Controversies in hyperbaric medicine – Réunion2013

Medical devices and procedures in the hyperbaric chamber

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Abstract

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The aim of this paper is to present current controversies concerning the safety of medical devices and procedures under pressure in a hyperbaric chamber including: defibrillation in a multiplace chamber; implantable devices during hyperbaric oxygen treatment (HBOT) and the results of a recent European questionnaire on medical devices used inside hyperbaric chambers. Early electrical defibrillation is the only effective therapy for cardiac arrest caused by ventricular fibrillation or pulseless ventricular tachycardia. The procedure of defibrillation under hyperbaric conditions is inherently dangerous owing to the risk of fire, but it can be conducted safely if certain precautions are taken. Recently, new defibrillators have been introduced for hyperbaric medicine, which makes the procedure easier technically, but it must be noted that sparks and fire have been observed during defibrillation, even under normobaric conditions. Therefore delivery of defibrillation shock in a hyperbaric environment must still be perceived as a hazardous procedure. Implantable devices are being seen with increasing frequency in patients referred for HBOT. These devices create a risk of malfunction when exposed to hyperbaric conditions. Some manufacturers support patients and medical practitioners with information on how their devices behave under increased pressure, but in some cases an individual risk-benefit analysis should be conducted on the patient and the specific implanted device, taking into consideration the patient's clinical condition, the indication for HBOT and the capability of the HBOT facility for monitoring and intervention in the chamber. The results of the recent survey on use of medical devices inside European hyperbaric chambers are also presented. A wide range of non-CE-certified equipment is used in European chambers.

Key words

Hyperbaric medicine, safety, equipment, implantable devices, patient monitoring, ventilators, resuscitation, review article

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Introduction

The aim of this paper is to present current controversies concerning the safety of medical devices and procedures inside a hyperbaric chamber. The presentation has been divided into three sections:

- defibrillation inside a multiplace hyperbaric chamber;
- implantable devices during hyperbaric oxygen treatment (HBOT) and
- results of a European questionnaire on medical devices used inside hyperbaric chambers.

Defibrillation inside a hyperbaric chamber

Electrical defibrillation is well established as the only effective therapy for cardiac arrest caused by ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). The scientific evidence to support early defibrillation is overwhelming; the delay from collapse to delivery of the first shock is the single most important determinant of survival. The American Heart Association (AHA) has given a strong recommendation for immediate defibrillation as the treatment of choice for VF of short duration, as seen in witnessed cardiac arrest. The goal for early defibrillation in the hospital and ambulatory clinics is for the shock to be delivered within the first few minutes after the victim's collapse.[1]

The need for rapid defibrillation should mean that every medical hyperbaric facility treating patients with life-threating conditions should have the potential to perform defibrillation while inside the chamber. However, the need for defibrillation during HBOT is rare. In our centre, we conduct almost 7,000 person sessions per year including intensive care (mostly with septic shock) and emergency patients (mostly with carbon monoxide (CO) poisoning) – a total of more than 120,000 person exposures during the past 20 years. Excluding one case of a patient with CO poisoning being resuscitated for VF during compression, with spontaneous restoration of a regular heart rhythm after a few minutes breathing 100% oxygen at 253 kPa, we have seen only a few fatal cases inside the chamber or immediately following HBOT when there was a need for defibrillation. Such a low incidence of cardiopulmonary resuscitation inside the hyperbaric chamber is probably because of careful medical examination of critically ill patients by a hyperbaric physician before each HBO session,

monitoring of ventilation and circulation while at pressure and significant hyperoxygenation during the session, which prevents cardiac insults occurring under hyperbaric conditions. On the other hand, hyperoxygenation extends the length of circulatory arrest that can be tolerated, giving additional time for accelerated decompression and out-of-chamber defibrillation. However, there are still clinical situations where having the means for defibrillation inside the chamber is highly recommended, for example, long recompression tables, including saturation exposures, when fast decompression would be deleterious for the patient and or for medical attendants.

It must be remembered that the procedure of defibrillation is inherently dangerous owing to the risk of fire caused by electrical discharges and voltaic arcing which may be generated between the paddles, high flow of current in older types of defibrillators and the risk of enhanced combustion from high local oxygen concentrations from leakage of oxygen from the patient's respiratory circuit. While it is an absolute contraindication to conduct defibrillation in the pure oxygen atmosphere of a monoplace chamber, the procedure for multiplace chamber defibrillation has been described previously.[2] Important requirements to be fulfilled before discharge include:

- the chamber is compressed with air and the oxygen fraction is kept below 21.5 vol%;
- large surface adhesive plates are attached to the patient's chest and the area around the plates is kept free from flammable materials;
- the standard defibrillator (including switches) is located outside the chamber and transmission cables pass through the chamber wall to the chest pads;
- additional personnel – an external defibrillator operator who controls the discharge unit located outside the chamber.

