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COVIDTrach; the outcomes of mechanically ventilated COVID-19 patients undergoing tracheostomy in the UK:

Interim Report 22nd May 2020

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Abstract

COVIDTrach is a UK multidisciplinary collaborative project that aims to evaluate the outcomes of tracheostomy in COVID-19 patients. It also examines the implementation of national guidance in COVID-19 tracheostomies and the incidence of COVID-19 infections amongst those health care workers involved in the procedure.

An invitation to participate in an online survey tool (REDCap) was disseminated to all UK NHS departments involved in tracheostomy in mechanically ventilated COVID-19 patients via the Federation of Surgical Specialty Associations, it's subsidiary organisations and the Intensive Care Society. To date 78 hospitals have submitted 564 COVID-19 tracheostomy cases.

Fifty-two percent (n=219/465) of patients who had undergone tracheostomy and were still alive had been successfully weaned from mechanical ventilation at the point of completing the survey. The all cause in-hospital mortality following tracheostomy was 12% (n=62/530), with 3% of these (n=2/62) due to tracheostomy related complications and the remaining deaths due to COVID-19 related complications. Amongst 400 cases submitting data two weeks after the tracheostomy, no instance of COVID-19 infection amongst operators was recorded. FFP3 masks or Powered Air Purifying Respirators were used by operators in 100% of tracheostomies and a face visor or hood with face shield was available in 99% of cases.

This interim report highlights early outcomes following tracheostomy in mechanically ventilated COVID-19 patients. Future reporting from COVIDTrach will include more detailed analysis at later timepoints using comparator groups in order to provide a more comprehensive assessment of tracheostomy in COVID-19.

Introduction

At the time of writing, the UK has the fourth highest number of confirmed COVID-19 cases in the world with over 11,000 patients with COVID-19 having been admitted to intensive care since the start of the outbreak.[1,2] Standard UK intensive care practice is to consider tracheostomy after 7-10 days of invasive mechanical ventilation in order to reduce the duration of mechanical ventilation, shorten intensive care stay and minimise complications relating to the prolonged presence of an endotracheal tube.[3-6] Whether this practice is beneficial in mechanically ventilated patients with COVID-19 infection has not yet been extensively evaluated.

There are also unique considerations regarding health care professional (HCP) safety when performing tracheostomy in COVID-19 patients due to the potential of aerosol generation and transmission of the infection.[7] Various professional organisations have issued guidance regarding COVID-19 tracheostomy in terms of timing, environment, technique and level of personal protective equipment (PPE).[8-10] The ability of hospital departments to implement this guidance and the effects of these measures in terms of preventing COVID-19 illness amongst those performing tracheostomy is unknown.

COVIDTrach is a UK multidisciplinary collaborative project that aims to evaluate the effectiveness of tracheostomy in patients diagnosed with COVID-19 who are receiving invasive mechanical ventilation. In parallel, we will collect data on the procedure itself, audit the implementation of national guidance in COVID-19 tracheostomies and examine the risk in terms of COVID-19 infections amongst operators.

Reporting Process

An invitation to participate in the COVIDTrach project was disseminated via the UK Federation of Surgical Specialty Associations (FSSA), it's various member organisations and the Intensive Care Society (ICS) to reach all UK departments involved in tracheostomy in COVID-19 patients. Participating departments were sent a link to an online survey tool (REDCap) to collect anonymised and de-identified data on mechanically ventilated COVID-19 patients undergoing tracheostomy. Patient medical history along with early outcomes were labelled as priority data fields and have been the focus of data inputting for this interim report; (see Appendix 1 for questions and response rate). Results are given in brackets as a fraction of results received (n=results/number of results received).

Participants

108 NHS departments across the UK registered to submit data to the COVIDTrach study with sites being led by a combination of ENT, Maxillofacial and Intensive Care Specialists. Between 6th April and 11th May 2020, data was received on 564 tracheostomies from 78 hospitals (Figure 1); 29 hospitals entered five or more cases which added up to 85% of all tracheostomies entered. These 29 were approached by email to establish the total number of tracheostomies in the above period; this was compared with the number of tracheostomies entered in COVIDTrach. For the 24 sites who replied, on average, 94% of all tracheostomies performed were recorded in the database.

Characteristics of COVID-19 patients undergoing tracheostomy

The average age (data available in 563 cases) of mechanically ventilated COVID-19 patients undergoing tracheostomy was 57 years (Table 1). The majority of patients were male (n=405/563, 72%) and BMI ranged from 18.5 to <25 (22%), 25 to <30 (35%), 30 to <40 (35%) and >40 (8%) (data available in 426 cases). The number of days from admission to hospital to intubation ranged from 0 representing the day of admission to 33 days (median 1, IQR 0, 4). Forty percent of cases used non-invasive ventilation (NIV) prior to intubation (n=202/505).

