



## EFFECT OF EzPAP DEVICE ON PULMONARY FUNCTION TESTS DURING PERIOPERATIVE PERIOD IN PATIENTS UNDERGOING GENERAL ANAESTHESIA FOR MORE THAN 2 HRS.

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### ABSTRACT

**BACKGROUND-**EzPAP is an option for treating and preventing atelectasis. It provides positive pressure that amplifies an input flow of either air or oxygen approximately 4 times and this augmentation provides a larger flow with less effort than an unsupported inspiration and PEEP provided on expiration. So it clears secretions, increases lung volume and improves gas exchange. It provides positive pressure therapy independent of patient efforts; thus improves lung functions. EzPAP is an easily implemented, disposable device that delivers continuous positive airway pressure using flow from an oxygen flow meter via a mouthpiece or facemask. It provides a cost-effective and easily utilized form of CPAP.

**OBJECTIVE-**This study was carried out to compare the effects of EzPAP therapy on pulmonary function test after abdominal surgeries under general anaesthesia for more than 3 hrs and compare the postoperative volumetric spirometric values FVC, PEFR, FEV<sub>1</sub> with preoperative baseline values.

**Method-**we conducted a prospective interventional study in 35 ASA I and II patients posted for elective abdominal surgeries. Various parameters such as age, sex, surgeries, time for surgery, pulmonary spirometric values FVC, PEFR, FEV<sub>1</sub> at preoperative 24 hrs and postoperative 48 hrs are noted. Quantitative analysis done.

**RESULTS-**In this selected group of patients who are taken EzPAP therapy difference between preoperative and postoperative lung volumes was higher in postoperative conditions for parameters FVC, PEFR, FEV<sub>1</sub> after EzPAP therapy. Medway NHS foundation trust department based clinical study in their study, EzPAP in relation to increasing or maintaining lung volumes and results in improvement in all physiological parameters.

**CONCLUSION-** This prospective interventional study suggests that; EZPAP positive airway pressure device is a useful to improve respiratory functions and clinical improvements in lung volumes in the post operative patients undergoing general anaesthesia for more than 2 hrs, preventing atelectasis and postoperative hypoxemia.

**KEYWORDS :** EzPAP Device; Pulmonary Function Tests; Positive Airway Pressure; Atelectasis

### INTRODUCTION

#### EzPAP therapy

It helps in providing positive airway pressure. In this simply connect device to a flow meter, adjust to 5-15 lpm, and instruct the patient to breathe diaphragmatically through the mouthpiece or mask. While monitoring with a gauge, slowly adjust the flow meter until the desired airway pressures are reached. Slow inhalations and exhalations should maintain adequate airway pressure throughout the breathing cycle. The EzPAP Positive Airway Pressure System includes the EzPAP lung expansion device, mouthpiece, pressure port cap, and 7 feet of tubing. The mask options are also available. As described in figure no.1.

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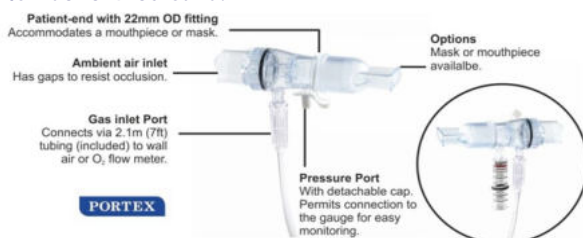


Figure no.1

The EZPAP positive airway pressure system is used to expand the lungs by increasing Functional Residual Capacity (FRC). Increasing FRC has been found to contribute to the prevention and reversal of atelectasis.

When incentive spirometry alone won't open patient's airways,

expand your options with EzPAP. It makes providing positive airway pressure positively easy.

EzPAP is a small, portable device that is normally used as post-operative therapy to prevent or reverse atelectasis in adult patients unable to do incentive spirometry or other maneuvers to augment lung volumes. It has been shown in adults to decrease atelectasis and hypoxia as compared to other traditional pulmonary physiotherapy and is very well hemodynamically tolerated. EZPAP works by amplifying an input flow of either air or oxygen approximately four times using the Coanda effect.

