

Original
Article

Determination of Treatment Efficacy after Revascularization of Intermittent Claudication Patients by Physical Function Assessment

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Purpose: There have been few reports examining changes in physical activity (PA) after revascularization of lower extremities from the perspective of physical function at discharge. The purpose of this study was to clarify the effects of physical function before discharge on the amount of PA after discharge in patients who underwent revascularization.

Methods: The subjects were 34 Fontaine class II patients admitted for elective surgical revascularization or endovascular treatment at two hospitals from September 2017 to October 2019. Triaxial accelerometers were used to measure changes in sedentary behavior (SB) before admission and 1 month after discharge. Multiple regression analysis was performed on the 6-min walking distance (6MWD) at the time of discharge and the change in SB 1 month after discharge; the cutoff value was calculated from the receiver operating characteristic (ROC) curve.

Results: SB 1 month after discharge significantly decreased in the decreased SB group compared to the increased SB group (575.5 [400–745.2] vs. 649.5 [453.8–809.2], $p < 0.01$). ROC curve was plotted with SB increase/decrease as the dependent variable and 6MWD at discharge as the independent variable; the cutoff value was 357.5 m.

Conclusion: 6MWD measurement at discharge may help predict changes in SB after discharge.

Keywords: peripheral artery disease, revascularization, physical activity, physical function

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Introduction

Patients with peripheral artery disease (PAD) have decreased physical activity (PA) and increased overall mortality; therefore, it is necessary to prevent a decrease in PA.^{1,2)} Intermittent claudication (IC) is a common symptom of PAD.³⁾ If claudication symptoms do not improve in IC patients, revascularization is indicated. After revascularization, supervised exercise therapy improves physical function and quality of life more than revascularization alone.⁴⁾ Therefore, it is important to continue exercise therapy as outpatient treatment both during hospitalization and after discharge to improve PA. In clinical practice, it is extremely difficult to continue supervised exercise therapy after discharge owing

to social constraints (distance, work, medical expenses, and lack of treatment facilities). It has been reported that walking speed is slow even after discharge.⁵⁾ Recently, attention has been focused on the relationship between PA intensity, such as sedentary behavior (SB) and moderate-to-vigorous intensity physical activity (MVPA), in patients with PAD,⁶⁾ and physical functions, such as 6-min walking distance (6MWD).⁷⁾ In particular, it suggests that reducing the duration of sitting time may be an important strategy to prevent peripheral arterial disease.⁶⁾ However, there are few reports regarding the relationship between physical function at discharge after revascularization surgery and PA at 1-month post discharge. Therefore, to set goals before discharge, it is important to compare PA 1 month after discharge to patients' physical function with revascularization of the lower limbs at the time of discharge. This study investigated the influence of physical function at discharge on post-discharge PA in patients who underwent revascularization.

Materials and Methods

Study design

The subjects included patients admitted to Aichi Medical University Hospital and Cardiovascular Institute Sakakibara Hospital between September 2017 and October 2019 for standby surgical revascularization or endovascular treatment for Fontaine Classification II PAD. All participants were requested to wear a PA monitor. Exclusion criteria included (1) patients who did not meet criteria for wearing a PA meter, (2) patients with cardiovascular events during hospitalization, and (3) patients who did not provide consent for this study. All subjects underwent the same rehabilitation program under the supervision of a physical therapist, from bed release to discharge. The rehabilitation program for all patients from the postoperative period to discharge complied with the Transatlantic Intersociety Consensus II.⁸⁾ Content started one day after surgery, with automatic passive exercise on the bed, and activities of daily living (ADLs) gradually expanded to sitting, standing, and walking. After gait independence, patients started walking on a treadmill five times a week for 60 min/day until discharge. At discharge, patients were instructed to walk as home exercise, and no supervised exercise therapy was provided except during hospitalization.

Ethical considerations

This study was conducted with the approval of the Aichi Medical University Hospital (approval number: 2017-H204)

and Cardiovascular Institute Sakakibara Hospital (approval number: A2017-05). Written informed consent was obtained from all patients participating in the study.

