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Original article

# Bioimpedance analysis is safe in patients with implanted cardiac electronic devices☆

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S U M M A R Y

*Background & aims:* There is an increase in the number of patients worldwide with cardiac implantable electronic devices (CIEDs). Current medical practice guidelines warn against performing bioimpedance analysis (BIA) in this group of patients in order to avoid any electromagnetic interference. These recommendations restrict using the BIA in patients undergoing heart failure or with nutrition disorders in whom BIA could be of major interest in detecting peripheral congestion and to help guide treatment. The present study was conducted to evaluate whether BIA caused electromagnetic interference in patients having CIEDs.
*Methods:* Patient enrollment was conducted during routine face-to-face consultations for scheduled CIEDs interrogations. Device battery voltage, lead impedance, pacing thresholds and device electrograms were recorded before and after each BIA measurement to detect any electromagnetic interference or oversensing.
*Results:* A total of 200 patients were enrolled. During BIA, no significant changes in battery voltage, lead impedance or pacing thresholds were detected, nor were there any inappropriate over- or undersensing observed in intracardiac electrograms. Furthermore, 6- and 12-month follow-up did not reveal any changes in CIEDs.
*Conclusions:* This study shows no interference in patients equipped with CIEDs and suggests that BIA can be securely performed in these patients.
Trial registered under the identifier NCT03045822.


## 1. Introduction

Current medical guidelines have prompted the implantation of an increasing number of cardiac implantable electronic devices (CIEDs) such as pacemakers (PM) and implantable cardioverter defibrillators (ICDs) [1]. A large survey in 2009 revealed worldwide implantation of 300,000 ICDs and over 1 million of PM [2]. These CIEDs rely on complex microcircuitry and are susceptible to interact with electromagnetic interference produced by medical equipment

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such as magnetic resonance imaging, electrosurgery and bioelectrical impedance [3,4].

Bioimpedance analysis (BIA) has been highly valued for its noninvasiveness, safety, low cost, ease of use and is widely used for measurements of the body composition [5,6]. BIA methodology allows the assessment of fat-free mass (FFM) and total body water (TBW). The analysis of body composition by BIA has gained increasing recognition in numerous biomedical applications, including nutrition, hemodialysis for the estimation of hydration state and sports medicine [7–10]. It is also applied in disease diagnosis such as late-stage lung cancer and pulmonary edema, as well as in gastrointestinal and cardiovascular diseases [11–15]. In particular, thoracic BIA has been applied for diagnostic, therapeutic and prognostic purposes in patients with heart failure, those waiting for heart transplantation and patients with hypertension [14,16,17].

While it is poorly acknowledged that BIA actually interferes with CIEDs function, guidelines and manufacturers recommend not performing BIA in patients with CIEDs, since it may cause inappropriate shocks or pacing inhibition (Nutriguard-MS: instructions for use. http://www.data-input.de/media/pdf_english_2014/instructions-for-use-nutriguard-ms.pdf. Accessed May 5th, 2017), [6]. These recommendations restrict performing BIA in many patients with cardiovascular diseases. Therefore, the present study aimed to assess whether BIA caused electromagnetic interference in patients with CIEDs during a BIA test, including over a follow-up of 12 months.

## 2. Methods

### 2.1. Study population

In this prospective study, patients were enrolled during routine face-to-face follow-up consultations for scheduled for PM and ICD interrogations. The study was reviewed and approved by the local ethics committee (Approval Reference: AU1069) and the National Security Agency of Medicines and Health Products (Approval Reference: 2013-A01060-45). Written and signed informed consent was obtained from all patients. The study was registered under the trial identifier NCT03045822. Subjects were eligible if they were over 18 years of age, had CIEDs (PM or ICDs), were not pacing-dependent and did not present acute heart failure. The follow-up period was determined according to the standard control verification of the ICDs and PM at 6 and 12 months, respectively. Patients were excluded if they had a known dysfunction of the implanted device, a particular device lead model prone to developing electronic issues such as the Medtronic Sprint Fidelis (Minneapolis, USA) or the St. Jude Medical Riata leads (St. Paul, USA), and patients implanted less than 2 months ago.

