

# Tracheostomy during the COVID-19 pandemic in Malaysia; a revised guideline

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## ABSTRACT

Performing tracheostomy on COVID-19 patients poses a significant risk to the procedural team. Such procedures should be evaluated individually via close communication between the otorhinolaryngology-head and neck surgeon and the intensivist. Comprehensive examination and preparation should be well-planned before tracheostomy, optimal technique during tracheostomy and special care following the surgery. We would like to highlight our revised guidelines at Hospital Kuala Lumpur, Malaysia on the timing of tracheostomy, management of anticoagulant and the surgical planning in COVID-19 patients during these challenging times.

## INTRODUCTION

As of July 1, 2021, Malaysia is battling with 758967 total COVID-19 cases, 6988 new cases, and 5254 deaths.<sup>1</sup> As such a revision of the previous tracheostomy guidelines anticipating open tracheostomy in COVID-19 patients is clearly needed.

Tracheostomy is an aerosol-generating procedure (AGP) and one of the most high-risk surgeries in COVID-19 patients.<sup>2,3</sup> Many clinicians believe that it should be avoided if possible as the secretion that spatter during the procedure poses a significant risk to surgeons, anaesthetists, and the staff in the operation theatre.<sup>4</sup> However, tracheostomy is necessary in some cases; after prolonged intubation or difficult weaning, as it eases the work of breathing, reduces dead space, and facilitates tracheobronchial toileting.<sup>5</sup>

Decisions regarding the need for open tracheostomy in COVID-19 patients must balance the risks and benefits to the patient as well as the medical staff involved. In some circumstances, open tracheostomy is inevitable.<sup>2,6</sup> Various recommendations are available, focusing not only on the indications of the tracheostomy, but also on the safety of the health care workers.

Thus it is timely for us to revise the tracheostomy guidelines that was published in 2020.<sup>7</sup> These revisions will highlight the timing of the tracheostomy, its surgical planning as well as the management of anticoagulants.

## RECOMMENDATIONS FOR TRACHEOSTOMY

### MANAGEMENT IN VENTILATED COVID-19 PATIENTS

#### A. Candidacy and timing of the tracheostomy

Candidacy is based on confirmed COVID-19 status via the reverse transcription-polymerase chain reaction (rt-PCR), the viral load as shown with the availability of cycle threshold (CT) value, and the general medical condition optimised for the procedure of the patients.<sup>5,6</sup> The benefits of tracheostomy have been proven but its timing remains controversial.<sup>8</sup> In critically ill non- COVID-19 patients, Andriolo et al, defined early tracheostomy as  $\leq 10$  days post tracheal intubation and late tracheostomy as  $> 10$  days post-intubation. Although the result of time spent on mechanical ventilator was variable, he found that patients with early tracheostomy had lower mortality rates.<sup>8</sup>

There are three timings for tracheostomy in ventilated COVID-19 patients based on recently published articles in the English literature, which are;

- *Less than 10 days:* Although this is not specifically for COVID-19 patients, this timing remains controversial, with many surgeons not agreeing to it. The TracMan trial showed no difference in 30 days mortality rate (30.8% early vs. 31.5% late) and two years mortality (51.0% early vs. 53.7% late). Median intensive care unit (ICU) stay (13 days early vs. 13.1 days late) were similar as were total hospital stay or the duration of the mechanical ventilation.<sup>9</sup> However, early tracheostomy showed a significant decrease in sedation.<sup>9</sup> Ahn et al. proposed on performing tracheostomy in COVID-19 patients whenever they were indicated, regardless of timing.<sup>10</sup>
- *Ten to 20 days:* COVID-19 viral load becomes undetectable around two weeks, reducing the exposure risk during tracheostomy.<sup>11</sup> Ferri et al. performed tracheostomies after 14 days of intubation in COVID-19 patients and found a mortality rate of 25%, which was similar with the previously reported overall mortality rate in ICU COVID-19 patients of 26%. They concluded that tracheostomy did not impact the natural course of the disease in these patients.<sup>12</sup> Martin-Villares et al. looked at 1,890 patients with a median time to tracheostomy of 12 days. These patients were followed up for one month with a mortality rate being 24%.<sup>13</sup> Prior studies have focused on tracheostomies performed between 10-20 days post-intubation and have demonstrated variable mortality rates of 7%-24%.<sup>13</sup>

