

Original article

Effect of a comprehensive heart failure treatment program on left ventricular ejection fraction and six-minute walk distance in heart failure patients with reduced ejection fraction at Lampang Hospital

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Objectives Patients with chronic heart failure have excessively high mortality and readmission rates and a poor quality of life. This single group, pre-post intervention study aimed to evaluate the effects of a comprehensive heart failure treatment program on left ventricular ejection fraction (LVEF) and the six-minute walk distance in patients diagnosed with heart failure with reduced ejection fraction (HFrEF).

Methods Patients with HFrEF participated in a comprehensive, on-going heart failure treatment program at Lampang Hospital. The program focuses on guideline-directed medical therapy (GDMT) for heart failure, cardiac rehabilitation, and health education for patients and caregivers regarding self-care and self-adjustment of diuretics. The program was managed by a multidisciplinary team comprised of cardiologists, heart failure nurses, pharmacists and physical therapists. LVEF was evaluated at baseline and at 6- and 9-month follow-ups. Six-minute walk distance was assessed at baseline and at 12±3 month follow-ups.

Results Sixty-one HFrEF patients were included. After participation in the program, there was significant improvement in LVEF (mean LVEF 27% before participation vs. 47% at 6- and 9 month follow-ups, $p<0.001$) and six-minute walk distance (mean 313 m before participation vs. 357 m at 12±3 month follow-ups, $p<0.001$). Patients also reported improved quality of life and New York Heart Association functional class.

Conclusions In patients with HFrEF, participation in a comprehensive heart failure treatment program may lead to improvement in LVEF and six-minute walk distance. **Chiang Mai Medical Journal 2020;59(1):1-9.**

Keywords: heart failure, comprehensive heart failure treatment, heart failure clinic, left ventricular ejection fraction, six-minute walk distance, multidisciplinary team

Introduction

In the terminal stage of all varieties of structural heart disease, heart failure is a chronic and progressive condition typically exemplified by intermittent episodes of acute decompensation, leading to high readmission rates and poor quality of life resulting from limited functional capacity. The mortality rate of heart failure is as high as that of coronary artery disease. Data from Thai Acute Decompensated Heart Failure Registry (Thai

ADHERE) reported that in-hospital mortality of patients admitted for heart failure was 5.5% (1). Moreover, the direct and indirect cost of care for patients with heart failure is considerable as there is no cure for this chronic condition.

A multidisciplinary team approach to heart failure care has been shown to decrease mortality and admission rates and to increase patients' quality of life (2-6). In Thailand, the Ministry of

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Public Health has developed a policy of providing comprehensive care for heart failure patients by a multidisciplinary team. Accordingly, specialized heart failure clinics have been established in general and regional hospitals in order to provide health education, proper assessment and investigation, optimal medication and rehabilitation, and appropriate referral when necessary. Initial reports have shown that heart failure clinics can decrease readmission rates and increase patients' quality of life (7-10). However, there are only a limited number of reports about the effects of heart failure clinics on cardiac function and functional capacity of heart failure patients.

Objectives

This study aimed to evaluate the effects of a comprehensive heart failure treatment program on left ventricular ejection fraction (LVEF) and six-minute walk distance in patients diagnosed with heart failure with reduced ejection fraction (HFrEF).

Methods

This quasi-experimental study used a single group, pre-post intervention design. The Research Ethics Committee of Lampang Hospital approved the study. All patients provided written informed consent before participation in the study.

Participants

Study participants were heart failure patients who were referred to the heart failure clinic of Lampang Hospital between January 1, 2015 and December 31, 2017. Subjects who met all of the following criteria were included in this study: 1) age 15 years or older; 2) having been diagnosed with heart failure; 3) LVEF of 40% or less by echocardiography prior to attending the heart failure clinic; and 4) being willing to participate in this study. We excluded subjects with one or more of the following: 1) being unable to communicate in the Thai language; 2) being unable to perform the six-minute walk test; and 3) lacking the results of echocardiography done before attending the heart failure clinic.

