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Endotracheal Tube Cuff Pressure Measurement Techniques: Safety and Reliability: A Randomized Comparative Study

Sylvanus Kampo, PhD[1], Thomas Winsum Anabah, MD[2], Fidelis Bayor, Mphil[3], Alexis DB Buunaaim, MD[4], Maite Esquijarosa Hechavarria, MD[5], Salia Osman, BSc[6], Eugene Dogkotenge Kuugbee, PhD[7] and Juventus B Ziem, PhD, MD[7]*

[1]*Department of Anaesthesia and Intensive Care, School of Medicine and Dentistry, C. K. Tedam University of Technology and Applied Sciences, Navrongo, Ghana*

[2]*Anaesthesia Unit, Habana Medical Services, Tamale, Ghana*

[3]*Department of Physiology, School of Medicine and Dentistry, University of Ghana, Accra, Ghana*

[4]*Department of Surgery, School of Medicine and Health Science, University for Development Studies, Tamale, Ghana*

[5]*Department of Anaesthesia and Critical Care, School of Medicine, University of Health and Allied Sciences, Ho, Ghana*

[6]*Department of Anaesthesia, Tamale Teaching Hospital, Tamale Ghana*

[7]*Department of Clinical Microbiology, School of Medicine and Dentistry, C. K. Tedam University of Technology and Applied Sciences, Navrongo, Ghana*

Abstract

Objective: The purpose of this study was to examine cuff inflation techniques and corresponding pressure estimations, as well as associated complications, in patients undergoing general anaesthesia with intubation for cesarean delivery at the Tamale Teaching Hospital's obstetric unit.

Methods: Finger palpation of the pilot balloon, predetermined volume of air, and a pressure gauge were used to measure endotracheal tube (ETT) cuff pressure after intubation. Associated side effects were determined after 24 hours of endotracheal tube extubation.

Results: Data for 384 patients were included in the analysis. Cuff pressure measured among patients varied from < 20-30 cmH_2O for the standard manometer group, 20 to 50 cmH_2O for the predetermined volume of air group and < 20 to > 50 cmH_2O for the finger palpation group. Side effects were recorded in 2.4% of patients from the standard manometer group, 53.2% from the predetermined volume of air group and 83.6% from the finger palpation group.

Conclusion: The finger palpation of a pilot balloon technique for cuff pressure estimation was unreliable and prone to cuff over inflation and associated with post-extubation airway complaints. Cuff pressure estimation using the standard manometer was associated with satisfactory patient outcomes.

Keywords

Endotracheal tube, Cuff pressure, Standard manometer, Predetermined volume, Manual palpation, Complication

Abbreviations

ASA-PS: American Society of Anaesthesiologists Physical Status; ECG: Electrocardiography; SpO_2: Partial Pressure of Oxygen Saturation; ETT: Endotracheal Tube; ID: Internal Diameter

Introduction

Endotracheal intubation is a critical clinical skill and lifesaving procedure [1,2] used by anaesthesia and intensive care professionals to secure an airway for patients who require mechanical ventilation [3-6]. The cuff inflation creates a seal between the tracheal tube and the tracheal wall, allowing anaesthetic gases to be delivered directly into the trachea for ventilation and oxygenation while also assuring airway conservation and safety [7-9]. Endotracheal tube cuff inflation and pressure assessment are commonly regarded as essential components of anaesthetic management in surgical patients [10]. It has been found that large volume, low pressure endotracheal cuffs are less damaging to the tracheal mucosa than high pressure, low volume cuffs. Low pressure

cuffs, on the other hand, can easily be overinflated to produce pressures that surpass capillary perfusion pressure [11].

The appropriate cuff pressure for preventing aspiration must be maintained within 20-40 cmH_2O using the hand-held analogue manometer or spirometer technique [12-16]. The cuff should seal the airway without putting so much pressure on the trachea that circulation is impeded or the trachea is dilated [17,18]. The minimal occlusive volume approach and the palpation method can also be used to determine the intra-cuff pressure, however these methods are usually more arbitrary and prone to complications. The hand-held analogue manometer or spirometer is regarded safe but not widely available in many countries, particularly in resource-poor settings where its use is limited by the cost of purchase and maintenance [19]. As a result, the majority of anaesthesia providers in these areas rely on manual palpation techniques to determine cuff pressure. Such approaches are prone to cuff hyperinflation [20,21] and may impose a mechanical strain as well as tissue-related complications [22-24]. If the intra-cuff pressure is also too low, the patient is at risk of aspiration.