Patient data

Patient characteristics such as age, sex, body mass index, smoking history, medical history, blood data before revascularization (creatinine, glomerular filtration rate, C-reactive protein, high-density lipoprotein cholesterol, and albumin), ankle-brachial pressure index (ABI), postoperative hospital stay, treatment region, and surgical procedure method were investigated.

Measures

Physical activity

PA was measured using a triaxial accelerometer (Active Style PRO HJA-750C; Omron Healthcare, Kyoto, Japan) for activity time and intensity. Activity time was investigated based on the number of steps, defined as time spent walking. For activity intensity (Mets/h), an exercise time of 1.5 Mets/h or less was classified as SB, 1.6–2.9 Mets/h as light-intensity physical activity (LPA), and 3 Mets/h or more as MVPA.^{9–11)}

During the survey period, the amount of daily PA outside the hospital was measured before admission and 1 month after discharge. The triaxial accelerometer was attached to the waist and measurements were collected continuously for 7 days, excluding times of bathing or bedtime. We adopted cases where wear time per day was 600 min or more¹²⁾ and wear time was 5 days or more. The obtained data were summed and divided by the number of hiring days to calculate the average value. If the continuous value of activity intensity was 0 for more than 60 min, it was considered as non-wearing time, and the time was excluded from wearing time. To evaluate factors influencing pre- and postoperative changes in SB, patients were classified into two groups: those whose SB decreased from before admission to 1 month after discharge (SB-decreased group) and those whose SB increased (SB-increased group); SB-decreased and SB-increased groups were compared.

Physical function

The short physical performance battery (SPPB), gait speed (usual and maximum gait speed [m/s]), and 6MWD were measured before surgery and day before discharge. SPPB was calculated according to the method defined by Guralnik et al.¹³⁾ by quantifying the results of the

comfortable 4-m walking speed, getting up from a chair, and standing balance on a scale of 0–4. The usual walking speed for 4-m and maximum walking speed was measured. Usual walking speed was measured as usual, and maximum walking speed was measured using a fast foot that did not run. Each patient was placed at the start of the 4-m course, and the time required to complete the course was measured using a stopwatch. The obtained values were converted into m/s, and the 6MWD was measured according to the standardized program¹⁴⁾ of the American Thoracic Society by instructing subjects to walk as far as possible in 6 min on a 30-m walking path on a level ground. The distance walked in 6 min was recorded. To investigate subjective symptoms, the Walking Impairment Questionnaire (WIQ) was used, based on previous studies, as a questionnaire index.¹⁵⁾ The WIQ was distributed by mail before admission and 1 month after discharge, and was collected by return mail after self-administration. Each WIQ item and total score were calculated and compared between the SB-decreased and SB-increased groups.

Statistical method

All continuous data are expressed as median (minimum–maximum), and statistical differences between the groups were analyzed using the Mann–Whitney U test. Statistical differences within the groups were analyzed using the Wilcoxon signed-rank test. Moreover, items on the nominal scale were compared using the Pearson’s chi-square test. A single correlation analysis using Spearman’s rank correlation coefficient was performed for all items shown in the measurement items, and multicollinearity was considered. Additionally, factors influencing SB increase and decrease were analyzed using multiple logistic regression analysis with SB increase/decrease as the dependent variable and 6MWD at discharge and WIQ pain items at 1 month as independent variables. A receiver operating characteristic (ROC) curve was plotted with SB increase/decrease as the dependent variable and 6MWD at discharge as the independent variable; cutoff values were calculated from the ROC curve. Statistical analysis was performed using SPSS Statistics 28.0 (IBM Corp., Armonk, NY, USA), and the statistical significance level was set at $p < 0.05$.

Results

Study sample

Of the 76 cases, 42 were excluded and 34 cases (27 males and 7 females; age, 72 years [51–87 years]) were

included. There were 17 patients (50%) in the SB-decreased group and 17 patients (50%) in the SB-increased group. There was no significant difference in patient backgrounds between the groups (**Table 1**). Similarly, there were no significant differences in the treatment site or surgical procedure. All participants had significantly increased ABI (0.7 [0.3–1.3] vs 1.0 [0.8–1.2], $p < 0.01$) and 6MWD (340 [120–479] vs 378.5 [182–491], $p < 0.01$) between before and after treatment (**Table 2**).

