Pre-operative pulmonary assessment and risk factors for post-operative pulmonary complications in elective abdominal surgery in Nigeria

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Abstract

Background and Objectives: Post-operative pulmonary complications (PPCs) are recurring causes of rising morbidity and mortality in surgeries. This study sought to evaluate pre-operative risk factors for PPCs in abdominal surgerypatients in Nigeria. **Methodology:** This was a prospective study in patients booked for surgery in 2014. Biodata, medical his tory, pre-operative respiratory and cardiovascular examination findings, body mass index, serum albumin, serum urea, ventilatory function, chest x-rays and oxygen saturation were obtained. The association between pre-operative variables and PPCs was determined.

Results: The pre-operative spirometry was predominantly restrictive (62%). Overall, the prevalence of PPCs was 52%. This included non-productive cough (14%), isolated productive cough (10%), productive cough with abnormal chest finding (16%), pneumonia (8%), pleural effusion (5%), ARDS (2%). Percentage predicted FEV1 and FVC were lower in participants with PPCs. (p=0.03 and p=0.01respectively). Pre-operative cough, shortness of breath and consolidation were associated with PPCs (p<0.05). Post-operative respiratory rate and pulse rate in participants with PPCs were higher than the values in those without PPCs (p=0.03 and p=0.05).

Conclusion: The prevalence of PPCs was high in this study. Pre-operative cough, shortness of breath, consolidation, abnormally low percentage predicted FEV1 and FVC were associated with PPCs.

Keywords: Post-operative pulmonary complications, pre-operative assessment, risk factors, cough, shortness of breath, consolidation, pneumonia, elective abdominal surgeries, Nnewi, Nigeria.

DOI: https://dx.doi.org/10.4314/ahs.v19i1.51

Cite as: Ufoaroh CU, Ele PU, Anyabolu AE, Enemuo EH, Emegoakor CD, Okoli CC, et al. Pre-operative pulmonary assessment and risk factors for post-operative pulmonary complications in elective abdominal surgery in Nigeria. Afri Health Sci. 2019;19(1). 1745-1756. https://dx.doi. org/10.4314/ ahs. v19i1.51

Introduction

Pre-operative assessment in all forms of surgery is important, complex, and multi-disciplinary, and is designed

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Ernest Ndukaife Anyabolu, Chukwuemeka Odumegwu Ojukwu University, Medicine; Imo State University, Medicine. Email: enhealer@yahoo.com to minimize post-operative complications, morbidity and mortality.^{1,2} The incidence, morbidity and mortality of post-operative pulmonary complications (PPCs) are increasing.³ This makes the role of pulmonologists central in pre-operative reviews of patients PCCs is defined as unintended pulmonary abnormalities arising from surgeries that cause identifiable dysfunction with adverse impact on the patients' clinical course leading to high morbidity and mortality.^{1,4,5,6,17}

The commonest PPC is pneumonia. Others include atelectasis, bronchitis, bronchospasm, pulmonary embolism,



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respiratory failure, exacerbation of underlying chronic lung disease and respiratory distress syndrome.⁸⁻¹⁰ The prevalence of PPCs varies widely (5-80%), and is influenced by patients' population and defining criteria. PPCs occur in 25-50% of major surgeries.¹¹

The complications are patient- or procedure-related. Majority develops from changes in lung volumes in response to respiratory muscles dysfunction and chest wall mechanics. Thoracic and upper abdominal surgeries are associated with restrictive lung volume reduction. Reduced vital capacities (50-60%) may smoother for one week, while functional residual capacity may decrease by about 30%. Diaphragmatic dysfunction, post-operative pain and splinting of diaphragm may cause atelectasis producing stasis and infection, Bronchospasm may result from the effect of anesthetic agents, tracheal intubation, or aspiration of secretions.¹⁴

Post-operative pulmonary complications are the most expensive medical outcomes from surgeries.⁶ Studies on pre-operative assessment have been conducted in the Americas.^{7,15} This study therefore sought to evaluate pre-operative and other factors which might influence PPCs in patients undergoing abdominal surgery in Nigeria, with a view to reducing adverse outcomes,

Materials and methods

This was a prospective study on patients booked for elective abdominal surgery between February, 2014 and April, 2015, in Nnamdi Azikiwe University Teaching Hospital (NAUTH), Nnewi, SouthEast Nigeria. The study subjects consisted of 50 patients >18 years, consecutively recruited from those booked for major elective abdominal surgeries during this period. Those with impaired consciousness were excluded. About 120 abdominal surgeries, 60% emergencies and 40% elective, were performed annually.

