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Efficiency of the Respiratory Training Prototype for Application in Hemodialysis Patients: A Preliminary Study

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Muscle wasting and activity limitations have been reported in patients undergoing hemodialysis, and these ultimately lead to poor quality of life. We aimed to develop a respiratory training device and determine its effectiveness in improving cardiorespiratory performance and dyspnea scores in patients undergoing hemodialysis. Twenty-five (25) patients aged ≥ 35 yr who underwent hemodialysis thrice a week were recruited in this quasi-experimental study. A respiratory training device was developed, and its effectiveness was examined. Participants performed a total of 45 inspirations (three sets of 15 inspirations) at 40% of the maximal inspiratory pressure (MIP) thrice a week. Respiratory muscle strength, 6-min walk distance, and dyspnea score were assessed before and after the 8-wk intervention program. Paired t-tests were used to compare pre- and post-intervention values. Of the 25 patients enrolled, 22 (88%) completed the 8-wk program. Significant improvements in inspiratory muscle strength ($\Delta 14.23 \pm 3.41$ cmH_2O), 6-min walk distance ($\Delta 20.09 \pm 9.10$ m), and rate of dyspnea ($\Delta 0.50 \pm 0.16$ scores) were observed after the 8-wk intervention. An 8-wk training program using a respiratory device prototype can effectively improve cardiorespiratory performance in terms of increase in inspiratory muscle strength, improved functional capacity, and dyspnea relief in patients undergoing hemodialysis.

Keywords: cardiorespiratory performance, hemodialysis, rehabilitation, respiratory muscle training, respiratory training device

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INTRODUCTION

Chronic renal failure (CRF) presents as an estimated glomerular filtration rate < 60 mL/min/1.73 mt^2, persisting for greater than 3 mo (KDIGO Consortium 2013). The most common causes of CRF are diabetes mellitus type 2 and hypertension (Webster *et al.* 2017). Muscle wasting and physical activity limitations have been reported in patients with end-stage renal disease. In addition, uremic myopathy has been described in patients with CRF. It leads to muscle strength decline, which may involve the respiratory muscles. It has been reported that respiratory muscle training can increase respiratory muscle strength, thereby increasing functional capacity in patients with CRF (Pellizzaro *et al.* 2013). Pellizzaro *et al.* (2013) found that respiratory muscle training during hemodialysis significantly improved the respiratory muscle strength and functional capacity of patients with CRF and that those who did not receive any intervention showed no improvement. In addition, a correlation was found between inspiratory muscle strength and functional capacity (evaluated using the 6-min walk test or 6MWT). Inspiratory muscle training (IMT) is commonly performed using threshold loading devices such as the POWERbreathe (Menzes *et al.* 2018). Patients are instructed to inspire through a mouthpiece, and the resistance to inspiration is adjusted. However, inspiration might be performed using accessory muscles such as the scalene or sternocleidomastoid muscles. Based on the findings of a previous study, we created a prototype respiratory training device (TU-Breath Training) that can be attached to the lower costal margin. Furthermore, training using the TU-breathe has been shown to reduce blood pressure in participants with hypertension (Yuenyongchaiwat *et al.* 2019). Therefore, we aimed to design and develop a new version of our respiratory training device and explore its effects on cardiorespiratory performance (respiratory muscle strength and functional capacity) and dyspnea score in patients undergoing hemodialysis.

MATERIALS AND METHODS

This study was approved by the Ethics Committee on Human Subject of Thammasat University and the Ethics in Human Research Committee of Thammasat University Hospital according to the principles of the Declaration of Helsinki 1975, the Belmont Report, Council for Organizations and Medical Sciences Guidelines, and the International Conference on Harmonization and Good Clinical Practice.

The number of participants was calculated according to a study by Figueiredo *et al.* (2012) with a statistical power of 0.8; therefore, 25 participants were recruited into the study. We enrolled adults aged between 30–75 yr who were diagnosed with end-stage renal failure (stage 5), had received hemodialysis for more than 3 mo, and underwent three sessions of hemodialysis per week for 3–4 hr per session. Both men and women were enrolled. The exclusion criteria were as follows: resting systolic blood pressure > 200 mmHg and/or diastolic blood pressure > 120 mmHg, neurological problems (*e.g.* stroke, head injury), musculoskeletal problems (*e.g.* severe osteoarthritis or difficulties in ambulation), uncontrolled pulmonary disease (*e.g.* exaggerated chronic obstructive pulmonary disease, acute asthma), mental health problems (diagnosed by a doctor or psychiatrist), and cognitive impairment; these patients were excluded owing to the inability to teach them how to use the respiratory training prototype.

