Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Adapted Diving Mask (ADM) device as respiratory support with oxygen output during COVID-19 pandemic

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1. Introduction

At the end of 2019, several cases of pneumonia were identified in Wuhan (Hubei, China) [1], caused by a new Orthocoronavirinae, commonly known as coronavirus, from the Coronaviridae family. In January 2020, there was a public health emergency declaration [2] and, as of March 2020, a pandemic [3,4]. At present, more than 2 million cases have been confirmed globally (2.160.2017 April 18th) [5-9].

In Spain, the first spots of epidemiological interest were identified in Madrid. Some of them were registered in the sanitary region where both *Hospital Universitario Infanta Leonor and Virgen de la Torre* Hospitals belong. The first PCR-positive patient was detected on March 4th. After two weeks, on 18th March, the number of positive cases increased to 302, and 41 patients died. By 1st April, one month after the outbreak, the total number of cases was 1714. These data confirmed the explosive progression of the pandemic and the high mortality of patients who were hospitalized and made it necessary to implement several and different therapeutic measures to try and revert the catastrophic progression of this infection.

The most extended therapeutic approach for COVID-19 is based on two main strategies [10-13]: pharmacological treatment directed toward several physiological targets (viremia, immunological reactions, prothrombotic reactions) and hemodynamic and respiratory support with positive end-expiratory pressure (PEEP) in addition to mechanical ventilation. This is vitally necessary until pharmacological treatment or patient immune responses become effective.

China and Italy have already described that acute respiratory distress syndrome.

(ARDS) is the most common manifestation in the clinical course of COVID-19 pneumonia [11-14]; however, this syndrome has a different progression than other respiratory diseases. The first-choice treatment for ARDS is mechanical ventilation (MV) with the use of orotracheal intubation (OTI). The ARDS mortality rate is over 50%, and the delay in this procedure is related to an even worse prognosis [15,16].

The main limiting factors that healthcare systems must face when handling these critical patients are the limited access to ventilators and ICU resources and the fact that they are already overwhelmed by massive hospitalization due to respiratory distress and OTI needs [17,18]. This is why current lines of work are focused on developing respiratory support alternatives that will gain time or allow the maintenance of an acceptable respiratory status until patients can access the ICU [19,20]. In the absence of approved mechanical devices, such as continuous positive airway pressure (CPAP), positive end-expiratory pressure (PEEP) devices are being used [14,16,21]. In this paper, we describe our experience with the adaptation of diving masks (Fig. 1) and predesigned and 3D-printed pieces (Annex) that work as respiratory PEEP valves and high-flow oxygen connectors.

2. Aim of the study

The main objective was to assess the efficacy of this alternative prototype for respiratory support in the context of the COVID-19 pandemic. The secondary outcomes were the clinical profiles of patients who could benefit from this device, as well as the safety parameters and potential adverse events.

3. Materials and methods

3.1. Study design and participants

A descriptive case series study of twenty-five patients with acute respiratory syndrome secondary to SARS-CoV2 infection was performed at a Spanish center, *Hospital Universitario Infanta Leonor of Madrid*, between March 30 and April 18, 2020. We tested the Easybreath First-generation Snorkel Mask (Decathlon©) adapted with 3D-printed appliances as a respiratory support device with oxygen output and a PEEP valve.

All patients provided written informed consent, and the study was approved by the Hospital Committee for Medical and Health Research Ethics.

