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### **Aerosol precautions and airway complications**

a national prospective multicentre cohort study

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## Original Article

# Aerosol precautions and airway complications: a national prospective multicentre cohort study

T. Potter,<sup>1</sup>  J. N. Cronin,<sup>2</sup>  J. Kua,<sup>3</sup>  E. Nurmi,<sup>1</sup> D. J. N. Wong,<sup>2</sup>  I. Ahmad,<sup>2,4</sup>   
T. M. Cook,<sup>5,6</sup>  K. El-Boghdadly,<sup>2,4</sup>  the AeroComp Trainee Research Networks<sup>#</sup> and Collaborators\*

1 Speciality Trainee, 2 Consultant, Department of Anaesthesia and Peri-operative Medicine, Guy's and St. Thomas' NHS Foundation Trust, London, UK

3 Clinical Research Fellow, Surgical Outcomes Research Centre, University College London, UK

4 Honorary Senior Lecturer, King's College London, UK

5 Consultant, Department of Anaesthesia, Royal United Hospitals Bath NHS Foundation Trust, Bath, UK

6 Honorary Professor, School of Medicine, University of Bristol, UK

## Summary

The perceived risk of transmission of aerosolised viral particles from patients to airway practitioners during the COVID-19 pandemic led to the widespread use of aerosol precautions, including personal protective equipment and modifications to anaesthetic technique. The risk of these aerosol precautions on peri-operative airway complications has not been assessed outside of simulation studies. This prospective, national, multicentre cohort study aimed to quantify this risk. Adult patients undergoing general anaesthesia for elective or emergency procedures over a 96-hour period were included. Data collected included use of aerosol precautions by the airway practitioner, airway complications and potential confounding variables. Mixed-effects logistic regression was used to assess the risk of individual aerosol precautions on overall and specific airway complications. Data from 5905 patients from 70 hospital sites were included. The rate of airway complications was 10.0% (95%CI 9.2–10.8%). Use of filtering facepiece class 2 or class 3 respirators was associated with an increased risk of airway complications (odds ratio 1.38, 95%CI 1.04–1.83), predominantly due to an association with difficult facemask ventilation (odds ratio 1.68, 95%CI 1.09–2.61) and desaturation on pulse oximetry (odds ratio 2.39, 95%CI 1.26–4.54). Use of goggles, powered air-purifying respirators, long-sleeved gowns, double gloves and videolaryngoscopy were not associated with any alteration in the risk of airway complications. Overall, the use of filtering facepiece class 2 or class 3 respirators was associated with an increased risk of airway complications, but most aerosol precautions used during the COVID-19 pandemic were not.

Correspondence to: K. El-Boghdadly

Email: kariem.el-boghdadly@kcl.ac.uk

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<sup>#</sup>AeroComp Trainee Research Networks: Pan-London Perioperative Audit and Research Network; North West Research and Audit Group; Sessa QI Audit and Research Network; Severn Trainee Anaesthetic Research; South Yorkshire Hospitals Audit and Research Collaboration; Welsh Anaesthesia Audit, Research and Engagement Network; and West of Scotland Anaesthetic Trainees Research Network.

\*See online Supporting Information Appendix S1 for a full list of contributors.

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Twitter: @t\_Potter\_1; @john\_n\_cronin; @justin\_kua; @EvieNurmi; @dannyjnwong; @dr\_imranahmad; @doctimcook; @elboghdadly; @PeriopResearch; @STARResearch; @SQuAResNet; @NWRAG; @WAARENgroup; @SHARCgroup; @wostrag

## Introduction

Although most airway management is uncomplicated, when complications do arise, they can be catastrophic and result in significant patient morbidity and mortality [1]. The COVID-19 pandemic resulted in significant changes to airway management [2] due to concerns of transmission of aerosolised viral particles to healthcare professionals [3]. Initial reports suggested that patients with COVID-19 may be more at risk of airway complications including hypoxaemia [4], airway trauma [5] and difficult tracheal intubation due to airway oedema [6]. These observations were further supported by analysis of registry data showing a relatively high rate of failed tracheal intubation (1 in 120) and emergency surgical airways (1 in 450) in patients who were critically ill with COVID-19 [7].

While it is possible that COVID-19 itself may be a risk factor for airway complications, the aerosol precautions designed to reduce the transmission of viral particles to healthcare workers may also contribute. These aerosol precautions include, but are not limited to: minimising the number of staff present; avoidance of bag-mask ventilation; increased use of videolaryngoscopy; and use of personal protective equipment (PPE) [2].

Anaesthetic management varies, in part, depending on a patient's SARS-CoV-2 status. In the UK, for the majority of the pandemic, anaesthetic airway management was classified as an aerosol-generating procedure (AGP). Throughout much of the pandemic period, aerosol precaution PPE was recommended when performing any AGP, comprising a respirator mask (single or multiple-use filtering facepiece class 3 (FFP3) or powered air-purifying respirator (PAPR), long-sleeved gown, gloves and eye protection. In the latter part of 2021, the PPE required for SARS-CoV-2 negative patients was reduced to droplet precautions comprising plastic gown, fluid resistant surgical mask, gloves and eye protection [8]. It is currently not known whether the use of PPE and other methods used to reduce viral transmission during airway interventions (hereafter referred to as the 'aerosol precaution bundle') increase the risk of airway complications. However, there are reports of airway management in patients with COVID-19 being associated with an increased risk of difficult tracheal intubation warranting further investigation of this potential association [4–6, 9].

While pandemic precautions were still in place, we undertook a national, prospective, multicentre observational cohort study to identify the rate of airway complications in patients undergoing elective or emergency general anaesthesia and any association between these complications and components of the aerosol precaution bundle.