The number of days from intubation (day 0) to tracheostomy ranged from 0-35 (median 16, IQR 13, 22) (Figure 2a, data available in 543 cases). The mean C-Reactive Protein (CRP) level on the day of tracheostomy was 123 (SD, 95) and there was a downtrend in 67% of reported cases (Figure 2b, n=366/547). A temperature of >37.5°C was recorded on the day of tracheostomy (28%), 1-2 days before (28%), 3-4 days before (18%) and 5 days before (26%) (data available in 489 cases). Inotropic support at the time of tracheostomy was reported in 41% of cases (n=220/538) although the type of inotrope was not established.

Figure 3 shows the oxygen requirements (Fi02 %), and positive end expiratory pressure (PEEP cmH2O) before the procedure. The median Fi02 was 40% (IQR 30, 45) (data available in 555 cases). Median PEEP was 8 (IQR 6, 10) (data available in 539 cases). The median Pa02/Fi02 ratio on the day of tracheostomy was 199 (IQR 151, 244) (data available in 476 cases).

Ninety-three percent (n=521/558) of cases had a positive COVID-19 PCR test during their admission to hospital (Table 2). Of those that did not have a positive COVID-19 PCR test documented prior to tracheostomy, 14 were being treated for symptoms of COVID-19 but had no PCR test on record, 21 had only negative tests on record and for two, no reason was given. The number of tests performed prior to tracheostomy ranged from 1 to 12 (median 1, IQR 1,2). The COVID-19 test was positive in 86% (n=443/503) of patients prior to tracheostomy with the length of time from the last test to the day of surgery recorded as median 14 days (IQR 7,19). In those that did have more than one test, the second to last test was positive in 74% of cases (n=222/301).

Tracheostomy (the procedure itself)

An anticipated “prolonged wean” was the most cited indication for tracheostomy (n=520/551), followed by failed extubation (n=64/551) (figure 4a). Other indications were the absence of a cuff leak (n=2/551), to free up ventilator capacity (n=2/551) and palliation (n=2/551). In 39 cases, both anticipated prolonged wean and absence of a cuff leak were cited.

An open method of tracheostomy was used in 58% of cases (n=323/560), a percutaneous method in 39% (n=217/560) and a hybrid method, that uses a combination of open and percutaneous techniques, was used in 3% (n=20/560) (figure 4b). Where a percutaneous method was used, a bronchoscope was used to identify the position for tracheostomy in 81% of cases (n=161/200) and an ultrasound used in 6% of cases (n=11/200). A range of surgical and Intensive care specialists performed the procedure with open cases being led exclusively by surgical specialists and percutaneous cases being predominantly led by intensive care specialists (76%, n=165/217).

Forty-three percent (n=226/527) of tracheostomies were performed by two consultant grade specialists and 35% (n=185/527) by a consultant grade lead and middle grade assistant. In 5% (n=24/527) of tracheostomies no assistant was used for the procedure. Fifty-five percent (n=293/530) of tracheostomies were performed in the operating theatre and 45% (n=237/530) in Intensive Care (n=237/530) (figure 4c). A negative pressure environment was used in 10% of cases (n=55/530).

A cuffed tube was used in virtually all cases (n=550/551) and a non-fenestrated tube was used in over 95% of cases (n=383/400). The size of tube varied from 6-9 with smaller tubes being used in female cases; size 6 in 0.4%, (n=2/553), size 7 in 12% (n=68/553), size 7.5 in 4% (n=21/553), size 8 in 64% (n=354/553) and size 9 in 20% (n=108/553). The brand of tubes included Portex in 44% (n=244/553), TRACOE twist in 49% (273/553), Shiley in 4% (22/553) and an undisclosed brand in 3% (n=14/553). An adjustable flange tube was used in 10% of cases (n=52/515).

Early Outcomes following tracheostomy in COVID-19 patients

The intraoperative complication rate was 10% (n=32/322) using the open method and 7% (n=16/216) using the percutaneous method. Across both open and percutaneous methods, the most common intraoperative complication was desaturation below 80% (n=17/558) and tear of the tracheostomy cuff (n=12/558) (figure 5). The post-operative complication rate was 20% (n=65/323) using the open method and 8% (n=17/217) using the percutaneous method. Bleeding was the most common postoperative complication (n=25/520). In addition to these complications, 36 instances of post-operative cuff leak were reported (28 following open method, 8 following percutaneous method) necessitating tube change in 21 cases.

Fifty-two percent (n=219/465) of COVID-19 patients who had undergone tracheostomy and were still alive had been weaned from mechanical ventilation at the point of completing the survey (Table 3). The number of days from tracheostomy to successful wean from mechanical ventilation in this group varied from one to 27 days (median 8; IQR 5, 12) (data available in 217 cases). Of those that had not yet been successfully weaned, the number of days from tracheostomy to entering data on weaning was less than 10 days in 44% (data available in 181 cases). At the point of survey, 38% (n=169/450) of patients who had undergone a tracheostomy had been discharged from intensive care.

The all-cause in-hospital mortality following tracheostomy in COVID-19 patients was 12% (n=62/530) with two deaths directly attributed to post-operative tracheostomy complications; a tracheostomy tube placed in a false passage and a displaced tracheostomy tube. The other 60 (97%) of these deaths were recorded as “COVID-19 related” (Table 3). The time from tracheostomy to COVID-19 related death ranged from one to 21 days (median 8, IQR 5, 12). There were no intraoperative deaths during tracheostomy.