**Coanda effect-** Coanda effect is the tendency of the fluid jet to be attached to a nearby surface. This phenomenon is also called wall attachment. When a narrow tube encounters a Y junction of the wide bore, because the flow tends to cling to one side, the flow will not evenly distribute between the two outlets, but flows through only one limb of the Y, due to Coanda effect, as in figure no.2.

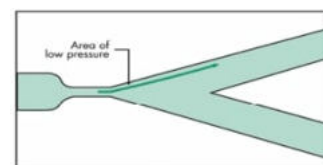


Figure no.2

In clinical implications; there can be unequal gas flow to the alveoli where there has been a slight narrowing of the bronchiole before it divides. As there is narrowing before the branching, the pressure drops, the velocity of the air increases

(Bernoulli's principle), but the flow tends to cling to one side and doesn't divide evenly between the branches (Coanda effect)

Mucus plug at the branching of trachea-bronchial tree may cause maldistribution of respiratory gases.

The Coanda effect is put to good use in a switching flow ventilator valve

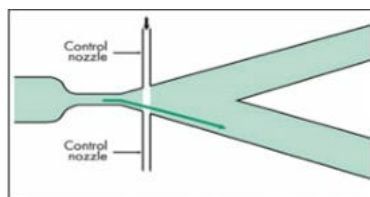


Figure no.3

This is a carefully designed valve whose shape causes gas to flow from an oxygen supply or ventilator to a patient during inspiration. The gas hugs the wall of the valve and bypasses an open vent on the opposite side of the wall. During expiration, air from the patient is redirected to the vent, because the flow pressure from the gas supply forces the gas to the opposite side of the tube, as in figure no.3

### AIMS AND OBJECTIVES

To Observe the Effect of EzPAP on Pulmonary Functions during periop period in patients undergoing general anaesthesia.

#### Primary objective

To compare postop values with baseline (preoperative) values of following parameters:

1. Volumetric Spirometric values: FVC, PEFR, FEV<sub>1</sub>.

#### Anesthesia and the respiratory system

Anaesthesia and the respiratory system; A fall in functional residual capacity (FRC) despite the maintenance of spontaneous breathing is one of the first and consistently occurring events caused by most anaesthetics.

The drop in FRC occurs whether the anaesthetics are inhaled or given intravenously. This is associated with a change in the elastic behavior of the lung and an increase in the respiratory resistance.

The fall in FRC, in turn, promotes airway closure and gas absorption behind occluded airways, leading to atelectasis formation. As a consequence, the distribution of ventilation is affected and the matching of ventilation and blood flow is impaired. This, in turn, impedes oxygenation of blood and removal of carbon dioxide.

In the adult human, the resting lung volume (FRC) is reduced by 0.7 to 0.8 L by changing body position from upright to supine, and there is a further decrease by 0.4 to 0.5 L with induction of general anaesthesia.

As a result, the end-expiratory lung volume is reduced from approximately 3.5 to 2 L, the latter being close or equal to residual volume.

The figure no. 4 describes during anaesthesia functional residual capacity (FRC) is reduced and lung compliance is reduced and airway resistance increased.

Loss of respiratory muscle tone causes a decreased in FRC

and the fall in compliance might be attributed to lung collapse and airway closure. The increase in airway resistance may be related to the reduced lung volume and the decrease in airway dimensions.

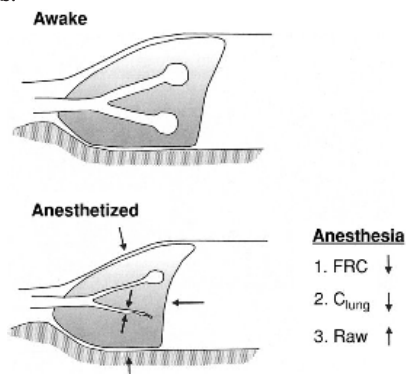


Figure 4: Respiratory Function during Anesthesia: Effects on Gas Exchange

#### Effects on lung volumes after anaesthesia;

The decreases in Functional Residual Capacity (FRC) and closing capacity. It was postulated that closure of basal airways was a consequence of the decrease in FRC and that the patients most likely to show this effect were those in whom the FRC and closing capacity, when awake, were very similar.