While there have been various research on endotracheal intubation protocols [25-27], the most of these have been limited to the developed world, with little data from underdeveloped countries. Furthermore, healthcare reforms in low-income countries have been extremely gradual, and nurse anaesthetists are those who frequently provide anesthesia services. Although technically competent, nurse anaesthetists may have a poor awareness of the relationship between intra-cuff and lateral tracheal wall pressure and its implications for tracheal perfusion [28]. These knowledge gaps, which the current study intends to fill, are key drivers of unfavorable patient outcomes following extubation such as sore throat, upper airway oedema, tracheal stenosis, and infections, etc.

Because cuff pressure assessed by palpation may not be the best method for detecting high cuff pressure [29,30], the purpose of this study was to compare intra-cuff pressure inflation procedures and related issues in patients undergoing general anaesthesia with intubation for cesarean delivery. The outcome of this study will contribute to the literature on endotracheal tube cuff pressure procedures at Tamale Teaching Hospital, as well as affecting anaesthesia clinical policy at the obstetric unit for required monitoring of endotracheal tube cuff pressure and its estimations.

Materials and Methods

Ethical statement

This prospective randomized comparative study was carried out at the obstetric unit of the Tamale Teaching Hospital from June 2021 to December 2021. The ethical committee of the University of Health and Allied Sciences approved the study protocol (ID No: UHAS REC A.9 [114]20-21). The clinical trial registration was obtained from ISRCTN Registry, BMC (No. ISRCTN66168037). All methods were performed under the relevant guidelines and regulations. The study protocol adhered to the CONSORT guidelines. Written informed consent was obtained from individual patients after providing them with adequate explanations regarding the aims of the study.

Subjects

This study recruited three hundred and eighty-nine (389) pregnant women who were to undergo elective cesarean section in which spinal anaesthesia was contraindicated or failed. The inclusion criteria were as follows: general anaesthesia and endotracheal intubation, age ranges of 18 to 40 years, American Society of Anaesthesiologists Physical Status (ASA-PS) score 1-4. The exclusion criteria were as follows; patients with a history of difficult intubation or multiple attempts (more than 3 attempts) during intubation, intubation performed by non-anaesthesia staff, parturient with known anatomical laryngotracheal abnormalities, and those expected to remain intubated beyond the operation room period.

Sample size determination

Due to the unknow population size, the sample size for this study was determined by the equation [31].

*Necessary Sample Size = (Z-score ^{2}*StdDev*(1-StdDev)/ (margin of error)$_2$*

95% confidence interval (Z-score = 1.96),

Standard Diviation (*StdDev* = 0.5*)* and margine of error = ± 6%.

Therefore, our sample size estimated was 384 patients.

Randomization

Each recruited parturient was randomly assigned to one of three groups using a computer-generated random number table. The group allocation was concealed in a sealed opaque envelope which was opened just before the intubation.

The standard manometer group (n= 128) represented those whose endotracheal tube cuff pressures were determined by the use of a pressure gauge.

The predetermined volume of air group (n = 128) represented those whose endotracheal tube cuff (ETT cuff) pressures were estimated by a predetermined volume of air (10 ml).

The finger palpation group (n = 128) represented those whose endotracheal tube cuff pressures were determined by finger palpation of the pilot balloon.

***Corresponding author:** Sylvanus Kampo, Department of Anaesthesia and Intensive Care, School of Medicine and Dentistry, C. K. Tedam University of Technology and Applied Sciences, Navrongo, Ghana

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Anaesthesia induction and cuff pressure measurement techniques

All parturients were prospectively assessed and classified according to the American Society of Anaesthesiologists physical status classification. Basic intraoperative monitoring (ECG, SpO_2, Temperature, and non-invasive blood pressure) were applied, and the baseline vital signs were checked and recorded. All recruited patients had no history of difficult intubation during anaesthesia and surgery. Patient was advised not to eat any solid food for at least 6-8 hours before surgery. Independent anaesthesiologist was assigned to perform intubation and monitor patient till discharge from hospital.