Physical activity

In a postoperative comparison, the decreased SB group had significantly more steps (4669.3 [556.7–13110.4] vs 3135.1 [322.0–6267.0], $p < 0.05$) and significantly less SB (575.5 [400–745.2] vs 649.5 [453.8–809.2], $p < 0.01$) than the increased SB group. Comparing preoperative and postoperative levels in each group, SB in the SB-decreased group was significantly lower after surgery (629.6 [402.7–799.7] vs 575.5 [400–745.2], $p < 0.01$) and MVPA was significantly higher after surgery (29.5 [5.8–116.9] vs 35.5 [17.2–137.4], $p < 0.01$) (**Table 3**). In contrast, the number of steps, LPA, and MVPA decreased significantly in the SB-increased group, while SB increased. However, no significant differences were found for any other items.

Physical function

After surgery, the SB-decreased group had a significantly longer 6MWD at discharge than the SB-increased group (420 [280–491] vs 352.5 [182–440], $p < 0.05$). Comparing each group before and after surgery, 6MWD at discharge in the SB-decreased group was significantly longer after surgery (385 [234–470] vs 420.0 [280.0–491.0], $p < 0.01$). Moreover, the 6MWD at discharge in the SB-increased group was also significantly longer after surgery (280 [120–479] vs 352.5 [182–440], $p < 0.05$).

WIQ

There was no significant difference between pre- and postoperative results for both groups. However, a comparison between pre- and postoperative periods in each group showed significant improvement, except for the climb item in the SB-decreased group and the pain item in the SB-increased group (**Table 4**).

SB-related factors

The 6MWD at discharge ($\beta = -0.015$; $p = 0.025$; 95% confidence interval = 0.973–0.998) was selected as the independent variable associated with SB increase or

Table 1 Comparison of SB increase and decrease in PAD patients

	SB decrease group	SB increase group	p value
Comorbidity			
Male, n (%)	15 (88.2)	12 (70.6)	0.20
Age (years)	74 (51–87)	70 (63–87)	0.54
BMI (kg/m ²)	22.6 (18.5–30.0)	24.1 (19.6–29.2)	0.32
Smoking, n (%)	2 (11.8)	1 (5.9)	0.50
Hypertension, n (%)	17 (100.0)	16 (94.1)	0.50
Hyperlipidemia, n (%)	12 (70.6)	11 (64.7)	0.50
Chronic kidney disease, n (%)	3 (17.6)	3 (17.6)	0.67
Diabetes, n (%)	11 (64.7)	7 (41.2)	0.15
Blood data			
Cre (mg/dL)	1.06 (0.48–2.23)	0.77 (0.58–12.71)	0.54
eGFR (mL/min/1.73 m ²)	54.1 (25–110)	64 (3.6–92)	1.00
CRP (mg/dL)	0.16 (0.04–0.79)	0.18 (0.04–6.90)	0.52
HDL (mg/dL)	46 (33–77)	48.5 (37–66)	0.95
Alb (g/dL)	4 (2.6–4.5)	4 (2.8–4.5)	0.89
Preoperative ABI	0.76 (0.48–1.25)	0.60 (0.31–0.96)	0.10
Postoperative ABI	1.03 (0.84–1.21)	0.99 (0.83–1.13)	0.19
Length of hospital stay (days)	9 (5–15)	7 (3–21)	0.57
Treatment region			0.09
CIA, n (%)	5 (29.4)	9 (52.9)	
EIA, n (%)	3 (17.6)	9 (52.9)	
CFA, n (%)	6 (35.3)	3 (17.6)	
SFA, n (%)	9 (52.9)	3 (17.6)	
DFA, n (%)	1 (5.9)	1 (5.9)	
Surgical procedure			0.63
Bypass graft, n (%)	2 (11.8)	3 (17.6)	
EVT, n (%)	17 (100)	16 (94.1)	

Data are presented as median (minimum–maximum) or numbers and percentages. There is a multiplicity. SB: sedentary behavior; PAD: peripheral artery disease; BMI: body mass index; Cre: creatinine; eGFR: estimated glomerular filtration rate; CRP: C-reactive protein; HDL: high-density lipoprotein cholesterol; Alb: albumin; ABI: ankle-brachial pressure index; CIA: common iliac artery; EIA: external iliac artery; CFA: common femoral artery; SFA: superficial femoral artery; DFA: deep femoral artery; EVT: endovascular treatment

