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Original Research Article

Effectiveness of sustained maximal inspiration along with transcutaneous electrical nerve stimulation in patients with malignant pleural effusion with intercostal drainage tube: a randomized controlled trial

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ABSTRACT

Background: Malignant pleural effusion (MPE) is one of the most common causes of an exudative pleural effusion. It is the most common cause of a unilateral massive pleural effusion. Most MPE s are secondary to metastases to the pleura, most often from lung or breast cancer. Medical management includes aspiration of fluid with the insertion of a chest tube, which may be necessary to relieve dyspnea. Hypoventilation does occur in certain areas of the lungs because of pain and muscle guarding after intercostal drainage tube (ICD) tube placements in pleural effusion. Therefore, it is important to emphasize pain management and expansion of affected areas of the lungs and chest wall. SMI is the basic maneuver of incentive spirometry and is mainly given to prevent atelectasis and lung collapse in postoperative patients. TENS is a method of producing an electro-analgesic effect and is effective in providing post-operative pain control.
Methods: The study design of the study was a randomized controlled trial. A total of 44 participants with a diagnosis of MPE with an intercostal drainage tube were included in this study. The study duration was 5 years with an intervention period of 2 weeks and the outcome measures were pulmonary functions and intercostal pain severity using the NRS Scale.
Results: There was a significant improvement in pulmonary functions in the control group and a highly significant improvement in pulmonary functions in the experimental group after 2 weeks of interventions and pain severity (NRS) was significantly reduced in the experimental group only ($p<0.001$)
Conclusions: This study concluded that sustained maximal inspiration (SMI) along with TENS significantly improves pulmonary functions and reduces pain at the site of ICD in patients with MPE

Keywords: MPE, SMI, IDT, Pulmonary functions

INTRODUCTION

Pleural effusion is a commonly diagnosed condition among respiratory diseases. It is defined as an excessive accumulation of serous fluid between the parietal pleura and the visceral pleura or within the pleural cavity. Types of pleural effusion are exudative, transudative (hydrothorax), parapneumonic effusion, chylothorax and hemothorax. The symptoms of pleural effusion include dyspnea, pleuritic chest pain, cough, fever, chills, and weight loss.[1,2]

The pleural space is normally filled with 5 to10 mL of serous fluid, which serves as a coupling system. A minimum of 300 to 500 ml fluid is necessary for the clinical detection of pleural effusion. Physical examination findings of pleural effusion itself can be normal if the amount of fluid is less than 300 ml. Physical examination findings show, the fullness of the affected chest, bulging of the intercostal spaces and reduction in the chest movements on the affected side. Pleural Effusion can result from increased pleural fluid formation in the lung interstitial, and parietal pleura, or decreased pleural fluid removal by the pleural lymphatics.[2-4]

Approximately 1.5 million patients are diagnosed with pleural effusion each year in the United States. Tuberculosis is a common cause of pleural effusion in India. Recent studies of populations with a high prevalence of tuberculosis report that tuberculosis pleural effusion occurs in approximately 30% of patients with tuberculosis.[5-7]

MPE is a clinical condition and common complication that develops in cancer patients in many types of tumors, its presence indicates the onset of the terminal stages of cancer.[6,7]

Medical management of pleural effusion includes treatment of underlying cause with antibiotics, treatment of pleuritic chest pain with analgesics like paracetamol, aspiration of fluid may be necessary to relieve dyspnea, insertion of chest tube if rapid accumulation of fluid occurs and pleurodesis in malignant effusion. Chest drains are also referred to as under-water sealed drainage, thoracic catheter, tube thoracotomy, or intercostal drainage tube. The ICD is inserted as an invasive procedure for the removal of fluid, from the pleural space or mediastinum or re-expand the lung and restore negative intrapleural pressure and respiratory function.[8-10]

