

Elective tracheostomy during COVID-19 outbreak: to whom, when, how? Early experience from Venice, Italy

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Abstract

Purpose

The need for prolonged invasive mechanical ventilation in COVID-19 patients is placing the Otorhinolaryngologist in front of an increasing request for tracheostomy. Nowadays, there is uncertainty regarding the timing of tracheostomy, the prognosis of these patients and safety of healthcare workers. The aim of this study is to evaluate the efficacy and safety of tracheostomy placement in patients with COVID-19.

Methods

It was conducted a retrospective cohort study on 23 COVID 19 patients, in order to analyse the timing of tracheostomy, the risk factors associated with in-hospital death and the infection of the involved health care workers. Early tracheostomy was defined as ≤ 10 days and late ones > 10 days.

Results

The mortality rate of COVID-19 patients admitted to ICU that underwent tracheostomy was 18%. The overall mortality of patients admitted to ICU was 53%. The univariate analysis revealed that early tracheostomy, SOFA score > 6 , D-Dimer level > 4 were significantly associated with a greater risk of death. At the multivariate analysis SOFA score > 6 and D-Dimer level > 4 resulted as significant factors for a higher risk of death. No health care workers associated with tracheostomy are confirmed to be infected by SARS-CoV2.

Conclusion

We suggest to wait at least 14 days to perform tracheostomy. In patients with SOFA score > 6 , and D dimer > 4 tracheostomy should not be performed or should be postponed. Optimized procedures and enhanced personal protective equipment can make the tracheostomy safe and beneficial in COVID-19 patients.

Introduction

Up to May 18, 2020, a total of 224,760 had tested positive for COVID-19 in Italy and 317,763 of them died. The metropolitan city of Venice, with an average population of 259,414 inhabitants had 2,617 confirmed cases with 256 deaths. In Venice, the incidence of SARS-COVID 2 was 1/110 inhabitants with a mortality rate of 9,8%^[i]. As a Hub Hospital, our institution was one of the first in Veneto and in Italy to treat confirmed COVID-19, as this local area was recognized as one of the most critical areas of North-Eastern Italy^[ii] ^[iii].

The critical cases have been defined by the occurrence of respiratory failure requiring mechanical ventilation and treatment in the ICU^[iv]. Recent data from Europe suggests that in the most critically ill

patients the duration of invasive ventilation could go up to 21 days[v].

The prognosis of this novel disease is not yet fully understood and mortality rates for those requiring critical care varies a lot among different countries: 26% in Lombardy[vi], 49% in Wuhan[vii], 39% USA[viii] , 51,6% UK[ix].

The guidelines of performing a tracheostomy asserted that it is a standard of care due to its potentiality of reducing the duration of mechanical ventilation and length of stay on intensive care, but its utility in the recovery of patients with Covid-19 is unknown⁹.

From the data found in literature, the need to tracheostomies for ICU patients ranges normally from 2 to 11%[x] [xi].

At the beginning of March 2020 the Italian Society of Otorhinolaryngology[xii] [xiii], the British Association of Otorhinolaryngology[xiv], the American Academy of Otolaryngology-Head and Neck Surgery[xv] warned the otolaryngologists on a possible increase in the request for tracheostomies related to the COVID 19 infection.

During the COVID emergency, 23 of the 50 patients, (46%), hospitalized in intensive care for COVID-19 in our hospital, underwent a temporary tracheostomy. Looking at the request for tracheostomy in the same period in 2019 and 2018, there was an increase in the execution of tracheostomies respectively of 69,5% and 56,5%.

As an aerosol generating procedure, tracheostomy increases healthcare worker exposure to COVID-19 infection, but the duration of viral load and correlation with transmission rate is not yet precisely known⁷.

Given these challenging issues we have retrospectively analyzed our data to try to give an answer to three main problems related to tracheostomy in the COVID-19 patients:

- for which patients is tracheostomy indicated?
- what is the best timing for tracheostomy?
- which is the correlation between viral load and staff security?

We hypothesized that patients with poorer prognosis have a higher SOFA score and higher D-dimer level.

The aim of this study was to evaluate the timing, appropriateness and staff security of tracheostomy in patients receiving PMV in our medical-surgical ICU for SARS- COVID19.

Methods

This is a retrospective cohort study, which was conducted at Angel Hospital and Saints Giovanni e Paolo Hospital (Venice, Italy) from 22th February 2020 to 26th April 2020.

The inclusion criteria for participants were: a) positive to covid-19; b) tracheostomy

It has been selected the following variables

- Age
- Gender
- Comorbidities (Diabetes, Hypertension...)
- Date of intubation
- Date of Tracheostomy
- Type of Tracheostomy (Surgical vs percutaneous)
- Mortality
- Sedation
- Date to Sub-intensive Unit
- Date of weaning from VAM
- Date of decannulation
- SOFA (Sequential Organ Failure Assessment)-score at the day of intubation and of the day before tracheostomy calculated using <https://www.mdcalc.com/> (see Figure 1[i]).
- D-dimer level

To explore the risk factors associated with in-hospital death, univariate and multivariate analyses were performed. Variables were chosen on the basis of previous findings and clinical constraints.

Previous studies have shown blood levels of d-dimer and Sequential Organ Failure Assessment (SOFA) scores to be higher in critically ill or fatal cases[ii] [iii].

Similar risk factors, including older age, have been reported associated with adverse clinical outcomes in adults with SARS and Middle East respiratory syndrome (MERS)[iv]. Other studies underlined the negative effect of hypertension, cardiovascular disease and diabetes on survival[v].