## Methods

AeroComp was a prospective observational cohort study conducted in NHS hospitals in England, Wales and Scotland. The study met the criteria for a service evaluation according to the NHS Health Research Authority tool [10], and therefore formal ethical approval was not required. The study was prospectively approved by Information Governance departments at all participating hospital sites, and Caldicott approval from the lead site was prospectively obtained. We report our findings according to the strengthening the reporting of observational studies in epidemiology (STROBE) guidelines [11].

Sites were invited to participate by members of the anaesthetic trainee research networks throughout the UK, and through wider advertisement by national societies. Individual sites were free to choose their own data collection period, defined as a consecutive 96-h period starting at 07:30 on one of the five Mondays in November 2021.

We studied adult patients (aged  $\geq 18$  y) undergoing an elective or emergency procedure where the primary mode of anaesthesia was planned to be general anaesthesia. We did not study patients having obstetric procedures and patients in whom induction of anaesthesia occurred in the emergency department, intensive care unit (ICU) or wards. Patients with an airway device already in situ or in cardiac arrest at the time of airway intervention were also not studied.

Patient data collected included age, sex and BMI, all within predefined categories to maintain de-identification. Patients were defined as being SARS-CoV-2 positive if they were either positive on reverse transcriptase-polymerase chain reaction (PCR) or lateral flow test (LFT), had at least one COVID-19 major symptom (new continuous cough, fever or anosmia) [12], or had recent exposure to a SARS-CoV-2 positive person. Patients were defined as SARS-CoV-2 negative if they self-isolated before hospital admission, were cohorted in a COVID-19-free pathway while within the hospital, had no recent positive PCR or LFT and had at least one negative PCR or LFT. All other patients were classified as SARS-CoV-2 unclear. Surgical urgency was defined as per the UK National Confidential Enquiry into Patient Outcome and Death [13]. Grade of first and second airway managers was based on current UK training grades and individual sites were asked to choose the closest equivalent grade if there was no exact match.

Components of the aerosol protection bundle included use of aerosol precaution PPE and modifications of anaesthetic technique. We grouped PPE into eye,

respiratory, body and hand protection. The use of FFP class 2 (FFP2) or FFP3 masks was split based on whether the respirator was reusable or not. Any respirator employing an air pump or power was categorised separately as a PAPR. Anaesthetic technique data collected included: method of induction of anaesthesia; oxygenation technique; airway device used; and use of ancillary equipment. Use of cricoid force during tracheal intubation was also collected. A complete list of all data collected is provided in online Supporting Information Appendix S2.

Airway complications were documented at induction of anaesthesia and emergence of anaesthesia (in those patients awakened at the end of the procedure). Complications occurring outside the operating theatre were not studied. Airway complications categorised as severe included: death; unrecognised oesophageal intubation; and emergency front-of-neck airway (eFONA). Non-severe complications included; lip/mucosal/dental injury or other airway trauma; difficult facemask ventilation; difficult supraglottic airway device (SGA) use; desaturation; laryngospasm; difficult laryngoscopy (defined as a Cormack–Lehane laryngoscopy view of 3 or 4 [14]); three or more attempts at tracheal intubation; failed tracheal intubation; pulmonary aspiration of gastric contents; and emergency re-intubation of the patient's trachea following emergence of anaesthesia within the operating theatre. Individual complications are defined further in online Supporting Information Appendix S2. The primary airway manager was asked to grade subjective ease of facemask ventilation, SGA insertion and tracheal intubation on a 5-point Likert scale.

The primary outcome was the incidence of patients having at least one airway complication. Secondary outcomes were defined as the risk of each individual complication stratified by each component of the aerosol precaution bundle.

Data were uploaded by the local investigating teams at each site to a data capture server (REDCap 10.4.1 software, Vanderbilt University, Nashville, TN, USA). Each site provided the total number of eligible patients during their data collection period to determine the response rate. Data were inspected for missing data and potential deviations from inclusion/exclusion criteria. Patients with incomplete data reported were not studied. Institutions reporting data for < 75% of eligible patients were also not studied to reduce the risk of selection bias [15, 16].

Overall complication rate was defined as the proportion of the total number of included patients that had any airway complication. Site complication rate was defined as the proportion of patients reported by a single site that described any airway complication. In order to identify the

impact of sites that may have systematically over- or underreported complications, we undertook a sensitivity analysis excluding those with a site complication rate outside the 95% limits of the binomial distribution. However, we chose not to remove these sites from the main analyses as the rates may have been valid, including, for instance, institutions that undertake surgical specialties associated with higher or lower complication rates, as well as those sites falling outside the 95% limits due to natural variation.

The primary outcome was analysed using a mixed-effects logistic regression model with the primary outcome as the response variable, components of the aerosol precaution bundle, SARS-CoV-2 status, BMI, grade of first intubator and surgical urgency as fixed-effects predictors and hospital site as a random-effects predictor. Given the large number of independent variables, the Akaike information criterion was used to identify those variables which did not improve model fit and variables were removed or combined such that Akaike information criterion was optimised [17, 18]. Variables with physiologically plausible associations with airway complications were re-entered into the model after this if necessary. Given the small number of SARS-CoV-2 positive patients in our dataset, the positive and unclear groups were combined for the analysis. Use of PAPR hoods was similarly poorly represented, and the use of these was therefore excluded from the analysis. Finally, both disposable and reusable FFP2 or FFP3 masks were combined as doing so increased the fit of the model. To explore the effects of these important components of respiratory protective equipment on airway complications, a separate analysis (with poorer Akaike information criterion quality) was performed with these re-added.

Given that some complications were only possible with certain predictors (e.g. difficult facemask ventilation could only be reported if post-induction facemask ventilation was used; SGA or tracheal tube complications could only be reported if that particular airway device was used), the primary analysis was repeated with several exclusions from the airway complication composite outcome (sequentially difficult facemask ventilation and the combination of difficult SGA usage, oesophageal intubation, failed tracheal intubation, Cormack–Lehane grade 3/4 and  $\geq 3$  attempts at tracheal intubation).