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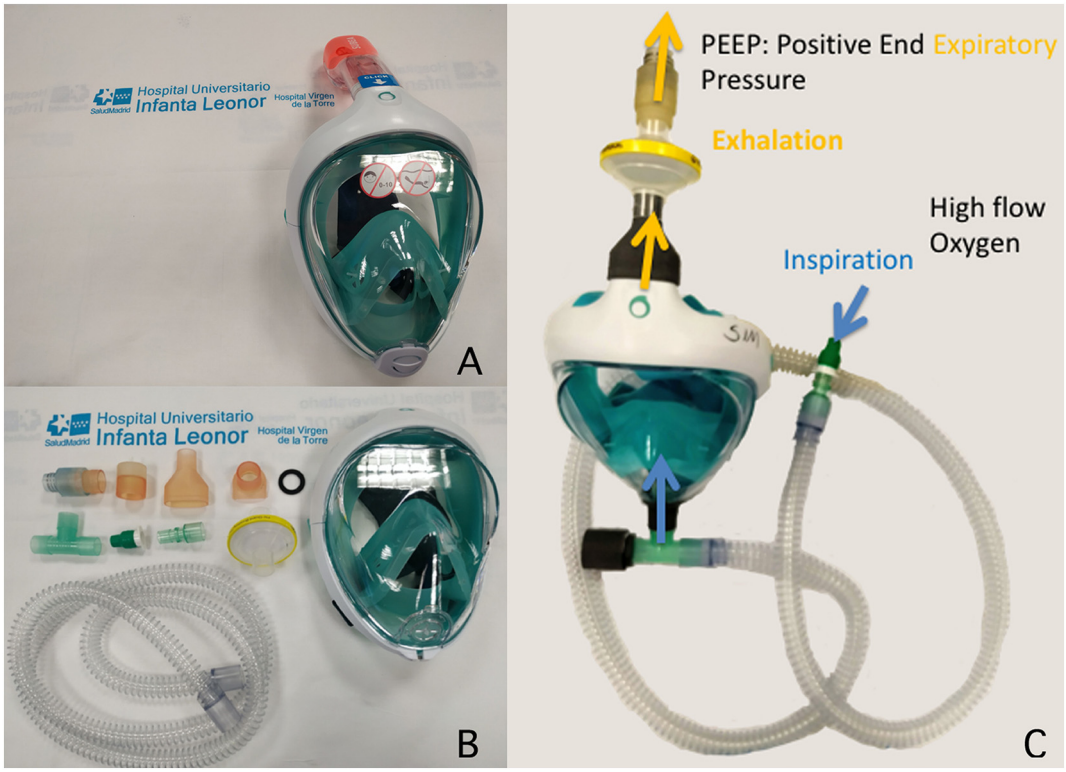

Fig. 1. A. First-generation Easybreath assembled for diving. B. Homologated connecting parts (Intersurgical) and 3D-printed adapters. C. ADM air flow diagram. During the inspiratory phase, oxygen reaches the fitted mask via a high-flow tube connected to a flowmeter at an outlet on a high-pressure hospital circuit or in a portable oxygen bottle. The residual volume of the mask becomes a reservoir. During the expiratory phase, the PEEP valve resists airflow. The exhaled air flows decontaminated through an N99 high-efficiency filter, reducing the possibility of contagion by viral aerosolization.

There were a total of twenty-five patients: twenty-one men and four women. The demographics, baseline characteristics and comorbidities are shown in Table 1.

We established two clinical settings for the use of an adapted diving mask (ADM) at the emergency department:

1. Patients with an oxygen saturation under 93% and oxygen reserve to 15 L.
2. Patients using Pulmodyne® CPAP who presented with mild to severe intolerance to their interface or with an oxygen saturation under 92% despite maximum oxygen airflow.

The mask was used with interrupted discontinuous character only to feed or hydrate the patient, aspirate secretions, if necessary, and administer artificial tears in the case of dry eye. In the absence of this nursing care, the patient was advised to maintain mask therapy for as long as possible.

Severe clinical status was established when radiographic pulmonary alterations and serologic alterations such as lymphocyte count, transaminases, LDH and D-dimer were present.

To assess the **initial response** of patients, we analyzed two variables:

1. Oxygen saturation improvement by comparing previous measurements and those immediately after oxygen saturation to the use of the mask.
   a. Qualitative variable: at least a 3-point improvement in oxygen saturation (yes/no).
   b. Continuous variable: improvement in mean-score mean from pre-mask saturation values.

2. Arterial blood gas analysis (ABGA) at one hour. Gas parameters were measured after one hour of mask use.

To assess patient **improvement**, we used the following variables:

1. ADM tolerability:
   a. Initial tolerability: percentage of patients who maintained their mask over one hour.
   b. Deferred tolerability: percentage of patients who maintained their mask without removal for the first 24 h.

2. Time of use and cessation of the ADM:
   a. Quantitative variable: mean number of days of ADM use in the patient population.
   b. Qualitative variable: reason for cessation (out of four): clinical improvement requiring less oxygen, intolerance to the ADM, ICU admission or death.

Table 1
Baseline characteristics of the included population.

N		25
Age, mean (SD)		63,44 (10,55)
Sex (%)	Male	84
	Female	16
Race (%)	Indo-European	64
	American	36
Comorbidity (%)		48
CVRF* (%)	Arterial hypertension	52
	Diabetes mellitus	20
	Dyslipidemia	36
	Smoking	8
Breathing pathology (%)	Asthma	0
	OSA**	16
	COPD***	4

* Cardiovascular risk factors.
** Obstructive sleep apnea.
*** Chronic obstructive pulmonary disease.

