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# Outcomes of COVID-19 Positive and COVID-19 Negative Adult Patients Who Underwent Tracheostomy for Prolonged Intubation in a COVID-19 Referral Center During the Pandemic

# ABSTRACT

**Objective:** To compare outcomes of COVID-19 positive and COVID-19 negative patients who underwent tracheostomy for prolonged intubation in terms of weaning duration, length of ICU and hospital stay, overall and 30-day mortality, and explore risk factors for particular outcomes (mortality, 30-day mortality and weaning duration post tracheostomy).

# Methods:

Design: Setting: Retrospective Cohort Study Tertiary National University Hospital

**Participants:** Of 122 adult patients that underwent tracheotomy between March 30, 2020 and March 30, 2021; 76 adult patients underwent tracheostomy for prolonged intubation were analyzed.

**Results:** Open tracheotomy was performed on 122 adult patients. Seventy six (62.3%) due to prolonged intubation and 46 (37.7%) for airway prophylaxis. Among the former, the mean age was 58.46±16.81 and 54 (71.05%) patients were female, 22 (28.95%) tested COVID-19 positive and 54 (71.05%) tested negative. Mean APACHE II score was 16.62±6.78. Average days of intubation prior to tracheostomy was 29.14±17.66 days. No statistically significant difference in outcomes (weaning days, length of stay, days discharge from ICU and hospital, 30-day mortality, days to death) were noted between COVID19 positive and negative patients who underwent tracheostomy for prolonged intubation. Mortality rates post tracheostomy in this institution appear to be higher than existing literature. On multiple linear regression analysis, days of intubation prior to tracheostomy was associated with increased weaning time post-tracheostomy (OR: 0.35 CI:0.18-0.51 95% p = <.001). This implies that for every additional day of intubation prior to tracheostomy, weaning days increase by 0.35 of a day.

**Conclusion:** Outcomes of COVID-19 compared to non-COVID-19 patients undergoing tracheostomy for prolonged intubation do not seem to be significantly different which is consistent with existing literature.

Keywords: COVID-19; tracheostomy; prolonged mechanical ventilation; ventilatory weaning.

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**Open tracheostomy** is often performed for patients under prolonged mechanical ventilation.<sup>1</sup> During the COVID-19 pandemic, tracheostomy was considered aerosol-generating, posing a high-risk of contamination for medical staff, and adjustments in its indications and conduct were recommended across institutions in various regions around the world.<sup>2</sup> Before the pandemic, patients under prolonged intubation were usual candidates for tracheostomy, involving ~10% of mechanically ventilated patients with significant variability in optimal timing and patient selection.<sup>3</sup> Because of the severity of symptoms in COVID-19 pneumonia, patients often required prolonged periods of mechanical ventilation, with reports of as many as 32% of patients with COVID-19-related MV undergoing elective tracheostomy due to prolonged intubation.<sup>4</sup>

As of this writing, there exists conflicting recommendations on patient selection, timing and performance of tracheostomy and eventual management in the setting of COVID-19.<sup>2</sup> Tracheostomy provides many advantages (improved comfort, reduced sedative and paralytic medications, reduced dead space and airway resistance, lessened work of breathing optimizing pulmonary toilette).<sup>5</sup> However, because of the poor prognosis of COVID-19 pneumonia and the risk to health care professionals, tracheostomies were generally deferred until patients tested COVID negative.<sup>6</sup> Mortality was also high among patients needing mechanical ventilation, with rates of 25% among ICU COVID-19 patients undergoing tracheostomy (close to overall mortality rates of 26%) suggesting that tracheostomy did not impact the natural course of the disease.<sup>5</sup> These studies evaluated outcomes of tracheostomies among patients with COVID-19; but currently, studies comparing the outcomes of tracheostomies between COVID and non-COVID-19 tracheostomies are still lacking especially in the local setting, with none in our hospital.

We aim to compare the outcomes of COVID-19 positive and COVID-19 negative patients who underwent tracheostomy for prolonged intubation in terms of weaning duration, length of ICU and hospital stay, overall and 30-day mortality, and to explore risk factors for particular outcomes (mortality, 30-day mortality and weaning duration post tracheostomy).

# METHODS

With University of the Philippines Manila Research and Ethics Board (UPMREB) approval (UPMREB CODE 2020-585-01), this retrospective review of records considered for inclusion all adult patients who underwent tracheotomy between March 30, 2020 and March 30, 2021 at the Philippine General Hospital (PGH).

