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Early vs. late tracheostomy in ventilated COVID-19 patients – A retrospective study

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ABSTRACT

Background: Tracheostomy is one of the most common surgical procedures performed on ventilated COVID-19 patients, yet the appropriate timing for operating is controversial.

Objectives: Assessing the effect of early tracheostomy on mortality and decannulation; elucidating changes in ventilation parameters, vasopressors and sedatives dosages immediately following the procedure.

Methods: A retrospective cohort of 38 ventilated COVID-19 patients, 19 of them (50%) underwent tracheostomy within 7 days of intubation (early tracheostomy group) and the rest underwent tracheostomy after 8 days or more (late tracheostomy group).

Results: Decannulation rates were significantly higher while mortality rates were non-significantly lower in the early tracheostomy group compared with the late tracheostomy group (58% vs 21% \( p < 0.05 \); 42% vs 74% \( p = 0.1 \), respectively). Tidal volume increased (446 ml vs 483 ml; \( p = 0.02 \)) while PEEP (13 cmH\( _2 \)O vs 11.6 cmH\( _2 \)O, \( p = 0.04 \)) decreased at the immediate time following the procedure. No staff member participating in the procedures was infected with SARS-CoV-2 virus.

Conclusion: Early tracheostomy might offer improved outcomes with higher decannulation rates and lower mortality rates in ventilated COVID-19 patients, yet larger scale studies are needed. Most likely, early exposure to COVID-19 patients with appropriate personal protective equipment during open tracheostomy does not put the surgical team at risk.

1. Introduction

Many of the critically ill patients with COVID-19 require invasive mechanical ventilation (IMV) through endotracheal tube, some for prolonged periods [1]. Tracheostomy has well described benefits for ventilated patients – reduction of breathing work to promote weaning off IMV, sedatives reduction, better pulmonary toilet, better patient comfort, larynx protection, etc. [2]. Thus, tracheostomy became one of the most common procedures in ventilated COVID-19 patients.

Since the outbreak of the pandemic there is a rigorous discussion regarding many aspects of the tracheostomy procedure and mainly regarding the appropriate timing. Current studies show conflicting results about the effect of the timing of the procedure on mortality, length of stay at the ICU, time to decannulation and more [1,3–6]. Due to the inconsistent results, different recently published guidelines on tracheostomy in COVID-19 patients present contradicting suggestions regarding the appropriate timing to operate [7–10]. Most studies lack long-term perspective that may allow better understanding on the lingering effect of the timing of the procedure.

The initial approach at our tertiary medical center was to perform tracheostomy as early as possible, but it was later changed to a more permissive approach due to conflicting reports on timing of tracheostomy and outcome. We retrospectively analyzed our data and followed the patients until either decannulation or death. We aimed to evaluate the effect of the timing of the procedure on these outcomes.

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2. Materials and methods

We conducted a retrospective single institution study on patients admitted to the COVID-19 intensive care unit between March 2020 and January 2021, who underwent elective open tracheostomy. The study was conducted in an Israeli tertiary referral center. The study was approved by the medical center's institutional review board.

The following data was gathered by reviewing electronic medical records: patient demographics, previous medical history, daily follow-up notes, dosage of different vasopressors and sedatives, mechanical ventilation parameters, tracheostomy procedural details, complications and outcomes.

Early tracheostomy group included all patients that were operated within 7 days of intubation. Late tracheostomy group included all patients that were operated in 8 days or more of intubation. The primary outcome was difference in mortality rates between the early tracheostomy and late tracheostomy groups. Secondary outcomes included comparing the groups for time to weaning from IMV, time to decannulation, time to discharge. We also assessed the effect of the tracheostomy on the dosage of vasopressor agents and sedatives. These were recorded and measured 3 days prior and 3 days after the procedure.

We used Fisher’s Exact Test for analyzing the correlation between categorical variables. For comparing means of independent groups with assumed normal distribution (age, BMI) we used Student’s t-test. When normal distribution could not be assumed (dosage of ionotropic support and sedatives), related-samples Wilcoxon Signed Rank Test was used for comparing means. Statistical analyses were performed using IBM SPSS® software version 26.

3. Results

Between March of 2020 and January of 2021, we performed 38 tracheostomies in patients intubated and ventilated due to acute respiratory distress syndrome (ARDS) secondary to COVID-19 infection.

Tracheostomy was performed within 7 days of intubation in 19 patients (50%). 87% were male with a median age of 64 years (interquartile range [IQR] 56–72 years). 87% of the patients had underlying chronic disease including obesity (BMI ≥ 30), diabetes, hypertension, and chronic lung disease. Laboratory results upon admission were significant for high C-reactive protein levels (median 160 mg/l; IQR 79–243 mg/l) and lactate dehydrogenase levels (median 434 IU/l; IQR 357–512 IU/l). Patients were intubated within a median of 3 days (IQR 1–8 days) from admission. No significant differences in patients’ characteristics were found between the early tracheostomy group (operated within 7 days of intubation) and the late tracheostomy group (operated 8 days from intubation or later). Baseline characteristics are shown in Table 1.

