Endotracheal tube cuff pressure measurement techniques: safety and reliability among patients undergoing general anaesthesia for cesarean section. A prospective randomized comparative study

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Research Article

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

Posted Date: March 24th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1447705/v1

Abstract

Objective This study aimed to qualitatively assess and compare some techniques involved in cuff inflation and its corresponding pressure estimations as well as associated complications among patient s undergoing general anaesthesia with intubation for cesarean section at the obstetric unit of the Tamale Teaching Hospital. Results Finger palpation of the pilot balloon, predetermined volume of air, and a pressure gauge were used to measure endotracheal tube cuff pressure after intubation . Associated side effects were determined after 24 hours of endotracheal tube extubation. Data for 384 patients were included in the analysis. Cuff pressure measured among patients varied from < 20 -30 cmH 2 O for the standard manometer group, 20 to 50 cmH 2 O for the predetermined volume of air group and < 20 to < 50 cmH 2 O for the finger palpation group. Side effects were recorded in 2.3 % of patients from the standard manometer group, 53.2 % from the predetermined volume of air group and 83.6 % from the finger palpation group. The findings of this study, therefore, suggested that finger palpation of a pilot balloon and a predetermined volume of air methods are prone to cuff over inflation and post-extubation airway complications.

Introduction

A standard hand-held analogue manometer is used to accurately measure the recommended cuff pressure of 20–30 cmH_2O, ideal for the prevention of aspiration and ventilator-associated pneumonia [1, 2]. These manometers are not readily available, especially in resource-limited settings where their use is limited by the cost of acquisition and maintenance [3]. Consequently, majority of anaesthesia providers resort to other techniques such as finger palpation to measure cuff pressure [4].

There have been several complaints of cough, sore throat, hoarseness, and blood-streaked expectoration by patients after general anaesthesia and cesarean section with no known established causes at the obstetric unit of the Tamale Teaching Hospital. The present study aimed to qualitatively assess and compare the techniques involved in cuff inflation and its corresponding pressure estimations as well as associated complaints among patients. The findings of this study will provide adequate information for literature on endotracheal tube cuff pressure procedures, as well as influencing anaesthesia clinical policies for mandatory monitoring of endotracheal tube cuff pressure and its estimations.

Materials And Methods

Subjects and 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.

This study recruited 389 pregnant women who were to undergo elective cesarean section in which spinal anaesthesia was contraindicated or failed. Each recruited patient was randomly assigned to one of three groups using a computer-generated random number table; Standard manometer group (n=128), represented those whose

endotracheal tube cuff inflation and pressures were determined by the use of a pressure gauge; Predetermined volume of air group (n=128), represented those whose cuff inflation and pressures were determined by a predetermined volume of air (10 ml) and Finger palpation of the pilot balloon group (n=128), represented those whose cuff were inflated with undetermined volume of air and cuff pressures measured by finger palpation of the pilot balloon.

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 among all the groups. 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.

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, 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 S1).** 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 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 S2).**

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 S1).** 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 S1)**.

Discussion

It is indicated that increasing lateral wall cuff pressure above 30 cm H_2O compromises blood flow, and cuff pressure more than 40 cm H_2O completely impede the tracheal wall blood flow [5–8]. In a study of 93 patients, it was observed that 27% of cuff pressure measured exceeded 40 cmH₂O using the manual palpation of pilot balloon irrespective of the experience of the anaesthesia provider [9, 10]. Similarly, our present study recorded high cuff pressure (≥ 40 cmH₂O) among the finger palpation and the predetermined volume of air groups. This suggested that finger palpation or predetermined volume techniques may correspond poorly with cuff pressure measured. [11, 12]. Conversely, the standard manometer technique recorded cuff pressure within the standard therapeutic range (20–30 cmH₂O). This was consistent with other studies which reported a significantly lower incidence of high cuff pressure [12–13].

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 15–94% [14, 15]. Existing literature has shown a relationship between high intra-cuff pressures and tracheal lesions [9, 16, 17]. 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 cmH₂O 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 cmH₂O 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) [18, 19]. In this study, the 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 October 2004, the World Health Organization (WHO) launched the World Alliance for Patient Safety in response to World Health Assembly Resolution 55.18 urging WHO and the Member States to pay attention to patient safety problems.' In Ghana, health care reforms have been so sluggish, cuff pressures during tracheal intubation are not routinely measured. In our studies, 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.

Conclusion

Finger palpation of a pilot balloon for cuff pressure estimation is unreliable and prone to cuff over inflation and associated post-extubation airway complaints. We recommend the use of a pressure gauge whenever available.

LIMITATIONS

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

List Of Abbreviations

ASA-PS - American Society of Anaesthesiologists Physical Status

ECG – Electrocardiography.

SpO_2 – Partial Pressure of Oxygen Saturation.

ETT- Endotracheal Tube

ID - Internal Diameter

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 JBZ contributed to revising and reviewing the manuscript. All authors read and approved the final manuscript before submission.

Acknowledgement: We thank the staff of the department of anaesthesia and intensive care of the Tamale Teaching hospital for providing all the necessary material we needed for this study. We also thank the management and staff of the department of obstetrics and Gynecology of the Tamale Teaching hospital for approving this study protocol and making available all the necessary materials needed for the study.

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Tables

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
31- 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

Supplementary Files

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