In the supine position, the patient was anaesthetized with propofol 1.5-2 mg/kg, succinylcholine 1.0 mg/kg, and then intubated with the appropriate endotracheal tube size (ID = 6.5 or 7 mm; cuff type - high-volume low-pressure; Lot No. - 20170905). Successful insertion of the endotracheal tube was confirmed by either direct visualization of the endotracheal tube between the vocal cords or using capnography or the presence of equal bilateral breath sound. The vital signs (pulse rate, blood pressure, oxygen saturation, and respiratory rate) were monitored and recorded every 5 minutes for the first 30 minutes and then for every 15 minutes. Nitrous oxide was not used to maintain anaesthesia due to its possible effects on cuff pressure. Independent anaesthesiologist who was blinded to the study was asked to inflate the endotracheal tube cuff immediately after intubation using either of the following techniques: Standard manometer (VBM, Sulz, Germany), Predetermined volume of air, or Finger palpation of pilot balloon. Prior to extubation, the standard manometer was used to measure the intra-cuff pressure generated during spontaneous ventilation at the end expiratory time. The technique used and the cuff pressure measured in each group were recorded; Cuff pressure associated complaints were determined after 24 hours of extubation by an interview, and the overall perioperative satisfaction was evaluated on the day of discharge by an interview as; 4 = excellent, 3 = good, 2 = satisfactory, 1 = poor.

Primary and secondary outcomes measured

The endotracheal tube cuff was inflated and the pressure determined at the end expiratory time using a standard manometer, predetermined volume of air, or manual palpation of endotracheal tube pilot balloon immediately after intubation or prior to extubation. The technique used and the cuff pressure estimated in each group was recorded; Cuff pressure associated complications (cough, sore throat, hoarseness, and blood-streaked expectoration) were determined during an interview after 24 hours of extubation, and overall perioperative satisfaction was also evaluated on the day of discharge during an interview as; 4 = excellent, 3 = good, 2 = satisfactory, 1 = poor.

Statistical analysis

The Statistical Package for Social Sciences Software (SPSS) version 20.01 (IBM Corporation, Armonk, NY, USA) was used for data entry and analysis. Mean and SD were computed for quantitative variables such as age, weight,

