

Original Article

The impact of threshold-loaded inspiratory muscle training and respiratory biofeedback on preserving inspiratory muscle strength and vital capacity after CABG: a randomized clinical trial

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Abstract: Objectives: Postoperative pulmonary complications (POPC) are common after cardiac surgeries such as coronary artery bypass grafting (CABG) and are influenced by factors including anesthesia and surgical trauma. Inspiratory muscle training (IMT) with visual biofeedback may mitigate these complications. This study investigates the impact of threshold loading inspiratory muscle training (TL-IMT) combined with respiratory biofeedback on the dynamic strength of inspiratory muscles (S-index) in patients undergoing CABG surgery during their hospitalization phase. Methods: A single-blind study was conducted with 38 CABG candidates at Shahid Modares Hospital, Tehran. Participants were randomized into two groups: the TL-IMT with biofeedback group and the placebo IMT group. TL-IMT exercises were performed at 30% of maximum dynamic inspiratory strength using the Power Breath K5 device, with visual biofeedback displayed on the screen. The placebo group performed the same exercises at minimal load without biofeedback. Both groups received standard respiratory physiotherapy. Measurements of S-index, peak inspiratory flow (PIF), and vital capacity (VC) were taken before surgery (T1), one day after surgery (T2), and at discharge (T3). Results: Both groups showed significant changes, with a decrease from T1 to T2 and an increase from T2 to T3. In the study group, T3 values remained the same as at T1, while the placebo IMT group experienced a significant decrease. After surgery, both groups had a drop in the S-index. However, the study group saw more pronounced changes between T3-T2 and T3-T1 compared to the control group, although no significant difference was found between T2-T1. By the time of discharge, the TL-IMT group had higher S-index values than the placebo group, returning to preoperative levels. Additionally, the TL-IMT group showed improvements in PIF and VC. Conclusion: TL-IMT with visual biofeedback effectively maintains dynamic inspiratory muscle strength and improves key pulmonary parameters in cardiac surgery patients. These findings suggest that integrating TL-IMT with biofeedback can enhance postoperative recovery and reduce the incidence of POPC.

Keywords: Inspiratory muscle training, threshold loading, respiratory biofeedback, cardiac surgery, pulmonary complications

Introduction

Surgical procedures involving the chest, particularly open-heart surgery and median sternotomy, often lead to postoperative pulmonary complications (POPC) such as atelectasis and

pleural effusion (PE). These complications arise due to the impact of anesthesia on normal ventilatory function, which can immediately affect pulmonary function tests [1, 2]. It appears that the main factor in causing POPC after cardiac surgery is an inflammatory response in the

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whole body, which also affects the function of the lungs, and is due to the sternotomy, general anesthesia, and mechanical ventilation [3], which ultimately causes respiratory muscle dysfunction and subsequent respiratory changes in the care unit [4]. For instance, a notable decrease of approximately 62% in the maximum inspiratory muscle strength (MIP) within the first week following valve replacement, and 27% following coronary artery bypass grafting (CABG), has been reported in various studies [5, 6].

The IMS is measured by the maximal pressure generated during inhalation through the mouth [7], and is expressed in two types of dynamic and isometric strength, that indicated the strength index (S-index) and the maximal inspiratory pressure (MIP) index, respectively [8].

Systematic studies have demonstrated positive effects in improving the respiratory muscles strength, tidal volume, pulmonary complications (POPC) and length of hospital stay through threshold loading-inspiratory muscle training (TL-IMT) in patients undergoing heart surgeries [9-11]. Although studies focusing on the hospitalization phase and the immediate postoperative period are more limited, one study utilizing inspiratory muscle training (TL-IMT) during hospitalization showed significant improvements in both static (MIP) and dynamic (S-Index) strength of respiratory muscles by the time of discharge [12].

In the respiratory biofeedback, a number of physiological events, such as the respiratory rate, the tidal volume, the respiratory flow, and the movements of the thorax and abdomen, are provided through the display of auditory and visual signals. In fact, the purpose of this method is to manipulate these variables by the individual and obtain therapeutic benefits through improving respiratory function [13].

It has been suggested that strengthening the inspiratory muscles and utilizing additional motor units through visual feedback from devices such as incentive spirometers may lead to a lesser decrease in maximum inspiratory muscle strength (MIP) post-surgery [14]. This approach may also enhance patient motivation, willpower, and cooperation [15].

