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Effects of individualized target setting on step count in Japanese patients with chronic obstructive pulmonary disease: a pilot study

Abstract

Introduction: Improving physical activity in patients with chronic obstructive pulmonary disease (COPD) is a very important issue; however, effective recommended targets for individual patients remain to be determined.

Material and methods: We developed a method for setting a target value for the step count for each patient using a measured value and the predicted step count. We then evaluated the effect of providing a pedometer or a pedometer with this target value for eight weeks on the step count in patients with COPD.

Results: Sixteen stable COPD patients were included in the analysis. Overall, no significant increase in the step count was obtained by providing the target value; however, when the patients were divided into two groups based on the median step count at baseline, a significant increase in the step count was observed in the low step-count group. In both the overall population and the low step-count group, there was a significant increase in the target achievement rate in patients who received a pedometer with a target value in comparison to patients who were given a pedometer without a target value.

Conclusions: Physical activity may be improved by providing a newly developed individual target step count to COPD patients with a low step count at baseline.

Key words: physical activity, step count, target value

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Introduction

In patients with chronic obstructive pulmonary disease (COPD), airflow limitation results in decreased physical activity (PA). Patients with reduced PA have a significantly poorer prognosis than those with adequate PA [1], and PA is the strongest predictor of all-cause mortality [2]. The importance of improving and maintaining PA has therefore been emphasized. The effect of medical intervention on improving PA remains controversial [3–5]; however, some reports have described the beneficial consequences of bronchodilators [6–10], pulmonary rehabilitation [11–13], rehabilitation with counseling [14–16], and increased motivation [17, 18] on PA. Among several interventions for improving PA, counseling has tended to result in better outcomes in comparison to other approaches [19]. Counseling requires several important elements, including target setting, feedback, target achievement, and increased motivation [5]. Moy *et al*. reported a series of studies to evaluate the effects of providing target step count values using an internet-mediated program [14, 20, 21]. The effectiveness of providing the target value was achieved after 3 or 4 months [14, 20], but was not observed after 12 months [21]. The possible reason why the number of steps did not increase at 12 months is that even if the patients worked hard to increase the number of steps, the target value was reviewed and increased weekly, and/or the target value was set according to the present step count but not to the disease condition of the patient, which could make it difficult for patients to maintain their motivation. Actually, half of the participants believed the automatically-determined step count target was too high and many did not feel comfortable reaching their

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objective [22]. For the step count to be increased and maintained, the target value should reflect the disease condition of each patient and should be one that allows patients to experience a feeling of achievement at reaching the goal. We recently created a formula to determine the predicted step count (Pred) using parameters associated with the step count in COPD patients. This formula consists of age, mMRC, and inspiratory capacity (IC) [23], and reflects the disease condition of each patient.

In the present study, we developed a method for setting the target step count (Targ) based on the measured step count (Meas) and Pred, and preliminarily evaluated the effect of providing this target value on the increase in the total step count.

Materials and methods

Patients

Stable COPD patients of ≥ 40 years of age were recruited from the outpatient clinic of National Hospital Organization Wakayama Hospital from August 2019 to April 2020. COPD was defined as a post-bronchodilator forced expiratory volume in one second (FEV_1) / forced vital capacity (FVC) value of < 0.7. The patients were excluded if they were being treated with oxygen therapy, had clinically evident bronchial asthma, had experienced an exacerbation in the past three months, or had factors that obviously influenced their PA, such as neuromuscular disease, severe osteoarthritis, an active malignant tumor, or acute myocardial infarction.

