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PROTOCOL

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Study protocol: A randomized controlled trial assessing the avoidance of endotracheal suction in cardiac surgical patients ventilated for ≤ 12 hr

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Abstract

Aims: To assess the safety and efficacy of avoiding endotracheal suction in postoperative cardiac surgical patients mechanically ventilated for ≤ 12 hr.

Design: A prospective, single centre, single blind, non-inferiority, randomized controlled trial evaluating the safety and efficacy of avoiding suction in uncomplicated, postoperative, adult cardiac surgical patients mechanically ventilated for ≤ 12 hr.

Methods: Randomization will be performed on return to intensive care (ICU) with allocation to either usual postoperative care including suction or to usual care with no suction (intervention arm). The primary outcome is the ratio of partial pressure of oxygen (PaO_2) to fraction of inspired oxygen (FiO_2) (P/F) 6 hr after extubation. Pain assessments will be performed before, during and after endotracheal suction (ETS) and the patient experience will be investigated with a brief interview the following day. Ethics approval was received in October 2015.

Discussion: Endotracheal suction is performed as part of airway management but has potential complications and there is little robust evidence to guide practice. This study will add to the evidence base about the need and benefit of endotracheal suction in this patient cohort.

Impact: As there is currently no published evidence about the safety of avoiding endotracheal suction. This study will provide the first evidence about avoidance of endotracheal suction in patients ventilated for less than 1 day. If non-inferior, the results have the capacity to change nursing practice by avoiding a potentially unnecessary procedure, it will build on the body of knowledge about the patient experience.

KEYWORDS

airway management, cardiac surgery, endotracheal suction, intensive care, nursing, patient experience, randomized controlled trial, safety

1 | INTRODUCTION

Cardiovascular disease continues to be a leading cause of death, both globally (Gaziano, 2005; Mcaloon et al., 2016) and in New Zealand (Ministry of Health, 2015), with cardiac surgery one of the most frequent major surgeries performed (D'Agostino et al., 2018; Stamp, Granger, & Larbalestier, 2017). Postoperative care in New Zealand requires admission to an Intensive Care Unit (ICU) for cardiovascular monitoring, haemodynamic management, analgesia, and a period of sedation and mechanical ventilation (MV) until the

patient is stable and ready to de-sedate. MV requires the use of an endotracheal tube (ETT) to maintain the patient's airway until the patient is deemed ready for extubation. Both cardiac surgery and MV can contribute to atelectasis (Caramez et al., 2006; Parke, McGuinness, Dixon, & Jull, 2013; Scott Stephens & Whitman, 2015). MV and the ETT may contribute to other complications such as inflammatory lung injury, infection, pneumothorax, and an inflammatory response to the ETT (Niël-Weise, Snoeren, & van den Broek, 2007; Puyo et al., 2017). The aim following cardiac surgery is to extubate the patient as soon as possible once they are cardiovascularly stable, usually within 3–6 hr of admission to ICU (Scott Stephens & Whitman, 2015).

1.1 | Background

The presence of an ETT prevents the patient being able to cough and clear secretions normally therefore endotracheal suction (ETS) may be performed as part of airway management. ETS consists of a suction catheter being inserted into the ETT, application of negative pressure and removal of secretions. ETS may also help reduce biofilm accumulation in the ETT so maintaining patency of the ETT and pulmonary hygiene (Day, Farnell, & Wilson-Barnett, 2002). ETS may require disconnection from the ventilator with subsequent loss of positive pressure, reduction in oxygenation affecting ventilation potentially increasing the risk of hypoxia, atelectasis and risk of infection, while the application of suction potentially contributes to tissue trauma, hypertension, and cardiovascular instability (Favretto et al., 2012; Overend et al., 2009; Pedersen, Rosendahl-Nielsen, Hjermind, & Egerod, 2009; Sole et al., 2003). ETS can cause pain and distress to the patient (Arroyo-Novoa et al., 2008; Puntillo et al., 2001, 2014). A recent survey of current practice in the unit identified that most nurses (84%) perform ETS at the time of extubation and that this is similar to previously described practice (Gilder, Parke, & Jull, 2019; Hodd et al., 2010; Scales & Pilsworth, 2007).