Before beginning the training program, the participants received an explanation regarding the objectives and methodology of the study and were asked to sign an informed consent form and complete a questionnaire on their medical history, duration of hemodialysis, and history of drinking and smoking. The participants' respiratory muscle strength was tested. The MIP and MEP (maximal expiratory pressure) were measured using a mouth pressure meter (Micro Medical, CareFusion, United Kingdom). The participants were asked to sit comfortably in a chair while wearing a nose clip. To measure MIP, they were instructed to take a deep breath after maximal expiration (near the residual volume) and hold it for 1.5 s. To measure MEP, they were instructed to rapidly exhale after maximal inspiration (near the total lung capacity) and hold it for 1.5 s. Each test was performed 3–5 times, and the maximum value was recorded (ATS/ERS 2002). The participants rested for five minutes or until heart rate recovery. Subsequently, they underwent the 6MWT to assess functional capacity. The 6MWT involves walking along a 30-m, level corridor for 6 min (ATS 2002). The participants' blood pressure, heart rate, rate of perceived exertion (modified Borg scale; 0–10), and oxygen saturation were assessed before and after the 6MWT. Dyspnea over the past month was rated on a Likert scale, which is a psychometric response scale used to differentiate between different sentiment levels such as "disagree" and "totally agree" (Preedy and Watson 2010). Therefore, the dyspnea scale ranged from 1 (very difficult to breathe) to 5 (not difficult to breathe).

We developed and used a new version of a prototype respiratory muscle training device (TU-breathe version II; Figure 1). Software algorithms used to interpret the respiratory sensor measurements were modified to keep the pressure sensor stable; therefore, the new version was more robust and stable than the previous one. The system comprised an airway-resistance-based respiration training

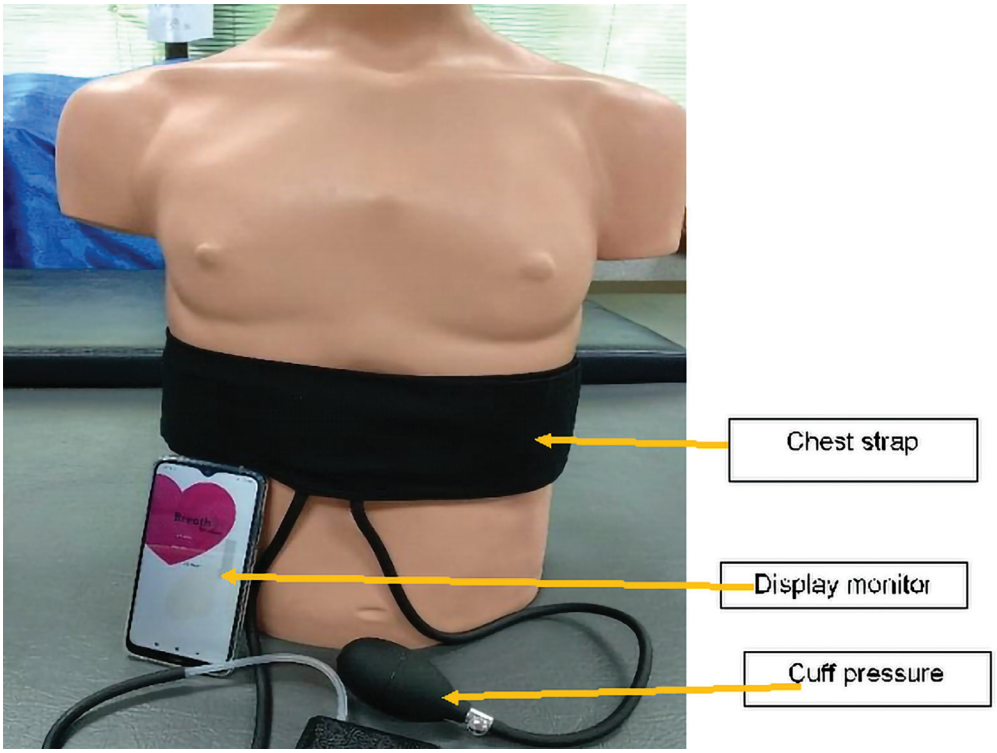

Figure 1. Prototype of respiratory muscle training version II (TU-breathe V. 2).

device and a respiration sensor. A pressure sensor was connected to the respiration sensor, and the pressure value was sent to a smartphone *via* Bluetooth®. The pressure sensor and system have been described in detail elsewhere (Yuenyongchaiwat *et al.* 2019).

