Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at a central academic hospital

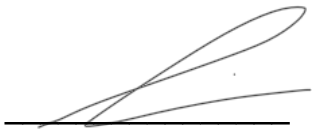
Bianca Boodaya Naidoo

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Johannesburg, 2024

Declaration

I, Bianca Boodaya Naidoo, declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



30 March 2024

Dedication

I dedicate this body of work to my amazing family, who have always made unconditional sacrifices to support me in my endeavours. Thank you dearly.

Abstract

Background

Paediatric endotracheal intubation plays an integral role not only in anaesthesia but in many other disciplines where having a secure airway is a priority. Studies challenging historical findings regarding paediatric airway anatomy are leading to increased use of cuffed endotracheal tubes (ETTs) in the paediatric population. Manufacturers of cuffed paediatric ETTs recommend a safe sealing pressure of 11 – 20 centimetres of water (cm H_2O) and no higher.

The aim of this study was to determine ETT cuff pressures in paediatric patients using an aneroid manometer. The study then compared various ETT cuff inflation techniques and the level of training of anaesthetists to the measured ETT cuff pressure.

Methods

A cross-sectional, contextual research design was used in this study. The population group studied were paediatric patients that presented to the operating and diagnostic theatre complexes of Chris Hani Baragwanath Academic Hospital (CHBAH) for procedures under general anaesthesia (GA) administered with a cuffed ETT. A convenience sampling method was used. In consultation with a biostatistician a sample size of 87 was calculated. Informed written consent and assent was obtained from the caregivers and study participants in a deferred manner. Data was collected on weekdays and weekends. Paediatric patients undergoing GA were screened for enrolment in the study. Written informed consent from the patient's anaesthetist was obtained before ETT cuff pressure measurement took place. Data was collected by the researcher using a standardised data collection sheet. The anaesthetist responsible for inflating the ETT cuff was asked what technique was used for ETT cuff inflation and this was documented together with the ETT cuff pressure obtained.

Results

The final study sample included 91 participants. In the study, 56 (61.54%) patients were subjected to inadequate sealing pressures, where the ETT cuff pressure was below 11 cm H_2O and only 25 (27.47%) patients had an ETT cuff pressure ranging between 11-20 cm H_2O. The

results also showed significant variability (p=0.011) on the ETT cuff pressure depending on the inflation method used. There was no difference in ETT cuff pressure measurement based on the experience of the person placing the ETT and inflating the cuff.

Conclusions

Optimal sealing pressures of ETT cuffs using subjective inflation techniques were not achieved in most paediatric patients undergoing GA at CHBAH. ETT cuff pressures should be monitored routinely using an objective method such as an aneroid manometer.

Acknowledgments

I would like to thank the following people:

My supervisors and the anaesthesiologists who reviewed the study. Thank you for your guidance, patience and support you provided.

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List of abbreviations

ETT: Endotracheal tube

cm H_2O: Centimetres of water

CHBAH: Chris Hani Baragwanath Academic Hospital

GA: General anaesthesia

MOV: Minimal occlusive volume

MLT: Minimal leak test

mmHg: Millimetres of Mercury

ID: Internal diameter

Statement

The Research Report consists of a draft article and appendices. The study proposal is included as appendices for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports.

The formatting of the draft article may differ from the Research Report to comply with the author guidelines of the Southern African Journal of Anaesthesia and Analgesia, the journal to which it is intended to be submitted.

Covering Letter for Draft Article Southern African Journal of Anaesthesia and Analgesia

Title: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at a central academic hospital

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Author declaration

The authors declare that this research report has not been previously published and is not under review elsewhere.

Conflict of interest

The authors declare no conflict of interest.

Funding source

None.

Ethical Approval

Clearance from Human Research Ethics Committee (approval number: M200333).

Bianca Naidoo	Alicia Carbonari	Kylesh Pegu

30 March 2023

Draft Article for the Southern African Journal of Anaesthesia and Analgesia

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Results

The final study sample included 91 participants. In the study, 56 (61.54%) patients were subjected to inadequate sealing pressures, where the ETT cuff pressure was below 11 cm H_2O and the ETT cuff pressure was found to be high (> 20 cm H_2O) in 10 (10.98%) patients. Only 25 (27.47%) patients had ETT cuff pressures ranging between 11-20 cm H_2O. The results also showed significant variability (p=0.011) on the ETT cuff pressure depending on the inflation method used. There was no difference in ETT cuff pressure measurement based on the experience of the person placing the ETT and inflating the cuff.

Conclusion

Optimal sealing pressures of ETT cuffs using subjective inflation techniques were not achieved in most paediatric patients undergoing GA at CHBAH. ETT cuff pressures should be monitored routinely using an objective method such as an aneroid manometer.

Keywords: endotracheal tubes, paediatrics, anaesthetists

Introduction

The primary roles of the ETT cuff are to prevent air leak and ensure adequate tidal volumes during mechanical ventilation and to reduce the risk of aspiration of gastric contents by creating a protective barrier between the ETT and tracheal mucosa (1).

Over-inflation of the ETT cuff leads to impairment of capillary blood flow to the tracheal mucosa resulting in mucosal inflammation and potentially mucosal ischaemia. This may result in tracheal ulceration causing tracheomalacia and tracheo-oesophageal fistulae (2–5). Postmortem studies assessing tracheal specimens of adults and children who required prolonged intubation or tracheostomy done by Bergström and Lindholm in the 1960s demonstrated similar macroscopic changes of the larynx and trachea between the two groups (6).

Paediatric endotracheal intubation plays an important role not only in anaesthesia but in many other disciplines where having a secure airway is a priority (7). Studies (8–14) challenging historical findings regarding paediatric airway anatomy are leading to increased use of cuffed ETTs in children younger than eight years. In 2004, Kimberly-Clark's™ paediatric Microcuff ETT, starting at size 3.0 mm internal diameter (ID) for use in term neonates weighing at least 3 kg, aimed to address these historical anatomical concerns by the tapered shape of the cuff as well as the cuff material - ultrathin polyurethane which has been shown to seal the trachea with pressures less than 11 cm H_2O (15). In 2017 a Cochrane review (16) showed that studies demonstrating cuffed ETTs as a contributor to post-operative morbidity in children younger than eight years were of low quality evidence and that larger randomised controlled trials need to be conducted to clarify the risks of cuffed ETTs, especially in neonates.

Methods for monitoring ETT cuff pressures include subjective clinical estimation techniques such as minimal occlusive volume (MOV); minimal leak test (MLT) and palpation of the pilot cuff (17). Objective methods for determining ETT cuff pressures include pressure regulating devices attached to the pilot balloon for continuous monitoring and aneroid manometers for intermittent measurements (17,18). A 2016 systematic review and meta-analysis (19), which included children, showed that the subjective method of ETT cuff inflation was associated with higher ETT cuff pressures and increased adverse events such as cough; sore throat and

hoarseness of voice versus objective methods of ETT cuff inflation, such as the use of an aneroid manometer. Krishna et al (20) also demonstrated subjective methods to be inferior to an aneroid manometer in paediatric cuffed ETTs and contribute to the increased incidence of postoperative tracheal morbidity.

Acceptable ETT cuff pressures (25 – 40 cm H_2O or 20 – 30 millimetres of Mercury (mmHg)) are based on studies done mainly in adult patients with the focus of morbidity associated with cuff pressures exceeding the higher end (21). A safe range for ETT cuff pressures in paediatrics has not been well established. Manufacturers of cuffed paediatric ETTs recommend a safe sealing pressure of 11 – 20 cm H_2O and no higher (22,23). In the United Kingdom, National Health Service guidelines recommend a maximum of 20 cm H_2O or a safe range of 15 – 20 cm H_2O (24,25).

