



A Scrutiny of Diverse Parameters and Post Tracheostomy Outcome with Quality of Life in Severe COVID-19 Infection

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Objectives: The primary aim was to investigate the prognostic factors among critically ill COVID-19 patients, who required mechanical ventilation and tracheostomy. Secondary aim was to analyse their Health-related Quality of Life (HrQoL) at 90 days after ICU discharge.

Study Design & Setting: An observational cohort study conducted at a quaternary care setting in Bengaluru, India.

Patients' demographics and clinical data including inflammatory markers, ventilatory parameters, details of intubation and tracheostomy were analysed.

Methods: Data were analysed and expressed as mean with percentage (%). Data from the 2 groups, survivors and non- survivors, were compared using Fisher's exact test for categorical variables and t test for continuous variables. The survivors and 'age and sex' - matched general population (not infected by COVID-19), from the same geographical area were subjected to questionnaires by the EuroQol group.

Results: Among 33 critically ill COVID-19 patients who underwent tracheostomy, 15 patients (45.4%) survived. Comorbidities and COVID-19 related complications were noted high among the non-survivors. Ventilatory parameters FiO₂, PEEP and PaO₂/FiO₂ were better in the survivors group which favored the recovery. Complication rate of tracheostomy was 18.1%. Ventilation

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liberation rate from our study was found to be 45.4% and decannulation rate 42.4%. Low values of D-Dimer and Ferritin strongly favored better recovery. Health-related Quality of Life of the survivor group and general population were comparable.

Conclusion: Ventilatory parameters, inflammatory markers and comorbidities do have a role in prognosticating outcome in patients who required tracheostomy. At 90 days follow up there was no significant impact of the disease in the quality of life of survivors.

Keywords: COVID-19; ARDS; ICU; ventilator; tracheostomy; health-related quality of life.

1. INTRODUCTION

COVID 19 has emerged as a pandemic affecting 220 countries and 23 crore population worldwide with a death toll of 48 lakhs till date. The first case was reported in Wuhan, Hubei province of China in December 2019. Cases peaked in the month of September 2020 and waned by February 2021, soon after which the second wave started. The increase is mainly because of genetic mutations resulting in contagious virus variants and lack of resources to contain the spread. It has surfaced as an unprecedented global healthcare concern.

The clinical spectrum of COVID-19 is broad, ranging from asymptomatic infection or mild symptoms like fever, cough, nausea, vomiting, diarrhoea to massive involvement of lower respiratory tract resulting in acute respiratory distress syndrome (ARDS). Complications such as myocardial dysfunction, shock, thromboembolism and multi-organ failure add to its severity leading to poor recovery from the disease [1].

Hypoxemia and worsening respiratory parameters lead to an overwhelming increase in the number of patients requiring prolonged mechanical ventilation, creating a rapid surge in the requirement of ventilator and Intensive care unit (ICU) beds. Overall, between one-fourth and one-third of hospitalized patients require ICU admission [2] and around 2.3 to 15.2 % of patients afflicted with COVID-19 require mechanical ventilation [3,4].

Tracheostomy is crucial to facilitate weaning of patients from ventilator support (ventilation liberation), hastening the shift out from ICU in this resource constrained scenario. It helps patients to get off the mechanical ventilation, reduces the respiratory effort in patients with limited pulmonary reserves, shortens the dead space and enables the suctioning of accumulated secretions. It reduces airway trauma from prolonged tracheal intubation and

perioral pressure sores, in addition to benefits such as reduced risk for ventilator-associated respiratory muscle atrophy, ability to communicate, reduced sedation, and maintenance of ICU capacity.

Decision making in the timing of tracheostomy in COVID-19 patients is a matter of concern due to the high infectivity rate leading to morbidity and mortality. Tracheostomy, being an aerosolizing procedure, has the potential risk of transmission of infection to health personnel, especially during the initial 10 days with high viral load. On the other hand, the exhausting ICU beds and rising cases disproportionate to the resources necessitates the procedure. The American Academy of Otolaryngology-Head and Neck Surgery recommends delaying tracheostomy for at least 14 days for allowing sufficient decline in viral load [4]. They recommend performing the procedure only in those patients displaying clinical signs of improvement, which signifies a reduced viral load. This is typically after 2–3 weeks of ventilation. Other recommendations are to perform tracheostomy not before two negative SARS-CoV2 tests have been obtained or only when the expected chance of recovery is high.