Sample size calculation

The minimum sample size was determined by Fishers' formula.¹⁶

Where:

n=Minimum sample size

Constant at 95% confidence interval from Z table

Average prevalence of PPCs following non-cardio-thoracic surgeries¹⁷ (10.5%).

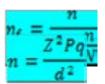
Using and taking Precision at 95% confidence interval = 0.05

Calculation

$$n = \frac{1.96^2 \times 0.105 \times 0.895}{0.0025}$$

$$n = 144.4$$

Applying the formula for calculation of sample size with population less than ten thousand.



The derived sample size when population is less than 10,000

The desired sample size when the population is more than 10,000

The estimate of the population

All consenting patients booked for elective abdominal surgery between February 2014 and April 2015 were assessed. A total of 50 participants were enrolled into the study to cover for possible attrition and also to increase the power of the study.

The hospital Ethics Committee approved this study. Informed written consent was obtained from each participant.

Computerized portable micro lab spirometer 3500 UK V.6.00, was used to perform ventilatory function tests.

Data collection

The following data were obtained by the researchers for each subject, using a questionnaire.

Demographic data; age, sex

Respiratory symptoms: cough, shortness of breath, wh eeze

Co-morbidities: hypertension, diabetes, asthma, HIV status, indication for surgery.

Social history: smoking and pack years of smoking. **Clinical examination:** standing height (m), weight (kg), pulse rate (beats/min), blood pressure (mmHg), respiratory rate (cycles/min), crackles. The participants pre-operatively were grouped into the American Society of Anesthesiologist (ASA) classes.

Relevant investigations: chest radiograph, lung function tests, oxygen saturation, serum urea and albumin. Spirometry: This was performed with the subjects relaxed, sitting, and without nose clips, tight clothing or removable dentures in the mouth. The purpose of the tests was explained to them. Each performed forced expiratory manoeuvers, from total lung capacity to residual volume, to obtain measurements for peak expiratory force (PEF), forced vital capacity (FVC) and forced expiratory volume in one second (FEV1). The best PEF, FVC and FEV1 from technically satisfactory forced expiratory manoeuvers were selected as representative values. Five minutes were allowed between manoeuvers to enable the participant rest.¹⁸

Relevant intra-operative parameters

Data on the procedure-related risk factors for PPCs such as duration of surgery, anesthetic agents, analgesics, type of incision, were retrieved from the operation notes of each participant.

Post-operative parameters

Each participant has a respiratory and cardiovascular sys-

tems examination, and oxygen saturation performed 48 hours post-operatively.

Data analysis

The data were analyzed using SPSS version 21.0. The association between categorical variables were compared using Pearson Chi square test and/or Fishers Exact test. The mean difference of the continuous variables was compared using Students t tests. Univariate linear regression analysis was used to determine the strength of the pre-operative variables to predict the PPCs. All tests were two-tailed. P≤0.05 was taken as statistically significant.

Definition of Terms

PPC is defined as unintended pulmonary abnormalities that occur as a result of surgery which cause identifiable dysfunction.³

Cough is defined as a common reflex action that clears the throat of mucus or foreign irritants.

Results

Fifty participants were studied. Their mean age was 50.60±13.70 years, range 26-72 years and age groups evenly distributed. Females constituted 62.0% and males 38.0%.

Intra-abdominal malignancy (52.0%) was the major indication for surgery. Others were ventral hernia (16.0%), uterine fibroid (10.0%), benign prostatic hypertrophy (8.0%), renal stone (8.0%), cholecystitis (4.0%) and liver abscess (2.0%).

Majority(98%) of the patients were within ASA class I-III; 12% had crepitations, whereas 6% had chronic obstructive airway diseases. Pre-operative respiratory symptoms were observed in 44% of the patients. Cough was the most common symptom (Table 1).

Risk factors	Frequency (%)	
Obesity	14(28)	
Smoking	6(12)	
Hypertension	13(26)	
Diabetes mellitus	5(10)	
Human Immunodeficiency Virus infection	2(4)	
American Society of Anesthesiology class		
I	11(22)	
II	18(36)	
III	20(40)	
IV	1(2)	
Chronic obstructive airway diseases	3(6)	
Pre-operative crepitation	5(10)	
Pre-operative respiratory symptoms		
Snoring	9(31.0)	
Shortness of breath	6(20.7)	
Cough	13(44.8)	
Wheezing	1(3.4)	
Hypoalbuminaemia (<30g/dl)	7(14)	
Urea(>10mmol/l)	7(14)	

The patients presented with reduced FVC, FEV1 and PEF. These were dominantly restrictive (62%), observed with increasing age (Tables 2).

