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Clinical Paper Clinical Pathology

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Challenges of tracheostomy in COVID-19 patients in a tertiary centre in inner city London

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Abstract. The rapid global spread of SARS-CoV-2, the causative agent of COVID-19, has dominated healthcare services, with exponential numbers requiring mechanical ventilation in the intensive care unit (ICU). Tracheostomy facilitates respiratory and sedative weaning but risks potential viral transmission. This study reviewed the tracheostomy provision, techniques, and outcomes for a single-centre prospective cohort during the resource-pressured COVID-19 period. Seventy-two of 176 patients underwent tracheostomy at a median 17 days: 44 surgical (open), 28 percutaneous. Their median age was 58 years, the male to female ratio was 2.4:1, 75.1% were of BAME backgrounds, 76% had a BMI \geq 25 kg/m², and 65% had \geq 2 major co-morbidities. Seventy-nine percent of patients were weaned from sedation at a median 2 days, 61% were weaned from mechanical ventilation at a median 10 days, 39% were discharged from the ICU at a median 11.5 days, and 19.4% were discharged home at a median 24 days. All patients survived the procedure. The mortality rate was 9.7% at a median 12 days. No clinician reported COVID-19 symptoms within 14 days of the procedure. The role of tracheostomy in COVID-19 is currently unclear. Delivery of tracheostomy by maxillofacial surgeons relieved the workload pressure from ICU clinicians. The choice of technique was influenced by the patient and resource factors, resulting in a mixed cohort of open and percutaneous tracheostomy in COVID-19 patients. Preliminary data suggest that open tracheostomy is as favourable as percutaneous tracheostomy for COVID-19 patients, and is safe for clinicians.

Key words: COVID-19; tracheostomy; ICU; resource management.

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Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19), emerged in late 2019 and spread rapidly with air travel to multiple countries. As of June 9, global confirmed COVID-19 cases had reached more than nine million, with over 470,000 deaths¹. In the UK, there were 272,826 confirmed cases with 38,376 deaths on 30 May 2020, placing the UK second for the prevalence of global COVID-19-related

death². Reports from China and Italy have suggested that up to 20% of patients develop severe disease requiring hospitalization and 5–16% develop severe disease in need of advanced critical care support^{3–5}.

King's College Hospital serves a local population of 700,000 people. Normal operating capacity for this institution is 1000 inpatient beds, with 80 level 3 capable intensive care unit (ICU) beds. Early predictions of 2.7% infection rates extrapolated to as many as 3780 patients requiring hospitalization and oxygen support and 945 patients requiring ICU care with advanced ventilator support⁶.

Prolonged mechanical ventilation is associated with a number of unwanted side effects, including ventilator-induced lung injury, ventilator-associated pneumonia, and disuse myopathies. Tracheostomy is a recognized strategy for weaning from both mechanical ventilation and sedation⁷. As such it may serve to conserve ventilators and other ICU resources during times of high demand. Experiences from the severe acute respiratory syndrome (SARS) outbreak in 2002-2004 and early reports on COVID-19 from Italy and the USA⁵, ¹² signalled the risk of aerosol-producing procedures such as tracheostomy with the potential to infect healthcare providers⁸. As a result, UK national surgical specialties collaborated to provide guidance and protocols for safe tracheostomy practices

in COVID-19 patients¹³⁻¹⁶.

When the first COVID-19 patient was admitted to the ICU of King's College Hospital on 10 March 2020, there were no published data or case series of tracheostomy in COVID-19 patients. In this institution, as in most such institutions in the UK, tracheostomy is commonly performed percutaneously by ICU clinicians, and small numbers are referred for open (surgical) tracheostomy, predominantly due to unfavourable anatomical factors. Unusually, in our unit, it is the oral and maxillofacial surgeons (OMFS) who exclusively provide the open tracheostomy service. Due to the high volume of cases, adaptations were made to the tracheostomy service to accommodate increased demand and relieve this workload from ICU colleagues. This, coupled with resource limitations, resulted in a uniquely high number of open tracheostomies.