Although clinical practice guidelines (CPG) for endotracheal suctioning of mechanically ventilated patients have been developed by the American Association of Respiratory Care (AARC, 2010), they are acknowledged to be based on low grade evidence (Restrepo, 2010) and are frequently not implemented in clinical practice (Beuret, Roux, Constan, Mercat, & Brochard, 2013; Negro, Ranzani, Villa, & Manara, 2014). CPGs recommend that ETS should be provided "as required" (American Association for Respiratory Care, 2010a); however, there is no specific recommendation to guide practice for patients who are ventilated for short periods of time, that is, ≤24 hr. Although the most common practices at extubation are asking the patient to cough and suctioning the ETT at/during extubation (Dawkins, 2011; Gilder et al., 2019; Hodd, Doyle, Carter, Albarran, & Young, 2010a; Scales & Pilswoth, 2007), ETS at extubation can increase the risk of atelectasis, in turn contributing to hypoxia (Loeckinger et al., 2002; Paulissian et al., 1991). There is contradictory evidence about the benefit of a positive pressure breath or recruitment manoeuvres at the time of extubation (Andreu et al., 2014; Hodd, Doyle, Carter, Albarran, & Young, 2010b; Hodd et al., 2010a; L'Hermite et al., 2018).

Why is this research needed?

- Endotracheal suction is known to be painful and distressing for patients.
- There is currently little robust evidence to guide endotracheal suction practice in Intensive Care.
- There is no published evidence about the safety and efficacy of avoiding endotracheal suction in the patients ventilated for short periods of time.
- This study will provide the first evidence about the safety and efficacy of avoiding ETS in patients ventilated for less than 12 hours.
- If this study demonstrates non-inferiority, there is the potential to change nursing practice by avoiding an unnecessary and and potentially distressing procedure in this patient cohort.

Given the known potential complications associated with ETS (Corley, Sharpe, Caruana, Spooner, & Fraser, 2014; Pedersen et al., 2009), the pain and distress experienced by patients (Gelinas, Fortier, Viens, Fillion, & Puntillo, 2004, Gelinas 2007), and the lack of robust data to guide practice, the avoidance of ETS may be desirable in patient cohorts with a planned short duration of mechanical ventilation and warrants investigation. If non-inferiority is demonstrated then this study has relevance for cardiothoracic nursing practice internationally providing an opportunity to review current practice for this patient cohort and avoid a potentially unnecessary procedure.

2 | THE STUDY

2.1 | Aim

To assess the safety and efficacy of avoiding ETS in postoperative cardiac surgical patients mechanically ventilated for ≤ 12 hr. We hypothesize that avoiding ETS in patients mechanically ventilated for ≤ 12 hr following cardiac surgery will result in a maximum difference of Pa02/FiO2 (P/F) ratio of 10% or less compared with usual postoperative care that includes ETS 6 hr after extubation.

2.2 | Design

A single centre, prospective, single blinded, parallel groups, non-inferiority randomized controlled trial (RCT).

2.3 | Participants

The study will be conducted in a Cardiothoracic and Vascular Intensive Care Unit (CVICU) in a metropolitan tertiary centre teaching hospital that performs approximately 1,200 cardiac surgical cases per year.

Participants will be screened and seen pre-operatively by experienced research nurses and given the opportunity to participate in the study. Written informed consent will be obtained. Inclusion criteria: age ≥ 16 years; having cardiac surgery with cardiopulmonary bypass; expected to be ventilated for ≤ 12 hr. Exclusion criteria: previously documented difficult intubation; non-English speaking; clinician preference for the patient to receive ETS.

Participants will be re-screened on admission to ICU by either the research nurses or the clinical nurse coordinator on duty and a decision made on the likely duration of MV. Participants who are anticipated to receive MV for ≤ 12 hr will be randomized and those anticipated to receive > 12 hr of MV will be excluded. Participants who are randomized but subsequently have > 12 hr MV will revert to usual care 12 hr after admission to ICU.

