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Management of tracheostomy in COVID-19 patients: The Japanese experience

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ABSTRACT

Objective: Involvement in the tracheostomy procedure for COVID-19 patients can lead to a feeling of fear in medical staff. To address concerns over infection, we gathered and analyzed experiences with tracheostomy in the COVID-19 patient population from all over Japan.

Methods: The data for health-care workers involved in tracheostomies for COVID-19-infected patients were gathered from academic medical centers or their affiliated hospitals from all over Japan.

Results: Tracheostomies have been performed in 35 COVID-19 patients with a total of 91 surgeons, 49 anesthesiologists, and 49 surgical staff members involved. Twenty-eight (80%) patients

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underwent surgery more than 22 days after the development of COVID-19-related symptoms (11: 22–28 days and 17: ≥29 days). Thirty (85.7%) patients underwent surgery ≥ 15 days after intubation (14: 15–21 days, 6: 22–28 days, and 10: ≥29 days). Among the total of 189 health-care workers involved in the tracheostomy procedures, 25 used a powered air-purifying respirator (PAPR) and 164 used a N95 mask and eye protection. As a result, no transmission to staff occurred during the 2 weeks of follow-up after surgery.

Conclusion: No one involved in tracheostomy procedures were found to have been infected with COVID-19 in this Japanese study. The reason is thought to be that the timing of the surgery was quite late after the infections, and the surgery was performed using appropriate PPE and surgical procedure. The indications for and timing of tracheostomy for severe COVID-19 patients should be decided through multidisciplinary discussion.

1. Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread worldwide, infecting over 67 million people since December 2019. As of December 8, 2020, coronavirus disease 2019 (COVID-19), the disease caused by SARS-CoV-2, had resulted in more than 1.5 million deaths worldwide [1,2]. In Japan, it was reported that 165,639 people had been infected and 2,310 had died due to COVID-19 [2]. Many infected people are asymptomatic or experience only mild symptoms, and recover without medical intervention. However, some infected people are critically ill and require mechanical ventilation.

Tracheostomy is a common procedure in critically ill patients who require an extended period of time on mechanical ventilation. In addition, tracheostomy might help in weaning patients from ventilation and increasing the availability of intensive care unit (ICU) beds. However, health-care workers are at risk of infection during the procedure as tracheostomy is an aerosol-generating procedure. Moreover, health-care workers' infection with SARS-COV-2 could lead to the collapse of the medical care system. Therefore, being involved in the tracheostomy procedure caused some anxiety among medical staff. To address concerns over infection, it is necessary to clarify whether tracheostomy resulted in infections among health-care workers as well as the appropriate timing of surgery, and the equipment that should be worn. Here, we gathered and analyzed experiences with tracheostomy in the COVID-19 patient population from all over Japan.

2. Materials and methods

The data for health-care workers involved in tracheostomies for COVID-19-infected patients were gathered from academic medical centers or their affiliated hospitals through the academic committee of the Oto-Rhino-Laryngological Society of Japan. It included when the tracheostomy was performed, time to tracheostomy after the development of COVID-19-related symptoms and after intubation, tracheostomy-related matters (anesthesia, room, technique: percutaneous/surgical), the number of personnel (surgeons, anesthesiologists, and medical stuff), their personal protective equipment (PPE), and transmission to staff (infect COVD-19 or not within 2 weeks after surgery).

This study was approved by the Institutional Review Board at Hokkaido University Hospital (No.020-0119) and the study was performed in accordance with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

3. Results

Tracheostomy procedures have been performed in 35 COVID-19 patients in 17 hospitals [Table 1]. Twenty-five of the 35 patients (71.4%) underwent surgery before June, 2020.

Table 1. Clinical characteristics of COVID-19 patients with tracheostomy.

Period of tracheostomy	
prior to the end of March, 2020	2
April to June, 2020	23
July to September, 2020	9
October to December, 2020	1
January to March, 2021	
Time to tracheostomy after the development of COVID-19-related symptoms	
0 to 7 days	1
8 to 14 days	2
15 to 21 days	4
22 to 28 days	11
after 29 days	17
Time of intubation before tracheostomy	
0 to 7 days	1
8 to 14 days	4
15 to 21 days	14
22 to 28 days	6
after 29 days	10
Method of confirmation of COVID-19 infection	
PCR with/without CT scan	33
CT scan (without PCR, with clinical course and symptoms)	0
LAMP with/without CT scan	2
The patient was placed on	
a ventilator	28
ECMO and the ventilator	6
Other	1

PCR, polymerase chain reaction; LAMP, Loop-mediated Isothermal Amplification method

Table 2. Tracheostomy procedural and technical factors.