Study design

This was a pilot, prospective, open-label, before-after study. The patients were obliged to visit our hospital three times: week –2 (visit 1), week 8 (visit 2), and week 16 (visit 3). A pedometer was provided at visit 1, and the subjects recorded their daily step count by themselves until week 16. The step count in the first 2 weeks was defined as the Meas at baseline, and the record of this step count was mailed back to our hospital. The Targ was calculated based on the Meas at baseline and the Pred calculated by Nakanishi's formula [23] and was provided to the patient at visit 2 (week 8). At visit 1, the patients were instructed to spend their time as usual from week –2 to week 0, but to increase the number of steps as much as possible from week 0 to week 8. In other words, at week 8, we evaluated the increase in the step count that was achieved by providing a pedometer. At visit 2, the patients were informed about the Targ and encouraged to increase their step count to exceed the Targ from week 8 to week 16. In other words, at week 16, we evaluated the increase in the step count achieved by providing the Targ. The patients were instructed to record the step count, weather and special activities in a diary every day, and to bring the diary on every visit. The primary endpoint was the change over time in the ratio of Meas/Targ. The secondary endpoints were the changes over time in the ratio of Meas/Targ in patients with the low and high step-count groups, the target achievement rate at week 16 among all patients, including those in the low and high step-count groups, and the correlation between the Meas/Targ at week 16 and the demographic factors of the patients.

This study was conducted in accordance with the Declaration of Helsinki and was approved by the local ethics committee (committee: IRB committee of National Hospital Organization Wakayama Hospital; Approval number: 26–1; approval date: October 31, 2014; Clinical Trial Registration: UMIN; registration number: UMIN000016363; registration date: January 28, 2015 [http://www.umin.ac.jp]). Written informed consent was obtained from all participants.

Data processing

The step count was measured using a previously validated pedometer, which detected steps with a triaxial-typed accelerometer, HJ-325 (OMRON Healthcare, Kyoto, Japan) [24]. The subjects were instructed to wear the pedometer on their waist. Rainy days and days when special activities were performed, were defined as invalid days. The average step count for two weeks, with the exclusion of invalid days, was used. If the number of valid days was fewer than three, the patient's data were excluded from the analysis. The average step count from week 6 to 8 was defined as the step count of week 8, and the average value from week 14 to week 16 was defined as the step count of week 16.

Setting the Targ

To reflect the disease condition of each patient, we used Nakanishi's formula to determine the predicted step count, which was determined using factors associated with the step count in Japanese COPD patients [23]. The formula was as follows: Step count = $(-0.079 \times [\text{age}] -1.595 \times [\text{mMRC}] + 2.078 \times [\text{IC}] + 18.149)^3$. First, we selected the patients who should be recommended to increase their step counts. In the Nakanishi's study population, 50% of patients had a Meas

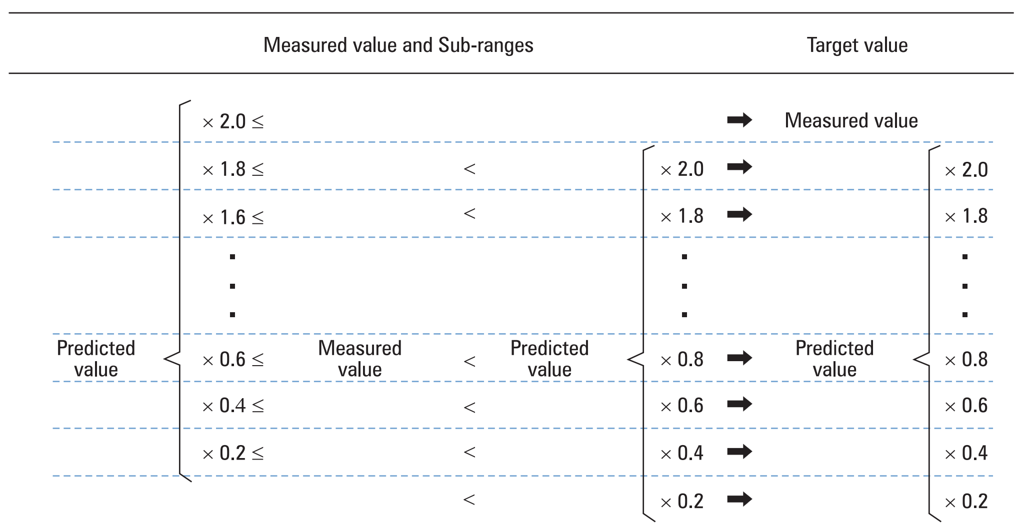

Figure 1. Target setting method based on the measured and predicted values

value that was less than the Pred value, while 75% had a Meas value that was less than Pred × 2.0. Furthermore, the Ministry of Health, Labor and Welfare of Japan recommends that individuals ≥ 65 years of age in the male general population maintain a step count of more than 7,000 [25]. Therefore, we selected patients whose Meas value was less than Pred × 2.0 and less than 7,000 as patients whose Targ value should be higher than the Meas value.

