Avoidance of Routine Endotracheal Suction in Subjects Ventilated for ≤ 12 Hours Following Elective Cardiac Surgery

Eileen Gilder, Shay P McGuinness, Alana Cavadino, Andrew Jull, and Rachael L Parke

BACKGROUND: Mechanical ventilation requires an endotracheal tube. Airway management includes endotracheal suctioning, a frequent procedure for patients in the ICU. Associated risks of endotracheal suctioning include hypoxia, atelectasis, and infection. There is currently no evidence about the safety of avoiding endotracheal suction. We aimed to assess the safety of avoiding endotracheal suction, including at extubation, in cardiac surgical patients who were mechanically ventilated for ≤ 12 h. METHODS: We conducted a single-center, noninferiority, randomized controlled trial in a cardiac ICU in a metropolitan tertiary teaching hospital. Subjects were assigned to either avoidance of endotracheal suction or to usual care including endotracheal suctioning during mechanical ventilation. In total, we screened 468 patients and randomized 249 subjects (usual care, *n* = 125; intervention, *n* = 124). Subjects were elective cardiac surgical patients anticipated to receive ≤ 12 h of mechanical ventilation. The primary outcome was the P_{aO_2}/F_{IO_2} on room air 6 h after extubation, with a noninferiority margin of 10% (lower bound of one-sided 95% CI to be < 30). RESULTS: There were no differences in group characteristics at baseline. The primary analysis was a per-protocol analysis performed on 154 subjects. The median P_{aO_2}/F_{IO_2} was 323 for the intervention group and 311 for the standard care group (median difference = 12, one-sided 95% CI –14.3). The results were consistent when using an intention-to-treat analysis and a 97.5% CI. There were no differences between groups in complications or safety measures, including the escalation of oxygen therapy. CONCLUSIONS: Endotracheal suctioning can be safely minimized or avoided in low-risk patients who have had cardiac surgery and are expected to be ventilated for < 12 h after surgery. *Key words: intensive care; endotracheal suction; mechanical ventilation; airway management; nursing; patient experience.* [Respir Care 2020;65(12):1838–1846. © 2020 Daedalus Enterprises]

Introduction

Worldwide, between 33% and 60% of patients admitted to an ICU will require a period of mechanical ventilation, which exposes 13,000–20,000 patients a day to the risks associated with mechanical ventilation.[1,2] These include ventilator-induced lung injury and ventilator-associated pneumonia.[3] Mechanically ventilated patients may receive endotracheal suctioning, which aims to maintain a patent

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airway and remove accumulated secretions.[4] However, endotracheal suctioning can also contribute to hypoxia, atelectasis, tissue trauma, and pain and distress for the patient.[5-7] Initiatives have been implemented to minimize the duration of mechanical ventilation and to reduce the frequency of endotracheal suctioning. These include early extubation[8,9] and development of clinical practice guidelines for the use of endotracheal suctioning.[10-12] Yet the guidelines differ in their recommendations about how to determine the patient need for endotracheal suctioning.[10,11] Suction at extubation is a common practice and aims to reduce the risk of aspiration and improve oxygenation.[13-15] A survey of endotracheal suctioning practice within the unit prior to the trial identified the most common triggers for endotracheal suctioning: oxygen desaturation, audible or visible secretions, patient coughing, and endotracheal suctioning at extubation. Laboratory evidence indicated that a positive-pressure breath at extubation may be more effective at reducing aspiration,[16] and a pediatric study reported an increased time to oxygen desaturation following the application of a positive-pressure breath at extubation when compared to suctioning.[17] The increased time to oxygen desaturation was not replicated in an adult population.[18]

An initial literature review failed to find any trials assessing the avoidance of endotracheal suctioning in adult patients mechanically ventilated for ≤ 24 h; we extended the timeframe to ≤ 72 h and broadened the search criteria to include animals. There were no trials in the human population, while several animal studies indicated that avoidance of endotracheal suctioning did not worsen oxygenation.[19-23] Given the lack of evidence about the avoidance of endotracheal suctioning in the adult population, we hypothesized that avoiding endotracheal suctioning in subjects mechanically ventilated for ≤ 12 h, including at extubation, would be noninferior to usual care that included endotracheal suction.[24]

QUICK LOOK

Current knowledge

Endotracheal suction is performed to remove secretions and to maintain airway patency and oxygenation. Procedural risks include hypoxia, atelectasis, cardiac arrhythmias, tissue trauma, and infection. There is currently no evidence about the effects of active avoidance of endotracheal suction.