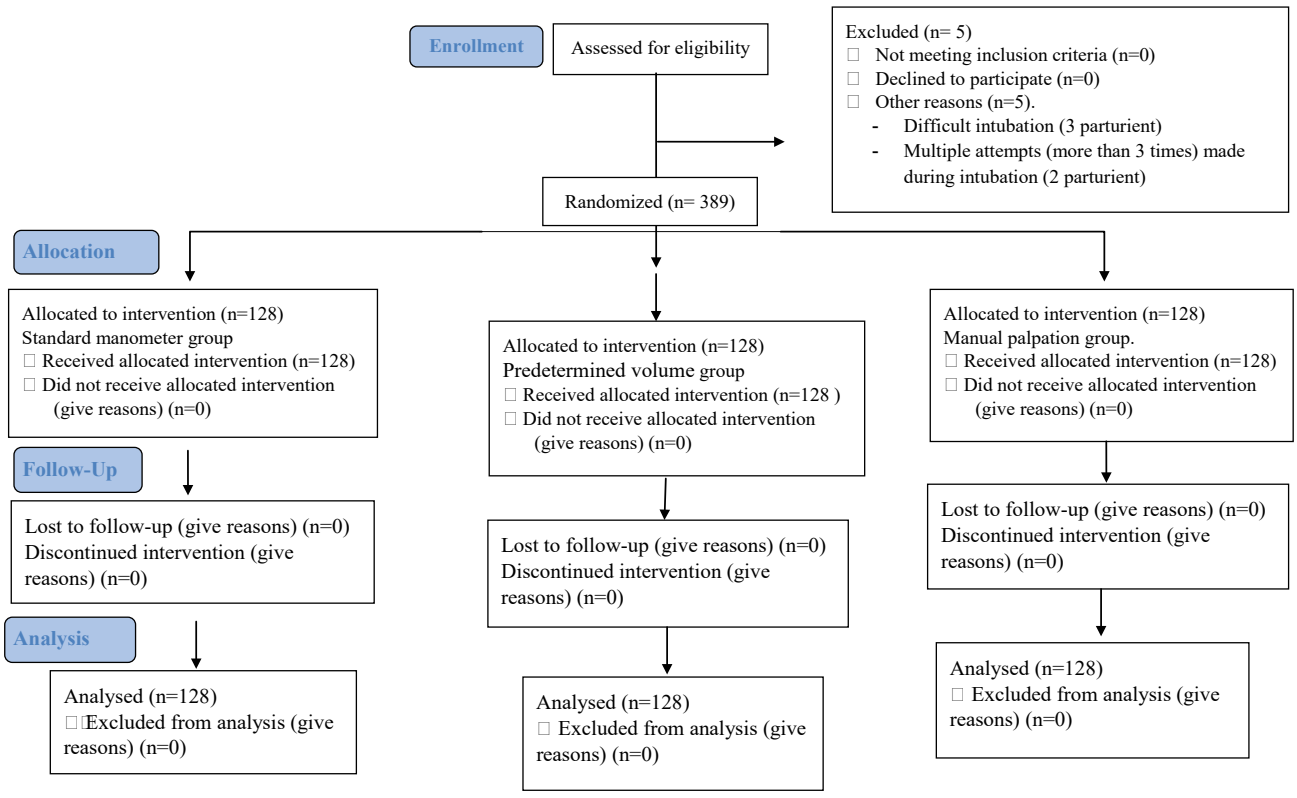

Figure 1: Consort recommended description for patient recruitment.

gestational age, BMI, cuff pressure, and the duration of intubation. Independent-samples *t*-test was applied for quantitative variables; age, weight, cuff pressure, BMI, duration of intubation, complaints and patient satisfaction of the anaesthesia service. Chi-square was applied for statistical comparisons between three or more groups. The data were presented in frequencies, percentages, means or SD wherever appropriate. $P < 0.05$ was considered significant.

Results

A total of 389 patients were recruited for the study, of which 384 met the inclusion criteria. The 384 were randomized into three groups of equal numbers of 128 each (Figure 1). The results showed no significant difference among patients from the standard manometer, predetermined volume of air, and the finger palpation of pilot balloon groups regarding age, weight, BMI, gestational age and duration of intubation (P < 0.96; P < 0.98; P < 0.67; P < 0.48; P < 0.96 respectively) (Table 1).

For the standard manometer group, the cuff pressure measured varied from < 20 to 30 cmH_2O with 99.2% (n = 127) of the patients recording cuff pressure of 20-30 cmH_2O. For the Predetermined volume group, the cuff pressure measured varied from 20 to 50 cmH_2O with 53.9% (n = 69) of the patients recording cuff pressure of 20-30 cmH_2O, 43.8% (n = 56) recording cuff pressure of 31-40 cmH_2O and 2.3% (n = 3) recording cuff pressure of 41-50 cmH_2O. For the finger palpation of pilot balloon group, the cuff pressure measured varied from < 20 to > 50 cmH_2O with 5.5% (n = 7) of the patients recording cuff pressure of < 20 cmH_2O, 26.6% (n = 34) recording 20-30 cmH_2O, 39.8% (n = 51) recording 31-40 cmH_2O, 15.6% (n = 20) recording 41-50 cmH_2O and 12.5% (n = 16) recording cuff pressure of > 50 cmH_2O. The data showed significant difference between the groups regarding the cuff pressures measured (P < 0.01; P < 0.01; P < 0.01; P < 0.01; P < 0.01 respectively) (Table 2).