To make it easier for patients to achieve their targets, we divided the number of steps from 0 to the Pred × 2.0 into 10 ranges and set the Targ as the lowest value in the area above (Figure 1). For example, when the Meas at baseline was ≥ 0.6 but < 0.8 of the Pred, the Targ was set at 0.8 of the Pred. When the Meas at baseline was ≥ 2.0 of the Pred, the Targ was set to the same value as the Meas. When the Meas at baseline was < 7,000 and the calculated target value exceeded 7,000, the Targ was set at 7,000. When the Meas at baseline was ≥ 7,000, the Targ was set to the same value as the Meas.

Statistical analyses

The D'Agostino and Pears test was used for evaluation of normality of distribution. The Friedman test was applied to compare the Meas/Targ between each time point. A Spearman's correlation coefficient was used to assess the correlation between the Meas/Targ at week 16 and the demographic factors of the patients. A chi-squared test was used to compare the number of patients who achieved the target between weeks 8 and 16. The Mann-Whitney test was used to compare the patient demographic factors between the high and low step-count groups.

Results

Nineteen patients were registered. Three individuals were excluded due to hospitalization (n = 1), pneumonia (n = 1), or withdrawal of consent (n = 1). Ultimately, 16 cases (male, n = 13; female, n = 3; mean age, 72.6 ± 7.2 years; FEV_1% of predicted value, 56.3 ± 17.0) were included in the analysis (Figure 2). All patients had data for ≥ 3 valid days. The GOLD stages of the subjects were as follows: I, n = 2; II, n = 8; III, n = 5; IV, n = 1 (Table 1). No increase in the step count over time was observed in the overall population (p = 0.06) (Figure 3). However, when the patients whose Meas at baseline was lower than the median value (low step-count group) were compared with the patients whose Meas at baseline was higher than the median value (high step-count group), the provision of the Targ was associated with a significant increase in step count in the low step-count group (p = 0.008). In contrast, in the high step-count group, the step count was not significantly increased (Figure 4). In the low step-count group, it was confirmed that the number of steps increased by 630 steps on average after the target value was provided compared to the number observed before the target value was set. There was not significant correlation between the

Table 1. Patient characteristics

Age	72.6 ± 7.2
Gender (M/F)	13/3
Smoking history	
pack-years	68.1 ± 39.3
non/ex/curr	1/14/1
Stage I/II/III/IV, n	2/8/5/1
CAT	9.0 ± 5.4
mMRC scale (0/1/2/3/4)	7/4/3/2/0
Pulmonary function	
IC [L]	1.98 ± 0.52
FVC [L]	2.81 ± 0.69
FEV_1 [L]	1.48 ± 0.45
FEV_1%pred [%]	56.3 ± 17.0
FEV_1/FVC [%]	53.4 ± 11.2

CAT — chronic obstructive pulmonary disease assessment test; curr — current smoker; ex — ex-smoker; FEV_1 — forced expiratory volume in one second; FEV_1%pred — forced expiratory volume in one second % of predicted value; FVC — forced vital capacity; IC — inspiratory capacity; mMRC — modified Medical Research Council; non — non-smoker