Personal protective equipment and wellness of operators

The question “Did any of the operators test positive for COVID-19 within two weeks of the procedure”, was answered by 71% (n=400/564) and all confirmed that no operators had become COVID-19 test positive within two weeks of the procedure. In all cases reported (n=545/545),

operators used either an FFP3 mask or Powered Air Purifying Respirator (PAPR) (Figure 6). Additional PPE used involved either a face visor or hood with face shield in 99% of cases (n=538/545), a disposable gown in 97% (n=527/545), double gloves in 90% (n=490/545) and disposable shoe covers in 25% (n=134/545) (Figure 6).

Discussion

A priority of the COVIDTrach collaborative project is to assess the safety of colleagues involved in COVID-19 tracheostomies. To date, in 400 tracheostomies, no instances of COVID-19 infection have occurred amongst operators within two weeks of the procedure. Whilst this finding is reassuring, it should be viewed within the limits of collecting data by survey and does not account for the remaining cases that are yet to reach the two-week time point. The use of an FFP3 mask or PAPR was reported in 100% of cases, the use of adequate face protection in 99% and the use of a disposable gown in 97%. These figures indicate adequate provision of key PPE for operators during tracheostomy. An effort should be made to improve the use of double gloves and disposable shoe covers in all cases and will be the subject of further audit in later reports. The use of a two-person operator team in over 95% of cases is in keeping with national guidance and should continue to be encouraged as standard practice in all COVID-19 tracheostomies.

At the start of the pandemic, there were questions over the utility of tracheostomy as an intervention in COVID-19 patients.[11-13] At the time of writing, the all-cause in-hospital mortality rate in COVID-19 patients following tracheostomy was 12%. As many of the patients are yet to complete their critical care, these rates should be interpreted with caution and a rise in mortality is possible as patients succumb to their illness after a protracted course. Fifty-two percent of cases were successfully weaned from mechanical ventilation at the time of reporting. Whilst this may indicate tracheostomy is effective in enabling weaning in COVID-19 patients, there is significant heterogeneity in terms of co-morbidity, disease severity and prior medical intervention which needs to be explored further. The success in tracheostomy decannulation and eventual discharge from hospital will be reported in due course.

The timing and clinical criteria that ought to be met prior to tracheostomy in COVID-19 patients has been discussed at length in the literature.[8,9,14] Earlier guidance suggested tracheostomy at or after 14 days of intubation whilst more recent guidance suggests at or after 10 days of intubation.[10] So far, 82% of cases were performed at 10 days or more and 69% of cases 14 days or more and it is too early to comment on the effectiveness of implementing these criteria. Delaying tracheostomy may have the potential benefit of targeting the procedure to those most likely to survive. Viral load is also known to fall with time from the onset of symptoms and thus may reduce infectivity.[15] Conversely, delays may result in a missed therapeutic window and increase the duration of mechanical ventilation with associated complications. Further data collection will enable more detailed analysis on patient outcomes with reference to timing of the tracheostomy and the clinical indicators.

The mean age and gender of the patient population with COVID-19 undergoing tracheostomy is similar to national UK demographic data on patients critically ill with COVID-19 reported by ICNARC.[1] Detailed data collection on the patient's comorbid state was not within the remit of the early phase of data collection but will be a focus of later analysis as well as inclusion of ethnicity data.

The role of identifying PCR test status in COVID-19 patients ahead of tracheostomy is unclear. Guidelines from the British Laryngology Association and Canada recommend two negative tests before proceeding with tracheostomy.[9,14] Eighty-six percent of our cases tested positive on the last swab before tracheostomy and in the majority of cases, this was performed around the time of admission with no follow up test nearer the time of tracheostomy. The relevance of determining test status in the days prior to tracheostomy is uncertain. ICU patients can remain test positive for several weeks after the onset of symptoms,[16,17] and whether the detection of viral RNA by PCR predicts risk of infectivity to operators and other health care professionals is unclear. Delaying tracheostomy to achieve two negative tests is likely to prolong endotracheal ventilation and thus defer the potential benefits of tracheostomy whilst increasing the risk of complications relating to endotracheal intubation. The inflammatory marker CRP has been shown to correlate with COVID-19 disease severity,[18,19] and may be a better test to inform on the timing of tracheostomy. In this report 67% of tracheostomies were performed in patients with a downward trending CRP, although it is too early to assess whether this is predictive of improved patient outcomes.

An open tracheostomy method was used in 58% of cases although the predominance of surgical specialists reporting data in this initial report may account for this. We expect that in future reports, with more intensive care units joining the COVIDTrach collaborative and submitting data, the number of percutaneous tracheostomies will increase relative to the open surgical technique giving a more representative national picture. In the dataset so far, the complication rate was higher in surgical open tracheostomies compared to percutaneous cases. This is consistent with outcomes reported in the literature of non COVID-19 patients undergoing tracheostomy.[20,21] Rates of thrombosis are known to be high in severe COVID-19 illness necessitating the use of high dose anticoagulant medication.[22] This may explain the high postoperative bleeding rate following tracheostomy in this data set.

