ORIGINAL ARTICLE

A 30-day Survival and Safety of Percutaneous Tracheostomy in Moderate-to-severe COVID-19 Pneumonia Patients: A Single-center Experience

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Abstract

Aims and objectives: In coronavirus disease-2019 (COVID-19) pneumonia, guidelines on timing and method of tracheostomy are evolving. The aim of the study was to analyze the outcomes of moderate-to-severe COVID-19 pneumonia patients who required tracheostomy and the safety with regard to the risk of transmission to the healthcare workers.

Materials and methods: We retrospectively analyzed 30-day survival outcome of a total of 70 moderate-to-severe COVID-19 pneumonia patients on a ventilator, wherein tracheostomy was performed only in 28 (tracheostomy group), and the remaining were with endotracheal intubation beyond 7 days (non-tracheostomy group). Besides demographics, comorbidities and clinical data including 30-day survival and complications of tracheostomy were analyzed in both groups with respect to the timing of tracheostomy from the day of intubation. Healthcare workers were monitored for COVID-19 symptoms by carrying out periodical COVID tests.

Results: The 30-day survival of the tracheostomy group was 75% as compared to 26.2% of the non-tracheostomy group. The majority of the patients (71.4%) had severe disease with PaO_2/FiO_2 (P/F ratio) <100. The first wave showed an 80% (4/5) while the second wave 100% (8/8) thirty days survival in the tracheostomy group performed before 13 days. All patients during the second wave underwent tracheostomy before 13 days with a median of 12th day from the day of intubation. These tracheostomies were performed percutaneously at the bedside, without any major complications and no transmission of disease to healthcare workers.

Conclusion: Early percutaneous tracheostomy within 13 days of intubation demonstrated a good 30-day survival rate in severe COVID-19 pneumonia patients.

Keywords: Aerosolized procedure, Coronavirus disease-2019 acute respiratory distress syndrome, Endotracheal intubation, Healthcare workers, Infection transmission.

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Highlights

Early percutaneous tracheostomy within 13 days of intubation demonstrated a good 30-day survival rate of 54.5% (6/11) in the first wave and 100% (10/10) in the second wave in the moderate-to-severe COVID-19 pneumonia patients but had no benefit with respect to the length of intensive care unit (ICU) stay.

Introduction

In March 2020, WHO declared COVID-19 as a world pandemic, the causative agent of which is severe acute respiratory syndrome coronavirus 2 (SARS-COV-2).[1] Although it is found to cause less mortality, the rate of transmission and infectivity is extremely high when compared with related viruses.[2] About 5–15% of the total COVID-19 infected patients are seriously ill and need artificial ventilation.[3]

Tracheostomy facilitates weaning off the ventilator support, probably improving prognosis and increasing available beds in the ICU. A tracheostomy performed within 10 days from intubation is called an early tracheostomy.[4] The benefits of which are early weaning off the ventilator, shorter duration of sedation and ICU stay making this a cost-effective treatment.[4] A recent meta-analysis showed that early tracheostomy lowered the incidence of pneumonia as well as the need for sedation.[5]

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However, tracheostomy is a highly aerosolized procedure that increases the risk of transmission to healthcare workers.[6,7] Therefore, for a safe procedure during COVID-19, it was recommended to delay the tracheotomy beyond the 14th day of intubation with signs of clinical improvement[8–12] or till the patient becomes COVID-19 negative.[10,11] Later guidelines recommended the need to balance potential risks against the benefits of tracheostomies.[13,14] However,

we have limited data available on the outcome of earlier vs late tracheostomy.

Hence, a retrospective comparison of prolonged intubation (non-tracheostomy group) beyond 7 days with patients who underwent tracheostomy was carried out. Within the tracheostomy group, we also analyzed the outcomes of early vs late tracheostomy. The risk of transmission of COVID-19 to healthcare workers during this procedure was also assessed.