3. Clinical improvement. In those patients who used an ADM, the following parameters were measured: mean oxygen saturation for each day of use in every patient and the ABGA results for the first 24 h.
   a. Qualitative variable: 3-point saturation improvement Yes/No
   b. Continuous variable: mean saturation improvement.
4. ICU dismissed patient survival: survival of patients using an ADM device who were not admitted to the ICU due to comorbidities or resource shortage/unavailability.
5. Overall survival: survival percentage after MEA use.

To assess **complications** of the device, we analyzed the following variables:

1. Insufficient air flow perception. A case where a patient requires urgent ADM removal due to device failure (even with normal functioning of the anti-suffocation valve).
2. Respiratory acidosis and/or hypercapnia. Percentage of patients who had respiratory acidosis (pH < 7.35) or hypercapnia (2.5 > arterial pCO2 upper limit) in any ABGA measurement during ADM use.
3. Eye dryness: percentage of patients who reported the clinical manifestation of eye dryness during ADM use.
4. Cutaneous irritation: percentage of patients who suffered from skin irritation and clinical manifestations during ADM use.

3.2. Data collection

The medical records of patients were analyzed by the research team of the Emergency Department, *Hospital Universitario Infanta Leonor*, Madrid. Epidemiological, clinical, laboratory, radiological and treatment outcome data were obtained via data collection forms from the electronic medical records. The data were reviewed by a trained team of physicians. The recorded information included demographic data, medical history, exposure history, underlying comorbidities, symptoms, signs, laboratory findings, and treatment measures.

3.3. Statistical analysis

Descriptive statistical analysis was performed using IBM SPSS Statistics version 22 software (IBM Corporation USA).

4. Results

In this case series, the most common radiological pattern was the bilateral interstitial pattern (92,85%), followed by the multilobular pulmonary consolidation pattern (7.14%). A total of 3.57% of patients had less than 1500/μL lymphocytes, 85.7% had less than 150,000/μL platelets, 78.5% had over 250 LDH U/L, 46.4% had D-dimer levels above 500 ng/mL, and 82.1% had a GOT over 40 U/L.

The mean baseline oxygen saturation on admission was 83.6%, distributed in severity ranges as shown in Table 2. There were two patients who had missing data.

Table 2
Patients´ status previous to inserting the mask.

02 Saturation on admission: mean (SD)		83,60 (11,22)
Distribution according to S02 range (%)	≤90%	68
	91–94%	8
	>95%	16
Previous therapy (%)	02 Reservoir	72
	CPAP Pulmodyne	16
	Extubation	12
02 Saturation previous to ADM	mean (SD)	90,24 (2,63)%
Distribution according to S02 range (%)	≤90%	60
	91–94%	36
	>95%	4

Table 3
Initial outcome.

O2 Saturation mean (SD)		95,8 (3,09)
3-point SO2 improvement (%)		84
Arterial blood gas 1 h	pH mean (SD)	7,41 (0,09)
	pCO2 mean (SD)	40,91 (8,16)
	pO2 mean (SD)	93,75 (33,0)
	HCO3- mean (SD)	24,77 (3,48)
	S02 mean (SD)	95,22 (5,76)

The distribution of patients according to the clinical setting is described in Table 2. ADM use was higher in patients with an oxygen saturation under 93% with reservoir masks at 15 lpm (18 patients).

Oxygen saturation was measured before initiating ADM therapy. The mean value was 90.24%, and the patient distribution was made according to severity at saturation levels, as shown in Table 2.

After ADM initiation, patients had a very positive initial response (Table 3). The immediate saturation value after ADM placement was 95.8%. In twenty-one patients, the saturation improvement was 3 or higher. The mean pO2 after one hour of ADM treatment was 93.75 mmHg, as measured by arterial ABGA (in five patients, we were not able to collect these data), the mean pCO2 was 40.91 mmHg, and all patients surpassed the 50 mmHg limit.

Table 4 shows the different variables used to analyze the improvement in the intervention and the mean value of all oxygen saturation measurements for all days that ADM therapy was used in those patients who prolonged its time of use. More than 50% of patients tolerated the mask for 24 h, switching to 3-h minimum rotational use in combination with other therapies or devices.