This article presents a single-centre prospective experience of open and percutaneous tracheostomy in COVID-19 patients, with preliminary outcomes and comparison to now available published data.

Materials and methods

Patient selection

A dedicated structured query language (SQL) report in the critical care

informatics system. IntelliSpace Critical Care and Anesthesia (ICCA, Philips Healthcare), was used to identify all patients admitted to the ICU with COVID-19 between 10 March and 18 May 2020. The search also identified those patients who underwent tracheostomy. The institution electronic health records (Sunrise Clinical Manager), paper operative notes, and paper clinical notes were also assessed. All patients were positive for SARS-CoV-2 on nasopharyngeal swab via reverse transcriptase polymerase chain reaction (RT-PCR) assay testing. Descriptive data are presented. The data were analysed using Microsoft Excel for Mac 2010. Tests for significance in outcomes between the open and percutaneous techniques were performed by Mann-Whitney U-test using the Social Sciences Statistics Calculator.

Technique

Patient suitability for tracheostomy to facilitate weaning was identified and agreed by a minimum of two ICU consultants and discussed with OMFS at the morning tactical meeting. Fourteen days of mechanical ventilation was chosen as an adequate duration for patients to be stable enough to tolerate and benefit from the procedure, which includes a period of cessation of ventilation, and to minimize the risk of infectivity to staff. It was noted, due to evolving knowledge, that guidance ventilatory limits of FiO₂ <0.4 and positive end-expiratory pressure (PEEP) <10 cmH₂O^{14,16} may need to be adjusted.

It became apparent early on that with increased patient density in ICU units, the initial plan for the OMFS team to deliver percutaneous tracheostomy at the bedside was not a viable setup. The increased constriction on physical space, a shortage of percutaneous kits, and disruption to ICU clinician time required to assist with bronchoscopy, pushed the choice of technique in favour of an open procedure. A new daily tracheostomy service with a dedicated operating theatre list was created to fulfil this need. Patients for open tracheostomy were referred via an electronic referral system (Sunrise Clinical Manager) and the highest priority cases for the following day were agreed between the critical care tactical consultant and the OMFS team the preceding evening.

The World Health Organization checklist was used prior to each procedure. Open tracheostomy was performed in the operating theatre by two senior OMFS surgeons with an assistant, using the standard operating procedure as described by ENT UK, with minor adjustments¹⁴. Percutaneous tracheostomy was conducted in the ICUs using a standard Seldinger/Rhino dilatation technique with ultrasound preassessment and bronchoscopic (video or fibreoptic) control, according to the protocol published in the King's College Hospital NHS Foundation Trust adult critical care guidelines. Two senior ICU/OMFS clinicians performed this procedure, with the assistance of an ICU nurse.

There were no negative pressure facilities. In all cases, staff within the procedure space wore FFP3 masks, full-face visors or goggles, full-length fluid-resistant gowns, surgical caps, and surgical gloves. All staff were 'fit tested' in advance of FFP3 use. Four powered air-purifying respirators (PAPR) were available for team members if they had failed their 'fit test', or as an option with a priority given to 'up-close' team members such as operators, anaesthetists, and operating department practitioners (ODPs). Team members were requested to report any COVID-19 symptoms occurring within 14 days of the procedure.

Results

Up to 18 May 2020, 1257 patients who tested positive for COVID-19 were admitted to King's College Hospital. During the study period, 10 March to 18 May 2020, 176 COVID-19 patients were admitted for advanced ventilation in the ICU. Of these, 72 (40.9%) required tracheostomy for prolonged respiratory weaning and/or failed extubation.

Patients

The median age of all COVID-19 tracheostomy patients was 58.0 years (interquartile range (IQR) 51.8-63 years), ranging from 28 to 78 years. The male to female ratio was 2.4:1 (51 male, 21 female). The median body mass index (BMI) was 28.5 kg/m^2 (IQR 25– 33.2 kg/m²), with 76.4% (n = 55) of patients in the overweight or obese range $(\geq 25 \text{ kg/m}^2)$ (Table 1). There was a predominance (75%) of patients from Black, Asian, and minority ethnic (BAME) backgrounds in the tracheostomy cohort. At least two major co-morbidities were present in 65.3% of the patients. Due to an increased incidence of thrombotic complications in these COVID-19 patients, 53% (n = 38) were anticoagulated with heparin or argatroban infusions (excluding prophylactic low molecular weight heparin). Therapeutic anticoagulation was paused to cover the procedure, as per local guidelines, prior to and immediately after the procedure.