### 2.2. Bioimpedance analysis (BIA) principles

Principles of BIA have been illustrated by applying the cylinder model to illustrate the relationship between impedance and geometry, an assumption made by considering the shape of the body as five tubes, namely two arms, two legs and a trunk, connected in electrical series. A whole body BIA measurement or the body segment BIA technique can either be performed. Measurement of whole body BIA by applying the hand to foot method is the most frequently used [18,19]. This method primarily assesses limb compartments and does not accurately predict the trunk water compartments, which is estimated around 50% of the body mass [20–22]. The segmental BIA allows a better assessment of skeletal muscle mass in comparison to whole body BIA and was introduced to circumvent trunk resistance [7]. In practice, we applied tetrapolar electrodes placed on hands and feet which consist on driving electricity into the body (two current electrodes) and detecting the impedance (two detection electrodes). These measurements are based on considering the body as a cylinder, provide reproducible results and allowed us to established an empirical relationship between the water volume and the square height to resistance ratio ($height^2/R$) [5,23]. In essence, the body reacts to the electrical current by providing two types of resistance: capacitance or reactance arising from the opposition of a condenser such as cell membranes, and resistance from the opposition of a conductor like extra- and intracellular fluid. The impedance is the combination of the two reactance and resistance parameters. All these measurements may vary according to several clinical and biological factors including weight, height, length, age, patient posture, body temperature, intra- and extracellular electrolyte concentration, dehydration and inflammation. In addition, the various tissues of the human body are characterized by different electrical resistance values. For example, adipose tissue and bones are poor electrical conductors (with high impedance), while blood and muscles are better conductors due to their high content in water and electrolytes (with low impedance) [18].

### 2.3. Protocol and data collection

Both clinical history and physical examination including device type implant time and programmed device parameters were recorded. Capture and sensing thresholds were assessed in all leads. These diagnostics included impedance trends, oversensing measurements and spontaneous activity recordings (Fig. 1). The bioimpedance analysis was performed with the Nutriguard-MS (München, Germany), in which sensing electrodes were placed at the upper limbs and in the opposite side of the device, and impedance measured at 5, 50 and 100 kHz (Fig. 2). All patients were at rest for at least 10 min before proceeding with the BIA. The device's battery voltage, leads impedance and pacing thresholds were recorded between each BIA measurement by a cardiac rhythm management specialist. The devices implanted in these patients were from five different manufacturers at the time in France (Biotronik, Boston Scientific, Medtronic, St Jude Medical and Sorin Group).

The measuring voltage depends on the R-value of the patient and is totally independently of the battery voltage. At this measurement method, a constant current flow called a “patient help-current” with 0.8 mA (=800 μA) via the electrodes through the human body. For the measurement that means for patients with R < 1000 Ohms the measurement current expected is about U < 1 V effective.

Thus, an output voltage of 1 V and a power of 1 V × 0.8 mA = 0.8 mW is applied; and this at all frequencies 5, 50, and 100 KHz. The output is on average between 0.3 and 0.8 V, always below 1 V.

For PM devices, measurements were performed in both bipolar and unipolar conditions, after which the PM was reset to its initial program. For the entire duration of the BIA, telemetry was sustained between device and programmer, from which continuous printing of the intracardiac electrograms was collected. The latter were then analyzed for any indication of interference between the Nutriguard-MS (München, Germany) and the PM or ICDs leads and device programmer.

### 2.4. Statistical analysis

Sample size was established on the estimation of the incidence of electromagnetic interference between BIA and CIEDs, and its 95% confidence interval (CI). On the hypothesis that no event will occur,

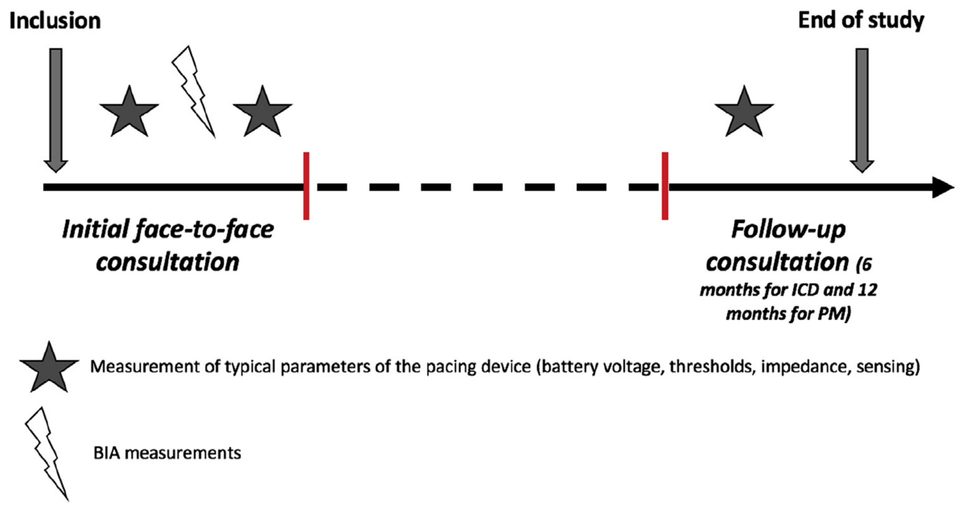


**Fig. 1.** *Flow diagram of the study design.* The study included two groups of participants, one group with implantable cardioverter-defibrillators (ICDs) and a group with pacemakers (PM). The follow-up visits were at 6 and 12 months, respectively.