This study aims to explore the role of inspiratory muscle training with threshold loading (TL-IMT)

combined with respiratory biofeedback using an electronic device (Power Breath K5) in cardiac surgery candidates during the hospitalization phase, both before and after surgery.

Materials and methods

Subjects

This single-blind study was conducted with 38 patients who were candidates for CABG surgery at the Department of Cardiac Surgery, Shahid Modares Hospital, Tehran, affiliated with Shahid Beheshti University of Medical Sciences. The study included patients diagnosed with coronary artery disease (CAD) of both genders, aged between 30 and 80 years, who were categorized in cardiac functional classes 1 and 2 (absence of symptoms or mild symptoms in routine physical activities according to the NYHA classification) and were non-emergency cases.

Patients were excluded from the study if they met any of the following criteria: 1. Atrial fibrillation, stroke, or prior heart surgeries. 2. Chronic renal failure (CRF). 3. Chronic obstructive pulmonary disease (COPD) with a decrease of more than 70% in forced vital capacity (FVC) and forced expiratory volume in one second (FEV1). 4. Any malignancy or chemotherapy. 5. Blindness or severe visual impairment. 6. Signs of hemodynamic instability during tests and exercises.

Additionally, patients were excluded from the study if the following conditions occurred post-surgery: 1. Mechanical ventilation for more than 24 hours. 2. Requirement for reintubation. 3. Need for surgical reintervention. 4. Sternum infection or instability at the incision site for any reason. 5. Pain at the operation site severe enough to prevent exercises.

Patients were randomly assigned to one of two groups: the study group (TL-IMT with biofeedback) and the control group (placebo IMT). Informed consent was obtained from all participants, and the study adhered to the Declaration of Helsinki principles. The protocol was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (approval code: IR.SBMU.RETECH.REC.1401.058), and clinical trial code IRCT2022080105559-6N1 was obtained.

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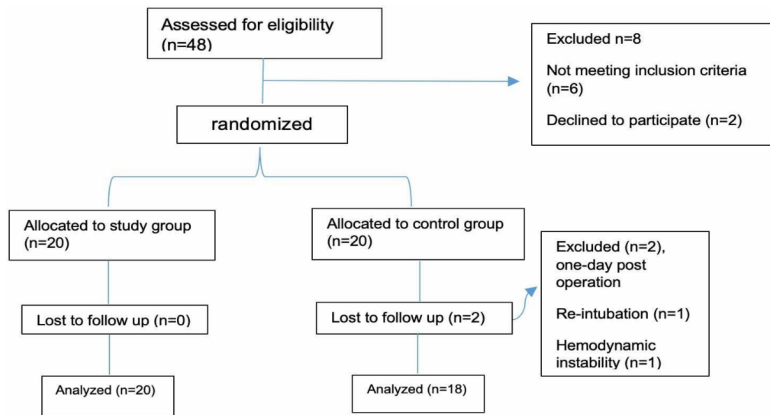


Figure 1. Consort flow diagram.

Study Group (TL-IMT with Visual Respiratory Biofeedback): In this group, TL-IMT exercises were performed at 30% of the S-index in 30 breathing cycles, twice daily, using an electronic device (Power Breath K5, HaB International Ltd., UK). The device was used with the mouth-piece placed in the mouth and the nose clipped to prevent air escape. The patient performed diaphragmatic breathing through the mouth with a 4.5-second interval between breaths to avoid hyperventilation. During the exercises, visual feedback, including various respiratory parameters such as flow, power, and tidal volume, was displayed on the screen via the connected software (Breath Link).

Control Group (Placebo IMT): In this group, diaphragmatic breathing exercises were performed with the same device but at the lowest load (nearly no load) for 30 breathing cycles and without visual respiratory feedback.

Both groups also received standard respiratory physiotherapy, including diaphragmatic breathing exercises, training and encouragement to cough, local lung expansion exercises, and light limb exercises. Interventions began 2 days before surgery, continued after surgery (post-extubation and once hemodynamic stability was achieved, usually one day after surgery), and continued until the patient's discharge.

Measurements

To assess dynamic inspiratory muscle strength (S-index), patients were placed in a comfortable sitting position. After placing the mouth-piece and installing a nose clip (to prevent air

escape), the patient took a deep exhalation to bring the lungs to residual volume (RV) and then performed a maximum inhalation. Three consecutive attempts were made with a 30-second interval between each.