Quite recently two defibrillators have been introduced into hyperbaric medicine, which could be used inside the chamber (including the discharge unit). This makes the procedure of in-chamber defibrillation much easier. The Physiocontrol LifePak 1000 has been approved for hyperbaric use by the classification body Germanisher Lloyd in close cooperation with the Biomedical Engineering Department of the Karolinska Institute in Stockholm, Sweden (Kronlund P, Lind F, personal communication, 2013). The other is the Corplus3 (GS Elektromed, Geräte G. Stemple GmbH, Germany). The former device is a popular automated external defibrillator (AED) well known to emergency medical service (EMS) teams as well as for in-hospital services. The latter device is a combined wireless monitor of physiological parameters with embedded defibrillator to be used inside a hyperbaric chamber. Both devices have been approved by Germanisher Lloyd and, among other aspects, the safety approval for these devices is based on the assumption that using a lower current in bi-phasic impulse mode during defibrillation with self-adhesive pads does not create a risk of sparking. Indeed, as reported in 2010, "*there were no case reports of fires caused by sparking when shocks were delivered using adhesive pads*".[3] The same statement has appeared in several other national guidelines, for example, those published by the Australian, New Zealand and United Kingdom Resuscitation Councils.

However, sparking during defibrillation even with adhesive pads has been observed several times and reported to the FDA Manufacturer and User Facility Device Experience (MAUDE) database.[4] In this database, there is also a description of a recent event (MDRFOI ID = 2922391, dated 12 October 2012), when a fire was ignited during defibrillation, which burned the patient's side in the EMS ambulance. The defibrillation shock of 200 joules was delivered for VT. There was no explicit statement that the impulse was delivered through the self-adhesive pads but, in the description of the event, there is information that the AutoPulse Non-invasive Cardiac Pump was used during resuscitation and transportation of the patient. The standard procedure in such cases is to attach self-adhesive pads for defibrillation, so one may assume that this event happened with such pads attached. If so, this event shows that fire can start during defibrillation, at least in specific circumstances.

In conclusion, having a modern, stand-alone defibrillator inside a hyperbaric chamber makes defibrillation under hyperbaric condition technically easier than ever, but such a procedure still presents a risk of fire. Therefore, every precaution must be taken while delivering a defibrillation shock in a hyperbaric environment.

Implantable devices

Implantable devices are being seen with increasing frequency in patients referred for HBOT. A review of such devices has been published previously and updated by direct contact with manufacturers to determine maximum allowable pressure for specific devices (from 151–709 kPa).[5,6] While all implantable devices that are exposed to the ISO-compatible ETO-standard sterilization process are exposed to pressures up to 253 kPa, this testing by manufacturers is not giving full legal standing against health providers for increased risk of damage by overpressure. Fortunately, there is direct support from at least one large manufacturer of implantable cardioverter defibrillators (ICD), which has provided a statement setting out the correct application and pressure tolerances of their pacemakers and implantable defibrillators both in diving activities and under hyperbaric conditions.[7,8] According to this statement, it is assumed that devices produced by this manufacturer will operate safely up to 253 kPa, but that performance may change at pressures in excess of 303 kPa (with return to normal operation after decompression). The device chassis will start to deform significantly only at pressures close to 507 kPa. For other implantable devices, for example, brain stimulators or implantable infusion systems, the pressure limitations are stricter, limiting maximum allowable pressure to only 203

kPa.[9] Interestingly, when looking at national guidelines from the same manufacturer it appears that the recommendations vary from region to region. An example is an implantable infusion system with either a programmable pump with a catheter access port or non-programmable pump without a catheter access port. The manufacturer advises a pressure limit to 203 kPa in one region of the world and 233 kPa or 303 kPa in others![10]

In the FDA MAUDE database there is at least one incident reported of an implantable pump inside a hyperbaric chamber (MDRFOI ID = 765802, dated 10 October 2005).[4] In this event, during a 2-hour session at a pressure of 152 kPa, a "*bang noise at the implant side*" was reported by the patient, with malfunction of delivery of an analgesic. X-ray confirmed dislocation of the catheter from the infusion pump. The units of pressure reported in this event are not documented precisely, but were probably gauge pressure, which is equivalent to 253 kPa.

