EFFECT OF MULTIMODAL PHYSIOTHERAPY ON OUTCOME OF MECHANICALLY VENTILATED PATIENTS AT ZAGAZIG UNIVERSITY RESPIRATORY INTENSIVE CARE UNIT IN (2014-2015)

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ABSTRACT

Background: In critically ill patients,physiotherapy and inspiratory muscle training are considered important components of pulmonary rehabilitation;as they enhance the weaning process and help patients to return to their optimal functional capacities. The aim of this work was to compare the possible benefits and risks of delivering multimodal physiotherapy (PT) to mechanically ventilated patients to improve patients' outcome.

Patients and Methods: Forty mechanically ventilated patients with acute or acute on top of chronic respiratory failure from ZUH (RICU) were enrolled in a randomized controlled clinical trial. The patients were classified equally into test group and control group, control group patients were subjected to conventional PT, while test group patients were subjected to inspiratory muscle training in addition to conventional PT. Pre and post assessment of SAPSII and Barthel index scores, PImax, RSBI and weaning outcomes were done for both studied groups.

Results: Both patients' groups were matched together as regards age, sex, ABG, diagnosis and comorbidities. The test group had a high significant lower frequency of conventional PT sessions in relation to control group 8 and 12 sessions respectively (P<0.01). Barthel index was improved post physiotherapy in the test group better than control group but without statistical significant difference (P>0.05).There was high significant improvement in PImax post-PT in the test group when compared to control group (-34.3±6.02 cmH2O) versus (-24.6±2.45 cmH2O) respectively (P<0.001).The indices of weaning were significantly improved in test group than control group as regards PaO_2/FIO_2, PImax and RSBI (P<0.05).The incidence of complications (VAP, Bed sore and Electrolyte imbalance) increased among the control group than the test group but without statistical significance differences (P>0.05).The weaning success was (90% &70%) in test group versus control group, while the duration of MV, duration of weaning and length of ICU stay were significantly reduced in test group (5, 4.5 and 8.8 ± 2.22 days) versus control group (6, 6 and 11.95 ± 3.4.2 days), (P<0.05, P<0.01 and P<0.001), respectively.

Conclusion: Conventional chest physiotherapy is safe ICU intervention with few complications. Adding inspiratory muscle training (using a threshold pressure device) to the conventional physiotherapy can improve maximum inspiratory pressure,functional capacity and RSBI, with potential reductions in length of ICU stay and the duration of invasive mechanical ventilation.

Keywords: Physiotherapy, Inspiratory muscle training, Mechanical ventilation, Intensive Care Unit.

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INTRODUCTION

Mechanical ventilation (MV) causes respiratory muscle weakness which is associated with prolonged duration of mechanical ventilation and may be even noticed several days after successful weaning [1,2].

Mechanically ventilated patients usually have large amounts of respiratory tract secretions due to mucociliary dysfunction and impaired mucous transport. So, many pulmonary complications e.g. lung collapse, retained secretions and ventilator associated pneumonia may develop. The application of different physiotherapy modalities to mechanically ventilated intensive care unit (ICU) patients may aid secretion clearance and improve lung volumes [3].

Ongoing advances in the management of critically ill patients have improved outcomes and survival rates for those patients. The use of physiotherapy techniques (PT) for critically ill patients may decrease the long-term complications which involve the ICU survivors after hospital discharge [4].

Inspiratory muscle dysfunction is a main prognostic factor for ICU readmission. As inspiratory muscle endurance and strength have been reported frequently in weaned patients, so improving the respiratory muscle endurance and strength are required to a certain threshold to allow successful weaning [5].

The aim of this study was to compare the possible benefits and risks of delivering multimodal physiotherapy (PT) to mechanically ventilated patients to improve patients' outcome.

PATIENTS AND METHODS

This study was carried out on a total of 40 intubated and mechanically ventilated patients with acute or acute on top of chronic respiratory failure who were referred to Respiratory Intensive Care Unit at Zagazig University Hospitals over a period of 2 years (May 2014 to April 2016) after the approval from IRB (Institutional Review Board) Zagazig University had been obtained.

Inclusion criteria:

1) Patient's age is more than 18 years old.
2) Patients on invasive mechanical ventilation for 24 hours and expected to continue at least 24 hours.
3) Hemodynamically stable: heart rate 40-150 beat/min, mean arterial blood pressure 65-110 mmHg, respiratory rate 5-35 breaths/min, $SaO_2 \geq 88\%$.
4) Barthel index score ≥70 two weeks before hospital admission.

