



Shrimpton, A. J., Gregson, F. K. A., Brown, J., Cook, T. M., Bzdek, B. R., Hamilton, F. W., Reid, J. P., & Pickering, A. E. (2021). A quantitative evaluation of aerosol generation during supraglottic airway insertion and removal. *Anaesthesia*, 76(12), 1577–1584. <https://doi.org/10.1111/anae.15542>

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Original Article

A quantitative evaluation of aerosol generation during supraglottic airway insertion and removal

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Summary

Many guidelines consider supraglottic airway use to be an aerosol-generating procedure. This status requires increased levels of personal protective equipment, fallow time between cases and results in reduced operating theatre efficiency. Aerosol generation has never been quantitated during supraglottic airway use. To address this evidence gap, we conducted real-time aerosol monitoring (0.3–10- μm diameter) in ultraclean operating theatres during supraglottic airway insertion and removal. This showed very low background particle concentrations (median (IQR [range]) 1.6 (0–3.1 [0–4.0]) particles. l^{-1}) against which the patient's tidal breathing produced a higher concentration of aerosol (4.0 (1.3–11.0 [0–44]) particles. l^{-1} , $p = 0.048$). The average aerosol concentration detected during supraglottic airway insertion (1.3 (1.0–4.2 [0–6.2]) particles. l^{-1} , $n = 11$), and removal (2.1 (0–17.5 [0–26.2]) particles. l^{-1} , $n = 12$) was no different to tidal breathing ($p = 0.31$ and $p = 0.84$, respectively). Comparison of supraglottic airway insertion and removal with a volitional cough (104 (66–169 [33–326]), $n = 27$), demonstrated that supraglottic airway insertion/removal sequences produced <4% of the aerosol compared with a single cough ($p < 0.001$). A transient aerosol increase was recorded during one complicated supraglottic airway insertion (which initially failed to provide a patent airway). Detailed analysis of this event showed an atypical particle size distribution and we subsequently identified multiple sources of non-respiratory aerosols that may be produced during airway management and can be considered as artefacts. These findings demonstrate supraglottic airway insertion/removal generates no more bio-aerosol than breathing and far less than a cough. This should inform the design of infection prevention strategies for anaesthetists and operating theatre staff caring for patients managed with supraglottic airways.

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Accepted: 18 June 2021

Keywords: aerosol-generating procedure; COVID-19; SARS-CoV-2; supraglottic airway device

*Aerosolisation and transmission of SARS-CoV-2 in healthcare settings (AERATOR) study group - see Appendix 1

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Introduction

The COVID-19 pandemic caused by SARS-CoV-2 continues to have a huge global impact. Direct droplet and indirect contact transmission are still regarded as important modes of SARS-CoV-2 spread. However, airborne transmission by aerosol particles of respirable size is of great concern [1–5]. Airborne spread is particularly important to consider when evaluating the potential increased transmissibility of new variants of SARS-CoV-2 (e.g. B.1.1.7 and B.1.617) [6–9]. Aerosol-generating procedures are specific patient care activities designated as carrying a higher risk of viral transmission via the airborne route [10], and are presumed to generate aerosols from the respiratory tract. The evidence on which current aerosol-generating procedures are defined has been mostly epidemiological, from retrospective cohort and case-controlled studies of transmission during the SARS pandemic in 2003 [11, 12]. These studies identified an association between certain medical procedures and the likelihood of healthcare workers involved contracting SARS. Increased risk of transmission was identified for tracheal intubation, non-invasive ventilation, tracheostomy and facemask ventilation (OR 6.6, 4.2, 3.1 and 2.8, respectively) [12].