Yet another problem with implantable devices is the potential for external electrical arcing during delivery of a shock. Such a risk has been raised by one manufacturer, leading to a statement that, although there has been no reported incidence of ICD shock-triggered ignition, it may be advisable, pending further study to the contrary, to disable the defibrillation mode while patients are undergoing hyperbaric treatments.[8] There are reports that malfunctioning implanted devices may lead to skin burns over automated ICD sites or even transmitting the shock to external rescuers performing external chest compression.[11,12] Theoretically there is a possibility of external arcing during shock delivery from an implanted defibrillator, but this would need sufficient current leakage from the intended path and an air gap to allow an alternate pathway (to ground) that would complete the circuit. Experiments on dogs assessed worst-case scenarios for external leakage of current during internal defibrillation.[13] These demonstrated energy outflow (estimated to be in the order of 0.4 W when defibrillating with 30 joules, which resulted in mean 0.0184 amp of current with 19.3 V of voltage) which would be significantly lower than that currently allowed by the NFPA 2010 for battery-operated devices for use in hyperbaric conditions (not exceeding 12V and 48W).[13,14]

In conclusion, when faced with a patient referred for HBOT, who has an implanted device, it is recommended that the manufacturer is contacted for confirmation that this specific device can be safely exposed to the treatment pressure and time. Alternatively, one can use any existing reference in the literature looking for specific data on that type of device. Regardless of this, an individual risk-benefit analysis should be conducted on the patient, taking into consideration his/her clinical condition, the indication for HBOT and the capability of the HBOT facility for monitoring and intervention in the chamber. In any such case, both patient and physician should sign a consent form accepting increased risk for either malfunction or damage to the device. It is highly advisable to constantly monitor implanted devices during every HBO session and to report any untoward events or malfunction to either national or international databases.

Survey of medical devices inside hyperbaric chambers in the European Union

In Europe, there is a Medical Device Directive (MDD 93/42) that defines a medical device as "*any instrument (...), including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: (...) treatment or alleviation of disease, (...) treatment or alleviation of or compensation for an injury (...)*".[15] According to this definition, the hyperbaric chamber itself and all its equipment should be approved for hyperbaric conditions and this confirmed by appropriate CE certification. Unfortunately the list of medical devices that are CE-marked for use in hyperbaric conditions is very short. At present, it consist of only two ventilators (Italian Siaretron 1000 Iper [60 VF] and the Maquet Servo-i HBO), one syringe pump (Pilot Hyperbaric, Fresenius Vial S.A.) and two systems for internal monitoring (Haux HMMS, Germany, and Corplus3, Germany). For any other device that is introduced into hyperbaric conditions, a formal risk assessment must be conducted, but the user still takes the full responsibility for any malfunction of the device that is exposed to environmental conditions other than those specified in the operating manual for that device.

Because the list of CE-marked medical devices used for intensive care during a hyperbaric session is so short, it is well known that many European medical hyperbaric facilities are using different unlisted devices inside hyperbaric chambers. In order to obtain a clearer picture of these practices, a survey on the use of medical devices inside hyperbaric chambers in Europe was conducted in 2013.

The list of European medical hyperbaric facilities included in the OXYNET registry <www.OXYNET.org> was used as a contact list. The OXYNET database is administered by the European Committee for Hyperbaric Medicine, <www.ECHM.org>. At the time of the survey (May 2013), there were 246 facilities included in the database. There was no e-mail address for 30, so 216 e-mails were sent with the questionnaire. Fifty-two e-mails were undeliverable and of the remaining 164 e-mails, 49 responses were received (only 30% of the e-mails successfully delivered). At the same time, the same survey was conducted in the USA giving a similar response rate (24%, 46 responses out of 192 centres; James Bell, personal communication, 2013). Out of the 49 centres, that completed the survey, 36 centres (73%) used only multiplace chambers; six centres used only monoplace chambers and seven centres were using both mono- and multiplace chambers.

It is interesting that out of 49 facilities that responded, only 33 reported that they were using any medical equipment inside the hyperbaric chamber. The remaining 16 centres,

including 11 centres with multiplace chambers and five with monoplace chambers, do not use any medical devices in their chambers. Of the 33 centres using medical devices inside the chamber, only six use solely CE-marked devices for ventilation, monitoring and infusions. The other 27 centres rely on some sort of risk assessment being conducted by the external company alone (11 centres), internally within the institution (five centres) or by both external and internal entities (eight centres).