Study interventions and procedures

The comprehensive heart failure treatment program consists of activities related to heart failure management which are based on a review of the literature. Specifically, the program focuses on guideline-directed medical therapy (GDMT) for heart failure, cardiac rehabilitation and health education for patients and caregivers regarding self-care and self-adjustment of diuretics. A multidisciplinary team comprised of cardiologists, heart failure nurses, pharmacists and physical therapists provides care according to the comprehensive heart failure treatment program to patients and follows them in the heart failure clinic.

Heart failure patients are eligible to attend the heart failure clinic if they have a left ventricular ejection fraction of 40% or less by echocardiography, have no plan for surgery or other invasive interventions, and are willing to visit the clinic on scheduled appointment dates.

When a patient visits the heart failure clinic, a clinic nurse takes a medical history and vital signs, assesses the patient's condition and evaluates the patient's quality of life using the Thai version of the EQ-5D-3L questionnaire. The nurse also provides health education to the patient and his/her caregivers. A pharmacist assesses drug administration, patient compliance, number of remaining pills, and concomitant medications prescribed elsewhere. A physical therapist performs the six-minute walk test to evaluate the patient's functional capacity and instructs the patient to do home exercises. Finally, a cardiologist assesses the patient's condition, evaluates the New York Heart Association (NYHA) functional class, provides appropriate treatments including adjustment of medications, and considers referring the patient to other experts such as a psychiatrist or a nutritionist as necessary.

For a stable patient, subsequent follow-up visits at the heart failure clinic is usually scheduled at 2, 4, 6, 8, 12, and 16 weeks, then every 16 weeks thereafter. Follow-up visits may be more frequent in case of clinical deterioration, adjustment of medications, or abnormal laboratory findings. NYHA functional class, six-minute walk test and

EQ-5D-3L questionnaire are assessed at every clinic visit. Echocardiography is performed using a standard protocol at least every 6 months during the follow-up period after initiation of GDMT. For each patient, the repeat evaluation may be performed by the same clinic staff member who performed the initial evaluation or by a different staff member.

The six-minute walk test is a standard sub-maximal exercise test used for evaluation of functional capacity of patients with various cardiopulmonary conditions including heart failure. The patient is asked to walk on a flat floor as far as he/she can in 6 minutes and the distance walked is recorded as the result of the test. Due to space limitations at our center, we used a 15 meter corridor for the test which required patients to walk back and forth multiple times. The test supervisor walks behind the patient to prevent falling, but does not provide any verbal encouragement during the test. A walking aid that the patient normally uses in daily life is allowed.

Statistical analyses

We used the mean and standard deviation to describe continuous variables and the frequency and percentage to describe categorical variables. The primary outcomes of the study are changes in LVEF at 6 to 9 months and in the six-minute walk distance after 12 months of participation in the comprehensive heart failure treatment program. If the value of the six-minute walk distance at 12 months was not available, we used the value that was measured at the point closest to the 12th month and within 3 months before or after for the analysis. We applied this same approach to the values of NYHA functional class and the EQ-5D-3L questionnaire.

We used the paired t-test to evaluate the mean change from baseline in LVEF, six-minute walk distance, and quality of life (the visual analog scale part of the EQ-5D-3L). We determined the proportion of patients who had an absolute increase in LVEF of greater than 10 percentage points and the proportion who eventually achieved LVEF of greater than 50% at 6-9 months

after beginning participation in the program. We used the McNemar's test to assess the change in the proportion of patients who received GDMT, who took at least 50% of the target dose, and who achieved the target dose of GDMT after participation in the program. We defined the target dose of each heart failure drug used in the heart failure clinic of Lampang Hospital as follows: 20 mg/day for enalapril, 100 mg/day for losartan, 50 mg/day for carvedilol, and 25 mg/day for spironolactone. A 2-sided p value of less than 0.05 was considered statistically significant.

Results

There were 129 patients enrolled to the heart failure clinic during the study period of whom 68 were excluded from the analyses: 15 lacked results of echocardiography before attending the heart failure clinic, 24 could not perform the six-minute walk test, 7 had LVEF of greater than 40%, 17 had been enrolled for less than 9 months, so the results of the six-minute walk test at 12±3 months were not yet available, 2 were unable to communicate in Thai, 2 died and 1 was lost to follow-up. Finally, 61 patients were included in this study.