Some of the recent studies propagate early tracheostomy. Performing early tracheostomy in COVID-19 patients might lead to improved outcomes with significantly higher decannulation rates. Livneh et al concluded the above by comparing their 2 study groups - early tracheostomy (done within 7 days) and late tracheostomy (done after 8 days) [5]. Similar findings were observed by Paul et al. Early tracheostomy as per their description included those who underwent tracheostomy within 10 days [6].

Our health system was unarmoured to fight COVID-19 pneumonia cases during the initial surge of cases. With the number of cases increasing disproportionate to the resources, lack of available beds, oxygen supply and unified guidelines, a lot of chaos happened in the

effective management. Ventilator availability was one among these requiring special mention and hence the importance of tracheostomy to facilitate weaning and reserving the ventilator support for another needy patient.

Through this study, we aimed to detect relevant parameters that help patient selection and planning of tracheostomy and prognosticating the outcome of treatment.

Our secondary objective was to analyse the HrQoL of critically ill COVID-19 patients at Day 90 of discharge.

Although it is known that patients who survive may be susceptible to developing poor HRQoL and persistent symptoms after ICU discharge there are very few studies which looked into this aspect [7,8].

2. MATERIALS AND METHODS

The COVID-19 Pneumonia patients who were mechanically ventilated in view of worsening respiratory parameters in a period of seven months from September 2020 to March 2021 were included in the study. Once the decision to go ahead with Tracheostomy was made by the ICU physician and communicated to the Otorhinolaryngologist, the preparatory workup was started to optimize the general condition of the patient. Since most of the patients were on heparin, a coagulation profile was done and if in the acceptable range, the anticoagulant was stopped as per the guidelines. Informed written consent of the patient's relatives were obtained after explaining the options, merits and risks of Tracheostomy. Manipal hospital Bangalore, ethics committee approval was obtained. Demographic, medical comorbidities and clinical data including ventilatory parameters, duration of intubation were collected for analysis later. A close follow up of the critical events (pertaining to COVID-19 and tracheostomy) that occurred during the hospital stay were recorded. Details of weaning and complications were recorded for analysis.

All those who recovered were followed up over a period of 90 days post discharge from ICU to analyse the general physical and mental status. The following questionnaires were handed over to patients at Day 90 after discharge. 1)European quality of life questionnaire- EQ-5D-3L 2)EQ- VAS (0-100) visual analogue scale 3)Post covid functional status scale (0-4). Similar

questionnaires (1 and 2) were distributed among the sex and age-matched random sample from the general Indian population. They were interviewed in parallel to create a reference group.

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HRQoL was assessed using the EQoL Group Association five-domain, three level questionnaire (EQ-5D-3L), which consists in two sections: the descriptive system and the visual analogue scale. The descriptive system assesses five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, with three possible responses options: no problems, some problems, or extreme problems. The visual analogue scale (EQ-VAS) represents 0 = worst imaginable health and 10 = best imaginable health. We chose this as this is cognitively undemanding, taking only a few minutes to complete [9]. Functional status was assessed according to the recently described post-COVID-19 functional status scale (PCFS) [10].

Data were analysed and expressed as mean with percentage (%). The study sample was divided into two groups, survivors and non-survivors. Comparisons were performed using Fisher's exact test for categorical variables and t test for continuous variables.

2.1 Procedure

The tracheostomy team included an Otorhinolaryngologist experienced in performing tracheostomy, an assistant to the main surgeon, an anesthetist for administering General Anesthesia, a nursing staff, a support staff and Operation theater (OT) technician. Complete personal protective equipment (PPE) kit was ensured for the entire health care team for protection against COVID-19 spread. Patient was shifted from ICU to the OT with complete monitoring, and assisted ventilation after clearing the route. All aseptic precautions were taken during the procedure. Sterile surgical gown, cap and mask over the PPE along with double surgical gloves were used to ensure asepsis during the procedure. Before starting the procedure, team members were assigned their roles clearly to avoid any communication gap and chaos.

