Available online at www.sciencedirect.com
ScienceDirect
British Journal of Oral and Maxillofacial Surgery 57 (2019) 1014–1018
BRITISH Journal of Oral and Maxillofacial Surgery
www.bjoms.com

Comparison of high-flow oxygen therapy with standard oxygen therapy for prevention of postoperative pulmonary complications after major head and neck surgery involving insertion of a tracheostomy: a feasibility study

P. Twose[a,*], C. Thomas[b], M. Morgan[c], M.-A. Broad[d]

[a] *Physiotherapy Department, University Hospital of Wales, Cardiff CF14 4XW*
[b] *Department of Oro-Maxillofacial Surgery, University of Wales, Cardiff CF14 4XW*
[c] *Critical Care Department, University Hospital of Wales, Cardiff CF14 4XW*
[d] *Queen Elizabeth Hospital Kings Lynn, Gayton Road, Kings Lynn PE30 4ET*

Accepted 23 August 2019
Available online 9 September 2019

Abstract

Major operations on the head and neck that involve microvascular reconstruction and a tracheostomy are prolonged procedures with considerable postoperative risk. Postoperative pulmonary complications are common because of mechanical ventilation, immobility, and inadequate humidification. High-flow heated oxygen therapy (HFOT) may overcome some of these issues, but we know of no published studies to support its use. The aim of this single-site randomised controlled trial therefore was to explore its feasibility and safety in these patients. Twenty patients were randomised to have HFOT (10 patients) or standard oxygen therapy (10 patients). HFOT was used from cessation of mechanical ventilation until decannulation of the tracheostomy. The primary outcome was feasibility. The secondary outcome measures explored the incidence of postoperative pulmonary complications, achievement of milestones of weaning from the tracheostomy, and hospital length of stay. A total of 21 patients were consecutively recruited and all provided informed consent. One who did not require a tracheostomy was later excluded. All patients initially had the intervention as planned, and one was electively changed to the control group because of discomfort caused by the high-flow oxygen. There were no adverse events or safety concerns in either group. Secondary outcomes showed a reduction in the incidence of pulmonary complications in the HFOT group. The use of HFOT is safe and feasible in patients who have microvascular reconstruction of the head and neck and a tracheostomy.

Keywords: Postoperative complications; Critical Care; Tracheostomy; High-flow oxygen therapy; Feasibility; Head & neck surgery with microvascular reconstruction

Introduction

Major head and neck operations that involve microvascular reconstruction are prolonged procedures with considerable postoperative risk.[1] Patients have a prolonged time in theatre because the operations involve two distinct surgical sites (head and neck, and peripheral flap donor site), and often require admission to a high-dependency unit for overnight sedation and invasive ventilation.[1] This, combined with the presence of coexisting conditions such as hypertension and respiratory disease, places the patient at considerable risk of

* Corresponding author. Tel.: 02920 743902.
E-mail address: Paul.Twose@wales.nhs.uk (P. Twose).

https://doi.org/10.1016/j.bjoms.2019.08.021
0266-4356/

postoperative complications.[2,3] A recent prospective cohort study reported complications in nearly 65% of cases, of which 29% were of pulmonary origin.[1] The risk of pulmonary complications seems to be further increased in patients who require a tracheostomy.

The risks of tracheostomy are well known,[4] and patients are prone to increased rates of infection, poor sputum clearance, and inadequate humidification.[5] To overcome these issues, national guidance documents[4,6] have identified the importance of adequate humidification to prevent the plugging of mucus and retention of secretions. Historically, humidification was provided by heated systems,[7] but these have fallen out of favour because of the perceived risk of increased infection, and passive humidification systems such as heat moisture exchangers have now become more popular.[7]

Clearly, the risks of major head and neck surgery combined with those of a tracheostomy place patients at considerable risk, and it is essential to develop new postoperative management protocols to reduce it.

