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Preoperative Incentive Spirometer to Prevent Postoperative Pulmonary Complications following Open Heart Surgeries: A Randomized Single Blinded Multi-Centric Clinical Trial

Jadeel Noor Faleh[1*], Sadeq AL-Fayyadh[2]

[1]Al-Muthanah Health Directorate, Ministry of Health, Al-Muthanah, Iraq.
[2]Department of the Adult Nursing, College of Nursing, University of Baghdad, Baghdad, Iraq.
*Correspondence to: Jadeel Noor Faleh (E-mail: jadeel.nour1202a@conursing.uobaghdad.edu.iq)
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Abstract

Objective: To determine the effect preoperative use of an Incentive Spirometer (IS) has on preventing postoperative pulmonary complications among patients undergoing open heart surgeries.

Methods: A prospective, randomized, controlled single-blinded parallel-group design. Data were collected from January 9th 2022 to April 1st 2022. A total of $n = 64$ eligible patients were equally randomized to either intervention or control group. Patients in the intervention group performed preoperative IS training for two days before the scheduled surgery. The primary endpoint was the incidence of in-hospital PPCs. The secondary endpoints were postoperative Peak Expiratory Flow Rate (PEFR), Intensive Care Unit (ICU) stay, Hospital Length of Stay (HLOS).

Results: Patients in the intervention group had a lower incidence of postoperative pulmonary complications compared to the control group (12.5% and 21.8%). There was a statistical significant difference between the two groups regarding postoperative PEFR, HLOS and intensive care unit stay.

Conclusion: Preoperative rehabilitation (involving incentive spirometer is related to a lower incidence of postoperative pulmonary complications for the group that received the intervention). Training with preoperative incentive spirometer resulted in a shortening of hospital length of stay and Intensive Care Unit (ICU) stay.

Trial registration: The study was registered in the Iranian Clinical Trial Registry, this at https://www.irct.ir/ reference number (IRCT20211224053503N1).

Keywords: Incentive spirometer, breathing exercises, postoperative pulmonary complications cardiac surgery

Summary Statement

What is already known about this topic?

- The use of IS in the postoperative period helps preventing pulmonary complications after major surgeries.
- The evidence supporting the inclusion of preoperative breathing exercises to prevent PPC, is inconclusive.

What this paper adds?

- The use of preoperative training using flow-oriented incentive spirometer for two days, had better outcomes to prevent postoperative pulmonary complications following open heart surgeries.
- Preoperative training using flow-oriented incentive spirometer for two days improves patients' outcomes.
- Use of IS as a routine care in the preoperative period shortens overall hospital stay.

Background and Aim

Cardiac surgery is considered a high-risk procedure in which a multidisciplinary team is required to manage patients throughout the whole operation phases. When performing a cardiac surgery, focused attention and maintenance are required since the respiratory system is related in both anatomic structure and physiological function.[1]

Open heart surgery can cause various cardiovascular, renal, mental, and infectious complications. However, the occurrence of pulmonary complications remains one of the most challenging difficulties due to the consequential association with increased morbidity and mortality.[2]

The incidences of developing PPC among cardiac surgeries patients range from 10% to 25%, approximately 2% to 5% patients are likely to experience severe pulmonary dysfunction, such as Acute Respiratory Distress Syndrome (ARDS). Patients undergoing CABG surgery are more likely to develop PPC, the incidence rate ranges from 30% to 60%, which contributes to increased morbidity, mortality and length of hospitalization that impose an economic burden on the health care system.[3-5]

In Iraq it was reported that 56% of patients' experience hypoxia as an early complication within the first 48 hrs. following CABG surgery.[6] Recently, Mohammed and Nadr,[7] reported that 14.2% of Iraqi patients undergoing CABG develop PPCs including chest infections and atelectasis.

