CHAPTER III

METHODS

Participants

Twelve volunteers with type 2 DM were recruited from the DM outpatient clinic, Maharajnakorn Chiangmai hospital. Inclusion criteria were: male aged 40-69 years, sedentary lifestyle (Note: no regular exercise more than 3 times per week, 20 minutes per session), diagnosed of type 2 DM at least 5 years prior to the study and fair controlled by diet or oral hypoglycemic agent (fasting plasma glucose level less than 180 mg/dl). Furthermore, the short form version of International Physical Activity Questionnaires (IPAQ) (Appendix A) (63) was used to identify the level of subject physical activity.

Exclusion criteria were: any conditions limiting the subject’s daily locomotion such as musculoskeletal problems, neurological condition, severe deformity of lower extremity joints, existing of any contraindications for exercise testing (Appendix B) (20), recent coronary artery disease, myocardial infarction during the previous month, and current or ex-smoker.

The study was approved by the research ethics committee of the Faculty of Medicine, Chiang Mai University. Information, benefits, risks, and testing procedures were clearly explained to subjects. A written informed consent was obtained prior to the study.
Procedures

All of the subjects were asked to avoid caffeine, alcohol, and vigorous physical activity within 2 hours on the day of test. Wearing comfortable exercise gears, having light meal, and taking regular medical regimen were recommended. The pulmonary function tests (PFTs), the 6MWT, and the isokinetic muscle strength tests were applied in all subjects. Subjects visited the laboratory on 2 occasions, at 1 day apart.

On the first visit, all subjects reported to the laboratory in the morning. Demographic data (age, weight, height, and BMI) and relevant medical record data (lipid profiles, fasting glucose level, HbA₁C, complication, medication use) were collected. Blood pressure and heart rate were measured after 5 minute rest. Testing procedures were explained. All subjects underwent PFTs (Sensormedics®, Yoba Linda, CA, USA). According to American Thoracic Society (ATS), the standardization of spirometry procedure was performed (34). Then, FVC, FEV₁, FEV₁/FVC, predicted value of FVC (pred FVC) and predicted value of FEV₁ (pred FEV₁) were measured and the best value of these variables were recorded and used for further analysis. After that, familiarization session on the 6MWT and isokinetic muscle strength test was provided to all subjects. This visit took about an hour.

On the second visit, all subjects arrived to the laboratory in the morning. The 6MWT and the isokinetic muscle strength test were performed. Prior to the test batteries, blood glucose after meal was determined by the commercial test kit (MediSense Optium, Abbott, USA). The standardization of the 6MWT procedure was followed (22). Vital signs (heart rate, blood pressure, and oxygen saturation) were measured prior to the test. Also, subjective responses (rating of perceived
exertion (RPE) and fatigue sensation) were rated and recorded. After the test was completed, the 6MWD were measured. The vital signs and the subjective sensation were immediately repeated by the end of the test. Only, the 6MWD and the heart rate immediately after the test (HRim) were used for further analysis. This visit took about one hour.

**Isokinetic muscle strength protocol:** The dominant leg of the subject was determined by using the preferable leg to kick a ball. Self-stretching of quadriceps, hamstring, tibialis anterior, gastrocnemius, and soleus were performed prior to the test. The subject was tested for muscle strength of knee extensor/flexor, and ankle dorsiflexor, and plantar flexor. The starting position for the tests of knee extensors, knee flexors, and ankle dorsiflexor/plantar flexors were in sitting and supine lying with slightly knee flexion, respectively, followed the manual protocol (CON-TREX MJ, Switzerland). The angular velocity was set at 60 degrees/second for all tests. The subject was instructed to exert maximal effort through the full available range of motion. Five repetitions with a one-minute rest in between of each muscle group were completed. Maximal isokinetic muscle strength of each muscle group indicated by peak torque were measured and recorded by the isokinetic dynamometer (CON-TREX MJ, Switzerland). During the test, the blood pressure was monitored.

All of the tests were terminated if the subject had the following signs/symptoms: angina, angina equivalent, fatigue, dyspnea, leg cramp, diaphoresis, pale or ashen appearance. Furthermore, the isokinetic muscle strength test was ceased if systolic blood pressure > 250 mmHg, exertional hypotension of systolic blood pressure and/or diastolic blood pressure > 115 mmHg (20).
Statistical analysis

1. Descriptive statistics was used for demographic data, PFTs, the 6MWT results (6MWD and HRim), and peak torques.

2. Pearson correlation was used to determine the relationship between the 6MWD and HRim, demographic data, PFTs, and peak torques.

3. Linear regression analysis was used to determine how much the following independent variables (demographic data, PFTs, and HRim, and peak torques) impact the 6MWD.

All data were reported as mean ± S.D. The significant level at 0.05 was selected.