



## ORIGINAL ARTICLE

# The impact of hyperbaric oxygen treatment for cardiovascular implantable electronic devices

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**Abstract**

**Introduction:** The safety of hyperbaric oxygen treatment (HBO<sub>2</sub>) in patients with cardiovascular implanted electronic devices (CIED) remains unclear.

**Methods:** We conducted a retrospective analysis of seven CIED patients (median age 79 [73–83] years, five males [71.4%]), including five with pacemakers and two with implantable cardioverter defibrillators (ICD), who underwent HBO<sub>2</sub> between June 2013 and April 2023. During the initial session, electrocardiogram monitoring was conducted, and CIED checks were performed before and after the treatment. In addition, the medical records were scrutinized to identify any abnormal CIED operations.

**Results:** All seven CIED patients underwent HBO<sub>2</sub> within the safety pressure range specified by the CIED manufacturers or general pressure test by the International Organization for Standardization (2.5 [2.5–2.5] atmosphere absolute × 18 [5–20] sessions). When comparing the CIED parameters before and after HBO<sub>2</sub>, no significant changes were observed in the waveform amplitudes, pacing thresholds, lead impedance of the atrial and ventricular leads, or battery levels. All seven patients, including two with the rate response function activated, exhibited no significant changes in the pacing rate or pacing failure. Two ICD patients did not deactivate the therapy, including the defibrillation; however, they did not experience any arrhythmia or inappropriate ICD therapy during the HBO<sub>2</sub>.

**Conclusion:** CIED patients who underwent HBO<sub>2</sub> within the safety pressure range exhibited no significant changes in the parameters immediately after the HBO<sub>2</sub> and had no observable abnormal CIED operations during the treatment. The safety of defibrillation by an ICD during HBO<sub>2</sub> should be clarified.

**KEYWORDS**

cardiovascular implantable electronic devices, hyperbaric oxygen treatment

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## 1 | INTRODUCTION

Hyperbaric oxygen treatment (HBO<sub>2</sub>) involves the inhalation of 100% oxygen in an environment with two to three times the atmospheric pressure, temporarily increasing the dissolved oxygen levels in the blood to enhance the peripheral oxygen supply.<sup>1</sup> Appropriate indications for HBO<sub>2</sub> include sudden hearing loss,<sup>2</sup> nonhealing wounds related to peripheral arterial diseases,<sup>3</sup> late effects of radiation exposure,<sup>4</sup> and refractory infections such as gas gangrene, necrotizing fasciitis, and osteomyelitis.<sup>5</sup>

While HBO<sub>2</sub> is applied in various medical conditions,<sup>6</sup> patients may sometimes have cardiac implantable electronic devices (CIEDs). However, there is a lack of comprehensive reports on the safety of utilizing HBO<sub>2</sub> in patients with CIEDs. Medical institutions worldwide are presumed to administer HBO<sub>2</sub> to patients with CIEDs based on general pressure tests by the International Organization for Standardization (ISO) and results from individual pressure tests performed by CIED manufacturers (Table 1). However, pressure test requirements by the ISO standard do not consider the conditions of HBO<sub>2</sub>, and individual pressure tests by CIED manufacturers did not follow a common protocol. In addition, the safety of implantable cardioverter defibrillator (ICD) therapy during HBO<sub>2</sub> has not been clarified so far. Further investigation is warranted to assess the safety of CIED treatment under HBO<sub>2</sub> in real-world settings.

## 2 | METHODS

### 2.1 | Purpose of this study

This study constituted a case series of patients with CIEDs who underwent HBO<sub>2</sub> at Tokyo Medical and Dental University (TMDU) hospital. The primary objective of this study was to assess the potential impact of HBO<sub>2</sub> on CIED parameters by comparing the results of the CIED checks before and after the HBO<sub>2</sub>. Additionally, we

analyzed the electronic medical data to investigate the CIED operation, including the pacing rate and ICD therapy, under HBO<sub>2</sub>.