Side effects were recorded in 2.4% of patients from the standard manometer group, among these, 1.6% (n = 2) complained of cough, and 0.8% (n = 1) complained of sore throat. For the predetermined volume of air group, side effects were recorded in 53.2% of the patients, among these, 39.1% (n = 50) complained of cough, 13.3% (n = 17) complained of sore throat, and 0.8% (n = 1) complained of hoarseness. For the manual palpation group, side effects were recorded in 83.6% of the patients, among these, 53.1% (n = 68) complained of cough, 17.2% (n = 22) complained of sore throat, 11.7% (n = 15) complained of hoarseness and 1.6% (n = 2) complained of blood-streaked expectoration. The results showed significant difference between the groups regarding the incidence of cough, sore throat, hoarseness, and blood-streaked expectoration, (P < 0.01; P < 0.01; P < 0.01; P < 0.01; P < 0.01 respectively) (Table 3).

We again assessed the endotracheal tube cuff pressure measured and the occurrence of associated side effects. For cuff pressure within 20-30 cmH_2O, we observed 2 of the patients who complained of cough. For those who recorded cuff pressure within 31-40 cmH_2O, we observed 79 and 13 of the patients who complained of cough and

Table 1: Demographic characteristics of respondents.

Variables	Standard manometer (n = 128) mean ± SD	Predetermined volume (n = 128) mean ± SD	Finger palpation (n = 128) mean ± SD	P Value
Age (years)	28.73 ± 7.57	28.59 ± 7.75	28.52 ± 7.71	0.96
Weight (kg)	68.21 ± 6.33	68.24 ± 6.32	67.37 ± 6.38	0.98
BMI	30.01 ± 3.58	30.50 ± 3.17	28.81 ± 3.38	0.67
Gestational age (weeks)	39.00 ± 1.00	38.95 ± 1.01	38.85 ± 0.99	0.48
Duration of intubation (minutes)	61.01 ± 8.87	60.81 ± 9.12	60.70 ± 8.94	0.96

Data were statistically significant at P < 0.05 compared with the standard manometer

BMI: Basal Metabolic index; n: number of respondents included in the analysis; SD: Standard Deviation

Table 2: Cuff pressure measurement. ETT cuff pressures measured prior to extubation.

Cuff pressure (cmH_2O)	Standard manometer (n = 128)		Predetermined volume (n = 128)		Finger palpation (n = 128)		P Value
	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	
< 20	1	0.8	0	0.0	7	5.5	< 0.01
20-30	127	99.2	69	53.9	34	26.6	< 0.01
3-40	0	0.0	56	43.8	51	39.8	< 0.01
41-50	0	0.0	3	2.3	20	15.6	< 0.01
> 50	0	0.0	0	0.0	16	12.5	< 0.01

Data were statistically significant at P < 0.05 compared with the standard manometer.

n: number of respondents included in the analysis; ETT: Endotracheal Tube

Table 3: Complications associated with the techniques use to estimate ETT cuff pressure during intubation.

Variable	Standard manometer (n = 128)		Predetermined volume (n = 128)		Finger palpation (n = 128)		P Value
	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	
Cough	2	1.6	50	39.1	68	53.1	< 0.01
Sore throat	1	0.8	17	13.3	22	17.2	< 0.01
Hoarseness	0	0.0	1	0.8	15	11.7	< 0.01
Blood-streaked expectoration	0	0.0	0	0.0	2	1.6	< 0.01
None	125	97.6	60	46.8	21	16.4	< 0.01

Data were statistically significant at P < 0.05.