What this paper contributes to our knowledge

In this randomized controlled trial of avoidance of endotracheal suction in a low-risk, postoperative cardiac surgical population that was mechanically ventilated for ≤ 12 h, there was no increase in the incidence of escalation of oxygen therapy or complications of extubation, including aspiration or re-intubation. These results indicate that avoidance of endotracheal suction in this patient population can be safely practiced.

Methods

The Avoidance of Routine Endotracheal Suction trial has been described previously.[24] Briefly, it was a noninferiority randomized controlled trial comparing the avoidance of endotracheal suction to usual care in subjects admitted to the ICU following elective cardiac surgery. The trial was conducted in a tertiary teaching hospital that performs approximately 1,200 cardiac surgical procedures per year. Ethics approval was obtained from the Northern B Health and Disability Ethics Committee (15/NTB/138). Written informed consent was provided before surgery. The trial was registered prospectively on the Australian and New Zealand Clinical Trials Registry (ANZCTR12615000897561), and a protocol outlining the trial in detail was published.[24]

Subjects

We screened elective cardiac surgical patients admitted between May 2017 and February 2019 for eligibility. Inclusion criteria were adults (ie, ≥ 16 y), requiring elective cardiac surgery using cardiopulmonary bypass, with an anticipated duration of ventilation ≤ 12 h. Patients who had a documented previous difficult intubation or were non-English-speaking were excluded. All enrolled subjects were rescreened postoperatively on admission to the intensive care unit and randomized if extubation was expected to occur within 12 h. Because this was the first time that active avoidance of endotracheal suctioning had been investigated, we limited the duration of avoidance of endotracheal suctioning to ≤ 12 h to minimize patient risk when investigating a novel intervention.

Intervention

All subjects received usual postoperative care, which included warming the subjects to at least 36°C, cardiovascular monitoring, appropriate pain and sedation management, and extubation as soon as clinically stable. Assessment of readiness for extubation was guided by the unit protocol and included that the patient was receiving ≤ 45% oxygen, was awake and obeying commands, and had no evidence of active bleeding. Airway management

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included endotracheal suctioning as required, and at extubation. Suction as required (ie, not mandated) is usual practice on our unit, and the need for suction is assessed by the bedside nurse. Subjects randomized to the intervention arm received all usual care with the exception of endotracheal suctioning, including at extubation. We anticipated a low-risk population, but safety caveats allowed endotracheal suctioning to be provided. Indications for endotracheal suctioning included oxygen desaturation ($S_{pO_2} < 90\%$), deterioration of P_{aO_2} to < 60 mm Hg, reduced air entry upon auscultation, and on medical advice.[24] Following extubation, arterial blood gas (ABG) analysis was mandated at 2, 4, and 6 h postextubation. Following randomization, and regardless of allocation, all subjects who required > 12 h ventilation reverted to routine postoperative management and were excluded from the study.

Quasi-closed endotracheal suctioning is usual practice in our unit and uses a swivel connector catheter mount that has a 1-way valve in situ. Patients do not require disconnection from the ventilator during endotracheal suctioning, reducing lung volume loss during suction.[25] The unit-recommended best-practice suction protocol mandated both the suction pressure (ie, ≤ 200 mm Hg) and suction catheter size (ETT size $- 2 \times 2$).