	Tracheostomy technique		All $(n = 72)$	
	Open $(n = 44)$	Percutaneous $(n = 28)$	$\operatorname{Am}(n-12)$	
Sex (n)				
Male	30	21	51	
Female	14	7	21	
Age (years)				
Median	56.5	60.0	58.0	
IQR	50.8-61.0	53.8-65.0	51.8-63.0	
Range	28.0-73.0	42.0-78.0	28.0-78.0	
BMI (kg/m^2)				
Median	31.1	26.8	28.5	
IQR	25.0-37.4	25.2-31.0	25-33.2	
Range	21.5-49.4	21.6-36.7	21.5-49.4	
Ethnicity (%)				
White	15.9	32.1	22.2	
Black	45.5	35.7	41.7	
Asian	9.1	0	5.6	
Mixed	2.3	3.6	2.8	
Other	22.7	28.6	25.0	
Not recorded	4.5	0	2.8	

BMI, body mass index; IQR, interquartile range.

Timing

Tracheostomy took place at a median time of 17 days (IQR 14–21 days) post intubation, with median FiO_2 of 0.4 (IQR 0.3– 0.4) and median PEEP of 8.5 cmH₂O (IQR 8.0–10.0 cmH₂O). The median P/F ratio at the time of the procedure was 26 kPa (IQR 23.8–36.0 kPa).

Early outcomes

A minimum 14-day follow-up was available for all patients. The median follow-up was 26 days (IQR 18.8–32 days).

The aim to wean sedation and mechanical ventilation for COVID-19 patients was achieved in 79.2% (n = 57) and 61.1% (n = 44) of cases, respectively. Overall, the median time to wean sedation was 2 days (IQR 0-6 days) and the median time to wean mechanical ventilation was 10 days (IOR 6-15 days). Comparison between the open and percutaneous techniques suggested earlier weaning for open cases: median 0.5 day versus 2 days for sedation and median 10 days versus 14 days for mechanical ventilation. The median time to discharge from the ICU was 11.5 days (IQR 7–14.3 days; n = 28) (Table 2) with median discharge home for 19.4% at 24 days.

In 91% of cases, the team members wore FFP3 masks and visors or goggles in addition to gloves and fluid-resistant long-sleeved gowns. In the remaining 9% of cases, PAPR were utilized in addition. None of the team members involved in either percutaneous or open tracheostomy procedures reported COVID-19 symptoms.

Complications

Intra-procedural complications were recorded for seven cases (9.7%). These included desaturation below 80% (n = 3), cardiac event (n = 1, one arrhythmia),bleeding (n = 1, open), and intra-procedural tube leaks requiring a change of tube for an alternative size and/or length (n = 3). One additional patient required an emergency covering cricothyroidotomy following a 'cannot intubate, cannot oxygenate' scenario during attempted rapid sequence induction, with subsequent conversion to a standard tracheostomy. All patients survived the tracheostomy procedure. The mortality

rate for the cohort was 9.7% to 18 May (7/72), with death occurring at a median 12 days (IQR 5.5–18.5 days) post-procedure. All deaths were related to complications of COVID-19 (Table 2).

Delayed complications included cuff leaks, reported in seven patients, with three of them requiring tube upsizing (n = 2 theatre, n = 1 ward); the other cases were managed conservatively. Anecdotally much higher cuff leak was experienced than for non-COVID-19 tracheostomy patients, but these were poorly documented. There were three cases of a bleeding stoma site $(n = 1 \text{ open}, n = 2 \text{ percutane$ $ous})$, and these were managed with local measures.

