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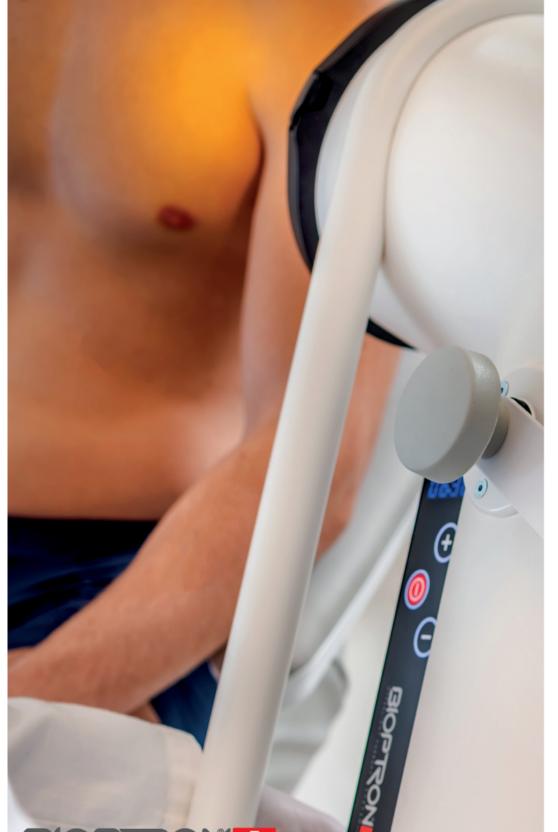
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Effects of Respiratory Resistance Training with a Concurrent Flow Device on Respiratory Muscle Strength and Functional Capacity in End Stage Renal Disease

Wpływ treningu oddechowego z zastosowaniem oporu z urządzeniem do równoczesnego przepływu na siłę mięśni oddechowych oraz wydolność funkcjonalną w przypadku schyłkowej niewydolności nerek

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Abstract

Background. Patients undergoing maintenance hemodialysis (HD) suffer from respiratory symptoms, uremic myopathy and protein catabolism leading to reduction of functional capacity and respiratory muscle strength. Objective. To determine the efficacy of intradialytic respiratory training using concurrent flow resistance (CFR) on respiratory muscle strength and functional capacity. Subjects and methods. Forty patients with end stage renal disease on hemodialysis for at least 4 months, with their age ranged from 30 – 40 of both sexes (20 men and 20 women) participated in this study at hemodialysis center of Fayoum University Hospital, Fayoum, Egypt. A Single- interventional study group designed. The study period was 12 weeks. Maximum inspiratory pressure (MIP) and maximum expiratory pressure (MEP), selected pulmonary function test, Functional capacity and fatigue severity scale (FSS) were evaluated before and after the study. Results. There was significant improvement in MIP, MEP, FEV1%, FVC%, 6MWT and FSS by 61.37%, 63.01%, 58.26%, 55.12%, 36.48% and 22.35% respectively, while no significant difference was recorded regarding to FEV1/FVC% ratio. Conclusion. It can be concluded that respiratory training using concurrent flow resistance (CFR) device for 12 weeks was effective therapeutic technique to improve respiratory muscle strength and functional capacity in patients with end stage renal disease on hemodialysis.

Key words:

Expand-a-Lung, Respiratory muscle strength, Functional capacity, Hemodialysis

Streszczenie

Informacje wprowadzające. Pacjenci poddawani hemodializie podtrzymującej (HD) cierpią na objawy ze strony układu oddechowego, miopatię mocznicową i katabolizm białek prowadzący do zmniejszenia wydolności funkcjonalnej i siły mięśni oddechowych. Cel. Określenie skuteczności śróddialitycznego treningu oddechowego przy użyciu współbieżnego oporu przepływu (CFR) na siłę mięśni oddechowych i wydolność funkcjonalną. Materiał i metody. Czterdziestu pacjentów ze schyłkową niewydolnością nerek poddawanych hemodializie przez co najmniej 4 miesiące, w wieku od 30 do 40 obu płci (20 mężczyzn i 20 kobiet), wzięło udział w tym badaniu w centrum hemodializy Szpitala Uniwersyteckiego Fayoum University Hospital w Fajum w Egipcie. Zaprojektowano pojedynczą interwencyjną grupę badawczą. Okres badania wynosił 12 tygodni. Maksymalne ciśnienie wdechowe (MIP) i maksymalne ciśnienie wydechowe (MEP), wybrany test czynnościowy płuc, skala wydolności funkcjonalnej i nasilenia zmęczenia (FSS) były oceniane przed i po badaniu. Wyniki. Wystąpiła znacząca poprawa w zakresie MIP, MEP, FEV1%, FVC%, 6MWT i FSS odpowiednio o 61,37%, 63,01%, 58,26%, 55,12%, 36,48% i 22,35%, podczas gdy nie odnotowano znaczącej różnicy w odniesieniu do stosunku FEV1/FVC%. Wniosek. Można wywnioskować, że trening oddechowy z użyciem urządzenia do współbieżnego oporu przepływu (CFR) przez 12 tygodni był skuteczną techniką terapeutyczną poprawiającą siłę mięśni oddechowych i wydolność funkcjonalną u pacjentów ze schyłkową niewydolnością nerek poddawanych hemodializie.