n: number of respondents included in the analysis; ETT: Endotracheal Tube

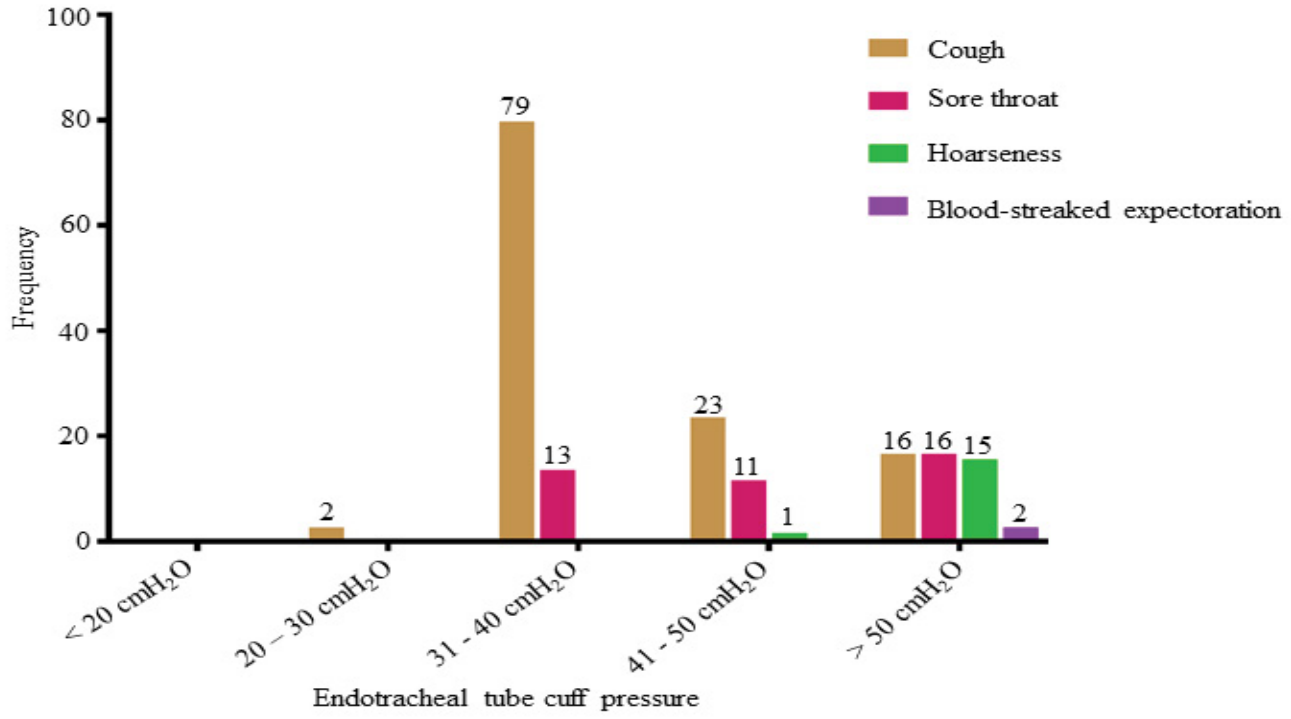

Figure 2: Endotracheal tube cuff pressure measured and the occurrence of associated side effects.

sore throat respectively. For the patients who recorded cuff pressure within 41-50 cmH_2O, we observed 23 of them who complained of cough, 11 who complained of sore throat, and 1 who complained of hoarseness. Whereas for those who recorded cuff pressure above 50 cmH_2O, we observed 16, 16, 15 and 2 of the patients who complained of cough, sore throat, hoarseness and blood-streaked expectoration respectively (Figure 2).

We next assessed the patient's satisfaction with the anaesthesia services rendered. For the standard manometer group, 73.4% (n = 94) scored excellent, 25.8% (n = 33) scored good and 0.8% (n = 1) scored satisfactory. For the predetermined volume of air group, 52.3% (n = 67) scored excellent, 43.8% (n = 56) scored good and 3.9% (n = 5) scored satisfactory. Whereas the manual palpation of the pilot balloon group, 2.3% (n = 3) scored excellent, 18.0% (n = 23) scored good, 47.7% (n = 61) scored satisfactory and 32.0% (n = 41) scored poor for the anaesthesia service (Table 4). The data showed a significant difference between the groups regarding those who scored excellent, good, satisfactory, or poor for the anaesthesia service (P < 0.01; P < 0.01; P < 0.01; P < 0.01 respectively) (Table 4).

Discussion

It is indicated that increasing lateral wall cuff pressure above 30 cmH_2O compromises blood flow, and cuff pressure more than 40 cmH_2O completely impede the tracheal wall blood flow [18,32-34]. In a study of 93 patients, it was observed that 27% of cuff pressure measured exceeded 40 cmH_2O using the manual palpation of pilot balloon irrespective of the experience of the anaesthesia provider [35]. Similarly, our present study recorded high cuff pressure (≥ 40 cmH_2O) among

Table 4: Patient satisfaction of the anaesthesia service.