2.4 | Intervention

Patients who are randomized to the study intervention will receive standard postoperative care as described below apart from ETS. Suction will be avoided including at the time of extubation unless specific conditions are met. The patient may have oral suction as part of usual care. For patient safety ETS will be allowed only in the following circumstances:

- Oxygen desaturation (SpO_2 <90%)
- Deteriorating arterial blood gases (PaO_2 8 kPa/60 mm Hg or below)
- Reduced air entry on auscultation
- On medical request

2.5 | Usual care

On admission to ICU the patient will have an ETT in situ and receive MV. Airway management includes monitoring of arterial blood gases (ABGs), peripheral oxygen saturations (SpO_2), and end tidal CO_2, as well as providing ETS as required, including at extubation.

2.6 | Background standard care for all participants

Usual postoperative care includes warming the patient to 36.8°C, monitoring cardiovascular status, managing the patient's airway and ventilation, monitoring urine output, mediastinal and pleural drainage, and providing analgesia. Patients are mechanically ventilated while warming and are sedated using a propofol infusion to achieve the prescribed sedation level. Oral suction is provided as part of oral hygiene whenever necessary. Once the patients are considered cardiovascularly stable, sedation is discontinued and the patient is allowed to wake. Once awake and assessed as suitable for extubation the patient is extubated onto standard oxygen therapy, either nasal prongs or simple face mask. Supplemental oxygen delivery is provided to achieve SpO_2 of 94–98%.

2.7 | Blinding

The participant will be blinded to the intervention as they will be unconscious; however, blinding the clinical staff is not possible, as bedside staff will need to know the participant allocation.

2.8 | Outcomes

2.8.1 | Primary outcome

The primary outcome is the PaO_2/FiO_2 (P/F) ratio 6 hr after extubation and the non-inferiority margin is a maximum of 10% worse P/F ratio in favour of usual care. The primary outcome was agreed following discussion with senior medical staff on the CVICU and based on clinical experience and expertise. To the best of our knowledge, this is the first time a study avoiding ETS has been undertaken and there was no previous data to guide the decision-making. This cohort of patients are anticipated to have ventilation duration of < 12 hr from admission to ICU, minimal co-morbidities, and will be mobilized and transferred to the ward the following day. We anticipated that any respiratory complications following extubation would manifest within 6 hr of extubation.

Calculating an accurate P/F ratio in non-ventilated patients can be difficult due to challenges in measuring FiO_2, predominantly due to variable entrainment of room air in patients receiving supplemental oxygen via low-flow devices.

To mitigate this, we will do the following:

- Participants receiving low flow supplemental oxygen (4 L/min or less) via nasal cannulae or simple facemask will be placed on room air for 5 min then an ABG taken. If the participants SpO_2 (measured with a pulse oximeter) drops below 90% during that 5 min they will be placed on high flow oxygen therapy (HFOT) at 50 L/min and the minimum FiO_2 required to achieve an SpO_2 ≥ 90%. An ABG will be taken after 5 min.
- Participants receiving oxygen > 4 L/min and with an SpO_2 <90% will be commenced on HFOT at 50 L/min and the minimum FiO_2 required to achieve an SpO_2 ≥ 90%. An ABG will be taken after 5 min. The patient will then be recommenced on the supplemental oxygen being received prior to the HFOT, discussion with the medical staff is recommended for any patients in this group to review their oxygen therapy requirements.
- Participants who are on HFOT or non-invasive ventilation 6 hr post extubation will have an ABG taken on their existing device.

A flow chart (Figure 1) has been provided to guide the bedside nurse undertaking collection of the ABG to be used for assessment of the primary outcome.

2.8.2 | Secondary outcomes

Pain assessments will be collected for all participants as described below and the remaining secondary outcomes are listed in Table 1.