Discussion

The role of tracheostomy in the management of COVID-19 patients is still unclear. This study, although limited in size, adds to the available data on the management of COVID-19 patients requiring prolonged ventilation. With the inclusion of a large series of open tracheostomy, this procedure was demonstrated to be safe and potentially useful. Interspecialty devolvement of a suitable procedure, i.e. tracheostomy, was useful during times of unprecedented demand.

This was an extremely challenging period of time. From 10 March to 18 May 2020, 1257 COVID-19 patients were admitted, with 176 admitted to the ICU for advanced organ support. ICU capacity was dramatically increased over a 2-week period from 80 to 180 beds. Staff from

Table 2. Outcome measures post-tracheostomy for patients with COVID-19.

	Tracheo	Tracheostomy technique		P-value
	Open $(n = 44)$	Percutaneous $(n = 28)$	All $(n = 72)$	<i>i</i> -value
Deaths, n (%)	5 (11.4)	2 (7.1)	7 (9.7)	
Time to death (d	lays)		<u>`</u>	
Median	16	7.5	12	0.24
IQR	4-21	5.3–9.8	5.5-18.5	
Range	7–21	3–12	3-21	
Time to wean m	echanical ventilation	n (days)		
n (%)	26 (59.1)	18 (64.3)	44 (61.1)	0.15
Median	10	14	10	
IQR	6-11.8	6–20	6-15	
Range	1–28	4–39	1-39	
Time to wean se	dation (days)			
n (%)	34 (77.3)	23 (82.1)	57 (79.2)	0.20
Median	0.5	2	2	
IQR	0–5	0-8	0–6	
Range	0-12	0–16	0-16	
Time to discharg	ge from ICU (days)			
n (%)	14 (31.8)	14 (50)	28 (38.9)	0.18
Median	10	13	11.5	
IQR	7.5-13.8	7.8–15	7-14.3	
Range	5-17	4–27	4–27	

ICU, intensive care unit; IQR, interquartile range.

multiple specialities was redeployed to the ICU and inpatient wards to support increased acute patient care due to COVID-19. The provision of a tracheostomy service by OMFS relieved clinical pressure on ICU personnel and space.

The demographic characteristics of the patients requiring critical care during the course of this study were broadly in line with those reported nationally in terms of age, sex, and BMI, but not for ethnicity¹⁷. It has been of considerable concern that patients of a BAME background appear to be more affected by COVID-19.

The 2011 UK Census reported that only 14% of respondents were from a BAME background¹⁸. However, London is more multi-ethnic in composition, and 44.3% of residents from the boroughs surrounding King's College Hospital (Lambeth and Southwark) reported as BAME. These patients were still overrepresented in the cohort who underwent tracheostomy at 78%. It is, however, important that we do not assume that there is an intrinsic reason that BAME patients are more affected and ethnicity is not just a confounding factor reflecting that in our area these patients are also subject to high housing density and a high deprivation index. A wider study of COVID-19 affected patients across the UK and worldwide may answer these questions in time.

As expected, patients who underwent an open tracheostomy had a significantly higher BMI when compared to those undergoing percutaneous tracheostomy: mean $31.7 \pm 7.6 \text{ kg/m}^2$ versus $27.8 \pm 3.6 \text{ kg/m}^2$ (P = 0.013). We would expect the difference to be greater, but the lack of percutaneous kit availability is likely to have had some influence on this, with patients not solely allocated for open tracheostomy due to their BMI or unfavourable anatomy.

Although not statistically significant in this cohort, the factors that further stand out as potential risk factors for severe COVID-19 illness include the presence of co-morbidities, in particular the presence of diabetes (31.9%, n = 23), hypertension (43.1%, n = 31), and obesity (44.4%, n = 32).

