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Desperate times call for desperate measures



Dear Editor,

The article of Bibiano-Guillen et al. [1] reminded us of the entrepreneurial spirit of Dr. Sullivan who invented the first CPAP device with a basic mask, tubing, and a vacuum cleaner in 1981. He had hypothesized that continuous air pressure in the respiratory tract could provide uninterrupted breathing during sleep. In almost four decades, this theory has been proved in many clinical settings [2]. At the same time, PAP devices have been passed through many technical revolutions leading to many choices of masks and modes.

The experience regarding non-invasive ventilation (NIV) in high-risk infections has been accumulating since the severe acute respiratory syndrome (SARS) epidemic in 2003. Afterward, the influenza epidemic in 2009 also provided clinical proof in favor of NIV in the management of respiratory failure related to viral infection [3]. The recent data also proved that NIV is also vital for COVID-19 related acute respiratory failure [4]. However, the global unhindered rise of COVID-19 cases causes great disruption in public health resources. Due to its accessibility and ability of rapid manufacturing, 3D printing has emerged as a savior against the shortage of medical equipment such as face shields, face masks, valves, and nasopharyngeal swabs [5]. Despite the concerns about the standards of medical equipment produced via 3D printing, it has been widely used during these desperate times. In the study of Bibiano-Guillen et al., the Easybreath First-generation Snorkel Mask (Decathlon©) adapted with 3D printed positive end-expiratory pressure (PEEP) valve and high-flow oxygen connector, is presented as an alternative for respiratory support. However, the statistical analysis is completely descriptive but analytic results comparing the variables before and after the treatment are missing. The distribution of the variables must also have been investigated to address the correct analytic test. Non-parametric tests would have yielded different results in such a small population.

Additionally, the authors did not share the analysis regarding the power of sample size or the method of patient selection. It seems arbitrary to conclude if 25 patients are enough to show the efficacy of this adapted diving mask (ADM) in a population with a possible selection bias. The high ratio of obstructive sleep apnea (64%) in the study population might lead to a greater initial tolerance than it would be in the general population. As a limitation of the study, it should be stated if these patients are treatment-naïve or if they were used to PAP devices with such masks. Despite the high ratio of OSA patients, 52% of good

tolerance rate for 24 h was reported and clinical improvement was achieved in only 20% of the patients. The lack of objective data about the air leak is another important issue to be considered before recommending ADM as a treatment alternative.

This mask can be connected to a high-pressure hospital circuit or a portable oxygen bottle and can provide PEEP with the help of a valve resisting airflow during expiration. Unless the oxygen flow rate reached in this study population is addressed, the low rate of hypercapnia can not be convincing. It is also impossible to measure the level of PEEP provided by the mask which can be an important issue in the ventilation of COVID-19 patients as they are prone to spontaneous pneumothorax especially during the second phase of the disease [6].

On the other hand, the material of which the valves for ADM are manufactured was compatible with the regulatory rules. Thanks to the highly efficient N99.99 filter placed in the exhalation port, viral dispersion is expected to be lower [7]. Nevertheless, the amount of unintentional leak around the facial silicone is unknown so personal protective equipment should be used in this setting.

We believe that the present data is not sufficient to suggest ADM as a treatment alternative. As they are reusable and have low cost, ADM must be accepted as a “desperate measure” in the lack of other devices until its efficacy is proven in a study with a control group or a randomized control trial.

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21 July 2021