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CLINICAL RESEARCH

Effects of hyperbaric exposure on mechanical and electronic parameters of implantable cardioverter-defibrillators

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Aims Hyperbaric oxygen therapy (HBOT) is the standard adjuvant treatment for life-threatening or disabling pathologies. Currently, mechanical and electronic variations of implantable cardioverter-defibrillators (ICD) in hyperbaric conditions have not been evaluated. As a result, many patients eligible for HBOT but ICD recipients cannot undergo this therapy, even in emergency situations.

Methods and results Twenty-two explanted ICD of various brands and models were randomized in two groups: single hyperbaric exposure at an absolute pressure of 4000 hPa and 30 iterative hyperbaric exposures at an absolute pressure of 4000 hPa. Mechanical and electronic parameters of these ICD were blindly assessed before, during, and after hyperbaric exposures. Regardless of the hyperbaric exposure, we could not find any mechanical distortion, inappropriate occurrence of anti-tachycardia therapies, dysfunction of tachyarrhythmia therapeutic programming, or dysfunction of programmed pacing parameters.

Conclusion Dry hyperbaric exposure seems harmless on ICD tested *ex vivo*. This result may lead to a reconsideration of the absolute contraindication of emergency HBOT to ICD recipients. A real-life study in these patients with an indication to HBOT should be performed to assess their tolerance to the treatment.

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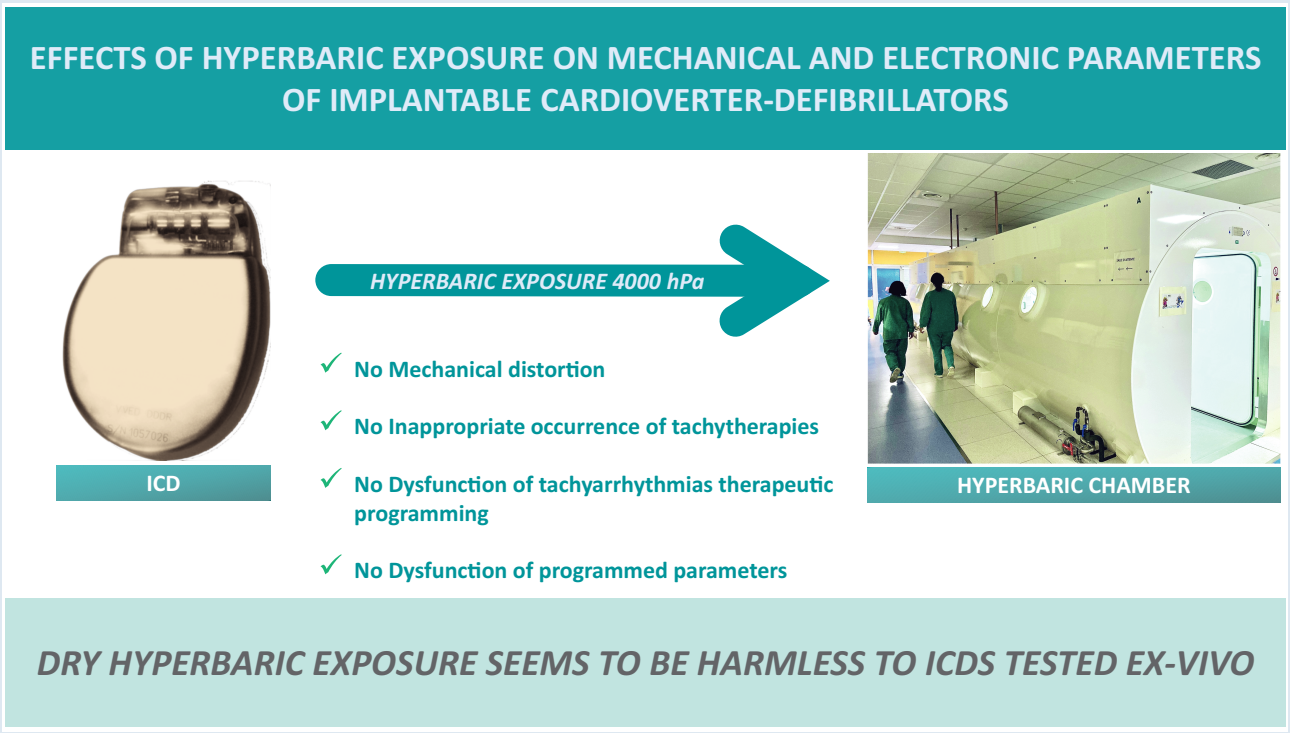
Graphical Abstract



Keywords ICD • Hyperbaric exposure • Hyperbaric oxygen therapy

What's New?