Future direction

This report represents an interim analysis of data entered so far in the COVIDTrach multi-disciplinary collaborative project. Early reporting was felt necessary to share the availability of PPE, rate of infectivity amongst operators and early patient outcomes. We would like to thank all of the individuals contributing to this project for their hard work in returning data and we encourage new sites to sign up and participate.

Further reporting will include more complete datasets and focus on later outcomes following tracheostomy up to the point of discharge from hospital. As the project expands and further cases are received, more detailed analysis can occur to establish meaningful conclusions on the role and outcomes of tracheostomy in COVID-19 patients. We will also continue to audit the use of PPE and survey wellness amongst operators to ensure the safety of our colleagues.

Data collection

Study data were collected and managed using REDCap electronic data capture tools hosted at University College London. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

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Disclosures

Asit Arora is a consultant for Cambridge Medical Robotics.

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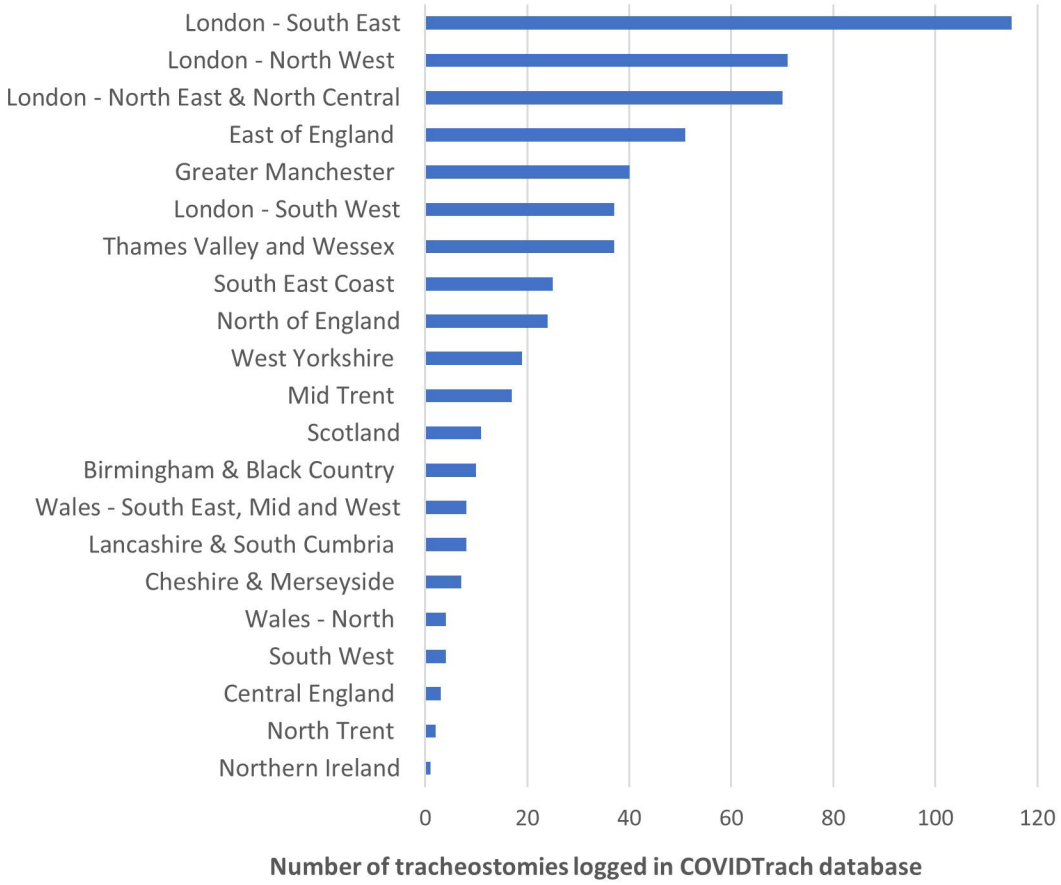