Patient characteristics

Baseline characteristics of study subjects are shown in Table 1. About 70% were male. The age ranged between 23 and 88 years with a mean of 58 years, and 48% of the subjects were 60 years old or older. About 60% had been diagnosed with non-ischemic cardiomyopathy. Patients had severe LV dysfunction with a mean LVEF of 27%. One-third of the patients had undergone coronary angiography, but only 10% had received revascularization prior to attending the heart failure clinic. Common comorbid conditions included dyslipidemia, diabetes mellitus, hypertension, atrial fibrillation and chronic obstructive pulmonary disease. Sixteen percent of the patients had chronic kidney disease stage 3 or higher. Four patients (6.5%) had had cardiac devices implanted. Before attending the heart failure clinic, 66% of the patients had NYHA functional class of 2 or higher.

Table 1. Baseline characteristics of participants (n=61)

Characteristics	Value
Age (years), mean (SD)	57.6 (13.4)
Male, n (%)	43 (70.5)
Etiology of heart failure, n (%)	
Ischemic cardiomyopathy	24 (39.3)
Non-ischemic cardiomyopathy	37 (60.7)
New York Heart Association Functional Class, n (%)	
1	21 (34.4)
2	32 (52.5)
3	8 (13.1)
4	0 (0.0)
Left ventricular ejection fraction (%), mean (SD)	27.4 (8.3)
Comorbid condition, n (%)	
Diabetes mellitus	12 (19.7)
Hypertension	6 (9.8)
Dyslipidemia	32 (52.5)
Chronic obstructive pulmonary disease	5 (8.2)
Atrial fibrillation	7 (11.5)
Chronic kidney disease stage ≥ 3	10 (16.4)
Previous coronary angiography	19 (31.1)
Previous revascularization	6 (9.8)
Quality of life (EQ visual analog scale, mm), mean (SD)	78.9 (9.6)

Guideline-directed medical therapy

The proportion of patients taking carvedilol and spironolactone increased significantly from baseline to 12 months after beginning participation in the comprehensive heart failure treatment program (carvedilol: 77% vs. 93%, $p=0.013$; spironolactone: 43% vs. 69%, $p<0.001$, Table 2). In addition, the proportion of patients taking at least 50% of the target dose as well as the proportion of those achieving the target dose of carvedilol and spironolactone both increased significantly (Table 2). Among patients who received the drugs, the mean dose of each drug increased since beginning participation in the program as well. More than 90% of the patients were already receiving either enalapril or losartan at baseline and that proportion did not increase significantly after participation in the program. However, the proportion of patients taking at least 50% of the

target dose and the proportion achieving the target dose of either enalapril or losartan did increase significantly after participation. Similar to carvedilol and spironolactone, the mean dose of either enalapril or losartan increased after participation in the program.

Outcomes

The outcomes of the study are shown in Table 3. LVEF improved significantly after participation in the comprehensive heart failure treatment program (mean LVEF 27.4% before participation vs. 46.7% after participation, $p<0.001$). Among the 61 patients in the study, 43 patients (70.5%, 95% CI 58.1% to 80.4%) had an absolute increase in LVEF of greater than 10 percentage points. In addition, 27 of 61 patients (44.3%, 95% CI 32.5% to 56.7%) achieved LVEF of greater than 50% after 6 to 9 months of participation in the program. Six-minute walk distance increased significantly by 44 meters (mean 313 m before participation vs. 357 m at 12 ± 3 months of follow-up, $p<0.001$). Patients also reported improved quality of life (mean EQ visual analog scale 79 millimeters at baseline vs. 83 millimeters at 12 months, $p=0.027$), and improved NYHA functional class (mean NYHA functional class 1.7 vs. 1.2, $p<0.001$). Only a few patients reported worsening of NYHA functional class. None of the subjects received coronary revascularization after beginning participation in the comprehensive heart failure treatment program. Two patients had an automated implantable cardioverter-defibrillator (AICD) implanted during follow-up period; they both had stable LVEF after AICD implantation. There were 4 hospitalizations during the follow-up period in the study. Three patients were hospitalized due to heart failure. The other patient was admitted due to recurrent supraventricular tachycardia.

