



Original Article

## Characteristics of physical activity in patients with critical limb ischemia

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**Abstract.** [Purpose] The purpose of this study was to evaluate the amount of physical activity of the patients with critical limb ischemia consecutively in order to clarify the characteristics of physical activity of critical limb ischemia. [Subjects and Methods] Twelve patients who were eligible for the 2 months of consecutive evaluation of the amount of physical activity were enrolled in the study (men: 11; woman: 1; mean age: 64.4 [range: 44–80]). A pedometer with an accelerometer was used for the measurement of the number of steps walked as an index of the amount of physical activity. Participants were asked to lead a regular life and no instruction was given as to the number of steps. [Results] The average number of daily steps walked was 2,323 steps (range: 404–6,505). There was no clear tendency in the number of amputation site-specific steps walked. There was also no correlation between the number of steps walked and age as well as the maximum strength of the knee-extension muscle, skin perfusion pressure of the sole and the dorsum, and QOL scores. [Conclusion] The number of steps walked of the patients with critical limb ischemia was remarkably low and no significant association with health-related QOL.

**Key words:** Physical activity, Critical limb ischemia, Quality of life

(This article was submitted Jul. 25, 2016, and was accepted Sep. 7, 2016)

### INTRODUCTION

With the increase of lifestyle-related diseases and the aging of society, the number of patients with peripheral arterial disease (PAD) is also increasing<sup>1)</sup>. PAD is a systemic arteriosclerotic disease that can lead to critical limb ischemia (CLI) associated with rest pain and wound when aggravated. It is reported by TASCII (Trance-Atlantic Inter-Society Consensus II) that 30% of the patients with CLI have to amputate limbs and 25% of them die within one year from the onset<sup>2)</sup>, indicating that CLI has an extremely poor prognosis.

Arteriosclerosis is associated with the progression of PAD. Increasing the amount of physical activity is reported to play an important role for the prevention of progression and improvement of arteriosclerosis<sup>3)</sup>. Once affected with CLI, patients will have to suffer from pain, wound, or amputation and consequently their walking ability might decrease, leading to a remarkable decrease of physical activity. However, no study has ever shown the properties of physical activity of CLI to date, and therefore the effect of the amount of physical activity on the patients' quality of life (QOL) remains unclear.

The purpose of this study was to evaluate the amount of physical activity of the patients with CLI consecutively in order to clarify the properties of physical activity of CLI and to examine the relationship between the amount of physical activity and ADL (activity of daily living) or QOL of the patients with CLI.

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## SUBJECTS AND METHODS

Among the patients who were admitted to our Kasukabe Chuo General Hospital for the treatment of wounds caused by CLI during April to December in 2015 and became able to make an ambulatory visit to our Foot Care Outpatient Department, a total of 21 patients agreed to participate in the study and signed the informed consent. Of them, 12 patients who were eligible for the 2 months of consecutive evaluation of the amount of physical activity were enrolled in the study (men: 11; woman: 1; mean age: 64.4 [range: 44–80]) (Table 1).

All the patients were asked to walk wearing prosthetics. Exclusion criteria were defined as patients who (1) were unable to walk outdoors and required nursing care in daily life, (2) were unable to respond to the questionnaire, (3) had difficulty to wear prosthetics on their own, or (4) got wounded during the study.

A pedometer with an accelerometer (Mediwalk<sup>®</sup>, TERUMO, Japan) was used for the measurement of the amount of physical activity, and the number of steps walked was used as the index of the amount of physical activity. Patients were asked to wear the pedometer all day except during bathing and sleeping. The number of steps walked during the 2 months was recorded and was confirmed on an outpatient basis once every two months. Dedicated software (NFC reader/writer) was used to download the data of the steps from the pedometer and to confirm it. Participants were asked to lead a regular life and no instruction was given as to the number of steps.

SF-8<sup>™</sup>, a profile-based comprehensive scale, was used for the analysis of QOL. For the numerical calculation, the SF-8<sup>™</sup> scoring program (excel version) was used, with 50 pts defined as the national standard value (based on the 2007 national standard value), to calculate the point based on the national standard value.