Anesthesia	
general	34
local	1
Tracheostomy was performed in	
negative pressure room	16
operating room (non-negative pressure)	1
ICU/ward	18
Surgical technique	
open tracheostomy	35
percutaneous tracheostomy	0
Number of personnel	
surgeons	91
anesthesiologists	49
surgical staff members	49
PPE used	
PAPR	25
N95+eye protection	164

ICU, intensive care unit; PPE, personal protective equipment; PAPR, powered air-purifying respirator

Twenty-eight (80%) underwent surgery more than 22 days after the development of COVID-19-related symptoms (1: ≤7 days, 2: 8–14 days, 4: 15–21 days, 11: 22-28 days, and 17: ≥29 days). Thirty patients (85.7%) underwent surgery ≥ 15 days after intubation (1: ≤7 days, 4: 8–14 days, 14: 15–21 days, 6: 22–28 days, and 10: ≥29 days). COVID-19 was diagnosed by PCR with/without CT examination in 33 patients (94.3%), and the remaining 2 were diagnosed on the basis of Loop-mediated Isothermal Amplification method (LAMP). Twenty-eight patients (80%) were placed on a ventilator, 6 on extracorporeal membrane oxygenation (ECMO), and the remaining one patient received conventional oxygen therapy (COT) at the time of tracheostomy. The COT patient underwent surgery under local anesthesia and the others under general anesthesia [Table 2]. Surgery was performed in 16 patients (45.7%) in a negative pressure room. All procedures were performed by open tracheostomy, with none performed by percutaneous tracheostomy in this study.

The 35 tracheostomies involved a total of 91 surgeons (median: 3 person per a procedure, range: 2–4), 49 anesthesiologists (median: 1 person per a procedure, range: 0–3), and 49 surgical staff members (median: 1 person per a procedure, range: 0–5). Among the total 189 health-care workers, powered air-purifying respirator (PAPR) was used by 25 and N95 mask and eye-protection by 164. As a result, no transmission to staff occurred during the 2-week follow-up after surgery.

4. Discussion

This retrospective study showed that no transmission to health-care workers occurred after surgery. However, this does not mean that we do not have to fear infection during tracheostomy. Aerosol generating procedures may expose health-care workers to pathogens causing acute respiratory infections [3]. Inadequate spacing and the ineffectiveness of personal protective equipment may also contribute to nosocomial transmission [4]. Additionally, performing tracheostomy is reported as a risk factor for severe acute respiratory syndrome (SARS) among health-care workers in one case-control study [5]. Here, we would like to mention several points regarding tracheostomy for COVID-19 patients.

Tracheostomy is generally recommended for stable patients who have had prolonged intubation with an endotracheal tube. Prolonged intubation can be associated with laryngotracheal stenosis, ventilator-associated pneumonia, and longer length of stay. A tracheostomy reduces dead space and work of breathing, improves secretion clearance, and typically allows the patient to require less sedation, which may subsequently hasten ventilator weaning [6]. However, initially, it was thought that tracheostomy in patients with COVID-19 might not always be beneficial as it does not always lead directly to recovery from COVID-19 and/or survival benefits. In addition, the procedure and subsequent care might put health-care workers at increased risk of SARS-COV-2 infection. Therefore, a multidisciplinary team has to consider the appropriateness of embarking on tracheostomy [7–9]. Queen Elizabeth Hospital Birmingham COVID-19 airway team reported a total of 164 patients with COVID-19 admitted to the ICU between March 9, 2020 and April 21, 2020 [10]. Despite similar Acute Physiology and Chronic Health Evaluation (APACHE)-II scores, the 30-day survival was higher in 85/100 (85%) patients after tracheostomy, compared with 27/64 (42%) non-tracheostomised patients {relative risk: 3.9 (95% confidence intervals [CI]: 2.3–6.4); $P < 0.0001$}.In patients with APACHE-II scores ≥17, 68/100 (68%) tracheotomised patients survived, compared with 12/64 (19%) non-tracheotomised patients ($P < 0.001$). Tracheostomy within 14 days of intubation was associated with a shorter duration of ventilation (mean difference: 6.0 days [95% CI: 3.1–9.0]; $P < 0.0001$) and ICU stay (mean difference: 6.7 days [95% CI: 3.7–9.6]; $P < 0.0001$).They concluded that independent of the severity of critical illness from COVID-19, the 30-day survival was higher and ICU stays shorter in patients receiving tracheostomy. Chao et al. reported that there was a weak positive correlation between pre-tracheostomy intubation time and post-tracheostomy ventilator dependence among COVID-19 intubated patients [7]. Patients who underwent earlier tracheostomy tended to achieve earlier ventilator liberation compared to patients who underwent later tracheostomy. They added that though there may be confounding factors including a selection bias of healthier patients for earlier tracheostomy and the delay of tracheostomy in patients with questionable prognoses, these results offer preliminary support for earlier tracheostomy.