MECHANICAL VENTILATION

Only 14 centres reported that they solely used CE-marked ventilators (Siaretron 1000 Iper, Maquet Servo i-HBO or the now obsolete Draeger Hyperlog). Other centres are using: Servo 900C modified for hyperbaric conditions; Evita 4; Draeger Oxylog; Penlon Oxford MKII; Brian Avian transport ventilator (for backup only) or Newport HT50 transport ventilator (for backup only).

PATIENT MONITORING

Among the 33 centres, there were a variety of different solutions for physiological monitoring other than the CE-certified devices (Haux HMMS and Corplus3). These included: the Kontron system (monitor outside, modules inside); Siemens Sirecust Monitor 620; Datex/Ohmeda (monitor outside, modules inside); GE Solaris 800i (with nitrogen flush); GE PDMS transmitting units; Propaq Encore; 106 EL/102; Marquette Tramscope or Draeger Infinity Delta PMS. Other medical devices used for monitoring of patients during HBOT included: Kontron $TcpO_2$; Radiometer TINA $TcpO_2$; Wright's spirometer; Magtrack respiration monitor; Life Pack 20 (discharge unit outside, defibrillation pads inside); Physiocontrol Lifepack 1000 defibrillator (certified by Germanischer Lloyd); Heine Minilux otoscope; Abbott Optimum Exceed or Accu-Check Performer glucometers and tonometer Omron M4-1 Intellisense (with manual start). Infusion devices included: Braun Perfusor Secura; Argus syringe pump 600 series; modified Alaris SE and IVAC P1000 peristaltic pumps; IVAC/Wellmed syringe P3000 and Terumo TE371 TIVA syringe.

With regard to policies for implantable devices, 26 centres had an explicit policy, including 13 centres requesting external approval (from the manufacturer). One centre has a policy for deep brain stimulators (up to 203 kPa).

Amongst the free text comments sent, there were many for an appropriate European organisation to officially tackle the problem of the lack of medical equipment that is CE marked for use in the hyperbaric environment, as well as the need for a shared repository of information about equipment used for medical purposes in different hyperbaric centres.

In conclusion, it is clear that the list of medical devices to be used inside hyperbaric chambers and approved by European regulations is deficient and does not fulfil the needs of many European hyperbaric centres. In this situation, medical directors take the responsibility of using non-CE marked medical devices, either based on a formal risk assessment (external or internal) or simply based on their personal experience and general knowledge. It is highly advisable to convince manufacturers of the need for testing their devices for hyperbaric conditions with appropriate CE marking for the European market. In the meantime, any risk assessment should be published or otherwise made available for the guidance of other hyperbaric facilities. This journal, *Diving and Hyperbaric Medicine*, is an appropriate vehicle for the publication of such technological reports.

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Appearance of gas collections after scuba diving death: a computed tomography study in a porcine model

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Introduction: Postmortem computed tomography can easily demonstrate gas collections after diving accidents. Thus, it is often used to support the diagnosis of air embolism secondary to barotrauma. However, many other phenomena (putrefaction, resuscitation maneuvers, and postmortem tissue offgassing) can also cause postmortem gas effusions and lead to a wrong diagnosis of barotrauma.
Objectives: The aim of this study is to determine topography and time of onset of postmortem gas collections respectively due to putrefaction, resuscitation maneuvers, and tissue offgassing.
Methods: A controlled experimental study was conducted on nine pigs. Three groups of three pigs were studied postmortem by CT from H0 to H24: one control group of nonresuscitated nondivers, one group of divers exposed premortem to an absolute maximal pressure of 5 b for 16 min followed by decompression procedures, and one group of nondivers resuscitated by manual ventilation and thoracic compression for 20 min. The study of intravascular gas was conducted using CT scan and correlated with the results of the autopsy.
Results: The CT scan reveals that, starting 3 h after death, a substantial amount of gas is observed in the venous and arterial systems in the group of divers. Arterial gas appears 24 h after death for the resuscitated group and is absent for the first 24 h for the control group. Concerning the putrefaction gas, this provokes intravenous and portal gas collections starting 6 h after death. Subcutaneous emphysema was observed in two of the three animals from the resuscitated group, corresponding to the thoracic compression areas.
Conclusion: In fatal scuba diving accidents, offgassing appears early (starting from the first hour after death) in the venous system then spreads to the arterial system after about 3 h. The presence of intra-arterial gas is therefore not specific to barotrauma. To affirm a death by barotrauma followed by a gas embolism, a postmortem scanner should be conducted very early. Subcutaneous emphysema should not be mistaken as diagnostic criteria of barotrauma because it can be caused by the resuscitation maneuvers.

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