The same logistic regression model was used to analyse the secondary outcomes. This model was repeated multiple times, each time replacing the response variable with each individual airway complication. This analysis was only performed if there were at least five events per independent variable for the airway complication. This

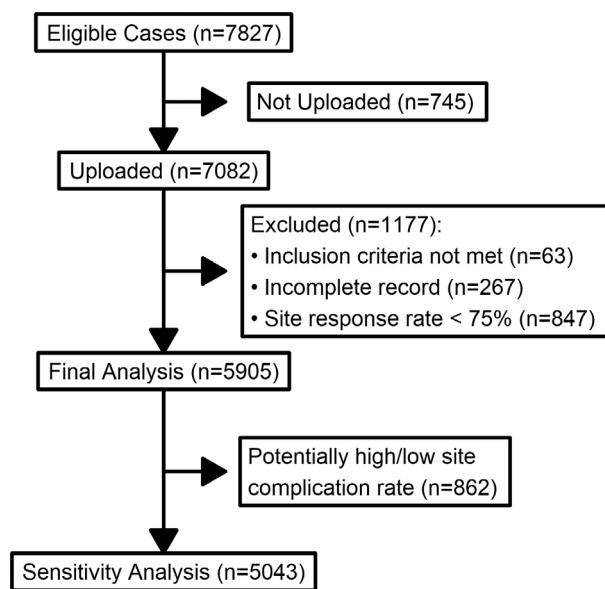
criterion exhibits similar rates of bias to 10 events per variable [19] but allowed inclusion of predictor variables in this secondary analysis that would otherwise have been excluded.

Preliminary analysis of the data identified a significant number of procedures that did not include rapid sequence induction (RSI) but reported use of cricoid force. Discussion with individual sites revealed that in many cases this represented backwards, upwards, rightwards pressure to improve the view at laryngoscopy, rather than cricoid force. Therefore, cricoid force was not included as an independent variable in the main analysis; rather, in a subgroup analysis comprising solely of patients receiving intravenous RSI, a separate logistic regression model was employed to assess the effects of cricoid force, COVID-19 status and BMI on the rate of airway complications.

All analyses were performed using the R statistical software version 4.0.2 (The R Foundation for Statistical Computing, Vienna, Austria). A p value of < 0.05 was considered statistically significant.

## Results

In total, 84 individual hospital sites reported 7827 potentially eligible patients of which data were collected for 7082 patients (90%) (Fig. 1). Following exclusions, 5905 patients from 70 hospital sites were included in our primary analysis. The total potential number of patients from these 70 sites was 6417, giving a response rate of 92%. Sites varied from small district general hospitals to large tertiary

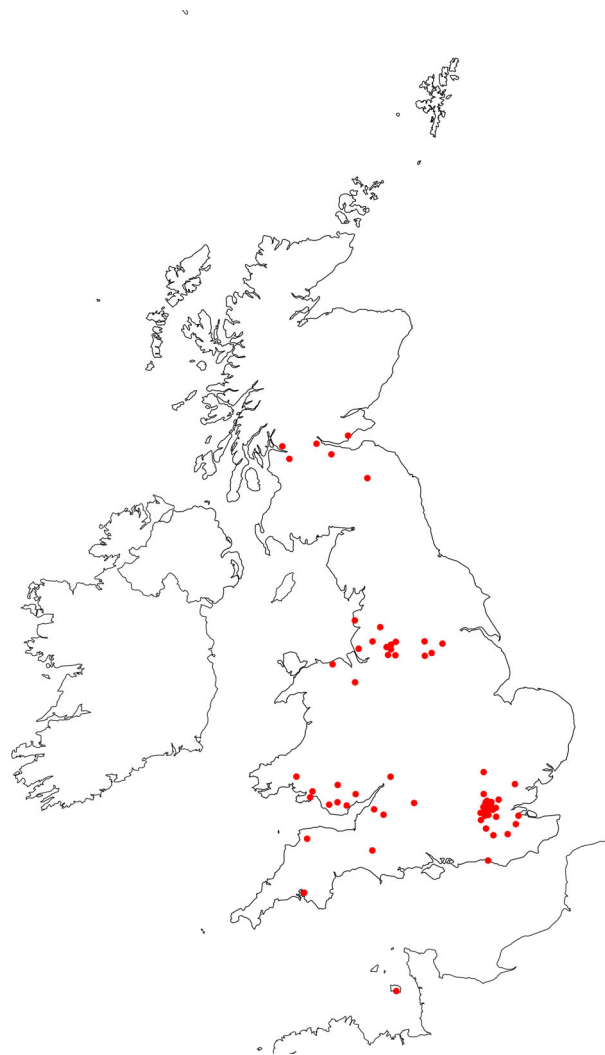


**Figure 1** STROBE flowchart of patient recruitment.

centres, the geographical spread of which is illustrated in Fig. 2. Baseline patient characteristics, surgical specialty and severity are summarised in Table 1. Components of the aerosol precaution bundle and other anaesthetic characteristics are reported in Table 2.

Respiratory protective equipment (FFP2 or FFP3 respirator or PAPR hood) was used in 49.4% of tracheal intubations and 30.4% of SGA insertions in SARS-CoV-2 positive or unclear patients, and was used in 13.0% of all SARS-CoV-2 negative patients (Table 3).

