Effect of perioperative complications after endovascular therapy in patients with peripheral artery disease due to femoropopliteal lesions

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Objective: **Despite wide use, high initial success, and acceptable durability of endovascular therapy (EVT) for femoropopliteal (FP) lesions, the frequency of 30-day perioperative complications (POCs) and their effect on clinical outcomes have not been systematically evaluated, which is the subject of this study.**

Methods: **We used a multicenter database of 2145 consecutive patients (70% male; overall mean age, 73 ± 9 years) who successfully underwent EVT for FP lesions to investigate independent predictors of POCs (logistic regression analysis) and effect of POCs on prognostic outcomes (Cox proportional regression).**

Results: **POCs were observed in 209 patients (10%). In multivariate logistic regression analysis, body mass index <18.5 kg/m^2, critical limb ischemia, and TransAtlanic Inter-Society Consensus for the Management of Peripheral Arterial Disease class D lesions were independently associated with POCs (adjusted odds ratios [95% confidence intervals], 2.0 [1.3-2.9], 2.5 [1.9-3.3], and 1.6 [1.2-2.1], respectively). After risk stratification of POCs according to the number of these risk factors, the incidence of POCs was higher in the groups with higher scores. Follow-up for >30 days (mean, 2.3 ± 1.8 years) was available for 2079 of 2145 patients. A Cox hazard regression model adjusted for baseline clinical characteristics showed POCs were negatively and independently associated with future occurrence of major adverse limb events (defined as major amputation and major reintervention) or death (hazard ratio [95% confidence interval], 1.6 [1.2-2.1]; $P < .05$).**

Conclusions: **Body mass index <18.5 kg/m^2, critical limb ischemia, and TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease class D lesion were positively associated with POCs after EVT for FP lesions. The occurrence of POCs may adversely affect clinical outcomes in the chronic phase. (J Vasc Surg 2015;61:1272-7.)**

Femoropopliteal (FP) lesions are found in 60% to 70% of patients with symptomatic peripheral artery disease.[1-3] Endovascular therapy (EVT) has proven efficacious and safe in treatment of TransAtlantic Inter-Society Consensus (TASC) II A-B localized atherosclerotic FP lesions, for which it is considered first-line therapy because of its less invasive nature and high initial technical success.[4] Bypass surgery is standard treatment for TASC II C-D extensive FP lesions because of its durable patency rate at 5 years of 39% to 52% and 74% to 76% with prosthetic and autogenous vein conduit, respectively.[4]

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Although long-term outcomes after EVT for TASC II C-D lesions had been far from satisfactory, recent device improvement has led to better midterm outcomes and widespread use in this setting. In addition, a lower perioperative complications (POCs) rate after EVT compared with bypass surgery supports the current trend. The incidence of POCs after bypass surgery was 21% to 41% (myocardial infarction [MI], 1%-7%; wound infection, 7%-16%; and acute occlusion, 3%-4%),[5-7] in contrast with 2% to 17% after EVT (MI, 0%-2%; puncture site complication, 2%-6%; and distal embolization, 1%-2%).[8-12] In the current era of endovascular predominance, the incidence of 30-day POCs and its effect on long-term clinical outcomes has not been systematically studied. We, therefore, investigated predictors of 30-day POCs after EVT with a provisional stenting strategy for FP lesions and compared prognostic outcomes between patients with and without POCs.

METHODS

The protocol for this study was designed according to the Declaration of Helsinki and approved by the Ethics Committee of each participating institution. The protocol was registered with the University Hospital Medical Information Network-Clinical Trial Registry (UMIN000010986). All patients provided written informed consent.

Study population. Data were collected retrospectively from January 2004 to December 2011 in 13 Japanese cardiovascular centers, and 2145 consecutive patients who underwent EVT with provisional stenting strategy for de novo FP disease were finally enrolled for analysis. Exclusion criteria were asymptomatic patients or patients with unknown symptoms before the procedure, restenotic lesions, lesions secondary to a nonatherosclerotic lesion, previous lower extremity bypass surgery or EVT, acute limb ischemia, failed endovascular revascularization, or inadequate data. Independent predictors of 30-day POCs after EVT for FP lesions and the effect of 30-day POCs on prognostic outcomes were assessed.

Interventional procedure. Vascular specialists, including interventional cardiologists, vascular surgeons, and interventional radiologists, decided on the indication for and strategy of the endovascular approach based on computed tomography, duplex ultrasound imaging, or diagnostic angiography. An endovascular-first concept was used in this study.