Exclusion criteria:

1) Progressive neuromuscular disease that may interfere with physiotherapy.
2) Active myocardial ischemia, dysrythmia and cardiopulmonary arrest.
3) Active GIT (gastro-intestinal tract) bleeding.
4) Increased intracranial tension.

Study design: randomized controlled clinical trial.

(1) Control group:

Twenty patients were subjected to conventional physiotherapy.

(2) Test Group:

Twenty patients were subjected to inspiratory muscle training (IMT) via threshold IMT device in addition to conventional PT protocol.

Study operations:

A) Informed consent were taken from the patients' relatives

B) The following data were reported for all patients:

1) **Clinical diagnosis** of the studied cases (thorough medical history from the relatives, full clinical examination, radiological examination, arterial blood gas (ABG), electrocardiogram (ECG), previous pulmonary function test (PFT) and previous Polysomnograph (PSG)).

2) Simplified acute physiology score II (SAPS II) [6].

SAPS II was measured to assess the severity of disease of studied patients on ICU admission. The point score is calculated from : 12 physiological variables during the first 24 hours, data about previous health status, age and type of admission (scheduled surgical, medical or unscheduled surgical) SAPS II was calculated by SAPS II calculator (Scholar Google)

3) Applied protocol of MV was Synchronized Intermittent Mandatory Ventilation Mode (SIMV) – pressure control (PC) or volume control (VC) with pressure support (PS) 20 and positive end-expiratory pressure (PEEP) 5 cmH_2O.

4) Medications which were used during ICU stay: Antibiotics, bronchodilators, sedatives, prophylactic anticoagulant (LMWH, UFH), corticosteroids and diuretics (loop and K sparing).

C) All patients of the study were subjected to the followings:

1) Calculation of Barthel index score [7]. Score (0-100)

This Index characterizes the ability of the patient to carry out daily living activities on a scale starting from 0 (total dependence) to 100 (complete independence), as the score gets higher the more the functional independence. Barthel Index consisted of 10 items: dependent or independent for feeding, bathing, grooming or dressing; toilet use; mobility on level surfaces (immobile, wheelchair use, need help to walk or independent): able to transfer (bed to chair and back) and to use stairs; continent or incontinent "bowels and bladder". Questions are as the followings: can do by yourself, can do with help of someone else or cannot do at all?

BI was calculated in the stable state, two weeks before admission, and it was attained from the main caregiver. Depending on the functional status, patients were divided into: in-dependent (Barthel score between 81 and 100) or dependent for basic daily living activities (≤80 points)

2) Physiotherapy modalities which were applied:

I- Control group:

Conventional PT *(done every 12 hours), It included:*

1) Mobilization

- Posture
- Passive and active limb exercise

2) Airway secretion management

- Active cycle of breathing technique (for cooperative patients): It is formed of 3 phases (deep breathing technique, thoracic expansion exercise and huffing "Forced expiratory technique").
- Percussion & vibration

II- Test group:

Conventional PT which was applied in control group in addition to Inspiratory muscle training (IMT)

Inspiratory muscle training using (Threshold IMT device). Threshold®, Philips Respironics, Brussels, Belgium

- Pressure-threshold setting is obtained by an adjustable, spring-loaded, threshold poppet valve device.
- Wide range of training intensities between 9-41 cm H_2O are provided by the device.
- Patient must generate an inspiratory negative pressure higher than the indicated threshold pressure setting to compress the spring and open the poppet valve.
- The inspiratory negative pressure must be sustained above the threshold pressure to maintain the poppet valve open.
- The device releases an auditory feedback once a successful breath is completed due to oscillatory motion of spring.
- Connected to endotracheal tube or mouse piece with the patient in bed 45 head-up tilt.
- It was applied twice daily till extubation at 9 am, 6 pm.
- Starting with 9 cm H_2O and each session was consisted of 4 sets of 6-8 breaths and each session was increased by 4 cm H_2O and 5 min in duration maximum 30 min.
- A period of 1-2 minutes rest between sets was done, during which the patients was placed on the ventilator.
- Supplemental oxygen if needed.

Discontinuation of PT sessions: [4]

The session was discontinued if;

- Mean arterial blood pressure <65mmHg or >110mmHg, systolic blood pressure >200 mmHg.
- Heart rate (HR) <40 beats /min or >130 beat /min.
- Respiratory rate (RR) <5 breath /min or > 35 breath /min.
- SaO_2 <88% (pulse oximetry).
- Development of serious side effects as unplanned extubation, arrhythmia.

3) Weaning protocol:

I-1) Criteria for starting weaning trial [8].