Therefore, hypertension and cardiovascular disease, diabetes, pulmonary disease, simultaneous presence of two and/or three diseases, d-dimer, SOFA score at intubation and at tracheostomy and age were selected for our logistic regression model.

A statistical investigation was conducted to determine whether the timing of tracheostomy procedure was a prognostic factor for the survival status of the patients. Hence, tracheostomy was defined as early if performed within 10 days after intubation, as late otherwise. The average intubation time in this study was 13.7 days; thus, a 10-day threshold allowed to investigate the effect of an earlier-than-average tracheostomy. Moreover, previous studies have considered as early those procedures performed between 7 and 14 days from intubation [vi] [vii]. At the moment there are no single criteria on the timing to perform the tracheostomy. In this study patients were evaluated daily; the procedure was performed when the anesthesiologists verified that they could not be weaned from mechanical ventilation and the clinical conditions were stable, albeit the severity. Given the greater propensity in our hospital to perform surgical tracheostomies by otolaryngologists, this was the most used technique.

Open surgical tracheostomy procedures:

We performed the first tracheostomy on the 10th March 2020 when no ENT guidelines on safe tracheostomy were already been published[viii].

The inclusion criteria in patients undergoing open surgical tracheostomy were: patients have tested positive for COVID-19 with nasal pharyngeal swab for rtPCR assay testing and need for prolonged mechanical ventilation (for five or more days). The exclusion criteria, on the other hand, included patients with grave hypoxemia, severe incorrect coagulopathy or with multi-organ failure.

For each patient we carried out a multidisciplinary discussion between the primary team, the team of procedures and the family to establish the objectives of the assistance, the general prognosis and the expected benefits of the tracheotomy.

For protective apparel we adopted as a reference handbook of COVID-19[ix], where level III protection consisting in mask FFP3 (Europe) or N95 , surgical cap, goggles and face shield (can be worn on top of goggles), surgical gown (use of double gown is preferable, where available), and gloves (use of double nitrile gloves) was suggested. Cap and shoe covers were considered necessary for safely dressing.

Even Personal Protective Equipment (PPE) doffing was a crucial moment which was carried out in dedicated room. It is important to note that the wear and removal of PPE was sequential processes requiring proper training.

For the surgical tracheostomy placements, we followed the procedure contained in the “Safe tracheostomy for patients with severe acute respiratory syndrome” [x]summarized in the Figure 2.

We performed all tracheostomies in the ICU in negative-pressure rooms to avoid unnecessary transport of patients and repeated connection and disconnection of ventilatory circuits during transfer. Staff includes two surgeons, one intensive care specialist, one nurse of intensive care and two scrub nurses. One of the scrub nurse did not enter in the room and supported the personnel in the wearing and removal of PPE and in preparing surgical instruments. Due to the respiratory issues, it was selected cannula with large inner

diameter (Shiley 8 or 10). Cannula change was planned 7-10 days later using the same precautions (PPE utilization and airflow interruption). Afterwards cannula change can be delayed 30 day after.

STATISTICAL METHODS

At univariate level, Fisher test was conducted to analyze the association between the response variable and all the categorical variables. Then, a multivariate logistic regression was performed to investigate the effect of the variables on survival. A significance level of 10% was selected. Statistical analyses were performed using Software "R".

Results

Totally, 50 patients were admitted in ICU and ventilated with IVM with a diagnosis of COVID-19. The study cohort comprises 23 patients (21 Men and 2 Women with a median age of 69 years) who underwent a tracheostomy. Population characteristics are summarized in Table I and II.

Twenty-two surgical tracheostomies and one percutaneous tracheostomy were performed.

The average time between the intubation date and the tracheostomy date was 13 days. The mean time that the patients were mechanically ventilated was 29 days. Mean time in ICU was 27 days.. Patients with a longer hospital stay in intensive care were suffering from pre-existing pathologies and in this case tracheostomy was necessary in prevision of a more difficult weaning by mechanical ventilation.

Nine tracheostomies were performed early, while 14 tracheostomies were performed late. After a median follow-up of 50 days (IQR, 30.0-71.0 days), 9 patients (39%) died, 5 (22%) were receiving invasive mechanical ventilation in the ICU, 3 (13%) were discharged from the ICU and are in the pneumological sub-intensive unit, 6 (26%) were decannulated and discharged. One patient have had complications; he presented post tracheostomy bleeding, he was on therapeutic anticoagulation.

In addition it was carried out a preliminary analysis of mortality rate of the entire sample of patients with COVID-19 recovered at ICU. The overall mortality rate was 53%; the mortality rate of patients with no tracheostomy was 33%; the mortality rate of patients with tracheostomy was 18% : of these 6 (66,7%) tracheostomy were performed early and 3 (33,3%) late.

Among alive patients, mean time between tracheostomy and decannulation was 26,8 day (with a minimum of 17 and maximum of 36). Among dead patients mean time between intubation and death was 21 days and mean time between tracheostomy and death was 13,7 days. In our study an early tracheostomy was associated with a greater risk of death. To date none of our tracheostomy team has developed any symptoms of fever, general malaise, cough, shortness of breath and/or have tested positive for COVID-19 with nasal pharyngeal swab for rtPCR assay testing.

