

ICHF (International Association of Francophone Hyperbaric Centres) Position Statement : resumption of clinical hyperbaric activities in the context of COVID-19 (SARS-Cov-2) pandemic

Since many weeks, a SARS-CoV-2 pandemic (commonly called COVID-19) is hitting our countries at different stages. If it is at its beginning in some countries, it seems to be regressing in others (like Switzerland, France, Belgium and others). A gradual deconfinement of their populations is now programmed.

However, the virus is still actively circulating; vaccination is not yet available; there is no effective treatment yet; and most populations are unlikely to be immunized thus not allowing a collective immunity. In addition, the prevalence of asymptomatic carriers of the virus is still not precisely known but seems to be very important.

It is therefore legitimate to think that asymptomatic patients suffering from a condition for which hyperbaric treatment is indicated could be carriers of the SARS-CoV-2 and possibly be the source of contamination to other patients and staff.

Furthermore, hyperbaric centres can also be called to take care of COVID-19 positive patients in the context of an urgent condition mandating a hyperbaric treatment, a research protocol or as a treatment of last resort.

For all these reasons, different and gradated should be applied to these specific cases.

Physical barrier protective measures (physical distancing, frequent hand washing and disinfection, use of mask,) are the main basic principles to be respected in all cases until the pandemic situation is resolved. With the deconfinement underway, these measures are promoted in the majority of countries. We should therefore apply these protective measure in our offices and hyperbaric centres.

3 levels of protective measures can be applied according to the clinical situation

- 1) Taking care of an asymptomatic patient (COVID-19 non-suspect) for a medical condition requiring hyperbaric treatment*
- 2) Taking care of SARS-CoV-2 infected patients during HBOT session for an emergency condition (see appendix 1 and 2)*
- 3) Taking care of a COVID patient in the context of a research protocol or as treatment of last resort*

Taking care of an asymptomatic patient (COVID-19 non-suspect) for a medical condition requiring hyperbaric treatment

Initial medical consultation and COVID-19 status assessment

Before the medical consultation, ensure that there are no symptoms suggestive of COVID-19, this can be achieved by the use of a standardized questionnaire aimed at identifying any recent COVID-19 symptoms. In doubt, prescribe initially a PCR test and/or a serology test, and if indicated a low dose thoracic CT-scan, which would help to detect any pulmonary sequelae of a recent infection and therefore identify any potential contraindication to HBOT.

Considering the protective measures to be respected, the total number of patients to be simultaneously treated will be limited. A prioritization of patients to be treated will have to be established in each centre with criteria to be defined locally.

Protective measures in a hyperbaric centre:

All of these protective measures should be adapted to the architectural, administrative and legal particularities of each centre. To achieve this, it is recommended to realize these items:

- assessment of the contamination risks;*
- simulation of the reorganization procedure.*

Physical distancing:

The compliance to a minimum spacing of 1 meter (ideally 2 meters) between individuals at all times is recommended.

It is also recommended to implement a one-way circulation of patients inside the centre, if this cannot be achieved, an individualized patient care procedure must be in place to prevent contacts between patients.

A minimum spacing of 1 meter between patients inside the hyperbaric chambers is recommended. This can be usually achieved by using only 1 out of 2 seats.

Hand washing –disinfection:

Hand disinfection with alcohol-based solution for patients and staff outside the hyperbaric chamber must be systematically reinforced before and after each contact or procedure.

Reminder: do not use any alcohol-based disinfecting solution inside the hyperbaric chamber.

During a treatment, while still in the pandemic period, the staff should be using gloves.

Protective gear:

All patients should wear a surgical mask (anti droplets). Hyperbaric gas delivery systems (BIBS or hoods) should be handled only by the hyperbaric staff and with compliance of hygiene measures. These respiratory items must be cleaned and disinfected after each use.

At the minimum, hyperbaric staff will be wearing their usual working garment and also a surgical mask at all times.

These measures will have to be adapted with the risk that can vary with the confinement associated with each specific hyperbaric chamber, the space available between patients, and a possible aerosolization of potentially contaminated droplets while using continuous high flow mask and/or venting the chamber.