Thirty-nine (78%) subjects had abnormal pre-operative chest radiograph, some showed multiple abnormalities. The abnormalities observed were aortic unfolding

(28.7%) in subjects, topping the list, followed by pneumonic consolidation (20.3%), cardiomegaly (17.8%), elevated diaphragm (7.9%), lung volume loss (7.9%), features of fibrosis (5.0%), pleural effusion (5.0%), tracheal deviation (3.0%) and the least, cavity (0.9%) and hyperinflation (0.9%).

Table 2: Baseline lung function of the participants

Age	Sex	FEV ₁ (L)	FVC(L)	FEV ₁ /FVC	PEF(L)
		Median	Median	(F/M)	Median
26-30	F/M	2.28 / -	2.28 / -	94 / -	3.54 / -
31-35	F/M	2.22 / 2.71	2.26 / 3.23	91 / 84	3.25 / 3.93
36-40	F/M	1.02 / -	1.06 / -	96 / -	1.34 / -
41-45	F/M	1.54 / 0.21	1.54 / 3.58	99 / 93	2.87 / 6.19
46-50	F/M	1.125 / 2.93	1.14 / 3.15	98 / 93	3.19 / 3.28
51-55	F/M	1.50 / 2.21	1.51 / 2.39	92 / 88	2.17 / 4.40
56-60	F/M	1.38 / 1.94	1.42 / 2.17	96 / 91	2.13 / 3.22
61-65	F/M	1.50 / 0.42	1.69 / 2.79	96 / 90	2.87 / 3.75
>65	F/M	1.43 / 1.65	1.61 / 1.75	91 / 95	2.25 / 2.48

FEV1=forced expiratory volume in 1 second. FVC=forced vital capacity. F=female. M=male. PEF= peak expiratory flow

The incision types were dominantly upper abdominal (supra-umbilical) midline (66.0%), trailed by lower abdominal (infra-umbilical) midline (26.0%) and flank (8.0%). Muscle relaxants used were short-acting (60.0%), long acting (26.0%), none (14.0%). Majority (56%) of the surgery lasted < 2 hours. The type of anesthesia employed were principally general using endotracheal tube (56%), general without using endotracheal tube (30%) and local 14%.

Post-operative pulmonary complications were observed in 52% of the subjects. These comprised of new onset productive cough plus crepitation without radiographic features of pneumonia (16%), isolated non-productive cough (14%), isolated productive cough (10%), pneumonia (7%), pleural effusion (2%) and hypoxemia, widespread coarse crepitations and pulmonary chest infiltrates

(suggesting acute respiratory distress syndrome (ARDS) (2%).

No significant association was observed between PPCs and the indications for surgery, namely, benign prostatic hypertrophy (p=0.09), cholecystitis (p=0.49), fibroid (p=0.35), intra-abdominal malignancy (p=0.79), liver abscess (p=0.48), renal stone (p=0.34), ventral hernia (p=0.70). Although intra-abdominal malignancy made up 52% of the indications for surgery, no significant association was found between intra-abdominal malignancy and PPCs.

There was significant association between PPCs and presence of cough (p=0.01), as well as shortness of breath (p<0.01). Other variables have no such association (Table 3).

Risk factors	Absence of POPC	Presence of POPC	\mathbf{X}^2	p-value
Age of patient				
<50				
>50				
<60 years	17	16	0.48	0.37
>60 years	7	10		
Obesity				
$BMI < 30 kg/m^2$	17	19	0.03	0.90
$BMI \ge 30 \text{kg/m}^2$	7	7		
ASA class				
I-II	15	14	1.76	0.40
III	8	12		
IV	1	-		
Pre-operative respiratory symptoms				
Snoring	5	4	0.251	0.446
Shortness of breath	-	6	6.29	0.014*
Cough	1	12	11.35	0.001*
Wheezing	-	1	0.942	0.520
Muscle relaxants				
Short acting	13	17	3.12	0.22
Long acting	4	9	2.09	0.15
None	5	2	1.70	0.18
COPD	1	2	0.28	1.00
No	1	~	0.20	1.00
Yes				
Co-morbidity	15	17	4.92	0.57
Duration of surgery	-			
>2 hours	11	11	0.06	0.80
	1	i .		