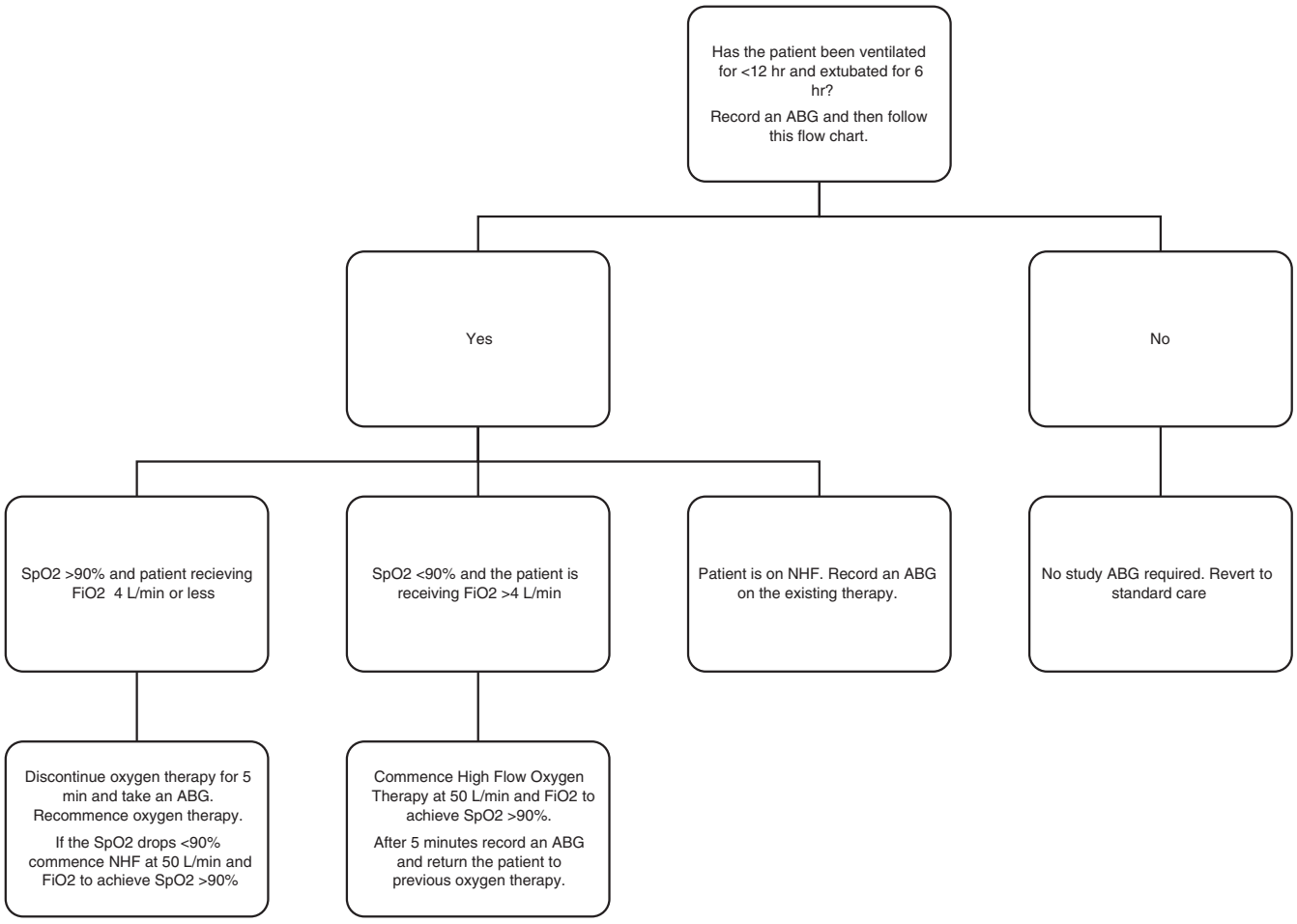

FIGURE 1 Flow chart for the Primary Outcome ABG 6 hours post extubation

TABLE 1 Secondary outcomes

1	Requirement for escalation to HFOT for the 6 hr post extubation ABG.
2	Complications at extubation; defined as laryngeal spasm, vomiting, aspiration, oxygen de-saturation (SpO_2 <90%) up to 30 min after extubation.
3	Requirement for the escalation of oxygen therapy in the first 6 hr after extubation.
4	Oxygen saturation SpO_2 <90% in the first 6 hr after extubation.
5	Tachycardia (>100 bpm) in the first 6 hr after extubation.
6	Increased mean arterial pressure (>85 mm Hg) in the first 6 hr after extubation.
7	Re-intubation rates.

