Examination of Changes in 6-minute Walk Distance and Related Factors in Patients with Perioperative Peripheral Arterial Disease

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ABSTRACT. Objective: This study aimed to clarify the effects of pre- and postoperative physical function on the 6-minute walking distance (6MWD) in patients with peripheral arterial disease (PAD). Method: Forty-two elderly patients with PAD who were hospitalized for revascularization and able to walk independently were included in the study. The 6MWD, ankle brachial index (ABI), weight-bearing index (WBI), gait, and intermittent claudication distance (ICD) were measured before and after the surgery, and skeletal muscle index was measured only before surgery. Analyses were performed by comparing the pre- and postoperative values of each factor using a paired t-test. In addition, multiple regression analysis was performed with 6MWD as the dependent variable before and after surgery. Results: Postoperatively, pain disappeared in 22 patients, and ABI, ICD, 6MWD, and stride length improved significantly. ICD and stride length were extracted as factors related to 6MWD before and after surgery, and ABI, WBI, and stride length were extracted as factors related to 6MWD after surgery. Conclusion: The improvement of intermittent claudication associated with revascularization suggests a stronger influence of functional aspects on postoperative 6 MWD.

Key words: Peripheral arterial disease, 6-minute walk distance, Revascularization

Peripheral arterial disease (PAD) is a chronic disease that causes atherosclerotic lesions in the blood vessels of the lower extremities, resulting in various disabling symptoms, including numbness, pain, ulceration, and necrosis of the legs. It has been reported that many patients with PAD experience ischemic symptoms in the lower legs, and typical intermittent claudication (IC) occurs in approximately one-third of patients⁷. Many patients with PAD are reported to exhibit functional weakness associated with limitations in daily activities due to pain in the lower extremities⁵, PAD has also been shown to cause decreased lower extremity muscle strength⁸ and exercise tolerance compared with non-diseased patients⁹. The International Guideline for the Diagnosis and Treatment of PAD (TASC II) advocates revascularization, pharmacotherapy, and exercise therapy as treatment methods for PAD, and recommends supervised exercise therapy as part of the initial treatment for all patients with IC (evidence level A). Exercise therapy is included in physical therapy; in this study, exercise for the purpose of treating and preventing diseases is defined as exercise therapy. Exercise therapy has been reported to improve vascular endothelial function⁷ and maximum walking distance⁸, with continued therapy showing improvements in patient prognosis⁷. Therefore, it is desirable to provide exercise therapy to patients with PAD, even during the postoperative period. A randomized controlled trial of revascularization alone versus revascularization with exercise therapy reported an effect of increased walking distance in
the combined treatment group\textsuperscript{15}. However, although previous studies have confirmed the utility of postoperative exercise therapy for increasing walking distance and improving long-term prognosis, there is a significant financial burden on patients associated with supervised exercise therapy. Moreover, a considerable burden is placed on medical personnel and the limited number of facilities that can provide continuous exercise therapy\textsuperscript{16}. Therefore, it is necessary for medical practitioners to evaluate patients shortly before and after surgery to identify functional problems and predict prognosis.

The treadmill graded exercise test according to the Gardner protocol is a commonly used method to evaluate functional impairment and exercise capacity in patients with PAD\textsuperscript{17}. However, the Gardner protocol is time-consuming, costly, and difficult to perform in ill-equipped environments. In contrast, the 6-min walk test (6MWT) is a highly versatile measure that is also used to evaluate exercise capacity in conditions such as congestive heart failure and respiratory diseases\textsuperscript{11,12}. The 6MWT can be performed in an environment with inadequate equipment, has a wide range of indications for older adults, and is easy to perform even in frail individuals. Its reliability and validity in patients with PAD have also been examined\textsuperscript{18}, and it is considered to be a useful index for evaluating the long-term prognosis of patients\textsuperscript{14,15}. Exercise tolerance in the 6MWT was evaluated by the 6-min walking distance (6MWD), the results of which are strongly influenced by the severity of claudication in patients with PAD. Conversely, since claudication symptoms improve after surgery, the effect of physical function on walking distance may become more apparent, especially in older adults. However, the differences in the factors that affect 6MWD before and after surgery have not yet been clarified. To provide more effective physical therapy, it is necessary to clarify these factors and provide interventions tailored to the characteristics of each patient. In this study, we hypothesized that the severity of claudication symptoms had a significant impact on walking distance in older adult patients with PAD before surgery, and that when pain during ischemia improved after revascularization, the influencing factors would shift toward functional aspects. The purpose of this study was to clarify the relationship between each factor and 6MWD in order to individualize postoperative physical therapy interventions.