During treatment sessions :

- *Staff keep their surgical mask during all the duration of the treatment session*

OR

- *Staff wear a hyperbaric specific breathing mask with filter*
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Staff will be wearing an individual protection equipment (IPE) according to the recommendations of local infectious diseases prevention committees and this equipment must respect hyperbaric safety rules.

(In case that the hyperbaric staff has to use under pressure a full IPE made with synthetic material, one should maintain the lowest oxygen concentration inside the multiplace chamber or diminish the ambient pressure to 2,0 – 2,2 ATA in order to mitigate the fire risk)

Hygiene, cleaning :

After each treatment session, the hyperbaric chambers are cleaned and disinfected with the usual disinfecting products known to be effective against the SARS-CoV-2 (products approved by the hygiene authorities of the hospital), with a special attention to seats and all surfaces in direct contact with patients.

The hyperbaric breathing systems (masks or hoods) must be disinfected by using a procedure known to be effective against the SARS-CoV-2 (procedure approved by the hygiene authorities of the hospital), or if not feasible they should be discarded after each treatment session. Their elimination should be done via the appropriate procedures for contaminated medical supplies.

Other measures:

It is recommended that patients maintain the wear of the oxygen mask or hood during all the duration of the treatment session, including the pressurisation and depressurisation phases. Thus eliminating the exhalation of particles directly inside the hyperbaric chamber.

It is recommended to avoid a systematic and continuous ventilation of the hyperbaric chamber during the treatment session in order to prevent the spreading of potentially contaminated respiratory droplets inside the chamber.

Follow-up medical consultation and treatments

Before each treatment session, patients should be systematically questioned for COVID-19 symptoms and body temperature should be checked. In case of a suspected COVID-19 infection, the patient will be referred to most appropriate medical resource. Hyperbaric treatment sessions will be postponed. In the case of conditions mandating urgent hyperbaric treatments, additional measures should be adopted. These measures will be addressed with specific recommendations.

Important reminders:

These described measures cover the management of asymptomatic patients who are not suspected to be SARS-CoV-2 carriers. These measures are not intended to be used for the care of known or suspected COVID-positive in the hyperbaric setting. This particular situation is being addressed with specific recommendations described in appendix 1 and appendix 2.

We would like to remind clinicians that the use of HBOT for the treatment of SARS-CoV-2 pneumonia can be recommended only in the setting of a research protocol or as a treatment of last resort when invasive ventilation cannot be considered. HBOT is recommended for COVID-positive patients that are suffering from an urgent medical condition mandating hyperbaric treatment. In these particular cases, all the individual protection precautions must be used in accordance with local directives.

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(77 médecins hyperbares et de plongée)

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Centre de médecine hyperbare du CHU de Toulouse (France)
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Appendix 1: Hyperbaric emergencies

To prioritize the medical conditions requiring HBOT, especially in the event of limited resources in the hyperbaric centres. The proposed prioritization of hyperbaric emergencies is presented with the level of recommendation and level of evidence.

1) Hyperbaric urgencies (immediate treatment)

- CO poisoning (type 1, level B)
- Major open fracture with crush injury (type 1, level B)
- Arterial gas embolism (type 1, level C)
- Decompression sickness (type 1, level C)
- Gas gangrene (type 1, level C)

2) Hyperbaric emergencies (to be treated in the next 24-48h)

- Idiopathic sudden sensorineural hearing loss of less than 15 days (type 1, level B)
 - Severe haemorrhagic radiation-induced injuries (type 1, level B)
 - Compromised graft or flap (type 2, level C)
 - Central retinal artery occlusion (type 2, level C)
- Even with a lower level of evidence, these conditions could be considered if no other interventions have a chance of helping the patient
- Vaso-occlusive crisis of sickle cell anaemia (type 3, level C)
 - Frostbites

3) Semi-urgent conditions with strongly recommended or recommended treatment (in a delay of 4-8 weeks)

- Non-haemorrhagic radiation-induced injuries which are disabling, of severe pain intensity, infected or with compromised healing (type 1, level B)
 - Osteoradionecrosis (ORN) and prevention of ORN (type 1, level B)
 - Avascular femoral head necrosis (type 2, level B)
 - Diabetic foot ulcer (type 2, level B)
 - Chronic ischemic wounds (type 2, level C)
 - Refractory chronic osteomyelitis (type 2, level C)
- And all the other medical conditions as recommended by the 2016 European Consensus

The decision to treat a patient with HBOT should be made in collegiality and with a multidisciplinary approach. The ratio benefits over risks should always be evaluated.