Criteria for starting weaning trial
Subjective assessment
Effective cough
No neuromuscular blockers
No excessive tracheabronchial secretion
Relieving of the cause of respiratory failure
No continuous use of sedatives infusion
Objective measurements
cardiovascular Stable
Heart rate ≤ 140 beat/minute
No activity of the myocardial ischemia
Hemoglobin ≥ 8 g/dl.
Systolic blood pressure 90–160 mmHg
No fever (36°C < temperature < 38°C)
No or low dose vasopressors or inotropes (< 5 µg/kg/minute dopamine or dobutamine)
Adequate oxygenation
Tidal volume > 5 mL/kg
Vital capacity >10 mL/kg
Adequate inspiratory effort
Respiratory rate ≤ 35/minute
$PaO_2 \geq 60$ and $PaCO_2 \leq 60$ mmHg
Positive end expiratory pressure (PEEP) ≤ 8 cmH_2O
No significant respiratory acidosis (pH ≥ 7.30)
Maximal inspiratory pressure (PImax) ≤ -20 – -25 cmH_2O
O2 saturation > 90% on $FIO_2 \leq 0.4$ (or $PaO_2/FIO_2 \geq 200$)
Rapid Shallow Breathing Index (RSBI)< 105

I-2) Spontaneous breathing trial (SBT):

- Method of SBT: Low level pressure support (reduction of pressure support by 2 cmH_2O as tolerated by patients to reach 5-8 cmH_2O).

- Classification of weaning outcome according to SBT: **[9]**

1- Simple: SBT is successful after the first trail.

2- Difficult: failure of initial SBT and patients need up to three SBT or less than or equal 7 days to reach the successful SBT.

3- Prolonged: failure of at least three weaning trails or patients need more than 7 days to achieve successful SBT.

I-3) Planning for extubation:

- By evaluating quantity of airway secretions, mental status and cough strength.
- When patients could breath unassisted and protect their airways, extubation was done 24hrs post successful SBT with follow up for 48 hrs after extubation.

I-4) Weaning outcomes:

a) Weaning success: Removal of endotracheal tube (ETT) and the absence of ventilator support for 48 h after ETT removal **[10]**.

b) Weaning failure: defined as: **[8]**

- Failed SBT. OR
- Reintubation and/or return to ventilatory support within 48h after extubation.

4) Assessment and follow up during the study (at commencement of training and at 48 hours post extubation)**:**

I- Simplified acute physiology score II (SAPS II) **[6]**

II- Barthel index score (Baseline functional independance) **[7]**

III- Assessment of muscle strength: PI max.

5) End point of the study

1- Number of functional independent ADLs: Independent functional status is defined as the ability to carry out 6 activity of daily living (ADLs) {bathing, dressing, eating, grooming, transferring from bed to chair, using toilet} and walking independently. ADL score ≥5 meant that the patient is independent (no need for further physiotherapy) **[4]**.

2- Death.

3- Transfer of patient to another ICU.

6) Major Outcomes: [11]

1- Weaning outcome.

2- Duration of the period of weaning from MV (i.e., commencement of SBT until extubation). **[12]**

3- Duration of MV, length of ICU stay.

4- Mortality

STATISTICAL ANALYSIS

All data were collected, tabulated and statistically analyzed using SPSS 16.0 for windows (SPSS Inc., Chicago, IL, USA). Quantitative data were expressed as the mean±SD & median (range), and qualitative data were expressed as absolute frequencies (number) & relative frequencies (percentage). Continuous data were checked for normality by using Shapiro Walk test. Independent student t-test was used to compare two groups of normally distributed data while Mann-Whitney U was used for non-normally distributed data. Percent of categorical variables were compared using Chi-square test or Fisher's exact test when appropriate. Spearman's rank correlation coefficient was calculated between major outcome, Barthel index, RSBI and PImax and between PImax and both pressure generated and duration of IMT, (+) sign indicate direct correlation & (-) sign indicate inverse correlation, also values near to 1 indicate strong correlation & values near 0 indicate weak correlation. All tests were two sided, $P<0.05$ was considered statistically significant, $P<0.001$ was considered highly statistically significant, and $P\geq0.05$ was considered statistically non- significant.

RESULTS

Both patients' groups were matched together as regards age, sex distribution, ABG, diagnosis and comorbidities ($P>0.05$), (Table 1).

The two studied groups were matched with no statistical significance differences as regards SAPS II on ICU admission and Barthel index scores two weeks prior to ICU admission ($P>0.05$). There were no statistically significant difference between the studied groups regarding ventilator mode and variables (Fio_2, tidal volume, respiratory rate, pressure support and PEEP) ($P>0.05$) (Data not shown).