There are no aneroid manometers available for the monitoring of pressures in cuffed ETTs in paediatric patients undergoing general anaesthesia at Chris Hani Baragwanath Academic Hospital (CHBAH). The aim of this study was to determine ETT cuff pressures in paediatric patients undergoing general anaesthesia (GA) at CHBAH.

Methods

A cross-sectional, contextual research design was used in this study. The population group studied were paediatric patients that presented to the operating and diagnostic theatre complexes of CHBAH for procedures under GA administered with a cuffed ETT. A convenience sampling method was used. Paediatric patients undergoing GA were screened for enrolment in the study. Ethics approval was obtained from the Human Research Ethics Committee (Medical) of the Faculty of Health Science at the University of the Witwatersrand (Wits) (Approval number: M200333). Written informed consent from the patient's anaesthetist was obtained before ETT cuff pressure measurement took place. Informed written consent and assent was obtained from the caregivers and study participants in a deferred manner.

The anaesthetic technique and drugs used at induction and maintenance was at the discretion of the child's anaesthetist. If nitrous oxide was used for gas induction or co-induction it was

turned off and the ETT cuff was inflated using the preferred method by the child's anaesthetist. Once the ETT was secured and the patient was stable, cuff pressure was measured.

Data was collected by the researcher using a standardised data collection sheet. The data included:

- demographics
- age
- sex
- surgical procedure
- time from intubation to measurement of ETT cuff pressure
- ETT size and brand
- position of child's head
- use of nitrous oxide and etN_2O concentration if ETT cuff pressure is measured during the maintenance phase of anaesthesia.
- level of experience of child's anaesthetist
- actual ETT cuff pressure (in cm H_2O)
- cuff inflation technique used by the anaesthetist.

The ETT cuff pressure was measured using an aneroid manometer from VBM Medizintechnik GmbH. The manometer was connected to the pilot cuff and pressure measured at the end of expiration. If the measured ETT cuff pressure was found to be above or below the expected range, this was communicated to the child's anaesthetist and the pressure adjusted accordingly.

Statistical analysis

A Microsoft Excel spreadsheet was used to capture data. Data was analysed in consultation with a biostatistician using the statistical program STATA version 13.1 (StataCorp, USA). Categorical variables were reported using frequencies and percentages. Continuous variables were

described using means and standard deviations or median and interquartile ranges depending on the distribution of the data. Chi-square and Fisher's exact tests were used to find associations between categorical variables. A p-value of 0.05 or less was considered statistically significant.

Results

The study was conducted at CHBAH from October 2021 to March 2022. ETT cuff pressures were measured and recorded at the convenience of the researcher.

There were 91 ETT cuff pressures measured. The patients taking part in this study included 53 males (58.24%) and 38 females (41.76%). The mean age of the patients was 3.91 years (SD 2.74) and is not normally distributed as Shapiro Wilk W = 0.944 ($p < 0.0001$) as seen in Figure 1. ETT sizes ranged from 3.0 to 6.5. Table 1 illustrates the distribution of ETT sizes described in this study.

The different surgical specialties comprised 64 (70.33%) general paediatric surgery, 25 (27.47%) ENT and 2 (2.2%) neurosurgical patients.

With regards to the different levels of training of the anaesthetists who took part in the study, interns were involved in 1 (1.09%), MOs 19 (20.87%), first year registrars 33 (36.26%), second year registrars 16 (17.58%), third year registrars 11 (12.08%), final year registrars 2 (2.20%) and consultants 9 (9.89%) cases respectively. These data are presented in Figure 2.

The mean time from intubation to measurement of ETT cuff pressure was 37 minutes (range 15 – 90 minutes). Nitrous oxide was not used with any study participant and thus the etN_2O measured zero with all cases at the time of ETT cuff pressure measurement. All ETT cuff pressures were measured with the head in supine position. The mean ETT cuff pressure recorded was 9.11 cm H_2O (range 0 - 45 cm H_2O). The ETT cuff pressure was found to be high (> 20 cm H_2O) in 10 (10.98%) patients, with a mean pressure of 29.5 cm H_2O in this group. Inadequate sealing pressures, where the ETT cuff pressure was below 11 cm H_2O, was present in 56 (61.54%) patients. Only 25 (27.47%) patients had an ETT cuff pressure ranging between 11-20 cm H_2O, where the mean pressure was 16.48 cm H_2O. Figure 3 displays the data.

MLT was the most frequent technique used by anaesthetists to inflate the ETT cuff and as seen in Figure 4 this was used in 53 (58.24%) patients. The palpation of the pilot cuff to estimate ETT cuff pressure was used in 20 (21.98%) patients followed by the MOV technique in 18 (19.78%) patients. The use of an aneroid manometer for objective measurement of the ETT cuff pressure was not used in any patients.

Table 2 illustrates the different inflation techniques versus the pressures obtained. Using Fisher's exact test there was a statistically significant difference (P=0.011) between the different inflation techniques and the cuff pressures obtained.

Table 3 illustrates the pressures obtained versus the anaesthetists according to their level of training. A junior anaesthetist was defined as an intern, medical officer or registrar with less than three years of training. A senior anaesthetist was a registrar with more than three years of training or a consultant**.** Using Fisher's exact test there was no statistically significant difference (P=0.709) between the different levels of training and the cuff pressures obtained.

Discussion

Endotracheal intubation plays an integral role in paediatric anaesthetic technique for airway isolation, ventilation and the maintenance of general anaesthesia. Studies (11–15) challenging historical findings regarding paediatric airway anatomy are leading to increased use of cuffed ETTs in children younger than eight years. These studies demonstrated clinical, environmental and economical benefits of cuffed versus uncuffed ETTs provided the cuffs were inflated to an optimal sealing pressure. Acceptable ETT cuff pressures (25 – 40 cm H_2O or 20 – 30 mmHg) are based on studies done mainly in adult patients (22).

A safe range for ETT cuff pressures in paediatrics has not been well established and manufacturers recommend a safe sealing pressure of 11 – 20 cm H_2O and no higher (23,24). This study found that most patients (61.54%) were subjected to inadequate sealing pressures, where the ETT cuff pressure was below 11 cm H_2O and only 25 (27.47%) patients had an ETT cuff pressure ranging between 11-20 cm H_2O. International and local research demonstrating the incidence of both under inflation and over inflation of ETT cuffs in the paediatric population is scant. A prospective study conducted at a university-affiliated hospital in San Antonio, Texas,

showed ETT cuff under inflation occurs as often as 45% in the PICU with no cases of overinflation found (33). In contrast, a prospective study conducted in the paediatric emergency department of Nationwide Children's Hospital in Ohio showed that 57% of patients were exposed to pressures exceeding the safe upper limit (7). These studies demonstrate the importance of standard guidelines in monitoring ETT cuff pressures in paediatric patients.

An aneroid manometer is an objective tool approved for both ETT cuff inflation and ETT cuff pressure measurement. This was not used with any of the patients in our study. Various studies demonstrate objective ETT cuff pressure measurement using a manometer to be superior to the other subjective ETT cuff inflation techniques demonstrated in our study (7,11,32). Furthermore, our study also showed significant variability on the ETT cuff pressure depending on the subjective inflation method used. We noted no difference in ETT cuff pressure measurements based on the experience of the person placing the ETT and inflating the cuff.

