CHAPTER III
METHODOLOGY
3.1 Study Design

Randomized Controlled Trial

3.2 Ethics Committee Approval

The trial was approved by Institutional Ethics Committee of Kasturba Medical College, Mangalore

3.3 Study Center

Department of Physiotherapy and Surgery in Kasturba Medical College Hospital, Attavar & Ambedkar Circle, Mangalore

3.4 Subjects

Patients who underwent Laparoscopic Abdominal Surgery in Kasturba Medical College Hospitals.

3.5 Sampling Method: Convenience sampling

3.6 Sample Size

The sample size was calculated based on the values obtained from pulmonary function test in a pilot study (20 subjects, 5 in each group). The following formula was used for calculating the same.

\[
    n = \frac{2 \left( Z\alpha + Z\beta \right)^2}{D^2 / S^2}
\]
Where \( n \) is the number of subjects in each group, \( Z_\alpha \) and \( Z_\beta \) are constants and they are substituted. Selected power for the study was 90%, \( D \) is effect size which is the absolute value of the difference in means, and represents what is considered a clinically meaningful or practically important difference in means.

\( D \) is taken from the pilot study which used the same variable, which compared pulmonary function test in subjects, and \( S \) is the standard deviation of the means. The sample size is 65 in each group.

**\( n = 65 \) (in each group) total 260 subjects**

\[ Z_\alpha = 2.7 \]

\[ Z_\beta = 1.28 \]

\[ D \text{ (effect size)} = 0.35 \]

\[ S \text{ (SD)} = 0.5 \]

\[ \alpha = 0.05 \]

**Duration of data collection:** 4 years (July 2010 to July 2014)

**3.7 Inclusion Criteria**

- Subjects of both genders in the age group of 18 to 80 years
3.8 Exclusion Criteria

- Patients who had undergone open abdominal surgery and laparoscopic obstetrics and gynecological surgery
- Patients with unstable hemodynamic parameters (Arterial Pressure <100 mm Hg systolic and < 60 mmHg for diastolic and Mean Arterial Pressure (MAP)< 80 mmHg)
- Patients with postoperative complications requiring mechanical ventilation
- Uncooperative patients or patients unable to understand or to use the device properly
- Patients with inadequate inspiration and a vital capacity < 10 ml/kg

3.9 Equipment used

- Ultra-sonography machine (voluson730) (Figure 1)
- Pulmonary function test machine (Easy One™ Spirometer, ndd Medizintechnik AG, Zurich, Switzerland) (Figure 2)
- Flow-oriented incentive spirometry machine (Triflow Device, IGNA Medical Devices, Mumbai) (Figure 3)
- Volume-oriented incentive spirometry machine (Coach 2 Device, Smiths Medical International Ltd, USA) (Figure 4)
Figure 1: Ultra sonography machine (voluson730)

Figure 2: Pulmonary Function Test Machine (Easy One™ Spirometer)
Figure 3: Flow-Oriented Incentive Spirometry (Triflow Device)

Figure 4: Volume-Oriented Incentive Spirometry (Coach 2 Device)
3.10 Procedure

The study was approved by the Institutional Ethics Committee of Kasturba Medical College Mangalore. Eligible patients were selected based on the inclusion and exclusion criteria. The purpose of study was made clear to each patient and a written informed consent was obtained prior to involving them in to the study.

The patients were divided into four groups;

- Flow-oriented incentive spirometry group (Triflow Device)
- Volume-oriented incentive spirometry group (Coach 2 Device)
- Diaphragmatic breathing exercise group
- Control group

The patients were allocated to groups by block randomization. The entire sample was divided into 13 blocks with 20 patients in each, 5 belonging to each group. Group information was concealed in a sealed opaque envelope and revealed to the patients only after they were recruited into the treatment group or the control group.

Following the allocation to groups, the patients in the treatment group were visited one day prior to the surgery; preoperative information was offered and, based upon his/her group, flow-oriented incentive spirometry, volume-oriented incentive spirometry or diaphragmatic breathing exercise was taught to each patient. Other therapies like airway clearance techniques, thoracic expansion exercise and mobilization were also taught to every patient in all treatment groups (Figure 5). Patients in the control group were not given any treatment or taught any exercises.
An experienced radiologist carried out ultrasound for diaphragm excursion on the preoperative as well as the 1\textsuperscript{st} and 2\textsuperscript{nd} postoperative day, for all groups.