The implementation of breathing exercises for cardiac surgery patients is now a widely established kind of nurse-led intervention. These exercises are designed for both the preoperative and the immediate postoperative periods in an effort to lower the likelihood of developing postoperative pulmonary complications (PPC), functional capacity impairment, and prolonged hospitalization.[8]

IS is a device that achieves sustained maximal inspiration through predetermined flow or volume. It provides a visual feedback when the patient inhales and sustains the inflation for minimally 5 seconds, it is commonly used in the perioperative care in particular for abdominal and cardiothoracic surgeries as a preventive maneuver for PPCs. Usually, it is nurses

and respiratory therapists' responsibility to instruct patients about the correct method of training using this mechanical device.[9-11]

This study aims to answer whether the preoperative use of an Incentive Spirometer reduces the occurrence of postoperative pulmonary problems and improve Peak Expiratory Flow Rate (PEFR), Intensive Care Unit (ICU) stay, Hospital Length of Stay (HLOS) for adult patients undergoing open heart surgeries?

Materials and Methods

Study Design

An interventional, prospective, randomized, controlled single-blinded parallel-group multi-centric study.

Participants and Study Design

The study recruited adult patients who were scheduled to undergo Coronary Artery Bypass Grafting (CABG) surgery, CABG combined with valve repair, or valve replacement/repair surgeries. Exclusion criteria of the study included: uncooperative patients, patients who lack intellectual capacity to demonstrate proper use of Incentive Spirometer, cases in which incentive spirometer is contraindicated such as thoracic, abdominal, or cerebral aneurysms (risk of rupture due to increased thoracic pressure), recent cardiothoracic or abdominal surgery. The Sample consisted of 64 patients. These patients were equally allotted to the control group and intervention group. The sample size was calculated according to A-priori sample sizes for student *t*-tests.

Settings of The Study

Data were collected from January 9th to April 1st at three different centers in Baghdad, Iraq: (the Iraqi Center for Heart Diseases (ICHD) of the Medical City Directorate, Ibn Al-Bitar Center for Cardiac Surgery of the Karkh Health Directorate, Ibn Al-Nafees Cardiology Hospital of the Rusafa Health Directorate).

Intervention

Eligibility was determined using the inclusion and exclusion criteria of the sample. Patients were randomly assigned to a Study Group (SG) who received preoperative incentive spirometer training for two days before the surgery and a Control Group (CG), who did not receive the intervention. Both groups received same postoperative deep breathing exercises, directed cough, early mobilization, and optimal analgesia.

Upon signing the consent forms, patients allocated to the intervention group received preoperatively individualized training, they were asked to maintain a sitting position on the edge of bed, hold the IS in an upright position, place the lips tightly around the mouthpiece and perform slow and deep inhalation, allow the first ball in the 600 cc chamber to rise to the top, enhance breathing by allowing the second ball in the 900 cc chamber to rise to the top, keep enhance breathing to set the target of 1.200 cc. At maximum inhalation, the mouthpiece is removed, followed by a breath-hold and normal exhalation allowing the three balls to fall to the bottom of the column. After ensuring proper demonstration of steps, patients were asked to repeat the maneuver in a set of ten times hourly while awake until the day of the surgical operation.

Table 1. **Minimum sample size determination**

Parameter of calculating the minimum sample size	Selected values
Anticipated effect size (Cohen's *d*):	0.5
Desired statistical power level:	0.8
Probability level:	0.05

Outcome Measures

The incidence of postoperative pulmonary complications throughout the in-hospital postoperative period was the primary outcome measure, they were scored by the attending physician who is blinded to participants' allocation. Secondary outcomes included, baseline peak expiratory flow rate which was recorded preoperative and then reassessed on the sixth postoperative days respectively by using TRUZONE® Peak Flow Meter which is a tool that measures peak flows from 60 liters per minute (lpm) to 800 lpm at fastest speed at which air is forced out of lungs after taking a deep breath. Length of postoperative hospital and length of ICU stay.

Randomization and Blinding

Simple randomization technique was used for the assignment of subjects into a particular group, flipping a coin method was chosen the side of the coin (i.e., heads - control, tails - intervention) determines the assignment of each subject. The study is single-blinded, since the participants are intentionally kept unaware of which of the two groups they have been assigned to.

Statistical Methods

Data were analyzed through the use of IBM-Statistical Package for Social Sciences (SPSS) version 24. Paired sample *t*-test (used to measure the difference between study and control groups in regard to their postoperative outcomes**.** Effect size (Cohen's *d* test) used to determine the level of impact that the pre-operative Incentive Spirometer exercise on the postoperative outcomes of patients.