Simultaneously, peak inspiratory flow (PIF) and vital capacity (VC) values were automatically recorded by the device. Each variable was recorded in two forms: best (B) and average (A), as obtained from the Breath

link software. These tests were performed at three time points: before surgery and initiation of the intervention (T1), one day after surgery (T2), and at discharge and the end of the intervention (T3).

Statistical analysis

The Shapiro-Wilk test was used to evaluate the normal distribution of all dependent variables. In the case of normally distributed variables the Repeated Measures ANOVA and Independent samples t-test were used for intra-group and between-group comparisons, respectively. The Friedman and Mann-Whitney U tests were employed for intra-group and between-group comparisons of non-normal variables, respectively. All statistical analysis of the current study was performed using SPSS 26.

Results

Baseline time assessments

After the initial evaluation of the patients in terms of inclusion and exclusion criteria, 40 patients were allocated into two groups of 20, subsequently 2 patients were excluded from the study, and then 18 subjects remained in the control group and 20 subjects remained in the study group (**Figure 1**). Also Shapiro-Wilk test was used to check the normality of the studied variables across the three measurement times, the results of which can be seen in **Table 1**. As can be seen in this table, all the dependent variables in this study had a normal distribution, in three measurement times. The demographic variables and comorbidities were compared between the two groups and you can

Table 1. The results of Shapiro-Wilk test for dependent variables

Variable	p-value (study group)	p-value (control group)
S-index(A) _{T1}	.694	.665
S-index(A) _{T2}	.215	.081
S-index(A) _{T3}	.227	.981
S-index(B) _{T1}	.097	.416
S-index(B) _{T2}	.012	.863
S-index(B) _{T3}	.066	.236
PIF(A) _{T1}	.019	.882
PIF(A) _{T2}	.003	.561
PIF(A) _{T3}	.039	.541
PIF(B) _{T1}	.095	.292
PIF(B) _{T2}	.008	.392
PIF(B) _{T3}	.095	.392
VC(A) _{T1}	.264	.925
VC(A) _{T2}	.009	.528
VC(A) _{T3}	.112	.209
VC(B) _{T1}	.048	.411
VC(B) _{T2}	.006	.709
VC(B) _{T3}	.015	.444

S-index: strength index, PIF: peak inspiratory flow, VC: vital capacity, (A): average, (B): best, T1: time point 1, T2: time point 2, T3: time point 3.

Table 2. Comparison of demographic characteristics and comorbidities (Mean ± SD)

Variable	Study group (mean ± SD)	Control group (mean ± SD)	p-value
Age	61.30 ± 7.65	59.67 ± 7.88	.52
BMI	28.37 ± 4.07	26.98 ± 3.15	.25
EF	52 ± 6.36	50 ± 6.64	.35
FEV1	96.83 ± 21.76	98.60 ± 17.10	.78
FEV1/FVC	77.56 ± 8.40	74.69 ± 8.62	.09
HTN (%)	45	50	.37
DM (%)	45	66	.30
Smoking (%)	30	27.77	.49
Sex (% male)	70	72	.44

BMI: body mass index, EF: ejection fraction, FEV1: forced expiratory volume in 1 second, FVC: forced vital capacity, HTN: hypertension, DM: diabetes mellitus.

see its results in **Table 2**. As seen in this table the results showed the homogeneity of these variables in two groups. In the continuation of the reviews, a comparison was made between the two groups in terms of dependent variables at the baseline time (**Table 3**). The obtained results indicated that there was no significant

difference between the two groups in terms of baseline values of the dependent variables.

Intra-group assessments in 3 measurement times

The comparison of the studied variables in the three measurement times (T1, T2, T3) using the repeated Measures ANOVA test for the study and control groups can be seen in **Tables 4** and **5**, respectively.

As can be seen the results of the Repeated Measures ANOVA test for comparison of values of the dependent variables in T1 (pre-operation), T2 (post-operation) and T3 (at discharge) showed a significant decrease at T2 relative to T1 (T2-T1) for all of the variables in both groups. Moreover, the values of all variables in both groups were significantly increased at T3 when compared to T2 (T3-T2). There was no significant difference between the values of all variables at T3 compared to T1 (T3-T1) in study group, while such a return to baseline value was observed only for PIF-average in control group.