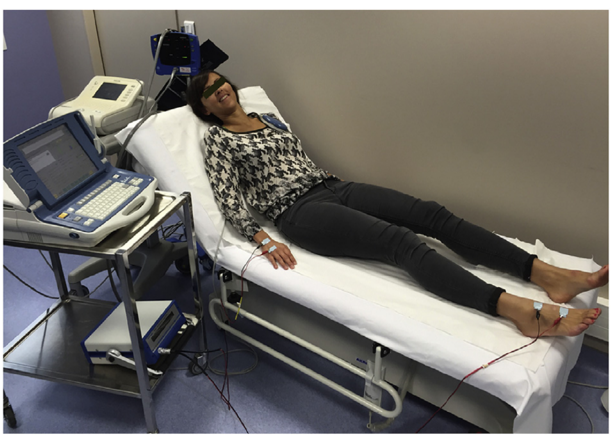

**Fig. 2.** *Patient installation.* Bioimpedance analysis (BIA) was performed with the Nutriguard-MS (München, Germany), in which sensing electrodes are placed at the upper limbs and on the opposite side of the device, with impedance measurements performed at 5, 50 and 100 kHz. All patients were at rest for at least 10 min prior to proceeding with BIA.

we needed 200 subjects in order to have an upper bound of the 95% CI at 1.5% considering Hanley 3/N formulae. No differences were expected between PM and ICDs to the BIA application, the reason for which we worked with a single group of patients (100 subjects with PM and 100 with ICDs).

The statistical analyses were completed using STATA software, version 12 (Stata Corp, College Station, TX, USA). Categorical variables are expressed as frequency and percentages while quantitative variables are stated as mean values ± standard deviation (SD, or by median and interquartile range). Normality was checked graphically and performing Shapiro–Wilk's test. In order to evaluate the possible interference of BIA on battery of the device, on lead impedance and pacing thresholds, paired Student t-test was performed (or Wilcoxon matched signed rank test according to data distribution). We performed measurements of the pacing device three times, before and after the BIA application for each patient. We completed theses analyses using generalized linear mixed models, with the subject taken as random effect. Pacing thresholds, lead impedance and battery voltage were considered as the dependent parameters. We tested time and BIA frequency as fixed effects.

## 3. Results

We enrolled 200 patients with CIEDs in the study between March 2014 and August 2015, comprising 100 subjects with PM and 100 patients with ICDs. Characteristics of patient are reported in Table 1. The majority of subjects implanted with PM were male and the mean age was 79.5 ± 11.7 years. For this group of patients, 25% had single-chamber ventricular pacing, 73% had a dual-chamber and 2% had a cardiac resynchronization therapy device. In

**Table 1**
Patient characteristics.

| Population | n (PM) = 100 | n (ICDs) = 100 |
|---|---|---|
| Age (years) | 79.5 ± 11.7 | 65.1 ± 13.3 |
| Sex (%) | | |
| Female | 35 | 24 |
| Number of leads (%) | | |
| Single chamber | 25 | 57 |
| Dual chamber | 73 | 20 |
| Cardiac resynchronization therapy | 2 | 23 |
| Localization of implantation (%) | | |
| Left | 63 | 95 |
| Years since implantation/replacement | 3.3 ± 3.6 | 3.5 ± 3.2 |
| Etiology of implantation (%) | | |
| *Atrial Fibrillation* (SSS or slow AF) | 25 | |
| *Atrioventricular block* | 47 | |
| *Chronotropic incompetence* | 26 | |
| *Cardiac resynchronization therapy* | 2 | 22 |
| *Primary Prevention* | | |
| Ischemic cardiomyopathy | | 47 |
| Dilated cardiomyopathy | | 48 |
| *Secondary prevention* | | |
| Sudden cardiac death | | 9 |
| Ventricular tachycardia | | 28 |
| Manufacturer (%) | | |
| Biotronik | 15 | 22 |
| Boston Scientific | 6 | 14 |
| Medtronic | 31 | 23 |
| St Jude Medical | 16 | 21 |
| Sorin group | 32 | 20 |
| Chamber: rate of pacing (%) | | |
| None | 47 | 70 |
| Atrial | 8 | 2 |
| Ventricular | 28 | 15 |
| Both | 17 | 13 |

ICDs: implantable cardioverter defibrillators; PM: pacemaker; SSS: sick sinus syndrome.