Methods

I. Study Participants

Among 62 patients with PAD admitted to the International University of Health and Welfare Hospital from June 2019 to September 2020 for endovascular treatment and bypass surgery of peripheral blood vessels, 51 patients aged 65 years or older were included in the study. Considering the indications for physical therapy and the influence of walking disabilities other than IC, we excluded (1) those with rest pain, (2) those with unstable angina, (3) those with walking limitations for reasons other than IC, and (4) those who developed postoperative complications (e.g., aspiration pneumonia or acute arterial occlusion), for a total of eight excluded patients. In addition, a patient with missing data (n = 1) was excluded from the analysis, resulting in 42 subjects in the final analysis (Fig. 1). The mean (± standard deviation) age of the participants was 75.24 ± 5.6 years, and the mean preoperative ankle brachial index (ABI) values were 0.89 ± 0.2 and 0.81 ± 0.3 for the right and left lower extremities, respectively.

This study was approved by the International University of Health and Welfare Hospital Ethics Review Board (approval number 20-Io-8). All patients provided written informed consent before their inclusion in the study.

II. Measurement Method

The primary endpoint was 6MWD, which was used as an index of exercise tolerance. Secondary endpoints included intermittent claudication distance (ICD), which represents the severity of claudication symptoms and is related to the decrease in physical activity; weight-bearing index (WBI), which is an index of lower limb muscle strength; skeletal muscle index (SMI), which is an index of total body muscle mass; gait, which is reported to be affected by IC; and ABI, which is used as an index of lower limb blood flow. Physical functions other than SMI were measured preoperatively and after the fifth postoperative day.

The measurement method of the 6MWD was based on the guidelines of the American Thoracic Society\textsuperscript{16}. The 6MWT was performed once at the maximum speed of the patient, walking a 40-m straight, flat course in the rehabilitation room. All patients were instructed to walk as fast and as long as possible within 6 min. The 6MWT was stopped...
if the patient experienced dyspnea, chest pain, or onset of pallor. It was explained to the patients in advance that a break could be taken if they experienced strong dyspnea or pain in the lower limbs and that the time would not be stopped. Measurements were taken preoperatively and after the fifth postoperative day.

ICD measurements were performed simultaneously with the 6MWT. During the 6MWT, patients were told to self-report when numbness or pain in the lower limbs occurred, and the distance of the appearance of subjective pain was recorded as ICD. Patients who did not experience pain within 6 min of walking were instructed to continue walking. The distance at which pain occurred was evaluated by measuring up to 500 m. If no lower limb pain occurred at 500 m, the pain was considered to have disappeared, and the presence or absence of residual pain was evaluated before and after surgery.

For WBI, based on a study by Hirasawa et al., the isometric maximum muscle strength of the quadriceps femoris muscle was measured using a hand-held dynamometer (Sakai Medical, Tokyo, Japan). The measurement was performed with the subject in an upright seated position with the knee joint flexed to 90°. The patient was instructed to maintain the trunk in a vertical position during the measurement, and both upper limbs were folded in front of the trunk. The sensor pad was fixed to the distal lower leg using a belt, and the patient performed isometric knee extension movements with maximal effort for approximately 3-5 s twice on each side; the maximal values were recorded. The mean value of each maximal value divided by body weight was used as the WBI.

To clarify customary gait, it was measured at a comfortable speed on 10-m and 3-m walking paths at both ends. The measurements were performed twice, and the walking speed and stride length were evaluated for each measurement. Stride length was calculated by dividing the stride length, which was calculated from the number of steps required to walk a distance of 10 m, by height, and it was used to calculate the stride-to-height ratio.