As for the other research items, factors such as age, gender, body mass index (BMI), possession status of risk factors of comorbidity and arteriosclerosis, disease history, and treatment course were included. In addition, skin perfusion pressure (SPP) as the blood flow of the lower limb artery was evaluated by using a Laser Doppler (SensiLase PAD3000, Kaneka Medix, Osaka, Japan) at the time of the first outpatient visit. Regarding the lower limb muscle strength, the maximum voluntary isokinetic knee extension muscle strength was measured using Hand-Held Dynamometer ( $\mu$ -tasF-1, ANIMA, Japan). For knee extensor strength measurements, subjects were asked to sit on a chair with knee flexion at 90 degrees and to push against the dynamometer pad as much as possible for 5 seconds. Isokinetic knee extensor strength was measured 2 times on each side, and the highest value for the right and left legs was used as the knee extensor muscle strength. The weight bearing index (WBI) was obtained by the knee extensor muscle strength divided by the body weight.

SF-8<sup>™</sup> and the knee extensor muscle strength were assessed every month from the time of the first outpatient visit.

All the research items were examined retrospectively using medical records and classified into the following groups such as the without toe-amputation group, the toe amputation (including multiple toes amputation) group, the metatarsal bone amputation group, and the lower leg amputation group in order to compare the number of steps walked with QOL in each group in addition to the overall target characteristics. All the data were described by median values (75–25 percentile). SPSS ver. 21.0 (IBM, Tokyo, Japan) was used for the statistical analysis, and an unpaired t-test and a correlation analysis was performed. With the use of a two-sided test, a p value of 0.05 was defined as statistically significant.

This study was approved by the Ethical Committee of Kasukabe Chuo General Hospital. All the patients gave their informed consent after being orally informed regarding the purpose, methods, interests, and risks of this study.

## RESULTS

Of the 12 target patients, 2 were classified into the without toe-amputation (with ulcer) group, 2 into the toe amputation group, 5 into the metatarsal bone amputation group, 3 into the lower leg amputation group, and 7 had wound in both legs. The patients with toe amputation wore a shoe-type orthosis, and those with metatarsal bone amputation wore a foot prosthesis and a shoe-type orthosis, and those with lower leg amputation wore a TSB (total surface bearing) type orthosis. The research results of risk factors of comorbidity and arteriosclerosis revealed that 10 patients (83.3%) had diabetes, another 10 patients (83.3%) had hypertension, 11 patients (91.7%) had cardiovascular disease, 6 patients (50.0%) had dyslipidemia, 7 patients (58.3%) had maintenance hemodialysis, and 9 patients (75.0%) had a smoking habit. Average maximum SPP, average maximum strength of the knee-extension, average weight bearing index and SF-8 score were shown in Table 1.

The average number of daily steps walked of all the patients during the measurement period was 2,323 steps (range: 404–6,505). Compared between patients with bilateral lesions (n=7) and those with unilateral lesions (n=5), the average number of steps walked of the patients with bilateral lesions was  $2,979 \pm 238$  steps and that of the those with unilateral lesions was  $1,403 \pm 1,198$  steps, showing no significant difference. There was no clear tendency in the number of amputation site-specific steps walked. There was also no obvious correlation between the number of steps walked and age as well as the maximum strength of the knee-extension muscle, the maximum SPP of the sole and the dorsum, and QOL scores (Table 2).

The followings were the specific QOL assessments; PF (physical function): 41.5 (41.5–16.7), RP (role physical): 54.1 (52.4–27.9), BP (bodily pain): 46 (60.4–38.2), GH (general health): 50.3 (50.3–35.9), VT (vitality): 53.7 (53.7–46.8), SF (social functioning): 45.6 (52.8–30.9), RE (role emotional): 54.2(54.2–35.6), and MH (mental health): 44.9 (53.9–38.5). In addition, PCS (physical component summary) and MCS (mental component summary) were 43.2 (45.4–26.8) and 48.6

**Table 1.** Patient clinical characteristics

Age [years; mean (range)]	64.4 (44–80)
Male [n (%)]	11 (91.7%)
Amputation region [n (%)]	
No amputation (with ulcer)	2 (16.7%)
Toe amputation	2 (16.7%)
Metatarsal bone amputation	5 (41.7%)
Lower leg amputation	3 (25.0%)
Bilateral lesions/Unilateral lesions (n)	7/5
Comorbidity and arteriosclerosis risk factor [n (%)]	
Diabetes merits	10 (83.3%)
Hypertension	10 (83.3%)
Cardiac diseases	11 (91.7%)
Dyslipidemia	6 (50.0%)
Hemodialysis	7 (58.3%)
Current smoking	9 (75.0%)
Maximum skin perfusion pressure	
Dorsum (mmHg)	59.1 (29–89)
Sole (mmHg)	60.6 (30–99)
Maximum strength of the knee-extension (kgf)	30.3 (17.0–60.3)
Weight bearing index (%)	46.7 (23.0–66.0)
SF-8	
PCS (physical component summary)	35.0 (29.4–52.8)
MCS (mental component summary)	46.7 (23.0–66.0)

