

# A novel respiratory device and the application of cardiorespiratory performance to hemodialysis patients

Kornanong Yuenyongchaiwat<sup>1</sup>, Chusak Thanawattano<sup>2</sup>, Chatchai Buekban<sup>2</sup>, Noppawan Charususin<sup>1</sup>, Karan Pongpanit<sup>1</sup>, Somrudee Hanmanop<sup>1</sup>, Phuwarin Namdang<sup>1</sup>, and Opas Traitanon<sup>3</sup>

<sup>1</sup>Thammasat University - Rangsit Campus

<sup>2</sup>National Electronics and Computer Technology Center

<sup>3</sup>Thammasat University Faculty of Medicine

January 22, 2021

## Abstract

**Background:** Muscle wasting and limitation in physical activity have been reported in patients with hemodialysis; this leads to poor quality of life at the end. **Objective:** To develop the respiratory training device and to determine the efficiency of the prototype on respiratory muscle strength, functional capacity and dyspnea perception in hemodialysis patients. **Design, setting and participants:** the development of respiratory device was created and then effects of respiratory device were examined in hemodialysis patients. A total of 25 patients with quasi experimental study was recruited in the present study with aged [?] 35 years old. All participants had a history of hemodialysis 3 days per week. **Outcome measurements and statistical analysis:** The protocol was conducted 15 inhales, three set per day with 40% of maximal inspiratory pressure; totally 45 inhales. The participants were asked to perform for three times per week during on hemodialysis. Respiratory muscle strength, the 6minute walk test and rate of dyspnea scores were assessed before and after 8-week intervention program. Paired t-tests was used to compare between initial values and follow-up values in respiratory prototype. **Results:** Of 25 patients at initially was enrolled, 22 individuals (88%) completed in the 8-week program. Significant improve in inspiratory muscle strength, 6minute walk distance and rate of dyspnea was observed after 8-week intervention ( $?12.44 \pm 3.55$  cmH<sub>2</sub>O,  $?24.78 \pm 8.89$  meters, and  $?0.50 \pm 0.19$ , respectively). **Conclusion:** Using porotype of respiratory device can effectively improve cardiorespiratory performance which is marked by increasing inspiratory muscle functional capacity and rate of dyspnea in hemodialysis patients after 8-week training program.

## A novel respiratory device and the application of cardiorespiratory performance to hemodialysis patients

### Abstract:

**Background:** Muscle wasting and limitation in physical activity have been reported in patients with hemodialysis; this leads to poor quality of life at the end.

**Objective:** To develop the respiratory training device and to determine the efficiency of the prototype on respiratory muscle strength, functional capacity and dyspnea perception in hemodialysis patients.

**Design, setting and participants:** the development of respiratory device was created and then effects of respiratory device were examined in hemodialysis patients. A total of 25 patients with quasi experimental study was recruited in the present study with aged [?] 35 years old. All participants had a history of hemodialysis 3 days per week.

**Outcome measurements and statistical analysis:** The protocol was conducted 15 inhales, three set per day with 40% of maximal inspiratory pressure; totally 45 inhales. The participants were asked to perform for three times per week during on hemodialysis. Respiratory muscle strength, the 6minute walk test and rate of dyspnea scores were assessed before and after 8-week intervention program. Paired t-tests was used to compare between initial values and follow-up values in respiratory prototype.

**Results:** Of 25 patients at initially was enrolled, 22 individuals (88%) completed in the 8-week program. Significant improve in inspiratory muscle strength, 6minute walk distance and rate of dyspnea was observed after 8-week intervention ( $\Delta 12.44 \pm 3.55$  cmH<sub>2</sub>O,  $\Delta 24.78 \pm 8.89$  meters, and  $\Delta 0.50 \pm 0.19$ , respectively).

**Conclusion:** Using porotype of respiratory device can effectively improve cardiorespiratory performance which is marked by increasing inspiratory muscle functional capacity and rate of dyspnea in hemodialysis patients after 8-week training program.

**Keywords:** respiratory device, hemodialysis, dyspnea, respiratory muscle, functional capacity, rehabilitation Thai Clinical Trials Registry (TCTR) number is TCTR20171107003.