### 2.2 | Management of CIED patients during HBO<sub>2</sub>

The HBO<sub>2</sub> treatment protocol at TMDU Hospital is determined by the physicians in the department of the hyperbaric medical center based on the patient's pathology and condition. The selected treatment pressure is typically 2.5 or 2.8 atmospheres absolute (ATA). During the initial HBO<sub>2</sub> session for patients with CIEDs, electrocardiogram monitoring was conducted, and CIED data checks were performed before and after the HBO<sub>2</sub>. If the initial HBO<sub>2</sub> session was completed without any issues related to the CIED, subsequent sessions with the same protocol were conducted without electrocardiogram monitoring and CIED checks and only assessed patient symptoms.

### 2.3 | Study population

Between June 2013 and April 2023, a total of 12 CIED patients underwent HBO<sub>2</sub> at TMDU hospital (Figure 1), including nine with pacemakers and three with ICDs. One pacemaker patient experienced difficulty equalizing the pressure in the ears, leading to the discontinuation of the initial HBO<sub>2</sub> session. Additionally, four patients were excluded due to the unavailability of CIED data in their medical records. As a result, seven CIED patients (five with pacemakers and two with ICD) were included in the analysis.

### 2.4 | Data collection

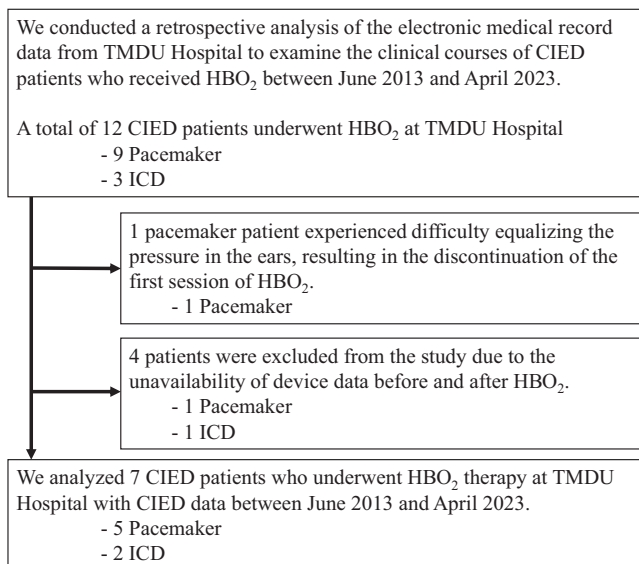
The CIED parameters, including the waveform amplitudes, stimulation thresholds, impedance for each lead, battery levels, and ICD therapy settings and log, were evaluated. These parameters were

TABLE 1 Safety pressure range for each CIED type and CIED manufacturers.

CIED type	Medtronic	Abbott	Boston	Microport	Biotronik
Pacemaker	4.0	7.0	5.0	3.0–4.0	2.5–3.0
Transvenous ICD	4.0	7.0	5.0	4.0	2.5–3.0
Subcutaneous ICD	-	-	3.0	-	-
CRT-P/D	4.0	7.0	5.0	4.0	2.5–3.0
ILR	4.0	5.0	-	-	1.5

Note: The safety pressure range for CIEDs from Biotronik (Berlin, Germany) is determined by the general pressure test requirements set by the International Organization for Standardization. For other CIEDs from manufacturers such as Medtronic (Minneapolis, MN, USA), Abbott (Chicago, IL, USA), Boston Scientific (Marlborough, MA, USA), and Microport (Irvine, CA, USA), the safety pressure range is established based on individual pressure tests conducted by the respective CIED manufacturers. It is important to note that this table is based on the results of pressure tests submitted by each CIED manufacturer and is applicable to current and general CIED models; it does not cover all CIED models from each CIED manufacturer.

Abbreviations: CIED, cardiovascular implantable electronic device; CRT-P/D, cardiac resynchronization therapy–pacemaker/defibrillator; ICD, implantable cardioverter defibrillator; ILR, implantable loop recorder.