The main cause of ADM cessation was physical intolerance (nine patients). Eight patients needed invasive mechanical ventilation due to disease progression. Finally, five patients experienced clinical respiratory improvement.

During the time of the study, eight patients died, five of whom were dismissed for ICU admission for prevalent comorbidities and advanced disease stage. Three of the patients who were admitted to the ICU for invasive mechanical ventilation died.

There were no adverse events related to oxygen system failure during clinical use of the ADM device or any eye or skin adverse events (See Table 5).

Four patients presented with isolated mild hypercapnia (pCO2 > 45 mmHg < 5° mmHg).

Table 4
Evolution of AMD therapy.

Good initial tolerance (%)		92
Good tolerance for 24 h (%)		52
Therapy cessation cause (%)	Improvement	20
	Poor tolerance	36
	Intensive care	32
	NIMV*	4
	Exitus	8
O2 saturation mean/day (SD)		
3-points SO2 improvement (%)		
	1° day	95,21 (2,80)
		75
	2° day	92,69 (3,87)
		66,6
	3° day	94,65 (2,45)
		66,6
	4° day	94,9 (0,14)
		100
General survival (%)		68
Survival in intensive care dismissal (%)		44,44
Accepted intensive care survival (%)		30

* Noninvasive mechanical ventilation.

Table 5
Adverse effects.

O2 supply failure (%)	0
Acidosis (%)	4
Mild hypercapnia (%)	20
Skin irritation (%)	0
Eye irritation (%)	0

during ADM use, two of whom presented in the first hour of therapy and two during the ADM rotation period with other therapies and interfaces, without any additional clinical or analytical repercussions. The mask was not indicated in any patients who, in their baseline situation, already had hypercapnia of any degree or respiratory acidosis. One patient presented with respiratory acidosis (pH < 7.35) and moderate hypercapnia (pCO2 > 50 mmHg) during mask use. This patient was not considered for ICU care due to late disease progression and poor respiratory dynamics, which ended in death a few hours later.

5. Discussion

The adapted Easybreath™ system is an efficient and safe alternative for respiratory support in the shortage of official devices in the current state of the pandemic.

It has already been described that COVID-19 disease has two differentiated phases: initial pulmonary alveolar affectation caused by viral access to AC2 receptors [22,23] and, second, an inflammatory phase mediated by macrophages [24]. Both have a common characteristic, hypoxemia, and this is why choosing the best respiratory support as soon as possible is of utmost importance for the clinical course of patients.

Regrettably, sanitary activity during the COVID-19 pandemic is conditioned by what the WHO has defined as "multiple victim incidence", where more patients are generated than those who can be treated in optimal conditions [18,20]. For this reason, many of the recent publications reference overwhelmed healthcare systems and compare the current situation to battlefield medicine practice.

The first-choice treatment for ARDS is mechanical ventilation (MV) with the use of orotracheal intubation (OTI) [14-16,21]. In the clinical event of resource and device shortage (full ICU, respirator shortage and lack of healthcare professionals), noninvasive respiratory support can be considered a valid alternative despite the worsening prognosis already published [11,21,25]. Both NIMV and CPAP or high-oxygen airflow therapy can be administered to patients by several devices depending on the availability and indication: oronasal masks, facial masks or helmets [26-28]. Through release valves, less nebulization is produced by helmets and the highest with oronasal masks. It is of high importance to take into account these devices in the COVID-19 pandemic context, as potential viral contamination to patients is caused by aerosolized particles, which is a limiting factor, as well as the limited availability of the CPAP/BiPAP device [29-31].

With the use of the Easybreath™ mask (ADM), we can address both issues. On the one hand, ADMs minimize contamination in the patient surroundings, as the facial silicone almost completely seals the faces of patient and because it is a semi-open device with just one output through the exhalatory port where air comes out already filtrated by a highly efficient N99,99 filter. This prevents exposure to other patients and healthcare professionals [29,32,33]. On the other hand, the technical requirements for ADMs are minimal: an oxygen flowmeter with as much oxygen airflow possible.

All necessary pieces needed for the adaptation of ADMs have been designed by a multidisciplinary team of engineers and doctors (see Annex). 3D impression technology for medical use needs to work with nontoxic, inert materials that would prevent leaching of one or more substances contained in the adaptor that was originally of powder base. To avoid this and at the same time comply with regulatory rules EN 5356 and EN 13544, the preferred material is PA12 (SLS) [34,35].