Outcomes

The primary outcome was P_{aO_2}/F_{IO_2} on room air 6 h after extubation.[24] Secondary outcomes included heart rate, breathing frequency, and mean arterial pressure, collected from ICU admission to 6 h postextubation. Safety data collected up to 6 h postextubation included P_{aO_2}, P_{aCO_2}, S_{pO_2}, and complications of extubation including requirement for escalation of oxygen therapy or re-intubation, oxygen desaturation ($S_{pO_2} < 90\%$), vomiting, and aspiration. The Critical Care Pain Observation Tool[26,27] was used to collect pain scores before, during, and after suction episodes. Subjects completed a brief interview the day following extubation, describing their experience of the endotracheal tube and endotracheal suctioning, if delivered. They also reported the amount of pain associated with the endotracheal tube and endotracheal suctioning. A numerical pain scale was used for the pain scores.[28]

Sample Size

A previous study conducted in the same unit and with a similar population provided the inputs for the sample size calculation.[29] In that study, the mean $\pm$ SD P_{aO_2}/F_{IO_2} at 4 h postextubation was 301 ± 83.9. Following consultation with senior medical staff, a noninferiority margin of 10% (ie, P_{aO_2}/F_{IO_2} no lower than 270) was agreed as clinically acceptable for subjects within the first 24 h after cardiac surgery. We calculated that, if there were no difference between usual care and the intervention, and using an anticipated SD of 80, 166 subjects in total would be needed to achieve 80% power with a lower limit of a one-sided 95% CI above the 10% noninferiority margin. G*Power was used for sample size calculation.[30]

Randomization and Blinding

Sequence generation was provided by an independent statistician, with 1:1 allocation in blocks of 8. Allocation concealment was achieved using sequentially numbered, sealed, opaque envelopes containing the subject's allocation and unique study number on a slip of paper. Non-study personnel prepared the study envelopes. Randomization occurred on admission to the ICU. It was not possible to blind bedside staff due to the nature of the intervention. Subjects were blinded to the allocation.

Data Collection and Monitoring

Unblinded research staff who were not directly caring for the subjects collected the data and conducted the interviews. Data were entered directly into the Research Electronic Data Capture (REDCap) platform, which included auto-validation.[31] An independent monitor audited 100% of the consents and the primary outcome. A Data Safety Monitoring Board (DSMB) was established prior to the start of the study, consisting of an independent ICU researcher (chair), a statistician, and an anesthetic researcher. The DSMB reviewed an unblinded report after the recruitment of 50 and 100 subjects.

Statistical Analysis

Statistical analysis was specified a priori, with the statistical analysis plan available on the ANZCTR trial registry. As recommended for noninferiority studies,[32,33] confidence intervals were reported. We anticipated that any change in P_{aO_2}/F_{IO_2} would be one-directional; that is, we did not anticipate that avoidance of endotracheal suctioning would improve oxygenation, therefore we used a one-sided 95% CI. Continuous data were tested for normality, with the appropriate nonparametric tests used when required. The primary analysis was per protocol, followed by an intention-to-treat (ITT) analysis for sensitivity.[32] The CI was also tested for sensitivity using a one-sided 97.5% CI. Noninferiority was accepted if the lower limit of the one-sided 95% CI was above the prespecified 10% noninferiority margin for both analyses. Between-subject differences in the secondary outcomes (ie, oxygenation, heart rate, breathing frequency, and mean arterial blood pressure) were tested using a repeated-measure multivariate analysis of variance. Categorical safety and complication outcomes were compared using a chi-square test. $P < .05$ were