Materials and Methods

From March 2020 to March 2021, a total of 662 COVID-19-infected severe pneumonia patients were admitted to the ICU at the Seven Hill Facility of Sir HN Reliance Foundation Hospital and Research Centre, Mumbai, Maharashtra, India. Two hundred and twenty-six patients among them were intubated for acute respiratory distress syndrome (ARDS) and a total of 70 of these were ventilated for beyond seven days. Of these 70 intubated patients, since there was sparse evidence on performing tracheostomy, 42 patients continued to remain intubated and hence categorized into the non-tracheostomy group while the remaining 28 patients underwent tracheostomy. We carried out a retrospective analysis of the outcomes of these 70 severe COVID-19 pneumonia patients. Being a retrospective study, the institutional ethics committee (IEC) waived off the requirement for written informed consent.

The data was collected in the form of demographic variables, comorbidity profile, COVID-19 pneumonia severity index [Acute Physiology and Chronic Health Evaluation II (APACHE II) score, computed tomography (CT) severity index (CTSI), and P/F ratio] on admission and intubation] and timing of tracheostomy from the initiation of mechanical ventilation (MV). The outcomes of patients regarding survival, type of procedural complications, and duration of MV post-tracheostomy were followed for 30 days. Healthcare workers directly involved in tracheostomy care were monitored for acquiring COVID-19, by assessing them clinically (signs and symptoms of fever/breathlessness) and also by a rapid antigen test done every alternate day and RT-PCR every fifth day.

Data were presented as frequency or percentage analyzed by Chi-squared statistics or Fisher's exact test for low expected cell counts. Medians and 25th/75th percentiles were estimated for continuous variables and examined for statistically significant difference between two values by Mann–Whitney *U* test. Statistical significance was considered at $p < 0.05$. Analysis was carried out using SPSS software, version 21.

Results

Over 13 months, we analyzed 70 severe COVID-19 pneumonia patients who were ventilated for more than 7 days. Of these, 42 continued without tracheostomy while 28 underwent tracheostomy. Table 1 depicts the demographics and comorbidities and Table 2 depicts the clinical data of the two groups. Both non-tracheostomy and tracheostomy patients were of a higher age (median 71 and 76 years, respectively) with equal distribution of gender. In comparison of the two groups with respect to the comorbidities, we found no difference except patients with ischemic heart disease were more in the tracheostomy group (17.4% vs 2.4%) (Table 1). Approximately, 75% of our patients in both groups had severe ARDS (P/F ratio < 100). There was no clinical difference in the severity of the patients between the two groups with respect to their APACHE II scores (median-14 vs median-15) (Table 2).

Clinical data of the non-tracheostomy vs tracheostomy group showed a significant decrease in the ventilator-free days, length of stay in ICU and hospital, in the non-tracheostomy group (Table 2). This was contributed due to higher mortality and lower 30-day survival rate (26.2%) in the non-tracheostomy group. The 30-day survival of the tracheostomy group was 75% as compared to 26.2% ($p = 0.001$) in the non-tracheostomy group.

In the subgroup analysis of the tracheostomy group (Table 3), we compared the above data of patients in whom tracheostomies were performed less than 13 days to more than 13 days; since the median duration of tracheostomy performed post-intubation was 12th day. A total of 66% of the patients were found to be obese [body mass index (BMI >24)] in the tracheostomy performed more than 13 days. However, no clinically significant difference was observed in the severity of ARDS (P/F ratio) and criticality of patients (APACHE II score). The duration of ventilatory support, days on MV post-tracheostomy and 30-day survival did not differ between the two groups (Table 4). The 30-day survival with respect to the severity of patients (P/F ratio) and the time of tracheostomy performed from intubation (Table 5) demonstrated that severely ill patients benefited from earlier (<13 days) tracheostomy.

