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"Efficacy Of spirometric Lung Exercise On Patients Of Chronic Obstructive Pulmonary Diseases Posted For Off-Pump Coronary Artery Bypass Grafting Surgery – Acomparative Study."

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Abstract
Aims& Objective - *To find out efficacy of preoperative incentive spirometry on patients of ischaemic heart disease with chronic obstructive pulmonary diseases posted for off pump coronary artery bypass grafting surgery.*
Materials & Methods *-Total 120 COPD patients* randomly allocated *in three groups.*
Each groups again divided on the basis of FEV1 % *case(n=20; A1,B1,C1) and control(n=20 ; A2,B2,C2) .All the cases received* pre-operative *incentivespirometry* and under went GA with similar agents . *Postoperative changes in inspiratory capacity, extubationtime*noted and analysed statistically.
Results/Discussion- *There were no significant differences among study groups in terms of age, weight & height .Patients in A1 group had better pos**t operative inspiratory capacity(IC)(6th-1240±367.64 vs 875±202.29;24th-1465±299.61 vs 980±198.94; 48th-1660±328.31 vs 1305±372.01)** & a relatively significant rapid regain of lung function to pre-op value compared to control group (A2). Patients in B1 group started showing im**proved IC(24th-1355±341.01 vs 1039.5±308.13;48th-1625±352.25 vs 1075±326.26{p<0.0001})** from pre op onwards till 48 hrs post op, excepting 6th hour post op value, compared to B2.Group-C1 showed inconsistent & marginally beneficial compared to C2.*
Pre op spirometry exercises showed *positive impact inchanges SpO2 & PaO2 in A1 & B1.*
M*ean time to extubation* was significantly less *A1(10.65±2.15 vs 15.47±1.98), B1(11.08±1.57 vs 15.65±2.32)C1(12.07±2.66 vs 14.27±2.16) compared to control arm.*
Conclusion-*Spirometric lung exercise significantly improves post operative lung function in FEV1>75% and FEV1 between 75-50% but not* effective significantly patients with *FEV1<50%* .Patients with *lung exercise has found positive impact in SpO2 & PaO2 in A1 & B1. Lesser mean time toextubation* found in COPD patients posted for off pump CABG.

Keyword: *Spirometric lung exercise,inspiratory capacity(IC), FEV1%, SpO2, PaO2*
Conflict of interest*-There is no conflict of interest in this study.*

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I. Introduction

Prevalence of chronic obstructive pulmonary disease (COPD) among patients with ischemic heart disease, scheduled for cardiac surgery, has a wide range from 5.7 % to >25 %. [1-4]The patients who have coronary artery bypass graft (CABG) are prone to postoperative pulmonarycomplications (PPC)[5] and the incidence is between 30% - 60%.[6] Development of PPC is associated with impaired oxygenation and inconsistencies in gas exchange.[7] PPC are the most significant contributor to morbidity, mortality, and expenses associated with the hospitalization.[8]

Cardiac surgeries are proved to have a negative impact on pulmonary function. All studied tests; VC, FVC, FEV1, FEV1/FVC, and MVV had lower values after the surgery than before it. This was true for both valvular and CABG procedures**.**

Current best available evidence from randomized controlled trials (Grade A/Level 1c) suggests that OPCAB reduces postoperative pulmonary dysfunction and OPCAB surgical procedures are more advantageous than on-pump methods especially for patients with COPD .

A systematic review was conducted by Agostini*et al*. of seven studies about insentivs spirometry (IS) after thorax surgery.[9] Three studies reported that IS can improve gas exchange .Finally, they concluded that IS can promote oxygenation and gas exchange after thorax surgery. Mordian*et al*. showed planned breathing exercise significantly improved PaO2 and SaO2 on the postoperative day of coronary artery bypass surgery.[10] Covino et al showed that myocardial revascularization without CPB(off pump) allows a better postoperative

clinical course in patients with advanced pulmonary disease.[11]Different methods are used for theimprovement of pulmonary function and oxygenation, of which incentive spirometry (IS) has beeninvestigated here. The aim of this study is to evaluate the effects of IS afterOBCAB among COPD patients.