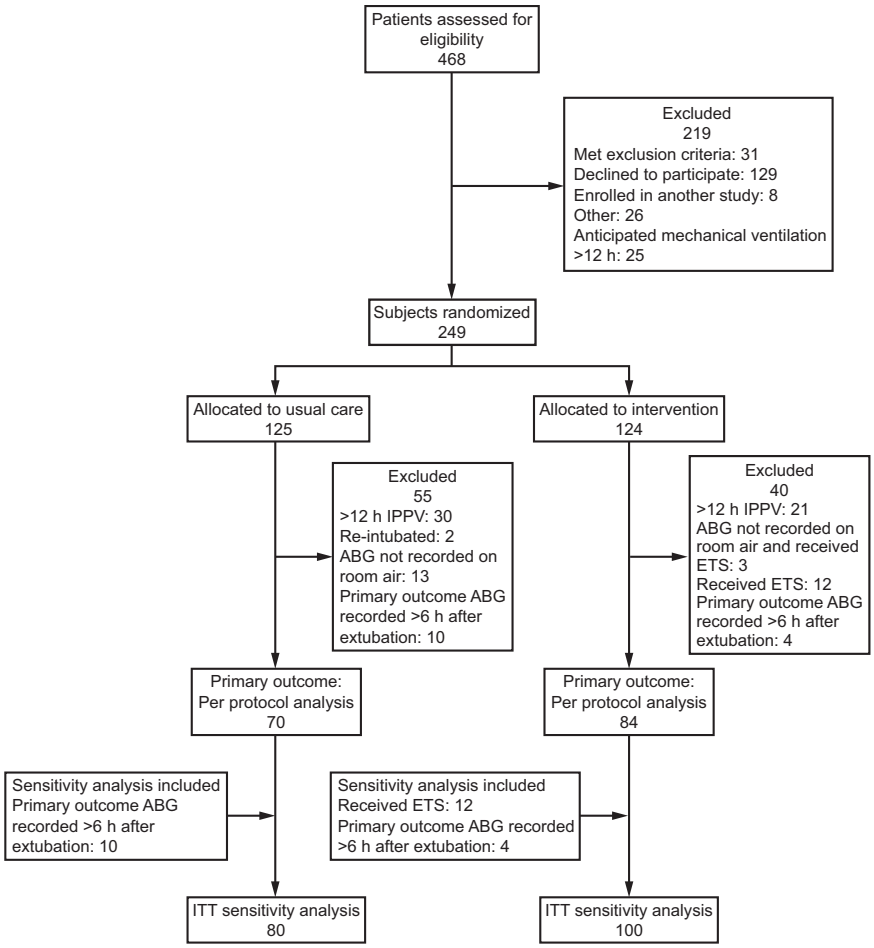

Fig. 1. Flow chart. IPPV = intermittent positive-pressure ventilation; ABG = arterial blood gas; ETS = endotracheal suctioning; ITT = intention to treat.

considered statistically significant. Data analyses were conducted using SPSS 25 (IBM, Armonk, New York) and GraphPad Prism (www.graphpad.com).

Results

We screened 468 patients; 249 were randomized with 154 subjects included in the per-protocol primary analysis outcome (Fig. 1). Inclusion in the per-protocol analysis required that those allocated to the intervention group had not received endotracheal suctioning, and that the primary outcome was available. There were 180 subjects included in the ITT analysis.

Baseline Characteristics

Subject groups were similar at baseline (Table 1). The majority were male (79.5%), were New Zealand European (73.1%), and had good left ventricle function (83.9%). The mean ± SD EuroSCORE II was 1.17 ± 0.72, and most subjects underwent isolated coronary artery bypass grafting (60.6%). The median duration of postoperative ventilation was 6.5 h (interquartile range [IQR] 4.6–10.1).

Primary Outcome

Under per-protocol analysis, the median P_{aO_2}/F_{IO_2} was 323 (IQR 286–349) for the intervention group and 311 (IQR 281–357) for the usual care group, with a median difference of 12 (a one-sided 95% CI –14.3, $P = .35$) (Fig. 2). When tested for sensitivity using an ITT analysis, P_{aO_2}/F_{IO_2} was 320 (IQR 282–353) for the intervention group and 311 (IQR 283–357) for the usual care group, with a median difference of 9 (a one-sided 95% CI –14.3, $P = .45$) (Fig. 2). The margins in both groups for the per-protocol and ITT analysis were within the anticipated 10% noninferiority margin and were robust when tested for sensitivity using the stricter 97.5% CI (per-protocol analysis median difference was 12, a one-sided 95% CI –14.3, $P = .35$; ITT analysis median difference was 9, a one-sided 95% CI –17.9, $P = .45$).

