



Technical Suitability of Implantable Cardiac Devices for Recreational Diving

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ABSTRACT

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Background: Diving is a diffused recreational activity, and the number of divers carrying cardiac implanted devices is similarly growing. Due to the lack of guidelines or technical indications, the suitability of such devices for diving or the fitness to dive for these patients still needs to be determined.

Objective: This work summarizes implantable cardiac devices' suitability for recreational diving, technical vulnerability factors, and recommendations to improve implanted divers' safety.

Methods: Between May 1, 2021, and March 20, 2022, three interventional cardiologists retrieved the technical documentation of selected implantable cardiac devices. In particular, any suitability and tests conducted in hyperbaric environments were tracked.

Results: Technical documentation was recovered for four companies. Most devices were tested in hyperbaric conditions in single, prolonged, or repeated exposures to pressurized air; underwater tests were not mentioned. No company expressly disclosed the suitability of the devices for underwater activities.

Conclusion: In the absence of technical indications or guidelines, a multidisciplinary evaluation between cardiology, diving medicine, and sports medicine is essential to establish the suitability for underwater sports in implanted patients. Before each diving trip, device control is advisable, and underwater physiological adaptations should be considered, especially in the cardiovascular domain. Stressors other than water and pressure must be considered during diving, such as lead strain caused by arm movements and pressure exerted by suits or buoyancy control devices on the chest. Future directions point towards a follow-up of implanted, active divers and developing leadless devices and underwater telemonitoring.

Keywords: cardiac arrest; diving; drowning; electrophysiology; implantable cardiac device; pacemaker

INTRODUCTION

Diving is an increasingly popular sport. Apart from professional or technical diving, Self-Contained Breathing Apparatus (SCUBA) diving is usually a recreational activity where subjects reach depths up to 40 meters underwater while breathing compressed air. Also, breath-hold diving is becoming a very popular sport around the world. An increased workload is required when diving, especially when facing harsh environmental conditions (such as currents, tides, or waves) or escaping dangerous situations. Current recommendations set the minimum aerobic capacity of individuals (measured in metabolic equivalents – MET) at 4 MET for swimming in normal diving conditions but suggest a 6 MET [1,2] or a 7 MET threshold [3] as a safety margin. Such requirements are still debated between cardiologists, sports medicine, and diving medicine physicians when dealing with patients with coronary artery diseases asking for a certification of suitability to diving. Along with human factors, pre-existing cardiovascular diseases (mainly ischemic heart disease) [4–7] or cardiovascular risk factors (such as obesity) [8] are consistently represented in the past medical history of diving fatalities and pose a heavy decisional burden on diving medicine practitioners.

Similar uncertainties are faced when dealing with patients carrying implantable cardiac devices since the available literature is limited to reports, simulated experiments in hyperbaric chambers [9], and expert considerations [10], despite the constantly growing, exponential number of patients implanted every year [11]. In general, implantable cardiac devices improve patients' quality of life and survival at high risk of life-threatening arrhythmias. Specifically, pacemakers (PM) are implanted in patients who usually suffer from conduction system disturbances. At the same time, subjects affected by severe structural heart disease or congenital arrhythmogenic syndromes receive Implantable Cardioverter Defibrillators (ICDs) or Cardiac Resynchronization Therapy (CRT) devices. ICD- or CRT-wearers are excluded from high-risk or demanding activities, while PM-implanted patients are subjected to fewer restrictions [12]. However, diving medicine physicians consider all implanted individuals unsuitable for recreation-

al diving, regardless of the underlying disease, and specific guidelines still need to be provided. Another concern affecting clinical decision-making strictly concerns the technical suitability of implantable cardiac devices, which needs to be better described in the literature and is currently related to Hyperbaric Oxygen (HBO₂) therapy only [10]. Previous investigators questioned the correct functioning of implanted cardiac devices when exposed to increased environmental pressure. However, the available literature did not explore other peculiar diving features, which could be the most critical limit for otherwise healthy patients to practice different underwater sports.