- Dry hyperbaric exposure seems harmless on implantable cardioverter-defibrillators (ICD) tested *ex vivo*.
- This result may lead to a reconsideration of the absolute contraindication of emergency HBOT to ICD recipients.

Introduction

In hyperbaric oxygen therapy (HBOT), patients are placed in a hyperbaric chamber where they breathe oxygen at a pressure higher than that at the atmospheric level. HBOT has various relative or absolute contraindications related to the confined environment, the effects of pressure and oxygen toxicity. Since there is currently no adequate assessment of how implantable devices resist pressure changes, having an implanted device that is not labelled as being 'hyperbaric safe' is a contraindication to HBOT. The absence of specific recommendations by EHRA, HRS, or other scientific societies is another obstacle to deliver this therapy, when necessary, in patients with implantable cardioverter-defibrillators (ICD).[1–3]

Acute HBOT indications are life-threatening or disabling conditions such as carbon monoxide poisoning, soft tissue necrotizing infections, or gaseous embolisms. Other indications include chronic pathologies such as arterial ulcers and diabetic foot lesions in patients with cardiovascular risk factors or underlying cardiopathy.[4]

There are little clinical data showing the effects of hyperbaric exposure on implantable cardiac devices, and existing data concern only pacemakers (PM).[5] Lafay *et al.* and Trigano *et al.* assessed the electronic operation and structural integrity of PM during and after hyperbaric exposures to 4000 and 7000 absolute hPa. They found no significant distortion after exposure at 4000 hPa and small deformations at 7000 hPa. No connector deformation and no pacing dysfunction were reported.[6,7]

Data concerning hyperbaric exposure on ICD are scarce. Manuals of 'medical procedures and precautions' supplied by some ICD manufacturers indicate that some models may stand a pressure as high as 4000 hPa, but no studies support that assertion. Phylax® ICD from Biotronik manufacturer was tested up to 6000 hPa and did not show any mechanical or electronic modification of the device.[6]

In the absence of further data assessing the risks of ICD exposure to high pressure, hyperbaric treatment is not an option for these device recipients.

The aim of this study was to assess mechanical and electronic alterations of explanted ICD of various brands and models after a single or repetitive hyperbaric exposures at an absolute pressure of 4000 hPa.

Materials and methods

From February to May 2021, we tested 22 ICD in the Haux® Starmed 2500 hyperbaric chamber of Brest University Hospital. These ICD were explanted devices from the interventional cardiology department of our hospital either for infection or because an elective replacement indicator was reached.

Hyperbaric exposures

The protocol included a compression phase from atmospheric pressure to 4000 absolute hPa lasting 5 min, then 30 min at 4000 hPa, and a decompression phase lasting 5 min to atmospheric pressure.

Table 1 Electronic and mechanical parameters before, after, and during the hyperbaric exposure protocol at 4000 absolute hPa