2.9 | Pain assessment – all participants

Pain will be assessed for all participants receiving ETS, regardless of group assignment. Both the critical care pain observation tool (CPOT) (Arbour & Gélinas, 2010; Gélinas, Fillion, Puntillo, Viens, & Fortier, 2006; Siffleet, Young, Nikoletti, & Shaw, 2007) and a numerical rating scale will be used to assess pain prior to, during and 10 min following ETS. CPOT assessments will be performed when the participant has a Richmond Agitation and Sedation Score (RASS) (Ely et al., 2003) of −3 - +1 and again when the participant has a RASS of 0, but prior to extubation. As the gold standard for pain assessment remains the patient reported pain score (International association for the study of pain, 2012; Jarzyna et al., 2011), a numerical rating scale will be used to assess pain when the participant is awake, but prior to extubation. A numerical rating scale will be estimated and recorded by the bedside nurse prior to the participant reporting his/her score and before, during, and after a suction episode as described above. The nurse will document their estimated numerical rating scale prior to asking the participant their numerical rating scale as the evidence identifies a difference between the nurses and patients pain scores (Kizza & Muliira, 2015; Wysong, 2014).

2.10 | Sample size

Based on previous work done in the same unit with a similar patient population (Parke et al., 2013) in a sample of 130 participants receiving supplemental oxygen 4 hr post extubation, the mean P/F ratio was 301 (*SD* 83.9). As there is no available data for patients without

supplemental oxygen, these data were used to estimate the sample size and for power calculations. The G Power sample size calculator (Fual, Erdfelder, Lang, & Buchner, 2007) was used for sample size calculation.

The International Council for Harmonisation (ICH) provides guidelines for the conduct of clinical trials, including selecting a non-inferiority margin. The guidelines state that 'the determination of the margin in a non-inferiority trial is based on both statistical reasoning and clinical judgment, should reflect uncertainties in the evidence on which the choice is based and should be suitably conservative' (International Conference on Harmonisation, 2000). Therefore, in consultation with the senior medical staff on ICU and an independent statistician and using the available data and clinical expertise within the group, a non-inferiority margin of 10% was considered clinically acceptable for the P/F ratio agreed as the primary outcome. An estimated total sample size of 170 patients achieving the primary outcome will provide 80% power, with a confidence interval of 95% assuming an α of 0.05. Recruitment will continue until 170 participants have met the primary outcome. It is not anticipated that there will be any loss to follow-up for the 170 participants achieving the primary outcome, as all the data will be collected prior to the participants leaving ICU.

2.11 | Assignment of intervention

2.11.1 | Sequence generation and randomization

Computer-generated random numbers, generated by an independent statistician, will be used for group allocation with blocks of eight ensuring an equal number of participants in each arm. Allocation concealment will be maintained with the use of opaque, sealed, sequentially numbered envelopes. Non-study personnel will be used to prepare the study envelopes. Each envelope will contain a slip of paper, folded once, with the group allocation and the unique study number allocated to each participant. The research nurse or clinical nurse coordinator on duty will perform randomization.

2.12 | Data collection

Data will be collected by trained research nurses and entered into an electronic database (Research Electronic Data Capture (REDcap) – Vanderbilt University, Tennessee (Obeid et al., 2012). Data will be collected on all randomized participants, those who receive > 12 hr MV will have all demographic and physiology data, pain scores, and ABG data collected for the first 12 hr following admission. Reasons for prolonged MV will be collected, as will reasons for exclusion for those not randomized at the secondary screening.