This work aims to give the reader a critical analysis of implantable cardiac devices' suitability for recreational diving and, specifically, technological vulnerability factors that should be considered when evaluating fitness to dive. The ultimate objective is to increase the knowledge in this field, improving divers' safety.

METHODS

The search was conducted between May 1, 2021, and March 20, 2022. First, three experts in interventional cardiology from the Cardiology Division, IRCCS Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi, Bologna, Italy, compiled a list of commercially available cardiac implantable devices by consensus (Table 1). The investigators then retrieved technical documentation for each device primarily through direct contact with companies' technical offices or on each company's website. Suitability and tests conducted in hyperbaric environments and available testing conditions were tracked.

RESULTS

Data were retrieved for four companies. A fifth manufacturer neither had documents available online nor answered the request and was therefore excluded (Table 1). Most devices were tested for hyperbaric conditions in single, prolonged, or repeated exposures. No company specifically allowed diving activities in the technical documentation. One recommended a shared decision with the patient's cardiologist/electrophysiologist and the diving physician; another suggested giving information re-

Company	Information Obtained	Models	Components	Tested in hyperbaric conditions	Diving clearance	Other recommendations related to environmental pressure changes	Date Confirmed
Boston Scientific Corporation	Direct contact with the company	All the models, starting with J, K, L, and S, of the following product families: ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™, ADANTIO™ MRI, EQUIO™, ALTRUA®.	It is not specified if the generator and leads were tested together or separately	1000 test cycles up to 5 ATA *	After consulting the patient's cardiologist/ electrophysiologist and a diving physician	Increase the frequency of device evaluations depending on the patient's health.	As of May 26, 2022
BIOTRONIK SE & Co. KG	Direct contact with the company	All devices	It is not specified if the generator and leads were tested together or separately.	One hour at 1.5 bar **	Not mentioned	Mandatory risk-benefit analysis by a physician	As of March 22, 2023
		Edora, Enitra, Enticos, Evity	It is not specified if the generator and leads were tested together or separately	40 test cycles up to 3.04 bar	Not mentioned	Mandatory risk-benefit analysis by a physician	As of March 22, 2023
Medtronic	Direct contact with the company	All devices	It is not specified if the generator and leads were tested together or separately.	Specific tests not mentioned.	Not mentioned	In hyperbaric chambers, do not use pressures higher than 4 ATA	As of March 20, 2023
	Device Manuals	Micra™ MC1VR01 (Leadless) Azure; Astra; Adapta; Advisa; Attesta; Ensura; Relia; Sensia; Sphera; Versa; Syncra.	It is not specified if the generator and leads were tested together or separately.	Specific tests not mentioned.	Micra™: information for SCUBA diving and recreational diving (see right)	Do not expose to pressures higher than 4 ATA (equivalent to about 30 meters/100 ft underwater)	Issued April 28, 2020 Issued December 16, 2021 Issued January 13, 2017
Abbott (former St. Jude Medical)	Direct contact with the company	All Devices	Generator and leads tested	Tested up to 7 ATA	Not mentioned	-	As of June 7, 2022 (Issued in July 2016)

* protocol internally developed by the company; ** compliant to the ISO 14708-1 clause 25.1 standards "Protection of the active implantable medical device from damage caused by atmospheric pressure changes." ATA: absolute atmospheres.

Table 1. List of commercially available pacemakers selected by the authors.

garding environmental pressure change to patients willing to perform SCUBA diving or recreational diving. Also, the retrieved documentation does not mention stress tests performed underwater.

DISCUSSION

This paper aims to provide insight into diving medicine and electrophysiology, whose connection is represented by divers wearing implantable cardiac devices, and focuses on their technical suitability for underwater activities.

The first consideration deals with the indications to implant ICDs, CRT devices, and PMs. ICDs and CRT devices are usually indicated in patients affected by structural heart disease with different levels of cardiac function impairment who cannot perform physically demanding activities such as those needed when diving [12].