Records of adults >18 years old who had undergone open

tracheostomy at PGH during this period were screened. All patients had been tested for SARS-CoV-2 RNA detection via documented polymerase chain reaction (PCR) swab test and were classified as COVID-19 positive or COVID-19 negative. Patients were further classified according to the reason for tracheostomy (prolonged intubation or airway prophylaxis), but only those under the prolonged intubation (intubated 14 or more days) category were compared and analyzed. Excluded were incomplete physical or electronic in-patient records, or those missing the official records of operative technique.

A study registry was formulated using patient case numbers obtained from the census of the operating room complex (since all tracheostomy procedures during the pandemic were only performed in the operating room). Medical records were retrieved and reviewed for demographic data as well as laboratory data, ventilator data, and medical comorbidities identified as potential prognostic risk factors for the outcomes of interest at the onset of the study. Medical comorbidities included in the study were hypertension, type 2 diabetes mellitus, obesity, dyslipidemia, cerebrovascular disease, chronic obstructive pulmonary disease, heart disease, asthma, chronic kidney disease, tuberculosis and malignancies.

The data collected included age, sex, comorbidities, APACHE (Acute Physiologic Assessment and Chronic Health Evaluation) II Score, days intubated, COVID status at the time of procedure, weaning days posttracheostomy, days post-tracheostomy discharged from critical care, days post-tracheostomy discharged from hospital or died, cause of death (if applicable) and total length of stay. For the tracheotomized patients due to prolonged mechanical ventilation, differences in outcome variables between COVID positive and COVID negative patients were analyzed.

# **Data Analysis**

Data was encoded using Microsoft<sup>o</sup> Excel 2016 for Mac version 16.16.18 (Microsoft Corp., Redmond WA, USA). Data for categorical variables were summarized in frequency counts and percentages while summary measures were presented in terms of mean and standard deviation. Pairwise comparisons were performed using Fisher exact test or the chi-square test for categorical variables and independent two-sample t-tests for continuous variables. Multiple logistic regression was used to explore possible factors associated to mortality and 30-day mortality and multiple linear regression for weaning days and its associated factors (95% confidence interval). All statistical results were considered statistically significant at a two-sided level of 0.05. The statistical software, Stata version 16.1 (StataCorp LLC College Station, Texas) was used for all statistical analyses.

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#### RESULTS

Of the 122 adult patients who underwent open tracheotomy at the PGH between March 30, 2020 and March 30, 2021, 76 (62.3%) were due to prolonged intubation and 46 (37.7%) were for airway prophylaxis. Of those who underwent tracheostomy for prolonged intubation, 22 (28.95%) tested positive for COVID-19 and 54 (71.05%) tested negative. Their mean age was 58.46±16.81 (range 19- 91 years old) and most were female (54; 71.05%). The most common medical comorbidity was hypertension (46; 60.53%) followed by cerebrovascular disease (28; 37.33%). Only 34 patients (44.74%) were admitted in an intensive care unit prior to performing the tracheostomy.

Mean APACHE II score was  $16.62\pm6.78$ . All in all, average days of intubation prior to tracheostomy was  $29.14\pm17.66$  days. The baseline characteristics between COVID-19 positive and COVID-19 negative patients were not significantly different. (*Table 1*)

**Table 1.** Characteristics of patients who underwent tracheostomy for prolonged intubation at the PGH from March 30, 2020-March 30, 2021 (N=76)

	ALL N=76; (%)	COVID-19 positive N=22; (%)	COVID-19 negative N=54; (%)	p-value
Age	58.46±16.81	59.27±17.37	58.13±16.73	.7901ª
Sex (female)	54 (71.05)	14 (63.64)	31 (57.4)	.616ª
Area (outside NCR)	37 (48.68)	11 (50.00)	26 (48.15)	.884ª
Hypertension	46 (60.53)	16 (72.73)	30 (55.56)	.165ª
Type 2 diabetes mellitus	19 (25.00)	6 (27.27)	13 (24.07)	.770ª
Dyslipidemia	4 (5.26)	1 (4.55)	3 (5.56)	.672 <sup>b</sup>
Cerebrovascular disease	28 (37.33)	11 (50.00)	17 (31.48)	.093ª
Chronic obstructive pulmonary disease	2 (2.63)	2 (9.09)	0	.081 <sup>b</sup>
Heart disease	6 (7.89)	4 (18.18)	2 (3.70)	.055 <sup>b</sup>
Asthma	1 (1.32)	1 (4.55)	0	.289 <sup>b</sup>
Chronic kidney disease	8 (10.53)	1 (4.55)	7 (12.96)	.262 <sup>b</sup>
Tuberculosis (any subsite)	9 (11.84)	5 (22.73)	4 (7.41)	.073 <sup>b</sup>
Cancer	9 (11.84)	1 (4.76)	8 (14.81)	.216 <sup>b</sup>
Apache II score	16.62±6.78	16.09±6.02	16.83±7.12	.6683 <sup>b</sup>
Days of intubation prior to tracheostomy	29.14±17.66	29.23±10.91	29.11±19.86	.9795⁵