Thoracotomy can be one of the most painful types of incision that a patient can experience. Pain may inhibit effective coughing, deep breathing and restrict chest expansion of the affected side. Thus, the goal of the therapist is to develop an analgesic regimen that provides effective pain relief and allows post-thoracotomy patient, the ability to maintain the functional residual capacity by deep breathing and effective clearance of secretion with coughing and early mobilization, which can lead to recovery and shorter length of hospital stay. Pain is a common symptom felt during the postoperative period at the incision site, which might interfere with pulmonary functions and healing.[11,12]

The goals of physiotherapy management are to relieve dyspnea and regain adequate chest expansion of the affected side; to achieve the goals, treatment consists of dyspnea relieving positions, breathing exercises, Lung expansion therapy, deep breathing, thoracic mobility and and posture correction exercises. Segmental breathing exercises for expansion of the lung on the affected side and also regain full thoracic expansion. The incentive spirometer is helpful in the expansion of the collapsed lobe of the lung.[8,9]

Lung expansion therapy consists of incentive spirometry and positive airway pressure breathing increases the lung volume by increasing trans pulmonary pressure gradient and incentive spirometry has been the mainstay of lung expansion therapy.[10] Sustained maximal inspiration (SMI) is the basic maneuver of incentive spirometry. An SMI is a slow, deep inhalation from the functional residual capacity to the total lung capacity, followed by a 5 to 10-second breath hold and it is mainly given to prevent atelectasis and lung collapse in postoperative patients.[10,12]

Transcutaneous electrical nerve stimulation (TENS) is a method of producing electro-analgesic effects through the spinal cord gating mechanism. TENS has been used as an effective adjunct for providing post-operative pain control. TENS facilitates movement and exercise by decreasing pain perception and improving physical functioning. (Wall and Melzack, 1989; Bonica, 2001).[11-13]

Pleural effusions produce a restrictive ventilatory defect and also decrease the total lung capacity, inspiratory capacity, and forced vital capacity (FVC) and it leads to lung atelectasis because the capacity of the thorax is limited, and excess fluid causes the lungs to collapse. Hypoventilation does occur in certain areas of the lungs because of pain and muscle guarding in patients with pleural effusion with intercostal drainage.[9,10]

Most of the studies have been conducted on the effect of incentive spirometry on pulmonary function in pleural effusion. Few studies have shown that sustained maximal inspiration (SMI) prevents pulmonary complications after cardiac surgeries. Few studies concluded that TENS is effective and safe in reducing pain in post-thoracotomy. It also improves the lung function and chest expansion. So present study aims to study the combined effect of sustained maximal inspiration along with TENS on pulmonary functions and intercostal pain in patients with MPE with an intercostal drainage tube.

Objectives

Objectives of the study were to see the effect of sustained maximal inspiration along with TENS on pulmonary functions (FEV_1, FVC and IC) in patients with MPE and to see the effect of TENS on intercostal pain in patients with MPE.

METHODS

Patient data was collected from the inpatient oncology ward and medicine ward of Pravara rural hospital, Loni, Maharashtra. The study design was a randomized controlled trial with a sample size of 44 which was calculated from open EPI software. Patients with a

clinical diagnosis of MPE with intercostal drainage tube were included in this study and study duration of this study was from July 2018 to June 2023 for 5 years.

Selection criteria

Patients with unilateral MPE with intercostal drainage tubes aged between 20 to 70 years were included in this study. Other pleural disorders (hydrothorax, empyema, hemothorax), chest trauma, Rib fracture, implanted pacemakers and cardiac conditions were excluded from this study.

Equipment used for this study was a pulmonary function test Machine (Spirometer-Helios 401) and TENS.

Outcome measures

The pulmonary function test was used to measure forced vital capacity (FVC), forced expiratory volume in one second (FEV1), and inspiratory capacity (IC). The numerical pain rating scale (NPRS) was used to assess the pain intensity or severity at the site of the intercostal drainage tube.