The participants were required to attach the chest strap at the lower costal margin (see Figure 1). All individuals were asked to take a deep breath, and the maximum pressure value was displayed and recorded on a monitor. Subsequently, the participants were instructed to take a deep breath at 40% of the maximum inspiratory pressure from the prototype respiratory muscle training device (TU-breathe version II). This was performed 15 times/set for three sets with an interval of 60 s between sets. Respiratory muscle strength was assessed after four weeks, and the respiratory load was adjusted accordingly. Functional capacity and respiratory muscle strength were reassessed after the completion of the 8-wk intervention program.

Data were analyzed using IBM SPSS Statistics version 24. Statistical significance was set at $p < 0.05$. The Kolmogorov-Smirnov goodness-of-fit test was used to analyze the distribution of the data. A normal distribution was detected; therefore, a paired t-test was performed to evaluate the effect of the 8-wk breathing training on respiratory muscle strength, functional capacity, and dyspnea.

RESULTS

Initially, 25 participants were enrolled for respiratory training sessions; however, three participants did not complete the program because they were busy. Therefore, we analyzed the data of 22 participants (88.0%). The demographic characteristics, cardiorespiratory status, and dyspnea scores of the patients undergoing hemodialysis at baseline and follow-up are shown in Table 1.

Table 1. Characteristics of patients with chronic kidney disease who completed baseline and follow-up sessions.

	Prototype (N = 22)	
	N (%)	Mean ± SD
Sex		
Female	7(31.82)	
Male	15 (68.18)	
Age (yr)		51.32 ± 8.65
HD time (yr)		4.36 ± 2.56
BMI (kg/m^2)		24.77 ± 4.33
MIP (cmH_2O)		68.32 ± 27.85
MEP (cmH_2O)		73.14 ± 32.37
6-MWD (meters)		354.91 ± 101.68
Dyspnea (scores)		3.96 ± 0.95

HD – hemodialysis; BMI – body mass index; MIP – maximal inspiratory pressure; MEP – maximal expiratory pressure; 6-MWD – 6-minute walk distance

Table 2. A comparison of cardiorespiratory performance in patients with chronic kidney disease before and after training program.

	Prototype (n = 22)		Change (mean ± SD)	*t*(21)	95% CI
	Post-test	Pre-test			
MIP (cmH_2O)	82.55 ± 29.63	68.32 ± 27.85	14.23 ± 3.41***	4.172	7.13 to 21.32
MEP (cmH_2O)	83.05 ± 33.02	73.14 ± 32.37	9.91 ± 6.40	1.549	6.40 to –3.40
Walking (m)	375.00 ± 107.72	354.91 ± 101.68	20.09 ± 9.10*	2.208	1.17 to 39.02
Dyspnea scores	4.46 ± 0.51	3.96 ± 0.95	0.50 ± 0.16**	3.169	0.17 to 0.83

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$
MIP – maximal inspiratory pressure; MEP – maximal expiratory pressure
Note: the dyspnea scale ranged from 1 (very difficult to breathe) to 5 (not difficult to breathe).

The study found that inspiratory muscle strength, functional capacity, and dyspnea scores significantly increased following respiratory training with TU-Breath Training version II for 8 wk (Δ14.23 ± 3.44, 95% confidence interval [CI] = 7.13–21.32, $p < 0.001$). The 6-min walk distance (Δ20.09 ± 9.10 m, 95% CI = 1.17–39.02, $p = 0.039$) and dyspnea score (Δ0.50 ± 0.16, 95% CI = 0.17–0.83, $p = 0.005$) also increased following the training program (see Table 2).

DISCUSSION

The purpose of this study was to develop a respiratory training device (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 patients undergoing hemodialysis. We found that respiratory training using our prototype improved respiratory muscle strength, functional capacity, and rate of dyspnea in patients undergoing hemodialysis. These results are in line with those of previous studies (Silva *et al.* 2011; Figueiredo *et al.* 2012, 2018; Pellizzaro *et al.* 2013; El-Deen *et al.* 2018).