In the last 13 months during the first wave, out of 11 patients, we achieved 70–80% 30-day survival between the moderate and severe ARDS patients. Of the 11 patients who survived in the first wave, 75% of the moderate ARDS patients had their tracheostomy performed in less than 13 days. In the second wave, there were no patients whose tracheostomy was performed beyond 13 days. During this period, 76.9% (10/13) of patients had 30-day survival outcome which included all severe ARDS patients. All the tracheostomies were performed percutaneous at the bedside, without any major complications. None of our healthcare workers got infected with COVID-19 infection in both waves of COVID-19.

We believe that percutaneous tracheostomy is a safe option and must be considered within 13 days of intubation, especially in the severe COVID-19 pneumonia group of patients.

Discussion

The course of ARDS differs among patients and is unpredictable as it is not a single disease but rather a syndrome.[15] Early reports described COVID-19 acute respiratory distress syndrome ARDS (CARDS) as a unique entity.[16] However, on comparing the earlier ARDS trials, CARDS revealed similar data,[17] suggesting indications of tracheostomy in COVID-19 patients were similar to other patients with respiratory failure. Tracheostomy helps patients wean off from ventilation and thus reduces the complications associated with the endotracheal tube during long-term intubation. In context of the same in this study, we did observe definite improvement ($p = 0.001$) in the 30-day survival of patients in the tracheostomy group (75%) as compared to the non-tracheostomy group (26.2%).

Tracheostomy is defined as early and late,[5,6,18] based on the time duration when tracheostomy is performed after intubation, and this duration depends on several factors such as the probability of weaning off from the ventilator, the predicted outcomes, and patients' and family's expectations.[19] In this pandemic another very crucial factor was added; the risk of infection to the healthcare professional performing the procedure. This raised an important

Table 1: Demographics and comorbidities data of non-tracheostomy group vs tracheostomy group

	Non-tracheostomy	*Tracheostomy*	
	N = 42	*N = 28*	
	Median (25th/75th quartiles)	*Median (25th/75th quartiles)*	*p-value*
Age	71 (58/79)	76 (70/80.5)	0.036
	No. (%)	**No. (%)**	
Gender			
Male	34 (81.0)	23 (82)	0.579
Female	08 (19.0)	5 (7.9)	
P/F ratio ≤100	35 (83.3)	20 (71.4)	0.234
P/F ratio >100	7 (16.7)	8 (28.4)	
APACHE II score <17	29 (69.0)	16 (57.1)	0.309
APACHE II score ≥17	13 (21.0)	12 (42.9)	
Comorbidities			
Obesity			
No	36 (85.7)	20 (71.4)	0.186
Yes	6 (14.3)	7 (25.0)	
Hypertension			
No	18 (42.9)	11 (39.3)	0.766
Yes	24 (57.1)	17 (60.7)	
Diabetes			
No	21 (50)	18 (66.7)	0.173
Yes	21 (50)	9 (33.3)	
IHD			
No	41 (97.6)	22 (71.6)	0.031
Yes	1 (2.4)	5 (17.9)	
CKD			
No	37 (88.1)	24 (85.7)	0.619
Yes	5 (11.9)	3 (10.7)	

CKD, chronic kidney disease; IHD, ischemic heart disease

Table 2: Clinical data of non-tracheostomy group vs tracheostomy group

	Non-tracheostomy	*Tracheostomy*	
	Median (25th/75th quartiles)	*Median (25th/75th quartiles)*	
	N = 42	*N = 28*	*p-value*
P/F ratio on admission	78 (56.0/98.3)	87 (70.5/113.8)	0.832
APACHE II score	14 (10.0/18.0)	15 (1.0/20.8)	0.452
CORADS score	5 (5/5)	5 (4.75/5.0)	0.075
Ventilator days	11 (8/15.2)	27.5 (20.5/33.8)	0.001
Length of stay in ICU	16.0 (10/22.3)	38.5 (27.3/49.5)	0.001
Length of stay in hospital	16.5 (11/23.5)	40.0 (28.3/53.0)	0.001
	No. (%)	**No. (%)**	
30-day survival			
Yes	11 (26.2)	21 (75)	0.001
No	31 (73.8)	7 (25)	

dilemma, faced throughout the world: When to perform the procedure?