Discussion

Previous studies of ACEIs, ARBs, beta blockers and aldosterone antagonists have demonstrated that these medications can significantly decrease the mortality rate of patients with heart failure (11-16). These findings have led to recommen-

Table 2. Use of guideline-directed heart failure drugs before and after 12 months of participation in the comprehensive heart failure treatment program

Drugs	Before participation	After 12 months of participation	p-value ^a
ACEI or ARB			
Use of enalapril or losartan, n/N (%)	57/61 (93.4%)	58/61 (95.1%)	1.000
Achieving at least 50% of the target dose ^b , n/N (%)	31/61 (50.8%)	47/61 (77.0%)	0.002
Achieving the target dose ^b , n/N (%)	5/61 (8.2%)	27/61 (44.3%)	< 0.001
Dose (mg/day), mean (SD)			
Enalapril	8.9 (6.8) (n = 42)	19.9 (12.1) (n = 42)	
Losartan	51.7 (24.0) (n = 15)	55.5 (27.8) (n = 16)	
Beta-blocker			
Use of carvedilol, n/N (%)	47/61 (77.0%)	57/61 (93.4%)	0.013
Achieving at least 50% of the target dose ^b , n/N (%)	13/61 (21.3%)	35/61 (57.4%)	< 0.001
Achieving the target dose ^b , n/N (%)	0/61 (0%)	5/61 (8.2%)	Cannot calculate
Carvedilol dose (mg/day), mean (SD)	14.9 (7.6) (n = 47)	23.8 (11.3) (n = 57)	
Aldosterone antagonist			
Use of spironolactone, n/N (%)	26/61 (42.6%)	42/61 (68.9%)	< 0.001
Achieving at least 50% of the target dose ^b , n/N (%)	26/61 (42.6%)	42/61 (68.9%)	< 0.001
Achieving the target dose ^b , n/N (%)	13/61 (21.3%)	31/61 (50.8%)	< 0.001
Spironolactone dose (mg/day), mean (SD)	18.8 (6.3) (n = 26)	21.7 (5.6) (n = 42)	

^aMcNemar's test; ^btarget dose: 20 mg/day for enalapril, 100 mg/day for losartan, 50 mg/day for carvedilol, and 25 mg/day for spironolactone

Table 3. Left ventricular ejection fraction, six-minute walk distance, Quality of life (EQ visual analog scale), and NYHA functional class before and after participation in the comprehensive heart failure treatment program

	Before participation	After participation	p-value ^a
Left ventricular ejection fraction (%), mean (SD)	27.4 (8.3)	46.7 (13.2)	< 0.001
Six-minute walk distance (meter), mean (SD)	312.8 (80.0)	357.4 (97.5)	< 0.001
Quality of life (EQ visual analog scale, mm), mean (SD)	78.9 (9.6)	83.0 (10.9)	0.027
NYHA Functional class, mean (SD)	1.7 (0.6)	1.2 (0.4)	< 0.001

^aPaired t-test

dations in standard guidelines to use these drugs as a mainstay treatment for heart failure (17,18). In addition, a multidisciplinary team approach focusing on health education and case/disease management was shown to decrease readmission rates and improve patients' quality of life (2-6).

Until recently, care of patients with heart failure at Lampang Hospital used a case management

program which focused on patients with a high readmission rate and multiple comorbid diseases (7). After operating the program in the heart failure clinic for 12 years, the readmission rate of patients with HFrEF were noticeably decreased. This was observed not only in patients who participated in the program, but also in those who did not. There are many possible

explanations for this observation. First, following the model case management program, the case manager provides health education to the patient before hospital discharge, emphasizing self-care and self-monitoring for worsening symptoms and signs. As a consequence, patients seek medical attention earlier in cases of clinical deterioration. Second, the number of cardiologists and cardiac surgeons in the hospital has increased over time. As a result, more patients with heart failure receive prompt cardiac investigation and management of their conditions. Third, a cardiac catheterization laboratory and a cardiac surgery facility were established in the hospital in 2014 and 2010 respectively. Heart failure patients who needed cardiac catheterization, percutaneous or surgical revascularization, cardiac device implantation, valvular surgery, and other cardiac surgical interventions can receive on-site treatment without waiting an additional period for the process of referral to other tertiary care centers. Fourth, since the establishment of the heart failure clinic general practitioners and general internists have gained more knowledge about proper management of patients with heart failure.