AIRVO™ 2 (Fisher and Paykel Healthcare), which delivers high-flow heated and humidified oxygen and air through a tracheostomy tube at a prescribed fraction of inspired oxygen and a maximum flow of 60 L/minute, is an attractive alternative to conventional oxygen therapy.[8,9] Previous studies have shown that HFOT generates a flow-dependent positive airway pressure[9,10] and improves oxygenation by increasing end-expiratory lung volume.[11] Although widely used in other clinical areas, including patients with tracheostomies, HFOT has not, to our knowledge, been explored or evaluated in patients who have operations on the head and neck.

In this study therefore we aimed to explore the feasibility of a randomised controlled trial to compare HFOT with standard care after major head and neck operations that involve the insertion of a tracheostomy tube.

Method

Study design

This study is a feasibility, randomised controlled trial that was completed in a tertiary head and neck surgery unit.

Participants

Twenty patients who had elective microvascular reconstruction of the head and neck involving a tracheostomy, were included. All patients provided informed consent. As a feasibility study, no formal size calculation was completed. Patients were excluded at the request of the consultant, if they were under 18 years of age, or did not give their informed consent.

Randomisation

Randomisation was completed at the point of recruitment by the use of sealed envelopes of equal proportions for the control and intervention groups. The process was completed by the chief investigator who had no previous knowledge of the patient, their history, or planned operation, beyond being aware that it involved microvascular reconstruction of the head and neck and a tracheostomy. It was done immediately after the patients had given their consent, and before transfer to theatre.

Procedures or interventions

All patients were admitted to the post-anaesthetic care unit as is standard after operation. Also as standard, they were sedated and ventilated overnight with a view to reducing or stopping sedation in the morning (postoperative day 1), and weaning them from mechanical ventilation. At the point when mechanical ventilation stopped, the trial intervention started. All other aspects of care remained as normal.

Trial interventions

Patients who were allocated to the intervention group were given high-flow oxygen through the tracheostomy tube. It was delivered by the AIRVO™ 2 system using the appropriate tracheostomy interface. High-flow oxygen was provided at a flow rate of 60 L/minute with a fraction of inspired oxygen (FiO_2) that was titrated by the clinician at the bedside to maintain a peripheral oxygen saturation of 95% or more (unless clinically indicated and documented by an appropriate consultant).

Once transferred to the ward, patients continued to be given HFOT 24 hours/day at a rate of 60 L/minute and at a maximum oxygen concentration of 40% to achieve oxygen saturations of 95% and above (unless otherwise documented).

Weaning from the tracheostomy continued as standard. To ensure readiness for decannulation, all patients had a two-hour trial off HFOT to ensure adequate oxygenation without the assistance of the increased flow rates. After decannulation, standard oxygen therapy was given as needed.

Standard care

Patients in the standard care arm were given routine postoperative care. After cessation of mechanical ventilation, oxygen was delivered by equipment and rates that were appropriate. Patients continued to use heat moisture exchangers as clinically indicated, and saline nebulisers were also prescribed and administered according to standard protocols.

Outcome measures

The primary outcome for this study was the feasibility of completing a randomised controlled trial to compare HFOT with standard care. Feasibility was assessed through the number of eligible patients, and their willingness to participate and be randomised. It was also assessed through the willingness of clinicians to recruit participants, the characteristics of the proposed outcome measures, and the adherence to, or compliance with, the interventions.

Secondary outcome measures included the incidence of postoperative pulmonary complications, postoperative length of hospital stay, time to deflation of the tracheostomy cuff, time to decannulation of the tracheostomy, the antibiotics given, and requirement for postoperative physiotherapy. All of these were included to guide future study designs. Postoperative pulmonary complications were classified as: exacerbations of chronic obstructive pulmonary disease (COPD); adult respiratory distress syndrome (ARDS), unspecified respiratory failure, pneumonia, or pneumothorax. Pneumonia was confirmed using the clinical pulmonary infection score (CPIS),[12] and ARDS using the Berlin definition.[13]

Ethics approval was obtained from the Wales Research Ethics Committee – REC3 (17/WA/0053). Written informed consent was provided directly by the patients.

