AIRWAY OXYGEN CONCENTRATION WITH HIGH FLOW NASAL OXYGEN

Project Summary

This is an observational study looking at patients undergoing airway surgery where High Flow Nasal Oxygen (HFNO) is used for patient oxygenation during a period of sustained apnoea.

The study aims to characterise the change in O2 concentration in the airway when an O2 delivered by HFNO is decreased from 100% down to 30%

This will enable us to objectively quantify oxygen levels at the surgical site when HFNO is being used to provide sustained apnoeic oxygenation

As such it is anticipated that the study will represent a valuable contribution to patient safety by informing strategies that ensure safe and optimal surgical conditions during airway surgery in the presence of an ignition source.

Investigators

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Rationale and Background Information

Shared airway surgery is a challenge for both surgeons and anaesthetists. Recently, an emerging technique using HFNO has gained increasing popularity for its utility in providing sustained humidified oxygenation with an open anaesthetic circuit providing an immobile surgical field free from anaesthetic devices.

Patel was the first to describe an HFNO-based apnoeic technique, Transnasal Humidified Rapid Insufflation Ventilatory Exchange (THRIVE), in 2015. They demonstrated that they were able to successfully use HFNO to achieve pre-oxygenation and sustained apnoeic oxygenation in patients with difficult airways undergoing airway surgery[1]. Since then it has been used successfully in case series of patients undergoing apnoeic oxygenation for subglottic stenosis surgery[2], and hypopharyngeal and laryngotracheal surgery[3].
In these latter publications improved surgical conditions with better field of view, better accessibility and less vibration were reported, compared to standard anaesthetic techniques[3].

THRIVE and related HFNO techniques involve the use of specialised nasal cannulae, which deliver up to 70L/min of humidified gas to the apnoeic patient. The continuous insufflation of gases achieves a continuous positive airway pressure of around 7cmH20[4] which is thought to splint the upper airway open and reduce respiratory shunting[5,6].
It has been demonstrated that the rate of CO2 rise with HFNO techniques is significantly less than that of patients undergoing classic (low flow) apnoeic oxygenation, suggesting that aventilatory mass flow is an incomplete explanation for the physiological basis of the technique[1,3]. One hypothesis is that the combined effect of both the high flows and CPAP facilitate oxygenation and CO2 clearance through gaseous mixing and flushing of deadspace[1].

As well as providing advantageous operating conditions, HFNO potentially avoids a number of the issues associated with jet ventilation including barotrauma (eg. pneumothorax, pneumomediastinum and surgical emphysema), dessication and hypoxia[7]. Furthermore, the presence of any device in the airway, even those deemed laser resistant, is a potential source of fuel in the presence of high O2 concentration and an ignition source[8]. HFNO is considered a 'tubeless technique' in that there are no non-surgical devices in the surgical field.

Airway fire is a feared event in airway surgery. The generation of fire requires three components known as the 'fire triad': An oxidiser, an ignition source and fuel[9]. A recent communication from the Australian and NZ College of Anaesthetists (ANZCA) raised the concern that increasing use of HFNO-based techniques may be associated with increased fires, as there is the potential for an oxygen enriched environment to exist at the surgical site where an ignition source is being used. In this context charred debris from burn tissue may provide a source of fuel to complete the triad[10]. Since HFNO has gained traction as a favourable technique for airway surgery there has been one case report of a monopolar diathermy tip arcing and leading to

a brief ignition on the diathermy grip[11]. In this report the FiO2 was 1.0 at the time of the incident.

To ensure safe airway surgery in the advent of this new technique it is important that any potential risks, and strategies to mitigate those risks, are well described.

International guidelines on OT fire prevention have reinforced that an FiO2 <0.3 is the 'safe' threshold for any surgery in the presence of an ignition source[9]. The recent ANZCA communication recommended that an air-oxygen blender be used with HFNO when performing airway surgery in order to reduce the FiO2 to the lowest possible value.
However with open O2 sources such as HFNO it is poorly characterised how long it takes for the O2 concentration at the relevant site (ie the surgical site) to decrease when delivered FiO2 is decreased, or indeed if it decreases at all and by how much. The 2013 ASA practise advisory document makes recommendations on timing based on what a small panel "believe is needed to reduce oxygen…concentration to a safe level" but suggest 1-5 minutes from turning down to FiO2 to using an ignition source[9]. The ANZCA communication suggests '2-3 minutes' but again without providing any objective evidence for this suggestion.