Słowa kluczowe

powiększenie płuc, siła mięśni oddechowych, wydolność funkcjonalna, hemodializa



Introduction

Chronic kidney disease (CKD) is a widespread disorder, reaching about 11 to 13% of the world population and recognized to be a global health problem attributed to the high economic cost of health systems [1]. It is a chronic and progressive pathological condition characterized by kidney structural and/or functional abnormality with glomerular filtration rate less than 60 mL/min/1.73 m² lasting for 3 months or more and has impact on many aspects of the health [2]. It leads to end stage renal disease (ESRD) and results in patients to require dialysis and/or renal transplantation which together known as renal replacement therapy (RRT) [3].

In renal dialysis, multiple systems such as the musculoskeletal, cardiovascular and pulmonary systems are highly affected [4]. With progression of dialysis, it contributes to the development of uremic myopathy which is characterized by muscle wasting, reduces oxidative metabolism and proteins and reduction of physical performance [5]. Respiratory muscles function and respiratory system affected by lung function defects, reduced endurance and respiratory muscle strength. In progression of muscle weakness, it predisposes patients to gradually increase breathlessness, fatigue and induces the load on respiratory function and result in respiratory failure [6].

Reduction in functional capacity consider one of the major problems of patients on dialysis which manifested by reduced tolerance to exercise and daily activities [5]. The 6-minute walk test (6MWT) is the most common physical function measure used by exercise studies in HD patients and indicator of all-cause mortality. It correlated with cardiorespiratory health and endurance [7].

Maximum inspiratory pressure (MIP) and maximum expiratory pressure (MEP) produced during static efforts are indicators of respiratory muscles strength [8]. There is a relation between respiratory muscle strength (MIP and MEP) and volumetric parameters (FVC, FEV1) and the overall functioning of the respiratory system. The significant reduction in inspiratory muscle strength is related to expiratory muscle strength loss [9]. With long duration of hemodialysis functional capacity, respiratory muscle strength and lung function are reduced [10].

Reviewed reports indicated that respiratory training is a safe and effective modality in the treatment of hemodialysis. It improves the strength of the respiratory muscles, increases the resistance to effort, physical performance and improves the quality of life in ESRD patients [11].

Respiratory resistance training (RRT) act by reducing the diameter and increasing the resistance to airflow. RRT flow devices promote a training stimulus, thereby resisting the respiratory muscles to work harder. Over time, RRT with either an inspiratory resistance loading (IRL) or concurrent flow resistance (CFR) device, the respiratory muscles become stronger and more effective. By delivering resistance during inhalation, IRL devices cause an increased strain on the inspiratory muscles, while CFR devices provide resistance during both inhalation and exhalation [12]. For inspiratory and expiratory muscle exercise, Expand-a-Lung has a pressure threshold function. The combined training of inspiratory/expiratory muscle strength was useful in its effects, while it could be superior [13]. So, the aim of this study was to investigate determine the efficacy of intradia-

lytic respiratory training using concurrent flow resistance (CFR) on respiratory muscle strength and functional capacity.

Materials and methods

Study Design

Single-arm study (Pretest – Posttest) was designed to investigate determine the efficacy of intradialytic respiratory training using concurrent flow resistance (CFR) on respiratory muscle strength and functional capacity. The study was performed between November 2018 to December 2019. The research related to human use has been approved by the authors institutional review board at the Faculty of Physical Therapy, Cairo University with a reference number (P.T.REC/012/001575).