Variable	Standard manometer (n = 128)		Predetermined volume (n = 128)		Finger palpation (n = 128)		P Value
	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	
Excellent	94	73.4	67	52.3	3	2.3	< 0.01
Good	33	25.8	56	43.8	23	18.0	< 0.01
Satisfactory	1	0.8	5	3.9	61	47.7	< 0.01
Poor	0	0.0	0	0.0	41	32.0	< 0.01

Data were statistically significant at $P < 0.05$ compared with the standard manometer

n: number of respondents included in the analysis

the finger palpation and the predetermined volume of air groups. This suggests that finger palpation or predetermined volume techniques may correspond poorly with cuff pressure measured [36,37]. Conversely, the standard manometer technique recorded cuff pressure within the standard therapeutic range (20-30 cmH_2O). This was consistent with other studies which reported a significantly lower incidence of high cuff pressure using a standard manometer [37,38].

Post-extubation airway complaint is an unpleasant experience often underestimated side effect of over-inflation of ETT cuff. Its incidence is estimated to vary from 15% to 94% [26]. Existing literature has shown a relationship between high intra-cuff pressures and tracheal lesions [25,28]. Our present study noted a high incidence of airway complaints (cough, sore throat, hoarseness, and blood-streaked expectoration) among those whose cuff pressure was ≥ 40 cmH_2O compared with 20-30 cmH_2O. It is therefore recommended that cuff pressure should be maintained within a narrow ideal range of 20 to 30 cmH_2O to prevent post-extubation airway complaints. This can be achieved by the use of a standard manometer. Recent literature showed that the duration of intubation was associated with airway complaints such as cough, sore throat, hoarseness, and blood-streaked expectoration and would occur even following a short duration of tracheal intubation (1-3 hours) [28,39]. In the contrary, our study's results showed no significant difference between the groups regarding the duration of tracheal intubation.

Patients' safety and satisfaction with anaesthesia services have been a major concern for many anaesthetists. In our study, we assessed the patients' satisfaction with the anaesthesia service. We observed that 73.4% of the patients from the pressure gauge group scored excellent for the anaesthesia service compared with 2.3% from the finger palpation groups.

Study Limitation

The study did not highlight the issue of experience among the anaesthesia providers regarding the cuff inflation and pressure measurement technique.

Conclusion

Inadequate or excessive ETT cuff inflation is a preventable risk factor for tracheal ischemia and its complications. Excessive pressure on the tracheal mucosa, greater than the mucosa's mean capillary perfusion pressure, should be avoided during cuffed intubation. The finger palpation of a pilot balloon technique for cuff pressure estimation was unreliable and prone to cuff over inflation and associated with post-extubation airway complaints. Cuff pressure estimation using the standard manometer was associated with satisfactory patient outcomes. Because finger palpation of a pilot balloon is not a reliable guide to cuff pressure, we recommend that the pressure on the lateral tracheal wall measured at end expiration be kept between 20 and 30 cmH_2O whenever possible using a pressure gauge.

Declarations

Ethics approval and consent to participate

The ethical committee of the University of Health and Allied Sciences approved the study protocol (ID No: UHAS REC A.9[114]20-21). The clinical trial registration was obtained from ISRCTN Registry, BMC (No. ISRCTN66168037). Written informed consent was obtained from each recruited parturient after providing them with adequate explanations regarding the aims of this study.

Consent to publish

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to patient confidentiality but are available from the corresponding author on reasonable request.

Competing interests

Authors declare that they have no competing interests.

Funding

No funding was obtained for this study.

Authors' contributions

SK, TWA, and FB conceived and designed the study. SK and TWA were responsible for the supervision and coordination of this study. SK, TWA, FB, MEH, ADBB and OS conducted the data collection.SK led the data analysis with inputs from TWA, FB, MEH, ADBB, EDK and JBZ. The first draft of the manuscript was written by SK and TWA, FB, MEH, ADBB, SO, EDK and JBZcontributed to revising and reviewing the manuscript.

All authors read and approved the final manuscript before submission.

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