Inter-group assessments between 3 measurement times

The changes of variables between different measurement times (T1, T2 and T3) were compared between two groups, through Independent Samples t-Test (or Mann-Whitney U Test) (**Table 6**).

As seen in **Table 6**, there was no between-group difference for any variables when T2 was compared with T1 (T2-T1) (P > .05), while there was a significant difference between two groups in terms of improvement in all dependent variables when T3 was compared with T2 and T1 (T3-T2 and T3-T1) in favor of study group (P < .05).

Discussion

Surgical interventions on the chest, compounded by the use of neuromuscular blocking agents during anesthesia and the reduction of lung volumes, can lead to a suboptimal length-tension relationship and respiratory muscle insufficiency. These factors are significant contributors to pulmonary complications following surgery [2, 4, 16].

Table 3. Comparison of baseline values for dependent variables

Variable	Study group	Control group	p-value
S-index (B)	38.04 ± 9.29	37.69 ± 4.95	.88
	47.56 ± 5.36	47.13 ± 7.25	.83
PIF (B)	2.17 ± 1.26	2.10 ± .78	.83
	2.64 ± 1.56	2.65 ± 1.10	.98
VC (B)	1.80 ± .85	1.97 ± .77	.52
	2.16 ± .87	2.45 ± .80	.30

S-index: strength index, PIF: peak inspiratory flow, VC: vital capacity, (A): average, (B): best.

A study conducted in 2020 compared the static (MIP) and dynamic (S-index) strength of inspiratory muscles in healthy individuals, revealing a strong and linear relationship between these two indices, though the values were not identical [8]. The MIP method used to measure static strength of inspiratory muscles is similar to the S-index method, but it involves measuring the maximum pressure generated during a deep breath against linear resistance without breath-holding, converted from airflow to pressure [8]. This approach reduces cardiovascular risk for patients [17, 18].

Our study is the first to examine changes in the dynamic strength of inspiratory muscles (S-index) immediately after surgery and at discharge due to a regimen of TL-IMT exercises with biofeedback during the hospitalization phase before and after cardiac surgery. As observed, there was a decrease in the S-index, both average and best values (SA, SB), immediately after open-heart surgery in both groups. Previous studies have similarly documented a sharp decline in maximum static inspiratory muscle strength (MIP) following such surgeries. For instance, Matheus et al. found a significant decrease in MIP immediately after heart surgery, with no significant increase in this index from IMT exercises performed for three days post-operation [19]. Barros et al. reported a marked reduction in the isometric strength of respiratory muscles (MIP and MEP) and lung volumes immediately after heart surgery, with values maintained in the IMT group at discharge [20]. Probably, the duration and intensity of IMT exercises before the operation are one of the determining factors in modulating the global inflammatory response during and after the operation [3, 21], as seen, performing 3 to 6 weeks of high-

intensity IMT exercises can change the function of inflammatory indicators such as interleukins and cytokines and possibly reduce pulmonary complications afterwards [21]. Savci et al. demonstrated that IMT exercises performed 5 days before and 5 days after surgery resulted in higher MIP strength at discharge in the study group compared to the control group, with MIP changes were not measured on the postoperative day [6].

In our study, the S-index on the first postoperative day was similar in both groups, indicating that two preoperative sessions of these exercises may not be sufficient to prevent a decrease in the S-index during surgery. However, results showed that the S-index values increased by the discharge day compared to the day after surgery in both groups, with the study group exhibiting a greater increase, effectively discharging with S-index values comparable to preoperative levels. This finding is significant as pulmonary function, IMS and chest expansion are typically at their lowest on the third or fourth postoperative day and return to baseline by the 30th day [22, 23]. Han et al. reported that early rehabilitation after CABG surgery, whether in an intensive care unit or general ward, not only enhances patient functional independence but also reduces complications risks within 30 days post-discharge [24].

Cordeiro et al. found that IMT exercises in the postoperative period did not significantly improve respiratory muscle strength (MIP and MEP) or functional capacity in high-risk POPC patients, though it did reduce hospitalization duration and the incidence of pulmonary complications [25]. Fortes et al. utilized an IMT electronic device for up to 6 days post-CABG, maintaining S-index and MIP indices at preoperative levels [12]. Limitations in previous studies, including small sample sizes and short intervention durations, were addressed in our study.