Table 1. Baseline Demography and Clinical Characteristics

	Total Sample ($N = 249$)	Usual Care ($n = 125$)	Intervention ($n = 124$)
Gender			
Female	51 (20.2)	23 (18.4)	28 (22.5)
Male	198 (79.5)	102 (81.6)	96 (77.4)
Ethnicity			
New Zealand European	182 (73.1)	89 (71.2)	93 (75.0)
New Zealand Maori	20 (7.9)	11 (8.8)	9 (7.2)
Pacific peoples	25 (9.9)	15 (12.0)	10 (8.6)
Asian	16 (6.3)	9 (7.2)	7 (5.6)
Other	6 (2.4)	1 (0.08)	5 (4.0)
EuroSCORE II	1.17 ± 0.72	1.15 ± 0.76	1.19 ± 0.68
Smoking status			
No	143 (56.7)	72 (57.6)	71 (57.2)
Yes	25 (9.9)	17 (13.6)	8 (6.4)
Former smoker	81 (32.1)	36 (28.8)	45 (36.2)
Weight, kg	87.9 ± 17.3	87.4 ± 17.8	88.5 ± 17.1
Co-morbidities			
Recent myocardial infarction	54 (21.4)	26 (20.8)	28 (22.5)
Diabetes (on insulin)	11 (4.4)	6 (4.8)	5 (4.0)
Class 4 angina	9 (3.6)	4 (3.2)	5 (4.0)
COPD	11 (4.4)	5 (4.0)	6 (4.8)
Previous cardiac surgery	5 (2.0)	4 (3.2)	1 (0.8)
Left ventricular function			
Good (> 50%)	209 (83.9)	107 (85.6)	102 (82.2)
Moderate (31–50%)	39 (15.6)	17 (13.6)	22 (17.7)
Poor (21–30%)	1 (0.4)	1 (0.8)	0
New York Heart Association Classification			
I	139 (55.8)	68 (54.4)	71 (57.2)
II	94 (37.7)	48 (38.4)	46 (37.0)
III	14 (5.6)	7 (5.6)	7 (5.6)
IV	2 (0.8)	2 (1.6)	0
Surgery and ventilation data			
Type of surgery			
Isolated CABG	151 (60.6)	72 (57.6)	79 (63.7)
Single non-CABG	78 (31.3)	42 (33.6)	36 (29.0)
2 procedures	20 (8.0)	11 (8.8)	9 (7.2)
Surgery and ICU			
Duration of surgery, h	4.1 (3.4–4.6)	4.1 (3.4–4.5)	4.1 (3.3–5.0)
Duration of ventilation, h	6.5 (4.6–10.1)	6.6 (5.1–11.5)	6.4 (4.5–9.0)
Length of ICU stay, h	23.1 (20.4–43.3)	23.1 (20.5–44.0)	23.0 (22.3–42.4)

Data are presented as *n* (%), mean ± SD, or median (interquartile range).
EuroSCORE = European System for Cardiac Operative Risk Evaluation
CABG = coronary artery bypass graft

Secondary Outcomes

There was no difference between groups in physiological outcomes (V = 0.05, F(3,225) = 0.344, $P = .79$), or for postextubation oxygenation (V = 0.01, F (5,170) = 0.327, $P = .90$) (Fig. 3). There were no significant differences between groups across safety outcomes, including complications of extubation (Table 2), with no incidence of re-intubation, aspiration, or laryngeal spasm.

A total of 167 of 249 (67%) subjects recalled the endotracheal tube, and 40 of 249 (16%) subjects recalled having endotracheal suctioning. The mean ± SD self-reported pain scores for the presence of the endotracheal tube and endotracheal suctioning, respectively, were 2.5 ± 2.8 and 2.9 ± 3.1. Of those who recalled the endotracheal tube most reported the endotracheal tube as bothersome rather than painful. Extubation was described by some as distressing; comments included, "I felt like I was being strangled" and "I couldn't get my breath."