In most cases, an ipsilateral antegrade or crossover approach was chosen, and a 6F sheath or guiding sheath was inserted through femoral access, followed by 5000 units of unfractionated heparin injection. A 0.035-, 0.018-, or 0.014-inch wire was used based on lesion morphology. If a wire crossing was not successful, especially in totally occlusive lesions, a bidirectional approach was used with distal superficial femoral artery, popliteal artery, or below-the-knee arteries as additional puncture sites to achieve wire crossing.

Balloon angioplasty was performed after wire crossing, and a self-expanding nitinol stent was implanted in cases of flow-limiting dissection or residual stenosis >30%. Stent selection and intravascular ultrasound use was at operator's discretion. Additional balloon angioplasty was done after stent implantation. An Angio-Seal STS Plus closure device (St. Jude Medical, St. Paul, Minn) was used whenever possible.

Dual-antiplatelet therapy with aspirin (100 mg/d) and cilostazol (200 mg/d) or ticlopidine (200 mg/d) was administered to all patients before EVT.

Follow-up was conducted at 1 and 4 weeks and every 3 months thereafter with routine assessment of restenosis by duplex ultrasound imaging and ankle-brachial index (ABI). Target lesion revascularization was planned when symptoms recurred secondary to restenosis or reocclusion.

Definitions. Cardiovascular disease was defined as a history of MI or revascularization or symptomatic status of coronary artery disease or cerebrovascular disease. Critical limb ischemia (CLI) was defined as patients presenting with typical ischemic rest pain or ischemic skin lesions, either ulcer or gangrene. CLI diagnosis was confirmed by ABI with an ankle pressure <50 mm Hg or a toe pressure <30 mm Hg in patients with rest pain; and <70 mm Hg or <50 mm Hg, respectively, in patients with ischemic skin lesions. MI was defined as significant elevation of levels of serum biomarkers (troponin T >0.1 ng/mL or twice normal creatine kinase level). Stroke was defined as a sustained neurologic deficit confirmed by computed tomography or magnetic resonance imaging. Intestinal bleeding was defined when patients presented bloody stool.

Major adverse cardiovascular events (MACE) included all-cause death, MI, and stroke. Major adverse limb events (MALE) included major amputation or any major reintervention. Major amputation was defined as above-ankle amputation. Surgical reintervention was defined as a surgical procedure (bypass surgery). Any reintervention, including endovascular procedures (balloon angioplasty, atherectomy, stenting) without thrombectomy or thrombolysis in addition to surgical reintervention, was performed only when indicated clinically by symptomatic recurrence. Restenosis was defined as >50% diameter stenosis as determined by angiography or a peak systolic velocity >2.4 m/s.[13]

Outcome measure. The outcome measure of this study was predictors of POCs by logistic regression analysis. We also used the Cox proportional model to assess the effect of POCs on clinical outcomes, including rates of MACE, all-cause death, MI, and stroke, MALE, major amputation, and restenosis.

Statistical analysis. Statistical analysis was performed with SPSS software (SPSS Inc, Chicago, Ill). Descriptive data are reported as means ± standard deviation for continuous variables or as percentages for dichotomous variables. Between-group differences were evaluated by the unpaired *t*-test for continuous or the Fisher exact test for dichotomous variables. $P < .05$ was considered statistically significant.

Independent predictors of POCs were determined by multivariate logistic regression analysis using three multivariate models for each outcome: model 1 included all variables in the univariate model; model 2 included all significant variables in the univariate model; and model 3 included significant variables in multivariate model 1. The risk of POCs was stratified by the number of risk factors. The Kaplan-Meier method and the Cox proportional hazard regression model were used to analyze the effect of POCs on prognostic outcomes.