All patients were admitted to a designated COVID-19 intensive care unit (ICU) and were treated with inotropic support and sedatives. The mean dosages of these medications were compared at the immediate period (three days) before and after the tracheostomy. Mean fentanyl dosage was significantly higher at the immediate period after the tracheostomy (2.4 mg/day standard deviation [SD] 2.1 vs. 3.3 mg/day SD 3.4, p = 0.04). There was no significant difference in mean dosages of noradrenaline, propofol and ketamine (Fig. 1). Mechanical ventilation parameters were also compared at the immediate period before and after the procedure. Mean positive end-expiratory pressure (PEEP) was significantly lower (13 CmH2O SD 8 vs 37 CmH2O SD 41, p = 0.04) while mean tidal volume (VT) was significantly higher (446 ml SD 134 vs 483 ml SD 136, p = 0.02) post-tracheostomy compared pre-tracheostomy period. There was no significant difference in the usage of vasopressors or sedatives between the early and the late tracheostomy groups, nor in the ventilation parameters (Fig. 2).

Patients were followed until death or decannulation. 42% of the patients were weaned off mechanical ventilation with a mean of 25 days (SD 19 days) from the procedure. All these patients were discharged to rehabilitation within a mean of 30 days (SD 22 days) from tracheostomy. All discharged patients, except one patient who was lost to follow up, were decannulated within a mean of 43 days (SD 20 days) from the procedure with rates significantly higher within the early tracheostomy group.

Table 1

| Variable                                   | All subjects, N (%) | Early tracheostomy N (%) | Late tracheostomy N (%) | P-value |
|--------------------------------------------|---------------------|--------------------------|-------------------------|---------|
| Number of patients, N (% of all patients)  | 38 (100)            | 19 (50)                  | 19 (50)                 | -       |
| Age, years, median [IQR]                   | 64 [56-72]          | 60 [54-67]               | 68 [59-74]              | 0.4     |
| Sex                                        |                     |                          |                         |         |
| Male                                       | 33 (87)             | 16 (84)                  | 17 (89)                 | 1^       |
| Female                                     | 5 (13)              | 3 (16)                   | 2 (11)                  | 1^       |
| Chronic disease^2                         |                     |                          |                         |         |
| Any                                        | 33 (87)             | 16 (84)                  | 17 (89)                 | 1^       |
| None                                       | 5 (13)              | 3 (16)                   | 2 (11)                  | 1^       |
| Smoking                                    |                     |                          |                         |         |
| Currently                                  | 3 (8)               | 2 (11)                   | 1 (5)                   | 1^       |
| Past                                       | 6 (16)              | 4 (21)                   | 2 (11)                  | 0.7^     |
| No                                         | 21 (55)             | 11 (58)                  | 10 (53)                 | 0.7^     |
| BMI, median [IQR]                          | 30 [26-32]          | 29 [26-32]               | 32 [28-34]              | 0.3     |
| Laboratory upon admission, median [IQR]    |                     |                          |                         |         |
| WBC (10^3/μl)                              | 8 [5-13]            | 8 [5-14]                 | 8 [6-9]                 | 0.4     |
| AST (IU/l)                                 | 48 [29-67]          | 47 [29-67]               | 54 [30-73]              | 0.5     |
| ALT (IU/l)                                 | 28 [22-52]          | 31 [22-59]               | 28 [22-51]              | 0.9     |
| LDH (IU/l)                                 | 434 [316-512]       | 434 [357-512]            | 429 [282-538]           | 0.6     |
| CRP (mg/l)                                 | 160 [79-243]        | 169 [89-196]             | 150 [49-260]            | 0.9     |
| Time to intubation from admission, days [IQR]| 3 [1-8]             | 2 [0-10]                 | 4 [2-8]                 | 1^       |
| Time to tracheostomy from intubation, days [IQR]| 7.5 [4-11]         | 4 [3-5]                  | 11 [9-18]               | -0.001  |

ALT, alanine transaminase; AST, aspartate aminotransferase; BMI, body mass index; CRP, C-reactive protein; IQR, interquartile range; LDH, lactate dehydrogenase; WBC, white blood cells.

^ Early tracheostomy group consists of all patients who underwent the procedure within 7 days from intubation.

^ Late tracheostomy group consists of all patients who underwent the procedure 8 days or more from intubation.

^ p-Value of the difference between baseline characteristics of patient in the early tracheostomy^2 and late tracheostomy^2 groups. Calculated with Student's t-test, unless stated otherwise.