**FIGURE 1** Study population. Between June 2013 and April 2023, a total of 12 CIED patients underwent HBO<sub>2</sub> at TMDU Hospital. Seven CIED patients (five with pacemakers and two with ICD) were included in this analysis. CIED, cardiovascular implantable electronic device; HBO<sub>2</sub>, hyperbaric oxygen treatment; ICD, implantable cardioverter defibrillator; TMDU, Tokyo Medical and Dental University.

compared before and after the initial session of HBO<sub>2</sub> to determine the influence of HBO<sub>2</sub> on the CIED. Electrocardiogram monitoring was conducted throughout the initial HBO<sub>2</sub> session, and the medical records were scrutinized to identify any observable abnormalities in the CIED operation during the entire session. The study was approved by the Institutional Review Boards of TMDU. Informed consent for this study was obtained through an opt-out form in accordance with the Declaration of Helsinki.

## 2.5 | Statistical analysis

Continuous variables are presented as the median (interquartile range) for nonparametric data and as the mean  $\pm$  standard deviation for parametric data. Categorical variables are expressed as absolute numbers (percentages). The comparison of continuous data before and after HBO<sub>2</sub> was conducted using the paired *t*-test to assess any significant changes. A *p*-value of .05 was considered statistically significant. Analyses were performed using JMP statistical software version 11.0.0 (SAS Institute, Cary, NC, USA).

## 3 | RESULTS

### 3.1 | Patient characteristics and the protocols of the HBO<sub>2</sub>

A total of seven patients with CIEDs (median age 79 [73–83] years, five males [71.4%]), comprising five with pacemakers and two with ICDs, were analyzed (Table 2). The primary indications for the CIEDs

were three cases of complete atrioventricular block, two cases of sick sinus syndrome, and two cases of ventricular arrhythmias. Regarding the indications for the HBO<sub>2</sub>, sudden hearing loss was the most common indication in three patients [42.9%], followed by two cases for peripheral arterial disease, and one each for osteomyelitis and radiation enteritis. The HBO<sub>2</sub> was conducted at pressures adhering to the safety pressure range specified by the ISO or the CIED manufacturer (2.5 [2.5–2.5] ATA). The median therapy cycle was 18 [5–20] sessions.

### 3.2 | CIED parameter comparison before and after the HBO<sub>2</sub>

Regarding the atrial lead data, the wave amplitude ( $3.23 \pm 1.61$  vs.  $3.36 \pm 1.76$  mV, *p* = .66), pacing threshold ( $0.62 \pm 0.22$  vs.  $0.54 \pm 0.17$  V/0.4 or 0.5 ms, *p* = .22), and lead impedance ( $568.6 \pm 149.1$  vs.  $559.3 \pm 133.1 \Omega$ , *p* = .57) did not exhibit any significant change when comparing before and after the HBO<sub>2</sub> (Figure 2A–C). Similarly, the ventricular lead data also did not exhibit a significant change in the wave amplitude ( $9.68 \pm 5.76$  vs.  $8.34 \pm 4.60$  mV, *p* = .33), pacing threshold ( $0.71 \pm 0.19$  vs.  $0.70 \pm 0.17$  V/0.4 or 0.5 ms, *p* = .85), or lead impedance ( $567.2 \pm 251.1$  vs.  $540.0 \pm 201.6 \Omega$ , *p* = .33) (Figure 3A–C). The remaining battery capacity did not demonstrate any significant change between before and after the HBO<sub>2</sub> in all seven cases. None of the seven CIED patients experienced any issues related to the CIED, even after completing the entire HBO<sub>2</sub> session.

### 3.3 | Pacing and ICD therapy under the HBO<sub>2</sub>

Two pacemaker patients underwent HBO<sub>2</sub> with the rate response setting activated, which included an accelerometer sensor. However, as carefully observed by one cardiologist and the other medical staff, among all seven patients, no significant changes in the pacing rate, pacing failure, or symptoms, clearly related to the changes in the pacing rate were observed during the initial session based on the electrocardiogram monitoring. Additionally, two patients with ICDs did not deactivate their therapy settings, including the defibrillation, during the HBO<sub>2</sub>. These two patients did not experience any appropriate or inappropriate ICD therapy activity during the entire HBO<sub>2</sub> session.