Short-term cognitive and psychomotor disturbances are common after general anesthesia and heart surgery, potentially due to incomplete drug clearance or stress responses, including cortisol and catecholamine release. These disturbances can affect concentration, memory, and hinder the rehabilitation process,

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Table 4. Comparison of the dependent variables at T1, T2 and T3 time points in study group (Mean \pm SD)

Variable		T1	T2	T3	p-value		
					(T2-T1)	(T3-T1)	(T3-T2)
S-index	(B)	47.56 \pm 5.36	24.98 \pm 9.96	41.50 \pm 19.36	P < .001***	.554	P = .003**
	(A)	38.04 \pm 9.29	20.77 \pm 5.67	34.83 \pm 11.15	P < .001***	.595	P < .001***
PIF	(B)	2.64 \pm 1.56	1.25 \pm .60	2.20 \pm 1.10	P = .002**	.399	P = .002**
	(A)	2.17 \pm 1.26	1.06 \pm .55	1.89 \pm .99	P = .003**	.882	P = .005**
VC	(B)	2.16 \pm .87	.77 \pm .43	1.65 \pm .44	P < .001***	.057	P < .001***
	(A)	1.80 \pm .85	.62 \pm .39	1.43 \pm .48	P < .001***	.166	P < .001***

** , P < .01; *** , P < .001. S-index: strength index, PIF: peak inspiratory flow, VC: vital capacity, (A): average, (B): best, T1: time point 1, T2: time point 2, T3: time point 3.

Table 5. Comparison of the dependent variables at T1, T2 and T3 time points in control group (Mean \pm SD)

Variable		T1	T2	T3	p-value		
					(T2-T1)	(T3-T1)	(T3-T2)
S-index	(B)	47.13 \pm 7.25	24.66 \pm 7.84	30.53 \pm 11.56	P < .001***	P = .009**	P < .001**
	(A)	37.69 \pm 4.95	21.76 \pm 6.46	27.35 \pm 6.52	P < .001***	P = .004**	P = .002**
PIF	(B)	2.65 \pm 1.10	1.26 \pm .45	1.59 \pm .61	P < .001***	P < .001**	P < .001**
	(A)	2.10 \pm .78	1.09 \pm .44	1.30 \pm .46	P < .001***	.067	P < .010*
VC	(B)	2.45 \pm .80	.91 \pm .39	1.35 \pm .61	P < .001***	P < .001***	P < .001***
	(A)	1.97 \pm .77	.78 \pm .39	1.01 \pm .44	P < .001***	P < .001***	P = .013*

* , P < .05; ** , P < .01; *** , P < .001. S-index: strength index, PIF: peak inspiratory flow, VC: vital capacity, (A): average, (B): best, T1: time point 1, T2: time point 2, T3: time point 3.

Table 6. Comparison of the changes of the dependent variables in different time points between the two groups (Mean \pm SD)

Variable		Study group	Control group	p-value
S-index(A)	T2-T1	-17.26 \pm 10.23	-15.93 \pm 7.67	.672
	T3-T2	14.06 \pm 11.01	5.58 \pm 6.20	P = .019*
	T3-T1	-3.20 \pm 10.75	-10.34 \pm 7.62	P = .048*
S-index(B)	T2-T1	-22.58 \pm 11.91	-22.46 \pm 8.25	.838
	T3-T2	16.52 \pm 18.85	5.86 \pm 7.16	P = .044*
	T3-T1	-6.05 \pm 19.66	-16.60 \pm 11.01	P = .048*
PIF(A)	T2-T1	-1.10 \pm 1.28	-1.00 \pm .65	.501
	T3-T2	.82 \pm .99	.20 \pm .35	P = .016*
	T3-T1	-.27 \pm 1.15	-.79 \pm .69	P = .022*
PIF(B)	T2-T1	-1.38 \pm 1.52	-1.38 \pm .91	.380
	T3-T2	.95 \pm 1.05	.32 \pm .30	P = .041*
	T3-T1	-.43 \pm 1.25	-1.05 \pm .82	P = .013*
VC(A)	T2-T1	-1.18 \pm .80	-1.19 \pm .74	.953
	T3-T2	.81 \pm .25	.22 \pm .31	P < .001***
	T3-T1	-.36 \pm .80	-.96 \pm .69	P = .024*
VC(B)	T2-T1	-1.39 \pm .82	-1.53 \pm .73	.587
	T3-T2	.88 \pm .41	.44 \pm .40	P = .002**
	T3-T1	-.50 \pm .88	-1.09 \pm .88	P = .028*