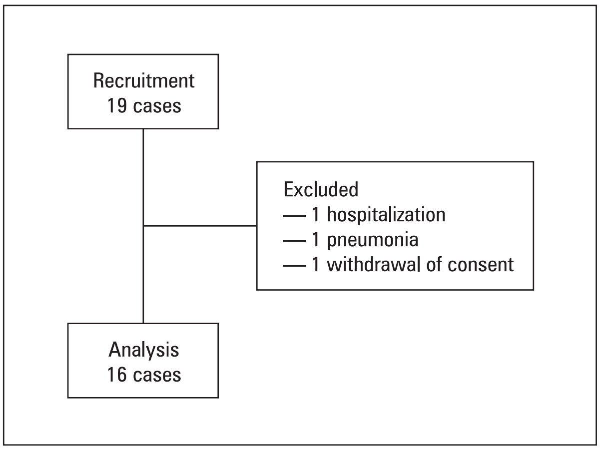

Figure 2. Flow diagram

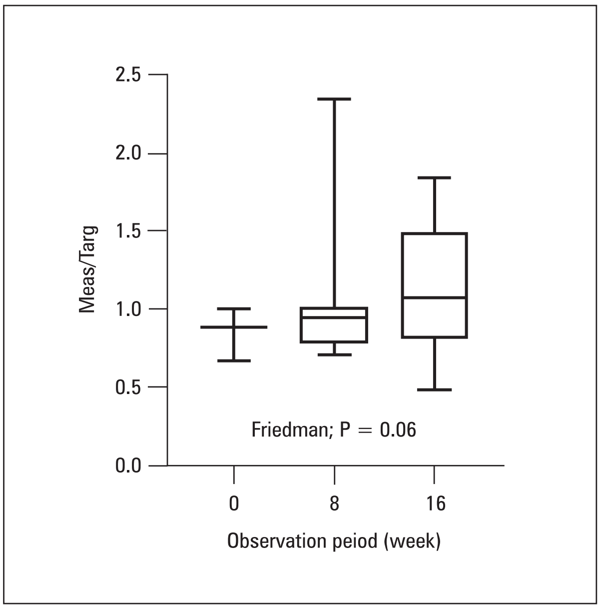

Figure 3. Changes over time in the Meas/Targ

Table 2. Correlation between the measured/target values at 16 weeks and the patient characteristics

	R	P value
Age	0.076	0.779
CAT	0.066	0.805
mMRC	–0.056	0.835
IC [L]	–0.018	0.949
FEV_1%pred	–0.004	0.989
Meas at baseline	–0.375	0.152
Meas/Pred at baseline	–0.318	0.228

IC — inspiratory capacity; FEV_1%pred — forced expiratory volume in one second % of predicted value; CAT — chronic obstructive pulmonary disease assessment test; mMRC — modified Medical Research Council; Meas — measured step count; Pred — predicted step count

Meas/Targ at week 16 and any demographic factor; however, the correlation coefficient between the Meas/Targ and the Meas at baseline was relatively higher in comparison to other factors ($r = –0.375$) (Table 2). In the overall population and in the low step-count group, the target achievement rate at week 16 was significantly higher than that at week 8 ($p = 0.034$ and $p = 0.039$, respectively), however, this association was not observed in the high step-count group (Table 3). In addition, the Meas/Pred ratio at baseline in the high step-count group was significantly larger than that in the low step-count group (Table 4).

Discussion

Providing the Targ did not increase the step count in the overall population but did significantly elevate the target achievement rate. Furthermore, it significantly increased the step count and the target achievement rate in the low step-count group but not in the high step-count group.

When the patients were classified into two groups based on the median Meas at baseline, the step count was significantly raised by providing the Targ in the low step-count group. In this study, the effect of supplying a pedometer was evaluated at week 8, and the consequence of providing the Targ was assessed at week 16. The increase in the step count at week 16 in comparison to that at week 8 therefore represented the effect of providing the Targ. By supplying the Targ, in low step-count group, the step count increased by 630 on average, which exceeded the minimal important difference of the amount of improvement in the step count by rehabilitation (600 steps) [26], and was considered a clinically significant increase.

Regarding the method of setting the target, Moy *et al.* set the target step count as the lowest of the following: 1) previous goal + 400 or 600 steps, 2) average of the most recent 7 days + 400 or 600 steps, or 3) 10,000 steps. The step count after 3 or 4 months was significantly increased in comparison to that in the control group [14, 20] but that after 12 months was not [21]. This might be why these target values did not reflect the disease condition of each patient, increased weekly, and did little to provide the patient with a feeling of achievement in reaching their goal or to prolong their motivation. In this study we newly developed a target setting method that reflected the disease condition of each patient, which could easily provide the patient with a sense of achievement in reaching their target, and which was fixed for a certain period. Furthermore, the patients who should increase their step count were extracted.