Analysis

Demographic data and feasibility outcomes were analysed using descriptive statistics.

Secondary outcome measures were analysed on an intention-to-treat basis using descriptive statistics (mean (SD) or median IQR, as appropriate). Statistical tests were not completed because of the limited sample size and the feasibility design.

Results

Participants

Twenty patients were recruited between April 2017 and June 2018. Table 1 shows their baseline characteristics.

Feasibility outcomes

During the 14-month recruitment period, all the patients had microvascular reconstruction of the head and neck involving the insertion of a tracheostomy tube.

Willingness to participate in the study

A total of 21 patients initially met the inclusion criteria, and they were all asked if they would participate in the study. All of them provided written informed consent. One who no longer required a tracheostomy was excluded on the day of operation.

Willingness of participants to be randomised

All 20 patients were willing to be randomised to HFOT or standard therapy. None asked to be transferred to the other treatment arm or to withdraw from the study.

Willingness of clinicians to recruit participants

All patients were recruited by the lead investigator or co-investigator. No clinicians asked for patients not to be involved, or to change the treatment protocol after inclusion and randomisation.

Characteristics of the proposed outcome measures

All outcome measures were completed for all patients. The CPIS was completed retrospectively using daily clinical observations and blood results. Chest radiographs were interpreted by one investigator who was not directly involved in the patients' care.

Adherence or compliance with the interventions

Of the 20 included, 19 participants completed the intervention as planned. One in the intervention arm was changed to standard care on day three because of discomfort caused by heat from the HFOT. Attempts had been made to reduce the temperature of the device from 37 °C to 31 °C, but with limited improvement. The patient remained apyrexial (temperature under 38.4 °C throughout).

Secondary outcomes

Postoperative pulmonary complications

Use of the CPIS showed that three patients in the control group, and none in the intervention group, had postoperative pneumonia. There were no cases of postoperative pneumothorax, exacerbation of COPD, ARDS, or any other unexplained respiratory failure.

Trends were observed towards reductions in time to mobilisation and independent mobility, requirement for physiotherapy, and total length of stay (Table 2).

Discussion

This study has shown that patients can be appropriately recruited, randomised, and included in a randomised controlled trial to compare HFOT with standard care. Our limited sample showed a reduction in the incidence of postoperative pulmonary complications in patients treated with high-flow oxygen through the Airvo^{TM} 2 system. There were also trends towards reductions in length of stay and requirements for postoperative physiotherapy. The need for respiratory physiotherapy was reduced considerably.

Table 1
Demographic data for each group.

	High-flow oxygen	Standard oxygen
Male:female	5:5	7:3
Mean (SD) age (years)	60.0 (10.3)	59.4 (9.9)
Mean (SD) BMI (kg/m^2)	24.7 (3.4)	25.4 (4.2)
Median (IQR) comorbidities	1 (0.75 – 1)	1 (0 – 2)
Median (IQR) current smoker	1 (0.75 – 1)	0 (0 – 1)
Mean (SD) duration of mechanical ventilation (hours)	14.3 (1.7)	13.8 (1.2)
Operation (number)	Hemimandibulectomy = 5 Maxillectomy = 2 Partial glossectomy = 2 Anterior glossectomy = 1	Hemimandibulectomy = 2 Maxillectomy = 1 Hemiglossectomy = 2 Partial glossectomy = 3 Floor of mouth resection = 2

Table 2
Additional secondary outcomes for both groups.