The test group had a high significant lower frequency of conventional PT sessions in relation to control group 8 and 12 sessions respectively ($P<0.01$) where the frequency of IMT was the same as conventional PT sessions among test group (8 sessions) (Data not shown).

The test group patients showed more adverse effects (new arrhythmia, HR change >130, desaturation ≤88%) during IMT sessions and there was statistical significant difference between both groups ($P<0.05$) (Data not shown).

There was statistical significance difference as regards the mean% of change of pressure generated and PImax at the start and end of the IMT sessions in the test group ($P<0.001$), (Table 2).

There was statistically significant positive correlation between PImax pre sessions and pressure generated, while there was significant negative correlation between PImax pre sessions and duration of IMT in test group (Table 3).

The median ADLs in test and control groups were (6 & 5) respectively with no statistical significant difference (Data not shown).

There were no statistical significance differences between test and control group in SAPS II pre and post sessions and mean percent of change ($P>0.05$) (Table 4).

Barthel index was improved post physiotherapy in the test group better than control group but without statistical significant difference ($P>0.05$) and also the mean% of change of Barthel index in the test group was significantly changed pre and post sessions ($P<0.001$), (Table 5).

There was high significant improvement of PImax post PT in the test group when compared to control group (-34.3±6.02 cmH_2O) versus (-24.6±2.45 cmH_2O) respectively ($P<0.001$) (Table 6).

The indices of weaning were improved in test group than control group with statistical significance differences as regards PaO_2/FIo_2, PImax and RSBI ($P<0.05$) (Data not shown).

The incidence of complications (Ventilator-associated pneumonia “VAP”, Bed sore and Electrolyte imbalance) increased among the control group than the test group but without statistical significance differences ($P>0.05$) (Data not shown).

The frequency of weaning success was increased among test group (90%) versus control group (70%), but statistically insignificant ($P>0.05$), while the duration of MV, duration of weaning and length of ICU stay were significantly reduced in test group (5, 4.5 and 8.8 ± 2.22 days) versus control group (6, 6 and 11.95 ± 3.4.2 days), ($P<0.05$, $P<0.01$ and $P<0.001$), respectively (Table 7).

There was statistical significant negative correlation between Barthel index pre sessions and duration of mechanical ventilation, duration of weaning and ICU LOS in both groups, while there was no statistical significant correlation between RSBI pre sessions and different major outcomes, lastly there was significant negative correlation between PImax pre sessions and duration of MV in both groups (Data not shown).

Table (1): Baseline characters of the two studied groups.

Variable	Test (n=20)		Control (n=20)		t	P
Age : (year)						
Mean ± SD	57.5 ± 8.66		58.1 ± 8.21		0.23	0.60
Range	35 - 67		41 - 69			NS
Variable	**No**	**%**	**No**	**%**	χ^2	**P**
Sex:						
Female	12	60	9	45	0.90	0.34
Male	8	40	11	55		NS
ABG					**t-test**	**P**
PH:						
Mean ± SD	7.27 ± 0.03		7.27 ± 0.03		0.142	0.887
Range	7.21 – 7.29		7.23 – 7.29			(NS)
PCO_2:						
Mean ± SD	80.35 ± 8.39		80.30 ± 7.42		0.020	0.984
Range	65 - 95		68 - 92			(NS)
PaO_2:						
Mean ± SD	51.60 ± 4.44		51.15 ± 4.15		0.331	0.743
Range	40 - 56		42- 57			(NS)
Diagnosis:					χ^2	
COPD	4	20	4	20		
Bronchial Asthma	2	10	2	10		
COPD & Bronchiectesis	2	10	2	10		
COPD & pneumonia	2	10	2	10	0	1
Bronchiectesis	2	10	2	10		NS
Neurologic (Myathenia gravis)	2	10	2	10		
Overlap syndrome (COPD+OSA)	6	30	6	30		
Comorbidity:						
Hypertension	6	30	5	25	0.12	0.72 NS
Diabetes mellitus	5	25	8	40	1.03	0.31 NS
Old stroke	0	0	2	10	2.11	0.15 NS
Hepatic	3	15	4	20	0.17	0.67 NS
Ischemic heart disease	4	20	3	15	0.17	0.67 NS

Table (2): Inspiratory muscle training in test group.

Time	Pressure generated	PImax
Start of IMT sessions:		
Mean±SD	-9	-12.9 ± 3.29
Range		(-7) – (-18)
End of IMT sessions:		
Mean±SD	-34 ± 4.83	-34.3 ± 6.02
Range	(-25) – (-41)	(-21) – (-43)
Mean % of change	**25.9%**	**157.1%**
P	**<0.001****	**<0.001****

Table (3): Correlation between PImax and both pressure generated and duration of IMT in test group.