Appendix 2: practical information

Hygiene measures and safety rules regarding the care of SARS-CoV-2 infected patients during HBOT sessions

A hyperbaric medicine centre can be called to take care of SARS-CoV-2 infected patients with medical conditions requiring hyperbaric treatments or in the context of a clinical research project or eventually as a treatment of last resort.

This information summary presents the hygiene measures and safety rules in order to minimize the risks of contamination of the staff and other hyperbaric patients that are not infected with SARS-CoV-2.

SECTORING OF THE HYPERBARIC CENTRE

Space sectoring

The hyperbaric centre is divided in 2 zones: COVID and non-COVID, with ideally if feasible, one chamber compartment dedicated to COVID-positive patients and one chamber compartment for non-COVID patients.

The waiting room and preparation room must be also distinct.

A gowning room must be in place in order to be able to enter and exit safely the COVID zone.

A specific procedure should be implemented in order to avoid mixing of patients and staff between the COVID positive zone and the non-COVID zone.

A sectoring plan must be in place.

Time sectoring

Schedule planning with a time spacing of HBOT sessions between COVID-positive patients and non-COVID patients can help avoid accidental contacts between these 2 types of patients.

GENERAL RULES :

- *Barrier protective measures and systematic reinforced gowning of all staff in contact with COVID-positive patients according to the recommendations of local authorities.*
- *Respiratory precautions at all times during the care to COVID-positive patients. These patients must be at all times wearing masks, either surgical masks or hyperbaric breathing masks.*
- *Inside hyperbaric chambers, patients will be breathing with hoods or masks connected to a circuit that will evacuate the expired gases outside the chamber.*
- *Systematic protection of the respiratory circuit with filters (Hydro-guard mini model or any model proven efficient for filtration of SRAS-Cov-2)*
- *Strict control of the evacuated gas: forbidden access at proximity of the evacuation port outside the chamber.*

EXAMPLE OF A PROTOCOL FOR COVID + ZONE

1. Staff preparation

- 1.1. *Team's composition : all staff must have the training for the proper use of barrier protective measures and individual protective equipment for the care of COVID-positive patients*
- 1.2. *Staff's gowning: this should be done according to procedure edited by the local authorities. A special attention must be paid to the individual protection equipment (IPE) going inside the hyperbaric chamber. This equipment must be compatible with the hyperbaric environment.*

2. Chamber preparation

- 2.1. *Make sure that patients inside the chamber can keep a safe distance of more than 1 meter between each other.*
- 2.2. *Protect the unused equipment*
- 2.3. *Verify the monitors for the SpO2 measure*

3. Preparation of the hyperbaric respiratory circuits

Respiratory circuits must be protected with antiviral filters

4. Starting of the console

- 4.1. *Cleaning and disinfection of the surfaces at the console*
- 4.2. *Make sure that an alcohol-based hand-washing solution is available at the console*
- 4.3. *Use an electronic format for pressurisation logs*

5. Taking charge of the patient

- 5.1 *The trajectory towards the hyperbaric chamber for the COVID-positive patient should be predefined*
- 5.2 *The patient must wear a mask at all times.*
- 5.3 *When arriving at the chamber, make sure that each patient wash their hands with an alcohol-based hand disinfecting solution*
- 5.4 *Patients must be installed one at a time*

6. Course of the HBOT session

- 6.1. *Systematic presence of inside attendants (nursing or medical staff)*
- 6.2. *Slow pressurisation with the patient wearing the hyperbaric breathing mask*
- 6.3. *Duration of the HBOT session : 50 to 75 min at a maximum of 2,0 ATA*
- 6.4. *Slow depressurisation with the patient keeping in place the hyperbaric mask or hood*
- 6.5. *Keep the patient on oxygen at the surface*
- 6.6. *case of a breach in the protocol, the HBOT session can be stopped upon medical decision*