Ethical Considerations and Official Agreements

Upon submission of the study protocol ethical approval was sought and granted from the Institutional Review Board (IRB)- Scientific Committee of the Nursing Faculty, University of Baghdad. The researcher submitted a detailed description about the study, including problem statement, objectives and questionnaire to the Ministry of Planning (Central Statistical Organization) and to the Medical City Directorate, the Karkh Health Directorate, the Rusafa Health Directorate (Human Development and Training Center), in order to obtain an official permission to carry out the study.

Clinical Registration

Upon approval from the committees, the study was registered for Iranian Clinical Trial Registry, This at https://www.irct.ir/ reference number (IRCT20211224053503N1). Date of enrollment: 4/01/2022.

Results

The total numbers of patients allocated in the study was (84) Figure 1. Of the 84 eligible patients; 20 were excluded for

various reasons including (postponement or cancellation of surgery, patients' infection with COVID-19, missing data). A total sample of 64 patients were therefore considered in the final analysis. The first group of 32 patients was the intervention group and the second group of 32 patients was the control group Table 1.

The study group that received the intervention consisted of 28 males (87.5%) and 8 females (12.3%). In which (65.6%) of them were within the age range (50–60) years old. Regarding smoking status those who were identified as light smokers and heavy smokers had the highest percentages of (31.3%) for both. More than a half of patients' (53.1%) were considered to be overweight.

The control group consisted of 24 males (75%) and 8 females (25%). Less than two thirds (62.5%) of the group were within the age range (50–60) years old. The results showed that (34.4%) of the control group patients were identified as heavy smokers. Regarding the patients' BMI, half of the control group (50%) were overweight.

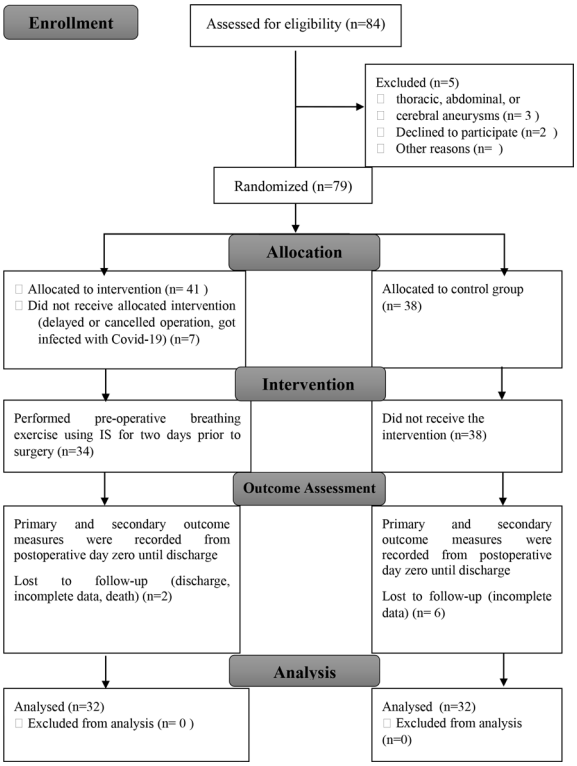

Fig. 1 **CONSORT study flow chart.**

The underlined numbers in Table 2 represent the highest percentages of the selected variables. In the study group, less than two thirds of the patients (62.5) had undergone CABG surgeries. All of the surgeries were elective with a Cardio Pulmonary Bypass (CBP) time of less than two hours for half of them and an operative time of 6 hours for (81.3%) in both groups.

More than half (59.4%) of the control group had undergone CABG surgery, the majority (87.5) of the procedures were elective with a CPB time of (2–4) hours for more than half (56.3) of the patients.

Peak Expiratory Flow Rate (PEFR), Hospital Length of Stay (HLOS) the https://doi.org/10.22317/jcms.v8i4.1261.