ABI was measured using a non-invasive vascular screening device (BP-203RPE III, Omron, Kyoto, Japan). The measurement procedure and prohibited maneuvers are described in the instruction manual for the device. The patients rested for approximately 5 min, and the measurement was started when the device detected a normal heartbeat signal. The lowest value of the measured ABI was used as the representative value.

SMI was measured using a multi-frequency body composition analyzer (MC-780A, Tanita Corporation, Tokyo, Japan). After confirming that the subjects had been in the resting position for at least 5 min, they were instructed to assume the measurement posture according to the instruction manual and not to move or speak during the measurement. Since it has been reported that postoperative inflammatory edema affects muscle mass, SMI was only measured preoperatively.

III. Postoperative physical therapy
The patients’ postoperative physical therapy started with treadmill gait training (12% gradient, 2.4 km/h) in accordance with the TASC II medical guidelines after the inhospital gait and wound pain evaluations were conducted on the first postoperative day. For cases in which it is difficult to use a treadmill due to, for example, strong walking instability, we prescribed flat-ground walking at the maximum walking speed. Physical therapy was performed for 40 min/day from Monday to Saturday. All patients were discharged from the hospital 6-15 days postoperatively.

IV. Sample Size
Approximately 50 patients with PAD are admitted to the International University of Health and Welfare Hospital for surgery every year. The sample size was calculated using GPower3. For the calculation of the sample size, α of 0.05, power of 80%, and a large effect size of 0.35 were set, which were selected based on a previous study that examined the factors associated with 6MWD with gait, ABI, and clinical information as explanatory variables. As a result, the total sample size in this study was 43 patients.

For statistical processing, SPSS Statistics Ver.24 (IBM Corp., Armonk, NY, US) was used to compare the disease background of the patients and the changes in their physical functions before and after surgery using corresponding t-tests. To clarify the relationship between the factors and the amount of change before and after surgery, a partial correlation analysis was conducted using age and sex as covariates. Based on the results, ICD, ABI, WBI, SMI, and stride-to-height ratio were selected as explanatory variables for factors related to 6MWD before surgery, and ICD improvement, ABI, WBI, SMI, stride-to-height ratio were selected as explanatory variables after surgery. Stepwise multiple regression analysis was performed with the 6MWD before and after surgery as the dependent variable. The significance level of all the variables was set at 5%. To clarify the severity of the disease and complications, the site of stenosis and complications were obtained from medical records.

Results
From the physical function and disease background of PAD patients (Table 1), the mean preoperative 6MWD was 321.6 ± 107.8 m, and the ICD was 173.0 ± 116.0 m. Of these patients, 33% were able to continue the preoperative 6MWT without interruption, and the main reason for interruption was pain in the lower extremities in all patients. The mean postoperative 6MWD was 364.5 ± 94.6 m, which was significantly improved compared with the preoperative period. ICD improved in 22 subjects and the prevalence of
complications was as follows: diabetes mellitus (n = 28), hypertension (n = 27), hyperlipidemia (n = 16), and chronic kidney disease (n = 6), all of whom had undergone percutaneous vasodilation. A comparison of physical functions before and after surgery showed significant improvement in ABI and stride-to-height ratio, and no significant changes in WBI and walking speed (Table 2). Partial correlation analysis revealed a significant correlation between 6MWD and the stride-to-height ratio (r = 0.43, p < 0.05), WBI (r = 0.43, p < 0.05), and stride-to-height ratio (r = 0.52, p < 0.01). There was also a significant correlation between the change in 6MWD and the change in stride length (r = 0.33, p < 0.05) (Table 3). Based on these results, we decided to substitute only the stride-to-height ratio and walking speed, which showed a significant difference by t-test, as explanatory variables in the multiple regression analysis. A multiple regression analysis was performed with 6MWD as the dependent variable before and after the surgery, and the stride-to-height ratio and ICD were extracted before surgery (X1: stride-to-height ratio $\beta = 0.31$, X2: ICD $\beta =$