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- *More than 21 days:* There were no previous studies that have evaluated outcomes of COVID-19 patients who underwent tracheostomy after 21 days of intubation. A few reports suggest that tracheostomy to be done after at least 21 days of ventilation for COVID-19 patients. This led to the recommendation to perform tracheostomies from 21 days onward.<sup>11,13,14</sup> Martin-Villares et al. suggested that waiting longer (at least 21 days) does not change the weaning process but may reduce the mortality risk.<sup>13</sup> Another study showed that waiting longer, on average 20 days, had a much lower mortality rate (11%). The report suggests that careful patient selection, with the patient having feasible respiratory dynamics, the outcomes after tracheostomy seemed promising.<sup>15</sup>

Our view is similar with Ahn et al., who demonstrated that the wait of 21 days is practically not feasible as negative conversion could take up to 43 days, thus delaying appropriate management and weaning. Ahn advocated that tracheostomy can be performed whenever indicated, regardless of time from intubation or COVID-19 test results.<sup>10</sup>

Hence, a multidisciplinary discussion should be held between the primary team, procedural team, and family to establish the overall prognosis, and expected benefits of tracheostomy.

**B. Antithrombotic Management**

COVID-19 may lead to a hypercoagulable state due to a combination of complement-mediated endothelial injury, stasis, and changes in circulating prothrombotic factors.<sup>16</sup> Hospital Kuala Lumpur (HKL), Malaysia is in line with international centres instituting aggressive protocols of anticoagulation in patients with COVID-19. Subcutaneous fondaparinux 2.5mg daily or subcutaneous enoxaparin 20mg daily is started in high-risk patients. Studies have found that tracheostomies might be safely performed while on therapeutic anticoagulation, with full-dose anticoagulation needing to be discontinued or withheld for a short peri-operative period.<sup>17</sup>

Antiplatelet therapy in HKL, aspirin and/or clopidogrel therapy, are not withheld before surgery. Since February 2021, with a total of 60 patients, and to date we have not had any bleeding complications. Nevertheless, we recommend platelet count of more than 60,000/ $\mu$ L, international normalized ratio (INR) of less than 1.5 and urea of less than 25mg/dL.

Nevertheless, these recommendations should not substitute appropriate clinical judgment and critical discussion between the intensivist and otorhinolaryngology-head and neck team regarding the patient's antithrombotic regimen.

**C. Procedure prerequisites**

The protection of the surgeon, anaesthetist, and staff during the procedure should be given utmost consideration.

- The procedure should be done in a dedicated operating room to minimise contamination, with a clean runner antechamber (as the only conduit to the outside). We suggest a negative pressure operating room if available.
- Any unnecessary endoscopic examinations should be avoided, as endoscopies are aerosol-generating procedure (AGP) as well.

- Adequate personal protective equipment (PPE) with proper training and familiarisation of the donning and doffing of the PPE upon entering and exiting the operation room.
- The minimum PPE requirements are: (a) double-layered disposable gloves; (b) double gowning, fluid barrier protection or coverall; (c) N95 masks; (d) full-face visor or goggles for eye protection; (e) disposable surgical cap; and (f) shoe and boot covers.
- We advocate a powered air-purifying respirator (PAPR) device for all positive Covid-19 patients diagnosed within 28 days. With compliance to these rules, we have yet to see any of our procedural team contracting COVID-19 after the procedure.
- The number of staff during the procedure should be minimum. Our practice is that only one or two experienced surgeons are involved during the procedure.

**D. Preoperative planning**

When there are limited ICU beds and shortage of ventilators, early tracheostomy is more appropriate as the best form of continuation of care. Under such circumstances, tracheostomy may liberate patients from the ventilator and facilitate transfer out of the ICU. Frequent positional changes of patients, copious bronchial secretions, and pronounced laryngeal oedema associated with COVID-19, make tracheostomy safer than endotracheal intubation.

