase in addition to the change in tabulation method. Surgeries for varicose veins accounted for most of venous surgeries at 97%. The procedure was most commonly performed by vein stripping ( $\pm$  sclerotherapy) in 12,164 patients (64%). In January 2011, endovenous laser ablation (EVLA) was approved in Japan for varicose veins and subsequently came into practice. In the 2011 tabulation, EVLA was speculated to be registered as "other"; however, 3,282 cases (17%) were registered as "other" surgery. Based on a survey conducted by the Japan Society of Phlebology in

 Table 6
 Venous surgery

 Table 6-1
 Varicose veins

2013, EVLA was the surgical procedure most commonly performed among surgeries for varicose veins.<sup>15)</sup> In the guideline by the American Venous Forum, the application of endovenous ablation is recommended for the saphenous vein,<sup>16)</sup> and the incidence of EVLA was expected to increase in the future in Japan.

### 2) Deep vein thrombosis

Treatment of thrombosis included thrombectomy, catheter-directed thrombolysis (CDT), and bypass surgery in 68 (20%), 40 (11%), and 6 patients (2%), respectively. Although a decrease of >40% was observed in comparison with the 2010 results, inferior vena cava filter (VCF) insertion was most commonly performed with 287 patients (82%). In December 2012, the Ministry of Health, Labour and Welfare issued a notice recommending the implementation of regular observations for permanent VCF and their removal; however, this was considered as one factor underlying the decrease in VCF. Furthermore, the inconsistency between the overall number of surgeries and the sum of the number of specific items is attributed to the existence of overlapping of patients who underwent

Table 0-1 Valicose veilis				
Varicose veins treatment	Cases*1)	Male	Female	30-day mortality
High ligation±sclerotherapy	3,418	1,102	2,316	0
Stripping±sclerotherapy	12,164	4,742	7,422	1
Others	3,282	1,012	2,270	0
Total	18,864	6,856	12,008	1

\*1) Only one procedure can be registered in one leg.

### Table 6-2 Deep vein thrombosis (DVT)

DVT treatment	Cases	Male	Female	30-day mortality
Thrombectomy	68	35	33	2
Catheter-directed thrombolysis*2)	40	23	17	0
Bypass	6	4	2	0
IVC filter insertion <sup>*3)</sup>	287	119	168	4
Total	348	153	195	6

\*2) Including the catheter-directed thrombolysis using hydrodynamic thrombectomy catheter.

\*3) Including temporary IVC filter.

Abbreviations; IVC: inferior vena cava.

Table	6-3	Upper limb vein obstruction	n
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Treatment of vein obstruction	Cases	Male	Female	30-day mortality
Thrombectomy	51	22	29	1
Catheter-directed thrombolysis	8	4	4	0
Bypass	32	18	14	2
SVC filter insertion	1	0	1	0
Total	88	44	44	2

3 Venous surgery (continued)	3-4 Vena cava reconstruction
9	9
Table 6	Table 6-4

		Mor	Mortality		Etiology			Tr	Treatment procedures	ures		Mater	Material for open surgery	surgery	
vena cava reconstruction	Cases	30-day mortality	Cases 30-day Hospital mortality mortality	Tumor	Thrombus Others	Others	Patch plasty	Bypass	Bypass Replacement PTA±stent Others	PTA ± stent	Others	Autogenous vessel	Polyester ePTFE Others	ePTFE	Others
SVC reconstruction	22	0	ю	13	5	4	~	5	4	6	ю	-	~	7	S
IVC reconstruction	45	2	7	39	-	5	5	0	14	<del>.</del>	24	9	7	œ	с
Total	67	2	5	52	9	6	9	5	18	10	27	7	ю	15	œ

Abbreviations; IVC: inferior vena cava, SVC: superior vena cava.

syndrome	
Budd-Chiari	
6-5	
Table	

		Ū	Gender	Mor	Mortality		Material for	Material for open surgery	
Treatment	Cases	Male	Female	30-day mortality	Hospital mortality	Polyester	ePTFE	Autogenous vessel	Others
Shunting	4	2	2	0	4	0	2	0	0
Decompression	0	0	0	0	0	0	0	0	0
Total	4	2	2	0	4	0	2	0	0

multiple surgeries.

### 3) Venous obstruction of the arms

Surgery was reported to be performed in 88 cases. The procedures included thrombectomy, bypass surgery, and CDT in 51 (58%), 32 (36%), and 8 patients (9%), respectively. There were four overlapping cases.

### 4) Vena cava reconstruction

Overall, 67 cases of vena cava reconstruction were reported, and based on the database, the reconstruction ratio for the superior vena cava system to the inferior vena cava system was 1:2. Tumor was the most common causative pathology (52 patients, 78%). There were two (3.0%) and five cases (7.5%) of operative and inhospital mortalities, respectively, in which treatment was aggressively performed. The surgical procedure most commonly performed was replacement, with 18 patients, and PTA $\pm$ stenting was often performed in the superior vena cava system, with 9 patients (the registration of the surgical procedure was possibly omitted in 1 patient). The registration included 33 prostheses used, of which ePTFE was the most commonly used, with 15 patients.