Groups

A total of 44 patients in the study were randomized into 2 groups: Group A **(**Control group) consisted of 21 patients treated with medical treatment including ICD and sustained maximal inspiration (SMI) with incentive spirometer. Group B (Experimental group) consists of 23 Patients treated with medical treatment including ICD and Sustained maximal inspiration along with transcutaneous nerve electrical stimulation for pain management.

Interventions

Sustained maximal inspiration (SMI) was given with an Incentive spirometer with 10-12 repetitions in one set, 3 sets in one session. The total time of exercise was 15 to 20 min and 2 sessions a day for 2 weeks.

TENS was given with conventional TENS i.e., high frequency (100 to 120 HZ) and low intensity at the side of the incision or ICD for 10 to 20 min and once a day for 2 weeks.

Data analysis

Statistical analysis was carried out utilizing the software version of SPSS 27.0 and Graph Pad Prism 7.0 and $p<0.05$ is considered as level of significance. Statistical measures such as mean, standard deviation (S.D.) was calculated and Student's Paired 't' test and unpaired 't' test was applied to analyze the data. The results were concluded to be statistically significant with $p<0.05$.

Figure 1: Patients receiving SMI with an incentive spirometer and TENS at the site of ICD tube.

RESULTS

In the present study, forty-four (n=44, 25 male and 19 female) participants were included after fulfilling the inclusion and exclusion criteria. Participants were randomly assigned into two groups. Twenty-one participants were included in the control group, in which 12 were male (57%) and 9 were female (43%). Twenty-three participants were included in the Experimental group, in which 13 were male (56%) and 10 were female (44%). All the 44 patients completed 2 weeks of intervention. There were no statistical differences in terms of physical characteristics, anthropometrics and physiological data between participants.

Baseline comparisons

All the participants completed both pre and post-test measurements. There was no significant difference between the groups before the starting of the intervention in terms of pulmonary functions; FEV_1 ($p=0.41$), FVC ($p=0.5$) and IC ($p=0.35$). There was a borderline difference in NPRS scores between the groups. Baseline comparisons confirmed that participants were equally assigned to the control group and experimental group

Table 1: Distribution of patients as per age groups, side of pleural effusion, site of cancer and stages of cancer.

Patients' particulars	N (%)
Total cancer patients included in study	44
Age group (In years)	
21-40	14 (32)
41-60	16 (36)
61-70	14 (32)
Primary cancer	26 (59)
Metastatic cancer	18 (41)
Side of pleural effusion	
Right	26 (59)
Left	18 (41)
Site of the cancer	
Lung	26 (59)
Breast	8 (18)
Uterus	4 (9)
Renal and bladder	5 (12)
Ewing sarcoma	1 (2)
Stages of cancer	
I	3 (7)
II	14 (32)
III	09 (20)
IV	18 (41)

Table 2: Age and gender wise distribution of patients of both groups.

Group	Group A (n=21), mean ± SD	Group B (n=23), mean ± SD	T value	P value
Age (In years)	52.09±13.88	50.82±16.21	0.32	0.78, p>0.05, not significant
Male (N)	12 (57.14%)	13 (56.52%)	-	1.00, p>0.05, not significant
Female (N)	9 (42.86%)	10 (43.48%)	-	1.00, p>0.05, not significant

Table 3: Baseline comparison of both the groups.

Group parameters		Group A (n=21), mean ± SD	Group B (n=23), mean ± SD	T value	P value
FEV_1	Liters	1.02±0.28	0.95±0.30	0.81	0.41, p>0.05, not significant
	Pred %	47.80±10.33	44±11.20	1.16	0.24, p>0.05, not significant
FVC	Liters	1.03±0.28	0.97±0.31	0.66	0.55, p>0.05, not significant
	Pred %	37.42±7.88	35.08±8.49	0.94	0.35, p>0.05, not significant
IC	Liters	0.84±0.24	0.77±0.24	0.93	0.35, p>0.05, not significant
	Pred %	40.61±7.68	38.73±8.20	0.78	0.43, p>0.05, not significant
NPRS score		5.90±0.88	7.30±0.92	5.10	0.01, p<0.05 borderline significant