Participants

Forty patients with ESRD on HD for at least 4 months and age range from 30 to 40 years both sexes (20 men and 20 women) were recruited to participate from hemodialysis center at Fayoum University Hospital, Fayoum, Egypt (figure 1). All patients received a complete explanation of the objectives and procedures of the study. The written informed consent was signed by each patient before participation in the study. Before starting the the training program, a complete medical history and physical examination were done for all patients with particular attention paid to identify any long-term complications of renal dialysis and all patients received intradialytic respiratory muscle training for 3 times/week for 12 weeks. Inclusion criteria: ESRD on HD for more than 4 months 3 sessions per week, each dialysis session continuing for 3-4 hours per day. Their age ranged from 30 to 40 years. Clinically stable patients. BMI > 18.5 kg/m². Exclusion criteria: cardiac patients, kidney transplantation, chronic respiratory disease, arterial blood pressure (BP) \geq 180/100 mmHg or \leq 100/60 mmHg; mean arterial blood pressure (MABP) < 60 mm Hg and patients with clear inability to use a respiratory device.

Instrumentations

Assessment equipment and tools

• Micro Respiratory Pressure Meter: (MicroRPMTM made in USA). It was a handheld manometer with a disposable mouthpiece and used to calculate maximum inspiratory pressure (MIP) and maximum expiratory pressure (MEP)

• Electronic Spirometer: (Model-Schiller AG, CH6304) was used to measure pulmonary function test; forced vital capacity (FVC), forced expiratory volume in 1st second (FEV1), and Tiffeneau index (FEV1/FVC).

• Fatigue severity scale (FSS): questionnaire containing 9 items used to measure severity of fatigue and how much it affects the activities of person and life style.

• Six-minute walk test: Used to measure Functional capacity for each patient.

Treatment tool

Expand-a-Lung: (made in USA). It is pressure threshold inspiratory/ expiratory breathing resistance trainer used to improve strength of respiratory muscles. It includes a comfortable silicone mouthpiece of medical grade, adjustable resistance valve (resistance includes 5 grades from 1 to 5) and only one moving component. Turning the valve to the left limits the flow of air and causes more resistance.



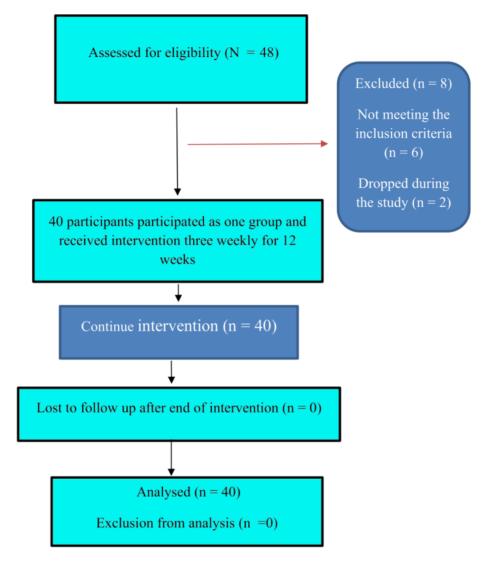


Figure 1. Flow chart of the study

Procedures

Assessment procedures

An assessment of each patient in the was performed before and after 12 weeks of training program as following:

Maximum inspiratory and expiratory pressure

Maximum respiratory pressures maneuver was explained to each participant using a disposable mouthpiece. In the sitting 90-degree position, the subject was instructed to keep a tight lip seal around the mouthpiece and give maximum effort. A tight-fitting nose clip was attached to the patient's nose to prevent leakage of air [14].

MIP: from tidal breathing ask patient to exhale slowly and completely then perform a strong inhalation as much as possible into the lungs and sustained for about 0.5–1 sec. and the highest three MIP were recorded

MEP: from tidal breathing ask patient to inhale slowly and deep then expire as fast and powerful as possible from the lungs sustained for about 0.5-1 sec. and the highest three MEP were recorded

Respiratory muscle weakness was determined when absolute MIP or MEP less than 80% of predicted. The predicted values determine using age, weight and height in each patient.

Pulmonary function test

The test was performed in the sitting 90-degree position and the correct maneuver was demonstrated. Then a nose-clip attached and a mouthpiece was inserted into the subject's mouth. Asked the patient to inhale completely and rapidly then exhaled maximally until no more air could be expelled. The highest three values were recorded.