## Introduction

Muscle wasting and limitation in physical activity have been reported in patients with end stage renal disease. In addition, myopathy uraemia has been described in chronic renal failure (CRF), and this leads to decline in muscle strength including respiratory muscle. It has been reported that respiratory muscle training in CRF patients could increase in respiratory muscle strength and thereby increase in functional capacity<sup>1</sup>. Pellizzaro et al reported the effect of respiratory muscle training in CRF patients during hemodialysis and found that respiratory muscle strength and functional capacity had a significantly improvement while the control group who did not any intervention were not improved<sup>1</sup>. In addition, a correlation was found between inspiratory muscle strength and functional capacity (defined as the 6-minute walk test). Inspiratory muscle training (IMT) commonly performs a threshold loading IMT such as POWERbreathe. Using the threshold loading IMT should inspire through a mouthpiece with adjusted or different resistance in the inspiration. Therefore, inspiratory muscle training might be carried by using accessory muscle for example scalene muscle or sternocleidomastoid muscle. According to the previous study, we created a respiratory prototype (named TU-Breath Training) that attached on the lower costal muscle instead. Further, it has been shown that training with TU-breathe could reduce blood pressure in hypertensive participants<sup>2</sup>. Therefore, the study was aimed to design and develop a new prototype of respiratory version II and explore the effect of the prototype version II on cardiorespiratory performance (i.e., respiratory muscle strength, functional capacity) and dyspnea score among hemodialysis patients.

## 2. Materials and Methods

The Research has been approved from the Ethics Committee on Human Subject of Thammasat University and the Ethics in Human Research Committee of the Thammasat University Hospital, according to the principles of the Declaration of Helsinki 1975.

Participants were adults aged 30-75 years old both males and females. Further, those had been diagnosed end stage renal failure at stage 5 and receiving hemodialysis more than three months, undergoing hemodialysis three times a week for 3-4 hours per day. The exclusion criteria were participants who had been resting systolic blood pressure greater than 200 mmHg and/or diastolic blood pressure greater than 120 mmHg, had neurological problems (e.g., stroke, had musculoskeletal problems (e.g., severe osteoarthritis, ambulation), uncontrolled pulmonary disease, mental health problems (diagnosis from doctor or psychiatrist) and cognitive impairment.

Prior to the training program, the participants were explained the objective and methodology of the study. Next, participants were asked to sign the informed consent and fill in a questionnaire, such as medical history, duration of hemodialysis, history of drinking and smoking. Participants performed respiratory muscle strength testing. Maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP) were measu-

red by a mouth pressure meter (Micromedical generation, micro DL no.2, Carefusion company). Participants were asked to sit on a chair comfortably and the noseclip was attached. After that, individuals were requested to take a deep breath near to residual volume and inhale deeply with hold on 1.5 seconds this could be defined as MIP. Next, for the MEP, participants take a deep breath near to total lung capacity and exhale fast and then hold on 1.5 seconds. Participants were requested to repeat the tests for three to five times and maximal value was recorded<sup>3</sup>. Participants rest for five minutes or rest until heart rate recovery. Prior to the functional capacity testing (i.e., the 6-minute walk test: 6MWT), the participants were recorded blood pressure, heart rate, rate perceived exertion (RPE: modified Borg scale 0-10) and oxygen saturation. Participants performed the 6MWT which is long level corridor 30 meters and walk within six minutes<sup>4</sup>. Blood pressure, heart rate, RPE and oxygen saturation were re-assessed after 6MWT. The perception of breathlessness is rated on a Likert scale between 1 (very difficult to breath) and 5 (not difficult to breath). Participants were asked to complete how difficult breath during the past month.

The respiratory muscle training program was used by the prototype of respiratory muscle training version II (TU-breathe V. 2); see Figure 1. The system composes an air resistive respiration training device including a respiration sensor. The pressure sensor is connected to the respiratory sensor and it is sent the pressure value via Bluetooth which has been installed by a smartphone. The pressure sensor and system have been described in detail elsewhere<sup>2</sup>.

The participants were asked to take a deep breath in deeply and the maximal pressure value was shown and recorded. After that, the participants were required to take deep breath in for 40% of maximal inspiration, 15 times/ sets for 3 sets, interval 60 seconds. Respiratory muscle strength was reassessed after 4-week intervention for adjusting respiratory loading. Functional capacity and respiratory muscle strength were performed after 8-week intervention program.

The data analysis was calculated with SPSS program version 20. The statistically significance is set  $p$  value less than 0.05. Kolmogorov - Smirnov (Goodness of fit) test was used for test of distribution data. Paired t-test was performed to evaluate the effect of breathing training on respiratory muscle strength, functional capacity and sensation of breathlessness in pre and post training program (before vs. after 8-week intervention).

### 3. Results

A total of 25 participants were enrolled at initial session; however, three participants who did not complete the program because their busy. Therefore, results were recruited 22 participants (88.0%). There were no significant differences in initial characteristic data between those who complete the study program and those who did not ( $p_s > .005$ ). The demographic, cardiorespiratory performance and rate of dyspnea of the hemodialysis patients at baseline and follow-up are shown in table 1.