STATISTICAL ANALYSIS

The univariate analysis revealed that early tracheostomy, SOFA score at intubation higher than 6, D-Dimer level higher than 4 were significantly associated with a greater risk of death with a p-value respectively of 0,077, 0,077 and 0,023. At the multivariate analysis SOFA score at intubation higher than 6 and D-Dimer level higher than 4 were significantly associated with a greater risk of death with a p-value respectively of 0,059 and 0,028. The variables age, sex, presence and number of comorbidities, SOFA score at tracheostomy did not correlate with mortality rate. Results of statistical analysis are summarized in Table 3.

Case N	Gender	Age	No Days intubated (ETT)	SOFA SCORE intubation	SOFA SCORE tracheostomy	Weaned of sedation	Days of VAM	D	No Days to decannulation	D-Dimero	Alive	No Days from tracheostomy to deaths	Days in ICU	Outcome (Ward, ICU, discharge)
1	M	81	10	7	4	Yes	-	No	-	1.59	No	12	13	-
2	M	84	17	4	5	Yes	48	No	-	2.11	Yes	-	-	ICU
3	M	75	16	4	-	Yes	46	No	-	0.53	Yes	-	35	Ward
4	F	77	9	7	6	No	-	No	-	1.44	No	7	15	-
5	M	81	10	10	5	Yes	-	No	-	>10	No	18	27	-
6	M	77	9	7	3	Yes	32	Yes	36	0.73	Yes	-	18	Discharge
7	M	72	15	6	8	Yes	40	No	-	0.87	Yes	-	32	ICU
8	M	67	23	8	9	Yes	40	No	-	3.42	Yes	-	30	Ward
9	M	60	18	4	10	Yes	18	No	-	2.20	Yes	-	16	ICU
10	M	60	10	4	11	No	-	No	-	>10	No	15	24	-
11	M	61	15	3	4	Yes	38	No	-	1.61	Yes	-	27	Ward
12	M	48	26	8	8	No	46	No	-	6.67	No	18	44	-
13	M	49	13	4	3	Yes	31	No	-	4.83	Yes	-	22	Ward
14	M	76	15	4	7	Yes	28	Yes	21	3.66	Yes	-	20	Discharge
15	M	77	13	7	9	No	-	No	-	4.21	No	4	46	-
16	M	71	5	6	5	Yes	25	Yes	29	6.28	Yes	-	11	Ward
17	M	73	10	7	12	Yes	22	No	-	0.96	Yes	-	38	ICU
18	M	42	22	5	4	Yes	26	Yes	30	0.49	Yes	-	24	Discharge
19	M	68	14	3	8	No	25	Yes	17	0.46	Yes	-	38	Discharge
20	F	79	11	4	5	Yes	21	Yes	22	3.14	Yes	-	27	Ward
21	M	51	8	6	5	No	-	No	-	>10	No	14	-	-
22	M	79	7	10	3	No	-	No	-	>10	No	10	17	-
23	M	82	21	5	9	No	-	No	-	0.89	No	26	47	-

Table I: COVID 19 patients medical value and follow up
D decannulation , VAM ventilation assisted mechanical

Table II: patients characteristics and comorbidity

Patients characteristics	ICU care (n=23)
Age ,years	69 (42-84)
Sex : Men	21(91%)
Women	2 (8%)
Current smoking	4 (17%)
Diabets	7 (30%)
Hypertension	11 (47%)
Cardiovascular disease	4 (17%)
Chronic obstructive polmonary disease	8 (34%)
Malignancy	0
Obesity	3 (13%)
Chronic liver disease	0

Table III: Statistical univariate and multivariate analysis results

	Total (n=23)	Survivor (n=14) 60%	Non survivor (n=9) 40%	p value univariate analysis	p value multivariate analysis
Early tracheostomy	9 (39%)	3 (21%)	6 (66%)	0.077	-
SOFA score intubation > 6	9 (39%)	3 (21%)	6 (66%)	0.077	0.059
D-dimero >4	8 (35%)	2 (14%)	6 (66%)	0.023	0.028

Discussion

Tracheostomy in patients with COVID-19-associated respiratory failure is a challenge procedure due both to its severity, duration and risk of infections.

From data emerging in literature and based on clinical experience, patients with COVID-19 associated respiratory failure, required ventilatory support more than four weeks, which causes side-effects such as prolonged rehabilitation as well as severe critical illness and neuropathy ⁵.

Tracheostomy is a widely used intervention in patients with acute respiratory failure needing for prolonged IMV, but so far, no recommendation on COVID-19-affected patients exists[i].

At the moment there are at least three unsolved questions regarding the execution of tracheostomies in COVID-19 patients.

The first concerns the prognosis of patients admitted to intensive care for COVID-19. Severe and critical illness occurred in approximately 20% of the patients after admission to hospital⁵. In order to decide whether to tracheostomize patients, it would be important to define prognostic survival indicators.

In contrast with Grasselli et al⁶, in our preliminary study elder age and coexisting medical condition were not associated with greater risk of poor outcome. On the other side in accordance with Zhou our preliminary experience identified as risk factors for COVID-19 mortality the high SOFA score and increased D-dimer ⁹. Further studies are needed to better understand this association, but clinicians should be aware that for patients with SOFA score higher than 6, and D-Dimer level higher than 4 tracheostomy could be not indicated or at least should be postponed.

The second problem concerns the timing of the execution of this operation[ii] [iii]: “Can an early tracheostomy improve the survival of patients since it reduces the ventilatory dead space, decreases the probability of ventilator pneumonia, decreases the stay in the ICU, decreases the probability of developing septic shock and CID¹⁹?” In such a serious escalating pandemic, the aim in treating patients with COVID 19 disease is to maximize the likelihood of recovery as quickly as possible for the greatest number of patients.