Six-minute walk test (6MWT)

6MWT performed according to American Thoracic Society (ATS-2002) in a hard surface, covered, flat and walled corridor that was 30 m long and signed every 3 m. Participants were instructed to walk as quickly as possible for 6 minutes without running. If required, the patient was allowed to rest, while the clock continued to run. In meters, the total distance was measured [15].



Fatigue severity scale (FSS)

Self-report fatigue questionnaire, containing 9 items used to measure severity of fatigue. Each item was rated on a 7-point Likert scale (1 'strongly disagree' and 7 'strongly agree') [16]. Patients were asked to complete the FSS analysis to estimate how tired they felt. They circled the number between 1 and 7 during the last week that they felt was best suited for the statements. For the Scoring Fatigue Severity Scale (FSS), the total score was estimated for each participant and the sum of all scores was divided by nine. Score 1 indicated lack of fatigue, 2-4 indicated medium fatigue, 5 and above indicate severe fatigue [17].

Training Procedures

Before the initiation of exercise training program:

• All patients were submitted to a clinical assessment that consisted of personal data collection, past and present history and physical examination.

• The purpose and procedures of the training program were explained for each patient.

Training Protocol

The protocol for respiratory training was executed using concurrent flow resistance (CFR) device (expand-a-Lung), which allowed 5 grades of resistance. Respiratory training was performed for 12 weeks, three times per week during the first two hours of hemodialysis session.

The training techniques were discussed orally to each participant to ensure the proper way of training. The patient was seated at 90 degrees and place the nose clip to ensure that the breathing is done through the mouth then instructed to: (a) Place the lips by forming a powerful seal around the mouthpiece. (b) Inhale as slowly and deeply as possible through the expanda-Lung device's mouthpiece, (c) breath holds for 2 to 5 seconds, (d) exhale slowly through the mouthpiece until almost out of breath. (e) Patients were encouraged to blow out as much of the remaining residual air [12]. This was performed for 3 sessions/week for 12 weeks. Each single training session contains 3 sets; 10 repetitions/set of respiratory training with 10 to 20 second rest periods between each maneuver and total are 30 repetitions in each session and 5-min rest between sets. Each 2 weeks adjusts the resistance. Once they were able to perform the sequence 10 times (1 set) without experiencing respiratory muscle fatigue, lightheadedness, or dizziness, they were instructed to increase the resistance to airflow by 1 level [5]. If the participant unable to move to the next level, he continued at the same level of training to the next week.

Statistical procedures

Statistical analysis

In this study, Results are expressed as mean, standard deviation and standard error of mean. Test of normality, Shapiro Wilk test, was used to measure the distribution of data. So in normally distributed variables, comparison between data measured at pre-training and 12 weeks post-training times was performed using paired t test. In not normally distributed variables, comparison between data measured at pre-training and 12 weeks post-training times was performed using Wilcoxon Signed Ranks test. Correlation between difference in six-minute walk test (6 MWT) and difference in different respiratory function tests and FSS in the studied group was performed using either Pearson correlation coefficient or Spearman's rho correlation coefficient whenever it was appropriate. Statistical Package for Social Sciences (SPSS) computer program (version 19 windows) was used for data analysis. P value ≤ 0.05 was considered significant.

Sample size calculation

Based on a pilot study, sample size was calculated according to the significant difference in the mean value of maximal inspiratory pressure measured at pre-training (52.6 ± 11.66) and their corresponding values measured after 12 weeks of training (82.5 ± 16.51) in paired t test, with $\alpha = 0.05$, power of 80%, and an effect size of 0.46. So a sample size of 40 patients/per group would be required (GPower 301 http://www.psycho.uniduesseldorf.de).

Results

Table 1 presents the demographic information for the study sample and summarized baseline measures.

Table 1. Demographic data of the participants

Variables	Mean ± SD
Age [years]	34.72 ± 3.25
Weight [kg]	82.43 ± 21.03
Height [cm]	165.55 ± 9.24
BMI [kg/m ²]	30.24 ± 8.36

SD – Standard deviation

Table 2 revealed statistically significant difference (p < 0.05) for FVC%, and FEV1% where the mean difference was 1.57 and 1.27 respectively with (p-value 0.001). However, there was no statistical significant difference (p > 0.05) for (FEV1/ FVC%) where the mean difference was 0.27 with (p-value 0.732). Additionally, there was significant difference (p < 0.05) as regard

to MIP and MEP and the mean difference was 37.37 and 35.87 respectively with (p-value 0.001). Also, there was a statistical significant difference (p < 0.05) for Six-minute walk test (6MWT) as the mean difference was 169.09 with (p-value 0.001) and statistical significant difference (p < 0.05) for Fatigue severity scale (FSS) as the mean difference was 1.41with (p-value 0.001).