II. Aims & Objectives

1. Changes of total Inspiratory capacity 7 days before the day of operation to 6thhrs, 24thhrs, and 48th hour post-operative period
2. Time of extubation from skin closure(**m**in) in two groups

III. Methodology

a) **Study design**- Prospective observational randomised controlled parallel group study.
b) **Study setting and time line**- February 2017-September 2018.
c) **Place of study**-Department of Cardiac Anaesthesiology, NilratanSircar Medical College and Hospital. (University affiliated tertiary care hospital and teaching institution).
d) **Period of study**-February 2017-September 2018.
e) **Study population**- Diagnosed COPD patients based of pulmonary function withFEV1 between >75% and 50% put for off pump CABG age between 35-65 years with coronary artery disease .
f)**Sample size**-It was calculated that 120 subjects were required to define this proportion with 5% margin of error and 95% confidence level. This calculation assumes no limitation of the population size.
Inclusion Criteria: All adult patients of coronary artery disease aged between 35-65years **with** predicted FEV1between >75% and <50% posted for off pump CABG,

Exclusion Criteria:unwilling patients, patients refusal ,cannot continue spirometricexercise,NYHA grade –III and IV, patientwith pulmonary stenosis, moderate pulmonary hypertension ,tricuspid stenosis, patient with RA,RV,PA mass like tumor,thrombus, e, DAC naht rehto ygolohtap caidrac yna,sesaesid traeh raluvlav endobronchial mass, significant arrhythmia., bundle branch block ,coagulopathy, thrombocytopenia,patient age<35years or >65years.,diabetes,asthma,respiratory failure, and patients required cardiopulmonary bypass support during operation. Study variable-Age (years), Sex (M/F) ,Height (cm) ,Weight (kg), Body Surface Area (m^2), FEV1,FEV1/FVC , Left ventricular ejection fraction (%), Left ventricular end diastolic volume (ml), Degree of Tricuspid regurgitation, CVP ,right ventricular end diastolic volume index.Data collection and evaluation- all data were collected in pre designed computer generated case record form.Data collection were started in 7 day preoperatively in our preanaesthesia evaluation room, record form were attached along with patients ticket, again data collected preoperatively and in post operation recovery room (ITU).Standard statistical method were used to evaluate the study.

Statistical analysis –The study data were recorded on a master sheet and will be summarized as mean and standard deviation for normally distributed numerical variables, median and interquartile range for skewed numerical variables and counts and percentages for categorical variables. Univariate analysis will be done to identify factors potentially influencing successful outcome. Those found significant on univariate analysis were entered into a binary logistic regression model<0.05 were considered as statistically significant.

Study technique: After obtaining institutional ethics committee permission, selected patients to undergo elective off pump Coronary artery bypass graft surgery were randomised into eerht groups.

Spirometric lung exercise procedures wereproperly demonstrated by the investigator. Data record form were dully filled by the investigator .Total 120 patients divided in eerht equal groups, Group-B-puorG,A and Group-C on the basis of FEV1Group-A- (n=40) FEV1>75% .Group-B -(40=n) 1VEF 75%-50%, Group-C (40=n) FEV1< 50%.

Anaesthesia was performed according to institutional practice. Vascular access and radial artery catheterization for measurement of arterial blood pressure and blood sampling for arterial blood gas analyses was done prior to induction.Oxygensaturation, three-lead electrocardiogram (leads II and V5) was monitored continuously. .doirep noitudnierp nevig saw citoibitna elbatcejnlDuring induction basal narcosis sawattained with intravenous opiate anaesthetic with fentanyl (5 to 10 µg/kg), midazolam (0.1mg/kg) followed by sleep dose of intravenous etomidate . Intravenous vecuronium (1mg/kg) given to achieve neuromuscular blockade prior to intubation. All patients were ventilated mechanically after intubation. Anaesthesia was maintained by oxygen and nitrous oxide in isoflurane (Mac-awareness) to maintained BIS between 40-60. Intermittent intravenous top up doses of Inj fentanyl (1-2 µg/kg), Injmidazolam(0.1mg/kg) and Injvecuronium(0.02µg/kg). A multi-lumen internal jugular catheter was inserted for measurement of central venous pressure and for fluid/medication administration after intubation. All patients were shifted to ITU after operation.

Schedule of data collection: Age (years), Sex (M/F), Height (cm), Weight (kg), Body Surface Area (m^2), inspiratory capcity in different time of study periods. Extubation time- Since skin closure.