In some hospitals, due to short supply of resources such as ventilators and sedatives, an early tracheostomy, within 7 days of intubation, was initially proposed to be performed to reduce the patient's need for sedation and to allow for an earlier transfer to the sub-intensive area. Others argued that reducing sedation and partially returning the patient to spontaneous breathing could cause negative effects on oxygenation and respiratory pattern²⁹. Furthermore, Chao et al. 2020 suggest to wait beyond 21 days for the viral load to decrease and to avoid unnecessary tracheostomies in particularly critically ill patients³⁰.

The American Academy of Otolaryngology-Head and Neck surgery suggests that tracheostomy should be performed after 14 days of endotracheal intubation, but there is no evidence as to the optimal timing of tracheostomy³¹.

Although outcome data on prone positioning in COVID-19 (used in 12% of patients in one ICU study from Wuhan) are currently lacking, the tendency for SARS-CoV-2 to affect the peripheral and dorsal areas of the lungs provides the ideal conditions for a positive oxygenation response to prone positioning³². Considering that some patients have to be prone in some cases for even 10 days and that tracheostomy within the first 24 hours is a relative contraindication to pronation it would be better to wait at least 10 days to perform tracheostomy³³.

The timing of tracheostomy is yet to be defined in such critically ill patients, but our results and recommendations worldwide would suggest performing a tracheostomy after at least 14 days of endotracheal intubation in patients who are unable to be weaned by ventilator but who have sufficient chances of survival.

Considering that in our study mean time from intubation to death was 21 days, for patients with higher SOFA score and higher d-dimer level, we suggest to wait until 21 days to decide for tracheostomy in order to avoid clinically vain procedures for patients and to rule out health care workers from worthless exposure risks.

The third problem concerns the viral load of COVID 19 and the infectious capacity of the virus.

In Italy at April 5th, 12,252 health workers have tested positive for COVID-19, resulting of 10% of Italy's COVID-19 cases; at the time we were writing, 165 medical doctors and 40 nurses have died^{34 35}. In China, more than 3,300 healthcare workers were infected (4% of the 81,285 reported infections). In Spain on the 25th March, nearly 6500 medical personnel were infected, 13.6% of the country's 47,600 total cases, 1% of the health system's workforce³⁶.

As an aerosol generating procedure, tracheostomy increases healthcare worker exposure to COVID-19 infection, but the duration of viral load and correlation with transmission rate is not yet precisely known³⁷.

Literature data show how the virus can remain in the body for up to two months⁷. However, in some cases it may not be clinically or practically feasible to wait for a negative result prior to undertaking tracheostomy.

Our preliminary experience and early experience from other Italian^{26 38} and Chinese³⁹ studies supports the safety of tracheostomy if appropriate protocols are strictly followed. After one month from the last tracheostomy we performed no one of our team developed symptoms of COVID-19. Specifically, recommendations contained in "Safe tracheostomy for patients with severe acute respiratory syndrome" revealed to be safe in our experience. The dress and undressing procedures and the use of specific DPI were of fundamental importance and limit the infections among clinicians; moreover, having a dedicated experienced team to fulfill tracheostomies will allow familiarity with the procedure, curtail the risk of contamination and decrease setup time.

This study has several limitations. First, our study might have selection bias because it was a single-center, retrospective study, with limited sample size, even if it had sufficient power to detect the significant differences between groups in mortality. Second, there is no assessment of the follow-up effect of the SARS-CoV-2 on discharged patients, although patients in this study were thought to have definite outcomes. Third, for the greater propensity in our hospital to perform surgical tracheostomies, it was not possible to carry out an analysis and comparison with percutaneous tracheostomies.

Finally due to the short follow-up we don't have data of beneficial effect of tracheostomy on long-term mortality and on the potential complications associated with tracheostomy; thus, further studies focusing on long-term outcomes are warranted.

The strength of our study is that is the first case series to report data on such a threatening issue and might help clinicians worldwide who will soon be dealing with the same challenges.

Declarations

COMPLIANCE WITH ETHICAL STANDARDS

Conflict of interest

The authors declare that they have no conflicts of interest.

Ethics approval

This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent

Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

References

1. Emergenza Coronavirus SARS-CoV-2 / COVID-19. <https://www.regione.veneto.it/web/sanita/nuovo-coronavirus>. [Google]
2. Giacomo Spinato, Cristoforo Fabbris, Jerry Polesel, Diego Cazzador, Daniele Borsetto, Claire Hopkins, Paolo Boscolo-Rizzo, Alterations in Smell or Taste in Mildly Symptomatic Outpatients With SARS-CoV-2 Infection. *JAMA*. 2020;323(20):2089–2090. doi:10.1001/jama.2020.6771
3. Paolo Boscolo-Rizzo, Daniele Borsetto, Giacomo Spinato, [Cristoforo Fabbris](#), [Anna Menegaldo](#), [Piergiorgio Gaudio](#), [Piero Nicolai](#), [Giancarlo Tirelli](#), [Maria Cristina Da Mosto](#), [Roberto Rigoli](#), [Jerry Polesel](#), and [Claire Hopkins](#) . New onset of loss of smell or taste in household contacts