Pulmonary functions

Forced expiratory volume in one second (FEV_1)

The pre-intervention mean value of FEV_1 in participants of the control group was 1.02±0.28 liters and 47.80±10.33% predicted and after 2 weeks of intervention mean value of FEV_1 was 1.14±0.29 liters and 53.33±10.0 of % predicted. The difference between the pre and post-values of FEV_1 in the control group was 0.12 Liters and 5.52 % predicted which shows a statistically significant difference after 2 weeks of treatment in the control group. Before the intervention, the mean value of the FEV_1 in participants of the experimental group was 0.95±0.30 liters and 44±11.20% predicted, and after 2 weeks of intervention, the mean value of FEV_1 was 1.25±0.33 liters and 57.86±10.77 of % predicted. The difference between the pre and post-values of FEV_1 in the experimental group was 0.30 Liters and 13.86 % predicted which shows a statistically highly significant difference after 2 weeks of treatment in the experimental group.

Forced vital capacity (FVC)

The pre-intervention mean value of FVC in participants of the control group was 1.03±0.28 liters and 37.42±7.88 of percentage of predicted and after 2 weeks of

intervention mean value of FVC was 1.15±0.28 liters and 42±7.19 of % predicted. The difference between the pre and post-values of FVC in the control group was 0.12 liters and 4.57% predicted which shows a statistically significant difference after 2 weeks of treatment in the control group.

Before the intervention, the mean value of FVC in participants of the experimental group was 0.97±0.31 liters and 35±8.49 of percentage of predicted and after 2 weeks of intervention mean value of FVC was 1.29±0.36 liters and 46.82±8.99 of % predicted. The difference between the pre and post-values of FVC in the experimental group was 0.32 liters and 11.73 percentages predicted which shows a statistically highly significant difference after 2 weeks of treatment in the experimental group.

Inspiratory capacity (IC)

The pre-intervention mean value of IC in participants of the control group was 0.84±0.24 Liters and 40.61±7.68 of percentage of predicted and after 2 weeks of intervention mean value of IC was 0.97±0.24 Liters and 45.76±7.20 of % predicted. The difference between the pre and post-values of IC in the control group was 0.12 Liters and 5.14 % predicted which shows a statistically significant difference after 2 weeks of treatment in the control group. Before the intervention, the mean value of IC in participants of the experimental group was 0.77±0.24 liters and 38.73±8.20 of percentage of predicted and after 2 weeks of intervention mean value of IC was 1.03±0.26 liters and 50.56±7.22 of % predicted.

The difference between the pre and post-values of IC in the experimental group was 0.26 Liters and 10.82 of % predicted which shows a statistically highly significant difference after 2 weeks of treatment in the experimental group.

Pain intensity on NPRS

The pre-intervention mean value of NPRS score (Pain intensity) in participants of the control group was 5.90±0.88 and after 2 weeks of intervention mean value of (Pain intensity) was 5.76±0.70. The difference between the pre and post-values of the NPRS Score in the control group was 0.14 which shows no significant difference in pre and post-intervention. Before the intervention, the mean value of NPRS score (Pain intensity) in participants of the experimental group was 7.30±0.92 and after 2 weeks of intervention, mean value of NPRS score (Pain intensity) was 2.82±0.83.

The difference between the pre and post-values of the NPRS score in the experimental group was 4.47. which shows a highly significant difference in pre and post-intervention pain intensity.

Mean difference comparison between the groups

Student's unpaired 't' test was used to compare the control group and the experimental group revealing that there was a statistically significant difference (p=0.0001) in FEV_1, FVC and the IC in liters and percentages predicted and in the pain intensity (NPRS score) between two groups.

Table 4: Pre-post comparison of pulmonary functions and pain intensity of group A.