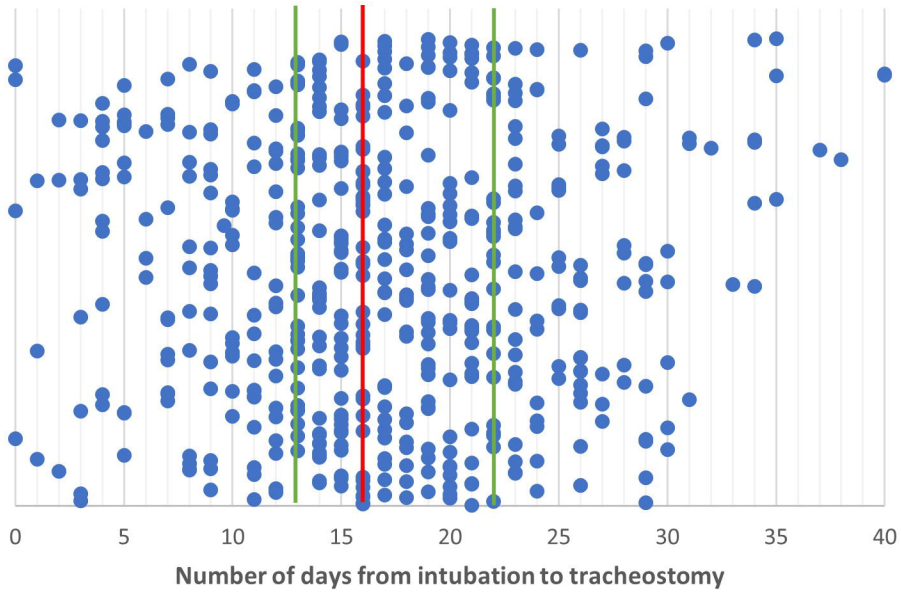
Figure 1. Number of tracheostomies in COVID-19 patients logged in the COVIDTrach database by UK region from 6th April to 11th May 2020 [N=564]

Demographics	COVID-19 patients undergoing tracheostomy
Age (years) [N=563]	
Mean (SD)	57 (11)
Sex n (%) [N=563]	
Male	405 (72)
Female	158 (28)
Body mass index, [N=426]	
18.5-<25	91 (22)
25-<30	150 (35)
30-<40	151 (35)
>40	34 (8)
Medical History	
Time from admission to hospital to intubation n (%), [N=521]	
on the day of admission	171 (33)
1-2 days after admission	141 (27)
3-5 days after admission	109 (21)
> 5 days after admission	100 (19)
Use of NIV* between admission to hospital and intubation (%) [N=505]	202 (40)
Key comorbidities n (%) [N=520]	
None	146 (28)
Asthma	80 (15)
Cancer	17 (3)
Diabetes	179 (34)
Hypertension	236 (45)

*NIV = non invasive ventilation

Table 1: Demographics and disease specific characteristics of COVID-19 patients undergoing tracheostomy.

a.



b.

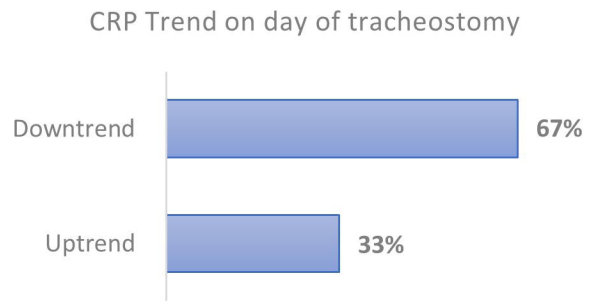
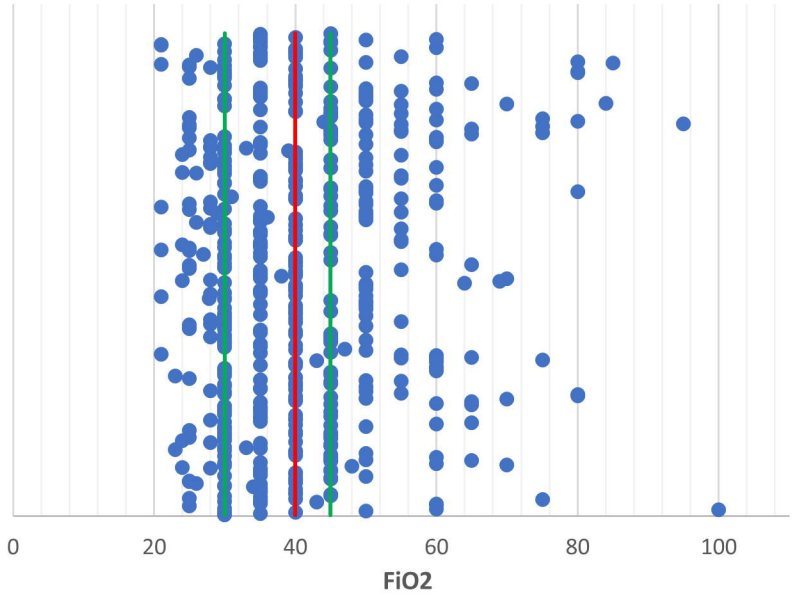


Figure 2 (a) The number of days of invasive mechanical ventilation prior to the day of tracheostomy. Each dot represents one case. The red line indicates the median and the green lines the first and third quartile [N=543] **(b)** The trend of C Reactive Protein on the day of tracheostomy [N=547]