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### Table 1. Baseline characteristics

| Characteristic                  | Total cohort |
|--------------------------------|--------------|
| Sample size, n                 | 42           |
| Gender (Male/Female)           | 33/9         |
| Age, mean±SD (year)            | 75.2±5.6     |
| BMI, mean±SD (kg/cm²)          | 23.1±3.0     |
| SMI, mean±SD (kg/m²)           | 7.4±1.5      |
| medical history (case)         |              |
| Diabetes mellitus              | 28           |
| Hypertension                   | 27           |
| Hyperlipidemia                 | 16           |
| Chronic kidney disease         | 6            |
| Stenotic vessel area (case)    |              |
| Common Iliac Artery            | 3            |
| External Iliac Artery          | 13           |
| Superficial Femoral Artery     | 20           |
| Below the popliteal artery     | 6            |
| Drug therapies (case)          |              |
| BB                             | 8            |
| Ca channel blocker             | 16           |
| Statin                         | 12           |
| Antiplatelet agents            | 39           |
| Heparin                        | 36           |
| Warfarin                       | 9            |
| NOAC                           | 3            |
| Alprostadil                    | 34           |

BMI, Body mass index; SMI, Skeletal muscle index; BB Beta-blocker; NOAC, Novel oral anticoagulant

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### Table 2. Pre- and post-operative comparisons

| Characteristic                  | Preoperative | Postoperative |
|--------------------------------|--------------|---------------|
| ABI, mean±SD*                   | 0.7±0.2      | 0.9±0.2       |
| WBI, mean±SD (kgf/kg)           | 0.4±0.1      | 0.4±0.1       |
| stride-to-height ratio, mean±SD (%)* | 0.3±0.1 | 0.4±0.1       |
| Gait velocity, mean±SD (m/sec)  | 1.1±0.2      | 1.1±0.3       |
| 6MWD, mean±SD (m)*              | 321.6±107.8  | 364.5±94.5    |
| Preoperative ICD, mean±SD (m)   | 173.0±116.0  |               |
| Postoperative Leg symptoms      | Not remained: 22 remained: 20 |

ABI, Ankle-brachial index; WBI, Weight bearing Index; 6MWD, 6 min walk distance; ICD, Initial claudication distance

*: paired t-test <0.05
Table 3. Correlation between 6MWD and each factor, between the amount of change in 6MWD and the amount of change in each factor

|                      | WBI | Gait velocity | stride-to-height ratio | SMI | ABI |
|----------------------|-----|---------------|------------------------|-----|-----|
| I. Preoperative 6MWD | 0.24| 0.34          | 0.43*                  | -0.01| 0.11|
| II. Postoperative 6MWD| 0.43*| 0.33          | 0.52*                  | -0.14| 0.20|
| III. Amount of change of 6MWD | 0.11| -0.08         | 0.33*                  | -    | -0.19|

WBI, Weight bearing Index; SMI, Skeletal muscle mass Index; ABI, Ankle-brachial index
6MWD, 6 min walk distance
*p<0.05 (two-tailed).

Comment
I. Preoperative 6MWD×Preoperative factors
II. Postoperative 6MWD×Postoperative factors
III. Amount of change of 6MWD×Amount of change in each factor (preoperative-postoperative)

Table 4. Multiple regression analysis

| factor                      | β   | P-value | r    | VIF |
|-----------------------------|-----|---------|------|-----|
| Preoperative 6MWD           |     |         |      |     |
| WBI                         | 0.12| 0.407   | 0.13 | 1.26|
| stride-to-height ratio      | 0.31| 0.023   | 0.36 | 1.14|
| ABI                         | -0.08| 0.540 | -0.10| 1.07|
| ICD                         | 0.50| 0.000   | 0.53 | 1.14|
| Adjusted R²                 | 0.42|         |      |     |

| factor                      | β   | P-value | r    | VIF |
|-----------------------------|-----|---------|------|-----|
| Postoperative 6MWD          |     |         |      |     |
| WBI                         | 0.31| 0.010   | 0.41 | 1.30|
| stride-to-height ratio      | 0.41| 0.001   | 0.50 | 1.26|
| ABI                         | 0.23| 0.046   | 0.32 | 1.19|
| IC                          | -0.28| 0.015 | -0.39| 1.17|
| Adjusted R²                 | 0.58|         |      |     |