Conclusion

Optimal sealing pressures of ETT cuffs using subjective inflation techniques were not achieved in most paediatric patients undergoing general anaesthesia at CHBAH. ETT cuff pressures should be monitored routinely using an objective method such as an aneroid manometer.

Study limitations

This study was contextual and conducted at one academic hospital in Johannesburg, therefore the results may not be generalisable to other hospitals. The data collection of various demographic, anaesthetic and surgical factors (Appendix 10) was demonstrated to show that unintended changes in ETT cuff pressure can occur at any point in the intraoperative setting. Further information and statistical analysis of each of these factors on ETT cuff pressure is

beyond the scope of this research study but may contribute to future guidelines on the best practice use for cuffed ETTs in the paediatric population.

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We would like to thank all the anaesthetists, caregivers and children who participated in this study.

Declaration conflict of interest

The authors declare no conflict of interest.

Funding source

No funding was required.

Ethics declaration

Ethical approval was granted by the Human Research Ethics Committee (Medical) of the Faculty of Health Science at the University of the Witwatersrand (Approval number: M200333).

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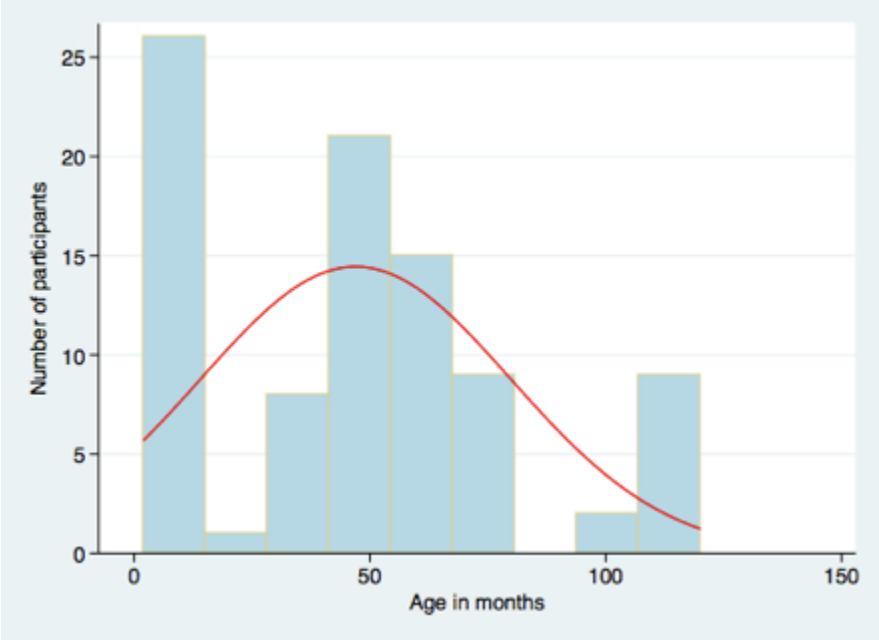

Figure 1. The distribution of age of study participants.

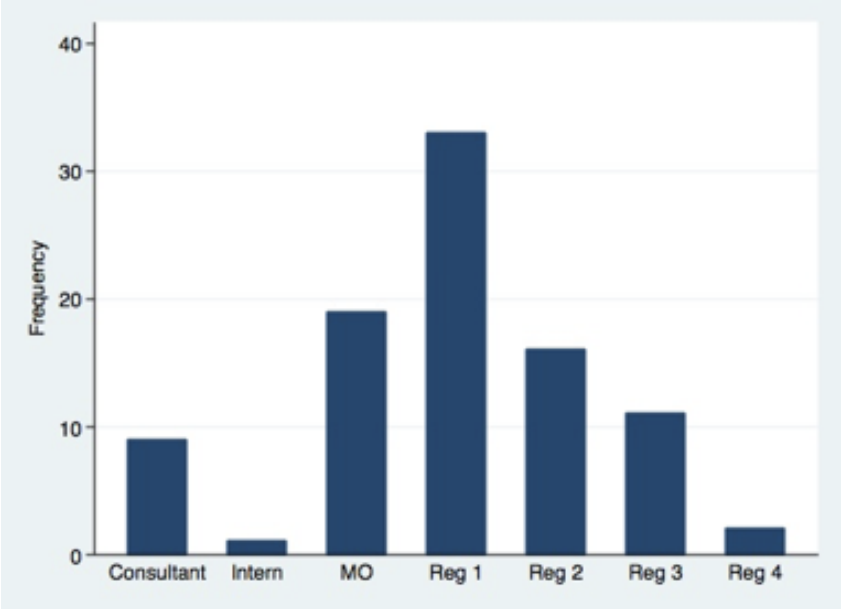

Figure 2. Different levels of training and their respective frequencies of anaesthetists who participated in this study.

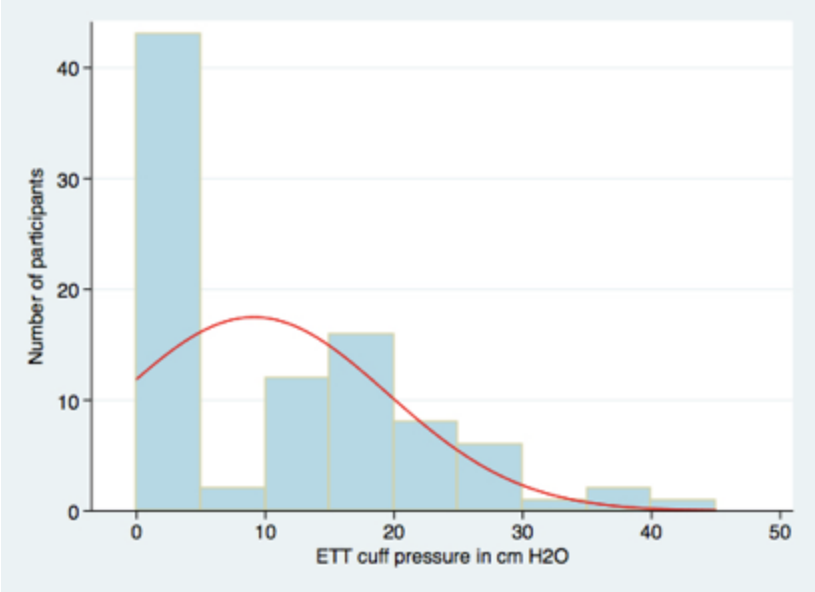

Figure 3. The distribution of measured ETT cuff pressure of study participants and their relative frequencies found in this study.