## 4 | DISCUSSION

### 4.1 | Safety of CIEDs during HBO<sub>2</sub>

While a Japanese study from 2002 addressed the safety of pacemakers during HBO<sub>2</sub>,<sup>7</sup> and there have also been reports on the impact of simple hyperbaric conditions on pacemakers<sup>8</sup> and ex vivo tests assessing the ICD operation with HBO<sub>2</sub>,<sup>9</sup> there is a lack of comprehensive reports in the English literature evaluating the safety of patients with CIEDs undergoing HBO<sub>2</sub>.

TABLE 2 Patient and CIED characteristics, and HBO<sub>2</sub> protocols.

Patient number	CIED				HBO <sub>2</sub>				
	Age, years	Gender	Indication	CIED type (pacing mode)	Name	Safety pressure range	ATA	Cycle, times	Indication
# 1	83	Male	CAVB	PM (DDD)	Evity8 DR-T	3.0	2.0–2.5	21	Osteomyelitis
# 2	81	Male	CAVB	PM (DDDR)	Accent MRI	7.0	2.5	8	Sudden hearing loss
# 3	91	Male	CAVB	PM (DDD)	Symphony DR 2550	3.0–4.0	2.5	19	Radiation enteritis
# 4	73	Male	SSS	PM (DDD)	Advisa DR MRI	4.0	2.5	3	Peripheral arterial diseases
# 5	77	Female	SSS	PM (AAIR)	Epyra8 SR-T	3.0	2.5	5	Sudden hearing loss
# 6	79	Male	VT	ICD (DDD)	Evera MRI/XT DR	4.0	2.5	20	Peripheral arterial disease
# 7	63	Female	VF	ICD (DDD)	RESONATE EL	5.0	2.0	18	Sudden hearing loss

Note: Patient characteristics of the CIED recipients who underwent HBO<sub>2</sub> and the treatment protocol.

Abbreviations: ATA, atmosphere absolute; CAVB, complete atrioventricular block; CIED, cardiovascular implantable electronic device; HBO<sub>2</sub>, hyperbaric oxygen treatment; ICD, implantable cardioverter defibrillator; PM, pacemaker; SSS, sick sinus syndrome; VR, ventricular fibrillation; VT, ventricular tachycardia.

Although the patient number was small, our study found no impact on the CIED parameters due to HBO<sub>2</sub>, and no abnormal CIED operation was observed during the HBO<sub>2</sub>. We also confirmed with the CIED manufacturers in Japan (Medtronic Japan, Abbott Japan, Boston Scientific Japan, and Biotronik Japan) that no case reports regarding CIED issues related to HBO<sub>2</sub> have been acknowledged to date. It is likely that if the pressurization remains within the safety range specified by ISO and each CIED manufacturer, the likelihood of CIED issues related to the HBO<sub>2</sub> seems to be low.