WBI, Weight bearing Index; ABI, Ankle-brachial index; ICD, Initial claudication distance
VIF: Variance inflation factor
IC (Intermittent claudication): ‘1’ if there is postoperative IC, ‘0’ if there is no IC

0.50). In the postoperative period, the stride-to-height ratio, ABI, WBI, and ICD improvement were extracted, and the multiple correlation coefficient (R = 0.62), adjusted coefficient of determination (R² = 0.58), and calculation model were significant (p < 0.01). Y = 733.5X1 - 108.0X2 + 247.8X3 - 52.4X4 - 71.1 (X1: stride-to-height ratio β = 0.41, X2: ABI β = 0.23, X3: WBI β = 0.31, X4: presence of ICD improvement β = -0.28) (Table 4). The variance inflation factor ranged from 1.07 to 1.26 preoperatively and 1.17 to 1.30 postoperatively, which was less than 10, and no multicollinearity was observed.

Discussion

Regarding the changes in physical function before and after surgery, there was no improvement in lower limb muscle strength, but significant improvement in stride length. As for the unchanged lower limb muscle strength, the results support the previous study by Kamiizumi et al. When the gait of PAD patients was compared with that of older adults living in the community, it was found that the PAD group experienced a decrease in walking speed and stride length regardless of lower extremity pain. It can be inferred that the change in gait in patients with PAD is the result of the establishment of a pain-avoidant walking strategy as a customary gait. Therefore, it is unlikely that the improvement of lower limb pain by revascularization affects gait independently and in the short term. In the present study, 22 patients underwent physical therapy for improvement in lower limb pain after surgery. Because the physical therapy included gait training at a speed of 2.4 km/h on a treadmill and at the maximum walking speed, the conventional gait was enforced, which may have resulted in an improvement in stride length. The significant correlation between the change in stride length and the change in 6MWD suggests that the effect of stride length on walking distance is strong. However, it is necessary to investigate the independent effect of stride length on the change in walking...
distance by conducting a comparative study of patients who underwent revascularization alone versus those who underwent physical therapy.

The results of multiple regression analysis showed that the 6MWD was related to ICD and stride length in the preoperative period, and stride length, WBI, ABI, and the presence of pain improvement in the postoperative period. These results suggest that factors related to 6MWD in the perioperative period include pathological aspects, such as pain during lower limb ischemia, and functional aspects, such as stride length and lower limb muscle strength. The influence of the functional aspect became stronger with the improvement of pain in the determinants of postoperative 6MWD. In terms of factors related to continuous walking distance in patients with PAD, previous studies have reported that lower limb pain and muscle strength are related. Many previous studies on changes in walking distance in the perioperative period have reported improvements in maximum walking distance with reduction of IC. Conversely, it has been reported that muscle weakness and exercise tolerance, which were unnoticed due to activity limitations caused by IC, are limiting factors for continuous walking after surgery. Thus, the improvement of walking distance in patients with PAD is affected not only by lower extremity pain but also by physical function, which may remain after surgery. In the present study, the relationship between 6MWD and WBI became stronger in the postoperative period, and in the multiple regression analysis, WBI was extracted as a related factor only in the postoperative period. This suggests that the postoperative 6MWD in patients with PAD is affected by lower limb muscle strength and that postoperative lower limb muscle strength training may contribute to the improvement of walking performance. When evaluating the exercise tolerance of patients with PAD, it is necessary to consider the pre- and postoperative lower limb ischemic pain severity when conducting the 6MWT. Furthermore, our results highlight the importance of considering the functional changes specific to PAD, such as muscle weakness and gait changes, in the interpretation of these results.

Conclusion

This study revealed that IC and stride length were related to the preoperative walking distance of patients with PAD and that the influence of gait and lower limb muscle strength became stronger after surgery. In contrast, the limitations of this study include the fact that unilateral and bilateral lesions were not separated in the selection of patients and that the interrelationship among 6MWD, lower limb muscle strength, and gait was only discussed in the literature. In the future, it will be necessary to conduct intervention studies on the mechanisms of temporal changes in gait and their interrelationships.

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