RESULTS

POCs. In the overall population, POCs presented ≤30 days in 209 patients (9.7%; Table I). Death occurred in 25 patients (1.2%) during the perioperative period: 11 deaths were from infectious death, 5 from cardiac death, 2 from cerebrovascular death, 3 from fatal bleeding, 1 from ischemic colitis, 1 from renal failure, and 2 from unknown reasons. MI, stroke, and intestinal bleeding occurred in 4 (0.2%), 12 (0.6%), and 3 patients (0.1%), respectively. Postprocedural worsening renal function requiring dialysis was documented in one patient (<0.1%). Distal embolism, a limb-threatening complication during EVT, was observed in 22 patients (1.0%). A bidirectional approach was conducted in 305 patients (14%), including popliteal in 256, tibial in 35, and distal superficial femoral artery in 15. Puncture site bleeding complication, which

Table I. Details of perioperative complications (*POCs*)

Variables	*No. (%)*[a]
Overall	209 (9.7)
Death	25 (1.2)
MI	4 (0.2)
Stoke	12 (0.6)
Renal function requiring dialysis	1 (<0.1)
Intestinal bleeding	3 (0.1)
Stent thrombosis	36 (1.7)
Pseudoaneurysm	14 (0.7)
Distal embolization	22 (1.0)
Puncture site bleeding/hematoma	92 (4.3)
Others	28 (1.3)

MI, Myocardial infarction.
[a]Data are the number (%) of POCs in 2145 cases.

was managed without surgical repair but required transfusion or prolonged hospitalization, occurred most frequently (92 patients [4.3%]). Site occlusion was treated ≤30 days in 36 patients (1.7%).

Baseline characteristics of patients with and without POCs. Baseline characteristics of patients with (POC+) and without (POC−) POCs are reported in Table II. Body mass index (BMI) was lower (22.3 ± 3.3 vs 21.4 ± 3.4 kg/m^2; $P < .001$) and frequency of male gender was lower (61.2% vs 70.5%; $P = .007$) in the POC+ group than in the POC− group. Distribution of risk factors, except for hyperlipidemia (51.3% in POC+ vs 41.1% in POC−; $P = .006$) and cardiovascular disease, was not significantly different between the two groups. Compared with the POC− group, the POC+ group was associated with higher frequency of CLI (55% vs 31%: $P < .0001$), TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) class D lesions (36.8% vs 25.9%; $P = .001$), and poorer below-the-knee runoff (1.5 ± 0.9 vs 1.7 ± 0.9 vessels; $P = .004$), indicating more severe limb and vessel status in the POC+ group.

Independent predictors for POCs and risk stratification. Table III reports predictors of POCs. In multivariate logistic regression analysis, BMI <18.5 kg/m^2, CLI, and TASC II class D lesions were independently associated with POCs (adjusted odds ratios [95% confidence intervals], 2.0 [1.3-2.9], 2.5 [1.9-3.3], and 1.6 [1.2-2.1], respectively). After risk stratification of POCs according to number of these risk factors, the POC incidence was higher in the groups with higher scores (Fig 1).

Prognostic effect of POCs on follow-up outcomes. The prognostic effect of POCs on follow-up outcomes is reported in Table IV. Mean follow-up period was 2.3 ± 1.8 years. The Cox hazard regression model adjusted for baseline clinical characteristics showed POCs at an early stage were positively and independently associated with future occurrence of MALE or death, MACE, and restenosis (hazard ratio [95% confidence interval], 1.6 [1.2-2.1], 2.3 [1.5-3.7] and 1.4 [1.0-2.0], respectively; $P < .05$). Fig 2 shows the effect of POCs on MALE-free survival up to 5 years, which was higher in the POC− group than in the POC+ group (45% ± 2% vs 28% ± 5%; $P < .001$).

Table II. Baseline characteristics

Variables[a]	*POC− (n = 1936)*	*POC+ (n = 209)*	P *value*
Patient characteristics			
Age, years	73 ± 9	73 ± 10	.260
Age ≥80 years	455 (23.5)	57 (27.3)	.232
Male sex	1364 (70.5)	128 (61.2)	.007
BMI, kg/m^2	22.3 ± 3.3	21.4 ± 3.4	<.001
BMI <18.5 kg/m^2	173 (8.9)	41 (19.6)	<.001
Diabetes mellitus	1193 (61.6)	125 (59.8)	.602
Hypertension	1650 (85.2)	170 (81.3)	.154
Hyperlipidemia	994 (51.3)	86 (41.1)	.006
Regular dialysis	502 (25.9)	68 (32.5)	.048
Smoking	524 (27.1)	51 (24.4)	.460
Cardiovascular disease	1181 (61.0)	135 (64.6)	.332
Limb and lesion characteristics			
CLI	600 (31.0)	115 (55.0)	<.001
TASC II class D	502 (25.9)	77 (36.8)	.001
Aortoiliac lesion	356 (18.4)	39 (18.7)	.925
Below-the-knee runoff, vessels	1.7 ± 0.9	1.5 ± 0.9	.004
Stent use	1462 (75.5)	164 (78.5)	.395
IVUS use	441 (22.8)	37 (17.7)	.097

BMI, Body mass index; *CLI,* critical limb ischemia; *IVUS,* intravascular ultrasound; *POC−,* without postoperative complications; *POC+,* with postoperative complications; *TASC II,* TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease.
[a]Data are presented as mean ± standard deviation or number (%).