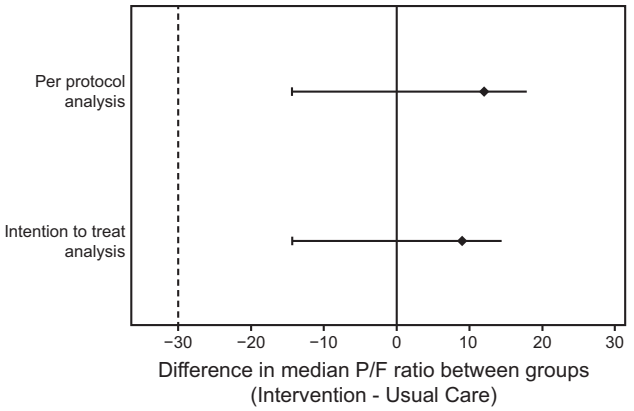

Fig. 2. Primary outcome per protocol and intention-to-treat analyses of the median difference P_{aO_2}/F_{IO_2} between groups, with one-sided 95% CIs.

Suction Episodes

In total, 99 subjects had documented suctioning episodes: 24 (19.2%) in the intervention group and 75 (60%) in the usual care group. Some subjects had > 1 suction episode, resulting in those allocated to usual care receiving a total of 108 suction episodes, whereas the intervention group received a total of 40 suction episodes. In total, 43 of 70 (61.4%) of the subjects receiving usual care received a total of 61 suction episodes in the per-protocol analysis. The mean ± SD suction pressure was –191 ± 47 mm Hg.

Discussion

Avoiding endotracheal suctioning was not inferior to usual care with regard to oxygenation on room air 6 h after extubation. There was also no increase in the requirement for escalation of oxygen therapy or the incidence of complications in the intervention group. These results suggest that avoiding endotracheal suctioning in a cohort likely to be ventilated for short durations is safe. In light of these findings, best-practice guidelines should be reviewed and updated to incorporate this new evidence.

To the best of our knowledge, this is the first trial to explore the avoidance of endotracheal suctioning in an adult ICU population. Other studies have compared suction to a positive-pressure breath, but only at extubation in postoperative pediatric and adult subjects.[17,18] The primary outcome in both of those studies was time to oxygen desaturation (ie, $S_{pO_2} < 92\%$). Although the pediatric study reported a more rapid oxygen desaturation to $S_{pO_2} < 92\%$ following suction,[17] this was not replicated in the adult study.[18] Unlike our study, subjects were extubated in the operating theater or in the post-anesthetia care unit, and the adults were extubated while in the supine position. In our study, subjects were extubated when awake and sitting up, with $F_{IO_2} \leq 0.45$, and usual care included suction at extubation. Another study reported no benefit from the application of positive pressure at the end of anesthesia through to extubation.[34] The extubation procedure was unclear, and the reasons for lack of efficacy remain uncertain. Our subjects comprised a low-risk cardiac population, as supported by the median EuroSCORE II of 1.17.

In our study, the primary outcome was P_{aO_2}/F_{IO_2} on room air 6 h after extubation. P_{aO_2}/F_{IO_2} is an accepted marker of hypoxia.[35] Postoperative cardiac surgical patients have reported $P_{aO_2}/F_{IO_2} > 300$.[36] A criticism of the P_{aO_2}/F_{IO_2} is the influence of F_{IO_2}.[37] For example, the influence of F_{IO_2} upon P_{aO_2}/F_{IO_2} can move patients from severe to moderate diagnosis when categorizing the severity of ARDS.[37] To mitigate this concern, we discontinued supplemental oxygen for 5 min before the ABG for the primary outcome was obtained.[24] There is increasing interest in the use of noninvasive assessments of hypoxia, such as S_{pO_2}/F_{IO_2}. S_{pO_2}/F_{IO_2} and P_{aO_2}/F_{IO_2} have been found to have good correlation.[38,39] Future studies could use S_{pO_2}/F_{IO_2} as the primary outcome and incorporate validation of P_{aO_2}/F_{IO_2}. We recorded the primary outcome at 6 h postextubation because we anticipated that any acute complications of avoidance of endotracheal suctioning would manifest within this period. Given the number of ABGs excluded from the primary analysis as a result of being recorded outside the 6-h window, future studies could consider the timing of any postextubation ABG analysis required.