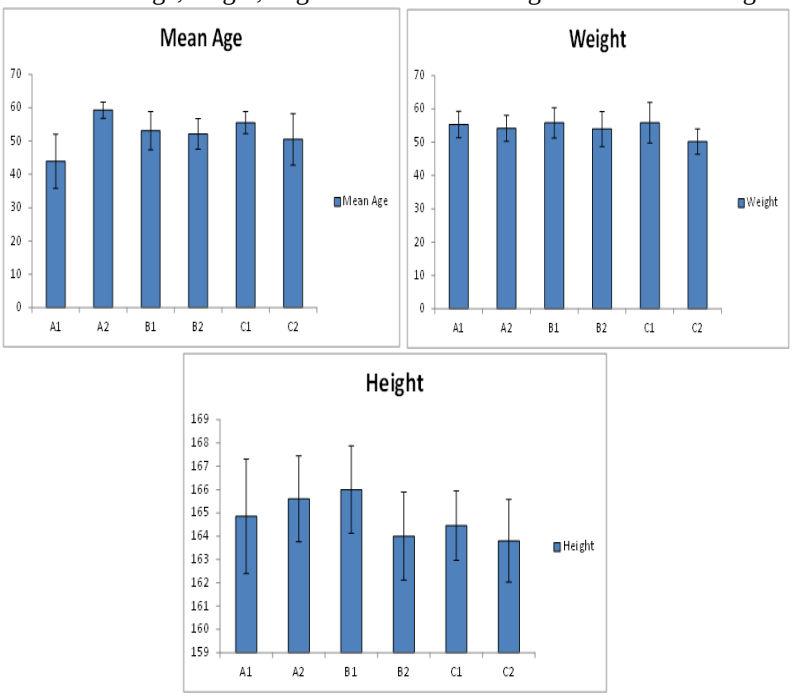
Parameters measured: Age (years).Sex (M/F).Height (cm).Weight (kg).Body Surface Area (m^2).Preoperative PFT reading, FEV-1 for group allocation. Changes of pre-operative and post-operative Inspiratory capacity from incentive spirometer.Time of extubation(mints) from skin closure.

Study tools:Incentive Spirometer. Multi-channel monitor for recording ECG, heart rate, SpO2, noninvasive blood pressure, invasive blood pressure, wave form of central venous pressure, wave form of pulmonary artery, core temperature, end tidal carbondioxide.Continuous cardiac output monitor (EV 1000) for recording systemic vascular resistance, pulmonary vascular resistance, central venous pressure, stroke volume, cardiac output, cardiac index, stroke volume variation, mixed venous oxygen saturation.

IV. Results And Analysis

Demographic parameters:

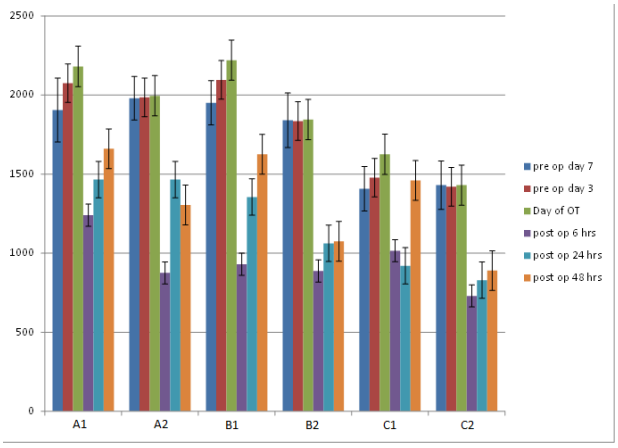
Figure 1: Y axis shows age,weight,height.Error bars showing distribution among study groups.



Mean age were significantly different between A1 & A2. No other significant intergroup difference noted in age distribution. Error bars showing wt (in kg) distributions among study groups with no statistically significant intergroup variation. Y axis shows height in cm. Error bars showing distribution of heights among study groups with no significant intergroup difference.

Figure 2: Study Parameters:

Group A includes patients with FEV1 >70%
Group B includes patients with FEV1 between 50% to 70%
Group C includes patient with FEV1< 50%



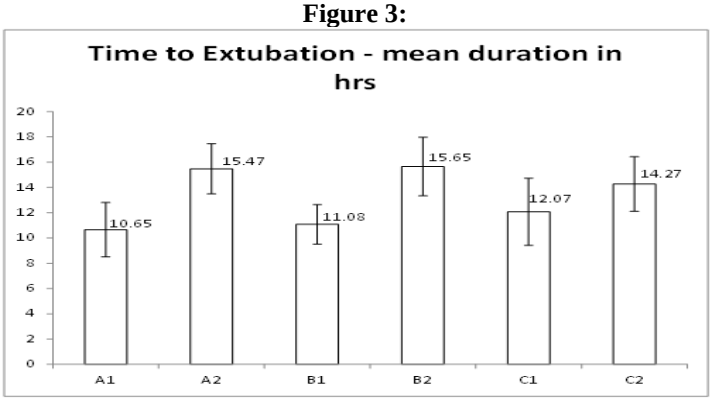
Y axis shows IC. Mean IC along with 95% confidence ranges have been depicted in the Composite bar diagram with error bars for broader intergroup comparison. Any overlap in the confidence intervals between two groups implies no statistically significant difference between them.This shows that spirometric lung exercises had a highly significant positive impact on A1 &B1 groups but less so on C1. Also in A1, C1 groups difference between Day 7 pre op & 48 hours post op IC was not Statistically significant implying rapid return to baseline lung function in the intervention arms.All 6 groups had a significant post operative 6th hour drop in IC from their baseline pre op levels with no significant intergroup difference implying intervention had little effect on immediate post operative period.