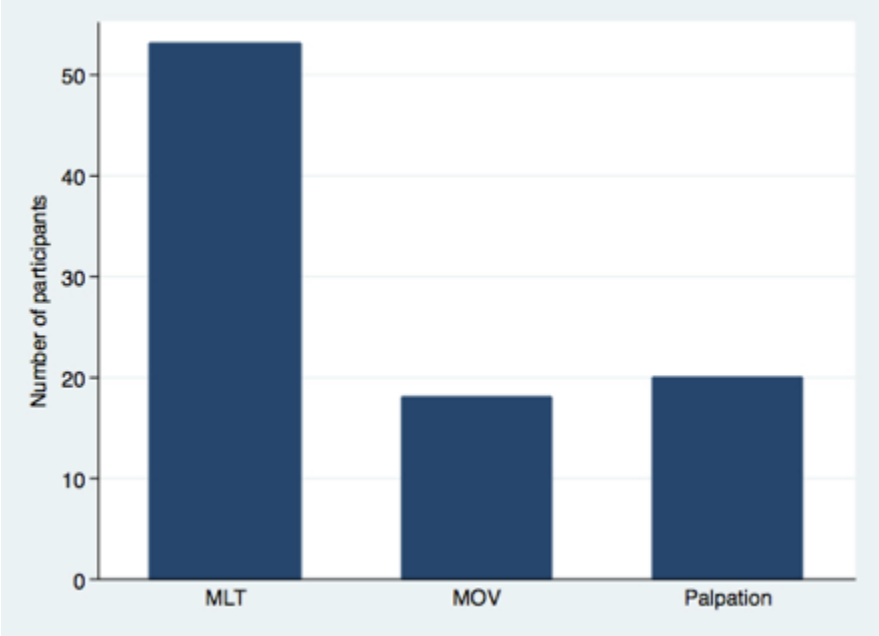

Figure 4. The various ETT cuff inflation techniques and their relative frequencies found in this study.

ETT size	Frequency	Percent (%)
3.0	8	8.79
3.5	18	19.78
4.0	18	19.78
4.5	13	14.29
5.0	10	10.99
5.5	12	13.19
6.0	8	8.79
6.5	4	4.40

Table 1. ETT Sizes and their frequencies in this study.

	Pressure < 11 cm H_2O	Pressure 11-20 cm H_2O	Pressure > 20 cm H_2O	Total	P-value
MLT	36 (67.92%)	14 (26.41%)	3 (5.67%)	53 (58.24%)	0,011
MOV	14 (77.78%)	3 (16.67%)	1 (5.56%)	18 (19.78%)	
Palpation	6 (30%)	9 (45%)	5 (25%)	20 (21.98%)	

Table 2. ETT cuff inflation techniques and ETT cuff pressure groups.

	Pressure <11 cm H_2O	Pressure 11-20 cm H_2O	Pressure >20 cm H_2O	Total	P-value
Junior anesthetist	49 (61.25%)	21 (26.25%)	10 (12.5%)	80 (87.91%)	0,709
Senior anesthetist	8 (72.73%)	3 (27.27%)	0 (0%)	11 (12.09%)	

Table 3. Levels of training and ETT cuff pressure groups.

Appendices

Appendix 1: South African journal of Anaesthesia and Analgesia Guidelines

Author Guidelines

Submitted manuscripts that are not in the correct format and without the required supporting documentation specified in these guidelines will be returned to the author(s) for correction and will delay publication.

AUTHORSHIP

Named authors must consent to publication **by signing a covering letter** which should be submitted as a supplementary file. Authorship should be based on substantial contribution to:

(i) conception, design, analysis and interpretation of data.

(ii) drafting or critical revision for important intellectual content; and

(iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to **www.icmje.org**); and

(iv) exact contribution of each author must be stated.

DECLARATION OF CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a product or subject that may constitute a conflict of interest. If there is no conflict of interest to declare please include the following statement: The authors declare no conflict of interest.

FUNDING SOURCE

All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated as follows: No funding source to be declared.

RESEARCH ETHICS COMMITTEE APPROVAL

The submitting author must provide written confirmation of Research Ethics Committee approval for all studies including case reports. The ethics committee as well as the approval number should be included.

STATISTICAL ANALYSIS

Authors are advised to involve medical statisticians at the protocol stage of their research project: to plan sample size, and the selection of appropriate statistical tests for analysis and presentation.

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Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to **www.icmje.org**.

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The rationale for analysis based on racio-ethnic-cultural categorisation should be indicated.

CATEGORIES OF SUBMISSIONS

Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Original articles

Original articles on research relevant to anaesthesia and analgesia should not exceed 3 200 words, no more than 30 references, with up to 6 tables or figures. A structured abstract under the following headings, Background, Methods, Results, and Conclusions is a requirement and should not exceed 300 words.

Clinical Review articles

Review articles relevant to anaesthesia and analgesia should not exceed 2 400 words, with a maximum of 20 references and no more than 6 tables or figures. A summary of 300 words or less is required.

Case reports

Case reports should not exceed 1 800 words with no more than 10 references. Figures are limited to 2 figures and may include images or photographs. The case report should have three headings: Summary (not exceeding 100 words), Case report (with no introduction) and Discussion. Case reports will be published online only. The summary and the URL will appear in the printed version.

Scientific Letters

Scientific Letters should not exceed 2 400 words with a maximum of 10 references. Only one table or illustration is permissible. A structured abstract under the following headings, Background, Methods, Results, and Conclusions, is a requirement and should not exceed 250 words.

Letters to the editor

Letters to the editor should be 800 words or less with only one image or table.

MANUSCRIPT PREPARATION

Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**. Manuscripts must be provided in **UK English**.

Qualification, affiliation and contact details

This information must be provided for ALL authors and must be submitted as a supplementary file.

Email addresses of all authors must be provided.

ORCID number of **ALL** authors must be provided - if authors do not have ORCID, please register at https://orcid.org/

Abbreviations

All abbreviations should be spelt out when first used and thereafter used consistently, e.g., 'intravenous (IV)' or 'Department of Health (DoH)'.

Scientific measurements

Scientific measurements must be expressed in SI units except blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g., 'ml' for millilitres). Units should be preceded by a space (except for %), e.g., '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age) should also be preceded by a space e.g., > 20 years. No spaces should precede ± and °, i.e., '35±6' and '19°C'.

Numbers should be written as grouped per thousand-units, i.e., 4 000, 22 160...

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...' Round **brackets** (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

General formatting

The manuscript must be in Microsoft Word or RTF document format. Text must be 1,5-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, except for Tables). *The manuscript must be free of track changes.*

Disclaimers should follow the Conclusion and it should be in the following order: Acknowledgements, Declaration conflict of interest, Funding source, Ethics declaration and ORCID.

ILLUSTRATIONS AND TABLES

If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

Tables may be embedded in the manuscript file **and** provided as **'supplementary files'**. They must be numbered in Arabic numerals (1,2,3...) and referred to consecutively in the text (e.g., 'Table 1'). Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged. Tables must be cell-based (i.e., not constructed with text boxes, tabs, or enters) and accompanied by a concise title and column headings. Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Figures must be numbered in Arabic numerals and referred to in the text e.g., '(Figure 1)'. Figure legends: Figure 1: 'Title...'. All illustrations/figures/graphs must be of **high resolution/quality**: 300 dpi or more is preferable, but images must not be resized to increase resolution. Unformatted and uncompressed images must be attached as '**supplementary files**' upon submission (not embedded in the accompanying manuscript). TIFF and PNG formats are preferable; JPEG and PDF formats are accepted, but authors must be wary of image compression. Illustrations and graphs prepared in Microsoft PowerPoint or Excel must be accompanied by the original workbook.

REFERENCES

Authors must verify references from the original sources. *Only complete, correctly formatted reference lists will be accepted.* Reference lists may be generated with the use of reference manager software, but the final document must be delinked from the reference database or otherwise generated manually. Citations should be inserted in the text as superscript, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6] The superscript reference number should come after the punctuation mark and should not be in brackets.

