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Supporting Information

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

Appendix S1. Summary statistics from a set of 129 randomised controlled trials about which integrity concerns have been raised.

COVID-19 tracheostomy Local Safety Standard for Invasive Procedures (LocSSIP): a single-centre experience

We welcome the recent COVID-19 tracheostomy National Patient Safety Improvement Program (NatPatSIP) [1], in providing a consistent and safe approach to tracheostomy in this challenging patient population, while also validating our own hospital's strategy. We had already safely undertaken 20 tracheostomies in patients with a mean (SD) age of 54 (8.6) years before the NatPatSIP publication (first case: 24 March 2020; 20th case: 27 April 2020).

We instituted a solely surgeon-delivered open tracheostomy service, liberating procedural responsibilities from scarce and over-burdened ITU physicians, while exploiting increased surgeon availability. We believed the surgical technique also offered superior physiological stability, and avoided the greater viral exposure of bronchoscopic-guided percutaneous procedures. Indeed, we report no intra-operative oxygen desaturations (S_pO_2 < 90%), loss of airway control or cardiovascular instability, and no confirmed COVID-19 diagnoses in tracheostomy team members (at the time of writing).

We devised a COVID-19 tracheostomy Local Safety Standards for Invasive Procedures (LocSSIP), incorporating standardised anaesthetic and surgical techniques (which included tracheal window excision and rescue suture insertion). The LocSSIP was refined and rehearsed using manikin-based in-situ simulation, and disseminated via instructional videos. We identified a multidisciplinary group of nine surgeons (general/endocrine, maxillofacial, burns and craniofacial plastics) that agreed to the standardised approach (despite their diverse surgical backgrounds), and established a 24/7 rota for tracheostomy placement and postoperative care.

To increase patient safety, procedures were only undertaken after cessation of proning for > 72 h and when F_IO_2 requirements were low (median 0.35, IQR 0.3–0.4). For staff protection, procedures were only performed in patients with normalising lymphocyte counts (a surrogate for reduced viral load) and after > 10 days of mechanical ventilation (median (IQR) 16.5 (14.0–19.5) days). The service was delivered safely at both the bed-side, for uncomplicated procedures (7/20 performed), and in the operating theatres for procedures with predicted difficulty (13/20 performed). For mobile procedures, we used a specially designed portable operating trolley that attached directly to the ICU bed for optimising head and neck position, and high-intensity head torches to compensate for the lack of theatre lighting.

We highlight the importance of developing a LocSSIP, specific to local resources, agreed and practised (simulation) by relevant personnel. A thorough pre-tracheostomy briefing, using the LocSSIP, is essential as communication is significantly impaired during these high-risk procedures once personal protective equipment is applied.

P. A. Ward
J. M. Collier
Chelsea and Westminster Hospital,
London, UK
Email: patrickward81@hotmail.com

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Looking beyond tracheal intubation: addition of negative airflow to a physical barrier prevents the spread of airborne particles

Although the SARS-CoV-2 virus is thought to be spread mostly by droplets, there are situations such as tracheal intubation, extubation and non-invasive ventilation where viral particles may be transmitted to healthcare workers by small airborne nuclei [1]. Of additional concern, turbulent gas clouds may carry droplets much further than the Centers for Disease Control and Prevention or World Health Organization recommendations suggest [2]. A study from Wuhan, China, detected viral particles on surfaces and in air samples within the general ward and the intensive care unit (ICU) [3]. Notably, the ICU had higher positive rates compared with the general ward, suggesting that sicker patients, or the therapies they require, increase viral dispersion. Several barrier enclosures have recently been described for use during tracheal intubation and extubation of COVID-19 patients [4,5]. Whereas these enclosures contain visible fluorescent particles during simulated coughing, they increase the difficulty of the procedure by restricting movement, and there is insufficient evidence that such enclosures actually protect staff from viral spread. We

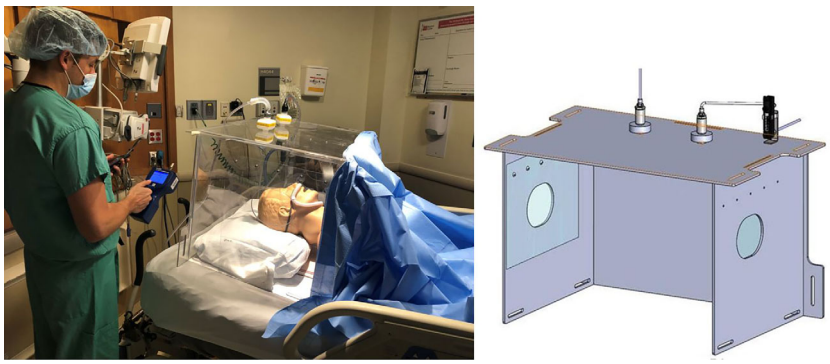

Figure 1 Photograph and diagram of polycarbonate enclosure with attached wall suction and HEPA filtration. Access holes on the sides were covered with clear plastic flaps and the torso of the simulated patient was covered with an adhesive surgical drape

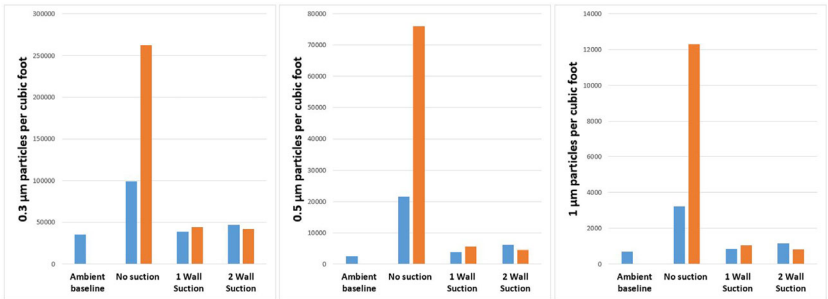

Figure 2 Number of 0.3, 0.5 and 1 micron particles per cubic foot detected outside the enclosure. Particle counts were measured at baseline, 1 min after (blue) and 5 min after (orange) release inside the enclosure