A reduction in FRC after anaesthesia in such patients would move the end-expiratory point into the closing capacity, promote airway closure in the dependent lung and initiate a shunt or reduce ventilation/perfusion ratios.

Anaesthesia on functional residual capacity and alveolar-arterial oxygen tension difference. One of the most consistent changes in pulmonary function after induction of anaesthesia is a reduction in functional residual capacity (FRC) due partly to a change in shape of the chest wall and partly to a change in intrathoracic blood volume.

The postoperative hypoxaemia: mechanisms and time course. Different methods of giving analgesics are likely to cause different degrees of hypoxaemia.

Postoperative hypoxaemia is based on the interaction of two factors: a gas exchange abnormality induced during anaesthesia which may persist for many hours or days into the postoperative period.

second factor is an abnormality of control of breathing which is manifest by episodic obstructive apnoea rather than a sustained decrease in respiratory rate, and which may last for several days/nights after operation.

Induction of general anaesthesia impairs gas exchange in the lungs, produces ventilation/perfusion (V/Q) mismatch in the immediate postoperative period. Such mismatches predispose patients to increased risk of postoperative complications like hypoventilation and atelectasis.

Multiple factors, including cardiac and respiratory comorbidities, surgical procedure, incision site and body habitus contribute to these risks. Clinically significant postoperative atelectasis and its associated decrease in functional residual capacity usually manifests as decreased arterial oxygen saturation.

EzPAP is an option for treating and preventing atelectasis. It provides positive pressure that amplifies an input flow of either air or Oxygen approximately 4 times and so positive pressure is maintained throughout patient's breathing cycle.

This augmentation provides a larger flow and volume with less effort than an unsupported inspiration and PEEP provided on expiration. So it clear secretions, increase lung volume and improve gas exchange.

It provides positive pressure therapy independent of patient efforts; thus may improve lung function.

EzPAP is an easily implemented, disposable device that delivers CPAP using flow from an oxygen flow meter via a mouthpiece or facemask.

EzPAP device is marketed in India. It is available on indent. The purpose of this study is to observe the effect of EzPAP during perioperative period in recovery of pulmonary function in patients scheduled to undergo abdominal surgery under general anaesthesia for more than 3 hours.

## MATERIAL AND METHODS:

**Study design:** It's a Prospective Interventional study.

**Sample size:**

The sample size is calculated as per the following and it is 35.  
 $E = \text{Difference of means/Standard deviation of either group} = 12.272/7.17 = 1.71$

$S(\Delta)$  is the standard deviation of change and was calculated as  $S(2(1-r_{\text{within}}))^{1/2}$

Where,  $r_{\text{within}}$  is the within subject correlation = 0.875,  $S$  is the standard deviation of the outcome, thus,  $S(\Delta) = 3.59$ .

The standard normal deviate for  $\alpha = Z \alpha = 1.960$

The standard normal deviate for  $\beta = Z \beta = 0.842$

$A = 1.000$

$B = (Z \alpha + Z \beta)^2 = 7.849$

$C = (E/S(\Delta))^2 = 0.227$

Sample size =  $AB/C = 34.59 = 35$  (rounded-off)

Thus, for the study we need to enrol at least 35 patients

## STUDY PROCEDURE

This is the prospective interventional study. This study will be conducted over a period of 1 year. After ethics committee approval, those patients who fulfill inclusion and exclusion criteria will be recruited in the study, then consent will be taken. Total number of patient included in the study will be 35.

EzPAP device will be used by patients only. For the first time, investigator will help the patient. It will be used by the admitted patients at hospital ward only. Patients with elective abdominal surgical procedures get admitted to surgical ward 2-3 days prior to surgery for proper workup. So, at that point we can recruit patients for study and consent will be obtained.

EzPAP device will be applied to patient 24 hrs (1 day) preoperatively and 48 hrs (2 days) postoperative period. Every day it will be used for 3 times and every time for 10 mins.