Regarding PPE, all health-care workers involved in the tracheostomy procedure wore full PPE in this study. During the COVID-19 pandemic, we might have to take into account health-care resources as well. Although they were limited during the first half of 2020 in Japan, PPE for health-care workers involved in surgery was considered to be adequate. All members used a N95 mask and eye-protection or PAPR. Further, 60% of the surgeries were performed in a negative pressure room, which might have helped to avoid transmission. According to the Indian experience, the use of PPE was independently associated with the reduction in the odds of becoming infected with SARS-CoV-2 among health-care workers according to multivariate analyses [11]. Therefore, full

PPE played an important role in the prevention of infection in this study. PAPR was used by 25 of the 189 staff involved in the procedures. Due to the closed system and the sound of motor in PAPR, it is hard to converse during the procedure. This might prevent the surgery from progressing smoothly. The clinical value of PAPR is controversial, so we cannot strongly recommend the use of PAPR at present.

All tracheostomies were performed with open approach in this study. In most hospitals in Japan, percutaneous tracheostomies are done by ICU staff and open tracheostomies by otolaryngologists. There was no percutaneous tracheostomy in this study as the data were gathered through the academic committee of the Oto-Rhino-Laryngological Society of Japan.

The timing of the procedure is important to whether transmission to health-care workers occurred or not after surgery. In this study, 28 of the 35 patients (80%) underwent tracheostomy >21 days after the development of COVID-19-related symptoms and 30/35(85.7%) >14 days after intubation. Further, in this study, tracheostomy was performed before June 2020 in 25/35 (71.4%) patients. At that time, we faced a shortage in health-care resources such as staff, equipment, medication and facilities. In addition, we did not have a good understanding of the nature of SARS-CoV-2 and the clinical course of COVID-19, so there was a vague sense of fear and a degree of social panic across Japan. We simply considered that the later the tracheostomy was performed, the lower the possibility of COVID-19 infection. Therefore, the timing of the procedure must have been a bit late before June 2020.

The precise interval during which an individual with SARS-CoV-2 infection can transmit infection to others is uncertain. Infected individuals are more likely to be contagious in the earlier stages of illness, when viral RNA levels from upper respiratory specimens are the highest [12,13].The SARS-CoV-2 viral load is normally most abundant around the time of symptom onset, as determined by PCR of viral RNA from mucosal samples from the upper respiratory tract. After symptom onset, the viral load typically decreases over the following 3-4 days [12]. Chen et al. collected 545 specimens from 22 patients, including 209 pharyngeal swabs, 262 sputum samples, and 74 feces samples. In these patients, sputum and feces remained positive for SARS-CoV-2 according to RT-qPCR up to 39 and 13days, respectively, after the obtained pharyngeal samples were negative [14]. Also, in patients with severe disease, the viral RNA load is significantly higher and decreases more slowly than in those with mild disease [15,16]. The American Academy of Otolaryngology and Head and Neck Surgery advises that tracheotomy can be considered in patients with stable pulmonary status but should not take place sooner than 2-3 weeks from intubation and, preferably, after negative COVID-19 testing [17]. The sensitivity of these tests in a clinical setting likely depends on the type and quality of the specimen obtained, the duration of illness at the time of testing, and the specific assay. Indeed, estimated false-negative rates have ranged from less than 5% to 40% [18,19]. Cheng et al. evaluated over 2500 close contacts of 100 patients with COVID-19 in Taiwan, and found that all of the 22 secondary cases had their first exposure to the index case within 5 days of symptom onset compared with those who were exposed later (0 cases from 852 contacts) [20]. Although COVID-19 status may contribute to broader decision-making around tracheostomy procedures, negative COVID-19 testing might not be a prerequisite for tracheostomy.