A paired sample *t*-test was conducted to compare the differences between pre-operative PEFR between the two groups. There was a statistically significant difference in the pre-operative peak expiratory flow rates (M = 40.00000, SD = 107.42589, t (31) = 2.106, P = .043).

There was a statistically significant difference in the Post-operative peak expiratory flow rates between control group and study group (M = 75.78125, SD = 81.43976, t (31) = 5.264, P = .0001. The effect size for this analysis (d = 0.93) was found to exceed Cohen's (1988) convention for a large effect (d = .80).

There was a statistically significant difference in the number of days' patients spent in the ICU setting between control group and study group (M = –.56250, SD = .91361, t (31) = –3.483, P = .002). The effect size for this analysis (d = 0.61) was found to be a medium effect size.

There was a statistically significant difference in the number of days' patients spent in the hospital from postoperative day zero between control group and study group (M = –1.37500, SD = 1.87943, t (31) = –4.139, P = .0001, The effect size for this analysis (d = 0.73) was found to be a medium effect size.

Discussion

The study result showed that (65.6%) of the study group and (62.5%) of the control group were within the age group (50–60) years old at the time of data collection. Mohammad et al.[12]

Table 1. **Descriptive statistics of patients' demographic and lifestyle data**

Variables		Study group *n* (%) *n* = 32	Control group *n* (%) *n* = 32
Age	50–60 years old	21 (65.6%)	20 (62.5%)
Gender	Male	**28 (87.5%)**	**24 (75.0%)**
	Female	4 (12.5%)	8 (25.0%)
Smoking status (pack/year)	Never Smoked (0.0 pack-year)	5 (15.6%)	10 (31.3%)
	Light Smoker (0.1–20.0 pack-year)	**10 (31.3%)**	4 (12.5%)
	Moderate Smoker (20.1–40.0 pack-year)	7 (21.9%)	7 (21.9%)
	Heavy Smoker (> 40 pack-year)	**10 (31.3%)**	**11 (34.4%)**
Body Mass Index (BMI)	Underweight – BMI < 18.5 kg/m^2	2 (6.3%)	1 (3.1%)
	Overweight – BMI ≥25 to 29.9 kg/m^2	**17 (53.1%)**	**16 (50.0%)**
	Obesity – BMI ≥30 kg/m^2	13 (40.6%)	15 (46.9%)

Table 2. **Descriptive statistics of patients' clinical and surgical data**

Variables	Study group *n* = 32		Control group *n* = 32	
Current surgical procedure	CABG	20 (**62.5%**)	CABG	19 (**59.4%**)
	MVR	6 (18.8%)	MVR	7 (21.9%)
	AVR	4 (12.5%)	AVR	4 (12.5%)
	CABG & MVR	1 (3.1%)	TVR	1 (3.1%)
	CABG & AVR	1 (3.1%)	CABG & DVR	1 (3.1%)
Operative time	5 hours	4 (12.5%)	5 hours	4 (12.5%)
	6 hours	26 (**81.3%**)	6 hours	26 (**81.3%**)
	7 hours	2 (6.3%)	7 hours	2 (6.3%)
Cardiopulmonary bypass time (Minutes)	Less than 2 hours	16 (**50.0%**)	Less than 2 hours	12 (37.5%)
	2–4 hours	15 (46.9%)	2–4 hours	18 (**56.3%**)
	More than 4 hours	1 (3.1%)	More than 4 hours	2 (6.3%)

CABG: Coronary Artery Bypass Grafting, AVR: Aortic Valve Replacement, MVR: Mitral Valve Replacement, DVR: Double Valve Replacement, TVR: Tricuspid Valve Repair.

