Synthesis of May 12, 2020 - WHO/CED WEBINAR - CPAP/BPAP - SESSION

First of all, it is necessary to understand when these non-invasive ventilation (NIV) techniques, CPAP and BPAP and HFNC[1], can be used in the Covid-19 patient's care pathway/protocol.

They are usually used in the early management of patients in pre-hospital, emergency and conventional management, i.e. outside the intensive care units.

Non-invasive is related to airway prosthesis placed on or around the face of the patient (facemask, nasal mask, helmet, nasal canula).

Pressurizing strategy of the gas in the airways depends on the moment positive airway pressure (PAP) is applied: inspiration (IPAP), expiration (PEP), continuous (full) respiratory cycle (I+E) with same pressure (CPAP) or differential pressure level during I and E (BiPAP) [2] .

The purpose of the medical feedback provided during the session was to show the results of using a simple machine-free CPAP/BiPAP ventilation mode and the reasons of this medical priority choice in the context of Covid-19, in an intensive care unit, which also had ventilators available.

The objective was to open the debate on the added value in LMICs of all the categories of NIV[3] medical devices available whether they work with or without a machine, giving both medical and biomedical (i.e. clinical engineering) insights to potential users of these NIV techniques in LMICs .

Whatever, due to the risk for the patient in the use of those medical devices, and due to the risk of contamination of the healthcare workers, it has always to be a medical choice.

The objectives of those noninvasive ventilation techniques are mainly to avoid intubation but also to re-educate the patient's airway after a long period of intubation in the intensive care unit to help the patient regain spontaneous breathing.

This is why these modes of ventilation are available throughout the patient's pathway in different contexts, in different specialized care units and necessarily embedded on the medical devices that equip these units. Those medical devices are more or less complex according to the level of treatment and the care unit where the patient is treated. The level of competencies of the medical and healthcare workers team depends on the healthcare level of the care unit.

These modes of ventilation allow **ventilation support** to be offered to patients who are still able to breathe spontaneously, with two objectives:

1/ to provide effective support for the patient's respiratory work.

It should be noted that patients in respiratory distress have an inspiratory effort 4 to 6 times greater than normal.

2/ to propose a massive oxygenation solution to these patients in more or less severe hypoxemia.

These indications and the associated specifications are clearly specified in the document, on line of recommendations on the WHO website[4].

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[1] Specifications in Adriana Velazquez's May 12 presentation (slide 7).

[2] Those ventilation techniques are designed to maintain positive pressure in the patient's airway at different levels and cycles, (presentation Dr. G.Dhonneur, (slide 7).

[3] Non Invasive Ventilation

[4] WHO Technical specifications for invasive and non-invasive ventilators for COVID-19-19 (part 1.2 and following specifications).

These ventilation modes can be proposed to Covid-19 patients in 2 principal ways:

1/ either by medical devices which are more or less complex ventilators

advantages:

Equipped with intelligent electronics and multi-parameters sensor, and monitors requiring a power supply (electricity) plus pressurized medical gas (Air and O2) supply.

They allows to keep a continuous feedback on patient treatment settings, and to be able to monitor some physiologic parameters, to set alarm limits, and to dispose of automatic alarms of the operating system. They do not consume more than 10 l/min of air or O2 to operate.

Disadvantages, (especially in BiPAP mode):

a/ control of the machine via the parameters setting. Those parameters are medical prescriptions and require high skills of the nursing staff, not equally distributed in the care units which are not familiar with intensive care practices. Continuous settings and adjustment of parameters. Sensitivity of the trigger of inspiratory aid, positive pressurization slope, inspiratory Plax,...

b/ Negative effects due to the complexity of the embedded algorithms which make parameter setting choices difficult.

Two non-exhaustive examples:

- The setting of the level of the inspiratory aid trigger to decrease the respiratory work without causing self-triggering,

- The setting of the “Cycling" which is adjusted according to the value of the expiratory flow (usually when it reaches 25% of the patient's peak inspiratory flow). In case of early cycling (>25%), the inspired tidal volume is decreased and thus the inspiratory effort can be increased.

c/ they are expensive, also demanding and expensive in terms of maintenance, and not particularly available in the LMICS.