Oral and endotracheal suction was done to minimize the aerosol generation during the procedure. Temporary cessation of ventilation

prior to incision of trachea, minimal suction and rapid inflation of cuff after introduction of tracheostomy tube were ensured to minimize aerosol generation. Non-fenestrated cuffed tracheostomy tube was preferred to avoid aerosol/air leak. Ventilation was resumed after checking the cuff and confirming the position of the tracheostomy tube with end tidal carbon dioxide by the anesthetist. Endotracheal tube was removed at the end of the procedure wrapped in the covering sheet to avoid contamination by tracheal secretions. The patient was shifted back to ICU, accompanied by Anaesthetist and support staff following COVID precautions. After the procedure proper doffing in a dedicated area and sanitization of the theater were done.

The following measures were advocated to minimize viral transmission during and after tracheostomy like expert surgical team, avoiding repeated connections and disconnections of ventilator circuits, minimal use of diathermy, stopping mechanical ventilation just before opening the trachea, closed suction circuits and negative-pressure room.

After tracheostomy, sedation was reduced progressively and a weaning protocol was initiated based on progressive reduction in pressure support. Once the weaning process was completed and the patient was able to maintain spontaneous ventilation for 48 hours, the tracheostomy tube cuff was deflated after placing a heat and moisture exchange filter with supplementary oxygen therapy at the top of the tracheostomy tube. During subsequent days, the tracheostomy tube was corked and observed in the ward. The tube was removed and the tracheostoma was taped when the patient was able to maintain adequate ventilation by himself with the corked tracheostomy tube and able to expel the tracheal secretions by coughing.

3. RESULTS

Tracheostomy was performed on 33 mechanically ventilated patients with confirmed COVID-19 pneumonitis in our quaternary care setting in a period of 7 months (from September 2020 to March 2021). Among them, 18 patients (54.5%) succumbed to death within a period of two months post tracheostomy due to various ailments and complications associated with the pneumonia and multi-organ failure. 15 patients (45.4%) recovered well and leading a normal life except for a single patient who is still tracheostomised due to aspiration and vocal cord

palsy. No harm or adverse events were encountered during the procedure.

Elderly with a mean age of 62 years and males (69%, n=23) constituted the majority of the study population. The patients were categorised into two groups: Non survivors and Survivors. The mean age was calculated to be 62.9 years among non survivors and 61.8 years among survivors with a p-value of 0.77. Since $p > 0.05$ the population characteristics were homogenous with respect to our analysis. Male preponderance of 69.7% in total and among each group was observed which is similar to the general scenario of males affected commonly than females. [4] Also, it was noted that females have more chances of survival when compared to males.

The most common medical comorbidity was Diabetes (DM 66.67%) followed by hypertension (HTN 57.5%) with no statistically significant difference noted between the 2 groups. HTN, DM, Obesity were the most common comorbidities in other studies too [6] In comparison, the prevalence of other comorbidities CVA, CKD, COPD, Cardiac disease and Carcinoma were high among non-survivors which could have contributed to the poor recovery from pneumonia. Both non-survivors and survivors had post COVID-19 complications like AKI, sepsis, shock, thrombovascular and neurologic which were marginally more in the non-survivors group.

Majority of patients in both groups were tracheostomised to facilitate weaning (61% in non survivors and 73% in survivors group) and the next common indication was prolonged ventilation. Only 3 patients (out of which 2 from non-survivors group) had attempts of failed extubation and underwent tracheostomy. Both groups were tracheostomised after 10 days of intubation. The mean duration of intubation was 11.8 days in non-survivors and 10.6 days among survivors.

The ventilatory parameters FiO_2 , PEEP and PaO_2/FiO_2 within 24 hours of tracheostomy were compared and found to be statistically significant. Non-survivors had high FiO_2 and PEEP with a mean value of 0.45 and 8.1 respectively whereas survivors had mean FiO_2 0.40 and PEEP 6.7. PaO_2/FiO_2 which is a good prognostic indicator of recovering lung condition averaged to 198.3 in non-survivors group and 217.8 in survivors group. The blood parameters related to COVID-19 severity D-Dimer and Ferritin were compared and low values strongly favored better recovery.

Table 1. Comparison of Demographic factors and co-morbidities among the two groups (Using Fisher's exact test analysis)

	Variables	Non-survivors (n=18)	Survivors (n=15)	Total	p value
1.	Age(years)	62.94	61.80	62.37	0.77
2.	Sex (Male: Female)	14:4 (77.8%:22.2%)	9:6 (60%:40%)	23:10 (69.7%: 30.3%)	0.26
3.	Comorbidities				
	Hypertension	12(66.6%)	7(46.6%)	19(57.5%)	0.24
	DM	14(77.7%)	8(53.3%)	22(66.6%)	0.13
	CVA	2(11.1%)	0	2(6.06%)	0.18
	CKD	2(11.1%)	1(6.6%)	3(9.09%)	0.65
	COPD	3(16.6%)	1(6.6%)	4(12.1%)	0.38
	Cardiac disease	2(11.1%)	2(13.3%)	4(12.1%)	0.84
	Carcinoma	2(11.1%)	0	2(6.0%)	0.18
4.	Post-covid complications				
a.	AKI	11(61.1%)	9(60%)	20(60.6%)	0.94
	ARDS	18(100%)	15(100%)	33(100%)	
	Sepsis	14(77.7%)	11(73.3%)	25(75.7%)	0.76
	Shock	14(77.7%)	10(66.6%)	24(72.7%)	0.45
	Thromboembolism	4(22.2%)	3(20%)	7(21.2%)	0.87
	Neurologic	11(61.1%)	11(73.3%)	22(66.6%)	0.55

Table 2. Comparison of Ventilatory and blood parameters among the two groups

Variables	Mean among Non-survivors	Mean among Survivors	t value	p value
Duration of intubation(days)	11.8	10.6	0.64	0.53
FiO2	0.45	0.40	2.3	0.03
PEEP (cm H2O)	8.1	6.7	3.1	0
PaO2	85.5	91.2	-0.62	0.54
PaO2/FiO2	198.37	217.82	-0.69	0.50
D-Dimer	7.9	1.9	2.0	0.05
Ferritin	1775	1000	2.02	0.05

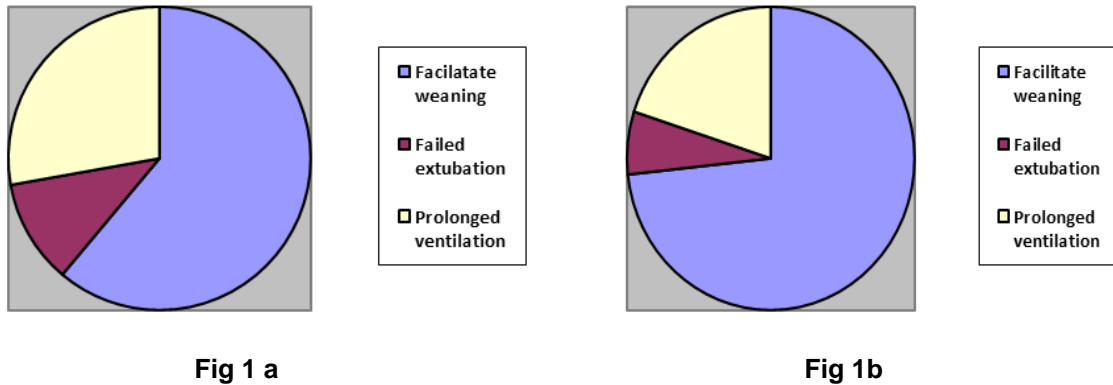


Fig. 1. Pie charts comparing Indication for tracheostomy among Non-survivors (Fig 1a) and Survivors (Fig 1b)

Most patients were decannulated in 2-3 weeks' time with an average of 10 days, unless complicated by sepsis, shock or bronchopleural fistula with pneumothorax. These complications deteriorate the general health of the patients thereby delaying the weaning from the ventilator. The complications were less frequent in COVID-19 patients with 4 cases of tracheostomy bleeding out of which one patient expired and the rest 3 were managed conservatively. Similarly, 2 tube blocks requiring immediate tube change and 3 cases of bronchopleural fistula were noted. The fistulae were later recognised as a sequel of the COVID-19 and unrelated to tracheostomy. The overall complication rate was calculated to be 18.1%.

The overall death rate of severe COVID-19 patients requiring tracheostomy from our institution amounts to 54.5% which means nearly half of the patients could not be saved in spite of all efforts taken. The high mortality is related to the general health and systemic complications

associated with COVID-19. Though it is advisable to wait for the general condition to improve, its applicability in a resource-constrained situation is limited.

HrQoL survey and PCFS in our survivor group (n=15) lead to the following findings. 93.3% (n=14) of our survivors were successfully decannulated. At the end of 90 days the majority of our subjects 93.3% (n=14) reported that they were experiencing good health (marked as a health score between 50 to 100 on VA scale of 0 to 100) and 13.3% (n=13.3%) experienced perfect health (VAS 100). Only 6.7% (n=1) still had the tracheostomy hence marked only 30 on VAS. In the assessment using the PCFS, 53.3% of patients had no limitations in their everyday life and no symptoms, pain, depression or anxiety. Whereas 13.4% still suffers severe limitations in everyday life - being not able to perform all usual activities to take care of themselves. However in comparison with the general population there was no significant difference.

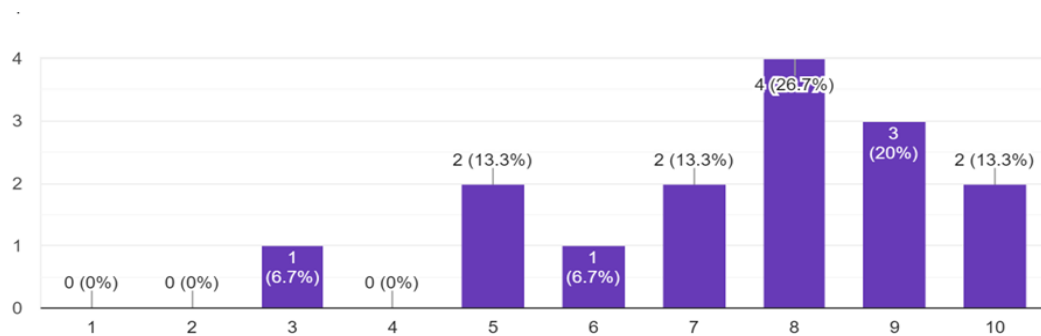


Fig. 2. Graph showing the EQ VAS (0-10) Score of the survivor group

Table 3. Comparison of Quality of life and functional status of the study sample (n=15) and age - sex matched general population (n=15)

		Group		Total	p value
		Survivor	General Population		
Mobility	No problems	13 (86.7%)	10 (66.7%)	23 (76.7%)	0.131
	Some problems	1 (6.7%)	5 (33.3%)		
	Unable to walk	1 (6.7%)	0 (0.0%)		
Self-care (e.g., washing or dressing myself)	No problems	11 (73.3%)	15 (100.0%)	26 (86.7%)	0.099
	Some problems	3 (20.3%)	0 (0.0%)		
	Unable to wash or dress myself	1 (6.7%)	0 (0.0%)		
Usual activities (e.g., work, study, housework, family or leisure activities)	No problems	11 (73.3%)	13 (86.7%)	24 (80.0%)	0.338
	Some problems	2 (13.3%)	2 (13.3%)		
	Unable to perform	2 (13.3%)	0 (0.0%)		
Pain/ Discomfort	No pain or discomfort	9 (60.9%)	5 (33.3%)	14 (46.7%)	0.143
	Some pain or discomfort	6 (40.0%)	10 (66.7%)		
Anxiety/ Depression	Not anxious or depressed	10 (66.7%)	10 (66.7%)	20 (66.7%)	1.000
	Moderately anxious or depressed	5 (33.3%)	5 (33.3%)		
EQ-VAS (0 to10)		7.47 (1.995)	7.20 (1.568)		0.687

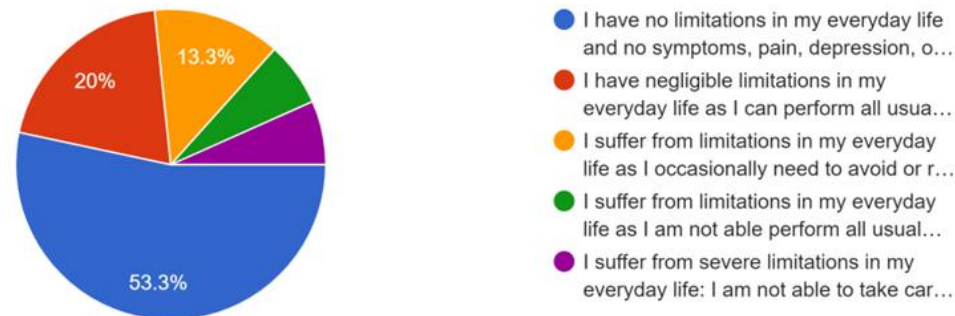


Fig. 3. How much are you currently affected in your everyday life by COVID-19? Pie Chart Showing Results of the post covid functional scale among survivors

Data are expressed as n (%) or mean (standard deviation). Quality of life was measured using the EuroQol, five-dimension, three-level questionnaire and the EQ-VAS (0 to 10).

EQ-VAS, EuroQol visual analogue scale; EQ-5D-3L, EuroQol Group Association five-domain, three-level questionnaire.

4. DISCUSSION

COVID-19 disease with its rapid evolution in society and dramatic deterioration of patient condition turned out to be a major threat to the health care system. Hospitals with limited facilities for ventilators and an overwhelming number of patients requiring ventilation suffocated the health system during the COVID waves both first and second. Tracheostomy had a critical role in weaning of patients thereby making available the ventilators for the next on demand.

On analysing the outcome following tracheostomy, only 45% of the total study population are alive. The majority 54% died in the immediate period following covid complications, except for one which was due to major hemorrhage from tracheostomy site. Though earlier studies reported high mortality rate of 52 to 86% among mechanically ventilated COVID-19 patients, subsequent studies from US and Italy reported it to be 24 to 26%[11].

Elderly constituted the majority of the population who underwent tracheostomy following COVID-19 pneumonitis which is similar to other studies. Males dominated the number in total and among each group signifying the fact that they are more prone for complications and requirement of mechanical ventilation. The similar result has been obtained in other studies conducted in the UK, US. Better the general health of an individual, the lesser the complications and early recovery [12].

Ventilatory parameters FiO_2 , PEEP, PaO_2 , PaO_2/FiO_2 represent how bad the lung is in lung pathologies like ARDS. Studies show that the better these values and lesser the oxygen requirement of the patient, the chance of survival and weaning is increased manifold. In our study, the parameters FiO_2 and PEEP show a significant difference between non-survivors and survivors. PaO_2 and PaO_2/FiO_2 were high among survivors but not to the level of significant

difference, which can be due to the small sample size. Hence considering these parameters while planning tracheostomy would help predict outcome.

Patients suffering from ARDS, with or without COVID-19 are known to have long term effects of the infection. The term 'long covid' is being used to describe illness in people who have either recovered from COVID-19 but are still reporting long-term effects of the infection or have had the usual symptoms far longer than would be expected. A probe into the quality life of post covid patients will help in determining the contributory factors and help in setting up post covid care clinics and planning rehabilitation measures [12,13].

Manueal Taboeda et al in their study , found that at 6 months after requiring ICU admission, a large proportion of the study group had worsened quality of life, diminution of functional status, and persistent symptoms compared with their pre-COVID-19 status. Their data was consistent with prior studies that reported poor long-term outcomes in critically ill survivors of ARDS not caused by COVID-19 [7,14].

We found that the HRQoL of COVID-19 critically ill survivors from our study was comparable to that of the general population. Our findings are slightly different from the existing studies probably because of the small sample size. In a recent study by Lorenzo et al , age, sex, number of comorbidities, ARDS class, duration of invasive mechanical ventilation, and occupational status have correlation to the QoL . They also observed that the clinical severity at ICU admission was poorly correlated to HRQoL[13].

A limitation of present study is that the sample size is small. It only included critically ill patients admitted to ICU who were on ventilators who required tracheostomy .The perceptions of the survivors about quality of life and functional status could be biased especially after going through a traumatic experience.

5. CONCLUSION

Ventilatory parameters and other biomarkers are good prognostic indicators in COVID-19 patients. Patients with better lung compliance (as indicated by FiO_2 , PEEP, PaO_2/FiO_2) signifies early recovery and decannulation within 10 days and a mean ICU stay of 26.2 days. These parameters require attention while planning for

tracheostomy to prognosticate the outcome. In scenarios when resources are constrained and risks of surgical procedures are high, determining patient parameters that predict outcome will be advantageous.

Study of the QoL of ICU survivors will help health services to plan ongoing support and rehabilitation of survivors of COVID-19 patients with ARDS.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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