The percentage predicted FEV1 and percentage predicted FVC of the subjects that developed PPCs were significantly low compared to those without the complications

(p=0.01) (Table 4). Pre-operative consolidation, unlike other chest radiograph findings, has significant association with PPCs (Table 5).

Table: 4: Comparing the mean values of the measurable risk factors between patients with and those without post-operative pulmonary complications PR RISK FACTORS mean±standard T P-value deviation AGE Absence of POPC 50.9±13.0 0.03 0.87 Presence of POPC 50.3±14.6 BMI Absence of POPC 26.14±6.0 0.34 0.57 Presence of POPC 27.3±7.5 FEV1 Absence of POPC 1.96±0.72 0.75 0.11 Presence of POPC 1.89±0.82 Predicted FEV1(%) Absence of POPC 81.38±19.01 5.14 67.31±24.30 Presence of POPC Predicted FVC(%) FVC(%) Absence of POPC 76.54±19.65 6.60 0.01 Presence of POPC 61.23±22.23 PEF 0.11 Absence of POPC 3.26±1.40 0.74 Presence of POPC 3.40±1.57 FEV1/FVC ratio Absence of POPC 92.05±9.47 0.20 Presence of POPC 91.01±7.06 Urea Absence of POPC 5.2±3.4 0.38 0.54 Presence of POPC 5.2±4.9 Albumin Absence of POPC 0.03 37.1±8.0 0.96 Presence of POPC 37.2±6.2

PR RISK FACTORS=Patient-related risk factors. BMI=body mass index. FEV₁=forced expiratory volume in 1secs. FVC=forced vital capacity. PEF=peak expiratory flow. POPC=post-operative pulmonary complication.

Table 5: Pre-operative pulmonary co	-	nest radiograph	n findings	and post-
Feature	Absence of POPC	Presence of POPC	X^2	P-value
Cavity	-	1	0.80	0.52
Features of fibrosis	1	4	1.745	0.351
Pneumonic consolidation	5	16	8.489	0.005
Pleural effusion	2	3	130	1.00
Tracheal deviation	1	2	0.15	0.70
Elevated hemidiaphragm	3	5	1.40	0.70
Hilar opacity	-	2	1.64	0.50
Lung volume loss	2	6	3.84	0.06
Aortic unfolding	14	15	0.002	1.00
Hyperinflation	1	-	1.30	0.48
Cardiomegaly	9	9	0.02	1.00
POPC=Post-operative pulmo	onary complica	ntions. X ² : chi squar	re.	

The mean respiratory rate and mean pulse rate were significantly higher in those with PPCs than in those without complications (p=0.03 and p=0.05 respectively) (Table 6). Pre-operative cough predicted PPCs in the study, (OR

0.045, p= 0.02, 95% confidence interval 0.003-0.634), whereas pneumonic consolidation (p=0.12), predicted FEV1 (p=0.57), and predicted FVC (p=0.69) did not (Table 7 and 8).

Table 6: Examination findings and post-operative pulmonary complication						
		Presence of POPC (mean±SD)	Absence of POPC (mean±SD)	T	P-value	
Respiratory rat	e Pre-op	22.0±4.30	20.7±2.30	1.68	0.20	
	Post-op	29.9±8.10	25.3±6.10	5.23	0.03	
Pulse rate	Pre-op	83.4±12.6	83.5±12.60	0.01	0.97	
	Post-op	100.4±20.50	88.8±20.70	3.98	0.05	
O ₂ saturation	Pre-op	95.0±8.20	97.0±1.60	1.43	0.24	
Dong	Post-op	93.2±5.00	94.9±5.00	1.95	0.17	

POPC=post-operative pulmonary complication. SD=standard deviation. op=operative, T=students' t test.

