ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES, SCHOOL OF MEDICINE

POSTOPERATIVE SORETHROAT: COMPARING MANUAL PILOT BALLOON PALPATION AND MONITORED ENDOTRACHEAL TUBE CUFF PRESSURE TECHNIQUES

AN ANALYTIC CROSS SECTIONAL STUDY

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DECEMBER 16, 2020
ADDIS ABABA, ETHIOPIA

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RESEARCH THESIS SUBMITTED TO THE DEPARTMENT OF ANESTHESIOLOGY CRITICAL CARE AND PAIN MEDICINE, SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCES, ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR SPECIALTY CERTIFICATE IN ANESTHESIOLOGY, CRITICAL CARE AND PAIN MEDICINE

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APPROVED BY THE BOARD OF EXAMINATION

The thesis here, entitled "Postoperative sorethroat- comparing manual pilot balloon palpation and monitored endotracheal tube cuff pressure technique- an analytic cross sectional study" is accepted in its present form by the board of examiners as partial fulfillment of the requirement for specialty certificate in Anesthesiology Critical Care And Pain Medicine.

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DECLARATION

I here declare that this is my original work has never been presented in this or any other university and all the source material used for this thesis have been duly acknowledged

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Date of submission----------

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ACKNOWLEDGMENT

I would like to express my gratitude to Addis Ababa University, College of Health Sciences for providing me with the opportunity to conduct this research. I would also like to express my heart felt gratitude to my advisors Dr.Faiza Hulala and Dr.Rahel Tilahun fortheir support and guidance throughout the progress of my research.

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SUMMARY

Background:

Postoperative sore throat is one of the most frequently reported symptoms following tracheal intubation. It has several risk factors that include demographic features as well as clinical aspects. Two aspects stand out regarding the anesthetic management, endotracheal tube (ETT) cuff pressure and cuff size. The ideal range for ETT cuff pressures is typically between 20 to 30 cm H2O. Despite this objective measurement of the cuff pressures is not done and professionals mostly rely on manual methods of estimation, often with less accuracy.

Objective:

The objective of this study was to compare the incidence and severity of post-operative sore throat in patients when endotracheal cuff pressure will be monitored and adjusted versus the conventional pilot balloon palpation technique.

Methodology:

The study was conducted at Tikur Anbessa specialized Hospital in Addis Ababa, Ethiopia. A hospital based analytic cross sectional study was conducted involving 100 patients. Patients 18 years and older scheduled for gastrointestinal, gynecology, thoracic, orthopedic, neurosurgery and open urology and ENT elective surgery under general anesthesia with ETT at Black lion specialized hospital between August – November , 2020 were recruited. Patients were grouped in to two and in the first group patients had their ETTc initially inflated, checked by a cuff pressure gauge, recorded and then set to 25 cmH2O. In the second group patients had their ETTc inflated using the pilot balloon palpation method. Patients were then followed up for post-operative sore throat at 24 hours post-surgery. Bivariate and multivariate logistic regressions were used to determine the association.

Results: From all of the patients 39(39%) of them had postoperative sore throat within 24 hours. 44% of patients from the manual pilot balloon palpation group had developed Postoperative sore throat while 34% of participants in the monitored endotracheal tube cuff pressure group had it.

From the total patients 51(51%) were male and 49(49%) were female; majorities of them were found age between 36-55 and mean age was 44. In terms of patients ASA status most of them 69(69%) were ASA 2 followed by ASA 1 who were 25(25%), rest 6% ASA 3: above half of

patients 72(72%) were laryngoscopic grade1. Majority of surgeries were general surgery (62%).ETT size 6 was used in sixty seven patients (67%)

Conclusion and Recommendation: Patients in whom endotracheal tube cuff pressure was measured and adjusted had similar risk of developing postoperative sore throat as compared to those patients in which manual pilot balloon palpation technique was used. The analysis based on binary and multiple logistic regression analysis showed that patient age was found to have significant association with development of POST (p-value 0.038, AOR .141 95% CI (.022, .901)). A research with a bigger sample size should be conducted on the topic. Also a randomized control trial can be conducted in the future. Simple yet relatively cheap and effective methods for continuous monitoring of cuff pressure such as using arterial line transducers can be applied.

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List of Acronyms

ACCPM- Anesthesiology, Critical care and Pain medicine

ASA- American Society of Anesthesiology

BMI- Body mass index

CMH20- centimeter of water

ETT- Endotracheal tube

ETTC- Endotracheal tube cuff

IRB- Institutional review board

PACU- Post anesthesia care unit

PONV- Post operative nausea and vomiting

POST- Postoperative Sore throat

TASH- Tikur Anbessa specialized Hospital

1. Introduction

1.1 Background

One of the fundamental responsibilities of the anesthesiologist is to establish airway patency and ensure adequate ventilation and oxygenation. This requires basic and advanced airway management skills. In contrast to basic airway management maneuvers such as head-tilt or jaw-thrust, advanced airway management relies on the use of medical equipment and surgical methods when required. Examples of methods used in increasing order of invasiveness include the use of supraglottic devices such as oropharyngeal or nasopharyngealairways, laryngeal mask airways and infraglottic techniques such as tracheal intubation and finally surgical methods[1].

Endotracheal tube (ETT) is often necessary to achieve airway control during general anesthesia. Cuffed ETTs are routinely used for tracheal intubation in most patients; cuffless ETTs without cuffs are used in neonates and infants. The high-volume, low-pressure cuff is inflated with air to provide a seal against the tracheal wall to protect the lungs from pulmonary aspiration and to ensure that the tidal volume delivered ventilates the lungs rather than escape into the upper airway.A pilot balloon with a one-way valve that allows for the inflation of the cuff and an assessment of the cuff pressure. The cuff should be inflated to the minimum volume at which no air leak is present with positive pressure ventilation.

Excessive cuff pressures may result in tracheal mucosal injury, sore throat and vocal cord dysfunction from recurrent laryngeal nerve palsy.[2] On the other end of the spectrum, it can lead to tracheal stenosis, necrosis, and even rupture. Conversely, lower cuff pressures place the patient at risk for aspiration and consequently, aspiration pneumonitis and pneumonia [3].

The most frequently reported symptoms following tracheal intubation are post operative sore throat (POST) and hoarseness with an incidence between 15% and 80% [4].