Our results show a rapid improvement in oxygen saturation maintained in time without any adverse events. In addition, adaptation of the ADM is safe for two main reasons. First, a 3D anti-suffocation valve adapted to our device allows for patients to inspire atmospheric air in case there is a pressure drop in the system (accidental decoupling of the oxygen source).

Second, there was no hypercapnia or respiratory acidosis in any of the follow-up tests performed in patients, meaning that rebreathing did not take place.

The mild hypercapnia that was detected in some patients may pertain to the high-oxygen airflow administered (FiO2 administered close to 100%). This may also occur with common reservoir masks. Therapy should be suspended only if hypercapnia progressively increases or increases to moderate hypercapnia levels (pCO2 > 50 mmHg) or if it is associated with acidosis of any degree (pH < 7.35). In other words, patients should remove their masks if hypercapnia is present, despite being mild, if it increases in the first hours of use, if it is moderate or if any of the above factors are also associated with respiratory acidosis. Patients will be able to maintain masks with stable mild hypercapnia in the first 3 h and if a lack of acidosis remains.

One alveolar recruitment technique that helps patient oxygenation in ICUs for patients with ARDS is pronation [13]. Few studies have shown that the pronation maneuver in a non-ICU setting in patients treated with any type of respiratory support in the emergency room or who are hospitalized may improve the ventilatory/perfusion gradient of lungs and, therefore, hypoxemia [16]. Therefore, pronation, when necessary, is best tolerated by patients wearing masks. In our series, patients had low saturation levels even in pronation and used ADMs with up to >90% oxygen saturation in the supine position and with head elevated to 30 degrees.

Some starting resources are necessary to be able to adapt to masks, but once the adaptation process is complete, masks can be completely reused by another patient, except for a high-efficiency filter following the Matachana sequence designed for our center:

1. Enzymatic detergent wash (Mediclean Forte™) 2. Rinse. 3. Wash the disinfector at 80° for 50 min to guarantee Ao = 3000. This is the reference value used for thermoresistant germs, including hepatitis B or mycobacteria. 4. 85° drying turbine.

This study has some limitations. The main limitation is derived from the design. We did not have a control group, as this was not possible in the critical clinical setting that has developed. Therefore, we cannot compare respiratory support with other therapies with the same characteristics, which would have been highly desirable. Additionally, 3D printing allows for the creation and testing of many prototypes in a rapid manner, but for midterm provisions and in a global pandemic setting, the final solution should be able to increase the production rate to respond to high demand when 3D printing is not available, perhaps via injection molding. Injection molding will make it possible to produce thousands of pieces per day at a lower cost, although initial investment (design and production of the mold) needs to be perfectly validated before starting the production process. Another disadvantage of 3D printing is that the production error has to be reduced to ±0,005 mm with a surface finish of 0,4 μm. This is not possible to guarantee with 3D printing methods, but it would be possible to produce with injection molding.

We are aware of the limitations of the ADM proposal as an alternative to respiratory support, and assuming its use in pandemics and the deep shortage of certified alternatives, we can conclude that it complies with clinical requirements to be produced in other centers with limited resources [17-19,36], especially in developing countries. This is a therapy that provides an ADM device; it only requires oxygen connection with a flowmeter with a minimum airflow of 15 lpm. It has also shown a lack of significant adverse events, presenting an optimal initial tolerability in twenty-three patients, and we propose it as a more

comfortable interface option for those patients highly dependent on noninvasive respiratory support.

Funding

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Ethical approval

The study protocol were approved by the ethical committee.

Data sharing statement

Code for all the analyses as well as the anonymised database will be made available on reasonable request.

Patient and public involvement

The research team informed all patients that a non-approved material was being used and that their participation in the study, approved by the hospital's ethical committee, in addition to having a clinical benefit for them, would contribute to the better development of the prototype. Likewise, the patient was informed that he could suspend the therapy at any time without this entailing the least impairment in his overall treatment.

The clinical results will not be shared with the participating patients.

Contributorship statement

RLG is the guarantor. Conceptualisation: CBG, RLG, MMM, BAA, JMT. Methodology: CBG, FCM, CLE, MMM. Writing (original draft): CBG, RLG, FCM, BAA, MMM, CCE. Writing (review and editing): CBG, RLG, FCM, BAA, MMM, CCE Supervision: CBG, RLG. Project administration: RLG.

Declaration of Competing Interest

The authors declare that they have no known competing interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajem.2020.10.043.

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