In the acute phase, we find more viral load in the nasopharynx and trachea which is observed till 21 days from symptom onset, while viral RNA can be detected up to 30 days.[20,21] Thus, simultaneous understanding of viral replication, infectivity, viral shedding, use of personal protective equipment, and aerosols reducing techniques while performing tracheostomy, set the protocols and practices to perform tracheostomy beyond 14 days.[22] With this background during the first wave, we learned the importance of tracheostomy with 70–80% survival rates in moderate-to-severe ARDS and among these survivors, 54.5% (6/11) survived when tracheostomy was

Table 3: Demographics and comorbidities data of tracheostomy group

	Below or equal to 13 days	*Above 13 days*	
	N = 22	*N = 06*	
	Median (25th/75th quartiles)	*Median (25th/75th quartiles)*	*p-value*
Age	77.5 (69/82.3)	76 (67.8/77)	0.365
	No. (%)	**No. (%)**	
Gender			
Male	20 (9.9)	3 (50)	0.05
Female	2 (9.1)	3 (50)	
P/F ratio ≤100	15 (68.2)	5 (83.3)	
P/F ratio >100	7 (31.8)	1 (16.7)	0.432
APACHE II score <17	13 (59.0)	3 (50)	
APACHE II score ≥17	9 (41.0)	3 (50)	0.521
Comorbidities			
Obesity			
No	18 (81.8)	2 (33.3)	
Yes	3 (13.6)	4 (66.7)	0.024
Hypertension			
No	10 (45.5)	1 (16.7)	
Yes	12 (54.5)	5 (83.3)	0.214
Diabetes			
No	14 (63.6)	4 (66.7)	
Yes	7 (31.8)	2 (33.3)	0.695
IHD			
No	18 (81.8)	2 (33.3)	
Yes	3 (13.6)	5 (17.9)	0.303
CKD			
No	19 (86.4)	5 (83.3)	
Yes	2 (9.1)	1 (16.7)	0.545

CKD, chronic kidney disease; IHD, ischemic heart disease

Table 4: Clinical data of tracheostomy group

	Below or equal to 13 days	*Above13 days*	
	N = 22	*N = 06*	
	Median (25th/75th quartiles)	*Median (25th/75th quartiles)*	*p-value*
P/F ratio on admission	91 (76.5/116)	71 (46/97.3)	0.088
APACHE II score	15 (9.75/18.75)	16.5 (10.5/21)	0.849
CORADS Score	5 (5/5)	5 (4.0/5.0)	0.700
Ventilator days	27.5 (20.0/33.3)	29.5 (23.0/41.3)	0.682
Days on MV post-tracheostomy	16 (10.0/24.3)	11 (7.0/24.5)	0.604
Length of stay in ICU	40.5 (26.8/51.3)	34 (27/46.3)	0.682
Length of stay in hospital	40.5 (27.8/53.5)	42.5 (29/52.3)	0.978
	No. (%)	**No. (%)**	
30-day survival			
Yes	16 (72.7)	5 (83.3)	0.522
No	6 (27.3)	1 (16.7)	

Table 5: Thirty-day survival with respect to severity of patients (P/F ratio) and on the day tracheostomy performed from intubation

	P/F ratio ≤100	*P/F ratio >100*		*P/F ratio ≤100*	*P/F ratio >100*
First wave	10	5	Second wave	10	03
Survive (*N* = 11)	7 (70%)	4 (80%)	Survived (*N* = 10)	8 (80%)	2 (66.7%)
T ≤13 days (*N* = 6)	3 (42.9%)	3 (75%)	*T* ≤13 days (N = 10)	8 (100%)	2 (66.7%)
T >13 days (*N* = 5)	4 (57.1%)	1 (25%)	*T* >13 days	–	–

performed less than or equal to 13 days as compared to 45.5% (5/11) when tracheostomy performed beyond 13 days. In the second wave, we achieved a 76.9% (10/13) survival rate of severe ARDS patients undergoing tracheostomy performed at less than or equal to 13 days. The treating healthcare workers of tracheostomized patients were not cross-infected.