Pulmonary function tests (PFT) measured the following variables: Forced Vital Capacity (FVC), Forced Expiratory Volume in the first second (FEV\textsubscript{1}), Peak Expiratory Flow Rate (PEFR). These were taken on the preoperative day, and 1\textsuperscript{st} and on the 2\textsuperscript{nd} postoperative day, for all groups. These measurements were taken by the primary investigator. (Figure 6 Flow chart)
Figure 5: The treatment protocol for post-operative laparoscopic abdominal surgery

**Step 1. Diaphragmatic Breathing Exercise, Flow or Volume-Incentive Spirometry**
(3 sets, 5 repetitions of deep breaths)

**Step 2. Airway clearance techniques** (huffing or coughing)

**Step 3. Circulation** (Foot and ankle pumping, hip and knee bending 10 times each hour)

**Step 4. Thoracic Expansion Exercise** (Position patient in long sitting in bed / high sitting over the side of the bed)

**Step 5. Mobilization:**
- a) sitting out of the bed in a chair (one hour twice daily)
- b) Walking (three times per day)
- c) Stair climbing done before the patient was discharged from the hospital
Figure 6: Consort Flow Diagram of the Study

Excluded (14 patients) Converted into open abdominal surgery

Meets Inclusion Criteria (274 patients)

Included (260 patients)

Block Randomization

Control Group (65)

DBE (65)

Volume-oriented IS (65)

Flow-oriented IS (65)

Pre-Operative Data collection

Diaphragm Excursion by USG, PFT (FEV<sub>1</sub>, FVC, PEF)

No treatment

DBE

Volume-oriented IS

Flow-oriented IS

Other therapies like Airway Clearance Techniques, Circulation, Thoracic Expansion Exercise, and Mobilization

Post-Operative Data Collection

- Diaphragm excursion by USG 1<sup>st</sup> and 2<sup>nd</sup> postoperative day
- PFT (FEV<sub>1</sub>, FVC, PEF) 1<sup>st</sup> and 2<sup>nd</sup> postoperative day
3.11 Description of Outcome Measures

3.11.1 Diaphragm Excursion (Figure 7)

The patient lay in the supine position and Diaphragm movements were recorded in the B-Mode. The probe was positioned between the midclavicular and anterior axillary lines, in the sub-costal area, So that the ultrasound beam entered the posterior third of the right hemi diaphragm perpendicularly. The procedure began at the end of normal expiration with the subjects being instructed to inhale as deeply as they possible. A fixed point at the edge of the image on the screen and the diaphragm margin at maximal inspiration and again at maximal expiration served as reference points between which measurements were made, with the average of three values being taken for both maximal inspiration and maximal expiration.²⁹

Figure 7: Measurement of Diaphragm Excursion by Ultra-Sonography
3.11.2 Pulmonary Function Test (Figure 8)

Pulmonary function test procedures (Easy One ™ Spirometer) were carried out according to the American Thoracic Society/European Respiratory Society guidelines. The following variables have been recorded: Forced Vital Capacity (FVC), Forced Expiratory Volume in the first second (FEV₁), Peak Expiratory Flow Rate (PEFR) the best value of 3 acceptable tests.
3.12 Treatment Procedures

3.12.1 Methods to perform flow-oriented and volume-oriented incentive spirometry

The patient was placed in a semi-recumbent position (45°), with a pillow under the knees. The patient was instructed to inhale with a slow and deep sustained breath, holding it for a minimum 5 seconds and then to exhale passively in order to avoid any forceful expiration. First, the patient was given a demonstrated and then asked to perform it to so as to ensure that she/he had understood the process. The patient was instructed to hold the spirometer in an upright and to perform flow-oriented incentive spirometry by inhaling slowly and thereby raising the ball, (Figure 9) followed by volume-incentive spirometry in order to raise the piston or plate in the chamber to the set target. (Figure 10)

The patient was instructed to perform 3 sets of 5 repeated deep breaths. This had to be performed by the patient every waking hour. The therapist administered the exercise four times a day and the patient was instructed to perform the same for the rest of the day. The patient was asked to keep a record of the exercise performed by entering in a log book which was provided beforehand.
Chapter 3

Methodology

Figure 9: Method to Perform Flow-Oriented Incentive Spirometer

(Triflow Device)

Figure 10: Method to Perform Volume-Oriented Incentive Spirometer

(Coach 2 Device)
Method to perform diaphragmatic breathing exercise

The patient assumed a semi Fowler’s position (back and head are fully supported and abdominal wall relaxed) and performed diaphragmatic breathing. The therapist placed his hands just below the anterior costal margin, on the rectus abdominis, while the patient was instructed to inhale slowly and deeply through the nose, form functional residual capacity to total lung capacity with a three second inspiratory hold. The patient was then instructed to relax the shoulders, keep the upper chest quiet in order that the abdomen be raised a little. The patient was then instructed to exhale slowly through the mouth.\textsuperscript{16, 31}

The Patient was made to experience a slight rise and subsequent fall of the abdomen during inspiration and expiration, by placing his or her own hand below the anterior costal margin. (Figure 11) The Patient was instructed to perform 3 sets of 5 deep breaths with the therapist administering them four times a day and the patient being instructed to perform the same once every waking hour for the rest of the day. In between the repetitions of the diaphragmatic breathing exercise, the patient was told to breathe normally.\textsuperscript{16, 31} The patient was asked to keep a record of the exercise performed by entering in a log book which was provided beforehand.
3.13 Data Analysis

Data was analyzed using SPSS package version 11.5

- Post hoc analysis was carried out using Bonferroni's t test, and was used to compare within the groups.
- Two factor ANOVA was used to compare the effect between the groups and difference over the duration.

Figure 11: Method to Perform Diaphragmatic Breathing Exercise