^ d-P-Value calculated with Fisher’s Exact Test.

^ Chronic disease includes obesity (BMI ≥ 30), diabetes, hypertension, and chronic lung disease.
Comparison of mean ionotropic support and sedatives three days before and three days after the tracheostomy

Comparison of mean noradrenaline, propofol, fentanyl, and ketamine dosages given to the patients, all in mg/day. Mean fentanyl dosage was significantly higher at the three days after the procedure. P-value was calculated using related-samples Wilcoxon Signed Rank Test.

Fig. 1. Comparison of mean ionotropic support and sedatives three days before and three days after the tracheostomy.

Comparison of ventilation parameters three days before and three days after the tracheostomy.

Comparison of mean PEEP (cmH2O), FiO2 (percent), tidal volume (ml) and PaO2/FiO2 levels. Mean PEEP was significantly lower while mean tidal volume was significantly higher at the three days after the procedure. P-value was calculated using related-samples Wilcoxon Signed Rank Test.

FiO2, fraction of inspired oxygen; PaO2, partial pressure of oxygen; PEEP, positive end-expiratory pressure.

Fig. 2. Comparison of ventilation parameters three days before and three days after the tracheostomy.
group (58% vs 21% in early vs late respectively, \( p = 0.045 \)). Mortality rate was high with 58% of the patient dying during hospitalization. The mortality rate in the early tracheostomy group (within 7 days of intubation) was much lower compared with late tracheostomy group (42% vs 74% respectively), with tendency towards significance using two-sided Fisher’s exact test (\( p = 0.1 \)). Time to death from the procedure was longer with the early tracheostomy group with 31 days (SD 15 days) vs 18 days (SD 14 days) in the late tracheostomy group with \( p = 0.05 \) (Table 2).

All procedures took place at the designated COVID-19 ICU and were done by different otolaryngology attending and residents using full PPE including full-body isolation gowns, N-95 masks, face shields and gloves. Notably, none of the participating staff members (surgeons, anesthesiologists, nurses) was found to be infected with SARS-CoV-2 virus.

4. Discussion

In this single-center study, we followed COVID-19 patients who underwent elective tracheostomy until death or decannulation. We changed our treatment paradigm along the evolution of the outbreak – in the first two months (March–April) we opted for early tracheostomy in this patient subset. However, later in the pandemic timeline (May 20’ – January 21’) we began postponing the surgical intervention. This change offered us a unique opportunity to compare the outcomes of procedures done by the same limited group of surgeons with mainly the timing of the procedure being different.

We found that decannulation rates were significantly higher among the early tracheostomy group, i.e. <8 days from intubation (58% vs 21%). Mortality rates were lower with the early tracheostomy group (42% vs 74%) but the difference was only trending towards significance. The patients in our cohort died significantly later when the tracheostomy was done early. Other outcomes such as time on IMV and length of hospitalization were not found to be significantly different between the early and the late tracheostomy groups. We also aimed to assess the benefit of performing tracheostomy - on the need for sedatives, inotropic support, and ventilation parameters. We found that PEEP was significantly lower while tidal volume and fentanyl dosages were significantly higher in the immediate days after the tracheostomy than before the procedure.

The debate regarding the appropriate timing for performing elective tracheostomy in ventilated ICU patients dates back even prior to the pandemic outbreak. Blot et al. found no difference in mortality, time spent at the ICU, amount of sedation and other complications between early and late tracheostomy in the general ICU population [11]. The TracMan study, performed also on an ICU population, found only reduction in the doses of sedation between the groups [12]. A large metaanalysis on more than 200,000 ICU patients found better outcomes when operation is done early. A Cochrane group review on that matter from 2016 found no clear evidence to support one approach over the other [13].

Several guidelines were published regarding different aspects of tracheostomy in the COVID-19 population such as necessity, indications, or staff protection. However, they are not unequivocal regarding the right timing for surgery. A systematic review of these guidelines found that European guidelines tend to propose early intervention while British and North American guidelines recommend late intervention [9]. Main reasons given for postponing tracheostomy is staff protection and the poor outcome of severely-ill COVID 19 patients [7,8,10,14]. Respectively, studies performed on this population are also inconclusive. Volo et al. found that early tracheostomy (within 10 days) was associated with higher mortality rate [3]. However, this study is an exception as the majority investigators report no difference in mortality, but found that early tracheostomy benefits in sedation reduction, secretion management, IMV weaning, ICU length of stay and time to decannulation [4–6,15]. Nevertheless, most of these studies did not follow the patients for long periods. The results in our study show improved outcomes when the procedure was done within seven days of intubation – significantly higher decannulation rates and a non-significant trend of lower mortality rates. We did find that time from procedure to death was much shorter in the late tracheostomy group, but this finding can be alternatively explained by the natural history of the COVID-19 disease.