All references should be listed at the end of the article in numerical order of appearance in the **Vancouver style** (not alphabetical order). Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus. Names and initials of all authors should be given; if there are more than six authors, the first four names should be given followed by et al. First and last page, volume and issue numbers should be given. **Wherever possible, references must be accompanied by a digital object identifier (DOI) link and PubMed ID (PMID)/PubMed Central**

ID (PMCID). Authors are encouraged to use the DOI lookup service offered by **CrossRef**. Crossref DOIs should always be displayed as a full URL link in the form https://doi.org/10.xxxx/xxxxx

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A covering letter to the editor is mandatory and must include statements that the manuscript has not been published previously and is not under review elsewhere. It should state details of

any prior publication of the research in abstract form or in Congress proceedings. The letter must declare if any of the authors have a conflict of interest and that the requirements for submission, including ethics approval and patient permission for case reports have been fulfilled. All authors must sign the covering letter.

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Appendix 2: Study proposal

Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

Bianca Boodaya Naidoo

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Co-supervisor	Helen Perrie Department of Anaesthesiology
Co-supervisor	Ryan Campbell Department of Anaesthesiology

Introduction and problem statement

The evolution of paediatric endotracheal intubation began in the early 1800s during the Diphtheria epidemic in France with the introduction of tracheotomy by Pierre-Fidèle Bretonneau, a French physician, to save the severely obstructed airway (1). Tracheal intubation was reintroduced by Eugene Bouchut after Bretonneau's pupil, Emile Trousseau demonstrated a 78 % mortality in 216 children requiring relief of airway obstruction secondary to diphtheria (1). Dr George Fell, American paediatrician, together with surgeon Dr Joseph O'Dwyer (2) refined Bouchut's rescue device used for children in theatre after anaesthetic overdose, the Fell-O'Dwyer apparatus (3). The polio epidemic in Europe (1950s) and United States (1960s) lead to valuable modifications of the Fell-O'Dwyer metallic rescue devices (4), mainly the introduction of plastic endotracheal tubes (ETTs) made with polyvinyl chloride (PVC) and the addition of a cuff attached to a pilot balloon, resulting in what we now know as the standard ETT. The primary roles of the ETT cuff are to prevent air leak and ensure adequate tidal volumes during mechanical ventilation and to prevent aspiration of gastric contents by creating a seal between the ETT and the tracheal mucosa (4).

Over-inflation of the ETT cuff leads to impairment of capillary blood flow to the tracheal mucosa resulting in mucosal inflammation, mucosal ischaemia and resultant tracheal ulceration causing tracheomalacia and tracheo-oesophageal fistula (5–8). Post mortem studies assessing tracheal specimens of adults and children who required prolonged intubation or tracheostomy done by Bergström and Lindholm in the 1960s demonstrated similar macroscopic changes of the larynx and trachea between the two groups (9).

Paediatric endotracheal intubation plays an integral role not only in anaesthesia but in many other disciplines where having a secure airway is a priority (10). Studies (11–15) challenging historical findings regarding paediatric airway anatomy by Bayeux (16) and Eckenhoff (17) are leading to increased use of cuffed ETTs in children younger than eight years. In 2004, Kimberly-Clark's paediatric Microcuff™ ETT, starting at size 3.0 mm internal diameter (ID) for use in term neonates weighing at least 3 kg (12), aimed to address these historical anatomical concerns by the tapered shape of the cuff as well as the cuff material - ultrathin polyurethane

which has been shown to seal the trachea with pressures less than 11 cm H_2O (18). In 2017 a Cochrane review (19) showed that studies demonstrating cuffed ETTs as a contributor to post-operative morbidity in children younger than eight years were of low quality evidence and that larger randomised controlled trials need to be conducted to clarify the risks of cuffed ETTs, especially in neonates.

Methods for monitoring ETT cuff pressures include clinical estimation techniques (subjective) such as minimum occlusive volume (MOV); minimal leak test (MLT); palpation of the pilot cuff (20). Objective methods for determining ETT cuff pressures include pressure regulating devices attached to the pilot balloon for continuous monitoring and aneroid manometers for intermittent measurements (20,21). A 2016 systematic review and meta-analysis (22), which included children, showed higher ETT cuff pressures and increased adverse events such as cough; sore throat and hoarseness of voice associated with subjective versus objective methods of ETT cuff inflation, such as the use of an aneroid manometer . Krishna et al (23) also demonstrated subjective methods to be inferior to an aneroid manometer in paediatric cuffed ETTs and contribute to the increased incidence of postoperative tracheal morbidity.

Acceptable ETT cuff pressures (25 – 40 cm H_2O or 20 – 30 mmHg) are based on studies done mainly in adult patients with the focus of morbidity associated with cuff pressures exceeding the higher end (24). A safe range for ETT cuff pressures in paediatrics has not been well established. Manufacturers of cuffed paediatric ETTs recommend a safe sealing pressure of 11 – 20 cm H_2O and no higher (25,26). In the United Kingdom (UK), National Health Service (NHS) guidelines recommend a maximum of 20 cm H_2O or a safe range of 15 – 20 cm H_2O (27,28). At present there are no aneroid manometers available for the monitoring of pressures in cuffed ETTs in paediatric patients undergoing general anaesthesia at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH); Chris Hani Baragwanath Academic Hospital (CHBAH) and Rahima Moosa Mother and Child Hospital (RMMCH). The ETT cuff pressures in these patients is unknown.

Aim and objectives

Aim

The aim of this study is to determine ETT cuff pressures in paediatric patients undergoing general anaesthesia at CMJAH, CHBAH and RMMCH.

Objectives

The primary objectives of this study are to**:**

- determine the ETT cuff pressures using an aneroid manometer.

The secondary objectives of this study are to**:**

- describe cuff inflation techniques used by anaesthetists
- compare ETT cuff pressures with cuff inflation techniques
- compare ETT cuff pressure measurements between junior and senior anaesthetists.

Research assumptions

The following definitions will be used in this study.

Anaesthetist: is any qualified doctor working in the Department of Anaesthesiology including interns, medical officers, registrars and consultants.

Intern: is a doctor who has completed a university degree but is currently undergoing practical training prior to registration with the Health Professions Council of South Africa as an independent practitioner.

Medical officer: is a qualified doctor practising in the Department of Anaesthesiology under specialist supervision. A medical officer with more than 10 years of experience is a career medical officer and are regarded as a consultant.

Registrar: is a qualified doctor who is registered with the Health Professions Council of South Africa as a trainee anaesthetist.

Anaesthesiologist: a qualified doctor who has registered with the Health Professions Council of South Africa as a specialist anaesthetist.

Consultant: is an anaesthesiologist or career medical officer.

Junior anaesthetist: is an intern, medical officer or registrar with three or less years of training.

Senior anaesthetist: is a registrar with more than three years of training or a consultant.

Recommended ETT cuff pressures: in this study will be within the range of 15 – 20 cm H_2O.

Child: in this study is a person 12 years and younger.

Caregiver: a person who factually cares for a child.

Demarcation of study field

The study will be conducted in the operating theatre complexes and diagnostic and intervention complexes at CMJAH; CHBAH and RMMCH. These three hospitals are affiliated to the Department of Anaesthesiology at the University of the Witwatersrand.

CMJAH is a 1200-bed central hospital. The hospital has 23 theatres. There are no dedicated paediatric theatres. On average 180 paediatric cases are done per month.

CHBAH is a 2888-bed central hospital. The hospital has 25 theatres. There are no dedicated paediatric theatres except for neonatal theatre in the maternity complex. On average 550 cases are done per month.

RMMCH is a 338-bed regional hospital. The hospital has 5 theatres, of which one is dedicated for paediatric cases. On average 120 paediatric cases are done per month.