Group	Variable		Pressure generated	Duration of IMT
Test	PImax pre	R	**0.533**	**-0.509**
		P	**0.01***	**0.02***

Table (4): Effect of physiotherapy on SAPS II score among the two studied groups.

Time	Variable	Test (n=20)	Control (n=20)	MW	P
Pre PT	**SAPS (points)**				
	Median	29	27	0.2	0.92
	Range	18 – 38	22 - 44		NS
Post PT	**SAPS(points)**				
	Median	23	20	-0.13	0.89
	Range	12 – 53	19 - 53		NS
Mean % of change		**-11.13%**	**-4.05%**	-0.79	0.43 NS
P		0.125 NS	0.79 NS		

Table (5): Effect of physiotherapy on Barthel index among the two studied groups.

Time	Variable	Test (n=20)	Control (n=20)	MW	P
Pre PT	**Total:**				
	Median	77.5	75	0.02	0.98
	Range	70 – 85	70 - 85		NS
Post PT	**Total:**				
	Median	100	90	-1.541	0.157
	Range	0 – 100	0 - 100		NS
Mean % of change		21.07%	13.5%	1.87	0.06 NS
P		**<0.001****	0.89		

Table (6): Effect of physiotherapy on PImax among the two studied groups.

Time	Variable	Test (n=20)	Control (n=20)	t-test	P
Pre PT	**PImax (cmH_2O)**				
	Mean ± SD	-12.9 ± 3.29	-13.4 ± 2.32	0.610	0.545
	Range	(-7) – (-18)	(-8) – (-16)		NS
Post PT	**PImax (cmH_2O)**				
	Mean ± SD	-34.3 ± 6.02	-24.6 ± 2.45	**6.63**	**<0.001****
	Range	(-21) – (-43)	(-20) – (-29)		