	Brand	Model	Prog	Pre-test			Post-test			Per test		
				Dys	Ina	MD	Dys	Ina	MD	Dys	Ina	Exposure
1	Sorin	Paradym DR	VVI	0	0	OK	0	0	OK	—	—	UN-EX
2	Sorin	Paradym CRT	DDD	0	0	OK	0	0	OK	—	—	UN-EX
3	Sorin	Paradym VR	VVI	0	0	OK	0	0	OK	—	—	UN-EX
4	Sorin	Paradym CRT	VVI	0	0	OK	0	0	OK	—	—	UN-EX
5	Sorin	Paradym CRT	VVI	0	0	OK	0	0	OK	—	—	UN-EX
6	Sorin	Paradym DR	VVI	0	0	OK	0	0	OK	—	—	UN-EX
7	Biotronik	Lumax VR	VVI	0	0	OK	0	0	OK	—	—	UN-EX
8	Biotronik	Lumax VR	VVI	0	0	OK	0	0	OK	—	—	UN-EX
9	Medtronic	Secura VR	VVI	0*	F	OK	0*	F	OK	—	—	UN-EX
10	Medtronic	Protecta VR	VVI	0*	F	OK	0*	F	OK	—	—	UN-EX
11	Medtronic	Secura VR	VVI	0*	F	OK	0*	F	OK	—	—	UN-EX
12	Medtronic	Virtuoso VR	VVI	0*	F	OK	0*	F	OK	—	—	UN-EX
13	Medtronic	Virtuoso VR	VVI	0*	F	OK	0*	F	OK	—	—	UN-EX
14	Medtronic	Viva Quad CRT	DDD	0*	F	OK	0*	F	OK	—	—	UN-EX
15	Sorin	Paradym CRT	VVI	0	0	OK	0	0	OK	0	0	IT-EX
16	Sorin	Paradym DR	DDD*	0	0	OK	0	0	OK	0	0	IT-EX
17	Sorin	Paradym CRT	VVI	0	0	OK	0	0	OK	—	—	IT-EX
18	Biotronik	Lumax VR	VVI	0	0	OK	0	0	OK	0	0	IT-EX
19	Biotronik	Lumax VR	VVI	0	0	OK	0	0	OK	0	0	IT-EX
20	Biotronik	Ilivia VR	VVI	0	0	OK	0	0	OK	0	0	IT-EX
21	Medtronic	Virtuoso VR	VVI	0*	F	OK	0*	F	OK	0*	F	IT-EX
22	Medtronic	Viva XT CRT	VVI	0*	F	OK	0*	F	OK	0*	F	IT-EX

Prog, ICD programming; Dys, dysfunction of anti-tachycardia pacing and cardioversion programming, dysfunction of programmed pacing parameters, and bradycardia threshold intervention; Ina, inappropriate occurrence of tachytherapies; MD, mechanical deformation; DDD*, AAI ↔ DDD; 0, no detected abnormality; 0*, no abnormality detected concerning pacing parameters; F, failure of data recovery; OK, no distortion.

ICD were randomized in 2 groups:

- In the 'single exposure' group (SIN-EX), ICD underwent a single exposure at 4000 hPa.
- In the 'iterative exposure' group (IT-EX), ICD underwent 30 daily exposures at 4000 hPa.

Mechanical and electronic parameter measurements

Mechanical and electronic parameters of ICD were blindly assessed before and after hyperbaric exposures. Some ICD of the IT-EXP group were also assessed during the session at 4000 hPa.

Electronic parameters were collected using the manufacturer interfaces, some of which allowed measurement through the hyperbaric wall. We explored the following:

(1) Inappropriate occurrence of tachytherapies
(2) Dysfunction of tachyarrhythmia therapeutic programming, dysfunction of programmed pacing parameters, and bradycardia threshold intervention

Mechanical parameters were length, width, and thickness of both the titanium housing and the lead connector of the ICD. A visual inspection using a magnifying glass completed the assessment in particular to check for an absence of deformation of the connector cavities.

For the primary endpoint, hyperbaric exposure was considered to be safe in the absence of significant electronic and mechanical deformation after a single or iterative exposures compared to the parameters before any hyperbaric exposure.

Results

We tested 22 ICD of various brands, models, and electronic programming. Nine ICD were Sorin® brand, 5 Biotronik® brand, and 8 Medtronic® brand. Seven ICD had cardiac resynchronization therapy function (*Table 1*).

ICD were programmed either:

(a) VVI mode
(b) DDD mode
(c) *AAI ↔ DDD*

Hyperbaric exposure

After randomization, 14 of 22 ICD were included in the SIN-EX group and 8 of 22 in the IT-EX group. All ICD underwent the planned protocol.

Mechanical parameters

No mechanical deformation was identified in the comparative pre- and post-exposure assessment. There was no significant difference in the length, width, and thickness of both the housing and the lead connectors of the ICD and no sign of any deformation in particular of the connector cavities. Results were the same in the two groups (*Table 1*)

Electronical parameters

No electronic dysfunction could be found in the comparative pre- and post-exposure assessment. There was no inappropriate occurrence of tachytherapies and no dysfunction of tachyarrhythmia therapeutic programming or bradycardia pacing.

The bradycardia therapy setting could be analysed for all ICD.

Medtronic® ICD were partially deactivated and could not be analysed for inappropriate occurrence of tachytherapies and tachyarrhythmia therapeutic deprogramming. Seven of the 8 ICD of the group IT-EX could be analysed during hyperbaric exposure. A Sorin® ICD could not be analysed through the wall chamber for technical reasons. Results were the same for all hyperbaric exposures (*Table 1*).