Table 7: Post-operative pulmonary complication	
Complications	Frequency N(percent)
Non-productive cough only	7(14%)
Productive cough only	5(10%)
Productive cough + crepitation (nil CXR features of pneumonia)	8(16%)
Pneumonia	4(8%)
Pleural effusion	1(2%)
Hypoxaemia+ wide spread coarse crepitations + pulmonary chest infiltrate (?ARDS)	1(2%)
No POPC	24(48%)
POPC=Post-operative pulmonary complications. CXR: chest radiogracute Respiratory Distress syndrome	aph. ? ARDS= suspected

Significant variables	P value	Odd ratio	Lower CI	Upper CI
Pneumonic consolidation	0.115	0.29	0.062	1.354
Pre-operative cough	0.021*	0.045	0.003	0.634
Predicted FEV1	0.571	0.975	0.893	1.065
Predicted FVC	0.688	0.981	0.895	1.076

Discussion

This study showed that pre-operative cough, shortness of breath, pneumonic consolidation, low percentage predicted FEV1 and low percentage predicted FVC were common in PPCs in patients undergoing elective abdominal surgery.

In this study, no significant association was observed between age and PPCs, similar to that by Kanat.et al²⁰ whose sample size was 60, but differing from the studies by Brooks-Brunn et al,²¹ Pereira et al¹⁵ and Nertila et al¹² where age >60 years, as in another study, >50 years, were predictors of risks.^{22,23,24} Unlike ours, large population and age >50 years in these studies^{12,15,21} perhaps, might explain the observed disparity.

This study found no significant association between obesity and PPCs, which agrees with that in 2 studies in Brazil and Asia^{15,20} but disagrees with that in another report in USA.²¹ Obesity causes reduced lung volumes, ventilation/perfusion mismatch and relative hypoxemia^{24,25} which may worsen with anesthesia and so may increase the risk of pulmonary complications. However, these were not observed in this study. Perhaps, the dominantly normal body mass index (BMI) noted in this study might explain the dissociation between obesity and PPCs.

This study observed a significant association between pre-operative presence of cough, shortness of breath and PPCs. It further showed that pre-operative cough predicted PPCs, similar to the report by Pereira et al.¹ The presence of these symptoms suggests pre-existing respiratory system disease which makes the lung more susceptible to the deleterious effect of changes in lung volume and mechanics during surgeries. Pre-existing respiratory disease, mirrored by these symptoms, influenced the development of PPCs, as found in the study.

In this study, though 50% of the current smokers developed PPCs, the association was not significant, similar to the report by Kanat et al.²⁰ However, it disagrees with the observations by Barrera et al,²⁶ Mitchell et al¹⁰ and Dilworth et al,²⁷ The small population size and few numbers of current smokers could explain the outcome in this study, similar to that by Kanat et al²⁰ but differing from those 3 workers^{10,26,27} who have more smokers with longer pack years of smoking.

Expectedly, ASA class I and II have no significant association with PPCs, as these levels usually have low risk of

developing surgical complications, as found in this study. This agrees with the report by Kanat.et al²⁰ but differs from that by Smetana et al24 which documented that patients in ASA > II have 4.87 fold increased risk of developing PPCs. Nonetheless, they have more patients in ASA III and IV classes than were observed in this study. Many (62%) of the participants have abnormal lung function; they were mainly restrictive, some mild, few moderate and yet others severe. This pattern could be explained by the dominant abdominal pains and swelling. Classing restriction into normal, mild, moderate and severe may depend on the site, size of abdominal lesion and degree of pain. Those who have normal spirometry were mainly participants with small lesions without pain, lower abdominal and pelvic conditions. There was no obstructive pattern found in this study. Perhaps this was attributable to the small number of the patients who were smokers. In this study, low percentage predicted FEV1 and low predicted FVC were significantly associated with PPCs, agreeing with the reports in 3 studies^{15,20,28} despite the high number of participants with obstructive spirometry pattern they observed.

Albumin aids opsonization and granulocyte function. Low serum albumin is a poor prognostic feature in pneumonia.²⁹ Most of this study participants have normal serum urea and albumin which might account for the absence of an association between them and PPCs in this study. This finding is similar to that documented by Kanat et al²⁰ but contrary to that observed by Varut et al.³⁰ It was further noted that the latter involved only colon cancer patients who were chronically ill and at risk of malnutrition and malabsorption.