POST has several risk factors that include demographic features (e.g. female and young age),[5 6] as well as clinical aspects (e.g. anesthetic management, airway suctioning, use of succinylcholine and nitrous oxide).[7,8] Concerning anesthetic management, two aspects stand out, cuff pressure and cuff size. As for cuff pressure, The ideal range for ETT cuff pressures is typically between 20 to 30 cm H2O. [9–12] Despite such guidelines, it was found that cuff pressure exceeded 40 cm H2O in 40–90% of tested patients.[13] When pressures exceed 50 cm H2O, total obstruction of tracheal blood flow occurs.[11]

Postoperatively, it seems reasonable that most of the signs and symptoms are the result of mucosal injury which leads to inflammation caused by the process of airway instrumentation. Also,the postulated etiology is mucosal dehydration or edema, tracheal ischemia secondary to the pressure of ETT cuffs, aggressive oropharyngeal suctioning, and mucosal erosion from friction between delicate tissues and the ETT and trauma from tracheal intubation [14,15]

ETT cuff pressure is most reliably assessed with direct continuous manometers during the operative period.[3][4] One can easily and inexpensively display real-time cuff pressures using an ordinary patient monitor with invasive pressure capability[16].

Despite this, few anesthesiologists use such methods in daily clinical practice and typically rely on less quantitative methods to estimate the cuff pressure such as minimal occlusive volume technique, minimum leak technique, predetermined volume and palpation technique, all of which are estimation techniques and often used with poor compliance.[3]. Additionally, these commonly used techniques are much less accurate and often poor estimates of ETT cuff pressures.[4,17] This dilemma is not remedied by clinical experience, as studies have shown that inaccurate cuff pressure assessments can occur in the hands of even the most seasoned anesthesiologists. [3]

Although POST complaints are often regarded as minor complications, they are distressing for the patient and often remains as an unpleasant memory decreasing patient satisfaction and quality of recovery.It may also increase analgesic use. Therefore, a lessening of the symptoms is worth attempting. It's my hypothesis that controlled endotracheal tube cuff pressure will result less incidence of postoperative sore throat and other minor airway complaints.

1.2 Statement of the problem

POST is a common complaint occurring most often following tracheal intubation.Routine tracheal intubation for elective surgical procedures can result in pathological changes, trauma and nerve damage which may also account for postoperative throat symptoms[18].

POST, often considered as a minor complaint, tends to be neglected despite its high incidence. High endotracheal tube pressure is considered as one among many risk factors. The importance of tracheal tube cuff pressures is highlighted by the spectrum of complications that can occur.

The ideal range for tracheal tube cuff pressuresis typically between 20 to 30 cm H2O and is easily measured with a cuff pressure manometer but is not done.[3] Instead manual methods such as pilot balloon palpation is employed mostly with less accuracy of prediction.

1.3 Significance of the study

A range of complications are associated with high cuffpressure. These include postoperative throat pain and discomfort, laryngeal nerve palsy, hoarseness and stridor. It can also impair tracheal mucosal blood flow resulting in tracheal mucosal ischemia, ulceration, necrosis or tracheoesophageal fistula.

Routine monitoring of endotracheal tube (ETT) cuff pressure in clinical practice is rarely done.

The purpose of this study is to identify the correlation of endotracheal tube cuff pressure and postoperative sore throat and factors associated. This will also pave the way for further research on the topic which may work to reduce more serious complications mentioned above.

2. Literature review

In a prospective, double-blind, randomised controlled study conducted involving two hundred and ninety-two surgical patients requiring intubation, Ganason et al [19] showed that the overall incidence of POST was 39.0% versus 75.3% (P = 0.000), hoarseness 6.2% versus 15.1% (P = 0.014) and cough 7.5% versus 21.9% (P = 0.001) in the group with measured endotracheal tube cuff(ETTc) pressure and second group which used ETTc palpation technique, respectively.
In the same study, the group in which ETTc pressure was checked and measured after the initial inflation (Group A), it was found that only 82 (56.3%) patients had a cuff pressure within the recommended range of between 20 cmH2O and 30 cmH2O after the initial inflation. Sixty-three patients (43.2%) had a pressure reading of above 30 cmH2O before adjustments were made to 25 cmH2O.

Liu et al. [20] conducted a similar study on 509 patients from four tertiary centers following a similar protocol and found a significant reduction in the incidence of POST. The incidences of sore throat, hoarseness, and blood streaked expectoration 24 hours after extubation in the study group were 34%, 3%, and 4%, respectively, which were significantly lower than 44%, 11%, and 11% in the control group.The incidence of cough, sore throat, and blood-streaked expectoration increased with the increasing duration of endotracheal intubation in both groups,especially when the duration of endotracheal intubation was longer than 180 minutes. This observation may mean that the pressure and time are both important variables in causingmorbidity after endotracheal intubation. Clinical symptoms were most prominent 24 hours after removing the tube.
They concluded that ETTc pressure estimated by clinical judgment is often much higher than the optimal values to prevent tracheal injury. The study also demonstrated that proper control of ETTc pressure using a manometer even in procedures lasting only a few hours helps to reduce postprocedural endotracheal intubation–related complications.

Jaensson et al [6] conducted a randomized control trial with the primary aim of assessing whether the size of the endotracheal tube (ETT) affects the risk of sore throat in women following anaesthesia. One hundred healthy adult women undergoing elective surgery were randomly allocated to oral intubation with either ETT size 6.0 or 7.0. The patients were randomly allocated to one of two groups using a computer-generated randomization list drawn up by a statistician.

Anaesthesia was based on either inhalation or total intravenous anaesthesia according to standardized routines. They found that women intubated with ETT 6.0 had less sore throat and less discomfort in the PACU than women intubated with ETT 7.0. They also found that the incidence of sore throat after intubation with ETT 7.0 was 48.9%. The overall incidence of sore throat at PACU in the whole group was 40%, in spite of the use of Betamethasone for PONV prophylaxis. This study showed no significant differences in hoarseness at any time between the groups.