The WHO has developed a list of aerosol-generating procedures [13] that healthcare organisations throughout the world have used as a framework for development of their guidelines [14, 15]. To date, few published data reported the amount of aerosol produced by any of the currently defined anaesthetic aerosol-generating procedures. This has now been rectified with the introduction of aerosol measurements within operating theatres during putative aerosol-generating procedures. Two groups have quantitated the degree of aerosol generated during tracheal intubation and extubation [16, 17]. Our group identified that intubation and extubation generate considerably less aerosol than a single voluntary cough and has, therefore, questioned whether these airway management interventions should still be classified as high-risk aerosol-generating procedures [16, 18]. As such, the risks from aerosol generated during airway management, and the optimum methods of preventing transmission, remain under debate.

Supraglottic airways are used in the majority of the approximately 2.7 million general anaesthetics performed in the UK each year [19]. In a UK survey in October 2020, 40% of responding hospitals reported that supraglottic airway removal, even in low COVID-19 risk pathways, is restricted exclusively to the operating theatre (rather than being performed in a recovery area), indicating the

presence of policies that assume it is an aerosol-generating procedure [20]. Designation of a procedure as aerosol-generating not only alters personal protective equipment worn by staff but also impacts operating theatre efficiency, as a fallow period is required to allow aerosol clearance after the procedure is conducted [21]. These precautionary measures have led to reduced operating theatre efficiency, with many operating at <75% of normal activity levels. The UK National Health Service (NHS) surgical waiting lists have grown substantially with over 385,000 patients currently waiting more than a year for planned surgery and a backlog in excess of 5 million surgical cases [22]. The designation of anaesthetic airway procedures as aerosol-generating has, therefore, an important impact on hospital operational efficiency, cost and the challenge of reducing surgical waiting lists.

Uncertainty remains as to whether insertion or removal of a supraglottic airway generates aerosols [23]. A recent consensus statement (based on expert opinion) suggested straightforward insertion of a supraglottic airway was unlikely to generate an increase in aerosol but noted a lack of evidence to support this conclusion. However, the statement also recommended supraglottic airway use be classified as an aerosol-generating procedure if airway suctioning, facemask ventilation, multiple attempts or conversion to tracheal intubation were required [24]. This statement needs to be reassessed in light of recent evidence indicating that tracheal intubation and associated facemask ventilation do not generate increased levels of aerosols [16]. Given the uncertain balance of potential risks and benefits associated with the protective strategies put in place to limit airborne viral transmission, we aimed to directly assess airborne particle emission during insertion and removal of supraglottic airways. We used real-time measures of aerosol generation with an optical particle sizer in a working operating theatre environment and compared the measured levels with reference to those generated by a volitional cough and the patient's own breathing.

Methods

This prospective environmental monitoring study was conducted in operating theatres in a UK hospital (North Bristol NHS Trust). Ethical approval was granted by the Greater Manchester Research Ethical Committee as part of the AERATOR study. As this was an observational study, the anaesthetic and operating theatre team undertook their normal practice during airway management. The researchers were not involved in the delivery of anaesthetic care. The methods for aerosol measurement have

previously been described in detail [16]. All recordings were made within operating theatres with an ultraclean ventilation system (EXFLOW 32, Howorth Air Technology, Farnworth, UK). This environment enables clear resolution of aerosol produced by coughing, singing, speaking or breathing [16]. The ultraclean ventilation system was placed in standby mode before recording. This decreases the frequency of the inverter in the air handling unit from 50 to 25 Hz which disables the 'surgical canopy' of clean air directed downwards over the operating table and reduces the number of air changes per hour from 500 to 25 (which is in line with most standard operating theatres in the UK). This results in an ultraclean environment (minimising interference from background aerosol) whilst reducing any possible dilutional effect. Air velocity was measured at 0.25 m.s^{-1} at 1 m above the ground. Air temperature in the operating theatres was set to 20°C and humidity between 40% and 60%. By way of contrast, completely powering down the ultraclean ventilation system leads to a dramatic increase in the background particle count (three to four orders of magnitude [25]), making identification of bio-aerosol associated with individual respiratory or airway management events impossible.