	High-flow oxygen	Standard oxygen
Mean (SD) length of stay in post-anaesthetic care unit (hours)	25.0 (9.1)	29.3 (10.1)
Median (IQR) time to cuff deflation (days)	4 (4 – 4)	4 (3 – 4)
Median (IQR) time to decannulation (days)	5 (4 – 5)	5 (4 – 5)
Median IQR time to sit out of bed (days)	3 (3 – 3.75)	3.5 (3 – 4)
Median (IQR) time to independent mobility (days)	5 (4.25 – 6.5)	6 (5 – 7)
Mean (SD) requirement for respiratory physiotherapy (minutes)	96.5 (30.6)	125.5 (21.7)
Mean (SD) requirement for rehabilitation physiotherapy (minutes)	39.5 (22.8)	28.5 (10.6)
Mean (SD) total requirement for physiotherapy (minutes)	136 (43.1)	154.0 (28.4)
Median (IQR) total length of stay (days)	14.5 (8.25 – 25)	16 (12 – 19)

Operations on the head and neck that involve microvascular reconstruction and a tracheostomy are associated with a high risk of postoperative complications, of which many are pulmonary in origin. They prolong stays in hospital, lengthen the duration of treatment, and increase the need for intensive care beds and antibiotics.

HFOT provides humidity and the ability to supply high fractions of inspired oxygen. It also improves compliance.[8–10] There is, to our knowledge, a paucity of studies to support its delivery through a tracheostomy tube, but the same principles that apply to patients with high-flow nasal cannulas also apply to those with tracheostomies. HFOT reduces heat and loss of moisture from the airway, and also reduces anatomical dead space.[8–10] It has improved outcomes in a range of situations, for example, after extubation in patients who have had cardiac surgery,[14,15] and when used to prevent the need for intubation in those with respiratory failure.[16]

Our finding of no adverse events suggests that HFOT is safe in this group of patients. Future studies should use the incidence of postoperative pulmonary complications as the primary outcome. These have been classified as the physician's diagnosis of exacerbation of COPD, radiological evidence of pneumothorax, ARDS confirmed using the Berlin definition,[13] unexplained respiratory failure, or postoperative pneumonia measured using the CPIS.

While apparently being effective in this feasibility study, however, both the CPIS for pneumonia and the classification for ARDS would need to be reviewed before they are used in future work. This is because they rely on the calculation of the ratio of partial pressure of arterial oxygen:fraction of inspired oxygen (PaO_2:FiO_2), which requires analysis of arterial blood gases, a test rarely needed in these patients. It must also be noted that the CPIS is primarily designed for the diagnosis of pneumonia associated with the use of a ventilator,[12] although there is some evidence to support its use in the diagnosis of hospital-acquired pneumonia.[17]

Analysis of the secondary outcomes showed no postoperative pulmonary complications in the patients treated with HFOT, although three in the standard care group had pneumonia. These compare favourably with previous local service evaluations and published studies. McMahon et al reported pulmonary complications in 28% of a large cohort study (n = 592 patients),[18] most of whom had lower respiratory tract infections that developed between three and seven days postoperatively. In a previous study the same author had reported such infections in 29% of patients, 14 of whom (of 56 diagnosed) required treatment in critical care.[1]

We acknowledge that the study has several limitations. Because of its nature, the sample size was limited, and this affected the ability to do any statistical analysis to test the validity of the findings. Most of the research team were directly involved in the patients' care so blinding was not possible, except for the interpretation of the chest radiographs. It was also not possible to blind the ward-based staff or patients to the intervention given.

In conclusion, a randomised controlled trial to compare the use of HFOT with standard care in patients who have microvascular reconstruction of the head and neck and a tracheostomy, is feasible. The use of HFOT may also reduce the incidence of postoperative pulmonary complications.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

Ethics approval was obtained from Wales Research Ethics Committee – REC3 (17/WA/0053). Written informed consent was provided directly by patients.