As the readmission rate of patients with HFrEF has declined, readmission of heart failure patients since 2016 has been confined primarily to patients who have heart failure with preserved ejection fraction (HFpEF) – especially those with atrial fibrillation and patients with ischemic cardiomyopathy or valvular heart disease who declined surgery. Since having HFrEF is the primary criterion for being referred to the heart failure clinic, the proportion of patients with high readmission rates in the heart failure clinic has decreased. Many patients had a fairly good NYHA functional class despite suboptimal GDMT when they were initially referred to the clinic. Under the model case management program, consultation with other specialties was carried out only when necessary for a particular patient. In 2015, a number of pharmacists and physical therapists joined the heart failure clinic, forming a multidisciplinary team that allowed a change in the care model from a case management program to a

comprehensive heart failure treatment program. As a result, more patients obtain GDMT and more patients achieve the target dose as recommended in the guidelines. In addition, patients also receive comprehensive care, which is the most evident benefit of establishing the heart failure clinic.

Previous studies have demonstrated that ACEIs and beta-blockers can help improve LVEF in patients with heart failure (19-22). This was also observed in our present study. Almost all patients took ACEIs/ARBs and beta-blockers after participating in the comprehensive heart failure treatment program. The mean LVEF at 6-9 months after beginning participation in the program was significantly better than the mean baseline LVEF. Patients with non-ischemic cardiomyopathy, particularly those with atrial fibrillation, gained the most benefits. Patients with ischemic cardiomyopathy who did not get revascularization seemed to have poorer LVEF than those who did. However, our data are insufficient to determine whether the change in LVEF in heart failure patients with ischemic cardiomyopathy who did not undergo revascularization differs from those who underwent the procedure.

Patients also had improvement in functional capacity as assessed by the six-minute walk test. This finding was consistent with previous meta-analyses indicating that beta blockers and ACEI can improve functional capacity in patients with heart failure, although the effect on six-minute walk distance from the meta-analyses may not be conclusive (23,24).

In our study, all patients reported improvement of symptoms after participating in the comprehensive heart failure treatment program regardless of the degree of improvement of their LVEF. This suggests that routine echocardiography to assess LVEF after providing GDMT and cardiac rehabilitation is unnecessary and is not cost-effective. The most important elements of concern are following the guidelines regarding adjusting patients' medication and providing cardiac rehabilitation as appropriate. Echocardiography should be performed only when there is a clear clinical indication.

Our study has some limitations. The first, and probably the most important limitation, is that it was not a randomized study. The effects of various types of bias related to non-randomized studies remain undetermined. We cannot be confident that the improvement of LVEF and six-minute walk distance was actually related to participation in the comprehensive heart failure treatment program. Other explanations are possible. Second, there was no attempt to blind the baseline values of the outcomes (LVEF and six-minute walk distance) at the time of subsequent measurements. Awareness of the values at baseline may have influenced the interpretation of later measurements, thereby introducing bias. Third, the sample size of the study cannot be considered large, and the study sample might not be representative of the target population.

Conclusions

In heart failure patients with reduced ejection fraction, participation in a comprehensive heart failure treatment program that is managed by a multidisciplinary care team consisting of cardiologists, heart failure nurses, pharmacists and physical therapists, and that focuses on guideline-directed medical therapy for heart failure, cardiac rehabilitation, and health education for patients and caregivers regarding self-care and self-adjustment of diuretics may result in improvement in left ventricular ejection fraction and six-minute walk distance.

Conflict of interests

Both authors declared no conflict of interest relevant to this work.

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ผลของรูปแบบการรักษาภาวะหัวใจล้มเหลวแบบครอบคลุมต่อการบีบตัวของหัวใจห้องล่างซ้ายและการทดสอบด้วยการเดิน 6 นาทีในผู้ป่วยภาวะหัวใจล้มเหลวชนิดที่มีการบีบตัวของหัวใจห้องล่างซ้ายลดลงในโรงพยาบาลลำปาง

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¹กลุ่มงานอายุรกรรม โรงพยาบาลลำปาง, ²ภาควิชาเวชศาสตร์ป้องกันและสังคม คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