In this study, 24 hrs (1 day) prior to surgery, patient will undergo spirometry test. It is a non invasive test. It works by measuring airflow into and out of lungs. It measures lung volume, rates of flow and gas exchange. For that patient's nose will be closed, in sitting position patient has to take deep breath, hold and exhale forcefully into Spirometer. Then the graph will be plotted on computer with the help of Software called 'Spirotech'. This test is advised for patients with abnormal chest conditions. Portable Spirometer device with Spirotech software is available in department. It will be done at bedside.

We will note down values of FVC, FEV1 and PEFR.

After measuring all baseline parameters, EzPAP therapy will be started 3 times a day for 10 mins each for 24 hrs prop.

Patient's starvation will be confirmed. Patient will undergo the scheduled surgical procedure with a standardized anaesthetic, consisting of general anesthesia (for a period of 3 or more hours) with volatile inhalational agent, intravenous narcotic, neuromuscular blockade, and reversal of neuromuscular blockade.

Postoperatively EZPAP will be given 3 times a day for 48 hours at the flow rate of 8L/min.

After 48 hrs, again we will do spirometry. Along with lung volumes, we will take readings of same parameters as preop.

Variables recorded in the 24 hrs preop and 48 hrs postoperative period will be compared. Parameters that will be noted are as follows.

1. Volumetric Spirometric values: FVC,  
PEFR,  
FEV<sub>1</sub>.

## DATA ANALYSIS PLAN

### Step I:

All responses were tabulated by the investigator using Microsoft-Excel 2016 Software. Graphical representations were made wherever necessary.

### Step II:

Data was analyzed by using SPSS software version 25.0

Statistical tools used were-

Mean

Standard deviation

Proportions and percentages and Paired t test

## RESULTS

### no. 1: Age wise distribution of patients (N=35):

Maximum patients were belonged to age group 31-40 years i.e. 37.1%, followed by 19-30 & 51-60 years (22.9%) and 41-50 years (17.1%). The mean age of patients was 39.1.

**no. 2: Gender wise distribution of patients (N=35):** In the selected group there are 54% females and 46% male participants.

### no. 3: Distribution of patients according to diagnosed conditions (N=35):

The distribution of patients according to diagnosis. Most common diagnosed condition was cholecystitis (34.3%). All patients in the study belonged ASA grade 1. None of the patients in the study had any co-morbidity. This distribution is presented by bar diagram in fig. no. 3.

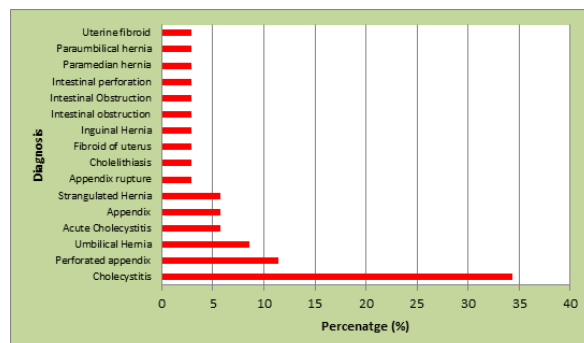
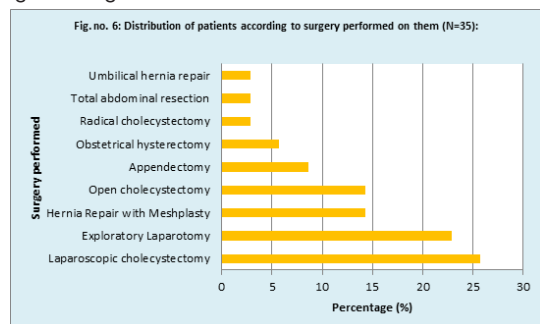


Fig. no. 5: Distribution of patients according to surgery performed on them (N=35).

**no. 5: Distribution of patients according to surgery performed on them (N=35):**

The distribution of patients according to surgery performed on them. Most common surgery performed was Laparoscopic cholecystectomy (25.7%). This distribution is presented by bar diagram in fig. no. 6.

