**A comparison of the pressures inside paediatric endotracheal cuffs filled with air or saline during aeromedical transport**

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**Study Investigators**

Principal Investigator: Dr Chris HandsI (Fellow, PICU)

ChHands@adhb.govt.nz

Co-Investigators:

Dr David BuckleyI (Consultant, PICU)

DavidB@adhb.govt.nz

Di FullerI (Nurse Specialist Transport, PICU)

DianeF@adhb.govt.nz

1. Starship Child Health, Te Whatu Ora - Health New Zealand, Te Toka Tumai Auckland

**Introduction**

Endotracheal tubes used for mechanical ventilation in critically ill paediatric patients are often fitted with a cuff. Cuffed tubes are less likely to be used in younger patients, but their use becomes increasingly likely over the age of one year. Cuff pressures are measured as part of standard care in intensive care units, as a high pressure in the cuff entails a risk of damaging the tracheal mucosa. Blood flow in the tracheal wall is compromised at cuff pressures greater than 30cmH2O and ceases at the critical perfusion pressure of 50cmH2O.1 These pressures may be lower in children, particularly those with cardiovascular compromise. PICU guidelines suggest inflating the cuff to 15 cmH20, and reviewing the cuff pressure once it rises above 25 cmH2O. Aeromedical transport introduces a new risk, as during ascent there may be rapid change of the relative pressures of the gas in the cuff and the surrounding atmosphere, leading to very high pressures inside the cuff.

Historically the cuffs of endotracheal tubes of mechanically ventilated children have been filled with saline prior to aeromedical transport in order to limit increases in pressure during ascent, although some paediatric and neonatal transport services in Australasia fill the cuffs with air and periodically monitor the cuff pressure. There are data to demonstrate1 2 3 the pressure changes at altitude associated with different strategies for endotracheal cuff inflation in artificial models of adult and child tracheas. However there are few paediatric data derived from patient observations to describe the pressure changes that occur in a patient’s trachea at altitude with air-filled or saline-filled endotracheal tube cuffs. This study aims to describe the measured pressures in the tracheal tube cuffs of paediatric patients undergoing aeromedical transport when filled with either air or saline, to provide empirical data on which practice can be based.

**Background**

Smith and McArdle’s[[1]](#endnote-1) work in a simulated altitude chamber suggests that the adult tracheal critical perfusion pressure (50cmH20) is reached between 2000 and 3000 feet altitude using a model of an adult trachea with air in the ETT cuff. With saline in the cuff, the tracheal critical perfusion pressure was reached at an altitude of 8000ft with one brand of ETT, whilst it was not reached with two of the cuff brands tested. Britton et al[[2]](#endnote-2) used a model simulated trachea and compared fixed air volume vs manual adjustment vs pressure control device vs fixed saline volume. Initial pressures when the cuffs were filled with saline were measured at 40mmHg = 54cmH2O and 21mmHg in the air-filled cuffs (28cmH2O). There was minimal variation in the pressure in the saline-filled cuffs thereafter, whilst the air-filled cuffs showed huge variation – the pressure-easy system mitigated that variation effectively. Extrapolating from this information, the authors suggested that if saline is to be used, the cuff should first be filled with air and that volume should be measured. The air should be removed, and the equivalent volume of saline should be injected.

Orsborn et al[[3]](#endnote-3) studied cuff pressures in a model paediatric trachea. Their model showed that air-filled paediatric cuffs quickly exceed recommended inflation pressure above an altitude of 1500ft. Kendrick et al,[[4]](#endnote-4) using models of a 1 year-old’s and 2 year-old’s trachea (with an uninflated cuff placed in the 1 year-old model), also showed that pressures in both rose rapidly, demonstrating need for active management of cuff volumes/pressures on ascent.

There are few published data on the pressures in the endotracheal cuffs of ventilated paediatric patients undergoing aeromedical transport. The studies that exist have used model tracheas which may not exhibit the same physical characteristics as a human trachea. There is variation in practice between different services which is driven by a paucity of experimental data on the benefits of saline vs air for paediatric patients. This study aims to provide data from patients being transported to inform the safest practice.

**Aims**

This study aims to obtain accurate information on the pressure changes that occur in paediatric endotracheal tube cuffs filled with either air or saline during aeromedical transport.

**Objectives**

To measure the changes in pressure in endotracheal tube cuffs filled with air or saline during aeromedical transport of paediatric patients.

**Hypothesis**

Null hypothesis: there will be no difference in the variation in pressures during ascent and descent in cuffs filled with air versus cuffs filled with saline.

**Study Design**

This is an open-label, randomised, study to evaluate pressure changes that occur in paediatric endotracheal tube cuffs filled with either air vs saline during aeromedical transport.

**Study Setting**

The study will be carried out by the Starship PICU transport service, which undertakes aeromedical transports to and from hospitals across New Zealand. Study participants may be recruited from any hospital site in New Zealand that refers a mechanically ventilated patient for retrieval by the PICU transport service.