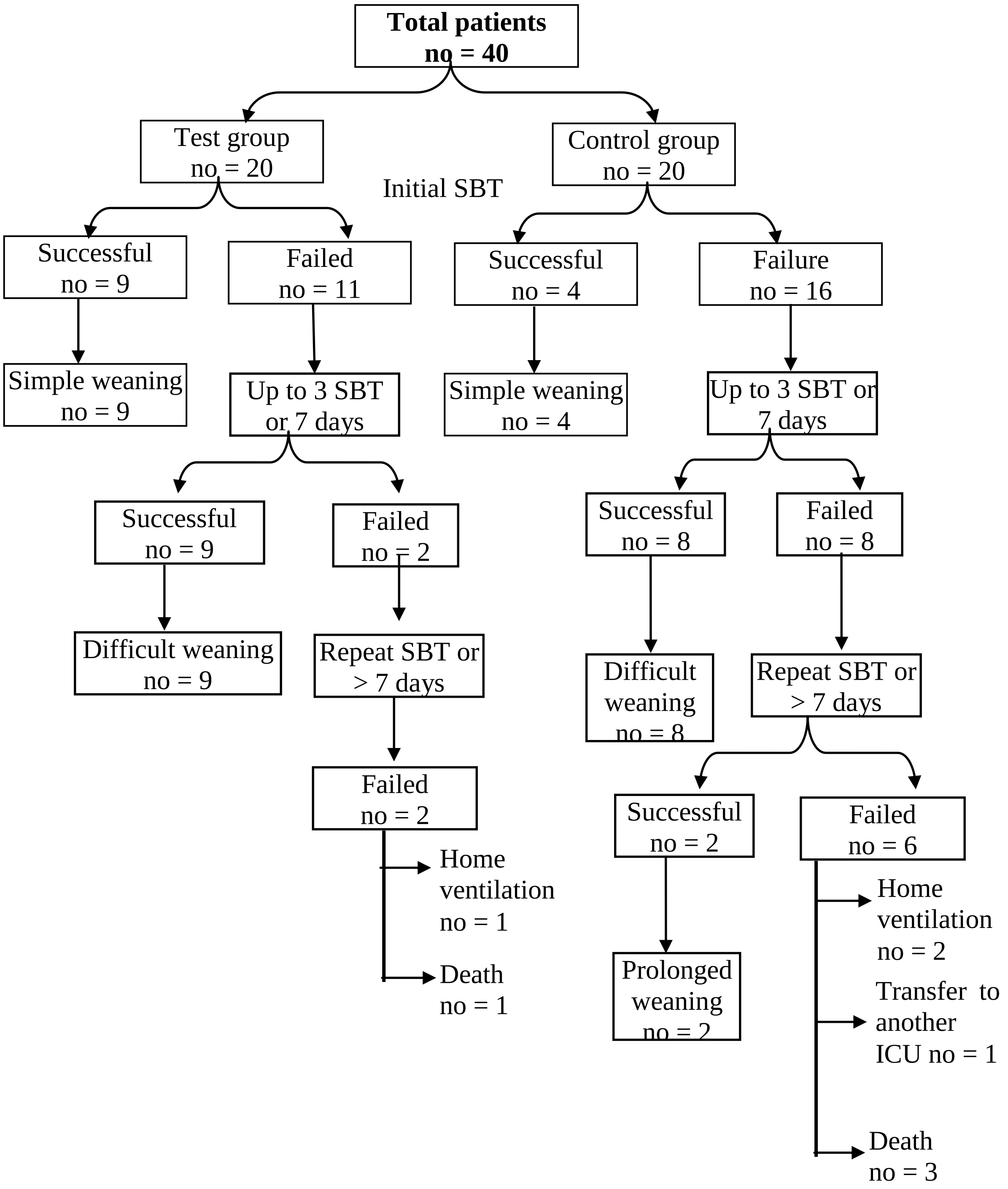

Fig. (1): Weaning outcome of the studied patients according to SBT.

Table (7): Final outcome in relation to different modalities of physiotherapy.

Variable	Test		Control		t-test	P
	No	%	No	%		
Weaning:						
Successful	18	90	14	70	2.5	0.11
Failure	2	10	6	30		NS
Duration of MV: (Days)						
Mean ± SD	5.65 ± 3.63		7.84 ± 4.62		2.10	**0.03***
Range	3 - 15		4 – 18			
Duration of weaning:(Days)					**MW**	
Median	4.5		6		**2.995**	**0.003***
(Range)	(3 – 14)		(4 – 17)			
ICU LOS: (Days)					**t**	
Mean ± SD	8.8 ± 2.22		11.95 ± 3.42		**6.13**	**<0.001****
Range	5 - 15		7 – 18			
Mortality:					X^2	
No	19	95	17	85	1.39	0.23
Yes	1	5	3	15		NS

DISCUSSION

In the critical ICUs, the objectives of physiotherapy are to provide cost-effective, advanced therapeutic techniques to decrease ventilator dependency, to prevent new hospitalizations and to make a better patient's quality of life. Early physiotherapy may avoid delayed weaning, limitation of mobility and complete ventilator dependency. So both physiotherapy and process of weaning are two important and closely related interventions that enhance the patient's recovery **[13]**.

We aimed at comparing the benefits and risks of delivering multimodal PT to mechanically ventilated patients to improve patients' outcome.

In the current study, the mean age of patients was 57.5±8.66 years old in test group and 58.1±8.21 years old in control group.

The reason for mechanical ventilation in this study was acute or acute on top of chronic respiratory failure due to COPD, Bronchial asthma, COPD & Bronchiectesis, COPD & pneumonia, Bronchiestesis, Neurologic (Myathemia gravis) and Overlap syndrome (COPD & OSA).

Elbouhy et al. [14] studied inspiratory muscle training on intubated and mechanically ventilated patients due to acute respiratory failure from COPD exacerbation. Others including **Martin et al. [15], Condessa et al. [16],** and **Schimizu et al. [17]** studied effect of inspiratory muscle training on mechanically ventilated patients due to acute respiratory failure from medical respiratory or non respiratory and surgical causes.

In the current study, there was no statistical significant difference between the studied groups regarding ventilation mode (SIMV) both volume control 90% and pressure control 10% of cases (COPD with pneumonia), also pressure support 20 cmH_2O and PEEP 5 cmH_2O were applied for all patients of the study.

Dixit and Prakash [18] applied SIMV+PS, CPAP and PSV on their study of IMT in mechanically ventilated patients in ICU due to medical causes. However, **Caruso et al. [19], Cader et al. [20]** and **Condessa et al. [16],** who studied effect of inspiratory muscle training on mechanically ventilated patients used the controlled ventilation mode as they applied their training programs of IMT on medical, surgical and trauma patients.

In the present study, the IMT was achieved by using a threshold pressure device. Similarly, **Cader et al. [20], Condessa et al. [16]** and **Dixit and Prakash [18],** applied training load by a threshold pressure device. While, **Caruso et al. [19]** and **Elbouhy et al.**

[14] applied the training load by adjustment of ventilator trigger sensitivity. The threshold devices are favorable than training by ventilator trigger sensitivity due to the followings: Using the threshold devices during training, the load is applied on the patient throughout the inspiration, while during training using sensitivity adjustments the load is applied only in the period between the start of negative deflection of pressure by the patient and onset of the inspiratory flow by the ventilator **[21].** Also while using the sensitivity adjustments during training, the patient may not generate adequate inspiratory effort to trigger the respiratory cycle and maintains breathing at positive end-expiratory pressure (PEEP), while with threshold devices, only a minimum tidal volume generated by patient was necessarily needed to open the device valve **[22]**. Lastly, the disconnection of the ventilator during IMT may help patients to control their anxiety and become confident in their ability to breathe without the ventilator **[23]**.

