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Evaluation of Effectiveness of Preoperative Inspiratory Muscle Training to Prevent Post-Operative Pulmonary Complication in Patients Undergoing on Pump CABG Surgery

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Abstract: ***On Pump CABG patients are at higher risk of developing Post-Operative Pulmonary Complications (PPC's), leading to increased post-operative morbidity and mortality. Aim &Objective: To study the feasibility and effects of Preoperative Inspiratory Muscle Training (IMT) in patents who are at higher risk to develop PPC's and are planned for elective on pump CABG. Material and Method: After institutional ethics committee approval and obtaining written informed consent, 78 patients scheduled for elective on pump CABG were randomly divided into two groups. Group A (n=42) Intervention group and Group B (n=36) control group. The intervention group received 2 to 4 weeks of preoperative inspiratory muscle training apart from the usual care received by the patient's in the control group. Primary outcome measures included patient's satisfaction and motivation, compliance with therapy and to assess the Inspiratory Muscle Strength expressed as Pimax at residual volume. Secondary outcome variables were PPC's and length of hospital stay. Results: The feasibility of IMT was excellent with no adverse events. Inspiratory muscle strength increased by 36% from 65.6 (15.8) cms of H20 at base line to 88.6 (29.1) cms of H20 at the end of the training period (p=0.001) compared to control group where the increase in inspiratory muscle strength was only 15% from 67.8 (26.3) cms of H20 to 77.83 (27.3) cms of H20 (p=0.18).Lung functions like forced expiratory volume in 1 sec (FEV1), Inspiratory Vital Capacity (IVC) and FEV1/IVC remained unchanged during training period and before surgery in both groups. Length of hospital stay was 8.93 (± 1.94)days in the intervention group and 10.92 (±5.78) days in the control group (p=0.24).Conclusion: IMT for 2 to 4 weeks in patients who are at high risk of developing PPC's undergoing on pump CABG are benefitted by preoperative IMT which is reflected by decreased incidence of PPC's.***

Keywords: PPC's: Post-Operative Pulmonary Complications, IMT: Inspiratory Muscle Training, FEV1: Forced Expiratory Volume in 1 second, IVC: Inspiratory Vital Capacity, Pimax: Inspiratory Muscle Strength

1. Introduction

Patients who are scheduled to undergo coronary artery bypass grafting (CABG) on Cardio pulmonary Bypass (CPB) are at very high risk to develop Postoperative Pulmonary Complication (PPC'S) which leads to increase post op ventilation time, Increased ICU stay, Increased hospital stay finally leading to increased postoperative morbidity& mortality (1).The Incidence of such complication ranges from 5% to 73% and is further aggravated by the presence of preexisting lung disease, the age of the patient whether the patient is smoker, has diabetes mellitus or not, is he obese or not (2).

Pre and post-operative respiratory muscle training has been used successfully for the prevention of PPC's in patient's undergoing cardiac surgery (3, 4).Many studies have revealed that the respiratory Muscle function is reduced after Cardiac surgery leading to increased risk of PPC'S due to unilateral or bilateral phrenic nerve paralysis (5, 6). Weakness of the respiratory muscle may lead to decreased Vital Capacity (VC), decreased Tidal Volume (TV) and decreased Total Lung Capacity (TLC) all these leading to inability of the patient to cough effectively which culminates into atelectasis of the basal lung segment and decreased Functional Residual Capacity (FRC) which is turn leads to increased ventilation/perfusion (V/Q) mismatch (7).

The objective of the present study was to evaluate the effectiveness of preoperative Inspiratory Muscle Training (IMT) in patients undergoing CABG on CPB to prevent PPC"s. Consequently we prepared a preoperative risk model by online search to identify those patients who are at high risk of developing PPC's after undergoing on pump CABG surgery (8) and to develop an appropriate preoperative intervention so as to evaluate the effectiveness of preoperative IMT in terms of incidence of PPC's and length of hospital stay.

2. Methods

This was a randomized clinical trial conducted at Sri Jayadeva Institute of Cardio Vascular Sciences and Research Bangalore (SJICSR) from Aug 2014 to July 2015. Seventy Eight patients all candidates for elective CABG ON Pump surgery were selected and were divided into two groups randomly using a computer generated randomized block design namely group A (n=42) Intervention group and group B (n=36) Control group. Inclusion criteria were age >40yrs, elective surgery and informed written consent. Exclusion criteria were presence of neuro muscular disorders, previous pulmonary surgery, cardiovascular instability, history of cerebro vascular accident or the existence of an aneurysm.