**Study Population**

Patients referred to the Starship PICU transport team.

**Eligibility Criteria**

*Inclusion criteria*

Patients aged 0 – 15 years being mechanically ventilated during aeromedical transport.

*Exclusion criteria*

1. Patients supported with non-invasive ventilation
2. Patients intubated with an uncuffed tracheal tube
3. Where patients have conditions that are complex to monitor and to manage, the feasibility of conducting the study under these conditions will be assessed by the clinical team and a decision taken as to whether the patient should be excluded

**Study Outcomes**

This study will provide objective data on the changes in endotracheal tube cuff pressure in mechanically ventilated patients during ascent, cruising and descent, in cuffs filled with air and saline. This will allow the development of evidence-based protocols for the management of paediatric endotracheal tube cuffs during aeromedical transport.

**Study Procedures**

*Recruitment of participants*

A series of 40 patients aged 15 and under will be recruited from those transported by the Starship paediatric intensive care transport service on rotary wing and fixed wing flights. Only those patients who are mechanically ventilated will be eligible for the study. When the transport is confirmed, a member of the transport team (transport registrar, consultant, or nurse) will call the referring hospital and explain the study to the patient’s caregiver. They will also email a copy of the patient information sheet to the doctor or nurse caring for the patient at the referring hospital, to ensure that they have the greatest possible information and time to consider their child’s participation in the study. Informed consent will then be gained by the transport team (usually the transport registrar) from the patient’s parent(s) or other legal guardian after arrival at the referring hospital and before departure from the referring hospital. The purpose and processes of the study will be described to the caregiver of each patient who meets the inclusion criteria during the study period. The patient’s caregiver will also be given a written participant information sheet, and it will be explained that they will be able to withdraw their consent at any time. If the caregiver consents to the child’s participation, the patient will be enrolled in the study and randomised to air or saline in the endotracheal cuff.

*Randomisation*

After consent, participants will be randomised to either an air-filled endotracheal tube cuff or a saline-filled endotracheal tube cuff. The clinical charge nurse in PICU will be informed that consent has been given and that randomisation is required. Randomisation will be performed using computer software in PICU and the study arm allocation will be communicated to the transport team by the clinical charge nurse.

*Study procedure and measurements*

The patients will be intubated by the treating team at the referring hospital; this is standard practice. On occasion the transport team may intubate the patient; this will not affect the other study procedures. The internal diameter and manufacturer of the tube, as well as the type of cuff on the tube, will be recorded by the transport team. Twenty patients will be managed with air-filled cuffs and 20 with saline-filled cuffs. The tracheal tube cuff will initially be inflated to 15 cmH2O. The pilots will be briefed before take-off about the need to inform the transport team when cruising altitude has been reached, when descent begins, of the changes in altitude during ascent and descent, and of any other changes in altitude. The altitude will be recorded every two minutes during ascent and descent; other changes during flight will also be recorded. The pressure in the cuff will be continuously monitored using a standard pressure transducer and the pressure recorded every ten minutes (every two minutes during ascent and descent). If the measured cuff pressure reaches 30 cmH2O, air or saline will be removed from the cuff in 0.2 ml increments until the cuff pressure falls to 25 cmH20. If the cuff pressure falls below 15 cmH2O (as it may do on descent), air or saline will be re-instilled into the cuff until the cuff pressure reaches 15 cmH2O. A pressure of 15 cmH2O is the standard minimum cuff pressure to minimise leak around the cuff in paediatric patients.[[5]](#endnote-5) [[6]](#endnote-6) The cabin pressure at cruising altitude will be recorded for each patient.

The demographic data for each participant will be recorded on a research chart identified only by study number. The physiological data for each participant will be recorded on a standard transport chart separate to the main clinical record, and again will be identified only by study number. The data will be uploaded to a secure database (REDCap), and the original paper charts will be kept in a locked filing cabinet on PICU until all data entry and analysis is complete, at which point they will be destroyed. A record will be kept linking each patient’s study number to their National Health Index (NHI) number, which will also be held on the secure database.

*Safety considerations*

As per the procedure described above, the pressure in the endotracheal tube cuff will be monitored frequently during ascent and descent. The strategy will allow the team to identify when the cuff pressure has increased beyond the normal upper limit but has not yet reached the tracheal critical perfusion pressure and to intervene before that pressure is reached, so that the pattern of pressure change can be identified, but patient safety is not compromised.

When the PICU team transports patients who have complex disease or a multi-system disorder, it is possible that that the serial measurements of the patient’s tracheal tube cuff pressure might interfere with other necessary clinical measurements. If it becomes apparent during the flight that measuring the endotracheal tube cuff pressure is interfering with any other aspect of care, the measurements will be discontinued and the patient will be excluded from the study. The measurements taken up to that point will be reviewed by the PI to assess whether there is any signal that suggests there may be a risk associated with the method of tracheal tube cuff insufflation.