It could be suitable for the LMICs but not very well adapted to the means, infrastructure and organization of care in LMICs. Therefore its application in LMICs requires a complete training for users and high level maintenance skills.

2/ either by medical devices which are much simpler to implement and do not require machines to operate and more or less well indicated for LMICs[5].

Note: it is important to specify that all these devices are **non-intelligent passive medical devices not requiring energy supply, but just pressurized medical gas (Air and O2) supply**

There are venturi valves, high flow systems with nasal cannulas, and free flow valves.

Like ventilators they are subject to the effective regulations in the countries where they are available and have all the guarantees of quality assurance due to the certification process of medical devices.

These oxygenation techniques are generally administered to patients by complete sets which include the central device, valve or nasal cannulas as well as single-use or reusable accessories enabling them to operate (masks, filters, tubes, connectors, peep valves, fittings, etc.). Those accessories can be captive equipment accessories or standard ones i.e. which can be purchased independently of the manufacturer of the device.

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5 Dr. Gilles Dhonneur’s presentation (slide 9)

The following analyses are valid only in the context of Covid-19 and are the sole responsibility of their authors. They are proposed from the angle of the 2 objectives mentioned in introduction.

It does not in any way replace the user's manual of each device, and the use of these medical devices must always be under the responsibility of a physician.

Their main advantage is that there is **no need to adjust processing parameters taking into account complex algorithms that require high healthcare workers skills.**

For all these devices, performance is left to the discretion of physicians. But oxygen supply in hospitals is a real problem for Sub-Saharan African countries. And Oxygen consumption of these medical devices is high 15 to 60 l/min, and does not allow a direct use with the oxygen concentrators widely distributed in the LMICs and particularly in Africa (10 l/min).

Attention: Except for HFNC, The pressure drop generated by the addition of an HME filter may result in a drop in performance that would make it unsuitable for some patients.
It is therefore necessary to monitor the evolution of the condition of these patients in order to avoid delaying intubation indications too long.

a/ Venturi valves

Moreover, the technology embedded in those devices is based on the Bernoulli Effect which permanently draws air from the outside towards the patient's airways during all the respiratory cycle. These valves are generally equipped with 2 inlets, one to create the venturi effect and one to increase the FIO2. They operate with a peep valve.

Pressure: Oxygen or air inlet pressure must be around 45 PSI

Flow rates: depending on the FIO2 setting and the peep wanted, between 15 to 40 l/min.

PEEP: from 0 to 20 cm H2O. Settings depending on the medical prescription.

advantages:

Effectiveness in emergency situations in some of the first affected countries by coronavirus Covid-19and to cope with the shortage of ventilators, with oxygenation and respiratory assistance in CPAP mode.

Medical protocols of use available

The only setting to be managed is the gas or oxygen flow rate. The only parameter to monitor is the oxygen saturation of the patient. If possible the cardiac frequency.

In order to secure the risks of "aerolization" of viral particles, a helmet can be used. To prevent risks of CO2 rebreathing, see the manufacturer recommendations.

More details in this video → **https://youtu.be/5gzzn0hj4Fk**

There is one brand new innovating medical device that solves the problem with dual-connection masks and a HME filter on the expiratory circuit.

More details in this video → **https://youtu.be/o6WkHwUl4U8** [6]

It could be suitable for the LMICs in the Covid-19 context with a good oxygenation but with a high oxygen consumption for LMICS, in Covid-19 clinical indication, and some no standard accessories. No maintenance required.

[6] Adriana Velazquez's May 12 presentation (slide 9)

b/ High Flow Nasal cannula

The objective of this device is to improve arterial oxygenation. The probe use to deliver O2 is different from NIV Masks, it's a nasal cannula. HFNC delivers humidified and rewarmed 02, at very high flow O2: 30 to 60 L/min. It's an open system that generates nasopharyngeal turbulences resulting in pressure generation in the pharynx: That's why it is called the "Pep effect".