Complications occurred in 10.0% (95%CI 9.2–10.8%) of patients. In total, 531 (9.0%) complications occurred on induction and 70 (1.2%) on emergence. Rates of individual complications are presented in Table 4. No severe complications were reported. Sixty (85.7%) hospital sites



**Figure 2** Map of sites with at least one patient included in the final data set.

**Table 1** Characteristics of patients included in the final analysis. Values are number (proportion).

	<b>Total n = 5905</b>
<b>Age; y</b>	
18–39	1596 (27.0%)
40–59	1890 (32.0%)
60–79	2007 (34.0%)
≥80	412 (7.0%)
<b>Sex</b>	
Female	3228 (54.7%)
Male	2668 (45.2%)
Other	9 (0.2%)
<b>ASA physical status</b>	
1	1206 (20.4%)
2	3075 (52.1%)
3	1467 (24.8%)
4	155 (2.6%)
5	2 (<0.1%)
<b>BMI; kg.m<sup>-2</sup></b>	
<18.5	105 (1.8%)
18.5–24.9	1901 (32.9%)
25.0–29.9	1973 (34.2%)
30.0–34.9	1025 (17.7%)
35.0–39.9	505 (8.7%)
≥40.0	267 (4.6%)
<b>SARS-CoV-2 status</b>	
Positive	13 (0.2%)
Negative	5351 (90.6%)
Unclear	541 (9.2%)
<b>Surgical urgency</b>	
Elective	4094 (69.3%)
Expedited	621 (10.5%)
Urgent	891 (15.1%)
Immediate	299 (5.1%)
<b>Surgical severity</b>	
Minor	1696 (28.7%)
Intermediate	2855 (48.3%)
Major	1354 (22.9%)
<b>Surgical specialty</b>	
Bariatric	28 (0.5%)
Breast	299 (5.1%)
Cardiac	109 (1.8%)
Cardiology	54 (0.9%)
Dental	101 (1.7%)
Ear, nose and throat	576 (9.8%)
General	1159 (19.6%)

(continued)

**Table 1** (continued)

	<b>Total n = 5905</b>
Gynaecology	873 (14.8%)
Maxillofacial	170 (2.9%)
Neurosurgery	178 (3.0%)
Ophthalmology	87 (1.5%)
Orthopaedics and trauma	1029 (17.4%)
Plastics	189 (3.2%)
Radiology	54 (0.9%)
Thoracic	71 (1.2%)
Transplant	22 (0.4%)
Urology	712 (12.1%)
Other	80 (1.4%)
<b>Anaesthetic start time</b>	
Day (07.30–17.59)	5685 (96.3%)
Evening (18.00–23.59)	150 (2.5%)
Overnight (00.00–07.29)	70 (1.2%)

reported complication rates within the 95% limits of a binomial distribution modelling site complication rate. These sites, representing 5043 patients, were included in a subsequent sensitivity analysis (online Supporting Information Figure S1).

The aerosol precaution bundle components associated with an increased risk of airway complications were: use of an FFP2 or FFP3 respirator; pre-oxygenation; and post-induction facemask ventilation (Table 5). The increased risk seen with facemask ventilation remained when difficult facemask ventilation was excluded as a potential complication. Use of a clear plastic visor and SGA were associated with a reduced risk of complications. The reduced risk associated with SGA use remained if complications specific to a particular airway device were removed from the composite outcome. The predictors excluded from or combined in the final logistical regression model based on Akaike information criterion are provided in online Supporting Information Appendix S3. These results persisted in the sensitivity analysis excluding sites with potentially high or low complication rates (see online Supporting Information Table S1). The greatest effect on risk of airway complications was seen with BMI > 25 kg.m<sup>-2</sup> with rates of complications increasing with higher BMI categories. More junior anaesthetists as initial airway managers were associated with an increased risk of airway complications. SARS-CoV-2 status and surgical urgency were not independently associated with an increased risk of airway complications.

**Table 2** Characteristics of personal protective equipment and anaesthesia grouped by patient SARS-CoV-2 status. Values are number (proportion).

	<b>SARS-CoV-2 negative n = 5351</b>	<b>SARS-CoV-2 positive/unclear n = 554</b>	<b>Total n = 5905</b>
<b>Eye protection</b>			
Goggles or safety glasses	412 (7.7%)	68 (12.3%)	480 (8.1%)
Visor or PAPR hood	126 (2.4%)	58 (10.5%)	184 (3.1%)
Other	266 (5.0%)	10 (1.8%)	276 (4.7%)
<b>Respiratory protection</b>			
Surgical facemask	4638 (86.7%)	305 (55.0%)	4943 (83.7%)
Single-use FFP2 or FFP3 respirator	636 (11.9%)	225 (40.6%)	861 (14.6%)
Re-usable FFP2 or FFP3 respirator	39 (0.7%)	18 (3.2%)	56 (0.9%)
PAPR	22 (0.4%)	3 (0.5%)	25 (0.4%)
Other	4 (0.1%)	1 (0.2%)	5 (0.1%)
<b>Body protection</b>			
Plastic apron	424 (7.9%)	58 (10.5%)	482 (8.2%)
Long-sleeved gown	258 (4.8%)	128 (23.1%)	386 (6.5%)
Hazmat suit	0	1 (0.2%)	1 (<0.1%)
Other	41 (0.8%)	1 (0.2%)	42 (0.7%)
<b>Gloves</b>			
Single pair of gloves	5130 (95.9%)	518 (93.5%)	5648 (95.6%)
Double pair of gloves	46 (0.9%)	12 (2.2%)	58 (1.0%)
Other	7 (0.1%)	1 (0.2%)	8 (0.1%)
Not used	168 (3.1%)	23 (4.2%)	191 (3.2%)
<b>Induction</b>			
Inhalational	79 (1.5%)	10 (1.8%)	89 (1.5%)
Intravenous: non-RSI	5000 (93.4%)	449 (81.0%)	5449 (92.3%)
Intravenous: RSI/modified RSI	272 (5.1%)	95 (17.1%)	367 (6.2%)
<b>Oxygenation</b>			
Pre-oxygenation	4922 (92.0%)	508 (91.7%)	5430 (92.0%)
Post-induction facemask ventilation	2968 (55.5%)	274 (49.5%)	3242 (54.9%)
Apnoeic oxygenation	187 (3.5%)	33 (6.0%)	220 (3.7%)
<b>Airway device</b>			
Facemask (as sole airway device)	83 (1.6%)	6 (1.1%)	89 (1.5%)
Supraglottic airway	2309 (43.2%)	185 (33.4%)	2494 (42.2%)
Tracheal tube	2884 (53.9%)	354 (63.9%)	3238 (54.8%)
Supraglottic airway and tracheal tube	76 (1.4%)	8 (1.4%)	84 (1.4%)
<b>Equipment</b>			
Bougie	613 (11.5%)	83 (15.0%)	696 (11.8%)
Stylet	175 (3.3%)	19 (3.4%)	194 (3.3%)
Oxford pillow	52 (1.0%)	4 (0.7%)	56 (0.9%)
High-flow nasal cannulae	49 (0.9%)	7 (1.3%)	56 (0.9%)
Low-flow nasal cannulae	14 (0.3%)	2 (0.4%)	16 (0.3%)
Clear, plastic 'aerosol' box	0	0	0
Other	50 (0.9%)	5 (0.9%)	55 (0.9%)