* , P < .05; ** , P < .01; *** , P < .001. S-index: strength index, PIF: peak inspiratory flow, VC: vital capacity, (A): average, (B): best, T1: time point 1, T2: time point 2, T3: time point 3.

potentially extending hospitalization and increasing infection risk [26]. It has also been detected that a decrease in level of cerebral blood oxygen is more likely in patients who have cognitive problems such as post-operative delirium [27].

The most common respiratory feedback for cardiac patients is the incentive spirometer with flow and volume feedback [28]. The improvement in S-index in our study might be attributed to the simultaneous use of respiratory biofeedback. Patients received visual feedback through the Breath Link Power Breath software, which displayed various respiratory parameters, including airflow, power, and lung vital capacity.

Manapunsopee et al. found that using an incentive spirometer

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could prevent a reduction in MIP in CABG patients post-surgery [14], highlighting the significant impact of respiratory biofeedback on muscle strength improvement, even without loading. Additionally, the effect of incentive spirometer feedback on hemodynamic variables in cardiac patients has been explored [29].

In fact, both the incentive spirometer (IS) and TL-IMT are components of IMT. However, TL-IMT has shown greater increases in inspiratory muscle strength (PIM) compared to IS after a specific period of use in healthy individuals [30].

Our study is the first to investigate the impact of respiratory biofeedback and TL-IMT exercises on cardiac surgery candidates during the hospitalization phase, both pre- and post-operation, until discharge. The applied load was measured daily based on the patient's respiratory muscle strength.

Results from this study indicate significant positive effects in PIF and VC in the study group compared to the control group. The contraction pattern of respiratory muscles appears to positively influence lung volumes and both inspiratory and expiratory airflow [31]. For example, a study found that performing 3 days of IMT exercises at 40% of MIP, while not increasing muscle strength, significantly improved VC and TV in patients post-heart surgery compared to the control group [19]. Additionally, 8 weeks of IMT exercises in COPD patients led to substantial increases in PIF, beneficial for the correct dosage of inhalers [32]. The results of a systematic study showed that performing IMT exercises in the pre-operative period leads to a clear improvement in pulmonary function tests such as FEV1 and FVC, while the effect of these exercises in the postoperative period on the improvement of indicators such as Peak flow rates has received less attention [33]. Results from the present study indicated significant positive effects in the pulmonary function tests such as PIF and VC with using TL-IMT and biofeedback in short post-operative phase.

Limitations

In this study, the intervention was performed only two days' pre-operation, which can be a reason for its lack of effect on the post-operative day. It is suggested that in future studies, both the number of interventions and the amount of load used in TL-IMT exercises, pre-

operation should be increased. Also, in this study, we only used visual feedback, but it is possible to combine it with auditory feedback at the same time to obtain a greater effect in terms of the mentioned respiratory parameters. Finally, in this study, we used a percentage of the S-index for loading in TL-IMT exercises, which had not been used until now, therefore, more studies are suggested with the aim of determining the appropriate amount of the S-index load and at the same time maintaining the safety of this group of Patients.

Conclusion

This study demonstrated that inspiratory muscle training with threshold loading and respiratory biofeedback led to maintaining dynamic inspiratory muscle strength and key lung parameters, such as vital capacity, at the time of discharge, compared to the placebo group in post-CABG cardiac surgery patients.

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Disclosure of conflict of interest

None.

Abbreviations

POPC, Postoperative Pulmonary Complications; PE, Pleural Effusion; MIP, Maximum Inspiratory Pressure; CABG, Coronary Artery Bypass Grafting; IMT, Inspiratory Muscle Training; TL-IMT, Threshold Loading Inspiratory Muscle Training; S-Index, Strength Index or Dynamic Inspiratory Muscle Strength; PIF, Peak Inspiratory Flow; VC, Vital Capacity; FVC, Forced Vital Capacity; FEV1, Forced Expiratory Volume in 1 Second; CRF, Chronic Renal Failure; COPD, Chronic Obstructive Pulmonary Disease; NYHA, New York Heart Association; B, Best; A, Average; IS, Incentive Spirometer.

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