Table 3. **Descriptive statistics of patients' clinical outcomes**

Variables		Study group (*n* = 32) *n* (%)	Control group (*n* = 32) *n* (%)
Pre-operative PEFR	Below normal (Male = < 450 L/Min) (Female = < 320 L/Min)	31 (**96.9%**)	31 (**96.9%**)
Post-operative PEFR	Below normal (Male = < 450 L/Min) (Female = < 320 L/Min)	32 (**100.0%**)	32 (**100.0%**)
Post-operative pulmonary complications	Atelectasis	4 (12.5%)	5 (15.6%)
	Tracheobronchitis	–	1 (3.1%)
	Pleural effusion	–	1 (3.1%)
ICU length of stay	2 days	28 (87.5%)	19 (59.4%)
HLOS	8 days	14 (43.8%)	8 (25.0%)

reported that Coronary Artery Disease (CAD) tends to occur earlier in Iraqi population. This finding may be attributable to the lifestyle profile of the participants including their propensity to smoke, poor dietary habits, and low levels of health literacy.[13]

The majority of the sample were males with a percentage of (87.5%) for the study group and (75.0%) for the control group. This result is supported by Jassim et al.[6] This gender difference could be attributed to many etiologies, including limited tobacco use among Iraqi females and dietary habits. Coronary artery disease (CAD) and the occurrence of a woman's first acute myocardial infarction occur several years later in women than in men, before menopause, the well-known biological defense that women have against CAD can postpone the onset of CAD symptoms by more than ten years.[14]

The study findings showed that half of the study sample was overweight with a BMI of ≥25 to 29.9 kg/m^2, which is similar to the results of the study conducted by Alam et al.[15]. These results are not surprising, because being overweight and obese are closely associated to both known and emerging risk factors for cardiovascular disease.[16]

Regarding smoking status, the highest percentages in the study group were heavy smoker and light smokers with (31.3%) respectively, whereas, (34.3%) of the control group were heavy smokers, this result is consistent with the results of Sharif-Kashani et al.[17] where 43.7% of patients had a cumulative tobacco exposure of >40 pack years. These findings own up to the fact that smoking contributes significantly to premature coronary atherosclerosis and to the acceleration of atherosclerosis by increasing the oxidation of low-density lipoprotein (LDL) and impairing coronary endothelial vasodilation.[18]

As for the performed surgical operation, 62.5% of the study group and 59.4% of the control group had underwent Coronary Artery Bypass Grafting (CABG), this result is similar to.[19]

With regard to cardiopulmonary bypass time (CPB), half of the study group had CPB time of less than 2 hours (> 120 minutes) similar to Faritous et al.[20] This difference in CPB time between the two groups could be attributed to intraoperative encountered complications possibly occurred to the control group.

The majority of the study sample of both group had an operative time of 6 hours, unlike a study conducted by Matsuura et al.,[21] where 109 patients out of 149 had an operative time of 480.90 ± 161.20, which exceeded the operative time in the present study. The patients involved in the aforementioned study may had more complex surgeries that required more time compared to the patients in the present study.

Postoperative Pulmonary Complications

The incidence of postoperative pulmonary complications in those who received the intervention and those who did not was (12.5% and 21.8%) respectively, these findings did not differ from the results of Chen et al. (2019),[22] in which the incidence of postoperative pulmonary complications was 10.2% in the study group and 27.3% in the control group. Another study confirmed these results where atelectasis was 14.10% in the study group and 27.10% in the control group.[23]

In contrast, Moradian et al.[24] reported that the incidence of postoperative atelectasis was the same in both groups with 20% incidence rate in each group.

This difference in the presented results may be due to the fact that the control group in the aforementioned study had received conventional physiotherapy which contributed to insignificance unlike the control groups of the current study and those that had similar results to it, who did not receive any form of physiotherapy or pre-rehabilitation in the preoperative phase.

The most prevalent complication in the current study was atelectasis with an overall incidence rate of (28.1%) for both groups compared to lower incidence in Hijas-Gómez et al.[25] who reported an overall incidence rate of (5.9%). It is possible that the decreased incidence rate was due to the fact that postoperative patients in the aforementioned study have received physiotherapy.

Patients' Clinical Outcomes

Tables 4, 5 and Figure 2 represent the differences between the two groups in terms of Peak Expiratory Flow Rates, which demonstrates that there was a statistically significant difference in the postoperative peak expiratory flow rates $P = .0001$ unlike the results of Herdy et al.,[26] who found that before discharge, PEFRs returned to baseline values in the rehabilitation group (336 ± 105 l/min) but not in the control group (271 ± 132 l/min).