fizjoterapia polska

Table 2. The mean values, standard deviations and mean difference between pre and post treatment for all measured variables of the participants

Study Group					
Variables	Pre-training Mean ± SD	Post- training Mean ± SD	Mean difference	% of change	Significance
MIP (cmH ₂ O)	60.89 ± 13.52	98.26 ± 21.35	37.37	61.37 ↑	S
$MEP(cmH_2O)$	56.93 ± 15.72	92.80 ± 25.16	35.87	63.01 ↑	S
FEV1 (%)	2.18 ± 0.49	3.45 ± 0.76	1.27	58.26↑	S
FVC (%)	2.86 ± 0.94	4.43 ± 1.33	1.57	55.12↑	S
FEV1/FVC (%)	80.15 ± 14.78	79.88 ± 11.20	0.27	0.34↓	NS
6MWT	463.56 ± 74.35	632.65 ± 87.55	169.09	36.48 ↑	S
FSS	6.31 ± 0.49	4.90 ± 0.63	1.41	22.35 ↓	S

Significant (p < 0.05) difference between pre and post 12 weeks, FVC (%): Forced Vital Capacity; (FEV1): Forced Expiratory Volume in one second; (FVC\ FEV1% ratio); MIP (cmH₂O): Maximum Inspiratory Pressure; MEP (cmH₂O): Maximum Expiratory Pressure (6MWT): Six-minute walk test; (FSS): Fatigue severity scale; SD: Standard deviation; NS: Non significant; S: significant, \uparrow or \downarrow .

Table 3 revealed that there was no statistical significant correlation between difference in six-minute walk test and difference in

FEV1/FVC (r = 0.285; p = 0.075), MEP (r = 0.059; p = 0.717), MIP (r = 0.084; p = 0.604) and FSS (r = 0.176; p = 0.277).

Table 3. Correlation between difference in six-minute walk test (6 MWT) and difference in different respiratory function tests and FSS in the studied group

	r	P value
FEV1/FVC	0.285	0.075
MEP	0.059	0.717
MIP	0.084	0.604
FSS*	0.176	0.277

 $r = Pearson \ correlation \ coefficient$; $r = Spearman's \ rho \ correlation \ coefficient$; $S = p > 0.05 = not \ significant$

Discussion

The current study was designed to investigate the possible effects of intradialytic respiratory training on respiratory muscle strength and functional capacity in ESRD patients. Results of present study evidenced that respiratory muscle training by expand-a-Lung for 12 weeks' increase MIP & MEP compared to pre-training by 61.37% and 63.48% respectively. Further support of these results arise from the previous data by Gee et al. [18] who reported significant increases of 40% and 25% in MIP and MEP after 6 weeks of respiratory muscle pressure threshold practice, respectively. The effect of combined inspiratory and expiratory muscle training increases respiratory muscle strength. Also, Bahey El-Deen et al. [4] stated that after three months of inspiratory muscle training, there was a significant difference in MIP and MEP. Pellizzaro et al. [5] documented the results of 10 weeks of aerobic exercise and inspiratory muscle training in 45 patients with HD showed a significant improvement in MIP, with a mean positive variation of 15% relative to the predicted. While there was no expiratory muscle training performed, MEP also increased significantly, which may be attributed to the work imposed on the abdominal muscles during the intervention. By increasing MIP, an improvement in inspiratory muscle strength improves MEP. Neural conditioning resulting from repeated exposures

to the same activity [learning effect], a mechanism that causes an improvement in the strength of the respiratory muscle by enhancing the pattern of neuromuscular recruitment [19].

Consequences by Soares et al. [20] who studied the effects of the two protocols of inspiratory muscle training for 6 months on HD showed that MIP increased by 28.3% and 39.8% respectively in both groups and no significant differences were observed in either group with MEP.