Delayed tracheostomy might reduce the risk of medical staff for infection but patients may have to suffer from complications of extended endotracheal intubation such as sedation, ventilator-associated pneumonia, poor pulmonary hygiene, longer ICU stay, and laryngeal complications. Early tracheostomy helps in shortening the weaning phase and reduces associated complications,[13,14,23] especially in COVID-19 patients where there are otherwise failed weaning and extubations.[23] These benefits imply the importance of early tracheostomy.[24]

There is little evidence to support that early vs late tracheostomy improves survival, shortens the duration of MV and ICU length of stay, or reduces lower respiratory tract infections in general ICU patients.[19] In fact, in this study, the length of ICU stay was slightly more in tracheostomy group performed less than or equal to 13 days as compared to tracheostomy group where it was performed beyond 13 days. Thus, our study corroborates with Mata–Castro et al. who have stated that tracheostomy in intubated COVID-19 patients does not reduce the length of ICU stay.[25] With respect to the days on the ventilator similar to Mata–Castro et al. who have stated reduction in the ventilator days, in this study, although not significantly different between the two tracheostomy groups, more than 13 days group had 75th percentile of ventilator days extended beyond 40 days as compared to 33 days in patients where tracheostomy was performed less than or equal to 13 days.

Studies and meta-analyses investigating the effect of tracheostomy timing on clinical outcomes have reported variable results. In patients with ARDS, the mean time for tracheostomy is 14 days,[26] while 10 days is considered as a conventional cut-off for early vs late tracheostomy in general ICU patients.[27] With respect to COVID-19, several national protocols and international guidelines on the management of tracheostomy have been published; however, there is a scarcity of evidence in the literature.[23,28] During the COVID-19 pandemic, the mean time of tracheostomy has often been longer than usual. Open surgical tracheostomy vs percutaneous dilatational tracheostomy (PDT) done after 3 weeks of intubation showed no healthcare worker cross infection, as in a study by Chao et al.[29] Subsequently, risks were taken in the favor of the patients' benefit and time duration was reduced. Angel et al.[30] in a cohort of 270 mechanically ventilated patients, of whom 98 underwent PDT, the mean time to tracheostomy was 10.6 ± 5 days. Kwak et al.[31] reported a mean time of 12.2 days, very close to that reported in a prospective observational study of 100 tracheostomized COVID-19 patients in the United Kingdom (13.9 ± 4.5 days).[22]

Many studies failed to show the favorable outcome of early tracheostomy, like the study by Tang et al.[32] who showed that after comparing with tracheostomies conducted after 14 days of intubation, tracheostomies within 14 days were associated with an increased mortality rate. Recently, Karna et al.[33] have reported that tracheostomy within 7 days of intubation did not improve weaning or survival. In fact, Bhosale and Khatib[34] suggested delaying tracheostomies on the basis of the unproven benefit of the early procedure performed as well as concerns of exposure to the healthcare workers.

This study corroborates with studies demonstrating the beneficial effects of early tracheostomy done to moderate-to-severe COVID-19 ARDS patients. However, in less than 13 days, tracheostomy improved the survival rate but had no benefit with respect to the length of ICU stay. The most important requirement to fight against the pandemic of freeing ICU beds was not achieved.

Conclusion

We believe that time should not be the only limiting factor for considering tracheostomy. Moreover, if indicated, then with proper protective equipment, and now supplemented with vaccination, one should not hesitate to perform even earlier especially in moderate-to-severe COVID-19 ARDS patients.

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