Table 1 Oximetry: Both Pulse-oximetry & arterial oxygen contents were analyzed pre & post operatively

Oximetry	**A1**	**A2**	**p value, Significance**
SpO2 Pre op	**98.85 ±0.38**	**97.5 ±0.85**	**0.004, S**
SpO2 Post op	**98.65 ± 0.46**	**95.7 ± 0.98**	**< 0.0001, S**
PaO2 Pre op	**93.55 ± 5.06**	**82.1 ± 4.27**	**0.0009, S**
PaO2 Post op	**148.45 ± 35.61**	**86.9 ±3.55**	**0.0009, S**
	B1	**B2**	**p value, Significance**
SpO2 Pre op	**96.2 + 1.67**	**96.2 + 1.47**	**1.00, NS**
SpO2 Post op	**96.8 ± 1.32**	**96.1 ± 1.33**	**0.103, NS**
PaO2 Pre op	**76.3 ± 2.66**	**82.45 ± 4.62**	**0.07, NS**
PaO2 Post op	**135.55 ± 27.39**	**96.8 ± 12.5**	**0.01, S**
	C1	**C2**	**p value, Significance**
SpO2 Pre op	**95.45 ± 2.63**	**96.05 ± 1.70**	**0.39, NS**
SpO2 Post op	**98.7 ± 0.45**	**96.3 ± 0.83**	**< 0.0001, S**
PaO2 Pre op	**79.75 ± 4.2**	**80.3 ± 3.56**	**0.83, NS**
PaO2 Post op	**130.8 ± 26.85**	**86.8 ±17.76**	**< 0.0001, S**

NS = Not Significant, S= Significant. The above table shows pre &post operative oximetry values. Pre op Spirometry exercises had a positive impact in both pre &post operative oximetry values with statistically significant improvement of both pre &post operative SpO2 &PaO2 . Spirometry exercises improved post operative oxygenation in B1 group in a significant manner. C1 group had a significantly higher mean post operative PaO2 level compared to C2.

Figure 3:



Error Bars Showing means of time to extubation in hours with 95% Confidence intervals. In each of the 3 broad groups viz A, B, C ; the intervention arm (i.e. volume based incentive spirometry exercises for 7 pre operative days), A1, B1, C1 had a lesser mean time to extubation compared to the Control arm, though this difference was statistically significant in A1 & B1 groups. (p value < 0.05, CI 95%)

V. Discussion

The patients who have undergone coronary artery bypass graft (CABG) are prone to pulmonarycomplications. like hypoxemia,ateletasis, edema ,pnumonia,pnumothorax and the incidenceis high, between 30% to 60%.[6,7]These complications are the most significant contributor to morbidity,mortality.[8] Development of pulmonarycomplication is associated with impaired oxygenation, arterial hypoxemia ,ventilation,ventilation/perfusion missmatch and inconsistencies in gas exchange occured .[8] Heart and lung are interdependable system . Therefore, identification of the complication and early interventions are needed toprevent this PPC . Some of the interventions are **to** prevent the pulmonary complication after CABG, which can be highlighted by deep breathingexercises, incentive spirometry (IS), continuous positive airway press.Lung exercises consist of deep breathing exercise,abdominal muscle strengthening, IS, intermittent positivepressure, and early mobilization, which are done with the aim of improving pulmonary function.

Any of the single method still not proved supirior or best mode of therapy.

Spirometric lung exercise used to reducepostoperative pulmonary complications(PPC) are not yet established, which has led tocontroversies in theimprovement of pulmonary function in the exchange of gases andoxygenation after CABG , and there is a need for further studies to clarify the effect of this techniques.As in our country and our institution incidence of COPD among IHD higher so post operative pulmonary complication also higher.Still nonconclusive results of spirometric exercise drag our interest to this study.