A prospective study conducted in Nigeria by Edomwonyi et al [21] involved 200 participants and studied the incidence of throat complications after surgery for sixteen months. Sizes 7mm - 8.0mm internal diameter (I.D) portex endotracheal tubes with cuff were used for females while sizes 8.5mm - 9.0mm I.D were used for males. 123 participants (63%) had an incidence of throat complications such as sorethroat cough and hoarseness. 62(49%) patients developed Postoperative sorethroat. The incidence of sore throat was similar in both males and females. There was no statistically significant difference P=1.0000, odd ratio = 1.035, 95% CI: 0.5064 - 2.115. While multiple attempts at intubation did not contribute to the development of sore throat in their study duration of intubation greater than 60 minutes contributed to a higher incidence of throat complications and it was considered statistically significant.

In a hospital based cross sectional study done by Chewaka and Temesgen [22] at Jimma university teaching hospital involving 245 patients with a response rate of 228 patients scheduled for elective gynecologic and general surgery, 129 (56.6%) participant had suffered postoperative sore throat (POST) and 68 (29.8%) of them developed hoarseness of voice. The sore throat complaint was severe in 27(11.8), moderate in 43(18.9) and mild in 59(25.9) patients as they indicated on numerical scale. Majority of them noticed that the suffering started immediately while they were in Postanesthesia care unit According to the same research sore throat is the second (56.6%) most reported problems by patients during postoperative period next to nausea and vomiting (68.2%). It was found to be more common with certain patients, anesthetic and surgical related factors,intubation difficulty, duration of ETT in trachea, unpremedicated with opioid, anesthetists' experience, type of induction agent, bleeding on tip of laryngoscope/ETT, perioperative hypotension and estimated blood loss during surgery.

Another hospital based cross sectional study was conducted in 2014 in Gondar University hospital by Gemechu et al [23]. A total of 240 out of 299 patients were included in this study. Postoperative sore throat was complained by 143 patients (59.6%). The highest proportion of sore throat occurred in patients who underwent general surgery (58.6% (92/157)). Female patients reported higher incidence of sore throat compared to male patients (65.9%vs 51.8% (87/132 vs 56/108)). Multiple intubation attempt and use of nasogastric tube were also associatedfactors in this study.

3. Objectives

3.1 General objective

To compare the incidence and severity of post-operative sore throat in patients when endotracheal cuff pressure will be monitored and adjusted versus the conventional pilot balloon palpation technique. The period of study was from August- October, 2020.

3.2 Specific objective

- To compare the incidence and severity of post-operative sore throat in patients at 24 hour postoperatively from August-October, 2020.
- To determine factors associated with postoperative sore throat.

4. METHODS

4.1 Study Setting

The study was conducted in Addis Ababa, Ethiopia at Tikur Anbessa specialized hospital, which was established in 1972. It is a teaching hospital of Addis Ababa University, College of Health Sciences, and School of Medicine. It is also the largest referral hospital in Ethiopia with multiple specialties and sub-specialties. It has around 800 beds in total and serves nearly 350,000 patients as outpatients and inpatients annually. Currently the hospital has 14 operation rooms of which 10 of them are for elective cases and 4 for emergency cases.

4.2 Study design

A hospital based analytic cross sectional study was conducted.

4.3 Source Population

All patients who were operated at Tikur Anbessa Specialized Hospital operation theatres.

4.4 Study population

Patients 18 years and older scheduled for gastrointestinal, gynecology, thoracic, orthopedic, neurosurgery and open urology and ENT elective surgery under general anesthesia with ETT at Black lion specialized hospital between August – September, 2020.

4.4 Sample size determination

The sample size is calculated using sample size calculation function of Epi info software version 7. With a power (beta) of 80%,95% confidence interval and prevalence of sorethroat in previous similar study by ganasson et al, being 75.3% and 39% in control and study groups. Sample size became a total of 56 patients and adding a 10% nonresponse rate became 62. A total of 100 patients with 50 patients in each group were included during the study period.

$$n_1 = \frac{\left[Z_{\alpha/2}\sqrt{(r+1)\bar{p}\bar{q}} + Z_{1-\beta}\sqrt{rp_1q_1 + p_2q_2}\right]^2}{r(p_1 - p_2)^2}$$

$$n_2 = r\,n_1$$

n_1 = number of cases

n_2 = number of controls

$Z_{\alpha/2}$ = standard normal deviate for two-tailed test based on alpha level (relates to the confidence interval level)

Z_{β} = standard normal deviate for one-tailed test based on beta level (relates to the power level)

r = ratio of controls to cases

p_1 = proportion of cases with exposure and $q_1 = 1-p_1$

p_2 = proportion of controls with exposure and $q_2 = 1-p_2$

4.5 Inclusion and Exclusion Criteria

Inclusion criteria

- Patients 18 years or older
- ASA physical status I–III patients scheduled for elective gastrointestinal, gynecology, open urology,orthopedic,thoracic and neurosurgical surgeries under general anesthesia
- Patients who consent for the research

Exclusion criteria

- Patients who do not consent for the research
- Patients with pre-existing sore throat
- Patients requiring double-lumen ETT intubation
- Patients undergoing oral and laryngopharyngeal surgery

4.6 Operational definitions

- **Sore throat**- described as present if patient describes pain, scratchiness or irritation of the throat, which is further graded using numerical rating scale from 0–10. The severity of the sore throat will be regarded as mild (score 1–3), moderate (score 4–7) or severe (8–10).
- **Hypotension**- A blood pressure reading of less than 90/60mmHg.

4.7 Study variables

- **Independent variables**

- Socio-demographic data – Age, sex
- ASA class
- Duration of anesthesia
- Duration of surgery
- ETT size
- ETT cuff pressure
- Number of intubation attempts
- Laryngoscopic Grade of airway
- use of oral airway
- Premedication before induction
- Intraoperative analgesic use
- Intraoperative hypotension

- **Dependent variables**

- Postoperative sore throat

4.8 Data Quality Assurance

During the data collection, regular and periodic supervision was made for quality and completeness by the primary investigator.

4.9 Data entry and Analysis procedures

The data was entered into statistical package for social sciences (SPSS) version 23 and analyzed.Statistically significant association was taken for p values of <0.05.

4.10 Ethical consideration

Ethical clearance was obtained from the Department of Anesthesiology, Critical Care and Pain medicine and Research and Publications Committee of the School of Medicine, College of Health Sciences, Addis Ababa University.

4.11 Dissemination of findings

The result of the study will be presented for research defense and a formal report will be submitted to the department of Anesthesiolgy, critical care and Pain medicine. The research output will also be published on scientific journals.