Discussion

To our knowledge, this study is the first to assess the impact of hyperbaric exposure on ICD of different models and brands. Each year, more than 15 000 patients undergo an ICD implantation in France for primary or secondary prevention due to high risk of ventricular tachyarrhythmias.

Our results show that dry hyperbaric exposure is safe for *ex vivo* ICD, as no electronic dysfunction and no mechanical distortion after single or iterative exposure at 4000 hPa could be found. There was a risk of distortion of the titanium housing or lead connectors, which could then have led to an alteration of the electronic components with the risk of cardiac stimulation dysfunction, inappropriate occurrence of a therapeutic event of tachyarrhythmias, or dysfunction of the parameters of the therapeutic algorithm for tachyarrhythmias. Furthermore, the absence of inappropriate occurrence of a therapeutic event reassures on the risk of defibrillation that could be induced in the hyperbaric chamber. In case of appropriate defibrillation, the risk of sparks and fire in the hyperbaric chamber is minimal as defibrillation is internal.

These results are consistent with the absence of deformation or dysfunction during the ISO-compatible standard sterilization process using ethylene oxide and pressurization at 2500 hPa. But this process does not explore the effects of iterative pressurizations as reported in a short communication by Wonhas *et al.* in Undersea and Hyperbaric Medicine in 1998.

The same author reported in 2000, in a short communication in the same journal, the results of tests performed 46 times during 135 min at 2500 hPa and 4 times at 6000 hPa on the Biotronik® Phylax ICD. No significant difference in mechanical or electronic parameters before and after exposures was found. It was concluded that patient carrying this ICD could receive hyperbaric treatment after individual assessment. Our results are therefore consistent with the scarce data available on the subject.

We could not analyse 8 ICD, all of the Medtronic® brand, for inappropriate occurrence of tachytherapies and tachyarrhythmia therapeutic programming because this mode was deactivated.

We assessed ICD at 4000 hPa which is the maximal pressure usually used for HBOT. For chronic disease and carbon monoxide poisoning, schedule treatments involve pressure between 2000 and 2500 hPa. For gaseous embolism, other recompression tables using greater pressure can be applied. There is no clear consensus of the schedule treatments of these injuries, but the US Navy treatment table 6 (USN 6) using oxygen breathing at 2840 hPa is mostly used[8] whereas higher pressure treatment tables (>4000 hPa) are not recommended[4] because of the lack of good evidence and of higher risk for the hyperbaric attendants.

Our study was performed on explanted ICD in a dry environment so that we could not assess exactly the sealing of the device that could be altered in case of damage. However, it can be hypothesized that their tolerance to hyperbaric exposure is the same as implanted ICD. A real-life study with patients carrying ICD should be performed to assess their tolerance to the treatment and confirm the absence of adverse event. When assessing a patient carrying an ICD and requiring a hyperbaric treatment, a physician must consider the severity of the ischemic or rhythmic heart disease that led to the implantation of ICD. To ensure patient safety, the patient should be monitored during hyperbaric exposure.

Furthermore, the absence of absolute contraindication for dry hyperbaric exposure cannot be transposed to SCUBA diving. Exercise, immersion, and increased pressure might interact with cardiac disorders. These environmental conditions increase the risk of a life-threatening event in patients with high-grade rhythm or conduction disorder, and a patient with an implanted ICD should refrain from SCUBA diving.

Study limitations

Our results are confined to an ICD generator only, and not with their attached leads (explanted in total). Hence, the findings cannot be extrapolated to the HBOT–related potential issues with the leads and their effects on the generator and functionality.

Another limitation mentioned earlier is that the testing of the devices was done 'dry'. One of the major risks for device damage would be loss of the hermetic seal with the intrusion of fluid into the device via a feed through in the connector (header).

However, our results are the first showing the absence of effect on different brands and models of ICD. These preliminary results are encouraging to continue *in vivo* evaluations to confirm the safety of HBOT.

Conclusion

After single or iterative dry hyperbaric exposure to 4000 absolute hPa, no mechanical or electronical parameter dysfunction could be found on studied ICD. Dry hyperbaric exposure seems harmless on ICD tested *ex vivo*. This result may lead to a reconsideration of the absolute contraindication of emergency HBOT in patients carrying an ICD. A real-life study in patients with ICD should be performed to assess their tolerance to HBOT.

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Conflict of interest: None declared.

Data availability

All data underlying the manuscript are available from the first and corresponding authors.

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