(continued)



Table 2 (continued)

	SARS-CoV-2 negative n = 5351	SARS-CoV-2 positive/unclear n = 554	Total n = 5905
<b>Significant deviation from the original airway plan?</b>			
No	5227 (97.7%)	535 (96.6%)	5762 (97.6%)
Yes	124 (2.3%)	19 (3.4%)	143 (2.4%)
<b>Grade of initial airway manager</b>			
CT 1/2	1140 (21.3%)	174 (31.4%)	1314 (22.3%)
CT/ST 3/4	623 (11.6%)	76 (13.7%)	699 (11.8%)
ST 5–7	700 (13.1%)	77 (13.9%)	777 (13.2%)
SAS	740 (13.8%)	48 (8.7%)	788 (13.3%)
Consultant	1919 (35.9%)	152 (27.4%)	2071 (35.1%)
Other	229 (4.3%)	27 (4.9%)	256 (4.3%)
<b>Grade of second airway manager (if any)</b>			
	<b>n = 322</b>	<b>n = 41</b>	<b>n = 363</b>
CT 1/2	8 (2.5%)	2 (5%)	10 (2.8%)
CT/ST 3/4	13 (4.0%)	1 (2%)	14 (3.9%)
ST 5–7	26 (8.1%)	6 (15%)	32 (8.8%)
SAS	31 (9.6%)	2 (6%)	33 (9.1%)
Consultant	244 (75.8%)	30 (73%)	274 (75.5%)
Other	0	0	0
<b>Technique(s) used to place tracheal tube</b>			
	<b>n = 2960</b>	<b>n = 362</b>	<b>n = 3322</b>
Awake direct laryngoscopy	13 (0.4%)	3 (0.8%)	16 (0.5%)
Asleep direct laryngoscopy	2110 (71.3%)	245 (67.7%)	2336 (70.3%)
Awake videolaryngoscopy	7 (0.2%)	1 (0.3%)	8 (0.2%)
Asleep videolaryngoscopy	857 (29.0%)	109 (30.1%)	953 (28.7%)
Awake bronchoscopy	22 (0.7%)	3 (0.8%)	25 (0.8%)
Asleep bronchoscopy	36 (1.2%)	5 (1.4%)	41 (1.2%)

PAPR, powered air-purifying respirator; FFP2, filtering facepiece class 2; FFP3, filtering facepiece class 3; RSI, rapid sequence induction; CT, core trainee; ST, specialty trainee; SAS, staff grade, associate specialist and specialty doctor.

**Table 3** Rates of respiratory protective equipment use beyond a surgical facemask (filtering facepiece class 2 or 3 or powered air-purifying respirator hood) grouped by airway technique and SARS-CoV-2 status. Combination and other airway techniques have been excluded. Values are number utilising respiratory protective equipment/all cases (proportion).

Airway technique	SARS-CoV-2 Status		Overall
	Negative	Positive/unclear	
Tracheal intubation	423/2690 (15.7%)	159/322 (49.4%)	582/3012 (19.3%)
Supraglottic airway	224/2294 (9.8%)	56/184 (30.4%)	280/2478 (11.3%)
Any	647/4984 (13.0%)	215/506 (42.5%)	862/5490 (15.7%)

Five individual airway complications were sufficiently represented to achieve the criterion of at least five events per variable, all of which occurred during induction of anaesthesia (online Supporting Information Table S2). Complications associated with use of an FFP2 or FFP3 respirator were difficult facemask ventilation (OR (95%CI) 1.68 (1.09–2.61)) and desaturation to  $\leq 90\%$  (2.39 (1.26–4.54)). Increasing BMI was associated with difficult facemask

ventilation as well as an association between BMI  $\geq 35 \text{ kg.m}^{-2}$  with desaturation to  $\leq 90\%$ . These results persisted in the sensitivity analysis excluding sites with potentially high or low complication rates (online Supporting Information Table S3).

Separation of respiratory protective equipment into disposable FFP2 or FFP3 masks, reusable FFP2 or FFP3 masks and PAPR hoods resulted in reduced fit of the model



**Table 4** Airway complications in included patients. The total number of patients analysed during emergence is fewer than that during induction because not all patients were immediately woken up after their procedure. Values are number (proportion).

	Induction n = 5905	Emergence n = 5706
Any	531 (9.0%)	70 (1.2%)
Airway Trauma	22 (0.4%)	2 (0%)
Aspiration	4 (0.1%)	0 (0%)
Death	0 (0%)	0 (0%)
Dental injury	4 (0.1%)	2 (0%)
Desaturation ( $S_pO_2 \leq 80\%$ )	16 (0.3%)	16 (0.3%)
Desaturation ( $S_pO_2 \leq 90\%$ )	65 (1.1%)	32 (0.5%)
Difficult facemask ventilation (two-person technique)	202 (3.4%)	6 (0.1%)
Difficult SGA (excessive leak; poor ventilation; hypoxia)	111 (1.9%)	3 (0.1%)
Emergency front-of-neck airway	0 (0%)	0 (0%)
Failed tracheal intubation - awoken patient	0 (0%)	0 (0%)
Failed tracheal intubation - continue with SGA	1 (0%)	0 (0%)
Laryngospasm not reversed with positive pressure	8 (0.1%)	5 (0.1%)
Lip/mucosal injury	64 (1.1%)	12 (0.2%)
Oesophageal intubation (delayed recognition)	0 (0%)	0 (0%)
Oesophageal intubation (recognised)	37 (0.6%)	0 (0%)
Re-intubation immediately post-procedure	0 (0%)	4 (0.1%)

SGA, supraglottic airway.

