

## Protocols

# Effectiveness of inspiratory muscle training (IMT) on pulmonary function and functional capacity in chronic smoker's v/s non-smokers patients undergoing open abdominal surgery – A study protocol



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## ABSTRACT

**Background:** Abdominal surgeries are performed for the treatment and diagnosis of many diseases. Smokers undergoing abdominal surgery, are high risk population, having underlying pathological changes in lung parenchyma due to inflammatory effect of smoking. Site of incision and history of smoking may significantly affect pulmonary function such as FVC and FEV1. Respiratory muscle training pre-operatively has shown significant improvement of pulmonary function compare to only conventional therapy and has led to reduction of PPCs, length of hospital stay and cost. This study aims to find effectiveness of IMT in chronic smokers undergoing abdominal surgery and its significance in reduction of PPC and in pulmonary function and functional capacity as compared to non-smokers.

**Methodology:** This study protocol is observational cohort study comparing smoker and non-smoker participants undergoing abdominal surgery. The participants will be assessed for pulmonary function test and functional capacity (6MWD); pre-operatively and post-operatively day 1 till the day of discharge. Both the groups will receive IMT and conventional chest Physiotherapy from POD1 and increment of IMT will be done by assessing MIP each day.

**Dissemination:** We plan to publish this review in a peer-reviewed journal. We may also present this review at local and/or national conferences.

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## 1. Introduction

Abdominal surgeries are performed for the treatment and diagnosis of many diseases [1]. Postoperative pulmonary complication (PPCs) following abdominal surgery are frequent and are responsible for the increased morbidity and mortality as well as length of hospital stay and health related cost of care [2,3]. PPCs comprises

of dyspnoea, dry or productive cough, bronchospasm, hypoxemia, atelectasis, pleural effusion, hypercapnia, pneumonia, pneumothorax, respiratory failure and ventilatory failure [4]. Physiological changes in respiratory muscle strength (RMS), pulmonary function and breathing pattern are influenced by site of incision and effects of anaesthesia. This results in reduction in pulmonary volume and capacities and cough efficacy [5].

The basic mechanism of PPCs is inadequate lung expansion due to shallow breathing, prolonged recumbent positioning, diaphragmatic dysfunction, impaired mucociliary function, ineffective cough and retention of secretion [6]. Primary Inspiratory muscle that is diaphragm is affected due to site of incision because of reflex inhibition of phrenic nerve. Pain at surgical site, recumbent position and altered lung volumes and capacities changes length tension relationship in inspiratory and expiratory muscles, affecting muscle recoil and leading to cough impairment [4,5].

**Abbreviations:** PPCs, Post-operative Pulmonary Complications; IMT, Inspiratory Muscle Training; PFT, Pulmonary Function Test; FVC, Forced Vital Capacity; FEV1, Forced Expiratory Volume In 1st Second; PEF, Peak Expiratory Flow; RMS, Respiratory Muscle Strength; MIP, Maximum Inspiratory Pressure; MEP, Maximum Expiratory Pressure; 6MWT, Six Minute Walk Test; 6MWD, Six Minute Walk Distance; POD, Post-Operative Day.

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PPCs depend on pre-disposing risk factors, procedure-related and patient-related. Chronic smoking is one of the patient-related risk factor [4]. Previous history of chronic smoking has an effect on pulmonary function, for instance reduced total lung capacity, tidal volume and reduction in Forced Expiratory Volume in one second (FEV1) and Forced Vital Capacity (FVC) [7]. Smoking increases the number of neutrophils and alveolar macrophages in the lung parenchyma, causing inflammation, goblet cell hyperplasia and release of cellular products like elastase which breaks down collagen and elastin causing destruction of alveoli and stimulating mucus production [8]. Smokers undergoing abdominal surgery, are high risk population, have underlying pathological changes in lung parenchyma due to inflammatory effect of smoking and post-operative physiological changes which cumulatively affects pulmonary function and functional capacity and often leads to PPCs [4,8].

Chest physiotherapy plays a substantial role in prevention and management of PPCs. Treatment methods such as deep breathing exercises (DBE), percussion, vibration, postural drainage (PD), coughing and huffing techniques as well as adjunct mechanical devices such as inspiratory muscle training device and incentive spirometer are incorporated and proved to be effective to reduce PPCs [9]. Inspiratory muscle training (IMT) consists of resistance and endurance training programme. Threshold pressure loading IMT improves both inspiration and expiration by strengthening muscles of respiration. Diaphragm morphologically and functionally is similar to skeletal muscle, follows the principles of strength training, that is overloading, specificity and reversibility [10].