<sup>a</sup>Chi-square test; <sup>b</sup>Fisher exact test

Outcome	ALL (n=45)	COVID-19 POSITIVE (n=15)	COVID-19 NEGATIVE (n=30)	p-value
Weaning Days	12.48±13.29	9.75±10.10	13.64±14.45	.4029ª
Days after tracheostomy before discharged from ICU	18.59±20.78	19.3±23.85	18.21±8.73	.8961ª
Total Days on mechanical ventilation	40.05±21.81	37.92±14.67	40.96±24.42	.6910ª
Days after tracheostomy discharged from hospital	30.07±23.75	26.93±28.80	31.69±21.07	.5352ª
Length of hospital stay	59.51±30.04	55.93±35.00	61.3±27.72	.5781ª

Table 3. Outcomes of Expired Patients who underwent Tracher	ostomy
for Prolonged Intubation	

Outcome	ALL (n=31)	COVID- POSITIVE (n=7)	COVID- NEGATIVE (n=24)	p-value
Days after tracheostomy prior to expiry	41.34±37.96	27.14±26.46	45.86±40.40	.2632ª
30-day mortality	17 (54.84%)	2 (28.57%)	15 (62.50%)	.198 <sup>⊾</sup>
Length of hospital stay	72.45±41.95	58.86±29.70	76.42±44.64	.3383ª

attest; bFisher exact test

Of the 76 who underwent tracheostomy for prolonged intubation, 45 (59.21%) survived and 31 (40.79%) expired. Among the 22 who were COVID-19 positive, 15 (68.18%) survived and 7 (31.81%) expired while among the 54 who were COVID-19 negative, 30 (55.56%) survived and 24 (44.44%) expired. (*Tables 2, 3*)

Among those who survived, there were no significant differences in outcomes between COVID-19 positive and negative patients who underwent tracheostomy in terms of weaning days, total days on mechanical ventilation, discharge from ICU, discharge from hospital after tracheostomy, and total length of hospital stay. Although COVID-19 negative patients who underwent tracheostomy had longer weaning days from mechanical ventilator, longer total days on mechanical ventilation, longer days to discharge from hospital after tracheostomy, PHILIPPINE JOURNAL OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY

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Table 4.	Multiple	Logistic	Regression	on	Factors	Associated	with
Mortality a	and 30-da	ıy Mortali	ity				

Mortality						
Variable	OR (95% CI)	p-value				
Age	0.88 (0.75-1.04)	.135				
Area (NCR)	0.55 (0.03-11.40)	.702				
Days of intubation	0.97 (0.88-1.06)	.491				
APACHE II Score	1.25 (0.84-1.86)	.277				
COVID status (positive)	0.91 (0.03-25.18)	.955				
	30-day Mortality					
Variable	OR (95% CI)	p-value				
Age	1.00 (0.95-1.05)	.921				
Sex (female)	1.60 (0.31-8.22)	.576				
Area (NCR)	0.92 (0.18-4.70)	.922				
Days of intubation	1.00 (0.99-1.00)	.443				
APACHE II Score	0.97 (0.87-1.08)	.567				
COVID Status (positive)	0.21 (0.03-1.61)	.132				

Table 5. Multiple Linear Regression on Factors Associated with Weaning

Weaning (days after tracheostomy liberated from mechanical ventilation)					
Variable	Coefficient (95% CI)	p-value			
Age	0.14 (-0.11-0.39)	.276			
Sex (female)	-2.82 (-10.06-4.40)	.433			
Area (NCR)	-0.53 (-7.30-6.25)	.875			
Days of intubation	0.35 (0.18-0.51)	<.001***			
APACHE II Score	-0.30 (-0.94-0.34)	.352			
COVID Status (positive)	-2.19 (-9.64-5.27)	.556			