**no. 6: Distribution of patients according to duration of General Anesthesia (N=35):**

Shows the distribution of patients according to duration of anesthesia. 77.1% patients had 3 hours of general anesthesia.

**Table no. 1: Comparison of FVC, pre-operative 24 hours and Post-operative 48 hours (N=35):**

Variable	Pre-operative 24 hours	Post-operative 48 hours	Statistical Test used	P value	Interpretation
FVC	1.89±0.78	2.13±0.63	Paired t test	0.0014	The FVC post-operative 48 hours was significantly more than FVC pre-operative 24 hours

Above table shows the Comparison of FVC pre-operative 24 hours and Post-operative 48 hours. The statistical test used was Paired t test and p value is 0.0014 (< 0.05). This data is statistically significant.

**Table no. 2: Comparison of PEFR, pre-operative 24 hours and Post-operative 48 hours (N=35):**

Variable	Pre-operative 24 hours	Post-operative 48 hours	Statistical Test used	P value	Interpretation
PEFR	2.63±1.83	2.9±1.84	Paired t test	0.0785	The PEFR post-operative 48 hours was comparable to PEFR pre-operative 24 hours

Above table shows the Comparison of PEFR pre-operative 24 hours and Post-operative 48 hours. The statistical test used was Paired t test and p value is 0.078 (> 0.05). This data is not statistically significant.

**Table no. 3: Comparison of FEV1, pre-operative 24 hours and Post-operative 48 hours (N=35):**

Variable	Pre-operative 24 hours	Post-operative 48 hours	Statistical Test used	P value	Interpretation
FEV1	1.8±0.53	1.97±0.45	Paired t test	0.0104	The FEV1 post-operative 48 hours was significantly more than FEV1 pre-operative 24 hours

FEV1	1.8±0.53	1.97±0.45	Paired t test	0.0104	The FEV1 post-operative 48 hours was significantly more than FEV1 pre-operative 24 hours
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Above table shows the Comparison of FEV1 pre-operative 24 hours and Post-operative 48 hours. The statistical test used was Paired t test and p value is 0.01 (< 0.05). This data is statistically significant.

**DISCUSSION**

General anaesthesia generally impairs pulmonary gas exchange ;alveolar ventilation perfusion mismatch and respiratory mechanics in anaesthetised patient after surgery. Strategies to improve pulmonary function in postoperative period after abdominal surgeries under general anaesthesia for more than 2 hrs would decrease atelectasis and postoperative hypoxemia.

The goal of this study was to examine postoperative respiratory effects, improve oxygenation and reduces risk of postoperative hypoxia and atelectasis.

Patients who used NIV positive airway pressure devices for 12-24 hrs in immediate postoperative period have significantly less postoperative spirometric pulmonary dysfunction ;suggestive of that effects of positive airway pressure therapy improves postoperative spirometric values and lung functions and maintain improved functions upto 24 hrs which is crucial period in postoperative timeperiod.

EzPAP positive airway pressure device which amplifies an input of either air or oxygen approximately 4 times greater by using coanda effect in ventilation, this augmentation provides a larger flow and volume with less effort than an unsupported inspiration and positive pressure during expiration.

This study is a single centre ,prospective, interventional study was conducted in surgical wards of teaching institute in metropolitan city.

Primary aim of this study was to compare postoperative values with baseline (preoperative) values of following parameters Volumetric spirometric values –PEFR, FEV1, FVC

**DISCUSSION OF STATISTICAL ANALYSIS**

**AGE**-In this study, mean age was 39.1±12.2. we found no correlation between age and incidence of postoperative pulmonary dysfunction. Similarly, Henry Clinton talley et. al . conducted a pilot study ;EzPAP in postoperative period, mean age of patients in this study was 47.7±9.9 which is slightly higher than the present study. In contrast study by sarah Elliott et al age range used in his study was 9-91 years ,whereas in present study was 19-60 years. The fraction of patients with postoperative pulmonary dysfunction higher in elderly age group.