The provision of suctioning in the usual care group was lower than anticipated. Given the results of the unit survey of endotracheal suctioning practice, we anticipated that 100% of subjects in the usual care group would receive suction. However, the short duration of mechanical ventilation may have influenced the amount of suction delivered. That said, there was clear separation between the groups on receipt of endotracheal suctioning (60.0% in usual care group vs 19.3% in the intervention group), demonstrating endotracheal suctioning had been minimized in the intervention group. The median suction pressure was also higher than recommended in practice guidelines (< 150 mm Hg),[10] but the unit protocol at the time of the study recommended that suction pressure be ≤ 200 mm Hg; this recommendation is currently under review. Twelve of the 15 intervention subjects who received endotracheal suctioning met the prespecified safety caveats,[24] indicating that the rescue protocol was used appropriately by the bedside staff.

Blocked endotracheal tubes, aspiration, or other complications of ventilation or extubation did not occur in our study. There were also no differences between groups in either the requirement for escalation of oxygen therapy or oxygen desaturation (ie, $S_{pO_2} < 90\%$). Although no previous human studies have compared

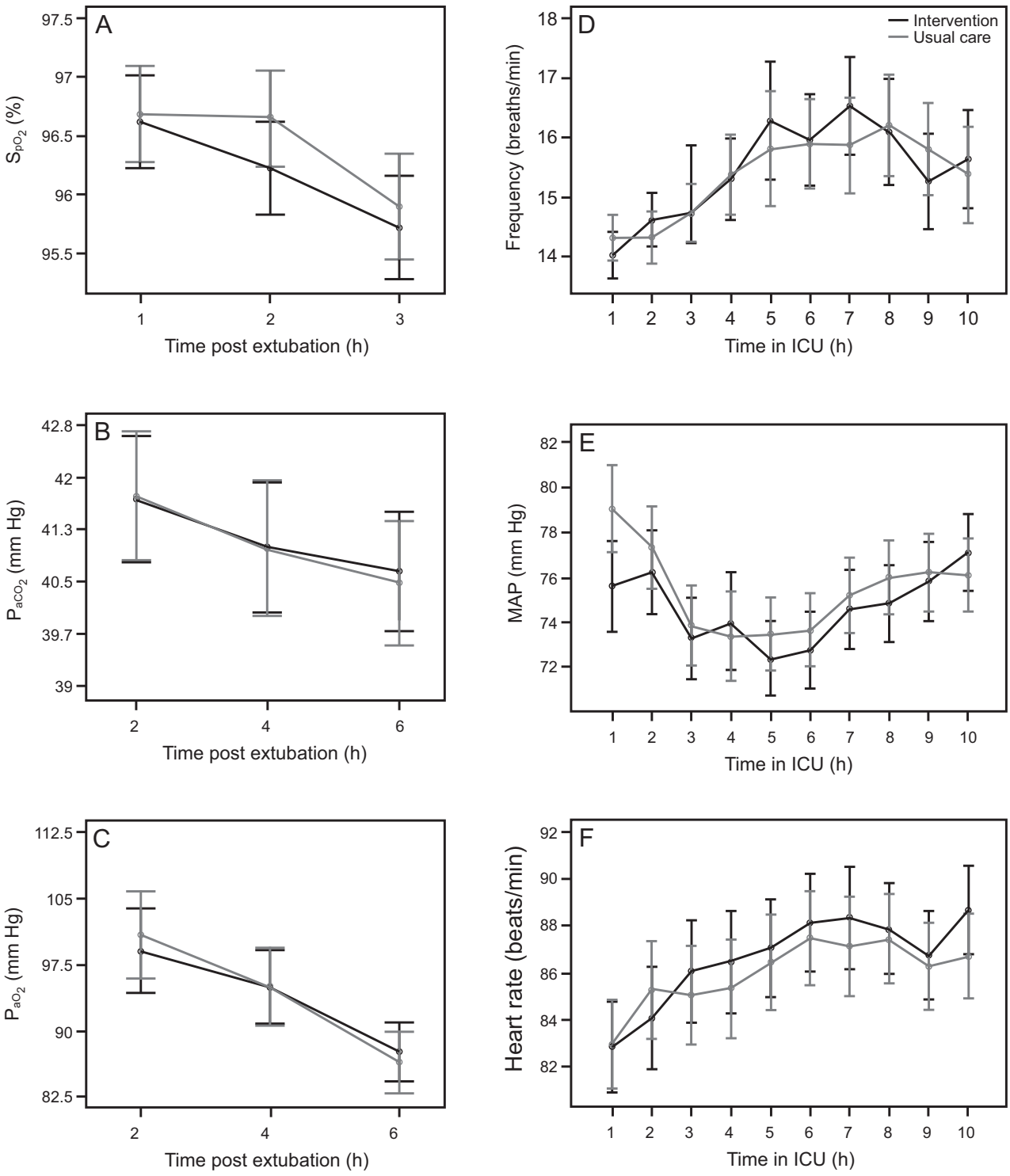

Fig. 3. Repeated measures of physiology and oxygenation outcomes. MAP = mean arterial pressure.

suction with avoidance of suction, some animal studies have investigated suction versus no suction.[19,20,22,23,40] None of the animal studies reported blocked endotracheal tubes or complications of ventilation, although all had a short duration of ventilation.

Our trial has 3 main limitations. First, the nature of the intervention meant that it was not possible to blind the clinical staff to the patient allocation, but there was a clear difference between the groups in terms of suctioning, and staff collecting the data were not involved in the subjects' care.

Table 2. Comparison of Secondary and Safety Outcomes Between Groups

Characteristic	Usual Care	Intervention	*P*	Risk Difference (95% CI)