The benefits of tracheostomy in advancing ventilator-dependent patients towards weaning are long described and discussed [16]. The mechanism for weaning is partially explained by reduction in dead space, airway resistance, work of breathing and improved airway toilet [17–19]. Chor-Kuan et al. found that ventilation parameters related to weaning were significantly improved after tracheostomy in patients that were later successfully weaned from mechanical ventilator [20]. A British retrospective study on 28 tracheostomies performed on COVID-19 patients demonstrated improvement in ventilatory requirements such as FiO2, PEEP and P/F ratio [15]. Our findings demonstrate a similar trend with significantly higher tidal volume and significantly lower PEEP when comparing the ventilation parameters three days before and after the procedure. There was a small yet significant rise in the usage of fentanyl at the immediate period following the procedure with no difference in dosages of other sedatives and inotropes. This difference could be possibly attributed to post-operative pain.

In order to minimize medical staff exposure to aerosol, a rigorous tracheostomy protocol was established in our center. Only open tracheostomy procedures were performed to allow adequate control of the

| Table 2: Outcomes. |
|-------------------|
| Outcome | All subjects (N = 38) | Early tracheostomy (N = 19) | Late tracheostomy (N = 19) | p-value |
| Weaned from IMV | # of patients (%) | | | |
| Days to off IMV from tracheostomy (±SD) | 16 (42) | 11 (58) | 5 (26) | 0.1 |
| Discharged | # of patients (%) | | | |
| Days to discharge from tracheostomy (±SD) | 25 (±19) | 26 (±18) | 23 (±22) | 0.8 |
| Decannulated | # of patients (%) | | | |
| Days to decannulation from tracheostomy (±SD) | 16 (42) | 11 (58) | 5 (26) | 0.1 |
| Death | # of patients (%) | | | |
| Days to death form tracheostomy (±SD) | 15 (40) | 11 (58) | 4 (21) | 0.04 |
| Outcome All subjects (N = 38) | Early tracheostomy (N = 19) | Late tracheostomy (N = 19) | p-value |
| Death | # of patients (%) | | | |
| Days to death form tracheostomy (±SD) | 22 (±16) | 31 (±15) | 18 (±14) | 0.05 |

- Early tracheostomy group consists of all patients who underwent the procedure within 7 days from intubation.
- Late tracheostomy group consists of all patients who underwent the procedure 8 days or more from intubation.
- p-value calculated with Student's t-test, unless stated otherwise.
- p-Value calculated with two-sided Fisher's Exact Test.
airway as well as to minimize aerosol exposure. Before incising the trachea, ventilation was paused, and the patient was disconnected from the circulation. Once the tracheostomy tube was secured and the cuff was inflated, ventilation resumed. Procedures were performed bedside with minimal staff (a senior and junior surgeon and anesthesiologist). The surgical team wore appropriate personal protective gear (PPE) including N95 face mask, protective face shield, full isolation gown and gloves.

The main limitation of this study is its small size which limits its power to find significant trends in the effect of the timing of the procedure. However, we preferred including ‘closed’ cases in which the final outcome (death vs. decannulation) were known, thus preventing us from analyzing more recent cases. Another possible limitation is the fact that besides the change in the approach to operate later in the course of ventilation, other paradigms in the treatment of COVID-19 patients were changed as well due to better understanding of this novel disease. One of these alterations was a more restrictive approach towards intubating patients presenting with respiratory distress, meaning that the patients operated later might have been more severely ill at presentation. This could be a significant confounding variable and affect the results presented in this study as worse condition can be expected to have higher mortality rates and lower decannulation rates. Nevertheless, baseline characteristics were not significantly different between the two groups.

5. Conclusion

Our study suggests that performing early tracheostomy in COVID-19 patients might lead to improved outcomes with significantly higher decannulation rates and non-significant lower mortality rates. Moreover, performing tracheostomy in intubated patients may allow for more effective and safe ventilation at the immediate post-operative period. These findings imply that the decision on the need and timing of the procedure needs to be dictated by a case-by-case approach with cooperation between the intensive care physicians and the otalaryngologists. As of the question of staff protection and exposure our study revealed no evidence of staff infection due to the procedure. We concluded that with appropriate PPE and surgical technique, open tracheostomy in early infected COVID-19 is entirely safe.

CRediT authorship contribution statement

Nir Livneh: conceptualization, methodology, formal analysis, investigation, writing–original draft. Jobran Mansour: conceptualization, methodology, formal analysis, investigation, writing – review and editing. Reut Kassif Lerner: conceptualization, writing – review and editing. Gilad Feinmesser: methodology, writing – review and editing. Eran Alon: supervision, conceptualization, writing – review and editing.

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Declaration of competing interest

All authors report no conflict of interest.

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Decloration of competing interest

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