5. Results

5.1. Socio demographic characteristics of the respondents

From total number of patients 51(51%) were male and 49 (49%) were female; majorities of them were between age 36-55 and mean age was forty four.

Table I: Sociodemographic characteristics of the respondents (n=100)

Variables	Frequency	Percent
Sex		
Male	51	51.0
Female	49	49.0
Age		
18-35	23	23.0
36-55	66	66.0
>55	11	11.0

5.2. Procedure related questions of the respondents

According to procedure related questions the professionals used a conventional manual Pilot balloon palpation technique in fifty patients (50%) and cuff pressure manometer to monitor endotracheal tube cuff pressure after inflation in another fifty patients (50%); Among the group where cuff pressure value measurement was implemented mean cuff pressure value before correction was seventy five centimeters of water(75cmH20). In terms of patients ASA status most of them (69 (69%)) were ASA 2 followed by ASA 1 who were twenty five in number (25%). General surgical procedures were the majority (62%) followed by gynecologic and neurosurgical procedures which accounted for 10% each. Experience of anesthesia providers was 2 years or less in sixty four percent of cases and more than 2years in 36%. More than half of patients (72(72%)) had a laryngoscopic grade 1 view. ETT size 6 was used in sixty seven patients (67%) while the remaining patients were intubated with ETT sizes ranging from 6.5 to 8. oral airway was inserted in ninety two patients (92%) but nasogastric tube was not inserted for majority (82(82%)) of the patients. Seven participants were administered steroid for premedication.

All of the patients took intraoperative analgesic medications; among the analgesic medications eighty six (86%) percent took opioids only while the rest fourteen (14%) participants took varying combinations of IV magnesium sulphate, IV ketamin or IV lidocaine in addition to opioids.

Thirty one patients (31%) had developed intraoperative hypotension. Majority (81(81%)) of the respondents duration of surgery and intubation was above 2 hours. Anesthesiology residents comprised a large majority of the anesthesia providers (89%) while non-physician anesthesia providers made 11%. Sixty four percent of the providers had experience of 2 years or less and 36% had a work experience of more than 2 years.

Table II: Procedure related questions of the respondents (n=100)

Variables	Frequency	Percent
What technique was used to monitor endotracheal tube cuff pressure after inflation?		
Manual pilot balloon palpation	50	50.0
cuff pressure manometer	50	50.0
Patient ASA status		
ASA1	25	25.0
ASA2	69	69.0
ASA3	6	6.0
ETT size		
6	67	67
6.5	10	10
7	10	10
7.5	9	9
8	4	4
Was Oral airway inserted?		
Yes	92	92.0
No	8	8.0
Was Nasogastric tube inserted?		
Yes	18	18.0
No	82	82.0

Variables	Frequency	Percent
Was the patient premedicated?		
Yes	48	48.0
No	52	52.0
Premedication With steroid		
Yes	7	7.0
No	7	93.0
Was intraop analgesic medication given?		
Yes	100	100.0
If your answer is yes" to the above question what class of medication was used for analgesia?		
Opioid	86	86.0
Multimodal Analgesic	14	14.0
Was there intraoperative hypotension?		
Yes	31	31.0
No	69	69.0
Duration of surgery		
30-60min	3	3.0
1-2hr	16	16.0
>2hr	81	81.0
Duration of Intubation		
30-60min	4	4.0
1-2hr	15	15.0
>2hr	81	81.0

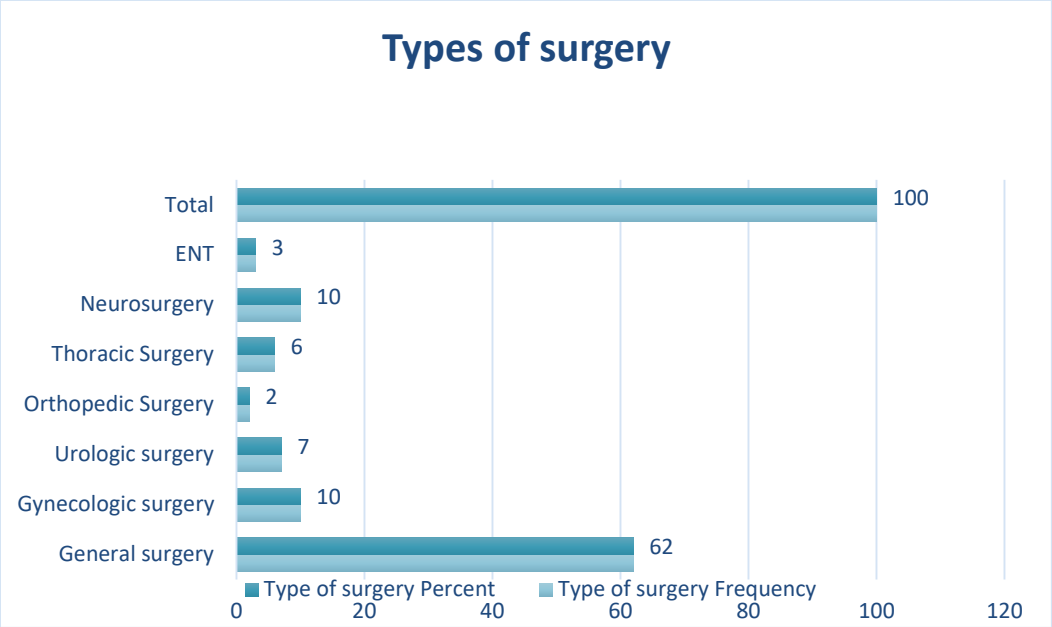

Figure I: Types of surgery

Table III- Patient characterstics in the two groups compared n=100

Variable		Technique used	
		Manual pilot balloon palpation group n=50	Controlled Cuff pressure manometry group n=50
Sex	Male	29	22
	Female	21	28
Age	18-35	9	14
	36-55	37	29
	>55	4	7
ASA class	1	13	12
	2	34	35
	3	3	3
Laryngoscopic grade	1 and 2	48	42
	3 and 4	2	8
Number of intubation attempt	Once	48	39
	Multiple times	2	11

ETT size used	6	33	34
	6.5	5	5
	7	6	4
	7.5	5	4
	8	1	3
Oral airway use	Yes	43	49
	No	7	1
NG tube inserted	Yes	6	12
	No	44	38