The elective and emergency theatres where general; plastic; ear,nose and throat (ENT); maxillo-facial; orthopaedic; urological; neurosurgical; ophthalmology; trauma and burns procedures take place will be used. Diagnostic and intervention complexes where radiological

procedures such as computerised tomography (CT) and magnetic resonance imaging (MRI), bronchoscopic and audiology procedures will also be used.

Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. The CEO of CMJAH; the Medical Advisory Committee of CHBAH and the Research Committee of RMMCH were approached for permission to conduct the study at the hospitals (Appendix 1). The Heads of Departments of Anaesthesiology at CMJAH; CHBAH and RMMCH were approached for permission to conduct this study at the hospitals (Appendix 2).

The child's anaesthetist will be approached, the study will be explained, and the anaesthetist will be invited to take part in the study. If the anaesthetist agrees an information letter (Appendix 3) will be given and written consent obtained (Appendix 3).

Deferred consent and assent will be obtained in this study. The reason for deferred consent is because it is not known beforehand what airway device will be used for the child requiring a general anaesthetic. The caregiver will be approached post-operatively in the ward once the general anaesthetic has worn off, the study will be explained, and the caregiver will be asked if their child can take part in the study. If they agree the caregiver will receive an information letter (Appendix 4) and written consent obtained (Appendix 4). Should the caregiver agree, and the child is seven years or older the study will be explained, and the child will be invited to take part in the study. If the child agrees, the child will receive an information letter (Appendix 5) and be asked to sign an assent form (Appendix 5). If either the caregiver or the child decline participation, the child will be excluded from the study.

Anonymity and confidentiality of all study data will be ensured by collecting data with no identifying information on the data collection sheets (Appendix 6). Each study participant will be assigned a study number. A list with study numbers, names and hospital numbers will be kept separately. Only the researcher and supervisors will have access to the raw data.

The ETT cuff pressure will be communicated to the child's anaesthetist and if found to be outside the recommended range, will be adjusted if necessary.

Data will be stored securely for six years after completion of study in a locked cupboard. The study will be conducted according to the principles of the Declaration of Helsinki (2013) (29) and the South African Guidelines for Good Clinical Practice 2019 (30).

Research methodology

Research design

A prospective, contextual, descriptive research design will be followed in this study.

In a prospective study a sample population is selected and followed over time to determine outcomes (31). This study will be a prospective study measuring ETT cuff pressures in children undergoing general anaesthesia in the operating theatre complexes of CMJAH, CHBAH and RMMCH. Data will be collected at the time the study is being conducted.

This study will be contextual in design as it describes the practice of ETT cuff pressures and ETT cuff inflation techniques in children undergoing general anaesthesia in the operating theatre complexes of three academic hospitals in Johannesburg.

A descriptive design is used in studies where more information is required in a particular field through the provision of a picture of the phenomenon as it occurs naturally (32). This study will describe the ETT cuff pressures in children requiring general anaesthesia and describe the ETT cuff inflation techniques of anaesthetists at three academic hospitals.

Study population

Children 12 years and younger undergoing general anaesthesia with an ETT in situ in the operating theatre complexes of CMJAH, CHBAH and RMMCH.

Study sample

Sample size

In consultation with a biostatistician a sample size of 87 was calculated using EpiInfo version 7. Based on a recent study evaluating ETT cuff pressures in paediatrics (10) , a prevalence of 55% of ETT cuff pressures greater than 30 cm H_2O was used. A finite population of 850 was used, this represents the total number of expected paediatric patients requiring a general anaesthetic at the three hospitals in a month. A precision of 10% and confidence interval of 95% was used to calculate the sample size.

Sampling method

In this study, a convenience sampling method will be used. Convenience sampling is a subtype of non-random sampling where the most easily accessible individuals are used to obtain an estimate of a particular element of interest (32).

Inclusion and exclusion criteria

The inclusion criteria for this study are:

- children who require elective or emergency surgery
- under general anaesthesia
- with a cuffed ETT between sizes 3.0 – 6.5 mm
- in whom consent from the anaesthetist and caregiver and assent, where appropriate, is obtained.

The exclusion criteria in this study are:

- children brought to theatre or procedure room intubated
- those requiring a double-lumen ETT
- those with known anatomical abnormalities of the pharynx, larynx or trachea
- those with nasogastric tubes
- those whose anaesthetist has been included in the study more than three times.

Data collection

Data collection will commence once all approvals have been obtained.

The anaesthetic technique and drugs used at induction and maintenance will be at the discretion of the child's anaesthetist. If nitrous oxide is used for gas induction or co-induction it will be turned off just prior to intubation and once an end tidal nitrous oxide (etN_2O) concentration of zero is noted on the gas analyser, the ETT cuff will be inflated using the preferred method by the child's anaesthetist. Once the ETT is secured and the patient is stable, cuff pressure will be measured. If the researcher is not present at induction, the corresponding etN_2O concentration will be documented with the measured ETT cuff pressure.

Data will be collected by the researcher using a standardised data collection sheet (Appendix 6). Included are factors other than cuff inflation technique found to have affects on the ETT cuff pressure (33,34).

The following data will be collected:

- demographics
- age
- sex
- surgical procedure
- time from intubation to measurement of ETT cuff pressure
- ETT size and brand
- position of child's head
- use of nitrous oxide and etN_2O concentration if ETT cuff pressure measured during maintenance phase of anaesthesia.
- level of experience of child's anaesthetist
- actual ETT cuff pressure (in cm H_2O)

- cuff inflation technique used by the anaesthetist.

The ETT cuff pressure will be measured using an aneroid manometer from VBM Medizintechnik GmbH. The manometer will be calibrated by the manufacturer and requires no further calibration for use in this study. A standardised method to measure ETT cuff pressure will be used for all patients. The manometer will be connected to the pilot cuff and pressure measured at the end of expiration. If the measured ETT cuff pressure is found to be above or below the expected range, this will be communicated to the child's anaesthetist and the pressure adjusted accordingly.

Data analysis

A Microsoft Excel spreadsheet will be used to capture data. Data will be analysed in consultation with a biostatistician using the statistical program STATA version 13.1 (StataCorp, USA). Categorical variables will be reported using frequencies and percentages. Continuous variables will be described using means and standard deviations or median and interquartile ranges depending on the distribution of the data. Comparisons between two groups will be done using a t-test or Mann-Whitney test and between more than two groups using ANOVA or Kruskal-Wallis tests. A p-value of 0.05 or less will be considered statistically significant.

Significance of the study

ETTs is used on a daily basis in paediatric patients. If a cuffed ETT is used, there are no devices to measure pressures objectively in the operating theatre complexes of CMJAH, CHBAH and RMMCH. International and local data show a high prevalence of unsafe ETT cuff pressures when clinical estimation techniques are used for cuff inflation (33,34). There is no data on ETT cuff pressures in paediatric patients who present for surgery requiring general anaesthesia at these hospitals.

The results of this study will inform the departments of anaesthesiology at the three hospitals if the ETT cuff pressures in children are within the recommended safe range (27,28) or not. If the results show that the ETT cuff pressures are not within the recommended safe range, it can be recommended that manometers be acquired for the paediatric theatres. The results of this

study may also make anaesthetists more aware of the ETT cuff pressures of their patients and their ETT cuff inflation techniques and monitoring of ETT cuff pressures and this may influence patient safety and comfort.

Validity and reliability of the study

Validity of a study, according to Botma et al (31), indicates “whether the conclusions of the study are justified based on the design and interpretation” and reliability represents “the consistency of the measure achieved”.