There is a clear need for systematic evaluation of gas concentrations at the relevant surgical site when HFNO is being used to provide sustained oxygenation. This will allow informed clinical decision making when providing anaesthetic care for airway surgery that is both surgically optimal, and most importantly, safe.

Study Goals and Objectives

The objective of this study is to evaluate the change in oxygen concentration in the larynx and trachea when O2 delivered by HFNO is reduced from 100% to 30%

Study Design

This is an observational, non-interventional study on patients undergoing planned hypopharyngeal or laryngotracheal surgery. The standard of anaesthetic care at our and many other institutions is for these patients to undergo apnoeic oxygenation using HFNO as outlined above. Study participants will undergo measurement of the oxygen levels in the airway during their planned surgery.

Participants

Adult patients undergoing elective hypopharyngeal or laryngotracheal surgery at Christchurch Public Hospital will be screened to participate in this study. Initially 10 patients will be recruited over a 6 month period.

Inclusion Criteria

Those included in the study will

- Be undergoing elective hypopharyngeal or laryngotracheal surgery where apnoeic oxygenation with HFNO is the chosen anaesthetic technique
- Be aged 18-75 years
- Be ASA 1-3

Exclusion criteria

- Unable to give valid consent
- BMI >35
- Not otherwise suitable for THRIVE technique as deemed by anaesthetist

Expected duration of study

It is expected the study will begin in September 2018 and continue for 6 months over which time we will recruit 10 patients

Recruitment

Patients will be invited to participate in the study at their pre-operative consultation with an anaesthetist.

At the point of recruitment they will undergo a brief screen for exclusion criteria carried out by the recruiter.
Once recruited, they will be given a patient information sheet (see appendix) and informed consent will be obtained.

Methodology

Anaesthetic and surgical technique

This will be as per the established technique for hypopharyngeal and laryngotracheal surgery at Christchurch Public Hospital (CPH).
Peripheral venous access will be secured prior to induction and monitoring applied as per ANZCA standards (REF), plus depth of anaesthesia monitoring and neuromuscular blockade monitoring.
The patient will be preoxygenated with 100% O2 via using Optiflow™ (Fisher & Paykel Healthcare, Auckland, New Zealand) at 30L/min for 3 minutes while awake and spontaneously ventilating.
Anaesthesia will be induced with propofol and remifentanil target controlled infusions (Alaris® PK syringe pump, Cardinal Health, Rolle, Switzerland) and rocuronium 0.5mg/kg. Following induction O2 will be increased to 70L/min
Once paralysis has taken effect direct laryngoscopy will be performed and the vocal cords sprayed with 4% lignocaine using a laryngotracheal topicalisation device.
Airway patency will be maintained using a jaw thrust until suspension laryngoscopy is performed.
Under general anaesthetic, direct suspension laryngoscopy will be performed, at which point airway oxygen concentration analysis will be performed, followed by surgery.

During the procedure, ECG, SpO2 and depth of anaesthesia will be measured continuously, non-invasive BP every 5 minutes and muscle twitch train of four (TOF) every minute.

Patients will receive 1mcg/kg Fentanyl and 0.1mg/kg Dexamethasone. Neuromuscular blockade will be reversed at the end of the procedure with Sugammadex 2mg/kg.

Following cessation of surgery the airway will be repossessed by the anaesthetist and the patient will be mask ventilated until spontaneous breathing is established. At this point the patient will be transferred to the Post Anaesthetic Care Unit for standard post operative cares.

Airway Oxygen Concentration Analysis
Following suspension laryngoscopy and prior to surgery being performed a dedicated filtered gas analysis line will be passed into the airway using surgical forceps to **1 cm** beyond the end of the rigid larygnoscope.