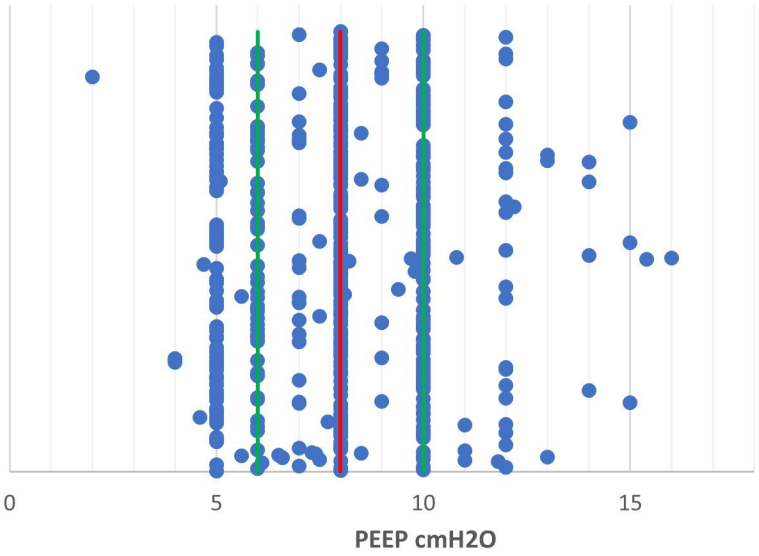


Figure 3. Oxygen requirements (Fi02%, N=544) and Positive End Expiratory Pressure (PEEP cmH20, N=539) on the day of tracheostomy. Each dot represents an individual case. The red lines represent the median value and the green lines the 1st and 3rd quartile.

COVID-19 PCR Test in patients undergoing tracheostomy	
Test positive during admission to hospital (%) N=558	
Postive	521 (93)
Negative	37 (7)
Total number of tests during admission to hospital, N=481	
Median (IQR)	1 (1, 2)
Outcome of last test before tracheostomy (%), N=503	
Positive	433 (86)
Negative	70 (14)
Outcome of second to last test before tracheostomy (%), N=301	
Positive	222 (74)
Negative	79 (26)
Number of days from last test to tracheostomy, N=499	
Median (IQR)	14 (7, 19)

Table 2. COVID-19 PCR test of patient prior to tracheostomy with number of swabs performed and outcome of swabs prior to tracheostomy.