Improvements were observed in MIP, 6-min walk distance, and perceived dyspnea following IMT using our prototype (TU-Breath Training version II). Patients with CRF experience dysfunction of multiple systems (*e.g.* musculoskeletal, cardiovascular, and respiratory systems). Decreased systemic protein levels may lead to loss of muscle mass that affects both type I and type II fibers, resulting in reduced muscle cross-sectional area. Furthermore, the proportion of slow-twitch fibers and the size of fast-twitch fibers can improve following IMT (Polla *et al.* 2004). Muscle atrophy involving type II muscle fibers results from a reduction in vascular and capillary blood flow (Sakkas *et al.* 2003). Patients with uremic myopathy experience muscle weakness, which may involve the diaphragm and intercostal muscles, leading to decreased MIP and poor functional capacity (Cury *et al.* 2010). Impaired respiratory muscle strength due to uremic neuropathy and myopathy can increase the work of breathing and cause neuromuscular dissociation (Cury *et al.* 2010). Furthermore, neuromuscular dissociation might lead to increased respiratory effort and perceived breathlessness in patients with CRF (Palamidas *et al.* 2014). Inspiratory muscle weakness leads to increased respiratory effort during exercise or physical activity, resulting in increased metabolic stress and metaboreflex stimulation of the respiratory muscle (Figueiredo *et al.* 2017). Thus, metaboreflex stimulation and uremic myopathy might partially explain why respiratory muscle training decreased perceived dyspnea and cardiorespiratory fitness (*i.e.* inspiratory muscle strength and 6-min walk distance) in our study. The increase in MIP (14.23 cmH_2O) and walking distance (20.09 m) after the training program in the present study was smaller than the minimal clinically important difference reported in previous studies (de Medeiros *et al.* 2017; Figueiredo *et al.* 2018). A systematic review in respiratory muscle training with hemodialysis patients found the minimal clinically important difference of 23 cmH_2O (95% CI 16–29) for MIP and 80 m (95% CI 41–119) for 6-min walk distance among the study participants (de Medeiros *et al.* 2017). The difference in intensity, frequency, duration, method of the intervention program, study design, and number of the participants might account for the differences in the changes in MIP and functional capacity. Therefore, the present study should be interpreted cautiously with regard to the study design (*i.e.* no sham group).

We observed a decrease in dyspnea intensity after the 8-wk intervention program (*i.e.* higher dyspnea scores lower rate of perceived dyspnea). Silva *et al.* (2011) found an improvement in perceived dyspnea after an IMT program in patients undergoing hemodialysis. Decreased dyspnea following IMT might be due to decreased dynamic hyperinflation of the rib cage, which improves gas exchange (Patessio *et al.* 1998). In addition, increased respiratory muscle strength can enhance the pattern of thoracoabdominal motion (Patessio *et al.* 1998). A

relationship between perceived dyspnea and respiratory muscle strength has also been reported in several studies (Patessio *et al.* 1998; McConnell and Romer 2004). Inspiratory muscle weakness has been defined as an MIP less than 80 cmH_2O (ATS/ERS 2002; Laveneziana *et al.* 2019). In this study, the mean MIP was 68.32 cmH_2O, which can be considered to indicate clinically important inspiratory muscle weakness. However, after the 8-wk training program, the MIP increased to 82.55 cmH_2O. It has been known that diaphragmic and costal muscles are the main respiratory muscles; therefore, an intervention based on the prototype of the respiratory training device (TU-Breath Training version II) could be useful to increase respiratory muscle strength. Thus, IMT might have improved inspiratory muscle strength and, thereby, decreased perceived dyspnea.

Some limitations of this study should be noted. It had a relatively small sample size, a quasi-experimental design, and a lack of control group. Therefore, further randomized studies with larger samples are needed to explore the effects of IMT. In addition, training parameters such as intensity, frequency, and duration should be considered as they might affect the results of the study.

CONCLUSION

IMT for 8 wk using a respiratory device prototype significantly improved inspiratory muscle strength and functional capacity and decreased dyspnea.

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STATEMENT ON CONFLICT OF INTEREST

There are no conflicts of interest in the study.

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