### 5) Budd–Chiari syndrome

In total, four patients had Budd–Chiari syndrome, indicating that surgery was rare. All procedures were performed by shunting. Only two cases were registered, and both used ePTFE as the prosthesis.

# 7. Other Vascular Diseases and Related Surgeries (Table 7)

## 1) Popliteal artery entrapment syndrome and cystic adventitial disease

Only a few cases were registered, and thus, these can be considered rare diseases; however, they are important diseases that require differentiation from other chronic arterial occlusions, such as arteriosclerosis obliterans, as specified in the guidelines for the management of peripheral occlusive disease of the Japan Circulation Society. The few registered cases might be attributable to the fact that treatment is administered without adequate differentiation from other chronic arterial occlusions. However, compared with 2006 (note that the tabulation method differs), 8 and 20 cases in 2006, and 13 and 49 cases in 2011 were registered for popliteal artery entrapment syndrome and cystic adventitial disease, respectively, indicating a large increase in both conditions and suggesting that the rate of diagnosis has improved.

### 2) Thoracic outlet syndrome

Twelve cases of thoracic outlet syndrome were registered

in NCD, which was a very small number. Among the registrations, bypass surgery was performed in five patients, and the remaining seven patients underwent scalenectomy or costectomy. As many surgical procedures other than bypass surgery are performed by departments of orthopedic surgery, the actual number of cases may not be fully reflected.

### 3) Vascular access surgery

This surgical procedure was performed even by the departments of urology and nephrology, with up to 16,296 cases registered in NCD, accounting for 24% of vascular surgeries. As noted above, "surgery for vascular complications after revascularization" is speculated to include surgical repair of vascular access, and more vascular access surgeries were speculated to be actually performed. In creating vascular access, the ratio of autogenous vessels to artificial vessels was 8,940:2,114, and methods of repair for access trouble included open repair and endovascular treatment in 1,840 and 3,075 cases, respectively.

### 4) Lymphedema surgery

Conservative treatment is indicated for most cases of lymphedema; therefore, only a few cases were registered in departments of surgery. In contrast, treatment using this procedure has recently increased in departments of plastic surgery, and it is inferred that surgery of the lymphatic vessels is often performed apart from vascular surgery.

### 5) Sympathectomy

Registrations for sympathectomy were few, suggesting that the number of candidate patients for this procedure is declining. The breakdown included thoracic and abdominal surgeries in 20 and 15 patients, respectively. The reduction in the number of cases has been speculated to be influenced by the fact that there are fewer patients with Buerger's disease and because highly advanced medical treatment comprising therapeutic angiogenesis is being performed for patients for whom sympathectomy was conventionally indicated.

### 6) Amputation of the upper and lower limbs

Upper and lower limb amputations were performed in 12 and 1,037 patients. As upper limb amputation was often performed by departments of orthopedic surgery, the actual number of cases is not reflected. With regard to lower limb amputations, such amputations are performed by plastic surgeons and orthopedic surgeons in an increasing number of facilities as part of team-based medical care; and thus, we believe that the actual number throughout Japan is not reflected. It should be noted that incidence of above-knee amputations was higher than that of belowknee amputations, as was the associated operative mortal-

### Table 7 Other vascular diseases

### Table 7-1 Popliteal artery entrapment syndrome

Table 7-1 Popliteal art	ery entrapment	t syndrome	Table 7-2         Adventitial cystic c	lisease	
Treatment	Cases	30-day mortality	Treatment	Cases	30-day mortality
Myotomy	5	0	Cyst excision±patch plastry	36	1
Revascularization	18	0	Replacement	12	0
Total	20	0	Bypass	4	0
			Total	49	1

### Table 7-3 Thoracic outlet syndrome (TOS)

Treatment	Cases	Male	Female	30-day	Тур	e of TOS*1)	
rreatment	Cases	Male	remale	mortality	Neurogenic	Venous	Arterial
Rib resection <sup>*2)</sup>	1	1	0	0	1	0	0
Rib resection+scalenectomy	7	3	4	0	6	0	2
Bypass	5	4	1	0	1	0	4
Total	12	7	5	0	8	0	5

\*1) In the case with mixture type, the type having the most significant impact on the clinical symptom is listed. But, if the impacts are similar, multiple response is allowed.

\*2) Including cervical rib.

### Table 7-4 Vascular access operation

Treatment	Cases	30-day mortality
Arteriovenous access creation by autogenous material	8,940	100
Arteriovenous access creation by artificial material*3)	2,114	38
Open surgery for access repair	1,840	34
Endovascular access repair	3,075	22
Arterial transposition	327	12
Total	16,296	206

\*3) Including cases with access repair using artificial graft.