The Meas/Targ at week 16 was not correlated with any patient demographic factors, but the correlation coefficient between the Meas/Targ at week 16 and the Meas at baseline was higher than other factors. Based on this result, we divided the patients into the high step-count and low step-count groups. When we evaluated the effect of providing the Targ to each group, the provision of the Targ significantly increased the step count in the low step-count group but not in the high step-count group. One possible reason for this difference might be that the patients in the high step-count

Table 3. Comparison of the achievement rate between with and without provision of the target values

	8w	16w	P value
Overall			
Number of patients (Y/N)	5/11	11/5	0.034
Achievement rate [%]	31.3	68.8	—
Low step-count			
Number of patients (Y/N)	3/5	7/1	0.039
Achievement rate [%]	37.5	87.5	—
High step-count			
Number of patients (Y/N)	2/6	4/4	0.302
Achievement rate [%]	25.0	50.0	—

Y — achieved the target; N — did not achieve the target

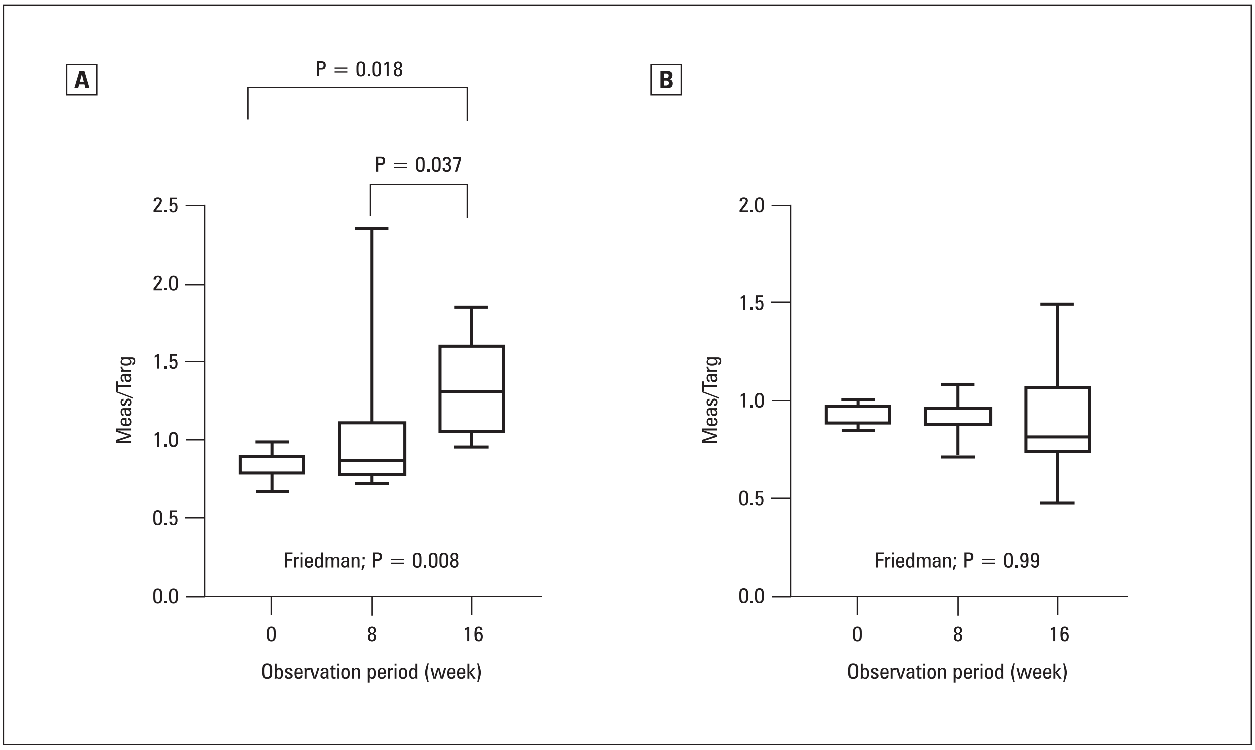

Figure 4. A subset analysis of the change over time in the Meas/Targ; **A**. The low step-count group; **B.** The high step-count group