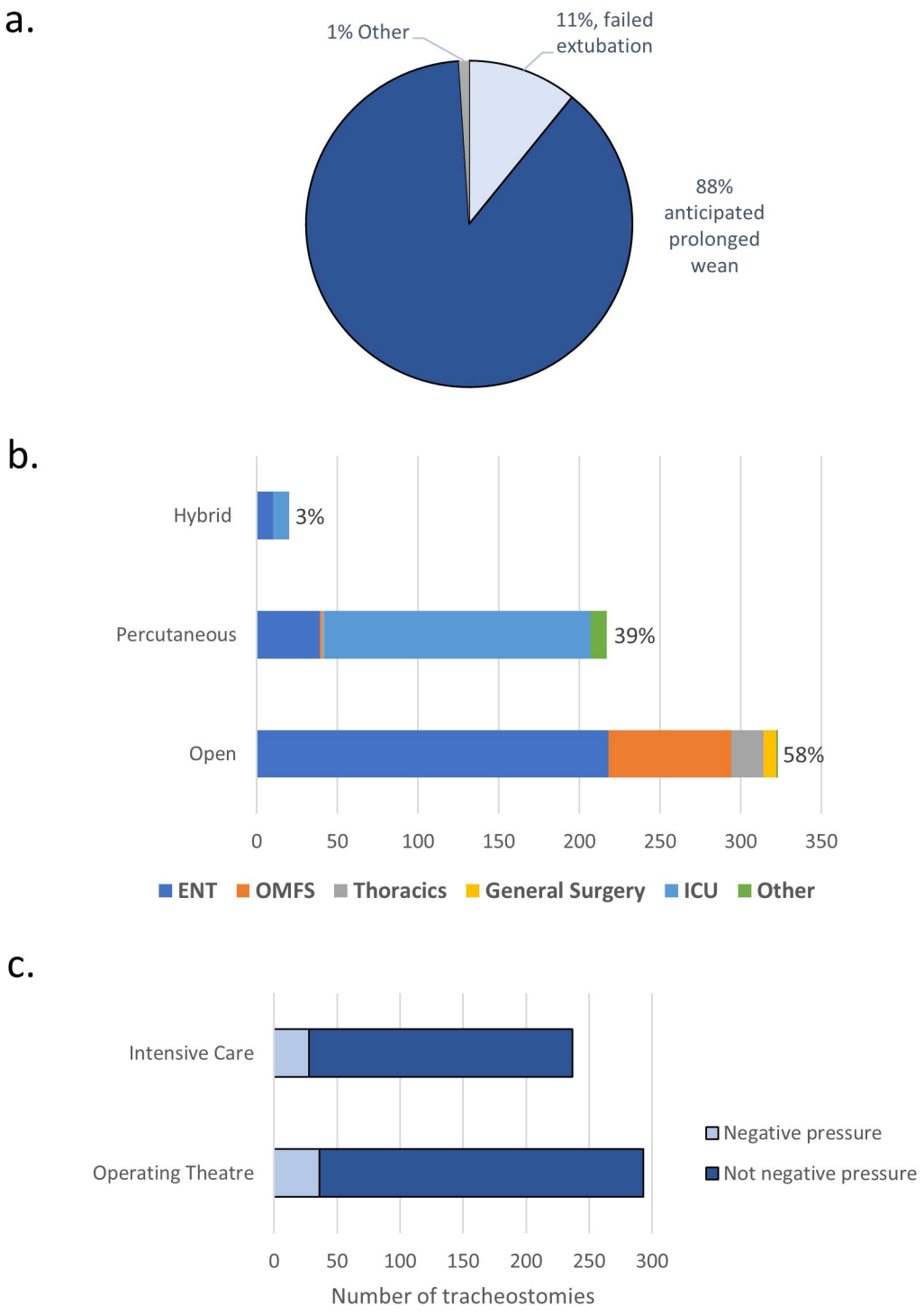


Figure 4 (a) Indication for tracheostomy in COVID-19 patients [N=551] **(b)** Method of tracheostomy and specialty of lead operator. Open refers to surgical tracheostomy, hybrid refers to a tracheostomy that uses a combination or surgical and percutaneous techniques [N=560] **(c)** Location of tracheostomy and use of negative pressure environment [N=530]

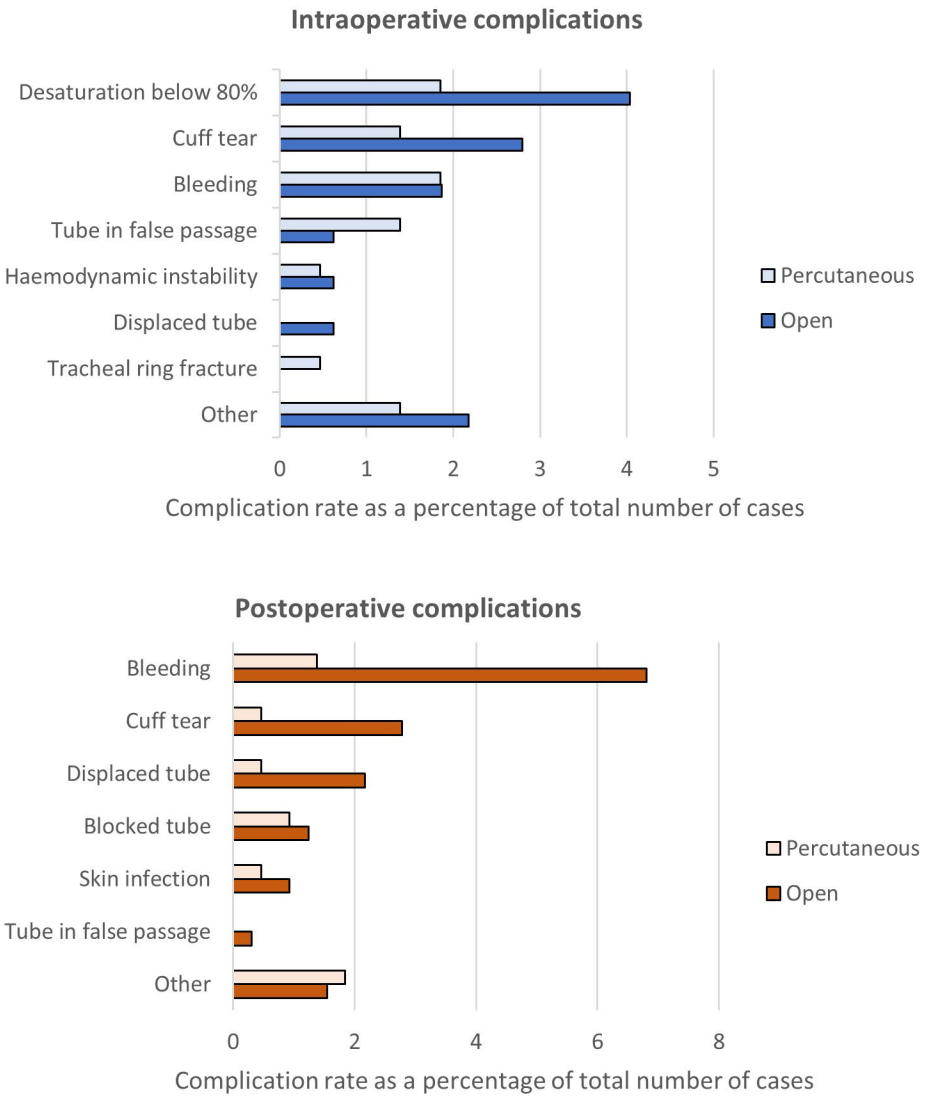
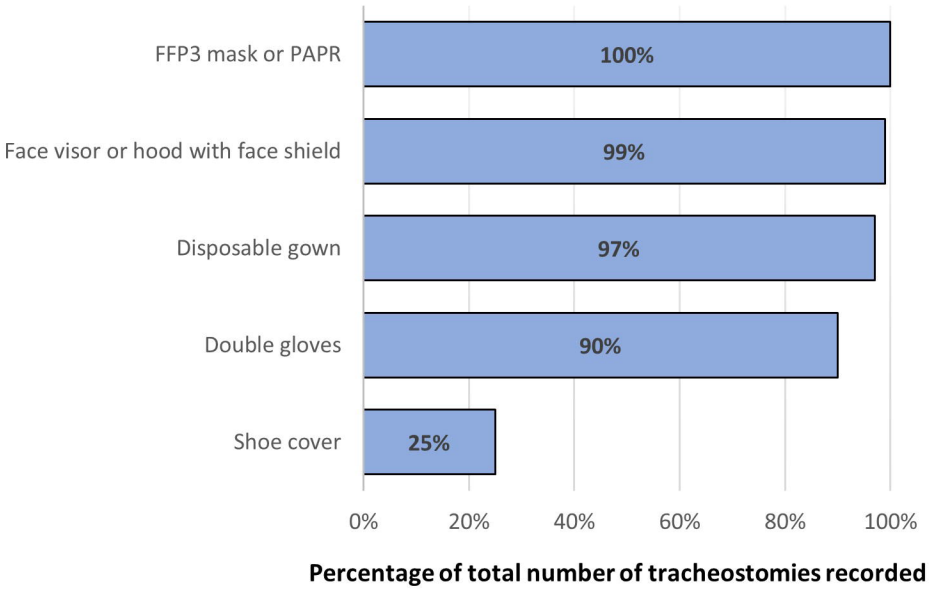