DISCUSSION

The study documented 30-day POCs in ∼10% of the patients. Multivariable analysis showed BMI <18.5 kg/m^2, CLI, and TASC II class D lesions were positively associated with POC incidence, which was higher in groups with higher risk score. In addition, POCs negatively affected clinical outcomes.

According to the TASC II guideline, first-line therapy for TASC II A-B and C-D FP lesions is EVT and bypass surgery, respectively,[4] whereas the latest 2013 American College of Cardiology/American Heart Association guideline recommends EVT only for extremely localized TASC II A lesions, with stent implantation only indicated for suboptimal results after balloon angioplasty, and evidence class III level for primary stenting in FP lesion.[14] In the clinical setting, however, stent-supported EVT is widely used because of the low operative complication rate and favorable long-term outcome.[15] Patency rate, MACE, and amputation-free survival were used as efficacy and safety end points in several studies,[5-11,16] but the incidence of 30-day POCs and the effect on clinical outcomes have not been systematically studied, especially in the current advanced endovascular era.

Estimating POC occurrence is clinically important when deciding on an EVT strategy. We, therefore, investigated factors associated with 30-day POCs after EVT for

Table III. Association of baseline characteristics with the risk for perioperative complications (POCs)

	Univariate model	*Multivariate model 1*[a]	*Multivariate model 2*[b]	*Multivariate model 3*[c]
Characteristics	*Unadjusted OR (95% CI)*	*Adjusted OR (95% CI)*	*Adjusted OR (95% CI)*	*Adjusted OR (95% CI)*
Age >80 years	1.22 (0.88-1.68)	1.00 (0.71-1.41)	N/I	N/I
Male sex	0.66 (0.49-0.89)[d]	0.78 (0.57-1.07)	0.81 (0.60-1.10)	N/I
BMI < 18.5 kg/m2	2.49 (1.71-3.62)[d]	1.86 (1.25-2.76)[d]	1.88 (1.27-2.79)[d]	1.97 (1.34-2.90)[d]
Diabetes mellitus	0.93 (0.69-1.24)	0.89 (0.65-1.22)	N/I	N/I
Hypertension	0.76 (0.52-1.09)	0.94 (0.63-1.40)	N/I	N/I
Hyperlipidemia	0.66 (0.50-0.89)[d]	0.79 (0.58-1.08)	0.79 (0.58-1.06)	N/I
Regular dialysis	1.38 (1.01-1.87)[c]	1.05 (0.75-1.48)	1.04 (0.75-1.45)	N/I
Smoking	0.87 (0.62-1.21)	1.14 (0.80-1.62)	N/I	N/I
Cardiovascular disease	1.17 (0.87-1.57)	1.23 (0.90-1.69)	N/I	N/I
CLI	2.72 (2.04-3.64)[d]	2.26 (1.62-3.15)[d]	2.24 (1.62-3.09)[d]	2.49 (1.85-3.34)[d]
TASC II class D	1.67 (1.24-2.25)[d]	1.55 (1.13-2.13)[d]	1.56 (1.15-2.12)[d]	1.57 (1.16-2.13)[d]
Aortoiliac lesion	1.02 (0.71-1.47)	1.04 (0.71-1.52)	N/I	N/I
Below-knee runoff	0.79 (0.68-0.93)[d]	0.97 (0.81-1.15)	0.96 (0.81-1.13)	N/I
Stent use	1.18 (0.84-1.67)	1.19 (0.82-1.72)	N/I	N/I
IVUS use	0.73 (0.50-1.06)	0.78 (0.53-1.15)	N/I	N/I

CI, Confidence interval; *CLI,* critical limb ischemia; *IVUS,* intravascular ultrasound; *N/I,* not included in the model; *OR,* odds ratio; *TASC II,* TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease.
[a]Multivariate model 1: all variables were entered.
[b]Multivariate model 2: Variables with $P < .05$ in the univariate model were entered.
[c]Multivariate model 3: Variables with $P < .05$ in multivariate model 1 were entered.
[d]$P < .01$.
[c]$P < .05$.