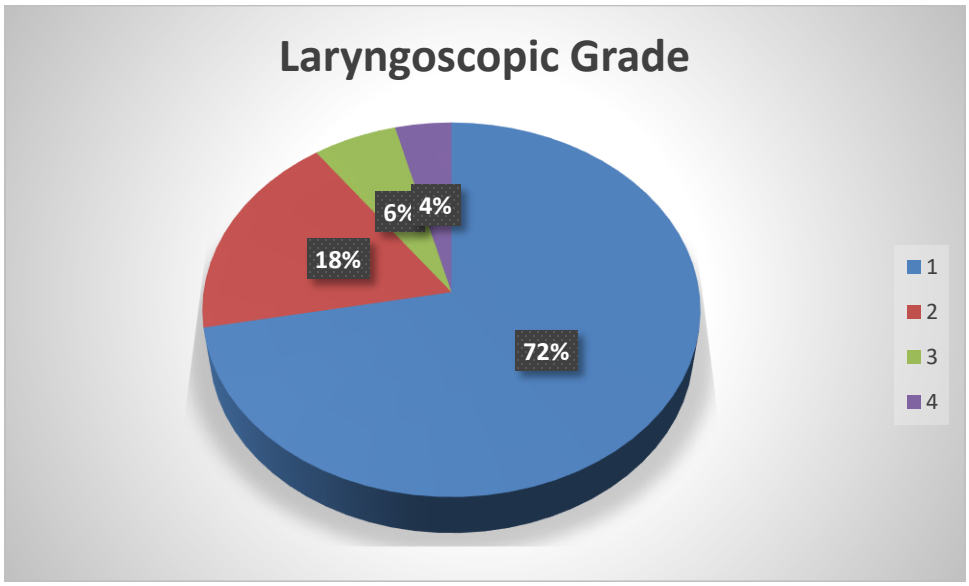

Figure II: Laryngoscopic Grade of the patients

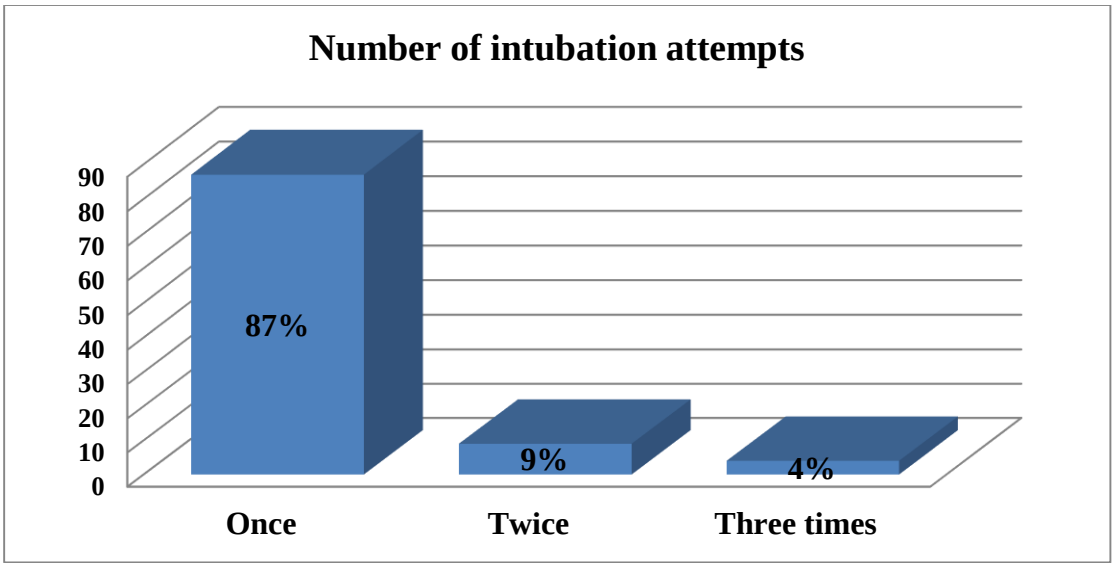

Figure III: Number of intubation attempts

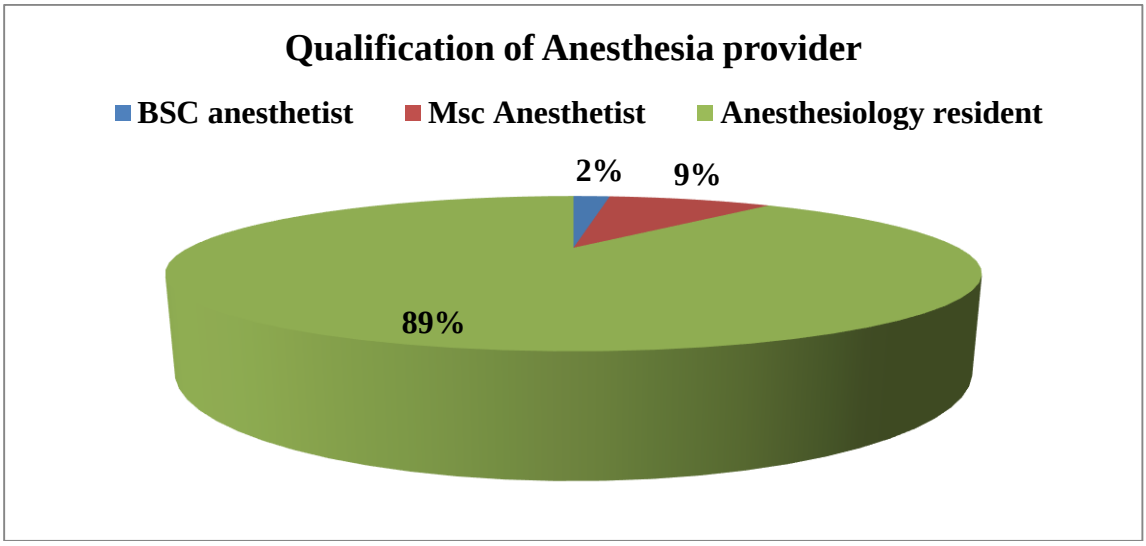

Figure IV: Qualification of Anesthesia provider

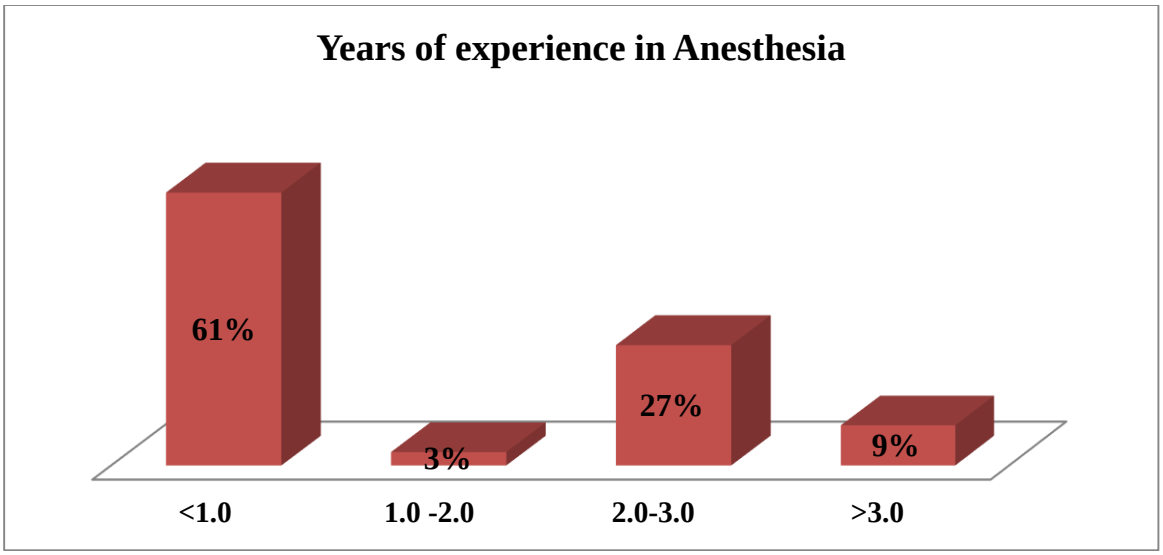

Figure V: Year of experience of Anesthesia providers

5.3. POST outcome of respondents

From all patients thirty nine (39%) of them had postoperative sore throat at 24 hours. Among those who had sore throat majorities 30(30%) of them had mild symptoms, eight patients (8%) reported moderate symptoms and one patient (1%) reported severe POST on a numerical rating scale. From the manual pilot balloon palpation group twenty two patients (44% of participants in the group) developed Postoperative sore throat while in the monitored endotracheal tube cuff pressure group seventeen patients (34% of participants in the group) had it.

Among Participants who complained Postoperative sore throat, twenty four were male (61.5%). Thirty two (82%) of them were ASA class II patients while the rest were ASA class I. 27(69%) of them were in between the age of thirty six to fifty five years. Among patients who had a nasogastric tube inserted tube inserted nine of them developed POST (50%) and and from those for whom oral airway was inserted 38 (41.3) had it. Out of the 7 patients premedicated with steroid only 1 had developed POST (14.3%). Regarding laryngoscopic grade, 35 out of 90 patients who had a laryngoscopic grade of 1 and 2 (38.9%) developed POST while 4 out of 10 patients (40%) who had a laryngoscopic grade of 3 and 4 developed POST at 24hours. 33 of the patients (37.9%) who were intubated with first attempt had developed POST and from those with multiple attempts at intubation 6 out of 13(46.2%) patients had it.

From surgeries of durations lasting more than two hours in our study 35 participants (39%) developed POST while for surgical duration of two hours or less the incidence of POST was less (4 out of 19 patients (21.1)). These figures were also similar for the duration of intubation. Of the total of 31 patients who had hypotension during their surgery in this study13 reported POST (41.9%).

Table IV: Post outcome of the respondents

Variables	Frequency	Percent
Does the patient have Postoperative sore throat at 24hr postoperatively?		