*Data Management Plan*

A data management plan has been developed for this study as a separate document.

*Data monitoring*

The data from each patient included in the study will be reviewed by a member of the research team within one week of the measurements being taken, to identify trends in the pressures within air- or saline-filled cuffs, and any instances of the pressures rising above the tracheal critical perfusion pressure.

A safety monitoring committee (including the medical and nursing leads for transport in PICU) will meet once a month to review the study data. The following rules for early conclusion of the study will be observed:

1. One study arm shows tracheal tube cuff pressures rising to >30 cmH2O for >10 minutes in multiple patients
2. One study arm consistently demonstrates tracheal tube cuff pressures <30 cmH2O whilst the other consistently demonstrates pressures rises > 30 cmH2O

*Sample size*

The data will be analysed to identify the range of ETT cuff pressure at different altitudes in the context of:

1. Air in the cuff
2. Saline in the cuff
3. Age and weight of the participant

Extrapolating from Britton et al’s3 data showing minimal change in the pressure in saline-filled cuffs and a large difference in pressure in the air-filled cuffs following ascent, we have calculated that sample size of 17 patients in each group has 80% power to detect a mean difference between air-filled cuffs and saline-filled cuffs of 10 cmH2O following ascent to cruising altitude with a medium effect size of 0.5.

*Statistical methods*

All data will be represented as mean ± standard deviation (SD) or Median (Inter-Quartile Range) for continuous variables and counts (percentages) for categorical variables. Generalised linear model (GLM) will be carried out to investigate the association between the outcomes of interest (the mean pressure recorded in saline and air-filled cuffs) during aeromedical transport (ascent, cruising, and decent) as described in Aims. A p-value less than 0.05 will be considered statistically significant.

**Ethical Considerations**

The study will be conducted in full compliance with the principles of the Declaration of Helsinki and Good Clinical Practice, and with the laws and regulations of New Zealand. This study will have received approval from an institutional or national ethics committee and locality approval before commencing.

The purpose and processes of the study will be described to the parents of each patient who meets the inclusion criteria during the study period. The patient’s parents will also be given a written participant information sheet, and it will be explained that they will be able to withdraw their consent at any time. If the parents agree to their child’s participation, they will be enrolled in the study and randomised to air or saline in the endotracheal cuff.

Participants will not be placed at risk of harm as a consequence of participation in the study, as both methods being investigated are currently accepted standards of care. Participation will mean that the endotracheal tube cuff pressure will be monitored more carefully than is standard practice.

In principle it is possible that the repeated measurements required for the study could interfere with the taking of other measurements that are required for the care of the patient, but patients needing more frequent observations due to their clinical complexity will be excluded from the study. Furthermore, if it becomes apparent during the flight that measuring the endotracheal tube cuff pressure is interfering with any other aspect of care, the measurements will be discontinued and the participant will be withdrawn from the study.

1. Smith RP, McArdle BH. Pressure in the cuffs of tracheal tubes at altitude. Anaesthesia. 2002 Apr;57(4):374-8. [↑](#endnote-ref-1)
2. 2 Britton T, Blakeman TC, Eggert J, Rodriquez D, Ortiz H, Branson RD. Managing endotracheal tube cuff pressure at altitude: a comparison of four methods. J Trauma Acute Care Surg. 2014 Sep;77(3 Suppl 2):S240-4. [↑](#endnote-ref-2)
3. Orsborn J, Graham J, Moss M, Melguizo M, Nick T, Stroud M. Pediatric Endotracheal Tube Cuff Pressures During Aeromedical Transport. Pediatr Emerg Care. 2016 Jan;32(1):20-2. [↑](#endnote-ref-3)
4. Kendrick, T. Thomas, E. Spears, K. & Grattan-Smith, T (2011) Paediatric endotracheal tube (ETT) cuff pressure at altitude during rotary wing retrieval: An in-vitro study. Australian Critical Care. 25(2):126. [↑](#endnote-ref-4)
5. Weiss M, Dullenkopf A, Fischer JE, Keller C, Gerber AC; European Paediatric Endotracheal Intubation Study Group. Prospective randomized controlled multi-centre trial of cuffed or uncuffed endotracheal tubes in small children. Br J Anaesth. 2009 Dec;103(6):867-73. [↑](#endnote-ref-5)
6. Chand R, Roy Chowdhury S, Rupert E, Mandal CK, Narayan P. Benefits of Using High-Volume-Low-Pressure Tracheal Tube in Children Undergoing Congenital Cardiac Surgery: Evidence From a Prospective Randomized Study. Semin Cardiothorac Vasc Anesth. 2018 Sep;22(3):300-305. [↑](#endnote-ref-6)