(Akaike information criterion 3473.86 vs. 3471.42) with OR (95%CI) of the primary outcome 1.32 (0.99–1.76), 2.65 (1.17–6.00) and 0.81 (0.10–6.71), respectively, compared with use of a surgical facemask (online Supporting Information Table S4).

Individual anaesthetists subjectively reported easy (1 or 2 on 5-point Likert scale) facemask ventilation (90.3%); SGA insertion (95.8%); and tracheal intubation (90.6%) (online Supporting Information Figure S2). A total of 250 out of 367 patients having RSI (68%) had cricoid force applied. After adjusting for SARS-CoV-2 status and BMI as potential confounders, use of cricoid force was associated with an increased risk of the composite outcome of any airway complication (OR (95%CI) 2.02 (1.01–4.05)).

## Discussion

This national, prospective, observational cohort study showed that non-severe airway complications occurred in 10% of general anaesthetics, and there was a 38% increase in the odds of airway complications associated with use of FFP2 or FFP3 respirators after adjusting for patient BMI, SARS-CoV-2 status, surgical urgency and grade of first person to intubate the trachea. Other PPE components, however, were not associated with an increased risk of airway complications.

Comparison of airway complication rates with other studies is somewhat hampered by variations in definition of

complications and case-mix [20–23]. Compared with the study by Huitink et al. of 2803 patients, we report a higher rate of complications (10% vs. 6%) but fewer severe complications (0% vs. 0.9%). However, comparison is challenging as their patient cohort included children (in whom > 18% of the complications occurred) and they included ICU admission as a severe complication, which we did not collect [20]. Similarly, compared with a pre-pandemic study of 1874 patients across London with similar methodology to ours, we report twice the rate of complications (10% vs. 4.9%) [21]. Notably the inclusion of ‘difficult facemask ventilation’ (which occurred in 3.4% of patients) in our dataset rather than ‘failed facemask ventilation’ (in just 0.05% of patients) in the study by Shaw et al. may partly explain this discrepancy. Compared with the recent quality improvement study by Pedersen et al., our rate of complications is lower than their rate before the quality improvement intervention (15%) and similar to the rate after intervention (11%) [23]. The absence of severe airway complications in our cohort of almost 6000 patients is arguably consistent with the Royal College of Anaesthetists and Difficult Airway Society’s Fourth National Audit Project, and a recent Oxford-based study, where rates of severe complications were reported as 1 in 22,000 and 1 in 15,000, respectively [1, 22]. Overall, it is difficult to draw a firm conclusion when comparing complication rates with

**Table 5** Association between aerosol precautions and any airway complication in any of the 5905 patients included. Values are odds ratio (95% CI).

Predictor	Number using predictor	Any complication	Any complication excluding difficult facemask ventilation	Any complication except those specific to airway devices
<b>SARS-CoV-2 pathway</b>				
Negative	5351	Reference	-	-
Positive/unclear	554	0.98 (0.69–1.39)	1.14 (0.78–1.67)	0.94 (0.63–1.42)
<b>BMI; kg.m<sup>-2</sup></b>				
18.5–24.0	1901	Reference	-	-
<18.5	105	1.09 (0.52–2.27)	1.00 (0.44–2.26)	0.87 (0.30–2.51)
25.0–29.9	1973	1.48 (1.17–1.89)*	1.32 (1.01–1.72)*	1.66 (1.22–2.25)*
30.0–34.9	1025	1.61 (1.22–2.12)*	1.46 (1.08–1.98)*	2.05 (1.47–2.86)*
35.0–39.9	505	1.91 (1.38–2.65)*	1.69 (1.18–2.43)*	2.59 (1.76–3.79)*
≥40	267	2.66 (1.83–3.88)*	2.01 (1.30–3.11)*	4.17 (2.74–6.33)*
<b>Eye protection</b>				
None	5251	Reference	-	-
Goggles	470	1.12 (0.78–1.59)	1.21 (0.83–1.75)	0.87 (0.56–1.36)
Visor	184	0.42 (0.21–0.83)*	0.58 (0.29–1.16)	0.34 (0.14–0.78)*
<b>Gloves</b>				
Single	5648	Reference	-	-
Double	58	0.29 (0.07–1.25)	0.19 (0.03–1.45)	0.23 (0.03–1.75)
<b>Respiratory protection</b>				
Surgical facemask	4943	Reference	-	-
FFP2/FFP3 respirator	917	1.38 (1.04–1.83)*	1.26 (0.93–1.71)	1.59 (1.14–2.20)*
<b>Pre-oxygenation</b>				
No	475	Reference	-	-
Yes	5430	1.74 (1.16–2.62)*	1.89 (1.18–3.01)*	1.62 (0.99–2.66)
<b>Post-induction facemask ventilation</b>				
No	2708	Reference	-	-
Yes	3242	1.71 (1.40–2.10)*	1.61 (1.29–2.02)*	1.85 (1.44–2.36)*
<b>Induction</b>				
Intravenous non-RSI	5449	Reference	-	-
RSI	367	1.25 (0.87–1.78)	1.58 (1.06–2.34)*	1.31 (0.88–1.97)
Inhalational	89	1.14 (0.55–2.39)	1.45 (0.67–3.13)	1.22 (0.51–2.94)
<b>Airway technique (excluding combination tracheal tube plus SGA techniques)</b>				
DL to place tracheal tube	2179	Reference	-	-
VL to place tracheal tube	833	1.10 (0.84–1.43)	0.88 (0.64–1.20)	1.26 (0.93–1.69)
SGA	2478	0.50 (0.39–0.64)*	0.56 (0.43–0.73)*	0.45 (0.33–0.61)*
<b>Grade of first airway manager</b>				
Consultant	2071	Reference	-	-
CT 1/2	1314	2.23 (1.73–2.88)*	1.73 (1.31–2.28)*	2.56 (1.87–3.49)*
CT/ST 3/4	699	1.57 (1.16–2.12)*	1.20 (0.85–1.68)	2.00 (1.39–2.88)*
ST 5–7	777	1.27 (0.93–1.74)	1.20 (0.86–1.68)	1.51 (1.03–2.22)*
SAS	788	1.03 (0.73–1.46)	0.89 (0.61–1.30)	1.18 (0.76–1.82)
Other	256	2.02 (1.31–3.13)*	1.17 (0.69–2.00)	2.26 (1.34–3.81)*