Yes	39	39.0
No	61	61.0
If the answer to the above question is Yes, please mention his/her symptom severity		
Mild	30	30.0
Moderate	8	8.0
Severe	1	1.0

Table – V Distribution of Postoperative Sore throat among variables after elective surgery with endotracheal intubation in Tikur Anbessa specialized Hospital, 2020

Variable		POST		Total
		Yes (n (%))	No (n%))	n =100 (100 %)
Sex	Male	24 (47)	27 (53)	51 (51)
	Female	15 (30.6)	34 (69.4)	49 (49)
Age	18-35	5 (21.7)	18 (78.3)	23 (23)
	36-55	27 (40.9)	39 (59.1)	66 (66)
	>55	7 (63.6)	4 (36.4)	11 (11)
ASA class	1	7 (28)	18 (72)	25 (25)
	2 and 3	32 (41.5)	43 (58.5)	75 (75)
Technique used	Manual pilot balloon palpation	22 (44)	28 (56)	50 (50)
	Controlled Cuff pressure	17(34)	33 (66)	50 (50)
Laryngoscopic grade	1 and 2	35 (38.9)	55 (61.1)	90 (90)
	3 and 4	4 (40)	6 (60)	10 (10)
Number of intubation attempt	Once	33 (37.9)	54 (62.1)	87 (87)
	Multiple times	6 (46.2)	7 (53.8)	13 (13)
ETT size	No.6	26 (38.8)	41(61.2)	67 (67)
	Above No.6	13 (39.3)	20 (60.7)	33 (33)
Oral airway	Yes	38 (41.3)	54 (58.7)	92 (92)
	No	1 (12.5)	7 (87.5)	8 (8)
NG tube	Yes	9 (50)	9 (50)	18 (18)
	No	30 (36.5)	52 (63.5)	82 (82)
Premedication with steroid	Yes	1 (14.3)	6 (85.7)	7 (7)
	No	38 (40.3)	55 (59.7)	93 (93)
Analgesic used	Opioids only	28 (32.5)	58 (67.5)	86 (86)
	Multimodal	3 (21.4)	11 (78.6)	14 (14)
Intraoperative Hypotension	Yes	13 (41.9)	18 (58.1)	31 (31)
	No	26 (37.7)	43 (62.3)	69 (69)
Duration of surgery	2 hrs and below	4 (39)	15 (78.9)	19 (19)
	More than 2hrs	35 (39)	46 (61)	81 (81)
Duration of Intubation	2hrs and below	4 (21.1)	15 (78.9)	19 (19)
	Above 2hrs	35 (39)	46 (61)	81 (81)

Variable		POST		Total
		Yes (n (%))	No (n%))	n =100 (100 %)
Qualification of anesthesia provider	Nonphysician	6 (54.5)	5 (45.5)	11 (11)
	Physician	33 (37.1)	56 (62.9)	89 (89)
Year of experience of anesthesia provider	2 years or less	21 (62.4)	43 (37.8)	64 (64)
	More than 2years	18 (50)	18 (50)	36 (36)

5.4. Results from Bivariate and regression analysis

The bivariate association showed significant association between POST and the following variables which include patient's age, Sex, patient ASA class, Insertion of oral airway, premedication with steroid, Analgesic use, duration of surgery, duration of intubation and years of experience of the anesthesia provider.