Second, ICDs are implanted in patients prone to life-threatening arrhythmias. Generally, each diving technique needs training and a range of specific skills proportional to the environment and the equipment used, making it a sport with challenging characteristics even in shallow waters. Arrhythmic events can, at minimum, cause transient obtundation and incapacitation of divers, exposing them to many possible harms – from incorrect decompression procedures causing decompression illness to barotrauma or direct traumatic events – similarly to previously described deaths due to disabling depth narcosis [4,7]. Also, until ICD-mediated shock, protracted significant arrhythmias can lead to loss of consciousness and, potentially, drowning; such events frequently happen in healthy breath-hold divers during the ascent phase [13–15] and in fit divers affected by depth narcosis [16].

Third, intense derangements in normal physiology caused by diving should be considered. The diving reflex is the most relevant adaptation, consisting of apnea, bradycardia, vasoconstriction, increased mean arterial pressure, and splenic contraction [13]. Such response is triggered by immersion of the face, especially in cold water, and mediated by an increase in the parasympathetic tone that could induce intracardiac conduction disturbances, worsening bradycardia, or sudden deterioration of cardi-

ac function, the latter due to the pooling of blood from the peripheral circulation to the chest. Cardiac volumes have been demonstrated to be significantly enlarged during SCUBA diving [17,18]; moreover, ejection fraction is considerably reduced in breath-hold divers [19]. On the other hand, harsh conditions or unpredicted events underwater can increase sympathetic tone and generate fatal arrhythmias in rare conditions such as arrhythmogenic right ventricular cardiomyopathy, congenital long-QT syndrome, or catecholaminergic polymorphic ventricular tachycardia, already proposed as one cause of drowning [20,21]. A recent multicenter registry of adverse events in ICD-implanted patients during or immediately after sport reported no tachyarrhythmias leading to death or external resuscitation. However, one or more shocks were delivered in 77 (21%) out of 372 patients [22], but no mention has been made regarding water-related sports. Despite the study's limits and the relatively positive finding, it remains advisable that patients carrying ICD or CRT devices do not perform activities underwater for all the reasons mentioned above.

PMs are less prone to malfunction than ICDs during sports [23]. Before definitively excluding a PM-wearer from diving, other considerations than environmental pressure alone should be considered. Such a recommendation is part of the current South Pacific Underwater Medicine Society guidelines for the cardiovascular risk assessment of divers [1]. Specifically, PM dependency can expose patients to life-threatening conditions in case of sudden malfunction underwater. PM dependency has neither a shared definition nor standardized testing, but can be described as the symptomatic inadequacy or absence of intrinsic rhythm [24]. Some studies identified an association between PM dependency and risk factors such as severe heart failure, more than 5 years from implant, or high-degree atrioventricular block at implant [25]. Diverse diagnostic techniques have been described in the literature, consisting of a gradual or abrupt cessation of pacing, thus revealing the above clinical picture [26]. Since these tests are not routinely performed, clinicians could consider the presence of such risk factors as predictors of PM dependency, but a consensus is needed. Conversely,

patients developing escape rhythms or subjected to infrequent pacing demands could be considered eligible for a multidisciplinary evaluation.

The issue of the eligibility or non-eligibility of implanted patients for HBO₂ therapy has been previously discussed in the literature, with marginal mention of recreational diving [27]. However, in a recent seminal paper, Kot extensively described the strengths and limits of cardiac implantable devices in hyperbaric conditions and, specifically, undergoing HBO₂ therapy [10]. Kot concludes that hyperbaric physicians should check manufacturers' clearance for HBO₂ therapy or obtain a specific certification before treating chronic patients. Instead, HBO₂ therapy should be considered for urgent or emergent cases when its benefits outweigh the risks.

The same careful, case-by-case evaluation should be carried out by diving medicine physicians. Unfortunately, none of the manufacturers disclosed underwater tests or clearance specifically intended for recreational diving, which transfers the responsibility to the practitioner. By excluding issues explicitly dealing with cardiovascular pathology and physical fitness (not the aim of this work), the technical aspects to consider when releasing medical clearance for recreational diving of cardiac device wearers can be summarized in the pulse generator, the device's leads and electrodes, and the interactions with diving equipment.