- of home-isolated SARS-CoV-2-positive subjects. *Eur Arch Otorhinolaryngol.* 2020;1-4.
doi:10.1007/s00405-020-06066. Online ahead of print
4. Chaolin Huang*, Yeming Wang*, Xingwang Li*, Lili Ren*, Jianping Zhao*, Yi Hu*, Li Zhang, Guohui Fan, Jiuyang Xu, Xiaoying Gu, Zhenshun Cheng, Ting Yu, Jiaan Xia, Yuan Wei, Wenjuan Wu, Xuelei Xie, Wen Yin, Hui Li, Min Liu, Yan Xiao, Hong Gao, Li Guo, Jungang Xie, Guangfa Wang, Rongmeng Jiang, Zhancheng Gao, Qi Jin, Jianwei Wang†, Bin Cao† . Clinical features of patients infected with 2019 novel coronavirus in Wuhan. *China Lancet* 395(10223):497–506.
[https://doi.org/10.1016/S0140-6736\(20\)30183-5](https://doi.org/10.1016/S0140-6736(20)30183-5)
 5. Henrik Planck Pedersen, Thomas Hildebrandt, Anne Poulsen, Bülent Uslu, Halfdan Holger Knudsen, Jakob Roed, Troels Dirch Poulsen, Henning Bay Nielsen. Initial Experiences From Patients With COVID-19 on Ventilatory Support in Denmark. *Dan Med J.*2020 ;67(5):A04200232.
 6. Giacomo Grasselli, Alberto Zangrillo, Alberto Zanella, Massimo Antonelli, Luca Cabrini, Antonio Castelli, Danilo Cereda, Antonio Colucello, Giuseppe Foti, Roberto Fumagalli, Giorgio Iotti, Nicola Latronico, Luca Lorini, Stefano Merler, Giuseppe Natalini, Alessandra Piatti, Marco Vito Ranieri, Anna Mara Scandroglio, Enrico Storti, Maurizio Cecconi, Antonio Pesenti. Baseline Characteristics and Outcomes of 1591
 7. Patients Infected With SARS-CoV-2 Admitted to ICUs of the Lombardy Region, Italy. *JAMA.* 2020; 323(16):1574-1581. <https://doi.org/10.1001/jama.2020.5394>.
 8. Zunyou Wu , Jennifer M McGoogan. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. *JAMA.* 2020.
<https://doi.org/10.1001/jama.2020.2648>. Online ahead of print
 9. Matthew J Cummings, Matthew R Baldwin , Darryl Abrams, Samuel D Jacobson, Benjamin J Meyer , Elizabeth M Balough , Justin G Aaron , Jan Claassen , LeRoy E Rabbani , Jonathan Hastie , Beth R Hochman, John Salazar-Schicchi , Natalie H Yip , Daniel Brodie , Max R O'Donnell. Epidemiology, Clinical Course, and Outcomes of Critically Ill Adults With COVID-19 in New York City: A Prospective Cohort Study. *Lancet.* 2020; S0140-6736(20)31189-2. [https://doi.org/10.1016/S0140-6736\(20\)31189-2](https://doi.org/10.1016/S0140-6736(20)31189-2). Online ahead of print
 10. Arunjit Takhar , Abigail Walker , Stephen Tricklebank , Duncan Wyncoll , Nicholas Hart , Tony Jacob , Asit Arora , Christopher Skilbeck , Ricard Simo , Pavol Surda . Recommendation of a Practical Guideline for Safe Tracheostomy During the COVID-19 Pandemic. *Eur Arch Otorhinolaryngol.* 2020; 21;1-12. <https://doi.org/10.1007/s00405-020-05993-x>.
 11. Nora H Cheung, Lena M Napolitano. Tracheostomy: Epidemiology, Indications, Timing, Technique, and Outcomes. *Respir Care.* 2014; 59(6):895-915; discussion 916-9.
<https://doi.org/10.4187/respcare.02971>.
 12. Mohammad Waheed El-Anwar , Ahmad Abdel-Fattah Nofal , Mohammad A El Shawadfy , Ahmed Maaty , Alaa Omar Khazbak. Tracheostomy in the Intensive Care Unit: A University Hospital in a