#### 4.2 | When pressurization beyond the safety range is required

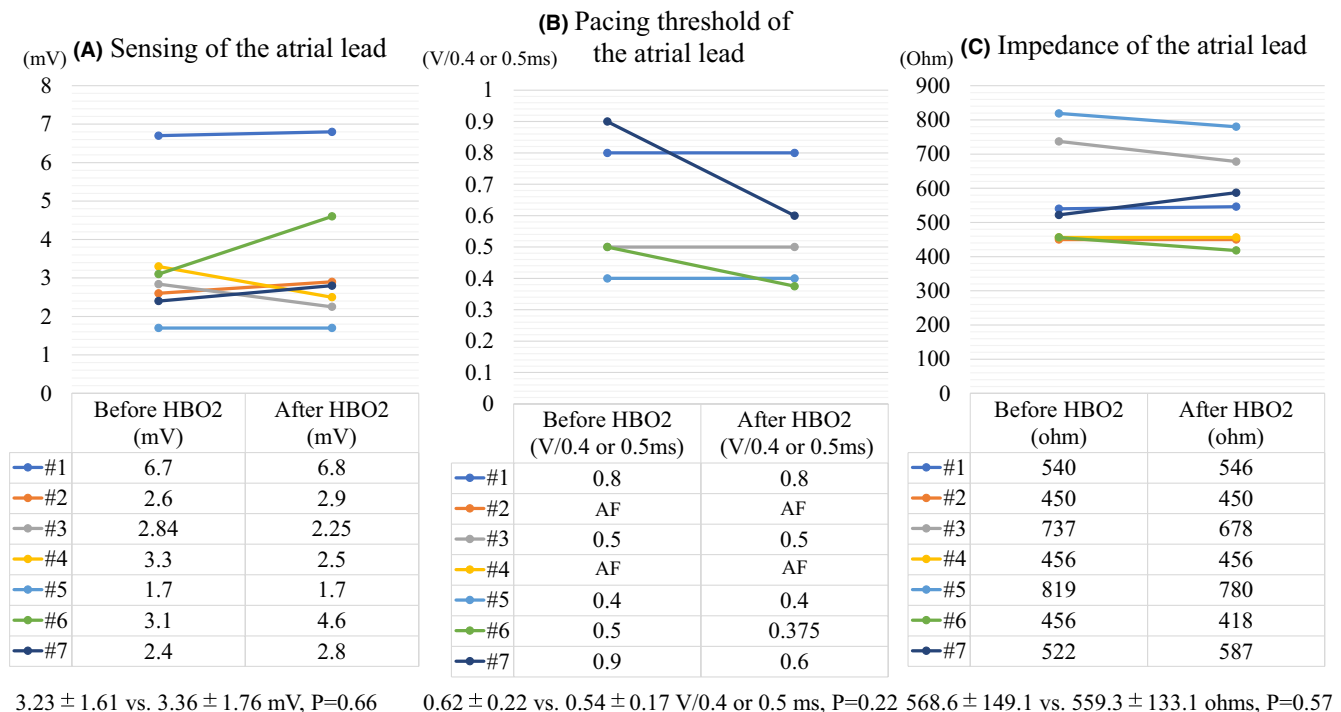
HBO<sub>2</sub> protocols are generally conducted under 2.5–2.8 ATA, and most CIEDs adhere to the safety pressure range. However, some reported HBO<sub>2</sub> protocols, such as those for gas embolisms,<sup>10</sup> include pressures exceeding 3.0–4.0 ATA. When pressurization beyond the safety range is necessary, the safety of CIEDs is not well established.

While HBO<sub>2</sub> is distinct, guidelines and reports related to CIED patients during diving might be informative due to the commonality of high-pressure environments.<sup>11</sup> Although there is also no comprehensive research on the safety of CIED operation during diving, the Undersea and Hyperbaric Medical Society advises CIED patients to avoid diving beyond 30 m (=4.0 ATA). Additionally, a prior report has revealed that a CIED submerged beyond 30–60 m (=over 4.0 ATA) in the sea exhibited deformation.<sup>12</sup> Based on these facts, in terms of high-pressure environments alone, when CIED patients undergo HBO<sub>2</sub> over 4.0 ATA, which exceeds the safety pressure range of the CIED, a careful evaluation is needed. In that case, conducting device checks during HBO<sub>2</sub> is ideal for evaluating the CIED operation. However, it remains uncertain whether it is truly necessary.