Group parameters		Pre-test, Mean ± SD	Post test, mean ± SD	Mean difference	T value	P value, p<0.05, significant
FEV_1	Liters	1.02±0.28	1.14±0.29	0.12±0.07	7.81	0.0001, significant
	Pred %	47.80±10.33	53.33±10.06	5.52±2.99	8.45	0.0001, significant
FVC	Liters	1.03±0.28	1.15±0.28	0.12±0.07	7.48	0.0001, significant
	Pred %	37.42±7.88	42±7.19	4.57±2.78	7.52	0.0001, significant
IC	Liters	0.84±0.24	0.97±0.24	0.12±0.06	9.07	0.0001 significant
	Pred %	40.61±7.68	45.76±7.20	5.14±2.63	8.95	0.0001, significant
NPRS score		5.90±0.88	5.76±0.70	0.14±0.35	1.82	0.83, p>0.05, not significant

Table 5: Pre-post comparison of pulmonary functions and pain intensity of group B.

Group parameters		Pre-test, mean ± SD	Post test, mean ± SD	Mean difference	T value	P value, p<0.05, significant
FEV_1	Liters	0.95±0.30	1.25±0.33	0.30±0.12	11.31	0.0001, highly significant
	Pred %	44±11.20	57.86±10.77	13.86±5.79	11.48	0.0001, highly significant
FVC	Liters	0.97±0.31	1.29±0.36	0.32±0.15	10.26	0.0001, highly significant
	Pred %	35.08±8.49	46.82±8.99	11.73±5.14	10.94	0.0001, highly significant
IC	Liters	0.77±0.24	1.03±0.26	0.26±0.11	10.74	0.0001, highly significant
	Pred %	38.73±8.20	50.56±7.22	10.82±5.69	9.96	0.0001, highly significant
NPRS score		7.30±0.92	2.82±0.83	4.47±0.99	21.60	0.0001, highly significant

Table 6: Mean difference (between group) comparison of pulmonary functions and pain intensity of both groups.

Group parameters		Group A (n=21), mean difference	Group B (n=23), mean difference	T value	P value, p<0.05, significant
FEV_1	Liters	0.12±0.07	0.30±0.12	5.71	0.0001, significant
	Pred %	5.52±2.99	13.86±5.79	5.91	0.0001, significant
FVC	Liters	0.12±0.07	0.32±0.15	5.50	0.0001, significant
	Pred %	4.57±2.78	11.73±5.14	5.66	0.0001, significant
IC	Liters	0.12±0.06	0.26±0.11	4.68	0.0001, significant
	Pred %	5.14±2.63	10.82±5.69	4.91	0.0001, significant
NPRS score		0.14±0.35	4.47±0.99	18.80	0.0001, significant

Results of this study indicated that pulmonary functions were more improved in group B (Experimental group) and pain intensity also significantly reduced in group B.

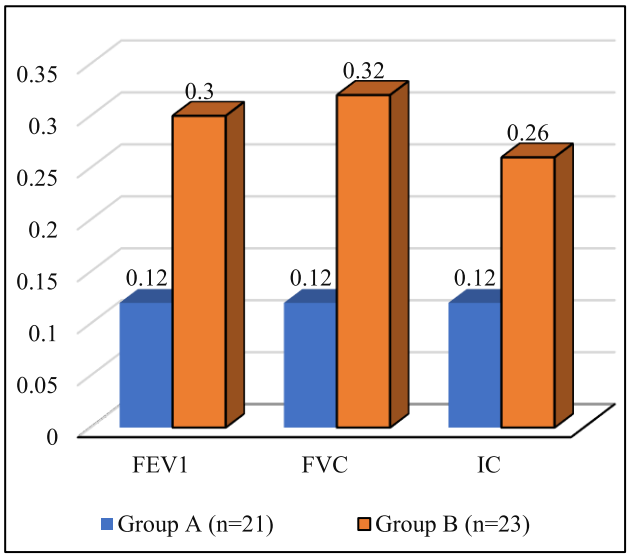

Figure 2: Mean difference comparison of pulmonary functions (in liters) of both groups.