The difference between the findings of the present study and those of the aforementioned article is that the PEFRs

Table 4. **Difference in pre-operative PEFR between study and control groups**

	Paired differences				
Preoperative PEFR (Study group)	Mean difference	Std. deviation	*t*	df	Sig. (2-tailed)
Preoperative PEFR (Control group)	40.00000	107.42589	2.106	31	.043

Table 5. **Difference in post-operative PEFR between study and control groups**

	Paired differences					
Postoperative PEFR (Study group)	Mean difference	Std. deviation	*t*	df	Sig. (2-tailed)	**Effect size**
Postoperative PEFR (Control group)	75.78125	81.43976	5.264	31	**.0001**	0.93

Effect sizes = small ($d = 0.2$), medium ($d = 0.5$), and large ($d = 0.8$).

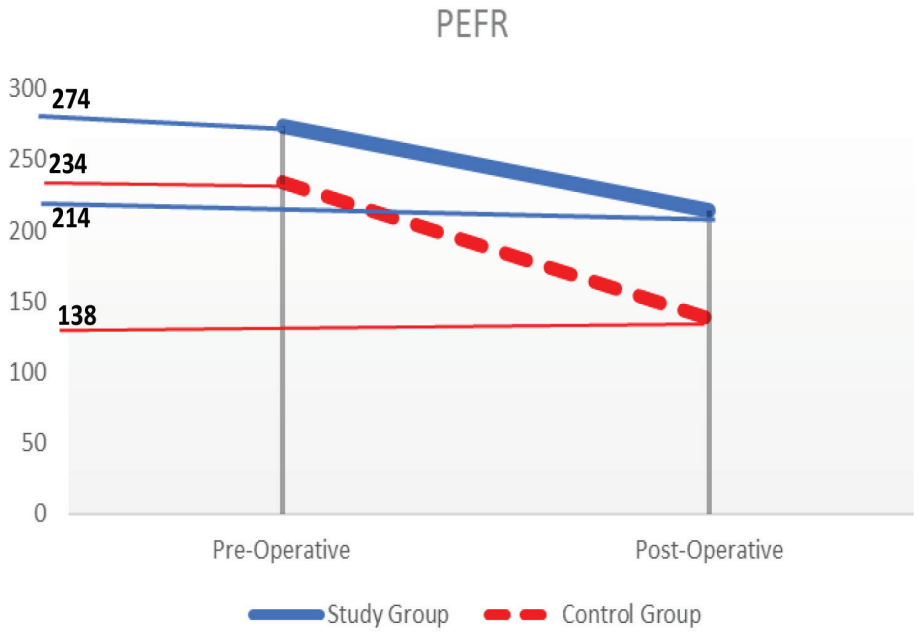

Fig. 2 **The mean plot shows that PEFR decreased in the postoperative period compared to the baseline values in both the study group and control group. However, the study group had better values in the postoperative period.**

values of the patients in the present study were already below the normal values in the preoperative period, and despite the significant difference between the two group none of them returned to the baseline values after the surgery.

The results in Table 6 represents the difference between the study group and control group regarding the length of days spent in the Intensive Care Unit (ICU) setting which shows that the use of preoperative IS has decreased the ICU stay in the study group compared to the control group as shown in Figure 3, a previous study conducted in Turkey supported these results as they stated that preoperative Inspiratory Muscle Training reduced the ICU stay.[27]

Regarding Hospital Length of Stay, as shown in Table 7 and Figure 4, there was a statistically significant reduction in the number of days the study group spent in the postoperative period ($P = .0001$), which indicates that the intervention had a

Table 6. **Difference in ICU stay time/days between study and control groups**

	Paired differences					
ICU stay time/days (Study group)	Mean	Std. deviation	*t*	df	Sig. (2-tailed)	**Effect size**
ICU stay time/days (Control group)	−.56250	.91361	−3.483	31	.002	0.61

Effect sizes = small ($d = 0.2$), medium ($d = 0.5$), and large ($d = 0.8$).