Pressure: Oxygen or air inlet pressure must be greater than 60 PSI.

Flow rates: depending on the FIO2 setting and the peep wanted, greater than 60l/min

PEEP: the high flow rate generates a "peep effect" between 4 and 8 cm H2O.

Advantages:
Very effectiveness on the oxygenation side. HFNC generates also a large alveolar-pharynx O2 gradient that promotes an incoming escalator flow for O2 transfer and ascendant outgoing flow for CO2. It can operate in addition to a CPAP/BPAP ventilator.
More details in this video → **https://youtu.be/_rTq99Y8T_w**

Medical protocols of use available

The only setting to be managed is the gas or oxygen flow rate. The only parameter to monitor is the oxygen saturation of the patient. If possible the cardiac frequency.

It could be suitable for the LMICs in the Covid-19 because of its very helpful clinical indications. It requires at least one electric heater-humidifier to operate to protect the patient's sinuses due to the high flow rates of 02 involved. Very high consumption of O2. Maintenance of the electric heater-humidifier is required.

c/ Free flow valves "Boussignac" type

For free flow valves, "Boussignac" type", the on-board technology is different and is based on theories of fluid mechanics used in particular in the design of jet turbines.

The turbulence generated in the center of the tube creates a virtual valve in an open system that makes it possible to provide patients with available flow rates of around 300 liters per minute without drawing air from the outside into the patient's airway[7].

Pressure: Oxygen or air inlet pressure must be around 45 PSI

Flow rates: depending on the peep wanted, between 15 to 30 l/min.

PEEP: from 0 to 10 cm H2O, according to the available medical protocols in the Covid-19 context. Settings depending on the medical prescription.

Advantages

As this is an open system, any excess airway pressure is instantly evacuated to the outside, thus preventing any risk of barotrauma (Boussignac Niv CPAP, page 2).

Unlike CPAP mode ventilators which control the patient airways parameters, it is the patient's pathophysiological characteristics that use and control the system in the most natural and appropriate way. More details in this video → **https://youtu.be/xd1urg_mJ6M**

Medical protocols of use available

[7] Afib Boussignac NIV_CPAP, for a contamination-free NIV

The only setting to be managed is the gas or oxygen flow rate. The only parameter to monitor is the oxygen saturation of the patient. If possible the cardiac frequency. **It's safer for the healthcare workers. (HME filter).**

Note: When the oxygen resource is not available, this system allows, thanks to air compressors widely used in Africa and in LMICS, to supply air to the device and thus to maintain assistance to the respiratory work even if oxygenation is not sufficient.

In addition, the concentrator at flows of 10 l/min, widely used in LMICs, and particularly in Africa, do not provide sufficient flows to operate the device, but can be connected to the connection socket of the manometer or by a socket sometimes available on NIV masks which must obviously be waterproof. To allow some oxygenation even if it is not optimal.

It could be suitable for the LMICs in the Covid-19 context with a good oxygenation and a high performance in respiratory work support, as it is actually a Cpap system with an inspiratory aid, with best performances than basics CPAP or BPAP ventilators (level 1 ot 2), but with a high oxygen consumption for LMICs. No maintenance required [8].

c/ Hybrid Venturi -Free flow valve

All the information about this only device of this category that we have been able to find are available on the website of the manufacturer

https://www.mercurymed.com/wp-content/uploads/Flow-SafeII_plus_faqs.pdf

The FAQ above talk about the possible use of an HME filter but it's not shown in the video dedicated to Covid-19 here → **https://youtu.be/q8jiEHUnwaA**

It could be suitable for the LMICs in the Covid-19 context on condition that more information is available, in particular medical feedback or medical protocols for its use.

Finally, indeed these devices require an increased monitoring by the nursing staff and in particular the monitoring of the oxygen saturation, a device also widely used in LMICs.

The use of all this medical devices must be accompanied by all the precautionary rules available in the general recommendations of the WHO.

We hope that this additional explanation will complete the answers to your questions during the session.

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[8] Gilles D'honneur's presentation (slide 10)