Using an Oxygen Blender () the delivered oxygen concentration will be reduced to 30%. Flows will remain at 70L/minute. After 60 seconds the delivered oxygen concentration will be restored to 100%. Airway oxygen concentration at the distal tip of the gas sampling line will be measured throughout.

This process will be repeated with the distal tip of the gas sampling line 6 **cm** beyond the end of the laryngoscope.

Discontinuation criteria
Unanticipated difficulty maintaining a patent airway
SpO2 <92%
Occurrence of malignant dysrhythmias

If any of these criteria are encountered the apnoeic period will be ended by intubation with an endotracheal tube and manual ventilation, or by jet ventilation.

Outcomes

Primary Outcome

The primary outcome of this study is the change in O2 concentration within the airway when delivered O2 is decreased from 100% to 30%

This will be considered in terms of

- the absolute change after 60 seconds
- the rate of change (%.second^{-1})

Secondary Outcomes

Apnoeic time (minutes)

Lowest recorded SpO2

Change of anaesthetic technique

Data management and statistics

Data management

Data will be collected prospectively using a standard proforma.

We will record the following baseline data

- Patient demographics
- Patient ASA
- Patient BMI
- Surgery being undertaken
- Intraoperative complications
- Post operative complications

Data Entry and Storage

Data will be entered by one of the investigators (PJ) into the study database (Numbers 5.0.1, Apple inc), which will be password protected.

Statistics

The primary outcomes of this study are descriptive and therefore no power analysis was done. We plan to recruit 10 patients to target the primary outcome

Expected outcomes of the study

It is expected that this study will provide quantitative information about the oxygen concentration at the surgical site in patients undergoing airway surgery with apnoeic oxygenation using HFNO.

In particular, the absolute change and rate of change of oxygen concentration within the airway, in response to a change in delivered O2, will be quantified.

It is also expected that this study will provide objective information on the consequences of oxygen delivered by HFNO being transiently reduced.

In particular, patient saturation and any change in technique will be observed.

Quality Assurance

This study proposal will be peer reviewed by two clinicians with expertise in this area of research. The study will be submitted to HDEC for ethical approval and to the CDHB research committee for consultation and approval

Ethics

This is an observational study and perioperative management of participants will be essentially identical to that received if they were not in the study. The differences are very minor and are not anticipated to have any impact on the wellbeing of the study participants or the ability of the anaesthetist or institution to provide an expected standard of care. These include **Increased duration of procedure:** Time under anaesthesia may be increased by a maximum of 5 minutes to allow measurement of O2 concentration. In the context of a 30-40 minute procedure this is considered insignificant.

Placement of gas analysis line in airway: the gas analysis line used for O2 concentration measurement is made of soft atraumatic PET and will be surgically placed by long forceps, which are a routine instrument in airway surgery.

Requirement for two anaesthetists: Accurate measurement will necessitate the presence of 2 anaesthetists. This is likely to be one consultant anaesthetist and one trainee, as is a common staffing pattern in airway lists at CDHB

Recruitment and consent: Care will be taken to ensure there is no undue influence exerted on patients in the recruitment process. The study will be described as purely voluntary, and if participation is declined they will continue to receive standard-of-care treatment.

References

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6. Duncan, Steven R. et al. "Nasal Continuous Positive Airway Pressure In Atelectasis." *Chest* 92.4 (1987): 621-624.

7. Cook, T.M., and R. Alexander. "Major Complications During Anaesthesia For Elective Laryngeal Surgery In The UK: A National Survey Of The Use Of High-Pressure Source Ventilation." *British Journal of Anaesthesia* 101.2 (2008): 266-272.
8. Roy, Soham, and Lee P. Smith. "Surgical Fires In Laser Laryngeal Surgery." *Otolaryngology-Head and Neck Surgery* 152.1 (2014): 67-72.
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12. "PS 18 - Recommendations On Monitoring During Anaesthesia." *ANZCA professional document* August 2008.Republished 2013 (2013)

Appendices

Appendix 1. Participant consent form

Consent form Version 1 25.07.2018

PARTICIPANT CONSENT FORM

Airway Oxygen Concentration with High Flow Nasal Oxygen

Location: Christchurch Public Hospital

Lead Investigator:
Dr Nick Abbott
Christchurch hospital department of anaesthesia
Phone 021373537

Once signed this form will be stored in a secure place for ten years

If you need an INTERPRETER, please tell us.