Figure 5. Intraoperative complications [N=558] and postoperative complications [N=520] divided by open surgical and percutaneous methods of tracheostomy in COVID-19 patients.

Outcomes following tracheostomy in COVID-19 patients	
All cause mortality following tracheostomy in COVID-19 patients n (%) [N=530]	
Died following tracheostomy	62 (12)
Still alive at the point of survey	468 (88)
Cause of death following tracheostomy n (%) [N=62]	
COVID-19 related	60 (97)
Tracheostomy related	2 (3)
Duration (days) from tracheostomy to death [N=62]	
Median (IQR)	8 (5, 12)
Weaning from mechanical ventilation n (%) [N=465]	
Successfully weaned from mechanical ventilation	244 (52)
Still ventilated at the time of completing the survery	221 (48)
Time (days) from tracheostomy to successful wean [N=217]	
1-3 days	28 (13)
4-6 days	50 (23)
7-9 days	48 (22)
10-12 days	40 (18)
13-15 days	26 (12)
>15 days	25 (12)
Discharge from ICU n (%), [N=450]	
Discharged from ICU at the point of survey	169 (38)
Still in ICU at the point of survey	281 (62)

Table 3. Outcomes following tracheostomy in COVID-19 patients

a.



b.

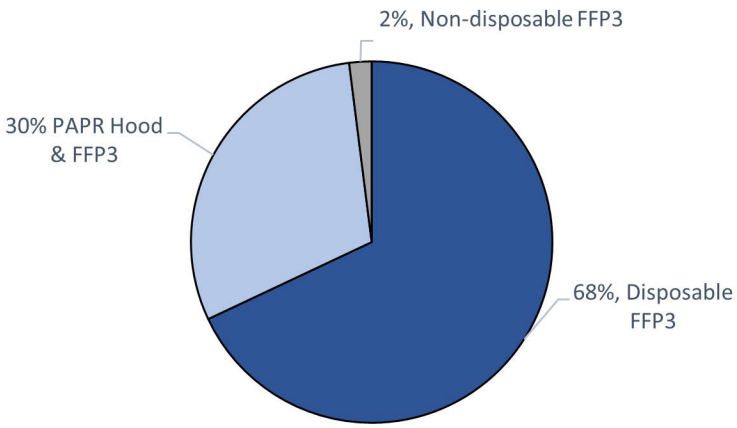


Figure 6 (a) The percentage of personal protective equipment (PPE) used as a percentage of the total number of tracheostomies recorded [N=545] **(b)** The type of face mask used during the tracheostomy [N=545]

Variable	N missing (%)
Demographic	
Age	1 (0.2)
Gender	1 (0.2)
BMI	138 (24)
Medical History	
Admission to intubation (days)	43 (7.6)
Use of NIV	59 (10)
Co-morbidities	44 (7.8)
Intubation to tracheostomy (days)	21 (3.7)
CRP before tracheostomy	17 (3)
Temperature before tracheostomy	75 (13.2)
Fi02	20 (3.5)
PEEP	25 (4.4)
COVID status	
Test positivity	6 (1)
Number of tests	40 (7.7)
Outcome of last test	18 (3.5)
Time from test to tracheostomy (days)	22 (4.2)
Tracheostomy details	
Indication for tracheostomy	13 (2.3)
Method of tracheostomy	4 (0.7)
Location of tracheostomy	34 (6)
Outcomes	
Intraoperative complications	6 (1)
Postoperative complications	44 (7.8)
Mortality	34 (6)
Cause of detah	0
Time to death (days)	0
Wean from ventilator	37 (7.4)
Time from tracheostomy to wean	27 (11)
Discharge from ICU	52 (10.4)
Use of PPE	19 (3.4)

Appendix 1. Summary of data completeness for each key variable