- Developing Country Study. *Int Arch Otorhinolaryngol*. 2017;(1):33-37. <https://doi.org/10.1055/s-0036-1584227>.
13. La tracheostomia in pazienti affetti da COVID-19. <https://www.sioechcf.it/wp-content/uploads/2020/03/La-tracheostomia-in-pazienti-affetti-da-COVID-19.pdf>. [Google]
 14. Massimo Ralli, Antonio Greco, Marco De Vincentis. The Effects of the COVID-19/SARS-CoV-2 Pandemic Outbreak on Otolaryngology Activity in Italy *Ear Nose Throat J*. 2020. doi:10.1177/0145561320923893. Online ahead of print.
 15. Guidance for Surgical Tracheostomy and Tracheostomy Tube Change during the COVID-19 Pandemic. <https://www.entuk.org/tracheostomy-guidance-during-covid-19-pandemic>. [Google]
 16. Tracheotomy Recommendations During the COVID-19 Pandemic. <https://www.entnet.org/content/tracheotomy-recommendations-during-covid-19-pandemic>. [Google]
 17. Sequential Organ Failure Assessment (SOFA) Score. <https://www.mdcalc.com/sequential-organ-failure-assessment-sofa-score>. [Google]
 18. Litao Zhang , Xinsheng Yan , Qingkun Fan , Haiyan Liu , Xintian Liu , Zejin Liu , Zhenlu Zhang. D-dimer Levels on Admission to Predict In-Hospital Mortality in Patients With Covid-19. *J Thromb Haemost*.2020.<https://doi.org/10.1111/jth.14859>. Online ahead of print
 19. Qingchun Yao, Peng Wang, Xingguang Wang, Guoqiang Qie, Mei Meng, Xiwen Tong, Xue Bai, Min Ding, Weiming Liu, Keke Liu, Yufeng Chu. Retrospective Study of Risk Factors for Severe SARS-Cov-2 Infections in Hospitalized Adult Patients. *Pol Arch Intern Med*; 2020. <https://doi.org/10.20452/pamw.15312>. Online ahead of print
 20. Fei Zhou , Ting Yu , Ronghui Du , Guohui Fan , Ying Liu , Zhibo Liu , Jie Xiang , Yeming Wang , Bin Song , Xiaoying Gu , Lulu Guan , Yuan Wei , Hui Li , Xudong Wu , Jiuyang Xu, Shengjin Tu , Yi Zhang , Hua Chen , Bin Cao. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet*.2020; 395(10229):10541062. [https://doi.org/10.1016/S0140-6736\(20\)30566-3](https://doi.org/10.1016/S0140-6736(20)30566-3).
 21. Di Ren, Chao Ren, Ren-qi Yao, Yong-wen Feng and Yong-ming Yao. Clinical features and development of sepsis in patients infected with SARS-CoV-2: a retrospective analysis of 150 cases outside Wuhan, China. *Intensive Care Med*. 2020; 14. <https://doi.org/10.1007/s00134-020-06084-5>.
 22. Hiroto Dochi, Masanori Nojima, Michiya Matsumura, Ivor Cammack, Yasushi Furuta. Effect of early tracheostomy in mechanically ventilated patients. *Laryngoscope Invest Otolaryngol*. 2019;4(3):292-299. doi:10.1002/lio2.265.
 23. Ahmed Adly · Tamer Ali Youssef · Marwa M. El-Begermy · Hussein M. Younis. Timing of tracheostomy in patients with prolonged endotracheal intubation: a systematic review. *European Archives of Oto-Rhino-Laryngology* (2018) 275:679–690 <https://doi.org/10.1007/s00405-017-4838-7>.
 24. Pierre Haen, Jean-Baptiste Caruhel , Sophie Laversanne , Pierre-Yves Cordier. CORONA-steps for tracheotomy in COVID-19 patients: A staff-safe method for airway management. *Oral Oncol*.

- 2020;105:104729. <https://doi.org/10.1016>.
25. Editor-in-Chief, Prof & Yu, Ligen. (2020). Handbook of COVID-19 Prevention and Treatment.[Google Scholar]
 26. Wei William, Tuen HH, Ng RW, Lam LK. Safe tracheostomy for patients with severe acute respiratory syndrome. *Laryngoscope*.2003;113(10):1777-1779.<https://doi.org/10.1097/00005537-200310000-00022>.
 27. Francesco Mattioli, Matteo Fermi, Michael Ghirelli , Gabriele Molteni, Nicola Sgarbi, Elisabetta Bertellini, Massimo Girardis, Livio Presutti, Andrea Marudi. Tracheostomy in the COVID-19 pandemic. *Eur Arch Otorhinolaryngol*. 2020;13. <https://doi.org/10.1007/s00405-020-05982-0>.
 28. Marcus J Shultz, Rajyabardhan Pattnaik, Arjen M Dondorp. Walking the line between benefit and harm from tracheostomy in COVID-19. *Lancet Respir Med*. 2020;S2213-2600(20)30231-9. [https://doi.org/10.1016/S2213-2600\(20\)30231-9](https://doi.org/10.1016/S2213-2600(20)30231-9).
 29. Brendan A McGrath, Michael J Brenner, Stephen J Warrillow, Vinciya Pandian, Asit Arora, Tanis S Cameron, José Manuel Añon, Gonzalo Hernández Martínez, Robert D Truog, Susan D Block, Grace C Y Lui, Christine McDonald, Christopher H Rassekh, Joshua Atkins, Li Qiang, Sébastien Vergez, Pavel Dulguerov, Johannes Zenk, Massimo Antonelli, Paolo Pelosi, Brian K Walsh, Erin Ward, You Shang, Stefano Gasparini, Abele Donati, Mervyn Singer, Peter J M Openshaw, Neil Tolley, Howard Markel, David J Feller-Kopman. Tracheostomy in the COVID-19 era: global and multidisciplinary guidance. *Lancet Respir Med*. 2020;S2213-2600 (20)30230-7. [https://doi.org/10.1016/S2213-2600\(20\)30230-7](https://doi.org/10.1016/S2213-2600(20)30230-7).
 30. China With The World: COVID-19 Experts Dialogues - The 2nd Talk Transcript. <https://healthmanagement.org/c/icu/pressrelease/china-with-the-world-covid-19-experts-dialogues-the-2nd-talk-transcript>. [Google]
 31. Tiffany N. Chao, Benjamin M Braslow, Niels D. Martin, Ara A. Chalian, Joshua H. Atkins, Andrew R. Haas, Christopher H. Rassekh, Tracheotomy Task Force, a Working Group of the Airway Safety Committee of the University of Pennsylvania Health System. Tracheotomy in ventilated patients with COVID-19 Guidelines from the COVID-19. *Ann Surg*. 2020;10.1097/SLA.0000000000003956. <https://doi.org/10.1097/SLA.0000000000003956>.
 32. American Academy of Otolaryngology and Head and Neck Surgery (2020) AAO position statement: tracheotomy recommendations during the COVID-19 pandemic. <https://www.entnet.org/content/aaoposition-statement-tracheotomy-recommendations-during-covid-19-pandemic>. Accessed 2 April 2020. [Google Scholar]
 33. Jason Phua, Li Weng, Lowell Ling, Moritoki Egi, Chae-Man Lim, Jigeeshu Vasishtha Divatia, Babu Raja Shrestha, Yaseen M Arabi, Jensen Ng, Charles D Gomersall, Masaji Nishimura, Younsuck Koh, Bin Du, for the Asian Critical Care Clinical Trials Group. Intensive care management of coronavirus disease 2019 (COVID-19): challenges and recommendations. *Lancet Respir Med*.
 34. Vanessa Martins Oliveira , Daniele Martins Piekala, Gracieli Nadalon Deponti , Danusa Cassiana Rigo Batista, Sílvia Daniela Minossi , Marcele Chisté , Patrícia Maurello Neves Bairros , Wagner da Silva