Laryngeal spasm	0	0	NA	NA
Aspiration	0	0	NA	NA
Re-intubation	0	0	NA	NA
Escalation of oxygen therapy	11 (15.7)	8 (9.5)	.25	–0.06 (–0.17–0.04)
Desaturation $S_{pO_2} < 90\%$	8 (11.4)	10 (11.9)	.93	0.01 (–0.10–0.10)
Vomiting	7 (10.0)	5 (6.0)	.35	0.04 (–0.13–0.05)
Episode of tachycardia > 100 beats/min	15 (21.4)	23 (27.4)	.39	0.06 (–0.08–0.20)
Episode of breathing frequency >25 breaths/min	20 (28.6)	21 (25.0)	.62	–0.03 (–0.18–0.11)
Episode of MAP > 85 mm Hg	27 (38.6)	41 (48.8)	.20	0.10 (–0.05–0.26)

Data are presented as *n* (%). *P* values are the result of chi-squared tests.
NA = not applicable
MAP = mean arterial pressure

Second, due to the number of protocol violations regarding the collection of ABG for the primary outcome, the number of subjects in the per-protocol analysis was lower than our sample size estimate (154 vs 166). However, the noninferiority margins between the groups for the primary analyses were well within the anticipated 10% lower bound of the CI, and post hoc recalculation of the power using the study data showed no loss of statistical power to detect a 10% noninferiority margin (80% for $n = 154$). Third, our study was conducted on a low-risk, post-surgical cardiac population and thus may not be generalizable to higher-risk patient cohorts.

Further research incorporating multiple cardiac centers and other patient populations exposed to planned short-term mechanical ventilation of $\leq$ 12 h would expand the generalizability of this trial. Future research could consider increasing the period of avoidance of endotracheal suctioning, in particular where routine use of humidification is in place. Future research could also investigate whether using S_{pO_2}/F_{IO_2} is a better outcome measure than P_{aO_2}/F_{IO_2}, primarily because S_{pO_2}/F_{IO_2} is noninvasive and therefore may have broader application as not all ICU patients have an arterial line in situ.

Conclusions

Avoiding endotracheal suctioning including at extubation in postoperative cardiac surgical subjects ventilated for $\leq$ 12 h with appropriate use of rescue protocols was safe with no effect on complications.

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