THE PULSE GENERATOR

Generators, consisting of hardware inside a biocompatible case, are conventionally implanted in the individual's subcutaneous tissue in the upper anterior chest and are exposed to the same ambient pressure as the diver. It is a common belief that the main problem is represented by the intrinsic resistance of the device to hyperbarism due to the small air quantity inside the case, potentially allowing case deformation under pressure. For this reason, generators are the main tested component of implantable cardiac devices.

As summarized in Table 1, ISO 14708-1 clause 25.1 requires active implantable medical devices to be tested for function after being exposed to 1.5 bar for one hour. However, the specific testing proce-

dures are not defined, and each manufacturer chooses different testing for their devices. Some stressful approaches consisted of tests up to 7 ATA or 1000 cycles up to 5 ATA, probably attempting to deform the surrounding case. Abbott (former St. Jude Medical) details that rate-responsive PMs implanted before 1999 employ a piezoelectric crystal sensor mounted on the inner surface of the case, whose functioning can be altered by an environmental pressure-mediated flexion of the case. As previously suggested by Kratz et al., using a resin-filled generator could be safer than a gas-filled model [28]. It is difficult to imagine that patients undergoing HBO₂ therapy or performing recreational diving could be exposed to the same high pressures used in test conditions. Another concern highlighted in technical documents is that increased environmental pressure could cause infiltration of fluids inside the case. Kot pointed out that every device undergoing sterilization procedures is subjected to pressures between 1.7 and 2.5 ATA (7–15 meters underwater), thus automatically being a test allowing the minimum operational depth attainable for recreational divers without needing other specifications. Recreational diving is usually carried out around 18 meters and to a maximum depth of 40 meters; deeper diving is probably unsafe for PM wearers since it needs specific training and technical equipment, and because a direct ascent without several decompression stops is impossible in case of device malfunction.

THE LEADS

Leads connect the generator to the sensing or stimulating electrodes through insulated conductors and are an underappreciated cause of device malfunctioning. In normal conditions, the lead shape continuously changes during thoracic expansion/deflation during the respiratory cycle, intrinsic movements of the heart during the cardiac cycle, and the movements of the upper limbs or torso. This dynamic environment puts leads under constant mechanical stress, making them the most vulnerable part of the devices [29,30]. Unfortunately, the literature dealing with leads' technical malfunction is limited, probably due to underreporting bias, but it could be fundamental in evaluating fitness to dive.

The most worrisome lead-related complication is cardiac perforation, potentially causing pericardial inflammation, effusion, tamponade, or damage to the surrounding structures in the chest or abdomen, since it may occur at any time after implantation. However, cardiac perforation is rare and usually manifests acutely after implantation (PMs: 0.1%-0.8%; ICDs: 0.6%-5.2%) [31]. More pertinent to the scope of the paper, late perforation is fortunately uncommon [32]. However, since the asymptomatic presentation of cardiac perforation can be more prevalent [33], device interrogation may become mandatory before diving fitness recertification to detect electrical anomalies and suspect this subtle complication.

Lead displacement is the position change of leads and electrodes from their original target, usually happening within six weeks of placement and affecting the atrial rather than the ventricular leads [34]. Macro-dislodgement can be easily detected through chest radiography and can occur after the patient manipulates the generator in its pocket (e.g., Twiddler's and Reel's Syndromes) or after direct trauma. These exact reasons can cause micro-dislodgement, which is more subtle and should be suspected when detecting malfunctioning [34], again recommending more frequent device interrogations to obtain fitness to dive.