Aerosol particles were sampled with an optical particle sizer (TSI Incorporated, model 3330, Shoreview, NM, USA). This reports the particle number concentration and optical size distribution within the diameter range 300 nm to $10 \mu\text{m}$ with a time resolution of 1 s. A sampling funnel was 3D printed (RAISE3D Pro2 Printer, 3DGBIRE, Chorley, UK) with a cone height of 90 mm, a 10-mm exit port and maximum diameter of 150 mm. A conductive silicone sampling tube of 1-m length and internal diameter 4.8 mm (3001788, TSI) connected the optical particle sizer to the sampling funnel. This had an internal volume of 72.5 ml giving a transit lag between the funnel and the particle sizer (with a flow of 1 l.min^{-1}) of 4.3 s.

Sampling was conducted with the funnel at 50 cm directly above the patient's mouth. The funnel was handheld to ensure it could be promptly removed from the airway management zone in case of clinical need. All healthcare workers and members of the investigating team wore airborne personal protective equipment during aerosol-generating procedure measurements. Standard anaesthetic monitoring was used including waveform capnography.

Supraglottic airway insertion and removal consists of a series of discrete events and procedures which we designated as sequences. Background sampling was recorded with the sampling funnel directed away from the patient and staff. A minimum of 30-s tidal breathing was

recorded before induction of anaesthesia to determine comparator baseline values. Anaesthetic induction followed a conventional sequence with pre-oxygenation, intravenous induction by administration of anaesthetic agents (without a neuromuscular blocking drug) then insertion of the supraglottic airway (i-gel®, Intersurgical, UK, sized according to the preference of the anaesthetist). The time of supraglottic airway insertion was taken as the reference point for the sequence which typically lasted 3–4 min. Continuous aerosol monitoring was performed throughout, and a 3-min period analysed (2 min before and 1 min after insertion of the supraglottic airway).

Supraglottic airway removal was undertaken in the operating theatre. Anaesthesia was discontinued and the supraglottic airway removed according to the anaesthetist's preferred practice. After removal, the patient received oxygen via an anaesthetic facemask followed by a Hudson mask after confirmation of airway patency. The reference time-point for this sequence was removal of the supraglottic device from the airway. Continuous aerosol monitoring with the optical particle sizer was conducted throughout. A 2-min period was analysed (1 min before supraglottic airway removal and up to 1 min after).

Airway management events were time-stamped by the researcher: supraglottic airway insertion; supraglottic airway removal; facemask ventilation; coughs; and any other events of note. Data were exported from the TSI optical particle sizer, processed in the TSI Aerosol Instrument Manager software, and analysed in Origin Pro (Originlab, Northampton, MA, USA) and Prism v8 (Graphpad, San Diego, CA, USA). The normality of data distribution was assessed using the Shapiro–Wilk test. Comparisons were made between aerosol measurements with parametric or non-parametric statistical analyses (as appropriate and as indicated in the text). Significance level was set at $p < 0.05$.

Results

The study was conducted over a 3-week period during surgical operating lists for orthopaedic, plastic, gynaecological and general surgery. Recordings were made during the insertion and subsequent removal of 12 supraglottic airways. The conduct of anaesthesia was left to the discretion of the anaesthetist, who ranged in experience from junior trainee to senior consultant. The investigators did not influence airway management decisions and the sampling funnel never needed to be repositioned or removed during the airway management sequences.

Baseline environmental monitoring recordings showed the ultraclean ventilation system produced a very low background level of aerosol (median (IQR [range]) 1.6

(0–3.1 [0–4.0]) particles.l⁻¹) measured just before induction of anaesthesia. We detected a higher concentration of aerosol (4.0 (1.8–13.5 [1.0–44.0]) particles.l⁻¹) during the period of spontaneous quiet tidal breathing (30–60 s) from each patient compared with background ($p = 0.048$). To act as a reference, 27 volitional coughs (from investigator JB) were sampled under identical conditions as the supraglottic airway measurements. These coughs showed a characteristic concentration profile with a rapid and transient spike of expectorated particles (Fig. 1a). Peak aerosol concentration occurred 2 s after the cough was registered with a median (IQR [range]) of 900 (660–1380 [60–2054]) particles.l⁻¹. The spike in aerosol particle count decayed back to baseline with a time constant of 4.0 s. On average, 104 (66–169 [33–326]) airborne particles were sampled from a cough (over the 12-s window). Most particles (83%) were < 1- μm diameter, forming a characteristic size distribution profile (Fig. 1b).

All supraglottic airway insertion sequences ($n = 12$) included a period of pre-oxygenation and some had a short period of facemask ventilation immediately before

supraglottic airway insertion ($n = 3$). The majority also had a period of manual ventilation to confirm airway patency after supraglottic airway insertion ($n = 8$). There were no coughs recorded during SGA insertion. The median (IQR [range]) number of particles detected in the 3-min sequence of anaesthetic induction and supraglottic airway insertion was 5 (3–13 [0–114]) ($n = 12$). There were 11 uneventful first-pass insertions of the supraglottic airway and one which required two attempts. The median (IQR [range]) concentration of particles recorded during the first-pass insertion sequences was 1.3 (1.0–4.2 [0–6.2]) particles.l⁻¹, $n = 11$ (Fig. 1c), which was not different to either the background level or that recorded during tidal breathing before induction ($p = 0.31$ and $p = 0.27$, respectively). During the uneventful supraglottic airway insertion sequences, the median (IQR [range]) total of 4 (2–11 [0–17]) particles were detected which is < 4% of that recorded from an average volitional cough (104 (66–169 [33–326]) particles, $p < 0.001$). The period of ventilation via the supraglottic airway (to confirm airway patency) did not generate an increased number of airborne particles above background levels.

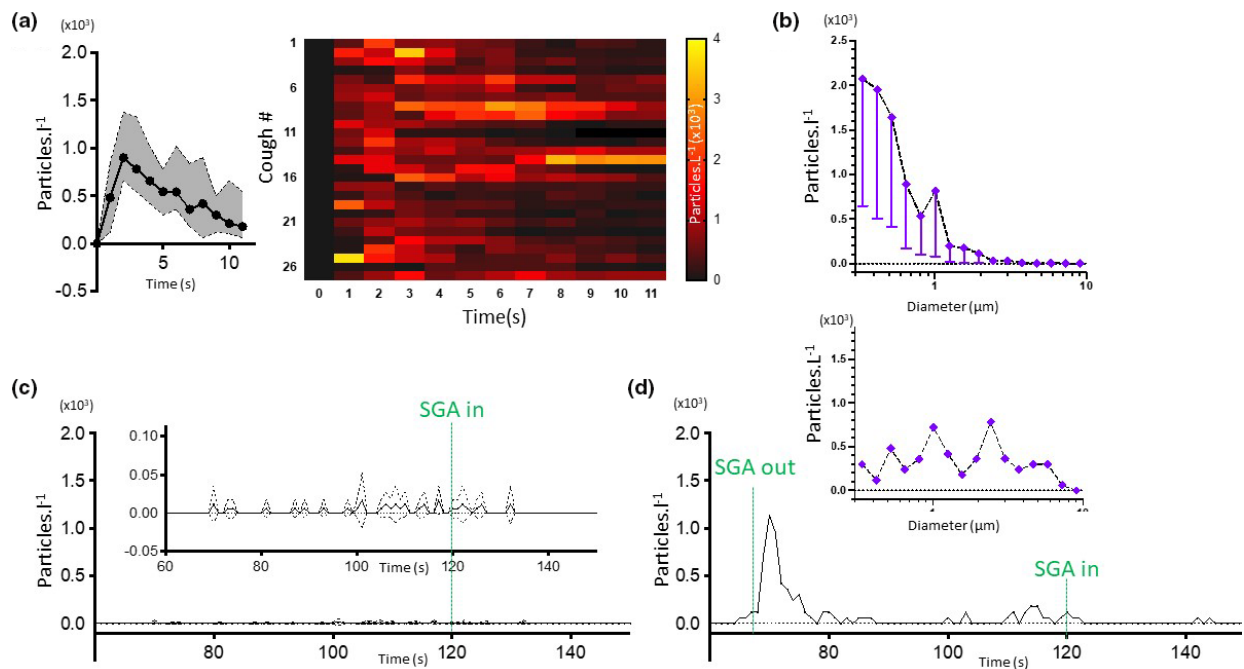


Figure 1 Aerosol measurements during supraglottic airway insertion and removal. (a) Time profile of aerosol generation from volitional coughs. Average time course of volitional coughs plotted (mean with 95%CI) showing a peak after 2 s and a rapid decay back to baseline. Individual recordings ($n = 27$) represented on heat map showing the total number particle concentration over time. (b) Size distribution of peak aerosol concentrations from volitional coughs ($n = 27$). (c) Time-course of aerosol during uneventful supraglottic airway insertions ($n = 11$, mean \pm 95%CI); inset chart with altered y-axis to demonstrate very low concentration of particles sampled. (d) Aerosol detected during the eventful insertion showing the period of supraglottic airway removal and reinsertion; inset chart shows particle size distribution of the peak aerosol sample associated with the supraglottic airway removal, note the difference in size distribution compared with a volitional cough (b).

Supraglottic airway removal sequences (90–120 s, $n = 12$) produced a median (IQR [range]) concentration of 2.1 (0–17.5 [0–26.2]) particles. $\cdot\text{l}^{-1}$ ($n = 12$, Fig. 2a,b), with (IQR [range]) of 4 (0–34 [0–51]) particles detected per removal. Overall, the supraglottic airway removal sequence was associated with an aerosol concentration no different to that seen during the period of spontaneous breathing before induction of anaesthesia ($p = 0.84$). Additionally, the average number of detected aerosol particles was < 4% of the number of particles produced by a single volitional cough ($p < 0.001$, Fig. 2c). The four supraglottic airway removals with the highest detected aerosol particle counts (ranging from 19 to 51 particles) each produced < 50% of the particle count sampled during an average volitional cough. Only one cough was noted during the removal sequences, this occurred with the anaesthetic facemask tightly applied to the patient by the anaesthetist and no increase in aerosol was detected.

In one patient, the first attempt at supraglottic airway insertion failed to produce a patent airway, the supraglottic airway was removed and a different size device inserted. This insertion sequence was associated with increased particle generation: a total of 114 particles were detected.

No coughing was noted but after the first insertion attempt there was a period of unsuccessful ventilation (due to a large leak); the anaesthetic trainee removed the supraglottic airway and moved position to allow the senior anaesthetist to insert a larger supraglottic airway. The increase in aerosol occurred after the initial failed insertion during the process of removal, not during manual ventilation (Fig. 1d). This spike of aerosol had a similar time-course to a cough, but the aerosol produced had a different size profile with substantially fewer small particles (<1 μm) (Fig. 1d). Of note, contemporaneous with these events, the patient's head was repositioned, the pillow adjusted and a new supraglottic airway pack was opened.

Having identified the unusual aerosol event associated with the single failed supraglottic airway insertion/removal sequence, we carefully scrutinised the time sequences of the aerosol data and found a further four transient aerosol-generating events during three patients' SGA removal sequences, typically between 10 s and 20 s after supraglottic airway removal. These were not associated with patient coughing or any airway intervention. The particle size distribution of all four events was investigated to determine their likely origin. In each case, these events had

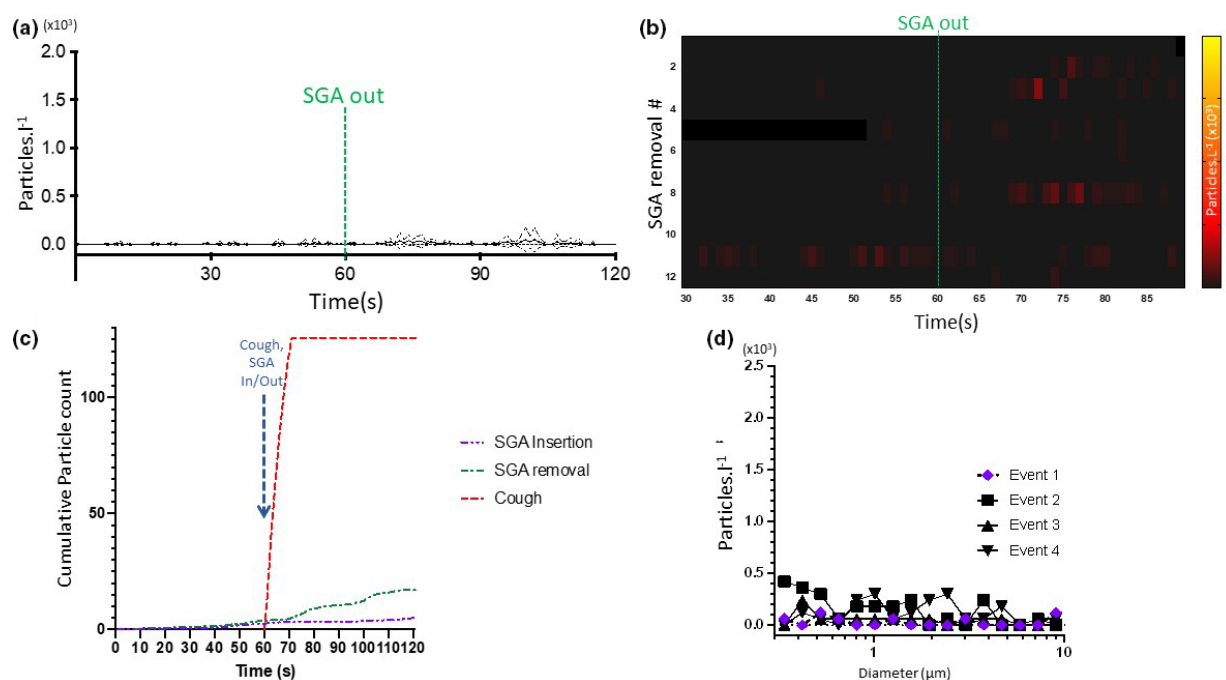


Figure 2 (a) Time course of aerosol measurements supraglottic airway removals ($n = 12$, mean \pm 95%CI). (B) Heat map showing the total number particle concentration over time for each supraglottic airway removal ($n = 12$). (c) Comparison of the cumulative average particle counts sampled over time. Reference point (aligned at 60 s) represents the supraglottic airway insertion, SGA removal and volitional cough ($n = 27$). (d) Particle size distribution of the peak aerosol samples of the four transient spikes not associated with respiratory activity, note the difference in size distribution compared with a volitional cough (Fig. 1B).

a particle size distribution different to that of a volitional cough (compare Figs. 1b and 2d) consistent with them not being of respiratory origin. These size distributions also resembled the aerosol particle spike associated with the failed supraglottic airway insertion and subsequent removal (Fig. 1d). The three supraglottic airway removal sequences with these unattributed aerosol events were those with the highest levels of aerosol generation and these singular events accounted for most of the increase above background.

In trying to identify the source of the unattributed aerosol events, we discovered several potential non-respiratory sources of airborne particles including tying ribbon gauze to secure the airway device ('tube-tie'); opening different types of woven gauze; opening a throat pack; manipulation of a pillow; and the scrunching of scrub tops. These materials generated particle size distributions that were strikingly different to coughs but were similar to the five unattributed aerosol events (Fig. 3) with a clear predominance of particles of a larger size ($> 1 \mu\text{m}$).

Discussion

This study demonstrates that uneventful insertion and removal of a supraglottic airway generates no more aerosol than tidal breathing in the same patient and far less aerosol than a single volitional cough. As such, the routine, uncomplicated use of supraglottic airways does not appear to carry an increased risk of generating aerosol and, on this

basis, does not meet the criterion to be classified as an 'aerosol-generating procedure' [14, 15]. This is in keeping with other studies undertaken by our group investigating the amount of aerosol generated from currently defined aerosol-generating procedures. These medical procedures, including tracheal intubation and extubation, non-invasive ventilation, tracheostomy and use of high-flow nasal oxygen, do not generate aerosol levels greater than natural patient respiratory events [16, 18]. These findings support existing guidance that the choice of airway and management strategy should not be made on the basis of perceived aerosol risk but rather should be informed by quantitative data [24].

Previous work has identified that bio-aerosols (of particle size $< 20 \mu\text{m}$) originating from natural respiratory events, such as breathing, speaking, coughing or singing, display two overlapping size distributions [26]. This has been postulated to reflect their site of origin arising from either the lower respiratory tract or vibrations in the larynx [27]. The overall respiratory particle size distribution consistently reports the highest concentration of particles in the sub-micron range [16, 26, 28–30], which is in agreement with the size distribution of the respiratory aerosols recorded in this study.

A transient increase in aerosol concentration was recorded during removal of a supraglottic airway after insertion failed (Fig. 1d) and after three other supraglottic airway removals; these were not linked to coughs or forceful

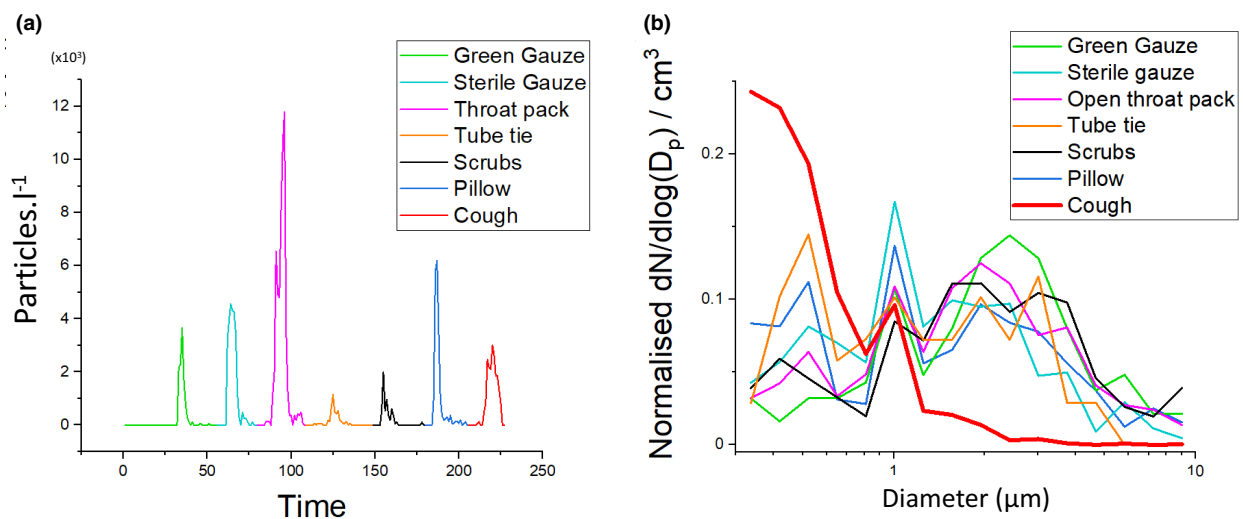


Figure 3 (a) Time course of aerosol detected following intentional manipulation of objects/fabrics involved in airway management to demonstrate relative amplitude of particle concentrations sampled. Single volitional cough (from investigator JB) as comparator. (b) Particle size distribution of the non-respiratory aerosol sources (normalised to total particle count to account for varying numbers of particles detected per event). Thick red line denotes mean particle concentration for all reference coughs from investigator JB ($n = 27$).