Validity and reliability will be ensured by the following measures:

- using an appropriate research design
- determining sample size in consultation with a biostatistician
- using a measuring device calibrated by the manufacturer
- using the same measuring device for all the children in this study
- measuring ETT cuff pressures in a standardised manner by the researcher only
- analysing data in consultation with a biostatistician.

Potential limitations

The study design will be contextual between operating theatre complexes of only three hospitals in Johannesburg and may not reflect practice in other departments where paediatric intubation is required and in other hospitals within South Africa.

Project outline

Time frame

Activity	Jan 2020	Feb 2020	Mar 2020	April 2020	May 2020	June 2020	July 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020
Proposal preparation												
Literature review												
Proposal submission												
Ethics approval												
Postgraduate approval												
Data collection												
Data analysis												
Draft article												
Submission												

Budget

Item	Price per page	Number of pages	Copies	Total
Proposal	1	28	10	R 280
Post graduate form	1	2	6	R 12
Complete report	1	100	4	R 400
Aneroid Manometer				R2530
Grand total				**R 3222**

The Wits Department of Anaesthesiology will incur the costs of paper and printing of the proposal, the post-graduate application, information letters, consent forms and data collection sheets. The aneroid manometer device and complete report will be covered by the researcher.

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Appendix 3: Clearance from Human Research Ethics Committee

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Dr BB Naidoo

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200333

NAME: (Principal Investigator)	Dr BB Naidoo
DEPARTMENT:	School of Clinical Medicine Department of Anaesthesiology Medical School University
PROJECT TITLE:	*Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals*
DATE CONSIDERED:	2020/03/27
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof J Scribante; Ms H Perrie; Dr R Campbell
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2021/02/01

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

Appendix 4: Approval of Title

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

06 January 2021
Person No: 0600628N
PAG

Dr BB Naidoo
2 Beaumont Street
Oaklands
Oaklands
2192
South Africa

Dear Dr Bianca Naidoo

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals.* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 5: Permission from Medical Advisory Board

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 3rd August 2020

TITLE OF PROJECT:

Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

UNIVERSITY: Witswatersrand

Principal Investigator: Dr Boodaya Naidoo

Department: Anaesthesia

Supervisor : Dr J Scribante

Permission Head Department (where research conducted): Yes

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Academic Hospital. The CEO / management of Chris Hani Baragwanath Academic Hospital is accordingly informed and the study is subject to:-

- **Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.**
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee Approval.

.....
Recommended
(On behalf of the MAC)
Date: 3/8/2020

.....
Approved/Not Approved
Hospital Management
Date: 2020/08/27

Appendix 6: Letter of permission from HOD Anaesthesiology at CHBAH

Bianca B. Naidoo

0600628N Tel 072 0136495 Email bianca.boodaya@gmail.com

27 January 2020

Dr D. Lines

Head of Department of Anaesthesiology

Chris Hani Baragwanath Academic Hospital

RE: Permission to conduct research study

Dear Dr D. Lines,

I am writing to request permission to conduct research at your institution. I am currently enrolled in the MMed programme in the Department of Anaesthesiology at the University of the Witwatersrand. I am registered with the HPCSA (number: MP0787183). The study is entitled: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals.

The approximate time frame to obtain my sample size for data collection will be from February 2020 until May 2020. The information obtained during this time will be confidential and used for research purposes only. This study will be of no cost to your department.

Your approval to conduct this study will be greatly appreciated. Please do not hesitate to contact me for any further questions.

Sincerely,

Dr B.B. Naidoo
0600628N
HPCSA MP0787183

Dear Dr. B. Naidoo

Permission is hereby granted to conduct your research in the department of anaesthesiology at CHBAH

29/01/2020

DR. D. LINES

Appendix 7: Information sheet and consent form for anaesthetist

Study title: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

Dear Colleague,

My name is Bianca and I am currently a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I am conducting a research project for my MMed on endotracheal tube (ETT) cuff pressures in paediatric patients undergoing general anaesthesia for surgery. I would like to invite you to take part in my study.

This is a prospective, descriptive study where I will be looking at ETT cuff pressures in all paediatric patients undergoing general anaesthesia. I will use a manometer from (company) to measure cuff pressures at the end of expiration. The ETT cuff pressure will be communicated with you and adjusted if necessary.

You will be asked what cuff inflation technique was used and this will be documented along with the ETT cuff pressure and your level of training. There will be no personal details documented.

You are allowed to withdraw from the study at any time and there will be no consequences.

Please do not hesitate to contact me for any further questions. Professor CB Penny, the chairperson of the Human Research Ethics Committee (Medical) at the University of the Waterwatersrand can be contacted on telephone 011 717 2301 or email Clement.Penny@wits.ac.za. Alternatively, the committee secretariat- Ms. Zanele Ndlovu on 011 717 2700 or email Zanele.Ndlovu@wits.ac.za or Mr Rhulani Mkansi on 011 717 1234 or email Rhulani.Mkansi@wits.ac.za.

Thank you for taking part in this research project.

Regards

Bianca B. Naidoo

Tel 010-900-0160

Email bianca.boodaya@gmail.com

Study title: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

I, …… (title and name) understand the attached information letter. I was also given the opportunity to ask any questions and these have been answered to my satisfaction. I understand the purpose of the study and the intended outcomes. I have also been informed that I am taking part in this study voluntarily and can withdraw consent at any time without any consequences. I have been given adequate contact information for any further questions.

I give consent to participate in this study.

……

(Participant name)

……

(Date)

……

(Researcher name)

……

(Date)

Appendix 8: Information sheet and consent form for caregiver

Study title: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

Hello,

My name is Bianca and I am a doctor in anaesthesia at the University of the Witwatersrand. My job is to help put people to sleep. I am conducting research as part of my master's degree in medicine. My research topic is on tubes we put in children's throats to protect their breathing pipe when they come to theatre for operations. I would like to invite you to allow your child to participate in the study.

The tube is placed in the throat to help your child breathe while they are sleeping during the operation. At the end of the tube is a small balloon which is blown up with air to keep the oxygen and sleeping gas only in the lungs. This balloon also protects the lungs from any food or water which can come up into the lungs from the stomach.

I will measure the pressure in this balloon, and I will let your child's anaesthetist know and they will decide to change it if it is too high or too low. I would like to use this information in my study so that we can learn from it. This information will be of benefit to your child and it may help to get the measuring device available so that all children can benefit in the future.

All information is kept confidential and I will not mention any personal details in my report. You do not have to allow your child take to part in this study. There will be no changes to your child's treatment if you do not give permission for them to participate and the information I get from your child will not be used in my study.

Please do not hesitate to contact me for any further questions. Professor CB Penny, the chairperson of the Human Research Ethics Committee (Medical) at the University of the Waterwatersrand can be contacted on telephone 011 717 2301 or email Clement.Penny@wits.ac.za. Alternatively, the committee secretariat- Ms. Zanele Ndlovu on 011 717 2700 or email Zanele.Ndlovu@wits.ac.za or Mr Rhulani Mkansi on 011 717 1234 or email Rhulani.Mkansi@wits.ac.za.

Thank you for your help.

Bianca B. Naidoo

Tel 010-900-0160

Email bianca.boodaya@gmail.com

Study title: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

I …… (name), parent to …… (study participant) understand the contents of the information letter attached. I had the opportunity to ask questions, and these were answered satisfactorily. I understand the purpose of the study and that personal information will be kept confidential. I was also explained that I am taking part voluntarily and can withdraw consent at any time without any consequence. I have been given adequate contact details for further questions.