Afrasiabi*et al.* have studied the effects of IS on atrial blood gas (ABG). In this study, patients used the IS during 6 h after extubation and it measured the ABG preoperatively, 1 h, 7 h after extubation. He found effect of IS on ABG parameters is insignificant.[12]

Carvalho*et al.*and **Overend*et al.*** found use of the IS to reduce POPC complications are not established yet, and they suggest need for more studies toclarify this subject.[13,,14]**Agostini and Sing**, have reported that method can be useful in improvement of pulmonary function.

Findings of study reports indicate inconsistency and scarcity of evidence regarding IS on lung compliance in RCTs gaugingthe effectiveness of IS on postoperative outcomes after cardiac, thoracic and abdominal surgeries.Only six trials had some reporting on compliance; but results were inconsistent andincomprehensive. Two trialsreport drew attention to the degree of noncompliance that existent in trials, while one.highlighted the possible drawbacks of data collection methodlogy. Another two trials provided some insights into the possible role of IS parameters on the effectiveness of therapy.One, which found no significant differences between continuous positive airway pressure therapy andIC on pulmonary function after cardiac surgery, indicated that frequency of IS use and target volumeachievements remained low and did not increase significantly for the duration of their trial ·Study found IS more effective than continuous positive airway pressure therapy onFRC and atelectasis after upper abdominal surgery It is difficult to drawany valid inferences as to the effects of IS performance on outcomes because these trials had inherentmethodological issues .

Out of five trials that assessed IS parameters,and had used the Bartlett-Edwards (BE) IS, which had incidence-counting features · BE IS and Spirocare models, which also have counterfeatures have since given way to single-use, disposable, less-expensive models without counterfeatures.

The variety of compliance monitoring and data collection methods in the included IS trials also reflectthe lack of standardization and consensus for such efforts. The degree of compliance cannot beascertained unless effective monitoring. Although there are no 'gold standards' fordetermining compliance, direct observation or measurement and electronic monitoring have beensuggested as more accurate and reliable techniques.

However, for IS interventions, direct methods, such as supervision by staff, may not be viable options in terms of cost, time and manpowerresource availability.Electronic technologies have been used in some areas involving the use of medicaldevices and four earlier trials have used IS counters to collect compliance data.Although the 'BE'-IS deemed less suitable for current respiratory physiotherapy practice, some of itsfeatures, such as the incidence counter, may be an indispensable component. In fact, the IS wasconceived not only to facilitate active maximal lung expansion, but also to keep record of themanoeuvres by its inventors . As such, innovative methods for reinstating suitable versions ofcounter devices capable of monitoring and collecting compliance data could be contemplated.

Gale GD, Sanders DE. in his study showed that that vital capacity fell after surgery to 41.5 % of the pre-operative level, but this rose after the use of the incentive spirometer by an average of 15.5 per cent. Arterial oxygen tensions were unaltered.Balandiuk, A. E.; Kozlov, I. A - Incentive spirometry significantly improved lung inspiratory capacity, arterial oxygenation and lung shunt after CPB. Spirometry training before and after operation is effective in decreasing the duration of MV.

Our results are similar with Gale GD, Sanders DE and Balandiuk, A. E.; Kozlov, I. A.

VI. Summary& Conclusions

This study included of 120 patients with COPDundergoing Off pump Coronary Artery Bypass Graft. They were divided into 3 major groups according to the severity of obstructive lung disease (FEV1/FVC) & each group was further divided into an Intervention arm (undergoing volume based incentive spirometry – lung exercises) viz. A1, B1, C1 & the Control arm viz. A2, B2, C2 respectively. The summary of data analysis is as follows

Study population is comprised of 99 male & 21 female patients, with majority of the patients belonging to age range of 40 to 70 years & of weight band 40 to 70 kg. There were no significant differences among study groups in terms of age, weight & height excepting that group A1 had a lower mean age of population than A2.

Patients in A1 group had better post operative lung function & a relatively rapid regain of lung function relieving the post op airway obstruction compared to control group (A2) significantly.

Patients in B1 group started showing improved lung functions from day 3 pre op onwards till 48 hrs post op, excepting 6^{th} hour post op value, compared to B2.

Post operative improvements were inconsistent & marginally beneficial in C1 group with rapid return of base line lung function within 48 hours post operative period compared to C2.

Pre op Spirometry exercises had a positive impact in both pre &post operative oximetry values (both SpO2 & PaO2), in A1 & B1 compared to A2 &B2 respectively & only on post op values in C1 than C2.

A1, B1, C1 had a lesser mean time to extubation compared to the Control arm, though this difference was statistically significant in A1 & B1 groups.

A moderately strong negative correlation found between time taken to extubate the patient &IC at 48 post op hours, implying the adverse effect of requirement of prolonged ventilation on lung function.

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