However, the association was not detected to be significant when those variables entered into final model multiple regression analysis except for age which showed that those in between the age of 18-35 were 96.2 % less likely to develop POST AOR .141 95% CI (.022, .901).

Table VI - Results from binary and multiple logistic regression analysis

Variable		Sore throat		COR(95% CI)	P-value	AOR(95% CI)	P-value
		Yes	No				
Sex	Male	24	27	2.015 (0.888 4.572)	**0.094**	2.004 (0.725, 5.528)	0.179
	Female	15	34	1		1	
Age	18-35	5	18	0.159 (0.033,0.789)	**0.022**	.141 (.022, .901)	**.038**
	36-55	27	39	0.396 (0.105, 1.485)	0.169	.313(.068, 1.437)	.135
	>55	7	4	1		1	
ASA class	1	7	18	0.523(0.195, 1.400)	**0.197**	1.036 (.305, 3.520)	.955
	2 and 3	32	45	1		1	

Variable		Sore throat		COR(95% CI)	P-value	AOR(95% CI)	P-value
		Yes	No				
Technique used	Manual pilot balloon palpation	22	28	1.525 (0.679,3.424)	0.306		
	Controlled Cuff pressure manometry	17	33	1			
Laryngoscopic grade	1 and 2	35	55	1.048(0.276 , 3.978)	0.946		
	3 and 4	4	6				
Number of intubation attempt	Once	33	54	1.403 (0.434, 4.534)	0.572		
	Multiple times	6	7	1		.	
ETT size	No.6	26	41	0.976(0.415,2.291)	0.955		
	Above No.6	13	20	1			
Oral airway	Yes	38	54	4.926 (0.582,41.7)	**0.143**	5.040 (0.513,49.478)	.165
	No	1	7	1		1	
NG tube	Yes	9	9	1.733 (0.620, 4.843)	0.294		
	No	30	52	1			
Premedication with steroid	Yes	1	6	0.241 (0.028,2.085)	**0.196**	3.869 (0.364, 41.094)	.262
	No	38	55	1		1	
Analgesic used	Opioids only	28	58	7.595 (1.961, 29.414)	**0.003**	4.971 (.946, 26.126)	.058
	Multimodal	3	11	1		1	
Intraoperative Hypotension	Yes	13	18	0.837 (0.353, 1.986)	0.687		
	No	26	43	1			
Duration of surgery	2 hrs and below	4	15	0.350 (0.107, 1.149)	**0.083**	0.313 (0.033, 2.948)	.310
	Above 2hrs	35	46	1		1	

Duration of Intubation	2hrs and below	4	15	2.853 (0.870, 9.354)	**0.083**	.681 (.066, .988)	.746
	Above 2hrs	35	46	1		1	
Qualification of anesthesia provider	Nonphysician	6	5	0.491 (0.139, 1.735)	0.270		
	Physician	33	56	1			
Year of experience of anesthesia provider	2 years or less	21	43	2.048 (0.887, 4.725)	**0.093**	1.515 (.478, 4.800)	0.480
	More than 2years	18	18	1		1	

6. Discussion

Postoperative sore throat following endotracheal intubation is a fairly common problem.

In a hospital based cross sectional study done by Chewaka and Temesgen [20] at Jimma university teaching hospital involving 245 patients with a response rate of 228 patients scheduled for elective gynecologic and general surgery, 129 (56.6%) participant had suffered postoperative sore throat (POST) and 68 (29.8%) of them developed hoarseness of voice. This figure showed higher incidence as compared to our study which showed 39% of participants developing postoperative sore throat. Age had significant association in this study with participants in between the age of 18-35 were 85.9 % less likely to develop POST P-value 0.038 AOR .141 95% CI (.022, .901). Similar to our study, the sore throat complaint was mild in majority of their patients 25.9% relatively comparable to our 30% of patients); severe and moderate POST were recorded in 27(11.8%), and 43(18.9%) of the study population, respectively; in comparison to our 8% and 1% moderate and severe POST complaints respectively.

Another hospital based cross sectional study was conducted in 2014 in Gondar University hospital by Gemechu et al 23. A total of 240 patients were included in this study. Postoperative sore throat was complained by 143 patients (59.6%) compared to 39 patients (39%) in our study. The highest proportion of sore throat occurred in patients who underwent general surgery (58.6% (92/157)); in addition, Female sex had significant association with postoperative sore throat (AOR = 3.3, 95% CI: 1.07, 10.375; p = 0.038). In contrary, our study observed higher incidence of POST in male participants (47.1% vs 30.6%); regardless of this value, sex didn't have a statistically significant association with POST. This data was also supported by a research done in Nigeria that enrolled 200 patients, showing the development Postoperative sorethroat had no sex predilection (males and females in development of POST, P = 1.0000, Odds ratio = 1.035, 95% CI; 0.5064 – 2.115)21.

Multiple intubation attempt and use of nasogastric tube were also associated factors in the study by Gemechu et al while there was no association between both factors and POST in our study. This could be due to the smaller sample size in our study.

Jaensson et al [6] conducted a randomized control trial with the primary aim of assessing whether the size of the endotracheal tube (ETT) affects the risk of sore throat in women following anaesthesia.

One hundred healthy adult women undergoing elective surgery were randomly allocated to oral intubation with either ETT size 6.0 or 7.0. Their overall incidence of POST was 40% which was comparable to our result. They found that women intubated with ETT 6.0 had less sore throat and less discomfort in the PACU than women intubated with ETT 7.0. In our study, however, most participants were intubated using ETT size 6" (67%) while the rest 33% of the patients were intubated with ETT size 6.5 and above (10 ,10, 9, 4 of patients were intubated with 6.5, 7,7.5 and 8 ETT size respectively) and there was no association between ETT size and POST.