Seventy eight patients only those at high risk of developing PPC's were selected using a six factor risk model (8). The risk factors for PPC's which are included

in this model are given in Table 1. Patients with a risk score of >-1 were classified as being at high risk of developing PPC's (8)

Table 1: Risk Factors for PPC's

1	Age> 70 yrs
2	Productive Cough
3	History of smoking
4	Diabetes mellitus
5	Inspiratory vital capacity <75 % of predicted
6	Maximal expiratory pressure<75% of predicted

The intervention Group received IMT for 2 to 4 weeks before surgery in addition to care as usual that is patient education about early mobilization and coughing with wound support, 1 day before surgery.The control group received care as usual. The subjects in intervention group were given IMT seven times a week, for at least 2 weeks before surgery. Each session lasting for 20 minutes (using POWER breath K3 series, an electronic IMT and monitoring system).The starting inspiratory load was aimed at 60% of the measured Maximal Inspiratory Pressure (Pimax).The load was Incrementally increased based on the Rate Of Perceived Exertion (RPE) score on Borg scale (9) from 0 to 10.When patients score of RPE was less than 7, the inspiration load of the threshold device was increased by 5% by the patient. Patients were asked to complete 30 dynamic inspiratory effects twice daily.

Primary Outcome Measures:

Primary outcome measures included patient satisfaction & motivation, compliance with therapy, & to access the effectiveness of IMT, Inspiratory muscle strength expressed as P_{imax} at residual volume. P_{imax} reflects the force of diaphragmatic contraction & respiratory muscle weakness which is responsible for Hypoventilation (10). Normal value for P_{imax} was calculated from regression equation according to age & sex (11). Secondary outcome measures: Included incidence of PPC's & length of hospital stay.

Post-operative pulmonary complication were defined according to clinical & Radiological criteria of clinical and respiratory criteria of center for disease control & prevention (table 2) (12).

Table 2: Definition of Postoperative pulmonary Complications

Bronchitis	Chest X-ray : negative Temperature of < 37.5° C Auscultation: rales Sputum abundant and clear
Atelectasis cause murmur	Chest X-ray: collapse, atelectasis Temperature of > 37.5° C without other documented Auscultation: diminished or abolished vesicular
Pneumonia	Chest X-ray : consolidation, pleurisy Temperature of > 38°C (≥ 4 days) Auscultation: rales Sputum abundant and purulent

*Conform definitions of the Centers for Disease Control and Prevention (12)

Lung function tests

Forced Vital Capacity (FVC), Forced Expiratory Volume in 1 second (FEV1) & Inspiratory Vital Capacity (IVC) well measured by spirometry. Spirometry was done in sitting position as described by the American Thoracic Society (13). The highest values of FVC, FEV1 & IVC measured in four consecutive attempts were used. Predicted values were calculated from regression equation according to age, height & sex of the patient (14). Functional status was assessed with Specific Activity Scale (SAS) (15).

Statistical Analysis:

Data analysis was done using SPSS (version 12.0.2) & with an intension to treat the principle. The Shapiro-Wilk goodness of fit test was used to check whether data were normally distributed. Descriptive assessments of primary outcomes were measured because only the intervention group completed the satisfaction questionnaire. Paired sample T-test was used to compare Inspiratory muscle strength & lung function at baseline & 1 day before the operation between the groups. A P value of less than 0.05 was regarded as statistically significant. The Incidence of PPC's were analyzed based on whether IMT was provided or not and was carried out with X^2 – test.

3. Results

78 patients who met the criteria for being at high risk for PPC's as assessed with the six factor risk model (8) were included in the study. The baseline characteristics of these 78 patients (39 men & 39 women), their risk model scores &peri-operative data are given in table 3. There were no statistically significant differences in peri-operative baseline scores between the two groups (table 3).

Table 3: Clinical Characteristics of patients

	Intervention group N= 42	Control Group N=36
Score on the Hulzebos risk model (SD)	1.64 (1.91)	1.92 (2.15)
Sex, n (%) Male Female	 21 (50%) 21 (50%)	 18 (50%) 18 (50%)
Age in Years (SD)	68.14 (9.86%)	68.50 (10.10)
Body mass Index (SD)	25.13 (2.93)	27.32 (3.47)
History of Cigarette Smoking, n (%)	12 (29%)	9 (25%)
Coughing, n (%)	12 (29%)	9 (25%)
Presence of comorbid conditions, n (%) History of COPD Diabetes Mellitus SAS 1-2 SAS 3-4	 18 (43%) 6 (14%) 36 (85%) 6 (15%)	 6 (17%) 9 (25%) 33 (92%) 3 (8%)
Lung Function Tests in % predicted (SD) FEV1 IVC FEV1/IVC Pimax	 82.93 (20.00) 89.57 (15.97) 94.07 (11.12) 65.60 (15.79)	 81.83 (20.20) 85.00 (18.60) 99.25 (12.98) 67.80 (26.31)
Duration of Surgery (Minutes)	255 (84.93)	270 (53.40)
Length of Hospital stay (days)	8.93 (1.94)	10.92 (5.78)