The threshold pressure loading device contains a spring loaded poppet valve of varying quantifiable intensities, which provides flow independent resistance to inspiration. The Resistance in threshold loading device requires negative pressure to overcome the resistance and thus inspiration can be initiated [10,11].

Incentive spirometry is a lung expansion technique and requires long slow deep breathes to sustained maximum inspiratory effort and maintaining patency of airways at risks of closure [12].

Exercise capacity and tolerance testing are important assessment tool to measure the improvement in functional capacity and prognosis of patients. Submaximal test such as six minute walk test is widely used for functional capacity. Decrease Functional capacity affects quality of life. Studies have been done on pre-rehabilitation of IMT in patients undergoing abdominal and cardio-thoracic surgery showing better results post-operatively in pulmonary function, functional capacity and reduction in length of hospital stay. Exclusive evidence on effect of IMT in chronic smokers undergoing abdominal surgery are less.

Thus, this study protocol is first to exclusively assess the effect of IMT in chronic smokers undergoing abdominal surgery.

### 1.1. Aims and objectives

**Aim:** To find out the effectiveness of Inspiratory Muscle Training (IMT) on pulmonary function and functional capacity in chronic smokers and non-smokers patients undergoing open abdominal surgery.

Objectives:

1. To compare effectiveness of IMT on pulmonary function in chronic smokers and non-smokers undergoing open abdominal surgery.
2. To compare effectiveness of IMT on functional capacity in chronic smokers and non-smokers undergoing open abdominal surgery.

## 2. Methods and analysis

### 2.1. Study design

This study is prospective observational cohort study.

### 2.2. Type of sampling

Purposive sampling.

### 2.3. Study setting

Participants data will be collected from Kasturba Medical College hospital, Mangalore.

### 2.4. Period of recruitment

Participants will be recruited from December 2019 to December 2020.

### 2.5. Participant's eligibility

- Inclusion criteria:** Participants of either gender undergoing abdominal surgery above age of 18 years, irrespective of their history of smoking will be included in this study.
- Exclusion criteria:** Patients undergoing laparoscopic surgery, Recent/unhealed rib fracture, Cancer: lung/oral, Recent Neurological conditions: stroke and head injury, Infectious, autoimmune, carcinogenic, genetic or idiopathic, congenital, musculoskeletal or neurological disorder affecting cardiovascular thoracic system. Patients records lacking sufficient data to determine the primary outcome will be excluded.

### 2.6. Operational definition of chronic smokers

According to Centres for Disease Control and Prevention, Chronic smokers can be classified by two criteria: 1) Number of packs/quantity of cigarette or bidi smoked. 2) Number of years consumed cigarette or bidi.

The term pack years was defined as the number of cigarettes smoked per day divided by 20 and multiplied by number of years. According to pack years, Non-smokers were defined as individuals who had not smoked in their lifetime, more than 1 cigarette per day for 1 year (<1/20 pack years). Whereas, Individuals who had smoked more than 100 cigarette in their lifetime were considered as chronic smokers; which includes current smoker, ex-smoker and reformed smoker. Thus, chronic smokers can be termed as someone who smokes more than 5 pack per year.

### 2.7. Intervention

Study protocol was submitted to the Scientific and Institutional Ethics Committee of KMC Mangalore for approval prior to the conduct of the study. Participants undergoing abdominal surgery will be referred for physiotherapy treatment by General Surgeon and will be screened based on the inclusion and exclusion criteria and those who meet the inclusion criteria will be recruited for the study after explaining the purpose of the study and getting informed consent from the participants. According to their smoking habit, Participants will be divided in to two groups group 1: smokers group or group 2: non-smokers group. Demographic and baseline data of all participants will be noted on the day prior to surgery.

The data includes demographic data, clinical diagnosis, vitals, co-morbidities, medications in use, RMS (MIP/MEP), PFT (FVC,