Post randomization data collected will be, date and time of intubation and extubation; ICU admission and discharge date and time; all ABG's from time of ICU admission through to extubation and for the mandated post extubation ABG's, at 2, 4, and 6 hr post extubation. ABG data will be PaO_2; $PaCO_2$; SaO_2; base excess; lactate; in addition to SpO_2 and FiO_2. There will be two ABG's recorded 6 hr post extubation, one while the participants are receiving supplemental oxygen and one when the participant is on room air (Figure 1). For patients who are receiving HFOT the 6-hour post extubation ABG will be performed on HFOT, no room air ABG will be performed (Figure 1).

Physiology data (heart rate, respiratory rate, and mean arterial pressure [MAP]) will be collected hourly from ICU admission through to 6 hr post extubation. Secondary outcome data previously described will be collected.

Pain assessment data will be recorded by the bedside nurse on a paper case report form before, during, and 10 min following ETS both when the patient is sedated with a RASS score of −3 to +1 and when awake with a RASS score of 0. All randomized participants will have a brief scripted interview about their experience of the ETT and ETS (for those who receive ETS); this will be conducted the day after surgery.

The numerical rating scale will be used for the interview and participants will be asked to rate pain from the ETT and ETS from 0–10, with 0 = no pain and 10 = the worst pain imaginable.

Participants will be asked:

- Do you recall having the breathing tube in place while you were in Intensive Care?
- If yes how painful was the tube?

Participants who received ETS will also be asked:

- Do you recall having the breathing tube suctioned while in Intensive Care?
- If yes how painful was suctioning?

This study provides an opportunity to explore the patient experience of both the ETT and ETS. The interview is designed to be brief, as it will be conducted the day after surgery. This may offer the best opportunity for the participants to recall their experience; but it is not appropriate to burden them with multiple questions at this time. An unpublished qualitative study undertaken by the investigators prior to commencement of this RCT tested the study interview tool.

2.13 | Data management

The REDCap platform will be used for data collection; the Medical Research Institute of New Zealand (MRINZ) will host this. Participants will have a unique identifier with all outcome data being de-identified; auto-validation will be used to help maintain data quality. All other data for example consent forms and source documents will be stored securely and source documents will be held on the secure hospital server. Data will be stored for 10 years before secure destruction.

2.14 | Statistical analysis

Data will be extracted into IBM SPSS Statistics (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk,

NY:IBM Corp.) for analysis with demographic, safety, and baseline data summarized by treatment groups. Descriptive statistics will be used for those participants who are ventilated for > 12 hr and all data will be tested for normality. Analysis of non-inferiority trial data and conclusions drawn are sensitive to the method of analysis (D'Agostino, Massaro, & Sullivan, 2003; Head, Kaul, Bogers, & Kappetein, 2012). Convention for superiority trials is an intention to treat analysis regardless of whether the participant received the intervention. For non-inferiority studies this has the potential to bias towards non-inferiority (Head et al., 2012), in particular if there is significant cross-over between groups. It is recommended that per protocol analysis is performed in addition to intention to treat analysis for non-inferiority studies (D'Agostino et al., 2003; Head et al., 2012; Snapinn & Point, 2000) as this analysis excludes those participants who have major protocol deviations; however, this may also contribute to bias as there may be differences in those who complete the protocol and those who do not (Pocock, 2003). Given these challenges, the data will be analysed with both intention to treat and per protocol analysis, with the per protocol being the primary analysis. The literature suggests conclusions of non-inferiority should only be drawn if both analyses lead to similar conclusions (D'Agostino et al., 2003; Head et al., 2012; Snapinn & Point, 2000).

Data will be tested for normality and the primary outcome will be analysed using Student's *t* tests with mean and standard deviation presented in treatment group tables, while categorical data will be analysed using Mann–Whitney test. To account for any ABGs being performed outside of the 6-hour time frame a sensitivity analysis will be performed on all those who recieved ABG's outside of the study protocol. Baseline variables will be assessed and if imbalances of prognostic significance are present an adjusted analysis will be performed using analysis of covariance (ANCOVA).