The optimal timing for non-COVID-19 tracheostomy is a controversial topic. The UK-based TracMan randomized controlled trial of 909 patients concluded that there was no advantage to 'early' tracheostomy (within 4 days of mechanical ventilation) over a 'late' procedure (10 days on) in terms of 30-day mortality, tracheostomy-related complications, or discharge from the ICU¹⁹. For COVID-19 cases, ENT UK and the British Larvngological Association suggest the procedure be performed at >14 days of mechanical ventilation. with parameters of $PEEP < 10 \text{ cmH}_2O$ and FiO₂ $\leq 0.4^{14,16}$, and this is reflected in the King's College Hospital NHS Foundation Trust adult critical care guidelines on tracheostomy. However, none of the trials or observational studies that led to the development of these guidelines was in the context of COVID-19. Our lower mortality rate of 5.6% (n = 4) at ≤ 14 days compares favourably relative to the rate of 41% reported at ≤ 7 days by Riestra-Ayora et al.²⁰.

Ventilator parameters did not differ significantly between the open and percutaneous groups. This was expected, as the criteria for patient suitability for the tracheostomy procedure were the same. Of note, oxygenation of ventilated COVID-19 patients was often dynamic, as these patients would deteriorate suddenly, thus requiring strategic planning of the operating list, with the 'most urgent case' and the 'back up first case'.

The choice between the techniques was initially driven by patient factors such as BMI and anatomy, but then by resource factors, i.e. space, personnel, and consumables (e.g. tracheostomy tubes, insertion kits).

The time from initiation of mechanical ventilation to tracheostomy differed significantly between the open and percutaneous tracheostomy groups, with a mean 23 days versus 14 days (P < 0.001). This is potentially due to the extra time required to schedule an open procedure and the daily limit of approximately three procedures per day in theatre due to the additional transfer time. In more usual times, the added transfer time, theatre time, and costs associated with an open procedure would favour a percutaneous bedside approach²¹, but in resource-limited times, it was found that this arrangement favoured the skills and environment available without adversely affecting outcomes.

Percutaneous kits were exhausted within the first 2 weeks, both locally and within the national supply chain. This played a role in the higher proportion of open procedures reported in the present study than in other reports (Table 3). Due to the volume of cases, there were also limitations in the sizes and types of tube available for open procedures, which may have accounted for the intra-procedural tube changes. A tendency to require a larger tube than expected was noted, as the trachea of COVID-19 patients was often dilated and inflamed at the time of the procedure. This brought challenges further down the line, as patients appeared to experience more cuff leaks and sometimes required downsizing as part of the weaning process.

Sparing protocols were developed to ration stocks of common sedatives such as propofol and fentanyl, including less frequently used drugs such as clonidine. Weaning from sedation was potentially more difficult due to longer-acting properties, active metabolites, and/or with-drawal effects. Despite this, 77.3% of open tracheostomy patients were weaned from sedation by a median 0.5 day, helping address shortages.

Tracheostomy is classified as a highrisk aerosol-producing procedure, so it is vital that precautions are undertaken to protect healthcare professionals from infection¹². Available evidence suggests that viral shedding is maximal in the first week of infection and that viable virus is not cultured beyond 8 days, although findings of positive RNA on swabs may persist for considerably longer^{22,23}. This supports our choice of later timing of the procedure. Modifications to suctioning were implemented, with closed suction tubing used as standard for COVID-19 patients and ported connectors for scoping rather than opening the circuit. Widely reported tracheostomy leaks were also of concern here, with potential low levels of aerosol escape from the stoma; however, we also experienced leaks from endotracheal tubes. As standard low pressure cuffs were used but hyperinflation of these was sometimes necessary to control leaks, this may be evident on long-term review of the patients. Repeated checking of the pilot balloon on the tracheostomy tube for pressure and hyperinflation has been reported to have deleterious effects on the valve, resulting in a slow leak in pressure. Bungs as for vascular access ports were used to prevent this.