References

1. McMahon JD, MacIver C, Smith M, et al. Postoperative complications after major head and neck surgery with free flap repair—prevalence, patterns, and determinants: a prospective cohort study. *Br J Oral Maxillofac Surg* 2013;**51**:689–95.
2. Ferrier MB, Spuesens EB, Le Cessie S, et al. Comorbidity as a major risk factor for mortality and complications in head and neck surgery. *Arch Otolaryngol Head Neck Surg* 2005;**131**:27–32.
3. Grønkjær M, Eliasen M, Skov-Ettrup LS, et al. Preoperative smoking status and postoperative complications: a systematic review and meta-analysis. *Ann Surg* 2014;**259**:52–71.
4. Wilkinson KA, Martin IC, Freeth H, et al. *On the right trach? A review of the care received by patients who underwent a tracheostomy*. National Confidential Enquiry into Patient Outcome and Death (NCEPOD); 2014. Available from URL: https://www.ncepod.org.uk/2014report1/downloads/OnTheRightTrach_Summary.pdf. [Last accessed 19 August 2019].
5. Woodrow P. Managing patients with a tracheostomy in acute care. *Nurs Stand* 2002;**16**:39–46.
6. Bodeham A. *Standards for the care of adult patients with a temporary tracheostomy: standards and guidelines*. Council of the Intensive Care Society; 2014. Available from URL: https://www.theawsomecourse.co.uk/ICS/ICS%20Tracheostomy%20standards%20(2014).pdf. [Last accessed 19 August 2019].
7. Kelly M, Gillies D, Todd DA, et al. Heated humidification versus heat and moisture exchangers for ventilated adults and children. *Cochrane Database Syst Rev* 2010;**14**:CD004711.
8. Chanques G, Constantin JM, Sauter M, et al. Discomfort associated with underhumidified high-flow oxygen therapy in critically ill patients. *Intensive Care Med* 2009;**35**:996–1003.
9. Chanques G, Riboulet F, Molinari N, et al. Comparison of three high flow oxygen therapy delivery devices: a clinical physiological cross-over study. *Minerva Anesthesiol* 2013;**79**:1344–55.
10. Parke R, McGuinness S, Eccleston M. Nasal high-flow therapy delivers low level positive airway pressure. *Br J Anaesth* 2009;**103**:886–90.
11. Corley A, Caruana LR, Barnett AG, et al. Oxygen delivery through high-flow nasal cannulae increase end-expiratory lung volume and reduce respiratory rate in post-cardiac surgical patients. *Br J Anaesth* 2011;**107**:998–1004.
12. Luyt CE, Chastre J, Fagon JY. Value of the clinical pulmonary infection score for the identification and management of ventilator-associated pneumonia. *Intensive Care Med* 2004;**30**:844–52.
13. Confalonieri M, Salton F, Fabiano F. Acute respiratory distress syndrome. *Eur Respir Rev* 2017;**26**, pii: 160116.
14. Hernández G, Vaquero C, González P, et al. Effect of postextubation high-flow nasal cannula vs conventional oxygen therapy on reintubation in low-risk patients: a randomized clinical trial. *JAMA* 2016;**315**:1354–61.
15. Hernández G, Vaquero C, Colinas L, et al. Effect of postextubation high-flow nasal cannula vs noninvasive ventilation on reintubation and postextubation respiratory failure in high-risk patients: a randomized clinical trial. *JAMA* 2016;**316**:1565–74.
16. Ni YN, Luo J, Yu H, et al. The effect of high-flow nasal cannula in reducing the mortality and the rate of endotracheal intubation when used before mechanical ventilation compared with conventional oxygen therapy and non-invasive positive pressure ventilation. A systematic review and meta-analysis. *Am J Emerg Med* 2018;**36**:226–33.
17. Kalil AC, Metersky ML, Klompas M, et al. Executive summary: management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clin Infect Dis* 2016;**63**:575–82.
18. McMahon J, Handley TP, Bobinskas A, et al. Postoperative complications after head and neck operations that require free tissue transfer—prevalent, morbid, and costly. *Br J Oral Maxillofac Surg* 2017;**55**:809–14.