**GENDER**-In this study ,54.3% were males and 45.7% females. In the other study conducted by Sarah Elliott et al 60% were males and 40% females which was nearly equivalent to present study .Study by Henry Clinton talley et al composed of all caucasians obese women ;suggested that the fraction of postoperative pulmonary dysfunction higher in elderly women because of obesity .

**DIAGNOSED CONDITIONS AND SURGICAL PROCEDURES**-Most common diagnosed conditions in this



present study ,we found cholecystitis ,83% grouped in abdominal and urogenital region and ASA I and II graded patient.This study involved surgical procedures like cholecystectomy ,exploratory laparotomy ,hysterectomy ,appendectomy ,hernia repair . **Sarah Elliott study et al** included in his study with medical conditions grouped into themes ;36% of EzPAP interventions were with patients admitted with respiratory conditions and 32% of admitted post abdominal or gynecological surgeries and rest orthopaedic ,majority of patients who received EzPAP to improve lung functions had undergone abdominal surgeries 70%.**Henry Clinton talley et al** study included 19 patients with ASA grade III and IV posted for nonemergent laparoscopic abdominal surgery .Conclusion is that positive airway pressure therapies useful in patients who undergone abdominal surgeries because of pulmonary dysfunction more common after this surgeries due diaphragmatic splinting.

**Wiersgella 2002 et al** suggested in his study that EzPAP was a viable treatment option for long term conditions like cystic fibrosis and multiple sclerosis.

**DURATION OF SURGERY**-In this study ,most of the patients undergone for surgery under general anaesthesia for more than 3 hrs(77%).In any previous study ,no correlation between hrs of surgery and EzPAP therapy effects on postoperative pulmonary dysfunction.

**PARAMETERS OF LUNG EXPANSION**-In this study ,comparison of parameters for lung expansion was done 24 hrs preoperatively and 48 hrs postoperatively ;difference between preoperative and postoperative lung volumes was higher in postoperative conditions for parameters-FVC,FEV1,PEFR after EzPAP therapy.EzPAP provides positive pressure that amplifies an input flow of either air or oxygen approximately 4 times and so positive pressure is maintained throughout the breathing cycle of patient ,so this augmentation provides a larger flow and volume and increases lung volumes. **Medway NHS foundation trust** department based clinical study (Elliott 2012) in their study , EzPAP in relation to increasing lung volumes and results demonstrated improvement in all physiological parameters.

#### Limitations of this study

1. In our study,sample size is small.
2. We include only abdominal surgeries.Thoracotomy or other major complicated surgeries not included.
3. We include only ASA I and ASA II patient.ASA III and ASA IV patients with chronic comorbidities patients were not included.
4. In this study ,we only observed the effects of EzPAP therapy in patients,not compared with other devices of oxygen therapy. Due to these limitations in our study ,for any further conclusion large study sample group with two different groups cases and control in different postsurgical procedures.

#### CONCLUSION

This prospective interventional study suggests that;EZPAP positive airway pressure device is a useful to improve respiratory functions and clinical improvements in lung volumes in the post operative patients undergoing general anaesthesia for more than 2 hrs , preventing atelectasis and postoperative hypoxemia .

It appears to aid in clearance of secretions of central airways in postoperative patients .

It appears too helpful for maintaining hemodynamic stability to patients( within normal range) in throughout the peri-operative and postoperative period.

#### ACKNOWLEDGEMENT

WE thanks to prof.DR.Satoskar ,HOD of Department of Surgery in KEM Hospital Mumbai,for sharing surgical information of patients.

#### FIGURES NUMBERING

- Fig no.1-EzPAP device
- Fig no.2,3-coanda effect
- Fig no.4-Anaesthesia effects on respiratory system
- Fig no.5-Graphical distribution of patients according to diagnosis
- Fig no.6 -Graphical distribution of patients according to surgery performed

#### TABLES NUMBERING

1. Comparison of FVC preoperative 24 hrs and postoperative 48 hrs
2. Comparison of PEFR preoperative 24 hrs and postoperative 48 hrs
3. Comparison of FEV1 preoperative 24 hrs and postoperative 48 hrs

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