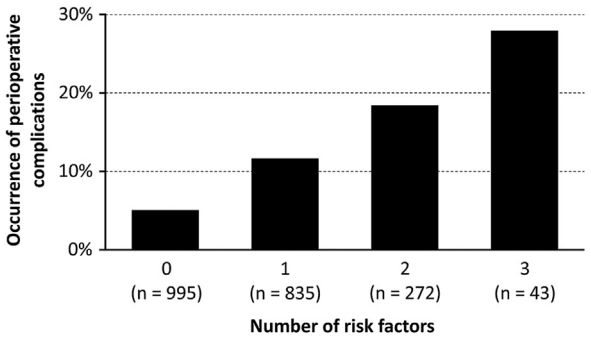


Fig 1. Occurrence of perioperative complications (POCs) according to the number of risk factors. POCs occurred in 209 patients (9.7%). Risk factors for POCs were body mass index (BMI) <18.5 kg/m^2, critical limb ischemia (CLI), and TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) class D lesions (Table I). According to the number of risk factors for POCs, incidence of POCs was higher in the groups with higher scores (0: 5.0% [50 of 995], 1: 11.6% [97 of 835], 2: 18.4% [50 of 272], and 3: 27.9% [12 of 43]).

FP lesions and compared prognostic outcomes between patients with and without POCs. In this study, POCs were observed in 209 patients (10%). BMI <18.5 kg/m^2, CLI, and TASC II class D legions were independently associated with POCs after multivariate logistic regression analysis, and the POC rate linearly increased with the number of predictors. The obesity paradox had suggested poor outcomes in both overweight and underweight patients, with a relative shortage of medication in underweight patients.[17-20] CLI status and TASC II class D lesions reflected baseline patient background and lesion severity, which along more complex endovascular procedures might have resulted in complications.[21] MACE, MALE, and restenosis were documented more frequently in the POC+ group than in the POC− group. Occurrence of POCs may adversely affect clinical outcomes in the chronic phase. The population at high risk for POCs in this study might also be at high risk for POCs with bypass surgery.

It is potentially and clinically important to consider the revascularization indication and to predict short-term and long-term outcome when treating patients. Results of this study have indicated an association between POCs and clinical outcomes, which might inform decision making on EVT strategy. This study included a large number of patients from multiple centers; however, it was limited by its retrospective nature and selection bias for intervention, even though intervention was decided by consensus using an EVT-first approach. In addition, the actual number of patients undergoing FP bypass could not be determined because of data collection limitations in this study.

Recent trials reported better patency with device improvement and development[9,22] that have led to wider application of EVT to FP lesions. Our results potentially play an important role in predicting outcomes and choice of devices.

CONCLUSIONS

A BMI <18.5 kg/m^2, CLI and TASC II class D lesions were positively associated with POCs after EVT for FP lesions. The occurrence of POCs may adversely affect clinical outcomes in the chronic phase.

Table IV. Hazard ratios of perioperative complications (*POCs*) for various future outcomes[a]