Table 3. Parameters used by the COVID-19 airway team to guide patient selection for tracheostomy [10].

- Isolated respiratory failure except for acute renal failure on dialysis or continuous renal replacement therapy
- Prolonged intubation and mechanical ventilation for 10 or more days
- Multiple failed sedation holds, failed extubation, or anticipated prolonged respiratory wean
- Improving oxygen requirements: fraction of inspired oxygen (FiO_2) <0.4 and positive end-expiratory pressure (PEEP) <10 cm H_2O.
- Appropriate coagulation with no evidence of coagulopathy
- Unlikely to require further prone position ventilation

In this study, fortunately, no one involved in the tracheostomies was infected COVID-19. According to the literature, Zhang et al. reported 11 patients with severe COVID-19 who received tracheostomy [21]. Before tracheostomy, the mean (range) number of hospitalization days was 26.6 (6, 58) days, and the mean (range) duration of intubation was 16.8 (6, 36) days. Only one patient with cerebral hemorrhage underwent percutaneous tracheostomy 6 days after the brain surgery and endotracheal intubation, while the other 10 patients underwent tracheostomy at least 12 days after endotracheal intubation. As a result, no health-care workers associated with the tracheostomy procedures were confirmed to be infected by SARSCoV-2 after 14 days out of the working environment.

Chao et al. also reported 53 patients with COVID-19 who underwent tracheostomy [7]. The average time of intubation before tracheostomy, defined as the time from first intubation to tracheostomy, was 19.7 days±6.9 days, with a range of 8–42 days. Again, no health-care worker transmission resulted from the procedures. In the Birmingham experience, a total of 100 patients underwent tracheostomy [10]. Nine patients underwent tracheostomy before 10 days, 55 between 10 and 14 days, and 36 after 14 days of intubation. As a result, no health-care workers developed COVID-19.

Takhar et al. stated that delaying tracheostomy to at least 14 days postintubation would represent the safest possible balance [9]. Given the natural disease course, this would likely represent at least 3 weeks from the onset of symptoms. This is one of the early recommendations. Table 3 shows parameters to guide selection for tracheostomy in the Birmingham study recently published [10]. They stated that delaying the tracheostomy over concerns for health-care personnel safety may prolong patients' time on a ventilator and ICU stay, without any benefit of improved safety for either the clinicians involved, or the patient. Health-care personnel infection during tracheostomy procedures was prevented to a great extent by appropriate PPE and appropriate surgical procedures with highly experienced surgical teams according to previous reports [4,8,10,21,22]. An international tracheostomy consensus working group suggests that tracheostomy be delayed until at least day 10 of mechanical ventilation and should be con-

sidered only when patients are showing signs of clinical improvement [8].

The Oto-Rhino-Laryngological Society of Japan proposed 5 scenarios that would require a tracheostomy according to the combination of SARS CoV-2 infection status and respiration controls [23]. For SARS CoV-2-positive patients who are under ventilator controls, the following procedures are recommended: tracheostomies with full PPE protection under general anesthesia at least 10 days after intubation ideally in a negative pressure room or in a room exclusively for COVID-19 patients. These principles were generally respected except for one patient who underwent tracheostomy under local anesthesia within 7 days after onset/intubation. Sixteen of 35 tracheostomies were performed in negative pressure rooms. As a result, no transmission to health-care workers developed, suggesting that the tracheotomy guidance for COVID-19 patients proposed by the Oto-Rhino-Laryngological Society of Japan may be valid in clinical practice.

In conclusion, fortunately, no one involved in the tracheostomy procedures in this study was infected COVID-19. One reason might be that 84% of patients underwent tracheostomy >14 days after intubation and the surgery was performed using appropriate PPE and surgical procedures. However, this does not necessarily mean that we recommend delaying the timing of tracheostomy for patients with COVID-19 as this was a retrospective study with only a small number of subjects. Further, tracheostomy for patients might not always be beneficial, and the procedure and subsequent care puts health-care workers at increased risk of SARS-CoV-2 infection. Therefore, the indication and the timing of tracheostomy for severe COVID-19 patients should be decided through multidisciplinary discussion of the patient's goal of care, overall prognosis, and expected benefits of tracheostomy.

Declaration of Competing Interest

We declare that we have no conflicts of interest.

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