(continued)

Table 5 (continued)

Predictor	Number using predictor	Any complication	Any complication excluding difficult facemask ventilation	Any complication except those specific to airway devices
<b>Surgical urgency</b>				
Elective	4094	Reference	-	-
Expedited	621	1.24 (0.92–1.68)	1.12 (0.80–1.57)	1.38 (0.98–1.96)
Urgent	891	1.29 (0.98–1.70)	1.14 (0.84–1.55)	1.36 (0.99–1.88)
Immediate	299	1.14 (0.73–1.79)	0.91 (0.55–1.52)	1.47 (0.89–2.43)

\*Confidence intervals excluding 1.

FFP, filtering facepiece; RSI, rapid sequence induction; DL, direct laryngoscopy; VL, videolaryngoscopy; SGA, supraglottic airway; CT, core trainee; ST, specialty trainee; SAS, staff grade, associate specialist and specialty doctor.

the literature due to differing methodologies and study populations; however, our complication rates appear to fall within a similar range as pre-pandemic studies.

Another key finding of our study is an association between the use of FFP2 or FFP3 respirators and airway complications, which was small but statistically significant. This increased risk remained even after adjusting for patient SARS-CoV-2 status, BMI and airway technique. This represents a novel finding and we are not aware of any other clinical studies reporting on airway complications under general anaesthesia in the context of PPE. Simulation studies have reported user discomfort when wearing both powered and unpowered reusable respirator masks due to heat, as well as worsened speech intelligibility [24]. Human factor challenges have been associated with a significant number of previously reported major airway complications [1, 25]. It is feasible that discomfort and impaired communication from the use of FFP2 or FFP3 respirators could make airway management more challenging, leading to undesired airway events, but this is purely speculative. On secondary analysis, the use of FFP2 or FFP3 respirators was mainly associated with difficult facemask ventilation and desaturation. While this study set out to report associations of the aerosol precaution bundle with individual complications as a secondary outcome, we have deliberately not attempted to interpret this association further due to the risk of potentially overanalysing the dataset.

We did note a stronger association between reusable FFP2 or FFP3 respirators and airway complications as compared with disposable FFP2 or FFP3 respirators (online Supporting Information Table S4). This increased risk associated with reusable FFP2 or FFP3 masks is plausible given their typically increased bulkiness further worsening communication difficulties. However, these results derived from a logistic regression model with reduced statistical quality compared with the main model, where reusable and

disposable FFP2 or FFP3 respirators were combined and given the relatively small use of reusable FFP2 or FFP3 respirators in our study ( $n = 56$ ), these results should be interpreted with caution. Additionally, there remains a risk that reusable FFP2 or FFP3 masks were misidentified as PAPRs within our study and vice versa, thus further weakening the strength of this finding.

Our results also show an association between both pre-oxygenation and facemask ventilation and the occurrence of airway complications. Pre-oxygenation was included as a predictor in our model due to its use in aerosol precaution bundles, as was post-induction facemask ventilation, the use of which is typically advised against in such bundles unless hypoxaemia develops [26]. We also chose to include difficult post-induction facemask ventilation as an outcome measure which was included in the composite airway complication primary outcome. Given that this complication is only possible if post-induction facemask ventilation was attempted, we analysed a separate composite outcome where difficult facemask ventilation was not included. Notably, the association between the use of post-induction facemask ventilation and airway complications persisted even when difficult facemask ventilation was excluded from the composite outcome. This, of course, does not imply a causal relationship; the increased risk of airway complications associated with pre-oxygenation and post-induction facemask ventilation may instead represent a pre-emptive attempt to reduce post-induction hypoxaemia in patients at risk or a response to it, respectively.

Use of a SGA was associated with a lower risk of airway complications, largely because of lower rates of lip/mucosal injury and difficult post-induction facemask ventilation. While the former is plausible as a potential association, the latter is not as in the vast majority of cases SGA placement typically occurs after facemask ventilation and is, therefore, unable to directly cause difficult facemask ventilation. Therefore, this most likely represents a selection effect due

to SGAs potentially being used in patients who are less likely to have predictors of difficult facemask ventilation. Plastic visors had a lower risk of complications when compared with no eye protection. While this is an intriguing finding; the number of episodes in which plastic visors were used was small ( $n = 184$ ) and therefore caution is advised in interpreting these results. Other components of the aerosol precaution bundle, including use of goggles as eye protection, PAPR hoods, long-sleeved gowns, wearing double gloves and use of videolaryngoscopy were either not associated with an altered risk of airway complications or excluded from the logistic regression model due to their inclusion not improving the fit of the model, and therefore similarly not associated with the primary outcome.