Despite the challenges, tracheostomy is a safe procedure. All COVID-19 patients survived their tracheostomy, and all deaths so far have been related to COVID-19 complications rather than the tracheostomy. The intraoperative desaturation noted in 4% of patients was likely multifactorial in origin, both ventilation- and perfusion-related, and reflected the extent of lung injury. No team members involved in the tracheostomy procedures, either percutaneous or surgical, reported COVID-19 symptoms. This would support the choice of personal

	Sample Size	Time Intubation to T racheostomy	Mortality	Time to Wean Sedation	Time to Wean Mechanical Ventilation	Decannulation Post- tracheostomy	Discharged Home
Current Study (2020) UK	44 Open 28 Percutaneous	19 days (median) 15 days (median)	11% (5/44) 7.1% (2/28) 12 days (median)	0.5 days (median) 2 days (median)	10 days (median) 14 days (median)	13/43 12/28	5/44 9/28 19.4%
RiestraAyora et al. (2020) Spain ²⁰	10 Open 17 Percutaneous		41% (11/27) ≤7 days				
Angel et al. (2020) USA^{24}	6 Open 98 Percutaneous	10.6 days (mean)	7% death 11 days (mean)		33% at 11days +/-6	8%	4%
Ferri et al (2020) Italy ²⁵	8 Open	>14 days	25% (2/8) 3 days (median)				
Vargas, Servillo (2020) Italy ²⁶	3 Percutaneous						
Prabhakaran et al. (2020) USA ²⁷	18 Open	20.4 days (mean)					
Piccin et al. (2020) Italy ²⁸	24 Open	10 days (median)				14/24 12 days (median)	
Takhar et al. (2020) UK submitted ²⁹	51 Percutaneous	17 days (median)	3.9% (2/51) 13.5 days (mean)				
Turri-Zanoni et al. (2020) Italy ³⁰	22 Open 10 Percutaneous	15 days (mean)	•				

Table 3. Summary of studies where tracheostomy was evaluated in the management of COVID-19.

protective equipment used. The low uptake of PAPR use was likely due to the cumbersome nature and difficulty with communication whilst wearing, worse than already noted with an FFP3 mask and visor.

Preliminary outcomes

The preliminary outcome data suggest that tracheostomy is of use in the management of patients with severe COVID-19 infection, with 79.2% of cases weaned off sedation and 61.1% weaned off ventilation overall. In this series, 20.8% of patients were weaned from mechanical ventilation at \leq 7 days post tracheostomy and 44.4% at ≤ 14 days. This is comparable to the data reported in the case series study by Angel et al.²⁴ in New York, involving 98 COVID-19 patients who underwent percutaneous tracheostomy, with 40% of patients weaned from mechanical ventilation by an average 11 days. Our discharges from the ICU were also comparable: 17% of the cohort reported by Angel et al. were discharged from the ICU by an average 11 days, while in the present study, 12.5% were discharged by \leq 7 days and 29.2% by ≤14 days. Angel et al. reported a 7%

mortality rate by an average 11 days and ours was 5.6% within a similar timeframe of ≤ 14 days. A summary of studies in which tracheostomy was evaluated in the management of COVID-19 is provided in Table 3.

The data for weaning from sedation – 63.9% of patients by ≤ 7 days and 77.8% by ≤ 14 days – are difficult to compare due to the complex mixtures of sedatives used, as necessitated by shortages.

From this cohort of 72 tracheostomies in COVID-19 patients, including 44 open tracheostomies, the following conclusion is drawn: Outcomes of open tracheostomy are comparable to those of the percutaneous technique, and open tracheostomy does not carry a greater risk of COVID-19 transmission to clinicians.

Devolvement of aspects of critical care to surgeons, such as tracheostomy, can relieve pressure on the ICU during surge periods. The oxygenation of ventilated COVID-19 patients was often dynamic, as these patients would deteriorate suddenly. Thus strategic planning of the operating list was required.

Tracheostomy does appear to be useful for COVID-19 patients, but global collaboration will provide vital information regarding the ultimate utility of tracheostomy in COVID-19 patients.

Supply chains are crucial to being able to meet increased demand. Advance planning and centralization of the existing stock is essential, but adaptations may also be needed.

Although current data suggest we are past the first peak of patients to be affected by COVID-19, we must be alert and prepared to meet the challenge of a second wave as lockdown measures are relaxed.

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Competing interests

None.

Ethical approval

This project had approval for service evaluation of tracheostomy during COVID-19 at King's College Hospital, London, UK.

Patient consent

Not required.

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