In a double blind randomized control trial conducted by ganason et al [19] involving 292 patients, it was found that only 82 (56.3%) patients had a cuff pressure within the recommended range of between 20 cmH2O and 30 cmH2O after the initial inflation. Sixty-three patients (43.2%) had a pressure reading of above 30 cmH2O before adjustments were made to 25 cmH2O. In our study only 2 patients (4%) had a cuff pressure within the recommended range and 48 patients (96%) in the measured group had a cuff pressure above recommended values before correction. Mean ETT cuff pressure before adjustment in this study was 75cmH2O. Their study showed that the overall incidence of POST was 39.0% versus 75.3% (P = 0.000) in the group where ETT cuff pressure was measured and adjusted to 25cmH2O versus in which the it was not measured or adjusted, respectively. In our study which is a comparative cross sectional one, Incidence of POST was 34% of patients in whom endotracheal tube cuff pressure was measured and adjusted while 44% of patients in whom manual pilot balloon palpation technique was implemented. Despite this there was no statistically significant association between both techniques and the outcome. This could have been to the primarily smaller sized endotracheal tube (No.6) used in a large majority of our patients 67(67%) during the study period.

7. Strength and Limitations of the study

The fact that there aren't much comparative studies done on this topic previously in our country can be accounted as a strength of this study. Some of the limitations of this study include small sample size, monitoring of the incidence of sore throat at only one time and being a single center study. Also equipment availability could have been a source of bias as only size 6 ETT was used for majority of our patients. Fibreoptic bronchoscopic evaluation of patients would have shown the true extent of tissue damage but routine evaluation of all participants was not applicable.

8. Conclusion and Recommendation

8.1. Conclusion

The objective of the study was to compare the incidence of Postoperative sore throat when manual pilot balloon palpation technique was used versus when endotracheal tube cuff pressure was monitored and adjusted. It was also our objective to determine associated factors. Based on this study, Patients in whom endotracheal tube cuff pressure was measured and adjusted had similar risk of developing postoperative sore throat as compared to those patients in which manual pilot balloon palpation technique was used. The analysis based on binary and multiple logistic regression analysis showed that patient age was found to have significant association with development of POST (p-value 0.038, AOR .141 95% CI (.022, .901)). The other characteristics were not found to have a statistically significant association.

8.2. Recommendation

This study has demonstrated the inaccurate estimation of Endotracheal tube cuff pressure using estimation technique and simple yet relatively cheap and effective methods for continuous monitoring of cuff pressure such as using arterial line transducers can be applied. In this study there was no statistically significant difference regarding Postoperative sore throat with the techniques applied. This may be attributed to our smaller sample size and calls for a research with a bigger sample size on the topic. Also a randomized control trial can be conducted in the future.

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ANNEX

Consent form and Questionnaire

MRN.

Hello, I am here on behalf of Dr. Sofoniyas Getaneh, a final year Anesthesiology, critical care and pain medicine resident in Tikur Anbessa Specialized Hospital. He's conducting a research on prevalence of Postoperative and severity of postoperative Sorethroat when endotracheal tube cuff pressure is monitored and corrected versus when conventional pilot balloon palpation technique is used following elective surgery under general anesthesia with endotracheal tube in Tikur Anbessa Hospital, Addis Ababa Ethiopia.

You are selected for this study as you are undergoing elective surgery with General anesthesia on a selected Operation theatre. Your participation in this study is only based on your full willingness and have the right to choose not to take part. If also willing, you have the right to withdraw at any point in time and no mistreatment will be subjected. There is no personal benefit for the participant by participating in this study but results will aid researchers and other professionals to give attention to Postoperative Sorethroat.

The information you provide will be kept confidential by using only coded numbers and only the researchers will have access to the noncoded data. The data collected will only be used for the purpose of this research. Your willingness to participate is important for the success of this study.

Based on your understanding of the above information, are you willing to participate?

A/ Yes B/ No

Questionnaire Code_____

Name of data collector _____signature___

Date of data collection. _____

For any question please contact Dr, Sofoniyas Getaneh on 0910-66 16 62

Part I Background Data			
No.	Question	Choice or replies	Remarks
1	Gender	A, Female B, Male	
2	Age (years) -		
3	weight (in Kilograms)		
4	Height (in centimeters)		
Procedure related Questions			
5	What technique was used to monitor endotracheal tube cuff pressure after inflation?	A, Manual Pilot balloon palpation B, Cuff pressure manometer	If Answer is B, Please mention cuff pressure measurement value before adjustment
6	Patient ASA status	A, ASA I B, ASA II C, ASA III	
7	Type of surgery	A, GI surgery B, Gynecologic surgery C, Urologic Surgery D, Orthopedic surgery E, Thoracic surgery F, neurosurgery	If others, please specify----------
8	Laryngoscopic Grade	A, 1 B, 2 C,3 D, 4	
9	Number of intubation attempts	A, Once B, Twice c, three times D, > Three times	
10	ETT size (internal diameter; ID in mm)	A, 6 B,6.5 C, 7 D,7.5 E,8	
11	Was oral airway inserted?	A, Yes B, No	
12	Was an NG tube inserted?	A, Yes B, No	
13	Was the patient premedicated ?	A, Yes B, No	If answer is A, please mention type of medication
14	Was Intraoperative analgesic medication given	A, Yes B, No	

15	If your answer is yes to the above question, what class of medication was used for analgesia?	A, opioids B, NSAID C, regional analgesia techniques D, IV lidocaine E, IV Magnesium sulphate F, IV ketamine	More than one answer is possible
16	Was there intraop hypotension (Bp< 90/60) ?	A, Yes B, No	If your answer is yes, please mention the duration here .....
17	Duration of surgery	A, 30 - 60 min B, 1- 2 h C, >2hr	
18	Duration of intubation	A, 30 min- 60 min B, 1- 2 h C, >2hr	
19	Qualification of Anesthesia Provider	A, BSC. Anesthetist B, MSc. Anesthetist C, Anesthesiology Resident D, Consultant Anesthesiologist	
20	Years of experience in Anesthesia	A,<1 B, 1-2 C, 2-3 D >3	
POST outcome			
21	Does the patient have Sore throat at 24 hour postoperatively?	A, Yes B, No	
22	If the answer to question is yes, please mention his/her symptom severity?	A, Mild B, moderate C, Severe	