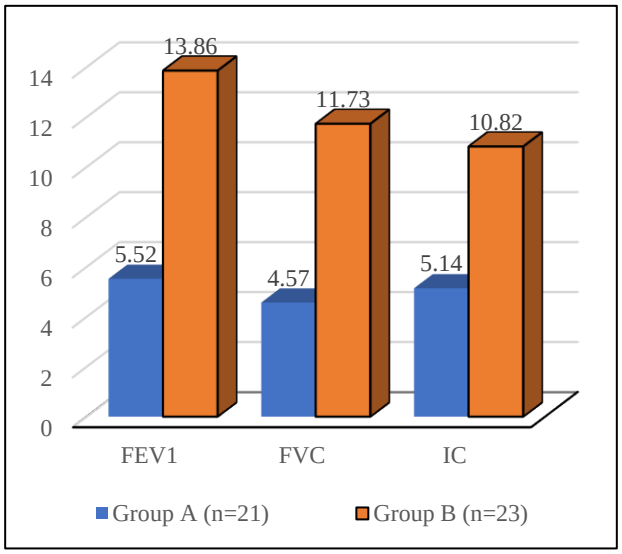

Figure 3: Mean difference comparison of pulmonary functions (% pred) of both groups.

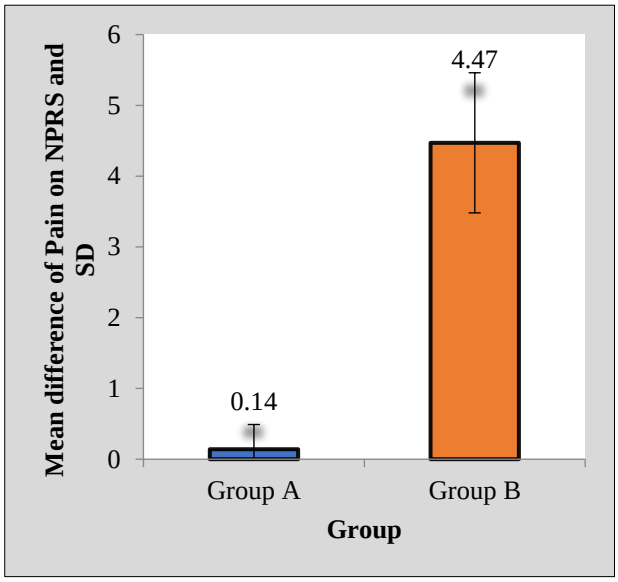

Figure 4: Mean difference comparison of pain intensity (NPRS score) of both the groups.

DISCUSSION

The present study was conducted to find the effect of Sustained maximal inspiration along with TENS on pulmonary functions and intercostal pain severity using the NPRS in patients with MPE with intercostal drainage tube.

Results of this study showed that pulmonary functions (FEV_1, FVC, IC) were more improved in the experimental group than in the control group. Pain intensity or severity was also significantly reduced in the experimental group. This study indicates that TENS is effective in improving pulmonary functions when it is given with sustained maximal inspiration and it is also effective in reducing pain intensity at the side of the Intercostal drainage tube.

The present study shows that the application of TENS provides an analgesic effect that reduces the nociceptive pathways and this helps the patient to breathe effectively which improves the depth of Inspiration. The first mechanism behind this was the 'gate control' theory of pain as postulated by Melzack and Wall. The pain was

largely transmitted by small unmyelinated C fibers which could be inhibited by the activation of myelinated Aδ and Aβ fibers. By the stimulation of these large diameter Aδ and Aβ fibers it could close the signals from a spinal segment by gating mechanism in the substantia gelatinosa and thus can prevent painful peripheral stimuli from gaining access to higher cortical centers.[12,13] Another mechanism to relieve pain by using TENS is the release of inhibitory neurotransmitters endorphin, dynorphin and enkephaline in substania gelatinosa. It inhibits C fibers and ultimately pain reduced by these 2 mechanisms.[13,14]