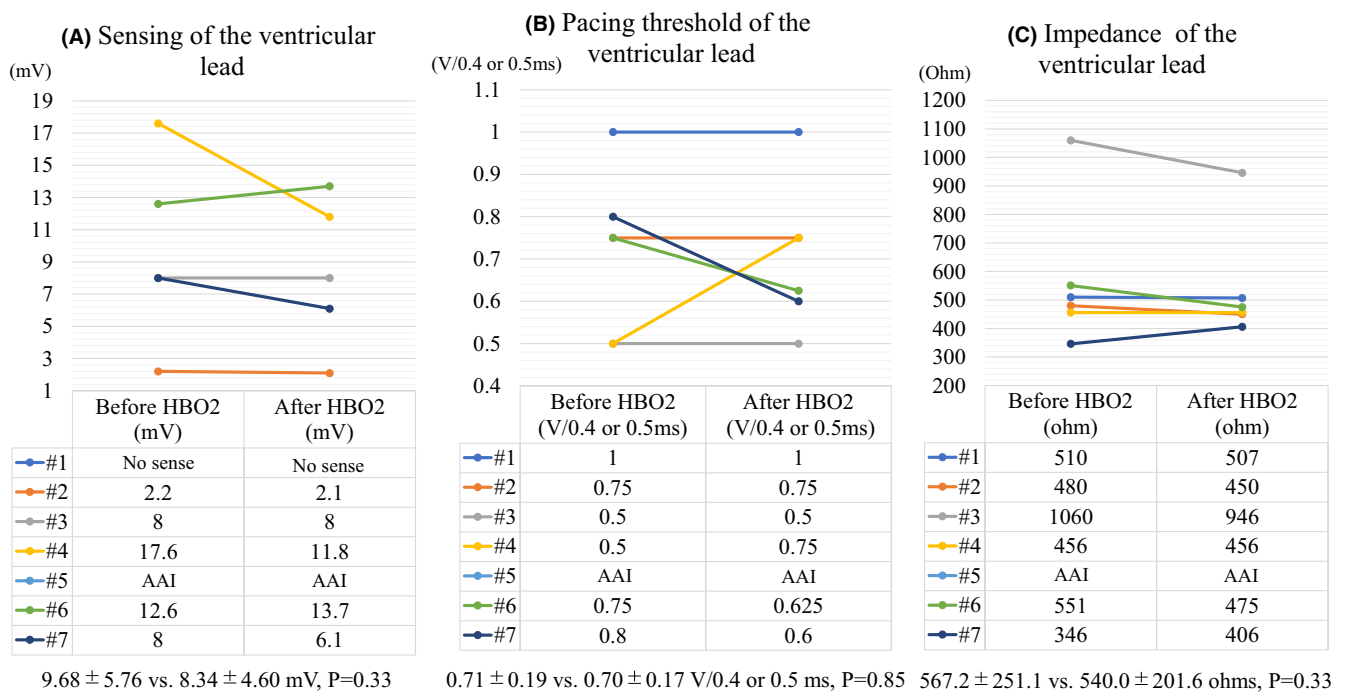
#### 4.3 | CIED settings during HBO<sub>2</sub>

Regarding the blood oxygen concentration, the impact of a high blood oxygen concentration on the pacing threshold and sensing has not been reported. A low oxygen concentration to some extent (pO<sub>2</sub> 41.3 mmHg) has not been reported to transiently or permanently change the pacing threshold.<sup>13</sup> Theoretically, it might possibly affect the pacing threshold or sensing if the myocardium at the pacing site has a more insufficient oxygen supply. However, it is difficult to imagine that a high oxygen supply would worsen the pacing threshold or sensing, at least in the acute phase.

The two patients with a rate response function activated during the HBO<sub>2</sub> had an accelerometer sensor on the circuit board, which possibly was not affected by the deformation of the pacemaker surface. Additionally, while this accelerometer sensor is designed to sense acceleration in an anterior–posterior direction, it might not be affected by the HBO<sub>2</sub>, when the pressure increases gradually from all directions. In addition, concerning any potential electromagnetic interference from the HBO<sub>2</sub> instrument, it generally complies with



**FIGURE 2** Comparison of the atrial lead parameters before and after the HBO<sub>2</sub>. A comparison of CIED parameters regarding the atrial lead before and after the HBO<sub>2</sub> did not reveal a significant change in the (A) sense amplitude, (B) pacing threshold, or (C) lead impedance. Values under the table represent the means ± standard deviation. The *p* value in each figure corresponds to the result of the paired *t*-test. CIED, cardiovascular implantable electronic device; HBO<sub>2</sub>, hyperbaric oxygen treatment; ICD, implantable cardioverter defibrillator.



**FIGURE 3** Comparison of the ventricular lead parameters before and after the HBO<sub>2</sub>. Comparison of the CIED parameters concerning the ventricular lead between before and after the HBO<sub>2</sub> did not reveal any significant change in the (A) sense amplitude, (B) pacing threshold, or (C) lead impedance. The values under the table represent the means ± standard deviation. The *p* value in each figure corresponds to the result of the paired *t*-test. CIED, cardiovascular implantable electronic device; HBO<sub>2</sub>, hyperbaric oxygen treatment; ICD, implantable cardioverter defibrillator.

electromagnetic compatibility regulations, ensuring that the instrument does not interfere with other medical devices. Regarding pacing settings alone, HBO<sub>2</sub> would not require changes, at least under the secure pressure ensured by each CIED manufacturer, in terms of high pressure, high oxygen concentration, or electromagnetic interference.