SF-8: Medical Outcomes Study 8-Item Short-Form Health Survey

**Table 2.** Univariate correlations between in-average steps and age, maximum skin perfusion pressure, maximum strength of the knee-extension, weight bearing index, and health-related QoL

Related factors	r
Age	0.403
Maximum skin perfusion pressure	
Dorsum	0.312
Sole	0.399
Maximum strength of the knee-extension	0.329
Weight bearing index	0.361
SF-8	
PCS (physical component summary)	0.370
MCS (mental component summary)	0.164

SF-8: Medical Outcomes Study 8-Item Short-Form Health Survey

(52.7–45.2), respectively. PF, BP, SF, and MH was lower than the national standard value (50 pts), and both PCS and MCS were also lower than the standard.

## DISCUSSION

CLI patients with rest pain and wound are likely to lose walking ability and ADL ability<sup>2</sup>). Walking ability is considered to be associated with the knee extension muscle strength<sup>4</sup>). In this study, we calculated the knee extension muscle strength using WBI. Kigawa et al. reported that WBI  $\geq 40\%$  is considered as an ambulatory level and that WBI  $\geq 60\%$  is considered necessary to lead a normal daily life<sup>5</sup>). The maximum WBI of the CLI patients in this study was 46.7% (23–66%) on average, while 3 out of 12 of them did not reach the ambulant level in the knee extension muscle strength and 11 out of 12 of them did not reach the necessary level in their daily life. McDermott et al.<sup>6</sup>) reported that even PAD patients without wound were likely to show a significantly low value of the lower limb extension muscle strength. In our study, too, CLI patients were found to have a remarkable decrease in the knee extension muscle strength.

This is the first study that used the number of steps walked to show whether or not the amount of physical activity of the patients with CLI was lower than the standard. The average number of steps walked of the patients with CLI was about 2,300 steps in this study. This was remarkably low compared with healthy individuals of the same age and patients with diabetic foot<sup>7, 8</sup>). The patients with CLI are forced to limit walking in order to reduce the burden on the wound, relieving of the lower limb is required. This was considered one of the factors reducing the number of steps walked. Furthermore, health-related QOL was evaluated by using SF-8 and it was revealed that PF (physical function), BP (bodily pain), SF (social functioning), and MH (mental health) were lower than the national standard value of 50 points.

There are some studies reporting the relationship between the lower-limb muscle strength and the amount of physical activity<sup>9, 10</sup>). In our study, however, no significant association was observed between the average number of steps walked and the lower-limb muscle strength among CLI patients. Moreover, it is generally considered that the amount of physical activity and health-related QOL are strongly correlated with each other<sup>11</sup>) and that the higher the sense of well-being, the more they are involved in physical activity<sup>12</sup>), but no correlation was observed between the number of steps walked and health-related QOL in our study. Patients with CLI need non-weight bearing exercise during the treatment of wound to reduce the burden to the wounded area, which consequently imposes restrictions on their walking. In addition to these restrictions during the treatment of the wounded area, the physical activity of the patients with CLI is affected by various factors such as age, amputation

sites, and complications, which may be the reason why no direct correlation was found. The fact that health-related QOL did not show any correlation with a single index was considered as reflecting the various obstacle images of patients with CLI.

As Ferrucci et al.<sup>13)</sup> reported that patients with high physical activity were likely to have lower mortality and lower risk of ADL, the amount of physical activity is important from the viewpoint of healthy life expectancy. During the 2 months of study period, some of the patients who experienced recurrence of wound that was probably caused by walking were lost to follow-up. As is reported, 30% of the patients with CLI will have to have amputation within one year<sup>9)</sup>, so the management of the risk of recurrence is also necessary. Therefore, providing guidance to simply increase the amount of physical activity is not enough. It remains unknown whether improvement of the amount of physical activity of patients with CLI is associated with life prognosis. Strict supervision to maintain the amount of physical activity is necessary while taking appropriate care of wound.

There are several limitations to our study. First it is a Japanese single center study with a limited number of patients. Further studies with larger numbers of subjects are obviously needed to confirm these findings. The majority of our sample was male, so it is possible that our study findings would have differed if more females were included in our sample. Confirmation of the findings of the current study in other populations will be needed. In our study we were unable to elucidate to what extent the amount of physical activity poses an influence on the patient's prognosis. Further study by longitudinal observations is required to fully understand the clinical significance of the amount of physical activity.

### *Conflict of interest*

All authors declare that there is no conflict of interest.

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