In the present study, the control group patients were subjected to greater number of conventional physiotherapy sessions than test group and this may be attributed to the former increased length of stay in ICU, the number of patients terminated the physiotherapy session was only one patient (overlap syndrome) in control group and frequency of terminated sessions was only one session due to unplanned extubation.

While, in the test group the IMT median session number was 8 and number of patients terminated IMT sessions were 3 patients and the frequency of termination was 11 times: the first case was COPD with bronchiectasis who was complicated with VAP terminated the sessions 5 times due to desaturation <88% and increase in heart rate above 130 beat/min and appearance of new arrhythmia then became uncooperative and hemodynamically unstable, the second case was COPD with pneumonia terminated the sessions 2 times and the third case was COPD terminated the session 4 times during the training period due to desaturation <88% and increase in heart rate above 130 beat/min.

Other studies as **Bisset et al. [23], Condessa et al. [16]** and **Pascotini et al. [24]** demonstrated that an IMT protocol using a threshold device is safe for use in selected ventilated patients with no significant adverse effects occurred.

In the current study MIP was measured via the ventilator (inspiron 5i ventilator), **Mohamed et al. [25], Bien et al. [26]** also measured the MIP through the ventilator. **De Souza et al. [27]** demonstrated that MIP values measured by a digital manner on mechanical ventilation are similar to MIP values measured by the analogue manometer.

In this study, the starting threshold device pressure was (-9) cm H_2O for all patients in test group, and the threshold pressure range at end of study was (-41) - (-25) cmH_2O and mean percent of change was -25.9% (P<0.001) and PImax at start of study (before the commencement of sessions) and at the end of study (before extubation) were (-12.9±3.29) versus (-34.3 ±6.02 cm H_2O in test group. While in the control group the PImax readings were (-13.4 ±2.32) versus (-24.6±2.45) cm H_2O.

The previous results were agreed with **Mohamed et al. [25]** who studied response of mechanically ventilated patients with respiratory failure to respiratory muscle training started IMT with pressure (-10.9±43) cmH_2O and end the training with pressure (-20.4±2.08) cmH_2O and mean percent of change increased by 30.3% (P<0.001) and MIP readings which measured by the ventilator showed that there was statistically significant improvement of MIP in test group (-20.95 ±3.05) versus (-29.417.8) cmH_2O and in control group (-19.1±2.36) versus (-21.25±1.41) cmH_2O and the degree of MIP change in test and control groups post physiotherapy was highly significant (P<0.001).

These results also in agreement with **Cader et al. [20]** who found that MIP in the IMT group was increased from (-15.1 to -25) cmH_2O while by conventional PT from (-15.3 to -17.6) cmH_2O.

In contrast to previous studies **Caruso et al. [19]** demonstrated that MIP in control group showed a slight increase and on contrary the training group demonstrated a little decrease in MIP and this was due to different IMT technique used which was the adjustment of trigger sensitivity which was applied on prolonged mechanically ventilated patients.

In this study, there were no statistical significance differences between test and control group in ADLs for patient returning to independent level of activity of daily living (P>0.05). **Schweickert et al. [4]** also showed that the ADLs at the time of hospital discharge occur with median 6, 4 in test and control groups respectively (P=0.06).

There was improvement of Barthel index post physiotherapy in the test group better than control group but without statistical significant difference (P>0.05) and there was statistical significant difference regarding mean% of change of Barthel index in the test group pre and post sessions (P<0.001). It agreed with the results of **Schweickert et al. [4]** who found that patients who start physiotherapy within 24h from ICU admission, had higher Barthle index score at hospital discharge 75 and 55 in test and control group and (P=0.05). **Chiang et al. [28]** who studied physical training effects on functional status in prolonged mechanically ventilated patients found that Barthel index score was significantly improved in test group and unchanged in control group.

The weaning criteria were improved in test group than control group with statistical significance differences as regards PaO_2/FIO_2, PImax and RSBI (P<0.05) and this was in accordance with **Mohamed et al. [25]** who found a statistically significant improvement of (PaO_2/FIO_2 ratio) (272.35±23.73 versus 330.73±28.6) in test group and (262.73±15.38 versus 307.26.6) in control group. **Elbouhy et al. [14]** found that there was insignificant improvement in the ventilation parameters before and at the end of training (RR, V_T, MIP, PaO_2, SaO_2).