Model	*Outcome measure*	*Observed events, No.*	*Early stage (<1 year)*	*Late stage (≥1 year)*
Univariate model	MALE or death	779	1.77 (1.32-2.38)[b]	1.61 (1.11-2.35)[c]
	MACE	318	1.80 (1.77-4.43)[b]	1.28 (0.73-2.26)
	All-cause death	265	3.24 (2.02-5.20)[b]	1.23 (0.65-2.34)
	MI	51	3.19 (1.08-9.41)[c]	2.76 (0.96-7.93)
	Stroke	57	8.87 (3.68-21.4)[b]	0.49 (0.07-3.59)
	MALE	593	1.34 (0.92-1.97)	1.62 (1.05-2.52)[c]
	Major amputation	46	2.55 (0.98-6.60)	1.43 (0.19-11.0)
	Surgical reintervention	46	1.81 (0.54-6.00)	4.78 (1.59-14.4)[b]
	Any reintervention	415	1.17 (0.71-1.91)	1.68 (0.99-2.85)
	Restenosis	674	1.61 (1.15-2.25)[b]	1.44 (0.90-2.30)
Multivariate model 1[d]	MALE or death	779	1.54 (1.14-2.08)[b]	1.49 (1.02-2.17)[c]
	MACE	318	2.31 (1.46-3.66)[b]	1.10 (0.63-1.94)
	All-cause death	265	2.60 (1.61-4.18)[b]	1.04 (0.54-1.97)
	MI	51	2.93 (0.99-8.72)	2.45 (0.85-7.06)
	Stroke	57	8.88 (3.66-21.6)[b]	0.48 (0.07-3.49)
	MALE	593	1.21 (0.82-1.77)	1.53 (0.98-2.37)
	Major amputation	46	1.87 (0.72-4.86)	1.19 (0.15-9.14)
	Surgical reintervention	46	1.47 (0.44-4.90)	4.36 (1.44-13.2)[b]
	Any reintervention	415	1.05 (0.64-1.73)	1.57 (0.93-2.67)
	Restenosis	674	1.48 (1.06-2.08)[c]	1.37 (0.86-2.18)
Multivariate model 2[e]	MALE or death	779	1.57 (1.16-2.11)[b]	1.58 (1.08-2.30)[c]
	MACE	318	2.30 (1.45-3.66)[b]	1.22 (0.69-2.15)
	All-cause death	265	2.64 (1.63-4.27)[b]	1.16 (0.61-2.21)
	MI	51	2.91 (0.97-8.74)	2.60 (0.89-7.59)
	Stroke	57	8.92 (3.64-21.9)[b]	0.48 (0.07-3.56)
	MALE	593	1.20 (0.82-1.75)	1.51 (0.97-2.34)
	Major amputation	46	2.12 (0.80-5.59)	1.12 (0.14-8.77)
	Surgical reintervention	46	1.45 (0.43-4.88)	4.41 (1.42-13.6)[c]
	Any reintervention	415	1.01 (0.62-1.66)	1.48 (0.87-2.51)
	Restenosis	674	1.43 (1.02-2.00)[c]	1.27 (0.79-2.03)

BMI, Body mass index; *CLI*, critical limb ischemia; *MACE*, major adverse cardiac event; *MALE*, major adverse limb events; *MI*, myocardial infarction; *TASC II*, TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease.

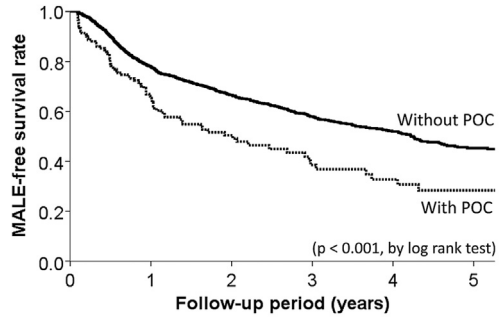
[a]Data are adjusted hazard ratios and their 95% confidence intervals.

[b]$P < .01$.

[c]$P < .05$.

[d]Multivariate model 1: adjusted for BMI <18.5 kg/m^2, CLI, and TASC II class D lesions (risk factors for POCs).

[e]Multivariate model 2: adjusted for BMI <18.5 kg/m^2, CLI, and TASC II class D lesions, as well as sex, age ≥80 years, diabetes mellitus, hypertension, hyperlipidemia, regular dialysis, smoking, history of cardiovascular diseases, aortoiliac lesion, below-the-knee runoff, stent use, and intravascular ultrasound use.



		0 yr	1 yr	2 yr	3 yr	4 yr	5 yr
Without POC	No. at risk	1925	1240	723	399	231	55
	Rate ± SE	100±0%	78±1%	67±1%	58±1%	52±2%	45±2%
With POC	No. at risk	154	81	39	22	15	10
	Rate ± SE	100±0%	65±4%	49±5%	37±5%	31±5%	28±5%

Fig 2. Effect of perioperative complications (*POCs*) on survival free of major adverse limb events (*MALE*). The MALE-free survival rate was higher in the group without POCs (POC−) than in the group with POCs (POC+) up to 5 years (45% ± 2% vs 28% ± 5%; $P < .001$). *SE*, Standard error.

AUTHOR CONTRIBUTIONS

Conception and design: KS, OI, MT, YS, MU
Analysis and interpretation: KS, OI, MT
Data collection: KS, OI, MT, YS, KS
Writing the article: KS, OI, MT
Critical revision of the article: KS, OI, MT
Final approval of the article: KS, OI, MT, YS, KS, TT, MI, MU
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