 $R^2 = 0.32$  or 32%

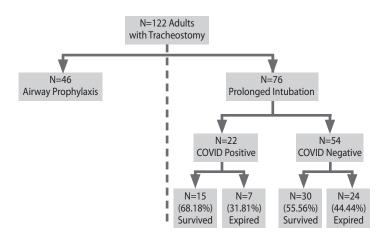


Figure 1. Outcomes of Tracheostomy March 30, 2020 - March 30, 2021

and longer total length of hospital stay, these were all not significant. (*Table 2*)

Among those who expired, there were no significant differences between COVID-19 positive and negative patients who underwent tracheostomy in terms of number of days after tracheostomy prior to expiry, 30-day mortality, and total length of hospital stay. However, COVID-19 negative patients survived longer after tracheostomy and had a longer length of hospital stay prior to expiry. (*Table 3*)

In this cohort of 76 patients, there was a 30-day mortality of 17 (22.36%) overall, involving 2 out of 15 (9.09%) COVID-19 positive patients and 15 out of 54 (27.78%) COVID-19 negative patients. *Figure 1* summarizes the outcomes of the study based on mortality and COVID status.

In analyzing the possible factors associated with mortality and 30day mortality, none of the listed factors (age, area of residence, days of intubation, APACHE II score, COVID-19 status) were significantly associated with the outcomes (mortality, weaning days and 30-day mortality). (*Table 4*) However, in terms of weaning days, for every additional day of intubation prior to tracheostomy, weaning days increased by 0.35 of a day (CI:0.18-0.51 95% p = <.001). (*Table 5*)

None of the participants were discharged against medical advice or transferred to a different institution. None of the patients who survived in the course of the study were decannulated.

## DISCUSSION

Our current study found no statistically significant differences in outcomes (weaning days, length of stay, days to discharge from ICU and hospital, 30-day mortality, days to death) between COVID-19 positive and COVID-19 negative patients undergoing tracheostomy for prolonged intubation. In our study, 59.21% (45/76) were successfully liberated from mechanical ventilation and discharged. Among the COVID-19 positive, 68.18% (15/22) while among the COVID-19 negative, 55.56% (30/54) were weaned and discharged. Mean days to wean off mechanical ventilation and days post-tracheostomy to discharge from the hospital were shorter for those who were COVID-19 positive (9.75 $\pm$ 10.10 days) than for those who were COVID-19 negative (13.64 $\pm$ 14.45 days), but the difference was not statistically significant (p = .4029; p = .5352, respectively).

These findings appear consistent with the existing literature. The COVID Trach collaborative group from the UK NHS study reported 11..00 median days (IQR 7.00 – 18.00) liberation from mechanical ventilation after tracheostomy COVID-19 patients with a weaning success rate of 52% (219/465) during the first two months of the pandemic,<sup>7</sup> while a national cohort study in Spain reported successful liberation from

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mechanical ventilation in 52.1% (842/1616) of patients undergoing tracheostomy.<sup>8</sup> In a systematic review on COVID-19 patients, metaanalysis showed 61.2% of patients were weaned from mechanical ventilation, the overall weighted mean time from tracheostomy to mechanical ventilatory weaning was 24.14±10.19 days.<sup>9</sup> A study done prior to the pandemic on tracheostomy for respiratory failure noted that 57% of survivors were liberated from mechanical ventilation in 16 median days (IQR 1-93) post tracheostomy.<sup>10</sup>

In our study, the mean hospital stay among COVID-19 positive patients ( $55.93\pm35.00$ ) was shorter than among COVID-19 negative patients ( $61.3\pm27.72$ ). However, the difference between the two groups was not significant (p= .5781).

Our post-tracheostomy mortality rates appear higher than those in other studies. Our overall mortality was 40.79% (31/76). The mortality rate among those who underwent tracheostomy was 31.81% (7/22) for COVID-19 positive patients and 44.44% (24/54) for COVID-19 negative patients. From existing literature, post-tracheostomy COVID-19 mortality rates ranged from 19.23 to 23.7%.<sup>9, 11</sup> In studies prior to the pandemic, hospital mortality rates for prolonged intubation patients who underwent tracheostomy were 19-20%.<sup>3,10</sup> It is interesting to note that a study comparing crude ICU and hospital mortality of ventilated COVID-19 and non-COVID-19 (including those who may or may not have undergone tracheostomy) were at 43.8 vs. 40% and 43.8 vs. 41.1% respectively; which were evaluated to have no significant difference  $p > .05.^{12}$ 

Overall, mortality data appears to vary across the literature. The higher mortality rates in our institution particularly in the COVID-19 negative group could be attributed to selection bias as we are the national end-referral center for both COVID-19 (severe and critical) and non-COVID-19 cases.