วัตถุประสงค์ เพื่อศึกษาผลของรูปแบบการรักษาภาวะหัวใจล้มเหลวแบบครอบคลุมต่อการบีบตัวของหัวใจห้องล่างซ้ายและการทดสอบด้วยการเดิน 6 นาที ในผู้ป่วยภาวะหัวใจล้มเหลวชนิดที่มีการบีบตัวของหัวใจห้องล่างซ้ายลดลง โดยเปรียบเทียบค่าการบีบตัวของหัวใจห้องล่างซ้ายและผลการทดสอบด้วยการเดิน 6 นาทีก่อนและหลังการได้รับการรักษาในผู้ป่วยกลุ่มเดียวกัน

วิธีการ ผู้ป่วยภาวะหัวใจล้มเหลวชนิดที่มีการบีบตัวของหัวใจห้องล่างซ้ายลดลงในโรงพยาบาลลำปางได้รับการรักษาตามรูปแบบการรักษาภาวะหัวใจล้มเหลวแบบครอบคลุม ซึ่งเน้นที่การให้ยารักษาตามแนวทางเวชปฏิบัติ การฟื้นฟูสมรรถภาพหัวใจ และการให้สุขศึกษาแก่ผู้ป่วยและผู้ดูแลเกี่ยวกับการดูแลตนเองและการปรับขนาดยาขับปัสสาวะด้วยตนเอง รูปแบบการรักษาดังกล่าวเป็นการดำเนินงานร่วมกันของทีมสหสาขาวิชาชีพซึ่งประกอบด้วยอายุรแพทย์โรคหัวใจ พยาบาลเฉพาะทางโรคหัวใจล้มเหลว เภสัชกร และนักกายภาพบำบัด ผู้ป่วยได้รับการตรวจการบีบตัวของหัวใจห้องล่างซ้ายเมื่อแรกเข้ารับการรักษและหลังรับการรักษาแล้ว 6-9 เดือน และได้รับการทดสอบด้วยการเดิน 6 นาทีเมื่อแรกเข้ารับการรักษและหลังรับการรักษาแล้ว 12±3 เดือน

ผลการศึกษา มีผู้ป่วยภาวะหัวใจล้มเหลวชนิดที่มีการบีบตัวของหัวใจห้องล่างซ้ายลดลงเข้าร่วมการศึกษาทั้งสิ้น 61 ราย หลังจากได้รับการรักษาตามรูปแบบการรักษาภาวะหัวใจล้มเหลวแบบครอบคลุมแล้วพบว่าค่าการบีบตัวของหัวใจห้องล่างซ้ายและการทดสอบด้วยการเดิน 6 นาทีดีขึ้นอย่างมีนัยสำคัญทางสถิติ (ค่าเฉลี่ยการบีบตัวของหัวใจห้องล่างซ้ายเพิ่มขึ้นจากร้อยละ 27 ก่อนรับการรักษาเป็นร้อยละ 47 หลังรับการรักษาแล้ว 6-9 เดือน, $p<0.001$ และค่าเฉลี่ยผลการทดสอบด้วยการเดิน 6 นาทีเพิ่มขึ้นจาก 313 เมตรก่อนรับการรักษาเป็น 357 เมตรหลังรับการรักษาแล้ว 12±3 เดือน, $p<0.001$) และยังพบว่าคุณภาพชีวิตของผู้ป่วยและความรุนแรงของอาการหัวใจล้มเหลวซึ่งประเมินตามระบบของสมาคมโรคหัวใจแห่งนิวยอร์กดีขึ้นด้วย

สรุป ในผู้ป่วยภาวะหัวใจล้มเหลวชนิดที่มีการบีบตัวของหัวใจห้องล่างซ้ายลดลง รูปแบบการรักษาภาวะหัวใจล้มเหลวแบบครอบคลุมอาจทำให้ค่าการบีบตัวของหัวใจห้องล่างซ้ายและผลการทดสอบด้วยการเดิน 6 นาทีดีขึ้น **เชียงใหม่เวชสาร 2563;59(1):1-9.**

คำสำคัญ: โรคหัวใจล้มเหลว การรักษาภาวะหัวใจล้มเหลวแบบครอบคลุม คลินิกหัวใจล้มเหลว การบีบตัวของหัวใจห้องล่างซ้าย การทดสอบด้วยการเดิน 6 นาที ทีมสหสาขาวิชาชีพ