- Naue, Dulce Inês Welter, Sílvia Regina Rios Vieira. Safe prone checklist: construction and implementation of a tool for performing the prone maneuver. *Rev Bras Ter Intensiva*. 2017;29(2):131-141. <https://doi.org/10.5935/0103-507X.20170023>.
35. Francesco Chirico, Gabriella Nucera, Nicola Magnavita .C OVID 19. Protecting Healthcare Workers is a priority. *Infect Control Hosp Epidemiol*. 2020. doi: 10.1017/ice.2020.148.
36. Elenco dei Medici caduti nel corso dell'epidemia di Covid-19. <https://portale.fnomceo.it/elenco-dei-medici-caduti-nel-corso-dellepidemia-di-covid-19/>[Google]
37. COVID-19 How many Healthcare workers are infected? <https://www.cebm.net/covid-19/covid-19-how-many-healthcare-workers-are-infected/> [Google]
38. Paul Mick , Russell Murphy. Aerosol-generating otolaryngology procedures and the need for enhanced PPE during the COVID-19 pandemic: a literature review. *J Otolaryngol Head Neck Surg*. 2020;49(1):29. <https://doi.org/10.1186/s40463-020-00424-7>. Medrxiv. <https://doi.org/10.1101/2020.04.07.20055723>.
39. Mario Turri-Zanoni , Paolo Battaglia , Camilla Czaczkes, Paolo Pelosi , Paolo Castelnuovo , Luca Cabrini. Elective Tracheostomy During Mechanical Ventilation in Patients Affected by COVID-19: Preliminary Case Series From Lombardy, Italy. *Otolaryngol Head Neck Surg*. 2020;194599820928963. <https://doi.org/10.1177/0194599820928963>.
40. Xiaomeng Zhang , Qiling Huang , Xun Niu , Tao Zhou , Zhen Xie , Yi Zhong , Hongjun Xiao. Safe and Effective Management of Tracheostomy in COVID-19 Patients. *Head Neck*. 2020 May 19. <https://doi.org/10.1002/hed.26261>.