The results of present study disagree with data presented by Silva et al. [21] who studied the impact of 8 weeks of inspiratory muscle training on 15 patients with chronic renal failure undergoing hemodialysis and did not display any statistically significant difference in respiratory muscle strength [MIP & MEP] when comparing findings before and after IMT. This may be due to inadequate training programme intensity; they increased duration but did not increase load training, while the other programmers increased the intensity of inspiratory muscle training. [22]

Results of the current study showed significant improvement in FEV1% and FVC% by 58.26% and 55.12% respectively, and no significant improvement for FEV1/FVC ratio by 0.34% after 12 weeks of training. These results coincided with the results presented by Bahey El-Deen et al. [4] who studied the role of the Inspiratory Muscle Trainer [IMT] on 15 patients with



sedentary hemodialysis and stated that there was a statistical significant difference in FVC%, FEV1% and no statistical significant difference in the FEV1/FVC ratio. Also, Elsisi et al. [23] studied the effects of 12-week IMT on pulmonary function in HD patients and demonstrated a significant increase in post-treatment FVC & FEV1 compared to pre-treatment. Hassan et al. [24] evaluated the effect of aerobic training combined with inspiratory muscle training on pulmonary functions in HD patients and confirmed that inspiratory muscle trainer improves respiratory muscle strength and pulmonary functions with regard to FVC & FEV1.

The results of present study disagree with data presented by Silva et al. [21] provided that the lung functions [FVC%, FEV1% and FEV1/FVC ratio] was not statistically significant difference after 8 weeks of inspiratory muscle training. Also, Soares et al. showed no significant difference in spirometric variables [FEV1, FVC and FEV/FVC ratio] after IMT for 6 months. [20] Reduction in FEV1 associated with decreased muscle strength (MIP & MEP) [25].

Results of the present study showed that there was a statistical significant increase in 6MWD measured at 12 weeks post-training by 36.48%. Our findings are remarkably similar to those previously reported by Pellizzaro et al. [5] who stated that the distance walked at 6MWT and functional capacity was significantly increased. A relation between MIP and the distance walked in the 6MWT was also found, indicating that strength training of inspiratory muscles in HD patients can increase functional performance. Further agreement of our results arise from the previous data by Yuenyongchaiwat et al. [22] after 8 weeks' inspiratory muscle training, the walking distance increased in inspiratory muscle training group. Also, Abdelaal and Abdulaziz [26] who stated that after 20 week of exercise training; there were significant increases in physical performance and functional balance in patients undergoing maintenance hemodialysis. Improvements of FC in HD patients due to various underlying mechanisms as increased blood flow to the exercised muscles and beneficial adaptations within the skeletal muscles.

Dipp et al. [1] showed no changes in functional capacity between groups in 6MWT after 5 weeks of intradialytic high intensity inspiratory muscle training. And there have been several influences that could explain the lack of positive functional capacity outcomes: short duration for peripheral effects to occur and patients in training group were more sedentary than in the control group. Results of present study showed that there was a statistical significant decrease in fatigue level measured at 12 weeks post-training by 22.35%. This result Compatible with Salehi et al., [27] who showed that after 3 months of exercise on mini-bikes, there was a significant decrease in fatigue levels between the study and control groups, stating that exercise is a potentially promising way of reducing the normal progression of fatigue in patients with hemodialysis. In line with our results, Maniam et al. [28] reported that in HD, simple low-to-moderate-intensity exercise is beneficial in improving fatigue and the overall quality of life. Also, Soliman [29] reported that there was a significant reduction in level of fatigue after 8 weeks of the Intradialytic exercise program. Post respiratory training there was decreasing in respiratory muscle fatigue. improved blood flow to the working muscles due to attenuation of the metaboreflex respiratory muscle and empowering subjects to walk a greater distance. [30]

From the above findings, structuring effective respiratory training programmers with concurrent flow devices are helpful for the improvement of functional capacity and respiratory muscle strength among patients in ESRD with HD and there was no statistical significant correlation between functional capacity [6MWT] and respiratory muscle strength (MEP, MIP).

Although effective respiratory training programmers with concurrent flow devices are helpful for the improvement of functional capacity and respiratory muscle strength among patients in ESRD with HD, it has some limitations as the finding cannot be generalized because absence of control group. In addition, the study lacked a follow-up of the effect of the respiratory training programmers on functional capacity and respiratory muscle strength among patients in ESRD with HD for several months after a rehabilitation program to evaluate the long-lasting effect.

Conclusion

In conclusion, this study support the previous studies which found that intradialytic respiratory training with concurrent flow resistance could counteract respiratory muscle deconditioning without increasing fatigue and improving functional capacity and respiratory muscle strength among patients in ESRD with HD.

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