The incidence of complications (VAP, Bed sore and Electrolyte imbalance) increased among the control group than the test group but without statistical significance differences (P>0.05). For adult ventilated ICU patients, one study of chest physiotherapy found low risk of VAP, compared to the control group without physiotherapy **[29]**.

In this study the frequency of successful weaning was higher in test group 18 patients (90%) in comparison to control group 14 patients (70%) with no statistical significant difference (P>0.05). One limitation was the sample size which was too small to find significant results regarding effect of IMT on outcome of weaning. However, in **Elbouhy et al. [14]** successful weaning was (90%, 55%), in test and control group respectively and failure to wean was (10%) and (45%) in test and control group and this was statistically highly significant. In **Martin et al. [15]** 71% and 47% of test and control were successfully weaned (P=0.039). On contrary, Caruso **et al. [19]** stated that respiratory muscle training is an ineffective technique as it does not facilitate weaning from mechanical ventilation.

In the current study, the duration of mechanical ventilation was significantly reduced in test group 5.65±3.63 days versus 7.84±4.62 days in control group.This result was consistent with **Elbouhy et al. [14]** who stated that the mean duration of mechanical ventilation was 11.67±1.95 days and 14.12±1.73 days in test and control group respectively.While in **Caruso et al. [19]** mechanical ventilation duration by hours was 207±87 and 235±193 in test and control group respectively which was not significant and in **Condessa et al. [16]** mechanical ventilation by hours was 219 and 220 in test and control group respectively.

In the present study, there was statistically significant decrease in weaning period between test and control group median (4.5, 6) days, respectively (P = 0.003) (Table 7). **Dixit and Prakash [18]** detected that the duration of weaning period was 4.27±1.49 and 6.27±1.71 in test and control group respectively with significant difference. It agreed also with the results of **Condessa and coworkers [16]** who found that the duration of weaning period, in experimental group was (53 hours), while in control group (61 hours) but this was non significant. **Schimizu et al. [17]** showed that the duration of weaning in the test group was 3.4±1.34 days and in control group 4.87±1.96 days which was non- significant.

In this study, the ICU LOS was significantly reduced in test group 8.8±2.22 versus 11.95±3.42 in control group and this coincide with the result of **Elbouhy et al. [14]** who recorded ICU LOS was 12.6±1.6 days and 17.1±1.29 days in test and control groups respectively. In **Mohamed et al. [25]** ICU LOS was significantly decreased in test group 4.45±0.9 days versus 10.25±2.8 days in control group.

In the current study, the mortality rate was 5%, 15% in test and control group respectively which was statistically non-significant. **Schimizu et al. [17]** who studied some factors that determine mortality for mechanically ventilated patients and the effect of a muscle training protocol in weaning found 59.37% of patients were extubated and 40.62% died and this high mortality rate because he was applied IMT on MV patients with different medical respiratory and non respiratory, surgical and trauma patients.

There was statistically significant negative correlation between Barthel index pre sessions and duration of mechanical ventilation, duration of weaning and ICU LOS in both groups. This was in agreement with **Koopmans et al.[30]** who studied effect of different interventions in decreasing the ICU acquired disabilities and ICU length of stay.

There was significant negative correlation between PImax pre sessions and duration of MV in both groups. **Chiang et al. [28]** who studied effects of physical training on functional status in prolonged mechanical ventilated patients stated that the increase in PImax associated with increase in ventilator free days which may improve patient mobility and ADLs and concluded that the limb muscle strength improvement significantly correlated with the ADLs and also general muscle strengthening program may improve the patient′ functional outcome.

Conclusions

1. Conventional chest physiotherapy is safe ICU intervention with few complications; also it results in positive changes in maximum inspiratory pressure for mechanically ventilated respiratory failure patients.
2. For selected patients in the intensive care unit and under constant supervision, adding inspiratory muscle training (using a threshold pressure device) to the conventional physiotherapy can improve maximum inspiratory pressure, functional capacity and RSBI, with potential reductions in length of ICU stay and the duration of invasive mechanical ventilation.

RECOMMENDATIONS

1. In most ICUs, physical therapy is considered an integral part of the interdisciplinary team, but its cost-effectiveness needs to be examined carefully via further randomized clinical trials.
2. Future research is needed in order to determine the appropriate time to initiate IMT and the optimal applied load and its progression in order to achieve the desired training effect.
3. Randomized controlled trials are needed to study the effects of IMT on long-term ventilator-dependent patients.

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