Table 2 Changes in PA and function

	Preoperative	Postoperative	p value
ABI	0.7 (0.3–1.3)	1.0 (0.8–1.2)	<0.01
SPPB total score	12 (4–12)	12 (6–12)	0.27
Gait speed score	4 (1–4)	4 (2–4)	0.31
Balance score	4 (2–4)	4 (3–4)	1.00
Chair stand score	4 (0–4)	4 (1–4)	0.27
Usual walking speed (m/sec)	0.9 (0.4–1.4)	1.0 (0.5–1.3)	0.35
Maximum walking speed (m/sec)	1.3 (0.6–2.1)	1.3 (0.7–1.9)	0.71
6MWD (m)	340 (120–479)	378.5 (182–491)	<0.01
Number of steps (steps/day)	3836.5 (317.5–17389.3)	3533.4 (322–13110.4)	0.98
SB (min/day)	584.6 (267.3–799.7)	605.6 (412–809.2)	0.48
LPA (min/day)	202.6 (82.1–363.5)	202.1 (75.7–415.9)	0.66
MVPA (min/day)	36.1 (5.8–116.9)	34.2 (10.4–137.4)	0.70
Total wearing time (min/day)	830.1 (600–1027.8)	829.2 (690.8–1079.3)	0.38

Data are presented as median (minimum–maximum) or numbers and percentages. There is a multiplicity. PA: physical activity; ABI: ankle-brachial pressure index; SPPB: short physical performance battery; 6MWD: 6-min walk distance; SB: sedentary behavior; LPA: light-intensity physical activity; MVPA: moderate-to-vigorous physical activity

Table 3 Comparison of SB increase and decrease in PAD patients

	Preoperative			Postoperative		
	SB decrease group	SB increase group	p value	SB decrease group	SB increase group	p value
Number of steps (steps/day)	4036.6 (317.5–17389.3)	3636.4 (726.0–6837.8) [†]	1.00	4669.3 (556.7–13110.4)	3135.1 (322.0–6267.0)	0.02
SB (min/day)	629.6 (402.7–799.7)*	526.1 (267.3–780.7)*	0.25	575.5 (400–745.2)	649.5 (453.8–809.2)	<0.01
LPA (min/day)	172.8 (82.1–298.8)	217.8 (122.2–363.5) [†]	0.09	214.8 (112.7–415.9)	200.6 (75.7–316.1)	0.45
MVPA (min/day)	29.5 (5.8–116.9)*	38.3 (18.8–104.5)*	0.11	35.5 (17.2–137.4)	31.5 (10.4–60.8)	0.18
SPPB total score	12 (6–12)	11 (4–12)	0.14	4 (2–4)	4 (2–4)	0.70
Gait speed score	4 (1–4)	4 (2–4)	0.42	4 (2–4)	4 (2–4)	0.68
Balance score	4 (4–4)	4 (2–4)	0.19	4 (3–4)	4 (3–4)	0.22
Chair stand score	4 (1–4)	3.5 (0–4)	0.17	4 (1–4)	4 (1–4)	0.85
Usual walking speed (m/sec)	1.0 (0.4–1.4)	0.9 (0.6–1.3)	0.17	1.1 (0.5–1.3)	1.0 (0.6–1.3)	0.85
Maximum walking speed (m/sec)	1.4 (0.6–2.1)	1.2 (0.7–1.9)	0.12	1.3 (0.8–1.8)	1.3 (0.7–1.9)	0.47
6MWD (m)	385 (234–470)*	280 (120–479) [†]	0.18	420 (280–491)	352.5 (182–440)	<0.05

Data are presented as median (minimum–maximum) or numbers and percentages. There is a multiplicity. *vs postoperative from the same group, $p < 0.01$. [†]vs postoperative from the same group, $p < 0.05$. SB: sedentary behavior; PAD: peripheral artery disease; LPA: light-intensity physical activity; MVPA: moderate-to-vigorous physical activity; SPPB: short physical performance battery; 6MWD: 6-min walk distance