Table 4. Patient characteristics of the low and high step-count groups

	Low step-count	High step-count	P value
Number of patients	8	8	—
Age	72.3 ± 6.2	73.0 ± 8.5	0.49
CAT	9.4 ± 6.4	8.6 ± 4.9	0.74
mMRC	0.9 ± 1.4	1.1 ± 0.8	0.40
IC	1.9 ± 0.5	2.1 ± 0.6	0.55
FEV_1% pred	58.2 ± 19.9	54.4 ± 14.6	0.88
Meas at baseline	1719.1 ± 799.2	4870.1 ± 1279.0	< 0.001
Meas/Pred at baseline	0.6 ± 0.4	1.6 ± 0.8	0.003

IC — inspiratory capacity; FEV1%pred — forced expiratory volume in one second % of predicted value; CAT — chronic obstructive pulmonary disease assessment test; mMRC — modified Medical Research Council; Meas — measured step count; Pred — predicted step count

group had already walked quite a lot at baseline, which made it difficult to further increase the step count. Indeed, in the high step-count group, the Meas/Pred at baseline was significantly higher than that in the low step-count group (Table 4). Another possibility is that the step count of the patients in the high step-count group was strongly influenced by several other factors, resulting in a greater variation in step count in comparison to the low step-count group. This might have made any further increase in the step count difficult, due to the already marked variation in the step count. Travis *et al*. compared the step count in COPD patients according to the stage of COPD and showed that the standard deviation of the step count was large and widely varied in patients with a high step count [27], which supports our hypothesis.

In the overall population, the target achievement rate increased significantly after the Targ was provided. This suggests that — to some extent — our method of setting a target was feasible and appropriate. However, as the target achievement rate was not significantly increased in the high step-count group, it might be necessary to improve the method for setting targets for these patients. As the number of steps walked by the patients in the high step-count group was already close to the Pred value, adjustment of the range of the Meas/Pred at baseline or the inclusion of the Meas/Pred value at baseline may be required to determine the target for these patients.

No significant increase in the step count was observed by providing a pedometer alone at week 8 in either group. Previous studies showed that the step count increased after three months with a pedometer alone [17] and with three-month intervention using a pedometer along with web-based intervention [20], which was inconsistent with the current results. In comparison to these reports in which the patients received counseling, in our study, we only verbally recommended that the patients increase their step count at each visit. This difference in approach might have caused differences in the effect of the provision of a pedometer on the step count.

Of note, the step count does not account for intensity, which may be important for the evaluation of PA. However, when the step count was employed in type 2 diabetic patients, the subjects showed increased satisfaction, and their PA become similar to that when a certain degree of intensity (continuously walking at a speed of ≥ 60 steps per minute for ≥ 10 minutes) was employed [28]. The American College of Sports Medicine and American Heart Association recommended improving PA using intensity as an indicator for healthy adults [29], but the step count alone, without intensity, has also been employed in several reports [14, 20, 21, 30, 31]. We therefore considered this study, which only used the step count, to have merit.

The present study was associated with some limitations. First, the number of patients was limited. Thus, the subset analysis of the study also has restricted reliability. A larger patient group will be required to clarify the effect of providing a target value on the increase in the step count among COPD patients. Second, though this was a pilot study without establishing a required number of recruited patients, an interventional study with reliable number of subjects should be conducted in the future. Third, as the observation period was quite short, whether or not this effect can be maintained over the long term is unclear. Another study with a long-term follow-up period will be required in the future. Fourth, it is not possible to confirm whether the patients correctly described the step count in their diaries. In a future study, the use of pedometer with a data memory function might be beneficial. Fifth, Nakanishi's formula has not been confirmed for different cohorts; thus, a further study should be performed to validate this formula. Finally, the parameters in the above-mentioned step count formula were limited to the age, mMRC, and IC. Future studies should evaluate other factors that might be relevant to the step count.

Conclusions

Setting and providing an individualized target step count that accounted for the disease condition and the current number of steps did not increase the step count in the overall population; however, it significantly elevated the step count in patients with a low step count. It significantly increased the target achievement rate in the overall population. Providing this target step count might be beneficial for improving PA in COPD patients with a low step count.

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Conflicts of interest

All authors declare no conflicts of interest in association with the present study.

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