1. Tracheostomy in COVID-19 patients should be a planned semi-elective procedure and not done as an emergency procedure.
2. A designated tracheostomy team should comprise of a senior otorhinolaryngology-head and neck surgeon, a senior otorhinolaryngology-head and neck trainee, a senior anaesthetist and senior operation theatre nurse.
3. The operation should occur in a dedicated operation room or preferably a negative pressure isolation room in ICU (if available) with an isolated donning/doffing room. Ideally, the tracheostomy should be performed in the ICU to avoid unnecessary movement of the patient.
4. We recommend the use of long-term cuffed non-fenestrated tracheostomy tubes to minimise tracheostomy tube change.
5. The patient must be relatively stable and able to tolerate supine position and brief apnoea. A complete paralysis with muscle relaxant throughout the procedure is used to reduce the risk of coughing and aerosolisation.

**E. Intraoperative procedure**

The operative procedure is similar to that stated in the previous Ministry of Health Malaysia, 2020 guidelines on tracheostomy.<sup>7</sup> We feel that adherence to the guidelines is feasible and safe.

1. The trays are opened, and instruments are laid out for easy access.
2. A 10ml syringe and catheter mount are attached to the preselected tracheostomy tube, to allow for readily inflation of the tracheostomy balloon.
3. A closed in-line suction must be used for the endotracheal tube (ETT) and tracheostomy tube.
4. The patient is then prepared for surgery.

5. A standard open tracheostomy is done through a horizontal neck incision.
6. Sutures or LigaClips are preferred instead of diathermy to prevent vaporization of viral particles.
7. The surgeon must inform the anaesthetist before incising the trachea.
8. The anaesthetist must ensure that the patient is totally paralyzed.
9. The anaesthetist is required to pre-oxygenate the patient, followed by turning off the flow, and allowing for passive expiration on an open APL valve.
10. The ETT is then clamped and advanced inferiorly, so that the cuff is beyond the planned tracheostomy site.
11. A tracheal window is created (rather than slit) taking care not to pierce the ETT cuff.
12. The ETT cuff is then deflated and withdrawn proximally until beyond the tracheal window under direct vision.
13. The surgeon must ensure the window is sufficient to allow easy insertion of the tracheostomy tube.
14. A cuffed, non-fenestrated tracheostomy tube (long term cuffed double-lumen silicone tube, if available) is inserted.
15. The tracheostomy tube cuff is immediately inflated, attaching it back to the circuit. Ventilation is resumed, and the tube position is confirmed with end-tidal CO<sub>2</sub> (to avoid contamination of the stethoscope).
16. The clamped ETT is withdrawn carefully.
17. The tracheostomy tube is secured with sutures and tracheostomy tapes.
18. An appropriate tracheostomy dressing is applied.

#### *F. Post-operative care*

We recommend that the following items be at the patient's bedside: A tracheostomy grab bag, consisting of a basic tracheostomy set with the tracheal dilator, suction equipment, spare inner cannula, and extra double-lumen silicone cuffed non-fenestrated tracheostomy tube which is one size smaller. This must be checked and restocked regularly.

When the patient is ready for weaning, a T-piece system with a viral filter on the expiratory end and an in-line suction catheter may be used. Placing a surgical mask over the tracheostomy site may also limit droplet spread. Patients who are weaned to a tracheostomy mask can undergo speaking valve trials as placement of the speaking valve and capping helps decrease the aerosolization.

#### *Nursing care*

Extreme care must be taken in transferring or positioning the patient. We prefer to use a heat moisture exchanger (HME), and if possible to avoid the use of a humidified oxygen. The suction circuits should be closed-line at all times and the cuff pressure is checked periodically. The nursing staff must be protected with the appropriate PPE as well.

#### *Tracheostomy change*

The first tracheostomy tube change should be delayed to days 8-10. The same sequence of pause in ventilation with flows off is advised before deflating the cuff. This is followed by insertion of a new tracheostomy tube with immediate inflation of the cuff and reconnection of the closed-circuit. Subsequent tracheostomy tube change is planned at 30-day intervals.

#### *Decannulation*

The decannulation should be decided on a case-to-case basis. Ideally, the decannulation is deferred until the patient is confirmed COVID-19 negative. It should be done as per standard decannulation protocols.

#### **CONCLUSION**

According to our revised guidelines at HKL, tracheostomy in COVID-19 patient needs to be pre-planned, taking into consideration the needs and well-being of the patients and the healthcare workers. All cases should be evaluated on a case per case basis with close communication between the otorhinolaryngology-head and neck surgeon and the intensivist.

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