Table 4 Comparison of WIQ before surgery and 1 month after discharge in the SB group

	Preoperative			Postoperative		
	SB decrease group	SB increase group	p value	SB decrease group	SB increase group	p value
WIQ total score	155 (41–269)*	113.6 (31.4–315.7) [†]	0.25	254 (24–400)	259 (29–400)	0.73
Pain	25 (25–100)*	25 (0–100)	0.86	75 (0–100)	50 (25–100)	0.70
Distance	25 (5–100) [†]	26 (2–58)*	0.63	89 (0.6–100)	79 (0.6–100)	0.61
Speed	30 (7–61)*	28 (0–100) [†]	0.63	61 (8–100)	62 (3–100)	1.00
Climb	42 (0–100)	29 (0–88) [†]	0.36	58 (0–100)	75 (0–100)	0.41

Data are presented as median (minimum–maximum) or numbers and percentages. There is a multiplicity. *vs 1 month after discharge from the same group, $p < 0.01$. [†]vs 1 month after discharge from the same group, $p < 0.05$. WIQ: Walking Impairment Questionnaire; SB: sedentary behavior

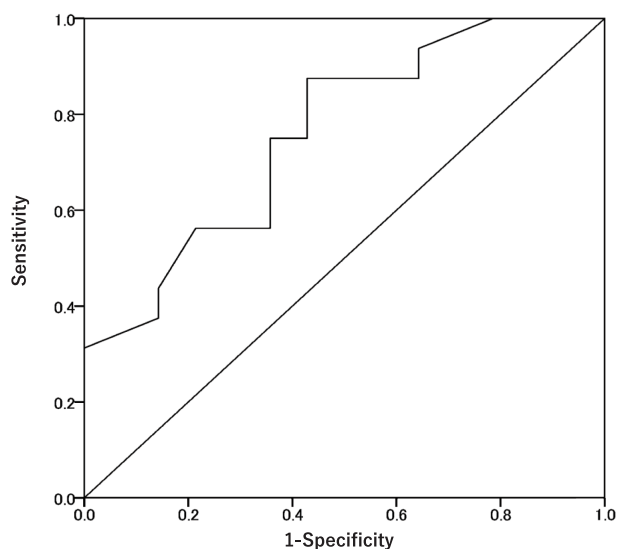


Fig. 1 ROC curves for SB increase or decrease and 6MWD after treatment. Cutoff value (specificity, sensitivity): 357.5 m (0.429, 0.875) and AUC (95% CI): 0.759 (0.973–0.998). $p < 0.05$. 6MWD: 6-min walk distance; SB: sedentary behavior; AUC: area under the curve; CI: confidence interval; ROC: receiver operating characteristic

decrease. Additionally, when the ROC curve was drawn with SB increase/decrease as the dependent variable and 6MWD at discharge as the independent variable, the cutoff value was 357.5 m (sensitivity 87.5%, specificity 42.9%), and the area under the curve was 0.759 (95% confidence interval = 0.973–0.998) (**Fig. 1**). Moreover, increase/decrease in MVPA was examined as a dependent variable, but no significant difference was observed.

Discussion

In the present study, we investigated physical function immediately after revascularization and PA after discharge in a two-center prospective cohort study. The results showed that physical function before discharge after revascularization for IC affected the amount of PA 1 month after discharge.

SB and physical function after surgery

All patients in this study underwent revascularization; ABI and 6MWD improved after treatment. However, SB decreased in half of the cases and increased in half of the cases after treatment. The ABI and 6MWD increase suggested that revascularization was performed appropriately. However, the 6MWD after treatment was significantly longer in the SB-decreased group, suggesting that 6MWD affects changes in SB. Several studies