respiratory events. Our analysis of particle size distribution indicates these do not display a characteristic respiratory aerosol size distribution 'fingerprint', with predominance in the submicron range. This secondary analysis, and further investigation exploring aerosol generation during other events in theatre, indicates these aerosols are non-respiratory in origin, likely due to particles released from items such as pillows or bedding, fabric from surgical scrubs, ribbon gauze and woven gauze swabs. Importantly the attribution of the non-respiratory origin of these aerosols was only possible through a combination of high temporal resolution aerosol monitoring, accurate time stamping of respiratory events and analysis of particle size distribution. The combination of both an ultraclean environment (with very low background particle counts) and aerosol sampling at 1 Hz are critical components for clinical aerosol studies examining the linkage between specific procedures (or events) and respiratory particle emissions. These study features provide confidence that non-respiratory aerosol sources (artefacts) are identified and excluded as confounds in analysis.

Our study is the result of an ongoing collaboration between aerosol scientists and clinicians using an established methodology [16]. All recordings were undertaken in an ultraclean operating theatre, with a very low background particle count, essential for the resolution of respiratory events. Additionally, subject paired measurements of supraglottic airway insertion and removals along with baseline tidal breathing, used as a reference, minimised the effect of inter-person variability which is typically a challenge for studies of bio-aerosols. This has enabled meaningful comparisons to be made with recordings from a relatively small sample of patients.

Detailed patient level information was not collected, reflecting the specific consent given for the project which did not include collection of patient characteristics. A further, larger study would be required to extend our results to assess the influence of specific type of supraglottic airway, anaesthetic technique (e.g. spontaneous vs. mechanical ventilation) or surgical indication.

We carried out sampling using a funnel placed 50 cm in front of the patient's face in order not to interfere with anaesthetic care and to enable our results to be compared with a previous intubation study [16]. It is possible that sampling at this distance missed small quantities of aerosol generated during supraglottic airway insertion or removal but, to place this limitation in context, we were able to reliably detect bio-aerosols from breathing at this distance. We used a volitional cough from one of the investigators

(a healthy volunteer with no respiratory disease) to provide a reference standard. We acknowledge there may be advantages to using the patient's own cough as a reference, in the same way we have for tidal breathing, as this will also take account of inter-subject variation in aerosol production. It is worth noting that analysis of the particle concentrations for the coughs used in this study shows that they fall well within the distribution of the large database of coughs from multiple individuals we have acquired as part of the AERATOR study. It is likely that a healthy volunteer will generate less aerosol than an individual with an acute respiratory illness, therefore using a volunteer cough as a reference is likely to represent a more stringent threshold against which a procedure can be identified as having a low risk of aerosol generation.

Our study suggests uneventful supraglottic airway insertion and removal is not associated with increased levels of bio-aerosol and, to place this in a relative risk context, is no different to the aerosol generated by a patient's tidal breathing and is considerably lower than a volitional cough. On this basis, we believe supraglottic airway insertion and removal should not be considered an aerosol-generating procedure.

Acknowledgements

The study was granted Urgent Public Health status by the National Institute for Health Research (NIHR) and is registered in the ISRCTN registry (N21447815). AS is an NIHR-funded doctoral Research Fellow (NIHR301520), BRB is supported by the Natural Environment Research Council (NE/P018459/1) and FH is a Wellcome GW4-funded Clinical Doctoral Fellow. The AERATOR study has been fully funded by an NIHR-UKRI rapid rolling grant. This report presents independent research commissioned by the NIHR. The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, UKRI or the Department of Health. No other external funding or competing interests declared.

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Appendix 1. AERATOR Study Group

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