Increased BMI was associated with airway complications, primarily difficult facemask ventilation and desaturation. Indeed, BMI was the best predictor of airway difficulty; patients with a BMI  $\geq 40$  kg.m<sup>-2</sup> were more than twice as likely to experience an airway complication, which is consistent with previous findings [1, 21]. Obesity was common in our dataset with >13% of patients having a BMI > 35 kg.m<sup>-2</sup> and 31% having a BMI > 30 kg.m<sup>-2</sup>, despite bariatric surgery only accounting for 0.5% of all patients. Body mass index was included in our model purely as a predicted confounder and, while our findings are strongly significant and similar to the established literature, we purposefully did not attempt to investigate this association further.

Similarly, SARS-CoV-2 status was also included as a potential confounder. Interestingly, the data did not demonstrate an increase in the primary outcome in the SARS-CoV-2 positive and unclear groups, although the number of SARS-CoV-2 positive patients included in the study was small and therefore caution is advised in interpreting this result. Secondary analysis did show desaturation on pulse oximetry and difficult SGA insertion were more common in patients whose SARS-CoV-2 status was positive or unclear. It is notable that our data showed tracheal intubation was more common than SGA insertion (56% vs. 44% of patients) which is not normal UK practice when compared with previous national audit projects [1, 27], and this might represent the influence of the pandemic on airway management.

In patients undergoing rapid sequence induction, use of cricoid force was associated with an increase in airway complications. Again, the observational nature of our study means causality is inappropriate to infer, and the relatively small number of patients undergoing RSI with cricoid force in our study ( $n = 250$ ) also reduces the strength of the findings. Despite these limitations, our findings are

consistent with a large randomised controlled trial reporting worsened grade of laryngoscopy and prolonged tracheal intubation times when cricoid force was used compared with sham procedure [28]. Notably, the apparent clinical equipoise with regards to cricoid force appears to be reflected in our data suggesting that one-third of RSIs were performed without it.

We noted an increase in airway complications, particularly difficult facemask ventilation and difficult SGA use, when the initial airway manager was a more junior trainee. We included the initial airway manager in our logistic regression model due to a potential confounding effect of more junior trainees often managing emergency cases which typically require aerosol precaution PPE. We, therefore, chose not to investigate this association further. Surgical urgency was not associated with risk of airway complications and surgical start time (daytime, evening, overnight) and surgical specialty were associated with a poorer model fit and excluded.

Strengths of this study include the large number of centres across the UK, broad range of surgical specialities, and high number of patients recruited, which gave a good reflection of UK practice at the time of the study. Most centres reported a high response rate, and data from centres with a response rate of < 75% were excluded to reduce the risk of selection bias. The principal findings were consistent between the main study group and a sensitivity analysis including only those sites with expected complication rates. The timing of our study was fortuitous since it coincided with a plateau in COVID-19 cases in the UK and preceded the Omicron wave that began in December 2021. We were therefore able to document work as done during a period of relative stability before elective cancellations began to become more prevalent.

Limitations of this study include its observational nature and therefore the inability to infer causation. While we were able to report airway complication events that occurred, there was insufficient granularity in the data to detect the sequence in which these events occurred (e.g. sequence of events relating to post-induction facemask ventilation and onset of hypoxia). In addition, we were reliant on anaesthetists to report airway complications, and it is possible that some airway events were not reported accurately. This was highlighted in a recent study where the researchers became aware of an intra-operative death which was not reported despite it fitting the criteria of a major airway complication [22]. We collected data only within the operating theatre location, and thus airway complications in post-anaesthesia care units or ICU were not included. Granular data about patient characteristics, such

as age and BMI, were not collected but were categorised to maintain de-identification for this service evaluation. Finally, we only collected data during 96-h windows at each recruiting site. Extending this further to a full 7 days may have provided a larger dataset, but this may have been detrimental to our response rate.

We noted poor compliance with certain elements of recommended PPE use (gown or apron use was < 15% overall) and high use of others (gloves and face covering both close to 100% use). There was also a lack of adherence to the guidelines at the time of the data collection for the study [8]: respiratory protection was only used in 44.2% of patients who were SARS-CoV-2 positive/unclear, and was used in 13.0% of patients who were SARS-CoV-2 negative. These findings raise the possibility of PPE use being focused on certain procedures or patients judged by the anaesthetist as being of high risk which might lead to confounding and influence the reliability of results.

In conclusion, in our study of anaesthetic airway management in the context of use of aerosol precaution PPE, minor airway complications were common and no major airway complications were observed. The use of FFP2 or FFP3 respirators was associated with a small but significantly increased risk of airway complications, and no other components of the aerosol precaution bundle were plausibly associated with airway complications. These findings should serve as reassurance that anaesthetists have continued to deliver safe care for patients requiring general anaesthesia, even in the wake of significant changes to airway management. Further research will be needed to establish any causality between the use of FFP2 or FFP3 respirators and airway complications.

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## Supporting Information

Additional supporting information may be found online via the journal website.

**Appendix S1.** AeroComp study collaborators.

**Appendix S2.** Supplementary methods.

**Appendix S3.** Supplementary results.

**Figure S1.** Individual site airway complication rates for all 70 hospital sites who contributed to the final data set plotted against the total number of cases reported by that site.

**Figure S2.** Subjective responses of individual anaesthetists of the ease of facemask ventilation, supraglottic airway insertion, and tracheal intubation using a 5-point Likert scale.

**Table S1.** Sensitivity analysis of primary outcome after excluding cases from sites whose overall site complication rate was outside the 95% expected limits.

**Table S2.** Association between aerosol precautions and individual airway complications in the 5905 patients included.

**Table S3.** Sensitivity analysis of association between aerosol precautions and individual airway complications outcome after excluding cases from sites whose overall site complication rate was outside the 95% expected limits.

**Table S4.** Primary outcome repeated using a logistic regression model that reintroduces use of PAPR hood, and unpowered reusable and disposable FFP2/3 respirators as separate variables.