on physical function and PA in patients with PAD have been conducted. McDermott et al. investigated physical function in patients with PAD and reported that the longer the 6MWD distance, the shorter the SB.⁷⁾ Germano-Soares et al. reported a positive correlation between 6MWD and MVPA in patients with PAD but reported no association with SB.¹⁶⁾ In our study, we investigated not only PA before revascularization, which has been previously investigated, but also PA immediately after revascularization. The 6MWD was longer in the SB-decreased group than that in the SB-increased group. However, the MVPA showed no significant difference. In the present study, IC improved in the SB-decreased and SB-increased groups after revascularization, which may have resulted in a longer 6MWD. Similarly, the total WIQ score improved in the SB-decreased and SB-increased groups, and the results were similar to those of a previous study.¹⁷⁾ Golledge et al. revealed that PAD patients who stopped during the 6MWD had a lower walking distance and number of steps than those who did not stop.¹⁸⁾ Although this study did not examine the number of times patients stopped walking, there was no improvement in the postoperative pain items of the WIQ in the increased SB group. In this study, there was no significant difference in the surgical technique, and the two groups were similarly invasive. However, it is possible that anxiety about pain in daily life reduced the amount of time patients spent on ADLs and increased SB. Since there is no report of a long-term study of the relationship between SB and pain anxiety after revascularization surgery, it is necessary to evaluate and discuss this issue in the future. In addition, the present study found no relationship between changes in SB and SPPB. Previous studies have reported that SPPB is an activity that uses leg muscles only for a short time and that 6MWD, which uses leg muscles for 6 min, is more suitable as a leg function test for IC patients.¹⁸⁾ From the results of our study, we found that the 6MWD is useful for IC lower extremity function evaluation, even in patients after revascularization, as well as in preoperative PAD patients, and it was considered appropriate for examining SB.

Effect of data during hospitalization on SB increase/decrease after discharge

The results of this study clarified that SB after discharge was improved by achieving a 6MWD of 357.5 m by the time of discharge after revascularization surgery. Saratzis et al. reported that the combination of exercise therapy under supervision can extend the walking

distance more than revascularization alone.⁴⁾ This report suggests that postoperative supervised exercise therapy may increase walking distance and decrease SB after discharge. Additionally, SB increased after discharge in patients who did not acquire the ability to walk 357.5 m by the time they were discharged from the hospital. In a long-term PA report, Peri-Okonny et al. reported that SB increased again after 6–12 months without supervised exercise therapy, even if SB decreased after discharge with or without revascularization treatment.¹⁹⁾ In our study, SB improved after discharge in many patients. However, this previous study reported, even if revascularization was performed, that SB may eventually increase if exercise was not performed under supervision. Therefore, continuation of outpatient-supervised exercise therapy after discharge from the hospital may be important in preventing an increase in SB. Furthermore, it has been reported that when PAD progresses to severe lower extremity ischemia, bypass surgery does not change the amount of PA after discharge.²⁰⁾ Therefore, it is important to manage patients who have undergone surgery for IC so that they do not progress to critical leg ischemia.

Number of steps and PA intensity

A comparison of the PA levels before and after surgery revealed an increase in MVPA in the decreased SB group. Moreover, the number of steps, LPA, and MVPA were decreased in the SB-increased group. A study that evaluated PA using accelerometers, similar to our study, reported that the prevalence of PAD increased with increasing SB and the shorter the SB, the longer the MVPA.⁶⁾ Moreover, a survey of patients with chronic obstructive pulmonary disease reported that the rate of change in SB and MVPA was negatively correlated with rehabilitation intervention.²¹⁾ In our study, MVPA increased after surgery in the SB-decreased group. Furthermore, in the group with increased SB, LPA and MVPA decreased after surgery. The result of this study was thought to be due to revascularization-improved lameness, reduced sitting time after discharge, and increased active intensity time.

Our study had several limitations. First, the sample size was not large; however, we performed revascularization surgery, which had not been examined in previous studies, and examined SB 1 month after discharge based on physical function during the admission period and found significant differences. Many subjects were excluded because of strict inclusion criteria to eliminate

bias. However, we cannot rule out the possibility that this may have affected the results. We expect that further evidence from similar studies will be constructed in the future. Second, although the present study revealed that the 6MWD at the time of discharge is an important item in evaluating SB 1 month after discharge, its long-term status is unknown. Therefore, in the future, a long-term survey is expected to be conducted after revascularization.

Conclusions

In this study, PA after revascularization surgery for IC was examined from physical function at discharge to PA after discharge. It was found that the 6MWD at discharge was associated with SB 1 month after discharge. Therefore, the 6MWD at discharge can help in predicting SB after discharge.

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Disclosure Statement

The authors have no conflicts of interest to disclose.

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