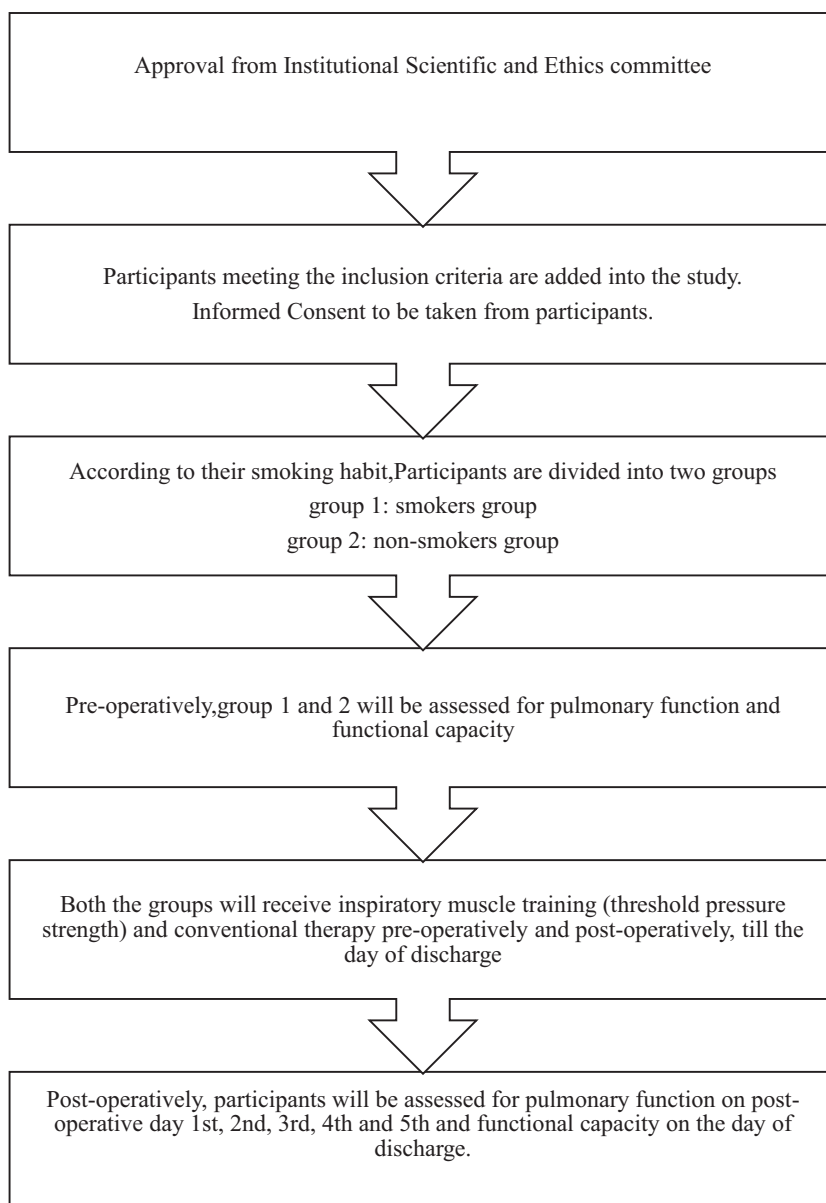
FEV1), Six-minute walk test and Borg scale for mobilization (bed mobility, edge of bed, spot marching, ambulation) pre-operatively will be taken. Once the participants are divided into two groups, participants in both the group will receive IMT (threshold pressure loading training), Incentive Spirometer, deep breathing exercise and Active Cycle of Breathing Techniques (ACBT) one day prior to the surgery.

After obtaining permission from the General Surgeon, Post-operatively, all the participants will receive Physiotherapy treatment which includes IMT, Incentive spirometer, breathing exercise and ACBT and post-operative data which includes RMS, PFT and functional capacity will be collected, from POD1 till the day of discharge. Both the groups, smokers group and non-smokers group will receive treatment twice a day, with an intensity starting from 30-50% of mean inspiratory pressure. Increment of IMT resistance

will be done by using MIP assessed on that day. Pressure will be increased based on RPE (rating of perceived exertion) on Borg scale. If the RPE is less than 5, resistance will be increased by 5%.

2.7.1. Method of performing threshold pressure loading inspiratory muscle training

Inspiratory muscle training will be performed according to the standardized procedure by using Threshold IMT. Treatment will be supervised and participant will be asked to breathe against a load equivalent to 30–50% of their maximum inspiratory pressure. IMT will be performed for 6 cycles of 30 breaths of 3.5 minutes with 1 minute of rest with frequency of two sessions per day, 7 days a week. Each effort requires the participants to inspire against a resistance and maintain continuous application of inspiratory pressure through inspiration for the poppet valve to remain open for unrestricted expiration [13].