Lastly, technical failure can arise from single, high-energy movements or repetitive activities. The bending fatigue of wires subjected to such external stress can affect the leads' functioning over time. Bending-prone weakness points can be identified in specific anatomical sites where leads change direction, typically near the proximal connection (due to movements of the generator and less mobility of the wires) and at the entrance in the thoracic cavity (due to direct compression between soft tissue and costoclavicular ligaments or between the clavicle and the first rib) [35]. The flexibility of the lead, which permits bending with a short radius of curvature, exerts high stress on metal components, potentially causing insulation breaches as the first sign of repetitive damage until the most worrisome lead conductor fracture.

Overall, the already mentioned pathophysiological

adaptations to the underwater environment, namely the diving reflex causing cardiac chamber enlargement and consistent changes in cardiac orientation, could also determine temporary or permanent lead displacement. Such events could pose high risks for PM-dependent patients, who could lose cardiac stimulation needed to overcome both their underlying disease and the diving reflex-induced bradycardia. Not to mention the extreme danger for ICD- and CRT device-wearers in case of loss of capture. Moreover, under hyperbaric conditions, bodily fluids can infiltrate the insulating sheet and the pulse generator connection, causing acute malfunction. Leads are usually tested to verify endurance to repetitive oscillations during the cardiac cycle. Table 1 shows whether the leads are tested with the case in hyperbaric conditions, except for Abbott (former St. Jude Medical), which is still being determined. It could be reasonable in the future to better specify if leads have also been tested and, if not, to include this component in the overall testing. Swimming underwater and the complete abduction of arms during breath-hold diving can also exert high stress on the leads, potentially causing repetitive damage or dislodgment. The European Society of Cardiology recommends avoiding activities involving, for example, strong upper extremity movements in the first weeks after implantation [12]. A conservative approach could, therefore, imply suspension of diving until stabilization of the whole device in the pocket and then activity restrictions, such as avoiding strong swimming movements. In addition, breath-hold diving could be allowed only at shallow depths without using a sled or similar device that exerts traction on the arms. SCUBA diving could be allowed only in optimal underwater conditions and at limited depths.

INTERACTIONS WITH DIVING EQUIPMENT

As an extreme environment sport, each diving technique needs its own equipment. In particular, the recreational SCUBA diver has to wear a buoyancy control device (BCD) that can be inflated and deflated, varying its compression on the diver's torso. SCUBA compressed air tanks are attached posteriorly to the BCD, increasing its weight. This jacket

exerts a variable mechanical compression on the shoulders, torso, and implantable cardiac device by adhering to the anterior chest. Moreover, BCDs put implantable cardiac devices under considerable shear stress due to relative movements of the torso during swimming, changes in directions and position towards the bottom or the surface, and when the diver manually adjusts the BCD, especially when dressing/undressing in the water. Wetsuits have also been demonstrated to increase pressure on the chest [36], especially at the end of inspiration.

FINAL CONSIDERATIONS

When considering fitness to diving in implanted patients, ICD- and CRT-wearers should be excluded due to the high risk of the underlying disease; instead, for PM-wearers, a multidisciplinary evaluation – involving the patient’s cardiologist, the diving medicine physician, and the sports medicine specialist – should consider, first, the physical level of the subject and exclude PM-dependent subjects, and those with restrictions to physical activities or severe rhythm disturbances (Figure 1).

Once implanted, subjects should wait a certain amount of time before going underwater to reduce

the probability of acute complications already present at the surface (such as cardiac perforation, lead displacement, or fracture). In lack of specific recommendations for diving, those emanated by international societies for general sports activities after implantation could be considered; for example, the European Society of Cardiology recommends “waiting a few weeks before resuming sport” [12], with at least four to allow proper healing and fixation of the leads, towards six weeks plus a normal exercise testing for ICD-implanted patients [37].