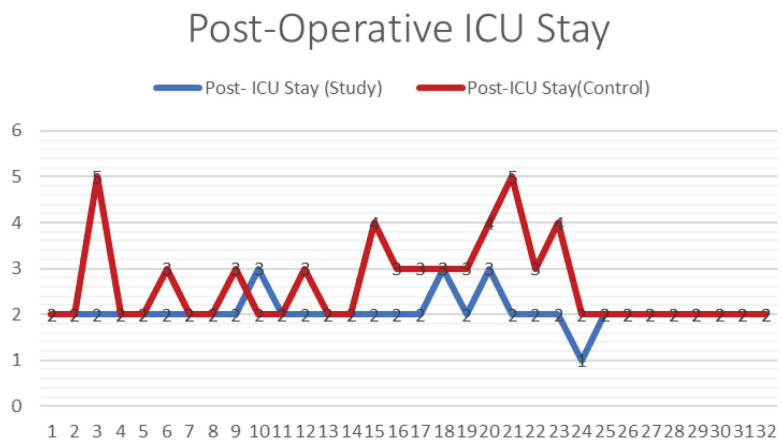

Fig. 3 **The mean plot indicates that patients in the control group spent more days in the ICU following surgery when compared to the study group.**

Table 7. **Difference in hospital length of stay/days between study and control group**

	Paired differences					
Hospital length of stay (Study group)	Mean	Std. deviation	*t*	df	Sig. (2-tailed)	**Effect size**
Hospital length of stay (Control group)	−1.37500	1.87943	−4.139	31	.0001	0.73

Effect sizes = small ($d = 0.2$), medium ($d = 0.5$), and large ($d = 0.8$).

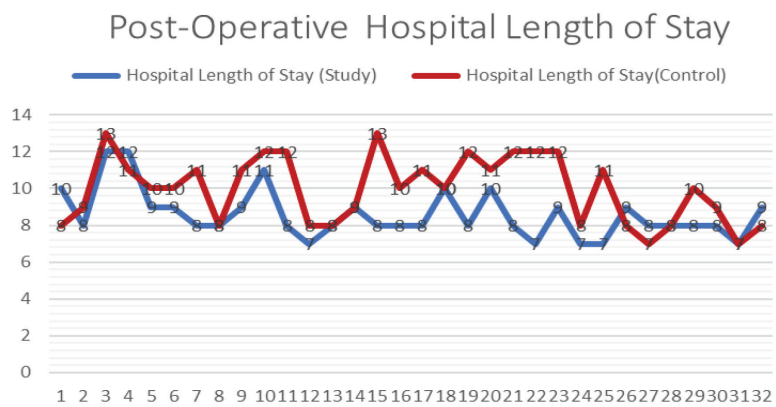

Fig. 4 **The mean plot shows that patients in the control group had longer length of hospital stay when compared to the study group.**

positive effect on reducing HLOS, supporting this conclusion, multiple clinical trials have demonstrated that preoperative respiratory physiotherapy utilizing various maneuvers is effective in reducing hospitalization for patients undergoing cardiac surgeries.[28-31]

Conclusion

This study showed that preoperative rehabilitation involving Incentive Spirometer is related to a lower incidence of postoperative pulmonary complications for the group that received the intervention (21.9% vs. 12.5%) a difference which may be considered relevant. Training with preoperative incentive spirometer resulted in a shortening of hospital length of stay and Intensive Care Unit (ICU) stay among patients in the intervention group than those in the control group. This, in turn, results in the efficient use of the limited resources and the reduction of health-care costs, which supports the well-established concept of "meaningful use" of healthcare resources.

Recommendations

Patients undergoing open heart surgery should have free access to incentive spirometers in the surgical units, as well as adequate training and encouragement, since this appears to have prophylactic effect against PPCs. Further studies with a larger sample size that specifically target patients with preexisting respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD), asthma are required to confirm these findings. Future clinical trials should consider double blinding in the recruitment and outcome assessment procedures. Patients' adherence considerations must be integrated into future clinical trials in order to establish a more solid evidence basis and to draw relevant conclusions.

Limitation

The primary limitation was the small sample size which limited the generalizability of the intervention effect. Two centers postponed the operations for a duration of one week for each due to rapid spread of Coronavirus Omicron variant which caused impediment in data collection and time constraints.

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Conflicts of Interest

None.

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