Paired t-tests was used to compare between initial values and follow-up values in respiratory prototype (table 2); these indicated that respiratory training with TU-Breath Training version II had increased significantly from initial period to the 8 weeks intervention ( $\Delta 14.23 \pm 3.44$ , 95%CI = 7.13 to 21.32,  $p < .001$ ). The walking distance was also increased in TU-Breath Training group after 8-weeks ( $\Delta 20.09 \pm 9.10$  meters, 95%CI = 1.17 to 39.02,  $p = .039$ ). Again, the efficacy of TU-Breath Training was reported in increased perceived of dyspnea scores after intervention program ( $\Delta 0.50 \pm 0.16$ , 95%CI = 0.17 to 0.83,  $p = .005$ ).

### 4. Discussion

The purposes of the study were to develop the respiratory device training (named TU-Breath Training version II) and examine the effect of the prototype on cardiorespiratory performance (i.e., respiratory muscle strength and functional capacity) and rate of dyspnea in hemodialysis patients. The study reported that use of respiratory prototype program could improve respiratory muscle strength, functional capacity and rate of dyspnea in hemodialysis patients. These results are in line with the previous studies<sup>1, 5-8</sup>.

The study was revealed that an improvement in MIP, 6MWD and sensation of breathlessness were observed in inspiratory muscle training through respiratory prototype (TU-Breath Training version II). Dysfunction

in multiple systems (e.g., musculoskeletal, cardiovascular and respiratory systems) could be found in patients with CRF. The reduction of systemic protein and skeletal muscle mass leads to loss of muscle mass whether in type I or type II fibers in cross-sectional areas. Further, the proportion of slow fibers and also in the size of the fast fibers can be improved inspiratory muscle training<sup>9</sup>. Muscle atrophy in particular type II muscle fibers, results from a reduction of vascular and capillary blood flow<sup>10</sup>. These results are part of uremic myopathy in relation to skeletal muscles including the diaphragm and intercostal muscle and may present in muscle weakness (decreased MIP) and poor functional capacity (i.e., 6-MWT)<sup>11</sup>. In addition, impaired respiratory muscle by the uremic neuropathy and myopathy could leads to increases the work of breathing and also the neuromuscular dissociation<sup>11</sup>. Therefore, neuromuscular dissociation might provoke an increase in respiratory effort and perceived in breathlessness among patients with chronic renal failure<sup>12</sup>. In addition, weakness of inspiratory muscle leads to increase respiratory effort during exercise or physical activity resulting to increase metabolic stress in respiratory muscle and metaboreflex stimulation<sup>13</sup>. Thus, metaboreflex stimulus and uremic myopathy might partially explain why respiratory muscle training improved sensation of breathlessness and cardio-respiratory fitness (i.e., inspiratory muscle strength and 6-MWT).

Regarding to breathlessness, the study found a decrease of dyspnea after 8-week intervention program. Silva et al found an improvement in the sensation of breathlessness after inspiratory muscle training program in hemodialysis patients<sup>8</sup>. Decreased dyspnea is reported in IMT, it might be a decreasing dynamic hyperinflation of rib cage and therefore increasing gas exchange<sup>14</sup>. In addition, increased respiratory muscle strength can be enhancing the pattern of maximal thoraco-abdominal motion<sup>(14)</sup>. Additionally, Patessio et al reported the relationship between the sensation of breathlessness and respiratory muscle strength<sup>15</sup>. MIP less than 80 cmH<sub>2</sub>O has been defined as inspiratory muscle weakness<sup>3,16</sup>. In the present study, MIP was an average 68.32 cmH<sub>2</sub>O which is clinically important inspiratory muscle weakness. However, after training programme for 8-week, the improvement in inspiratory muscle rose to 82.55 cmH<sub>2</sub>O. Therefore, it might be, in part, inspiratory muscle training improved the inspiratory muscle strength and thereby decreased sensation of breathlessness.

Some limitations of the present study should be noted. A relative small sample size with quasi experimental design which is lack of a control group. Therefore, further study need to explore the effect of inspiratory muscle training with a large sample size and randomized control trails. In addition, the training protocol such as intensity, frequency and duration of the study should be a consideration that might affect the result of the study.

## 5. Conclusion

IMT with the prototype of respiratory device displayed significantly improved inspiratory muscle, functional capacity and decreased sensation of breathless after 8-week intervention program.

## Declaration of conflicting interests

There are no conflicts of interest in the study.

## Funding

The financial support provided by a research grant from the National Research Council of Thailand.