Increasing age creates vulnerability for respiratory and cardiac diseases with evident chest radiograph abnormalities.³¹ In this study consolidation was significantly associated with PPCs. The complications comprised of new infiltrates and worsening radiographic findings post-operatively, supporting the assertion that an already diseased lung is at higher risk of worsening pre-existing condition. This contrasts with the observations reported by Kanat et al.²⁰

General anesthesia alters lung volumes, impairs respiratory muscles and mucociliary actions. However, this study found no significant association between general anes-

thesia and PPCs, similar to those by Pedersen et al³² and Kanat et al²⁰ but differing from those by Grigorakos et al³³ and Rodgers et al³⁴

Additional use of long-acting skeletal muscle relaxants during general anesthesia increases the risks of developing PPCs by prolonged residual neuromuscular blockade which plays a vital role in critical respiratory events in the immediate post-operative period.³⁵ This study however, did not observe any significant association between the type of muscle relaxants and PPCs. However, significant association between duration of surgery/anesthesia and PPCs was observed in this study, contrary to the studies by Nertila et al¹² and Kiekkas .et al.³⁶ The shorter duration of surgery and anesthesia for most participants in this study might have minimized the residual effect of these muscle relaxants. Many of the surgeries in this study lasted <2 hours as these effects are more evident in prolonged surgeries. This is similar to the findings of Kanat et al²⁰ but contrary to those of McAlister et al,³⁷ Celli et al³⁸ and Pederson et al,³⁹ where many patients have surgeries >3 hours.

The closer the incision to the chest and diaphragm, the greater the risks of developing PPCs. These might result from disruption of respiratory muscle movement. Pain also limits the movement of the chest and splints the diaphragm. Although 60.6% of the patients in this study who have upper midline incision developed PPCs, there was no significant association between the type of surgical incision and these complication, contrasting with the findings of Brooks-Brunn et al²¹ which have a large study size; and many of their subjects have co-morbidities. Absence of other procedure- and patient-related risk factors in this study might be explained by this difference.

This study found no significant association between the presence of endotracheal tube with assisted ventilation during general anesthesia and PPCs, contrary to the findings of Joia.et al,⁴⁰ a study in which both elective and emergency abdominal surgeries were involved.

The prevalence of 52% of early PPCs in this study is similar to 58.3% observed by Kanat et al²⁰ that enrolled 60 participants, but is higher than 14% reported by Pereira et al¹⁵ that studied >400 patients, and 11.7% by Joia et al [40] (with 5075 participants). In the studies by Pereira et al¹⁵ and Joia et al⁴⁰, the participants were also undergoing measures to prevent PPCs like pre-operative incentive spirometry, chest physiotherapy as recommended by their

Ethics Committees. These measures might have reduced the prevalence of the complications in their respective studies. Theirs, like this study, also supports the assertion that early pre-operative intervention could reduce the incidence of PPCs.

Productive cough with basal crepitations was the commonest PPC found in this study. Among these, 8% have new infiltrates and pneumonic consolidation on their post-operative chest X-ray. In contrast, pneumonia was the commonest PPC reported by Kanat. et al²⁰ and Joia et al.⁴⁰ The study by Pereira et al¹⁵ documented broncho-constriction, a study that has dominantly chronic obstructive pulmonary disease (COPD) patients with significant smoking history, intubation and surgeries > 210 minutes, unlike those in this study with one COPD patient, and surgery <2 hours.

This study found that only one patient has suspicious ARDS and this patient needed assisted ventilation but died in the course of this study.

The post-operative respiratory rate and pulse rate were significantly higher in those who developed PPCs than in those without complications, suggesting the presence of complications, perhaps, infection in these subjects.

Overall, this study has demonstrated that pre-operative pulmonary symptoms and features were associated with PPCs in subjects undergoing abdominal surgeries in NAUTH, Nnewi, Nigeria. There is a need for clinicians, surgeons, anesthesiologist and other stakeholders involved in patients' management to institute adequate pre-operative pulmonary assessment, including mandatory spirometry, of these patients prior to abdominal surgeries with a view to whittling down adverse post-operative pulmonary complications.

Conclusion

The prevalence of post-operative pulmonary complications was high in this study. Pre-operative cough, shortness of breath, consolidation, low percentage predicted FEV1 and FVC were associated with PPCs. There is a need for stakeholders to institute adequate pre-operative pulmonary assessment, including mandatory spirometry, prior to abdominal surgeries, with a view to whittling down adverse post-operative pulmonary complications.

Limitations of the study

Arterial blood gases for the participants were not done. These if done would have improved the overall results of the oximeter especially in those who have anemia. And peripheral vasoconstriction. Surgeries were performed by different categories of surgeons with varying years of experiences which might possibly affect outcomes. The study population size was small. A larger study sample, or overtly a multi-center study, would have been more representative of the population.

Conflict of interest

The authors declare that there is no conflict of interest.

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