It is important to note that there were no statistically significant differences in outcome variables between COVID-19 and non-COVID-19 groups. This is consistent with the findings of Tang, where tracheostomy-specific and all-cause mortality rates between the COVID-19 and non-COVID-19 groups were not statistically significant—indicating that tracheostomy is safe to perform on COVID-19 patients.<sup>13</sup>

On the association of factors to outcomes of post-tracheostomy patients, we did find that the number of days of intubation prior to tracheostomy was associated with increased weaning time posttracheostomy, implying that for every additional day of intubation prior to tracheostomy, weaning days increase by 0.35 of a day. Although the comparison of outcomes between early and late/delayed tracheostomies is not within the scope of this study, it is interesting to look into how the additional days of intubation increase weaning time. In a systematic review in 2012 on early vs. late tracheostomy outcomes, no mortality difference was found.<sup>14</sup> In another systematic review on COVID-19 tracheostomy patients, no difference was found in mortality (RR 1.57, p = .43) between early and late tracheostomy, and timing of tracheostomy was not able to predict time to decannulation.9 Although delaying tracheostomy for patients with COVID-19 might reduce risks for staff, extended duration of intubation, sedation, mechanical ventilation, and ICU stay associated with such delays can lead to further complications.<sup>2</sup> Questions are raised on the utility of negative tests prior to tracheostomy procedure and whether the detection of viral RNA by PCR predicts risk of infectivity to health care professionals still uncertain. In the study of the COVID Trach collaborative group, delaying tracheostomy to achieve negative tests could possibly prolong endotracheal ventilation and thus lessen the potential benefits of the procedure whilst increasing the risk of complications relating to prolonged intubation.7

In our study, average days of intubation prior to tracheostomy were 29.14±17.66; 29.23±10.91 days for COVID-19 positive and 29.11±19.86 days for COVID-19 negative. The timing of tracheostomy for patients in our study was notably longer than existing literature. In a multicenter cohort in Japan in 2021, tracheostomy for 66 COVID-19 patients was performed at a median of 15 days (IQR: 10.5-21.5) after commencement of mechanical ventilation.<sup>15</sup> In a national cohort in Spain, the median timing of tracheostomy was 12 days (4-42 days) since orotracheal intubation.<sup>11</sup> In practices of other centers, the tracheotomy was performed within 24 hours from the indication.<sup>16</sup> This delay in surgery in our institution is not purely by choice of the medical team but due to the inherent limitations on accommodation with limited operating rooms during this time, existing hospital operational protocols on COVID-19-related surgeries, and poor surgical optimization. Given this finding, important decisions have to be made balancing the possible effect of further prolonging intubation vs. optimal surgical timing coupled with existing hospital policies on infectious diseases.

Our study has several limitations. Because this was a retrospective observational study, our results are more prone to misinterpretation and residual confounding. A recent study suggested tracheostomyrelated complications and decannulation as an outcome to monitor.<sup>9</sup> Decannulation rates were not monitored in the study sample due to unavailability of out-patient records for their specific follow up. This can be explored further to analyze the survival rate of the cohort of patients. In addition, day-by-day knowledge on COVID-19 progresses. Since the study was performed prior to public availability of COVID-19 vaccinations, the effect of vaccinations on COVID-19 related mortalities was not studied. Hence it can also be recommended to extend the existing study with a larger sample size, including vaccination status **ORIGINAL ARTICLES** 

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as a comparator for analysis since most of the countries now have high vaccination rates.

In conclusion, outcomes of patients under prolonged mechanical ventilation between COVID-19 and non-COVID-19 tracheostomies do not seem to be significantly different. In our study, a day longer of intubation is found to be associated with a 0.35 day longer weaning time; with no associations to mortality or 30-day mortality. Evaluating the need and timing for tracheostomy in both groups of patients is still best decided on the overall status of the patient in accordance with existing hospital protocols and relevant guidelines.

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