Values are means± Standard Deviation (SD)

Score on the Hulzebos risk model:-4up to -2 points= low risk, -1 up to points = high risk

FEV1 = Forced Expiration Volume In 1 Second, IVC=Inspiratory Vital Capacity; Pimax=Maximal Inspiratory Pressure; COPD= Chronic Obstructive Pulmonary Disease ; SAS=Specific Activity Scale

Primary outcome: The rating of perceived exertion was marked in Borg scale. No participants dropped out & no adverse events were reported. In the Interventional group, the inspiratory muscle strength increased by 36% from 65.6 (15.8) cm H_2O at baseline to 88.6 (29.1) cm of H_2O at the end of the training period and 1 day before surgery (p = 0.001). In control group the Inspiratory the Inspiratory muscle strength increased by 15 % from 67.8 (26.3) cm of H_2O to 77.83 (27.3) cm of H_2O (p= 0.18). (table 4)

Table 4: P_{imax} cm of H2O at base line & 1 day before surgery

	Intervention Group Mean (SD)		Control group Mean (SD)	
	Base line	Pre Op	Base line	Pre Op
$P_{1\ max}$ cm of H2O	-65.6 (15.8)	-88.6 (29.1)	-67.8 (26.3)	-77.8 (27.9)
Paired T-test (2 tailed)	* 0.00		0.18	
95 % CI	-32.18 to -11.13		-25.40 to 5.36	

Pimax = Maximal Inspiratory Pressure; SD= Standard Deviation; CI= Confidence Interval Of The Difference; *= P< 0.05; Pre-Op= Preoperative.

Secondary outcome: Lung functions remained unchanged during training period& before surgery in both groups.

Table 5 a: Pulmonary function at baseline and 1 day before surgery (control group)

Pulmonary 95% CI	**Control Group (N=36)**		**Paired T-test**	
Function Tests	mean (SD)		**(2-tailed)**	
	Baseline	Pre-op		
FEV_1 % predicted -5.23 to 5.06	81.8 (20.2)	81.9 (20.3)	0.97	
IVC % predicted to 2.12	85.0 (18.6)	88.4 (17.8)	0.20	8.95

FEV1 = Forced Expiration Volume in 1 Second; IVC= Inspiratory Vital Capacity; Pimax = Maximal Inspiratory Pressure; SD= Standard Deviation; CI= Confidence Interval Of The Difference; *= P< 0.05; Pre-Op= Preoperative.

Table 5b: Pulmonary function at baseline and 1 day before surgery (interventional group)

Pulmonary 95% CI	Intervention Group (N=14)		Paired T-test	
Function Tests	mean (SD		(2-tailed)	
	Baseline	Pre-op		
FEV_1 % predicted to 6.16	82.93 (20.0)	81.7 (20.6)	0.13	-0.93
IVC % predicted to 4.91	89.6 (16.0)	88.3 (18.1)	0.45	-2.30
FEV_1/IVC % predicted 2.31 to 5.70	94.1 (11.1)	94.0 (9.6)	0.38	

FEV1 = forced expiration volume in 1 second; IVC= inspiratory vital capacity; P_{imax} = maximal inspiratory pressure; SD= standard deviation; CI= Confidence interval of the difference; *= p< 0.05; Pre-op= preoperative.

4. Discussion

In patients undergoing on pump CABG who are at risk to develop PPCs IMT significantly improves Inspiratory muscle strength in our study inspiratory muscle strength increased by almost 36 % thereby preventing the development of post operative atelectasis. A study by Weiner Et al (4) which included patients who are at lower risk of developing PPC's also showed an increase in Inspiratory muscle strength after IMT. The main aim of this study was to provide preoperative IMT thereby reducing the incidence of PPC's such as atelectasis, pneumonia & bronchitis.

The protocol of 30 breathe twice daily is easy to perform & takes only few minutes per training session, resulting in higher compliance to this specific training. POWER breathe has a range of 5 to 200 cms of H_2O of Inspiratory load which helps to set the load for each individual. POWER breathe also has the advantage of tapered flow resistive loading, gradual increasing of load during the first three Inspiration, the recording of average load, average power, average volume & training index.

In conclusion pre-operative IMT in patients undergoing on pump CABG who are at high risk of developing PPC's are significantly benefited by decreased incidence of atelectasis, pneumonia & bronchitis.

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