I hereby give consent to take part in this study.

……

(Parent name)

……

(Signature)

……

(Date)

……

(Place)

……

(Researcher name)

……

(Date)

……

(Witness name)

……

(Signature)

……

(Date)

Appendix 9: Information sheet and consent form for child

Study title: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

Hello,

My name is Bianca and I am a doctor training at hospitals in Johannesburg. I help put people to sleep for their operations.

When you come to theatre there is a doctor like me, who also puts people to sleep and they need to decide how they are going to keep you asleep. We use different kinds of plastic tubes that we place into your mouth so that we can pass our sleeping gases from our anaesthetic machine into your lungs and that's how we keep you asleep. Have you ever choked before and sometimes you feel the wonderful meal you just ate slowly comes upward in the wrong direction? Well when you sleep, we also need to protect your lungs from that! We do this by blowing up a small balloon at the end of our plastic tube. If we blow the balloon up too much or too little it doesn't do its job properly. I want to see how big the balloon on your tube is blown up to and to make it the correct size if it is not. You won't feel anything while I do this because you will be asleep.

All your details will be a kept a secret and nobody will know you participated in my study.

Please write your name on the assent form to allow me to use your information in my study. You are allowed to say no, and this will not change anything to your treatment plan. Please make sure you understand everything I have said, and you can always ask me questions in the future. If you choose not to share your information, I will not use it in my study.

Please do not hesitate to contact me for any further questions. Professor CB Penny, the chairperson of the Human Research Ethics Committee (Medical) at the University of the Waterwatersrand can be contacted on telephone 011 717 2301 or email Clement.Penny@wits.ac.za. Alternatively, the committee secretariat- Ms. Zanele Ndlovu on 011 717 2700 or email Zanele.Ndlovu@wits.ac.za or Mr Rhulani Mkansi on 011 717 1234 or email Rhulani.Mkansi@wits.ac.za.

Thank you.

Bianca B. Naidoo

Tel 010-900-0160

Email bianca.boodaya@gmail.com

Study title: Endotracheal cuff pressures in paediatric patients undergoing general anaesthesia at three academic hospitals

I ..... (name) am happy to participate in this study. I understand that I will not be hurt while the size of the balloon is measured. All my questions have been answered. I understand why the study is being done. I know my details will be kept secret and that I can say I do not want to be part of this study at any time without any change to my treatment. I have been given enough contact details should I have any questions in the future.

.....

(Participant name)

.....

(Signature)

.....

(Date)

.....

(Parent name)

.....

(Signature)

.....

(Date)

.....

(Researcher name)

.....

(Signature)

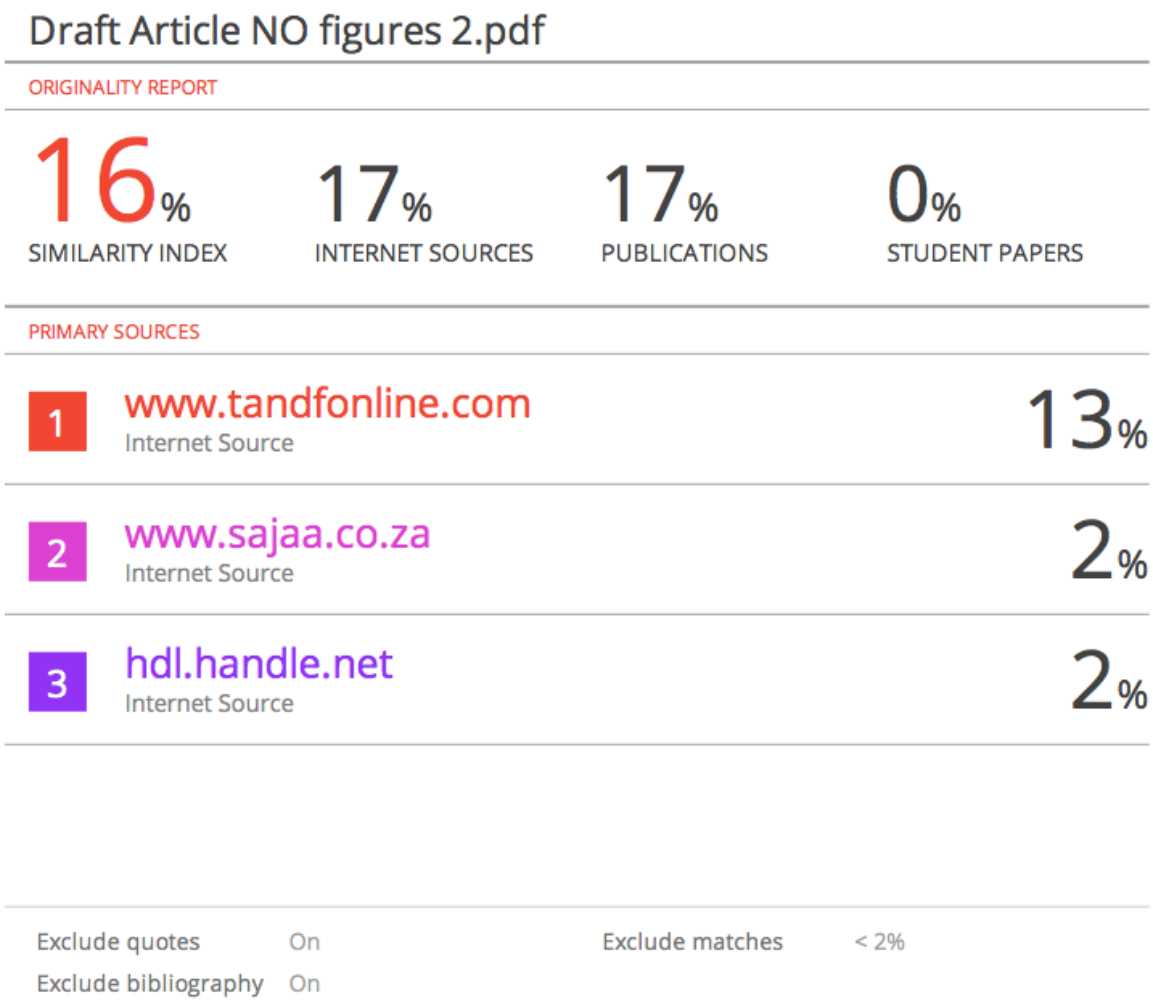
.....

(Date)

Appendix 10: Data collection sheet

STUDY PARTICIPANT NUMBER	
AGE	☐ months/years
SEX	M/F
SURGERY	
TIME FROM INTUBATION TO ETT CUFF PRESSURE MEASUREMENT	☐ min
ETT SIZE	☐ mm
ETT BRAND	
POSITION OF HEAD AND NECK	Supine ☐ Prone ☐ Neutral ☐ Flexed ☐ Extended ☐ Lateral rotation ☐
NITROUS OXIDE USED DURING MAINTENANCE? **IF YES, ETN_2O CONCENTRATION:**	Y/N ☐ %
ANAESTHETIST LEVEL OF TRAINING	Intern ☐ Medical Officer ☐ Registrar First year ☐ Second year ☐ Third year ☐ Final year ☐ Consultant
MEASURED ETT CUFF PRESSURE	☐ cm H_2O
CUFF INFLATION TECHNIQUE	Aneroid manometer ☐ MOV ☐ MLT ☐ Palpation of pilot balloon ☐ Other:

Appendix 11: Turnitin report



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