Subsequent steps should consider adequate device programming to meet physical demand and anticipate cardiovascular physiology adaptations to the underwater environment. A background in expedition medicine could also be advisable as part of the counseling to organize an adequate retrieval in case of acute malfunctioning while on a remote diving trip. A discussion with the patient regarding a more frequent cardiac check-up should be made to detect potential macroscopic and microscopic damages or malfunction before immersion. Lastly, patients should be advised about diving at shallower depths where an emergency rescue is more manageable and avoid going below 40 meters (130 feet)

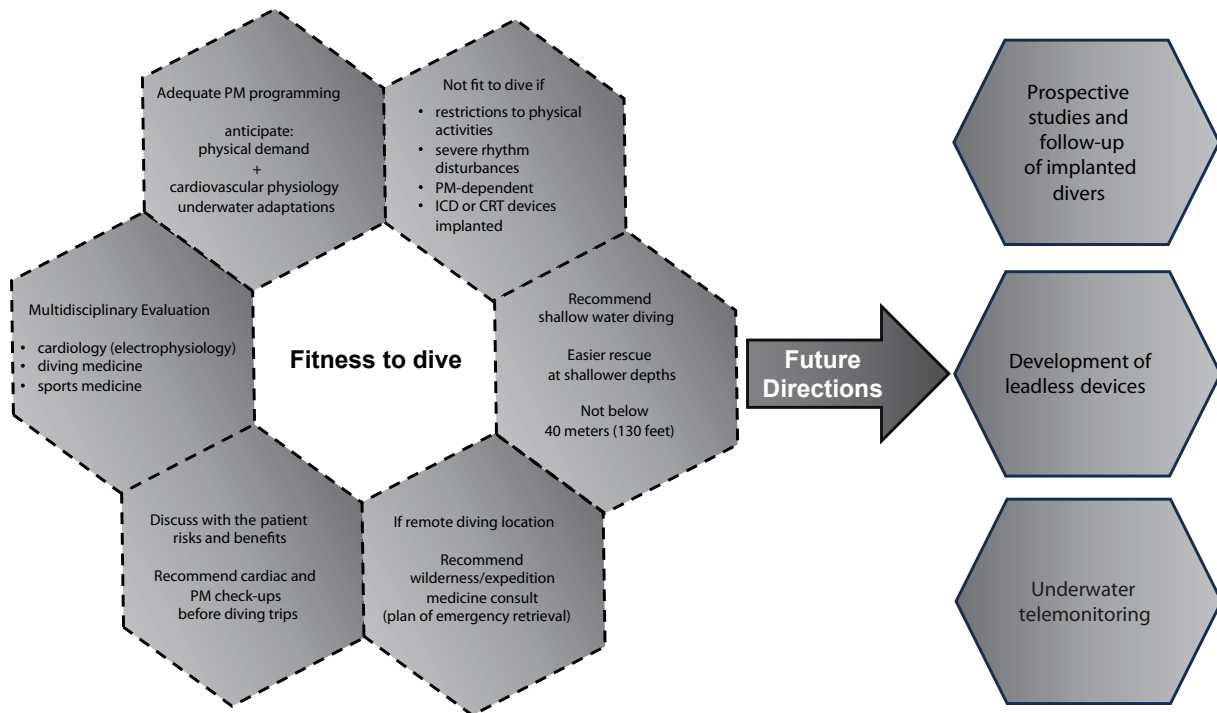


Figure 1. Considerations to be made during fitness to dive evaluation of implanted divers

or exceeding bottom times to ensure a direct and safe ascent.

Future directions point towards developing leadless devices, removing a critical source of device failure, and underwater virtual telemonitoring. Also, a prospective evaluation of currently implanted divers could help understand the actual epidemiology in this subset of patients.

In conclusion, no company explicitly allows underwater activities in the retrieved technical documentation of selected cardiac implantable devices. ICDs and CRT devices exclude patients from diving

for several reasons, while a case-by-case evaluation could allow some PM-wearing individuals to continue practicing underwater recreational activities.

LIST OF ABBREVIATIONS

BCD: Buoyancy Control Device
 CRT: Cardiac Resynchronization Therapy
 HBO₂: Hyperbaric Oxygen
 ICD: Implantable Cardioverter Defibrillator
 MET: Metabolic Equivalents
 PM: Pacemakers
 SCUBA: Self-Contained Breathing Apparatus

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