A systematic review performed by Freynet et al on TENS effective in relieving postoperative pain after thoracotomy. The 74 papers found with a report search, nine prospective randomized controlled trials (RCT), among which three were double-blind, presented the best evidence to answer the clinical question. All investigated the effect of TENS as an adjunct therapy for relieving acute post-thoracotomy pain in patients undergoing thoracic surgery. Hence, current evidence shows TENS associated with postoperative medications to be safe and effective in alleviating postoperative pain and in improving patient recovery.[15]

A similar study supporting the present study was conducted by Rajesh et al on TENS in patients presenting intercostal drainage. This study consists of 10 patients with intercostal drainage tubes chosen by convenient sampling at Darbhanga medical college. In the results, both (FEV_1 and FVC) have shown critical improvement after the utilization of TENS in patients with intercostal drainage tubes. This study concluded that the utilization of TENS is safe and increases pulmonary functions in patients with intercostal drainage tubes. [16]

A study performed by Stratton et al on effect of TENS on FVC in postop thoracotomy. In this study, 21 patients were randomly assigned to an experimental group and a control group. Data indicated a statistically significant increase in FVC during electrical nerve stimulation suggesting that TENS improves chest expansion and mobility in patients who have had thoracotomies.[17]

A randomized clinical trial conducted by Alireza et al on the effect of TENS on postoperative pin and pulmonary function in patients undergoing coronary artery bypass surgery. In this study, 100 patients undergoing CABG were divided into two groups. In the intervention group 50), patients received routine care along with TENS. In the placebo group (50) patients only received routine care. The pain intensity and pulmonary function were assessed at 24, 48, and 72 hours after surgery. Pain intensity was significantly lower in the TENS group than the placebo group in both resting and coughing conditions ($p<0.05$). FVC and FEV_1 were significantly better and faster in the TENS group than in the placebo group. TENS may reduce postoperative pain in resting and coughing conditions, improve pulmonary function, and reduce narcotic use in patients.[18]

Lung expansion therapy consists of incentive spirometry and positive airway pressure breathing increases the lung volume by increasing trans pulmonary pressure gradient and incentive spirometry has been the mainstay of lung expansion therapy. An incentive spirometer (IS) encourages deep inspiratory and expiratory breathing by having the patient take long, deep breaths with subsequent pauses. This maneuver emphasizes lung inflation, increasing tidal volume, and maintaining patency of the smaller airway. It also reduces pulmonary complications and improves pulmonary functions in postoperative patients.[8,10,19]

SMI is a slow, deep inhalation followed by breath-hold which prevents atelectasis and lung collapse in postoperative patients. So sustained maximal inspiration gradually increases lung expansion of the atelectatic lung area and also improves lung volume capacities and pulmonary functions.[9,10]

Essa et al performed a randomized controlled trial study on Preoperative incentive spirometry for preventing postoperative pulmonary complications in patients undergoing coronary artery bypass graft surgery. In this study, 80 patients were selected as candidates for CABG. Patients were randomly assigned into two groups: the incentive spirometry group (study group) and the control group. The study findings showed a significant difference between the IS and control groups in the incidence of postoperative atelectasis. Mechanical ventilation duration was significantly less in the IS group ($p<0.005$). The study concluded that preoperative incentive spirometry for two days along with deep breathing following CABG is in connection with prevention and decreased incidence of atelectasis, hospital stay, mechanical ventilation duration, and improved postoperative oxygenation with better pain control.[20]

So, TENS reduces the severity of pain at the side of the ICD tube and when TENS is given along with Sustained maximal Inspiration its combined effect improves the depth of inspiration and indirectly improves pulmonary functions in patients with intercostal drainage tube.

CONCLUSION

The Present study concluded that the combined effect of conventional TENS and Sustained maximal inspiration with an incentive spirometer improves pulmonary functions and reduces pain in MPE with ICD. These Physiotherapy interventions are safe and effective in cancer patients with intercostal drainage tubes**.**

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