Name of Participant.....

1. I have read and understand the participant information sheet provided

2. I have had sufficient time to discuss my participation in this study with the researchers and any support people of my choosing, and have had the opportunity to ask questions

3. To the best of my knowledge I fit the criteria for inclusion in this study as outlined in the information sheet

4. I know that participation in the study is entirely voluntary and that I am free to withdraw from the study at any time without disadvantage

5. I understand that if I withdraw from the study all information collected up until the time of my withdrawal will be kept by the investigators

6. I understand the results of the study may be published and available in the University of Otago library

7. I understand there is no payment for the study and that no commercial use will be made of the data

8. I understand the researchers may access my medical records

9. I wish to receive a summary of the results of this study.
   Yes ☐ **No** ☐

10. I give permission for my participation in this study

Signature of participant | Date

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

Appendix 2. Participant information sheet

Participant Information Sheet

Airway Oxygen Concentration with High Flow Nasal Oxygen

Location: Christchurch Public Hospital

Lead Investigator:
Dr Nick Abbott
Christchurch hospital department of anaesthesia
Phone 021373537

Thank you for showing an interest in this project. Please take your time to read this information sheet carefully and decide whether or not you want to take part. You are welcome to discuss this with your support people, whanau and health care providers. Whether or not you take part is your choice, and if you choose not to you do not have to give a reason, and will not be disadvantaged in any way.
This is an observational study and the treatment you receive at this hospital will be the same regardless of whether you are in the study or not.
If you do decide to take part, thank you. If you do not wish to take part we thank you for considering our request.

What is the purpose of this research project?
The purpose of this project is to measure the oxygen levels that people receive in their airway (throat and windpipe) when they are having an anaesthetic for airway surgery. This will be useful because it will help us to

understand how oxygen levels change in the airway when the amount of oxygen administered changes.

This will help us decide on the correct level of oxygen to administer to patients undergoing airway surgery.
It will also help us to decide whether we can safely perform certain types of surgery where an ignition source (such as a laser or electrocautery) is being used. In this sort of surgery it is important to have low oxygen levels in the airway to minimise the risk of causing a spark or a fire.

Who are we seeking to participate in this project?
We are asking adults who are booked to undergo planned surgery on their airway (throat and windpipe) to participate in this study. We are asking people aged 18 - 75 years and who are in good or fairly good health.

If I decide to participate, what will I be asked to do?
If you decide to participate, your care will be identical to the standard care provided at this hospital for your sort of surgery.
When you are asleep, we will pass a small plastic sampling line into your windpipe to measure the oxygen levels.
You will not have to do anything extra for the study. Your anaesthetic may be up to 5 minutes longer than it otherwise would be.

Is there any risk of discomfort or harm from participation?
There is a very small chance that the oxygen sampling line may cause a scratch or bruise to the airway. This is very unlikely, as it is smaller and softer than the normal surgical instruments being used.

What about my confidentiality and privacy?
The anonymity and confidentiality of your health information will be ensured by a process called de-identification. This means you are allocated a study ID and only primary investigators will be able to link your study ID to your identity and health information. All of your electronic information

relating to the study will be stored on a secure password protected database and all hardcopy information will be stored under lock and key. These will only be accessible to the primary investigators. If any information is shared with a third party (e.g., a statistician or an overseas researcher), no information identifying you (e.g., NHI number or name) will be provided to them.
It is possible that data generated in this study, but not reported, will be made available for use in future research. If this happens, it will be ensured all data will be provided in an entirely de-identified manner.

Any Questions?
If you have any questions, concerns or complaints about the study you can contact:

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021373537
nicholas.abbott@cdhb.health.nz

Dr Pippa Jerram
Department of Anaesthesia
021747710
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If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz