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Long-term Outcomes After Tracheostomy for COVID-19



Resultados a largo plazo después de la traqueotomía en pacientes con COVID-19

Dear Editor,

Since the emergence of the 2019 novel coronavirus (SARS-CoV-2) infection in Wuhan, China in December 2019, it has rapidly spread across China and many other countries. Although the majority of patients have only mild symptoms, some of them deteriorate and develop respiratory failure owing to severe acute respiratory distress syndrome (ARDS) requiring ICU admission, intubation, and mechanical ventilation.^{1,2} For patients needing prolonged mechanical ventilation, percutaneous or surgical tracheostomy have been proposed,^{3–5} however these patients are susceptible to developing increased nosocomial infections, mortality rates and existence of relevant impacts on their quality of life in the months following Intensive Care Unit (ICU) discharge. The aim of present study was to describe patient characteristics, hospital course, and long-term outcomes (at six months) such as mortality, quality of life, functional status, and persistent symptoms of critical COVID-19 patients who needed a tracheostomy during the March–April 2020 outbreak.

In this prospective, multicenter, observational cohort study, we included all patients admitted to ICU with severe respiratory failure by COVID-19 requiring tracheostomy for prolonged mechanical ventilation in seven Hospitals in Northwestern Spain, during the March–April 2020 outbreak. A confirmed case of COVID-19 was defined by a positive result on a reverse-transcriptase-polymerase-chain-reaction (RT-PCR). The following information was collected during ICU admission: demographics, coexisting disorders, treatments, Acute Physiology and Chronic Health Evaluation II (APACHE II) score, laboratory tests, nosocomial infections, complications during tracheostomy, duration of mechanical ventilation, time to tracheostomy after mechanical ventilation was initiated, time to decannulation after tracheostomy was performed, ICU and Hospital outcomes. All patients who survived ICU admission were included to assess health-related quality of life (HRQOL), functional status, and persistent symptoms, using a structured telephone survey conducted by designated trained research coordinators at participating sites, six months after hospitalization. Patients were also asked to retrospectively recount their quality of life and functional status 3 months before COVID-19. HRQOL was assessed using the EuroQol 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 measures five domains of health including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression and assesses each domain across three levels: no problems, some problems, or extreme problems. The visual analogue scale (EQ-VAS) represents 0 = worst imaginable health and 100 = best imaginable health (5). Functional status was assessed according to the recently described post-COVID-19 functional status scale (PCFS), which consists

in an ordinal scale for assessment of patient-relevant functional limitations⁶ (0: No limitations in my everyday life, 1: Negligible limitations with persistent symptoms, 2: Limitations in my everyday life, and occasionally need avoid or reduce usual activities, 3: Limitations in my everyday life, and I am not able to perform all usual activities, 4: Severe limitations. I am dependent from another person due to symptoms). Other persistent symptoms potentially correlated with COVID-19 were obtained also. All analyses were performed using R (version 4.0.2; R Foundation for Statistical Computing) and IBM SPSS (version 26; SPSS, Inc, Chicago, IL, USA). The ethics committee of Galicia, Spain (code No. 2020-188) approved this study. Informed consent was obtained from all participants.

From March 1 to April 31, 2020, a total of 98 COVID-19 patients were intubated needing mechanical ventilation in the ICUS in seven Hospitals of Galicia. Of these patients, twenty-nine (29.6%) needed tracheostomy and they were included in the present study. Mortality rate during Hospital admission was higher in patients who needed tracheostomy (12/29 (41%)) compared with patients who did not need tracheostomy (13/69 (18%), ($p < 0.001$). Of the 29 tracheostomized patients, 17 (59%) remain alive at six months after ICU discharge. **Table 1** displays patient characteristics, clinical course, tracheostomy complications, nosocomial infections, treatments, and ICU and Hospital outcomes of the 29 patients. At six months the 17 survivors responded to a 6-month follow-up survey. Of the survivors, worsened quality of life measured with the EQ-VAS was observed among 84% of patient. The EQ-VAS decreased from 87.06 (14.48) to 61.18 (18.33) ($p < 0.001$). With the EQ-5D, we observed that 76% patients had moderate to extreme problems in any of the five dimensions studied. Eleven (65%) patients reported problems with mobility, 11 (65%) patients reported problems with usual activities, 8 (47%) patients reported problems with self-care activities, 9 (52%) patients reported pain or discomfort, and 10 (59%) reported anxiety or depression. At six months interview, fourteen (82%) and 10 (59%) patients had lowered one and two grades respectively in the Post COVID-19 functional status scale. Eleven (65%) patients had persistent functional limitations (grade 2–4 in the PCFS). A high proportion of patients recounted dyspnoea on exertion (65%), asthenia (53%), insomnia (29%) myalgia (23%), and arthralgia (18%). Only 2 (12%) patients were completely free of persistent symptoms at six months (**Table 1**).

This study represents a description of critically ill COVID-19 patients that required a tracheostomy in seven hospital in the northwest of Spain. These patients had a high rate of mortality, nosocomial infections, and prolonged ICU and Hospital stay similar to other previous studies.^{3–5} At six months, a large proportion of survivors had persistent symptoms and reduced quality of life and functional status.

The limitation of this study includes the relatively small number of patients, and that the study was conducted in seven hospitals in Northwest Spain and may not be representative of other patient populations. However, these findings have implications for health service planning and for planning the ongoing support and treatment of survivors of critical illness by COVID-19. There is a need to

Table 1
Demographics and clinical characteristics during ICU and Hospital admission of the study sample (n = 29).

Demographics	All patients n = 29
Age, mean (SD)	69.59 (8.16)
Male sex, No. (%)	18 (62.1)
Coexisting conditions, No. (%)	
Hypertension	18 (62.1)
Hyperlipidemia	15 (51.7)
Diabetes	6 (20.7)
Asthma	3 (10.3)
COPD	4 (13.8)
Heart disease	8 (27.6)
Obesity (BMI ≥ 30 kg m ⁻²)	10 (34.5)
Not comorbidity	3 (10.3)
Home treatments, No. (%)	
ACE inhibitors	8 (27.6)
Antiplatelets	7 (24.1)
Statins	13 (44.8)
Laboratory parameters, median (IR)	
Lymphocyte count, /μL	510.0 (295.0–795.0)
Lactate dehydrogenase, U/L	480.0 (385.5–856.5)
D-dimer, ng/mL	1602.0 (750.5–3930.0)
C-reactive protein, mg/L	13.0 (7.7–29.3)
Serum ferritin, μg/L	906.0 (604.3–1303.0)
ICU medical treatments (No. (%))	
Lopinavir–ritonavir	25 (86.2)
Hydroxychloroquine	29 (100)
Azithromycin	28 (96.5)
Tocilizumab	16 (55.2)
Corticosteroids	28 (96.5)
Antibiotics	29 (100)
Anticoagulant intermediate or high dose	28 (96.5)
Characteristics during ICU admission	
APACHE II, mean (SD)	19.28 (6.76)
Renal replacement therapy, No. (%)	5 (17.2)
Use of prone positioning, No. (%)	24 (82.8)
Duration since intubation to tracheostomy, days, mean (SD)	15.0 (12.0–17.5)
Duration of MV, days, mean (SD)	31.0 (19.5–35.5)
Duration since tracheostomy to decannulation, days, mean (SD)	34.0 (22.0–41.5)
Length of ICU stay, days, mean (SD)	37.0 (31.0–48.5)
Length Hospital stay, days mean (SD)	45.0 (34.0–66.5)
Complications of the tracheostomy	7 (24.1)
Bleeding needing surgery revision	3 (10.3)
Stoma infection	2 (6.9)
Air leak	1 (3.5)
Decannulation, pneumomediastinum and death	1 (3.5)
Patients with positive cultures during hospitalization, No. (%)	29 (100%)
Patients with positive respiratory culture results	25/29 (86%)
<i>Stenotrophomonas maltophilia</i>	8/25 (32%)
<i>Pseudomonas aeruginosa</i>	4/25 (16%)
<i>Escherichia coli</i>	4/25 (16%)
<i>Klebsiella</i> spp	2/25 (8%)
<i>Candida</i> spp	9/25 (36%)
<i>Aspergillus</i> spp	2/25 (8%)
Patients with positive blood culture results	16/29 (55%)
Coagulase-negative staphylococcus	12/16 (75%)
<i>Serratia</i> spp	2/16 (12%)
<i>Klebsiella</i> spp	2/16 (12%)
<i>Enterobacter</i> spp	2/16 (12%)
<i>Candida</i> spp	3/16 (18%)
Patients with positive urine culture results	2/29 (7%)
<i>Klebsiella</i> spp	1/2 (50%)
<i>Candida</i> spp	1/2 (50%)
Patients with positive ulcer culture results (multiple pathogens)	1 (3%)
Death during hospitalization	12/29 (41%)

Table 1 (Continued)

Demographics	All patients n = 29
<i>Persistent symptoms at six months of the 19 survivors' patients</i>	
Dyspnoea on exertion	11 (6.7)
Dyspnoea on slight exertion	7 (41.2)
Myalgia	4 (23.5)
Asthenia	9 (52.9)
Insomnia	5 (29.4)
Arthralgia	3 (17.6)
Cough	3 (17.6)

Date are number (percentage), median (interquartile range), or mean (standard deviation). COPD, chronic obstructive pulmonary disease; ACE: angiotensin-converting-enzyme inhibitors; APACHE II: Acute Physiology and Chronic Health Evaluation II; BMI: body mass index.

identify strategies during the hospital course, such as early rehabilitation, or after hospital discharge, such as follow-up clinics, to improve long time quality of life for COVID-19 survivors.

Summary statement

Our critically ill Covid-19 patients who needed a tracheostomy had a high rate of death, nosocomial infections, and prolonged ICU and Hospital stay. At six months, a large proportion of survivors had persistent symptoms and reduced quality of life and functional status.

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Authors' contributions

Conception of the study: Manuel Taboada.
Study design: Manuel Taboada.
Data collection: All authors.
Data analysis: Teresa Seoane-Pillado.
Drafting the manuscript: All authors helped to revise the draft of the manuscript.
Editing and approval of the manuscript: All authors.

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Conflicts of interest

The authors declare the absence of conflict of interests.

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Telemedicine Strategy for CPAP Titration and Early Follow-up for Sleep Apnea During COVID-19 and Post-Pandemic Future



La estrategia de la telemedicina para la regulación de la CPAP y el seguimiento temprano de la apnea del sueño durante la pandemia de covid-19 y el futuro post-pandémico

Dear Editor,

With the acute first wave of the COVID-19 pandemic over,¹ the long waiting list for sleep tests for OSA management has been further increased.^{2,3} The new preventive health measures against Covid-19 imply that patients go to the health centers as little as possible, which is why it is necessary to implement and start up a telematic workflow with home studies to guarantee sleep tests,⁴ especially CPAP titration.^{5–8} We aimed to test a new telematic workflow to deliver CPAP therapy to OSA patients and to evaluate it in terms of CPAP compliance, costs, residual events, symptoms and satisfaction of patients. The usual titration strategy has the following steps. The patient is scheduled to the daytime-hospital for information, and educational and practical training session with the device (45 min). Then, our CPAP equipment is delivered to him/her for home titration (to be returned the next day), the data is downloaded, and a fixed pressure is prescribed. If the registration is incorrect, the titration is repeated another day. Finally, the patient is scheduled by the service company providing CPAP equipment that informs again how the equipment works, selects a final mask for treatment, and give a short practical session of the CPAP use.

The new telematic titration strategy was developed at 3 university hospitals—Clínica (Barcelona), Clínico Lozano Blesa (Zaragoza) and Bellvitge (L'Hospitalet del Llobregat) in collaboration with a healthcare provider company (Esteve-Teijin). By phone calls from the Sleep Unit, OSA-diagnosed patients waiting for CPAP titration were informed about the telematic process. Patients also received an email with detailed information and links to educational videos made by the group (sleep, hygiene, OSA and a real educational and training session similar as performed at the hospital) as well as written information of all the procedure. Subsequently, patients were addressed to the healthcare provider to pick-up their CPAP device (Dreamstation CPAP Pro, Respirationics) with a suitable mask

and to attend a CPAP educational as a practical session. CPAP devices were initially set to automatic CPAP mode (range: 6–12 cmH₂O) and equipped with a modem for remote data transmission and titration (EncoreAnywhere platform). The titration procedure was as follows. After the first night with CPAP treatment at home and for the following 2–3 days, a sleep technician telematically analyzed the automatic titration data from the A-trial program in order to set a fixed CPAP pressure value that normalized breathing (AHI < 15 without major leaks). Patients received a phone call if massive leaks occurred based on the device data for > 15% of sleep time or if CPAP use was < 3 h. If leak was moderate no action was performed. If central apneas appeared, CPAP pressure was fixed at 70% of the initial value suppressing obstructive events. If a final decision-making on CPAP pressure was not established until the end of the third day of therapy, it was considered as a re-titration. In addition, at the end of the first week all patients received a brief phone call from the nurse to identify and solve any possible complications with the treatment (nasal congestion and leaks among others). CPAP parameters could also be modified if needed. During the first month of treatment the sleep technician/nurse could call the patient to solve any possible problems. In addition, the patient could contact the Sleep Unit nurse at any time through email or voicemail to solve any problem. At the end of the first month with CPAP, the nurse performed a follow-up visit by phone or videoconference aimed to assess the main outcomes: CPAP compliance, residual events and symptoms such as snoring, restless sleep, witnessed apneas and Epworth sleepiness scale. The nurse could solve any possible problem. Patients also received a phone call from staff who was not involved in patient management to answer a satisfaction questionnaire (9 modified) about the titration procedure.

To analyze the usefulness of the telematic titration two procedures were considered: CPAP compliance and cost-effectiveness. Regarding compliance, two groups were analyzed. Compliance of the telematic titration group ($n = 77$) was compared with a historical cohort of 193 OSA patients from the year 2019 who were prospectively recruited from the 3 hospitals mentioned. Descriptive statistics were used for basic features of study data. Categorical variables were compared between groups (telematic vs control) using the chi-square test, whereas continuous variables were compared using the t-test or the nonparametric Mann-Whitney U test. Propensity score (PS)^{10,11} was used to obtain a 1:1 balance between patients in the telematic group ($n = 55$) and control group ($n = 55$).