However, determining whether ICD therapy should be ON or OFF during HBO<sub>2</sub> poses a challenging decision. In this study, two patients with ICDs had their therapy settings left ON throughout the entire course of the HBO<sub>2</sub>. However, there were no appropriate or inappropriate ICD activities. In the event of a life-threatening arrhythmic event during the HBO<sub>2</sub>, there is a potential delay in treatment due to the emergency decompression of the chamber. From this perspective, it is considered reasonable to keep the ICD therapy ON. However, similar to temporarily interrupting the oxygen supply during external defibrillation, although it is extremely rare, in oxygen-rich environments, arcing between two electrodes has been known to cause fires.<sup>14</sup> Regarding extracorporeal defibrillators, risks of fire and an inappropriate operation under high-pressure environments have been reported in prior studies,<sup>15,16</sup> and a recent comprehensive review of cardiopulmonary resuscitation during HBO<sub>2</sub> also recommended that extracorporeal defibrillators should not be stored inside the pressure chamber. The use of biphasic devices placed outside the chamber with a connection to chest panels inside should be preferred.<sup>17</sup>

Further, the safety of defibrillation with transvenous or subcutaneous ICDs during HBO<sub>2</sub>, conducted under high pressure and 100% oxygen administration, remains unclear. While the risk is presumed to be low, especially for transvenous and subcutaneous ICDs with shock leads/devices inserted into the body and a low output compared to extracorporeal defibrillators, the safety of defibrillation, particularly with the subcutaneous ICDs with shock leads closer to the skin, needs further investigation in the HBO<sub>2</sub>.

## 5 | LIMITATIONS

This analysis was conducted with a small sample size at a single center, so it may not provide robust enough clinical evidence to demonstrate the safety of CIEDs under HBO<sub>2</sub>. A subsequent HBO<sub>2</sub> session was performed without electrocardiogram monitoring. Although we conducted CIED checks only before and after the first session of HBO<sub>2</sub>, repetitive HBO<sub>2</sub> sessions could affect the CIED. It is advisable to perform a CIED check at least at the end of each treatment series. We did not have any detailed data on the heart rate variability during HBO<sub>2</sub> in patients with the rate response function activated. No arrhythmia events or ICD therapies occurred during the HBO<sub>2</sub>, and as a result, the safety of ICD defibrillation during HBO<sub>2</sub> could not be evaluated. Patients with CIEDs who underwent HBO<sub>2</sub> at our institution were referred specifically for HBO<sub>2</sub> treatment, and after the completion of the treatment, they returned to their previous hospital. Therefore, we do not have any data on the CIED performance in the chronic phase.

## 6 | CONCLUSION

The seven cases of CIED patients who underwent HBO<sub>2</sub> under the safety pressure range specified by the ICD manufacturers exhibited no significant changes in the CIED parameters before or immediately after the HBO<sub>2</sub>, and there were no observable abnormalities in the CIED operation. Further investigation is required to assess the safety of defibrillation by ICDs during HBO<sub>2</sub>.

### ACKNOWLEDGEMENTS

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### CONFLICT OF INTEREST STATEMENT

Dr. Goto, Dr. Takigawa, and Dr. Miyazaki belong to the endowed departments of Medtronic and Boston Scientific. Dr. Miyazaki received speaker honoraria from Medtronic.

### DATA AVAILABILITY STATEMENT

The datasets used in the current study are available from the corresponding author upon reasonable request.

### ETHICS STATEMENT

The study was approved by the Institutional Review Boards of Tokyo Medical and Dental University.

### PATIENT CONSENT STATEMENT

Informed consent for this study was obtained through an opt-out form in accordance with the Declaration of Helsinki.

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