## References

1. Pellizzaro CO, Thomé FS, Veronese FV. Effect of peripheral and respiratory muscle training on the functional capacity of hemodialysis patients. *Ren Fail* . 2013; 35: 189–197.
2. Yuenyongchaiwat K, Thanawattano C, Buranapuntalug, S, Pongpanit K, Saengkrut P. Development of respiratory device and the immediate effect of prototype of respiratory device on blood pressure in adults with high blood pressure. *Interv Med Appl Sci*.2019;11(1):21-26.
3. American Thoracic Society/European Respiratory Society. ATS/ERS statement on respiratory muscle testing. *Am J Respir Crit Care Med* . 2002; 166:518-624.

4. American Thoracic Society. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med* . 2002; 166: 111-117.
5. Figueiredo RR, Castro AAM, Napoleone FMGG, Faray L, de Paula Júnior AR, Osorio, RAL. Respiratory biofeedback accuracy in chronic renal failure patients: a method comparison. *Clin Rehabil* . 2002; 26: 724–732.
6. Figueiredo PHS, Lima MMO, Costa HS, Martins JB, Flecha OD, Goncalves PF, et al. Effects of the inspiratory muscle training and aerobic training on respiratory and functional parameters, inflammatory biomarkers, redox status and quality of life in hemodialysis patients: A randomized clinical trial. *PLoS One* . 2018; 13(7): e0200727. <https://doi.org/10.1371/journal.pone.0200727>
7. El-Deen HAB, Alanazi FS, Ahmed KT. Effects of inspiratory muscle training on pulmonary functions and muscle strength in sedentary hemodialysis patients. *J Phys Ther Sci* . 2018; 30:424-427.
8. Silva VG, Amara C, Monteiro MB, Nascimento DM, Boschetti JR. Effects of inspiratory muscle training in hemodialysis patients. *J Bras Nefrol* . 2011; 33: 62–68. pmid:21541465
9. Polla B, D’Antona G, Bottinelli R, Reggiani C. Respiratory muscle fibres: specialisation and plasticity. *Thorax*. 2004; 59: 808–817. doi: 10.1136/thx.2003.009894
10. Sakkas GK, Ball D, Mercer TH, Sargeant AJ, Tolfrey K, Naish PF. Atrophy of non-locomotor muscle in patients with end-stage renal failure. *Nephrol Dial Transplant* . 2003; 18(10) 2074-2081.
11. Cury JL, Brunetto AF, Aydos RD. Negative effects of chronic kidney failure on lung function and functional capacity. *Rev Bras Fisioter* . 2010; 14(2):91- 98.
12. Palamidis AF, Gennimata SA, Karakontaki F, Kaltsaka G, Papantoniou I, Koutsoukou, A, et al. Impact of hemodialysis on dyspnea and lung function in end stage kidney disease patients. *Biomed Res Int* . 2014; 2014: 212751. doi: 10.1155/2014/212751
13. Figueiredo PHS, Lima MMO, Costa HS, Gomes RT, Neves, CDC, de Oliveira ES, et al. The role of the inspiratory muscle weakness in functional capacity in hemodialysis patients. *PLoS One* . 2017; 12(3): e0173159. doi: 10.1371/journal.pone.0173159
14. Patessio A, Rampulla C, Fracchia C, Ioli F, Majani U, De Marchi A, et al. Relationship between the perception of breathlessness and inspiratory resistive loading: report on a clinical trial. *Eur Respir J Suppl* . 1998; 7: 587s-591s.
15. Laveneziana P, Albuquerque A, Aliverti A, Babb T, Barreiro E, Dube BP, et al. ERS statement on respiratory muscle testing at rest and during exercise. *Eur Respir J* . 2019; 53:1801214, DOI: 10.1183/13993003.01214-2018
16. McConnell AK, Romer LM. Dyspnoea in health and obstructive pulmonary disease: the role of respiratory muscle function and training. *Sports Med* . 2004; 34: 117–132. doi: 10.2165/00007256-200434020-00005.

## Figure Legends

*Figure 1: prototype of respiratory muscle training version II (TU-breathe V. 2)*



**Figure 1** prototype of respiratory muscle training version II (TU-breathe V. 2)

### Hosted file

Table 1 Characteristics of patients with chronic kidney disease who completed baseline and.pdf available at <https://authorea.com/users/391093/articles/505269-a-novel-respiratory-device-and-the-application-of-cardiorespiratory-performance-to-hemodialysis-patients>

### Hosted file

Table 2 A comparison of respiratory fitness.pdf available at <https://authorea.com/users/391093/articles/505269-a-novel-respiratory-device-and-the-application-of-cardiorespiratory-performance-to-hemodialysis-patients>