## 2.8. Outcome variables

Primary outcome measures:

1. Respiratory Muscle strength:
  - A. Maximum inspiratory pressure (MIP in cm H<sub>2</sub>O)
  - B. Maximum expiratory pressure (MEP in cm H<sub>2</sub>O)
2. Pulmonary function testing:
  - A. Forced vital capacity (FVC in %)
  - B. Forced expiratory volume in 1st second (FEV1 in %)
  - C. FEV1/FVC
3. Six-minute walk distance

Secondary outcomes:

1. Length of hospital stay (in days)
2. Development of post-operative pulmonary complications
3. Borg scale for fatigue and dyspnoea

## 2.9. Data measurement

### A. Respiratory Muscle strength:

1. **Maximum inspiratory pressure (MIP):** MIP is a tool that measures the mouth pressure, established as a standard for assessment of inspiratory muscle strength. It reflects the force generating ability of inspiratory muscles. MIP is initiated from residual volume. MIP calculated in cm H<sub>2</sub>O [14].
2. **Maximum expiratory pressure (MEP):** MEP is tool that measures the mouth pressure for assessment of expiratory muscle strength. It reflects the force generating ability of expiratory muscle. MEP is initiated from Total lung capacity. MEP calculated in cm H<sub>2</sub>O [14].
  - B. **Pulmonary function testing:** is a tool in investigation and monitoring respiratory function
    1. **Forced vital capacity (FVC):** FVC is the volume of air that can be exhaled during maximum forced inspiration. FVC calculated in %.
    2. **Forced expiratory volume in 1st second (FEV1):** FEV1 is the volume of air forcefully expired in 1st second after maximum inspiration. FEV1 calculated in %.
    3. **FEV1/FVC**
      - C. **Six minute walk test:** Objective and subjective evaluation of functional capacity. Objective assessment in distance covered in six minutes, monitoring pulse rate, blood pressure and respiratory rate. Subjective assessment using Borg scale for level of fatigue and breathlessness. 6MWD calculated in meters. The 6MWT will be performed according to the standardized procedure. Test will be supervised by a physiotherapist and participants will be asked to walk at their own maximal pace along a 30-m long, flat, and straight hospital corridor. The test is symptom limited, so participants will be allowed to stop if signs or symptoms of significant distress occurred (severe dyspnoea, dizziness, angina, skeletal muscle pain), though they are instructed to resume walking as soon as possible. The distance covered during the test will be recorded in meters [15].

### D. Development of post-operative pulmonary complications

Postoperative pulmonary complication diagnostic tool: Melbourne group score.

## 2.10. Data collection

Data of primary and secondary outcome measures will be collected pre-operatively and post-operatively from day 1 till the day of discharge.

## 2.11. Sample size

The sample size was determined based on anticipated accrual. With an assumption of 60% changes in Pulmonary function among non-smokers and 30% changes in smokers following IMT and conventional therapy etc, 80% power, 95% confidence interval, 1:1 ratio of exposed and control group and adding 10% non-response error.

Using the formula,

$$n = \frac{\left[ z_{\alpha} \sqrt{(1 + 1/m) \bar{p}(1 - \bar{p})} + z_{\beta} \sqrt{p_0(1 - p_0)/m + p_1(1 - p_1)} \right]^2}{(p_0 - p_1)^2}$$

$$\bar{p} = \frac{p_1 + mp_0}{m + 1}, n_c = \frac{n}{4} \left( 1 + \sqrt{1 + \frac{2(m + 1)}{nm|p_0 - p_1|}} \right)^2$$

Where,  $p_0 = 0.6$ ,  $p_1 = 0.3$  and  $m = 1$  where  $\alpha = \text{alpha}$ ,  $\beta = 1 - \text{power}$ ,  $n_c$  is the continuity corrected sample size and  $z_p$  is the standard normal deviate for probability  $p$ .  $n$  is rounded up to the closest integer. The sample size calculated was 41 in each group.

## 2.12. Data analysis

The collected data will be coded and entered into IBM SPSS statistics NY: IBM corp. Results will be expressed as proportions and summary measures (Mean with standard deviation) using appropriate tables and figures for comparison, a paired t-test and repeated measures ANOVA test will be used. A p-value of <0.05 will be considered statistically significant.

## 3. Discussion

Studies have shown reduction in PPC and improvement in MIP following IMT. Post-surgery, often the chances of PPCs are high due to presence of ventilator defects. Respiratory muscle following the principle of strength and endurance training responds to increasing load of IMT by recruiting motor units that promotes muscle strength. Also, studies have shown reversal of negative effect of smoking followed by IMT [4,16]. Thus, this study aims to observe the effect of IMT on combined effect of smoking and abdominal surgery in pulmonary function and functional capacity.

## 4. Implications of the study

The result of the study will determine the effect of IMT compared to conventional therapy among smokers undergoing open abdominal surgery. If found to be ineffective, additional measures will be taken to reduce post-pulmonary complications to improve pulmonary function, functional capacity and to reduce length of hospital stay post-surgery.

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## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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