### Table 7-5 Surgery for lymphedema

Treatment	Cases	Male	Female	30-day mortality
Lymphovenous anastomosis	24	2	22	0
Lymph drainage operation	1	0	1	0
Resection	24	14	10	0
Total	49	16	33	0

### Table 7-6 Sympathectomy

Table 7-6 Sympathectomy			Table 7-7 Amputation of	f upper limb	
Sympathectomy	Cases	30-day mortality	Amputation level	Cases	30-day mortality
Thoracic sympathectomy	20	0	Digit	12	1
Lumbar sympathectomy	15	0	Forearm/upper arm	0	0
Total	35	0	Total	12	1

Table 7	Other vascular diseases	(continued
		(continueu

Table 7-8 Amputation of lower limb\*4)

Amputation loval	Casas	20 day martality		Eti	ology	
Amputation level	Cases	30-day mortality	ASO	DM-ASO	TAO	Others
Тое	387	11	156	201	7	23
Transmetatarsal	123	2	42	73	0	8
Lisfranc/Chopart	40	2	10	27	0	3
Syme	6	0	1	5	0	0
Below-Knee	202	18	63	125	3	10
Through-Knee/Above-Knee	273	28	159	84	3	27
Hip	6	0	1	5	0	0
Total	1,037	63	436	516	13	71

\*4) Except the amputation not due to ischemia. Abbreviations; ASO: arteriosclerosis obriterance, DM-ASO: diabetic ASO, TAO: thromboangiitis obliterans (Buerger's disease).

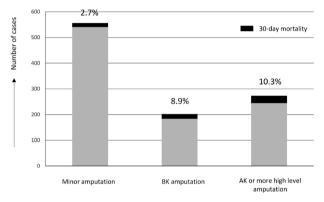


Fig. 4 The number of lower limb amputations and their mortality rates in each amputation level. The value on the top of each bar indicates the 30-day mortality rate. The mortality rate after amputation surgery became significantly higher in according to higher amputation level (p<0.001). BK: below the knee, AK: above the knee.

ity (Fig. 4). For foot amputation, below-knee amputations, and above-knee amputations, the operative mortalities were 2.7%, 8.9%, and 10.3%, respectively (p < 0.001). That is, for major amputations, the operative mortality was significantly higher, and the results showed an even higher operative mortality rate when amputations were performed higher than above the knee.

### Conclusion

Surveys of vascular surgery have been conducted continuously, and with the appearance of a new tool, i.e., NCD, the survey in the field of vascular surgery made great strides. The determination of vascular surgery items registered in NCD, as a rule, followed the items in the questionnaire survey items, which is an important asset. The number of registering institutions has increased, and while due care is required when interpreting changes in the number of surgical procedures, the fact that the details of vascular surgery throughout Japan have been clarified marks significant progress in ascertaining the state of vascular surgery in Japan. However, many issues remain. The first major purpose of participation in NCD is to apply the NCD data to improve the quality of medical care. Fortunately, vascular surgery has a low operative mortality rate, and thus the quality of most procedures cannot be evaluated by the mortality rate in the short-term, i.e., one month postoperatively. These vascular surgeries aim to improve the quality of life of patients and to this end, studies should be conducted to identify an evaluation index for surgical quality and how the results of such evaluations could lead to better surgical outcomes. By contrast, the operative mortality rate, such as that for surgery of the major blood vessels, can serve as an indicator of quality; therefore, a method of providing feedback for treatment outcomes in actual practice should be examined. Although already in practice in the field of cardiac surgery, we anticipate the implementation of a function capable of comparing the outcomes of an individual institution after risk adjustment with the outcomes throughout Japan in real time. Proceeding with clinical research using NCD is a means of improving the quality of medical care. Clinical research is planned in the future based on the clinical research promotion committee of JSVS. Furthermore, to improve the reliability of the database, we hope that efforts will be made to verify the quality of the data by site visits. Working to address these issues will enable further progress. With the future remarkable cooperation of all members, we hope to further develop the vascular surgery database in NCD. We hope that the NCD data will be useful to all members of this society.

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### Appendix

Team responsible for analyzing the 2011 annual report as follows;

Database Management Committee of the Japanese Society for Vascular Surgery: Nobuyoshi Azuma (Chairman), Yukio Obitsu (Vice-chairman), Nobuya Zempo, Yoshinori Inoue, Kunihiro Shigematsu, Ikuo Sugimoto, Hitoshi Okazaki, Hideaki Obara, Hirono Satokawa, Daisuke Fukui, Tetsuro Miyata (Chief director of the Japanese Society for Vascular Surgery)

NCD Vascular Surgery Data analyzers: Ai Tomotaki, Arata Takahashi, Hiroaki Miyata

### **Disclosure Statement**

None of the co-authors have any conflict of interest to declare. We thank all persons involved in this report.

### Additional Remarks

This annual report was published in the Japanese Journal of Vascular Surgery Vol. 26 (2017) No. 1; however, after publication errors in the numerical data and resulting errors in the tables and figures were detected, the corrections in the report were published in Vol. 26 (2017) No. 6 of the same journal. This English translation reflects those corrections.

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