7. Inside attendant

- 7.1. *The inside attendant should check the proper functioning of the patient's monitoring inside the chamber*
- 7.2. *Regular checking of the oxygen saturation of each patient during the session, and disinfection of the oxygen sensor after each patient.*

8. Patients exiting the chamber (one by one)

- 8.1. *Removal of the whole respiratory circuit, patient by patient*
- 8.2. *Make sure that each patient wash their hands with an alcohol-based hand disinfecting solution*
- 8.3. *The used respiratory equipment is disinfected*

9. Patients leaving the HBO department

- 9.1. *Clinical and Para clinical assessment : check pulse rate, blood pressure, respiratory rate and oxygen saturation*
- 9.2. *Transfer of patients with oxygen mask on*
- 9.3. *Ventilation between HBOT sessions : open doors and windows of the hyperbaric centre*

10. Hyperbaric chamber cleaning

- 10.1. *Remove the used linens : disposal as edited by the local procedure for COVID-19 contaminated laundry*
- 10.2. *Forced ventilation of the chamber with doors closed at a pressure of 1 meter during 5 minutes*
- 10.3. *Cleaning and disinfection of the chamber's surfaces*
- 10.4. *Repeat the cleaning and disinfection of the chamber's surfaces*

11. Cleaning of the HBOT respiratory circuits

- 11.1 *Cleaning and disinfection of the HBOT respiratory circuits*
- 11.2 *Repeat the cleaning and disinfection of the HBOT respiratory circuits*
- 11.3 *Masks and straps are immersed in a disinfecting solution for 15 minutes, then rinsed with water.*
- 11.4 *Cleaning and disinfection of the interior and exterior surfaces of the oxygen hoods, neck rings and neck seals are immersed in a disinfecting solution for 15 minutes, then rinsed with water.*

12. Donning and duffing of individual protective equipment

This should be done in the dedicated space that should be well identified in the department. The procedure should respect the rules edited by the health care facility.

Appendix 3 : HBOT as a treatment of last resort

Could HBOT be proposed as a treatment of last resort for some severe cases of SARS-Cov-2 pneumonia ?

For a patient, nothing is as psychologically and humanely difficult as having to deperish or being confronted to incoming death and knowing that some experimental treatments could be available, but these experimental treatments being not yet approved. These days, patients and their families are more than ever aware of new therapeutic options, even if they are not yet validated. Medical research is not being kept secret anymore. In some countries, legal authorities have dealt with this situation by making available experimental treatments as a treatment of last resort. This avenue allows to treat patients who do not have any other options and cannot wait until clinical trials are completed and all medication authorization procedures are done.

The discussion on the use of HBOT as a treatment of last resort for some severe cases of COVID-19 pneumonia is a complex question for which we should take into account numerous scientific and ethical parameters.

It is important to note that some experimental treatments (ref. Green et al, NEJM) and some recommendations are already being proposed as treatments of last resort for the care of COVID-19 patients.

Concerning HBOT, these information points should be highlighted:

- *there is currently no treatment with proven efficacy against COVID*
- *some patients do not have access at the whole recommended treatment arsenal (invasive ventilation) due to lack of resources and can be excluded on the basis of age and medical conditions*
- *Some level of evidence for efficacy seems to exist for HBOT in the treatment of COVID patients (some case-reports from China have been published with good outcomes, some RCT have started in France and in the USA)*
- *HBOT for COVID-19 patients appears to be safe ; no major side effects have been reported in the available case-reports with PO₂ of 1,6-2,0 ATA*
- *Contamination risks of staff and other patients during HBOT sessions is controlled ; specific hygiene and security procedure are implemented in the hyperbaric centres involved in RCT*
- *Conventional treatment can be continued in parallel (normobaric oxygen and others) ; conventional treatment has been always continued in the case-reports and is planned in the RCTs that have started*

ICHF Position Statement:

Prescribing HBOT as a treatment of last resort must respect regulations and laws in force in each respective country.

In order to consider HBOT as a treatment of last resort on a case-by-case approach, an interdisciplinary committee or ethical committee appointed by the local authorities should evaluate the case. Informed consent of the patient and/or its family is essential.

Contamination risks of the staff and other patients must be under control as mentioned above.

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