2.15 | Data safety and monitoring

For patient safety, a data safety monitoring committee (DSMC) has been formed consisting of a senior intensive care researcher not working in the study unit (Chair), a biostatistician, and an independent medical researcher. An unblinded interim safety analysis will be provided once 50 and 100 participants have been randomized. The principle investigator will notify the DSMC of any serious adverse events within 24 hr. A trained clinical trials monitor will independently monitor the study. There will be 100% monitoring of consent and primary outcome.

2.16 | Ethics

Ethics approval has been obtained from the New Zealand Health and Disability Ethics Committee (15/NTB/138) in October 2015 with prospective registration on the Australian and New Zealand Clinical Trials Registry (ACTRN12615000897561) and the World Health Organisation International Clinical Trials Registry Platform (www.who.int/ictrp/en/). Any protocol amendments will be approved by ethics prior to implementation. Recruitment started in May 2017 and the study is anticipated to complete recruitment in December 2018.

2.17 | Validity and reliability

The inclusion and exclusion criteria, together with random allocation and the use of a control group help to ensure internal validity. The non-inferiority margin has been discussed and agreed with the senior medical team in the ICU and is based on clinical practice and expert knowledge as recommended by D'Agostino et al. (2003) and has been agreed as appropriate for this cohort. The CPOT pain assessment tool is a validated tool (Gélinas, Harel, Fillion, Puntillo, & Johnston, 2009; Marmo & Fowler, 2010) and all the staff performing the pain assessments will have appropriate training.

3 | DISCUSSION

To ensure protocol adherence staff training will be provided prior to starting the study and will include education about the protocol and pain assessment tools. On-going one to one teaching will be provided while the study is running for new and returning staff with the aim of achieving adherence to the study protocol and intervention. This will ensure bedside nurses are familiar with the study, the rationale for the intervention and required bedside data collection. The study mandated post extubation ABG's will be performed by bedside staff. To facilitate the primary outcome data collection study tools and aid memoires will be left at participant's bedside and the research team will contact the nurse, to ensure that study handover has been received, in addition the Clinical Nurse Coordinator on duty will be notified of any study patients. As the participant will have secondary screening on admission it CVICU, the research nurses will liaise closely with the shift coordinator to facilitate randomization of participants if the research nurses are unavailable.

3.1 | Limitations

This is a single study centre and although this may limit the generalizability of the findings for some patient populations we consider that there will be generalizability among the cardiac population in a publicly funded health service, our practice may differ from privately funded health care. As this intervention has not been previously investigated, the non-inferiority margin selected has not been tested, however experts in the clinical filed have been consulted. It is not possible to blind the staff providing the intervention, however the participants will be blinded to their group allocation.

4 | CONCLUSION

Based on a yet to be published systematic review, this trial is a first-in-world effort to evaluate the effects of minimizing the otherwise

routine and potentially unnecessary practice of endotracheal suctioning in uncomplicated cardiac surgery patients. The evidence base for ETS in the ICU patient population is recognized to be of low quality (Restrepo, 2010), with ETS having known effects on ventilation (Corley et al., 2012, 2014) and causing pain and distress for patients (Arroyo-Novoa et al., 2008). There remains a divergence between CPGs and what happens in clinical practice (Beuret et al., 2013; Gilder et al., 2019; Jansson, Ala-Kokko, Ylipalosaari, Syrjälä, & Kyngäs, 2013; Negro et al., 2014). If the results of this study show that avoiding suction is non-inferior for this patient cohort then this has significant implications for clinical practice. There is the potential to avoid a painful procedure, aligning with the international Choosing Wisely initiative (http://www.choosingwisely.org/) that seeks to reduce the number of unnecessary medical treatments and interventions. Suction avoidance may potentially reduce workload for the nursing staff, in addition to improving the ICU experience for patients recovering from cardiac surgery. The study will provide an opportunity for patients to share their experience of the ETT and ETS in turn helping to inform future practice by adding to the body of knowledge about the patient experience of an ETT and ETS. A non-inferiority result has implications for future research, including further investigation about the avoidance of ETS with other patient groups, using the data to guide sample size calculations for future studies.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE [http://www.icmje.org/recommendations/]):

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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