Figures

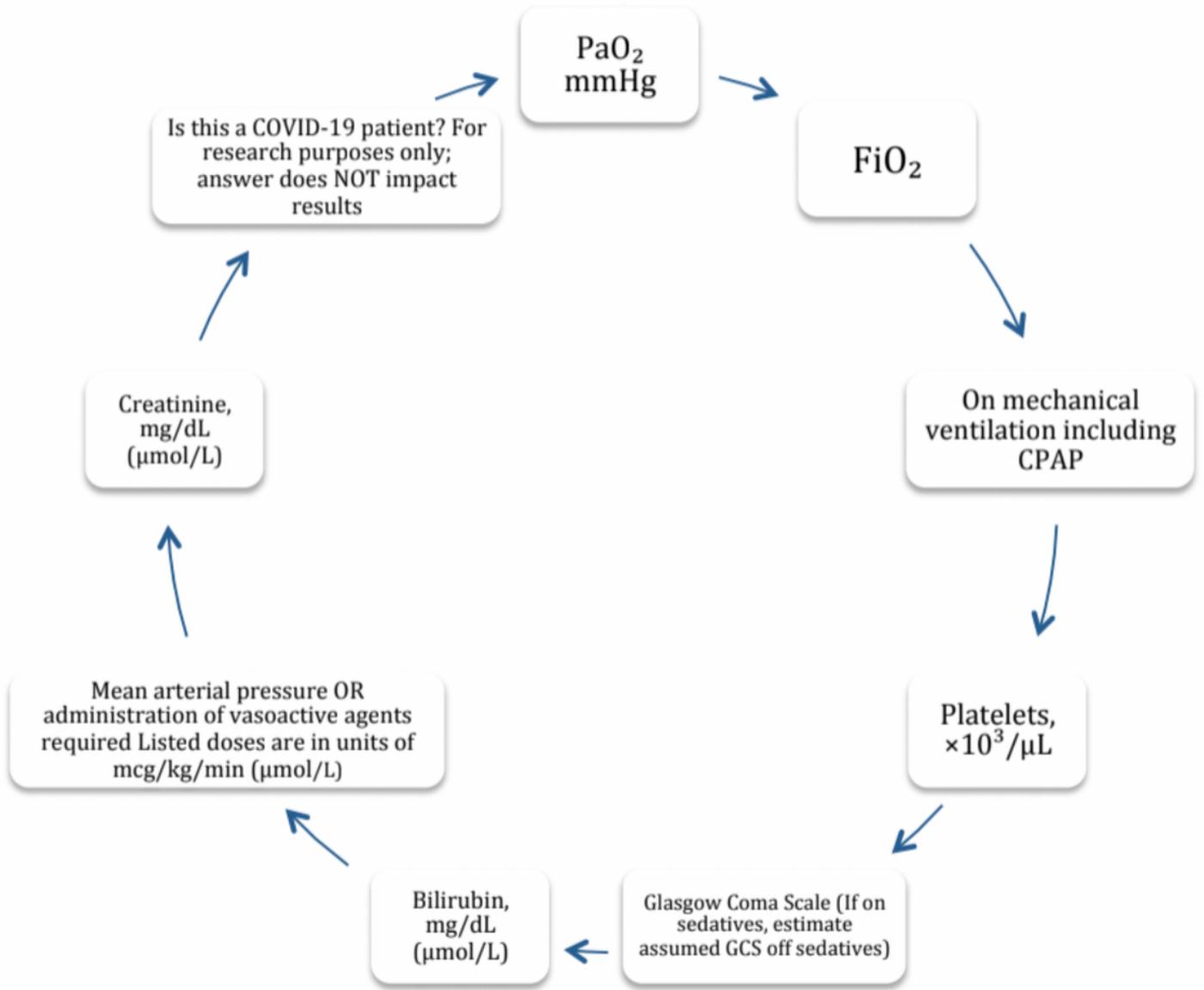


Figure 1

Sequential Organ Failure Assessment (SOFA) Score

OPEN SURGICAL TRACHEOTOMY

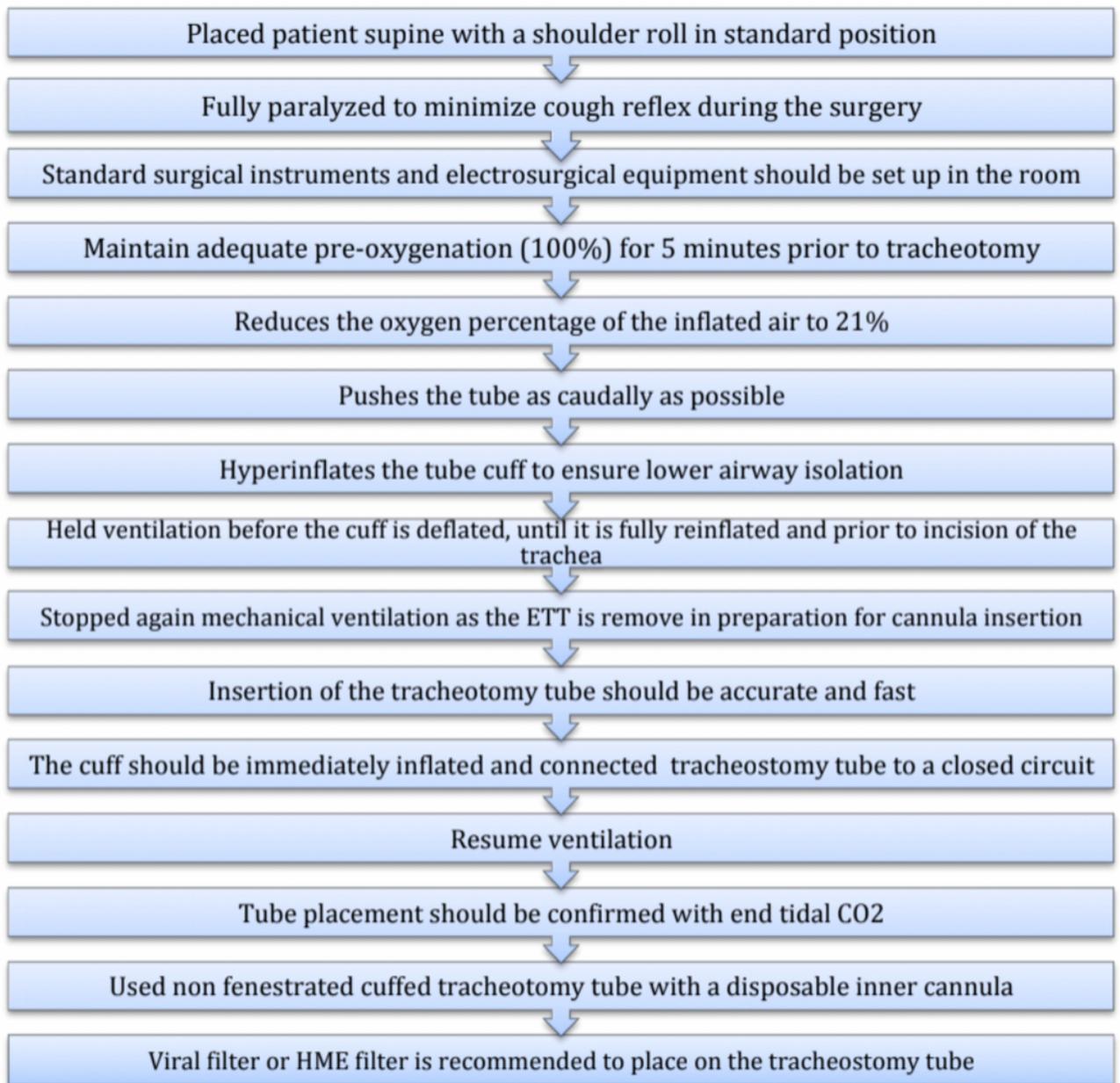


Figure 2

Procedure of open surgical tracheotomy.