**Table 2**
Parameters of CIEDs before and after BIA.

| | PM – Unipolar (5, 50, 100 kHz) | | p-value | PM – Bipolar (5, 50, 100 kHz) | | p-value | ICDs – Bipolar (5, 50, 100 kHz) | | p-value |
|---|---|---|---|---|---|---|---|---|---|
| | Before | After | | Before | After | | Before | After | |
| Pacing thresholds (V) | | | | | | | | | |
| Right atrium | 0.60 | 0.59 | 0.20 | 0.64 | 0.64 | 0.63 | 0.61 | 0.60 | 0.587 |
| Right ventricle | 0.62 | 0.62 | 0.88 | 0.75 | 0.74 | 0.95 | 0,90 | 0,91 | 0.837 |
| Left ventricle | 0.98 | 1.00 | 0.36 | 1.02 | 1.0 | 0.36 | 1.43 | 1.42 | 0.618 |
| Lead impedance (Ohms) | | | | | | | | | |
| Right atrium | 523 | 522 | 0.707 | 624 | 622 | 0.273 | 687 | 690 | 0.193 |
| Right ventricle | 461 | 462 | 0.482 | 625 | 608 | 0.296 | 543 | 553 | 0.184 |
| Left ventricle | 578 | 573 | 0.203 | 715.5 | 720.7 | 0.831 | 737 | 739 | 0.340 |
| Battery | | | | | | | | | |
| Voltage (V) | 2.78 | 2.78 | 0.319 | 2.77 | 2.77 | 1.0 | 3.15 | 3.12 | 0.847 |
| Impedance (Ohms) | 1111 | 1112 | 0.187 | 1050 | 1051 | 0.057 | ND | ND | ND |
| Programmed pacing mode | | | | | | | | | |
| AAI | 17 | 17 | 1.0 | 17 | 17 | 1.0 | 0 | 0 | 1.0 |
| VVI | 19 | 19 | 1.0 | 19 | 19 | 1.0 | 58 | 58 | 1.0 |
| DDD | 29 | 29 | 1.0 | 29 | 29 | 1.0 | 8 | 8 | 1.0 |
| VVIR | 12 | 12 | 1.0 | 12 | 12 | 1.0 | 4 | 4 | 1.0 |
| DDDR | 23 | 23 | 1.0 | 23 | 23 | 1.0 | 30 | 30 | 1.0 |

CIEDs: cardiac implantable electronic devices; BIA: bioimpedance analysis; V: volt.

patients with ICDs, the majority were male with an average age of 65.1 ± 13.3 years. Single-chamber models were recorded in 57% of subjects, dual-chamber models in 20%, and a cardiac resynchronization therapy device in 23% of patients (Table 1). The diagnosis leading to CIED implantation is reported in Table 1. Prior to BIA, all batteries and leads displayed normal function.

### 3.1. Evaluation during BIA

During BIA, no changes in the devices' battery voltage, lead impedance or pacing thresholds were detected (Table 2, Fig. 3). There were no inappropriate under- or oversensing in far field channels and intracardiac electrograms identified during the continuous telemetry monitoring (i.e. no complete AV block, no pacing inhibition in PM, no oversensing in ICDs leading to inappropriate therapy as anti-tachycardia pacing or shock). No interferences were detected between the programming and cardiac devices. The different aforementioned device manufacturers were tested and no alterations were observed in the functioning of the implanted device.

### 3.2. Evaluation during 6–12 months follow-up

Out of 100 subjects implanted with PM, 23 patients were lost to follow-up and 65 were examined at 12 months after BIA measurements. Four scheduled replacements (before BIA measurements) were performed prior to the 12-month follow-up visit, one patient had a new implant of a left ventricle lead for cardiac resynchronization, and seven patients were controlled at 2 years instead of at 1 year.

Of the 100 patients implanted with ICDs, 8 were lost to follow up and 85 were examined at 6 months according to the protocol. Four ICDs were replaced prior to the 6-month visit for scheduled CIED end of life, and three patients were controlled at 12 months.

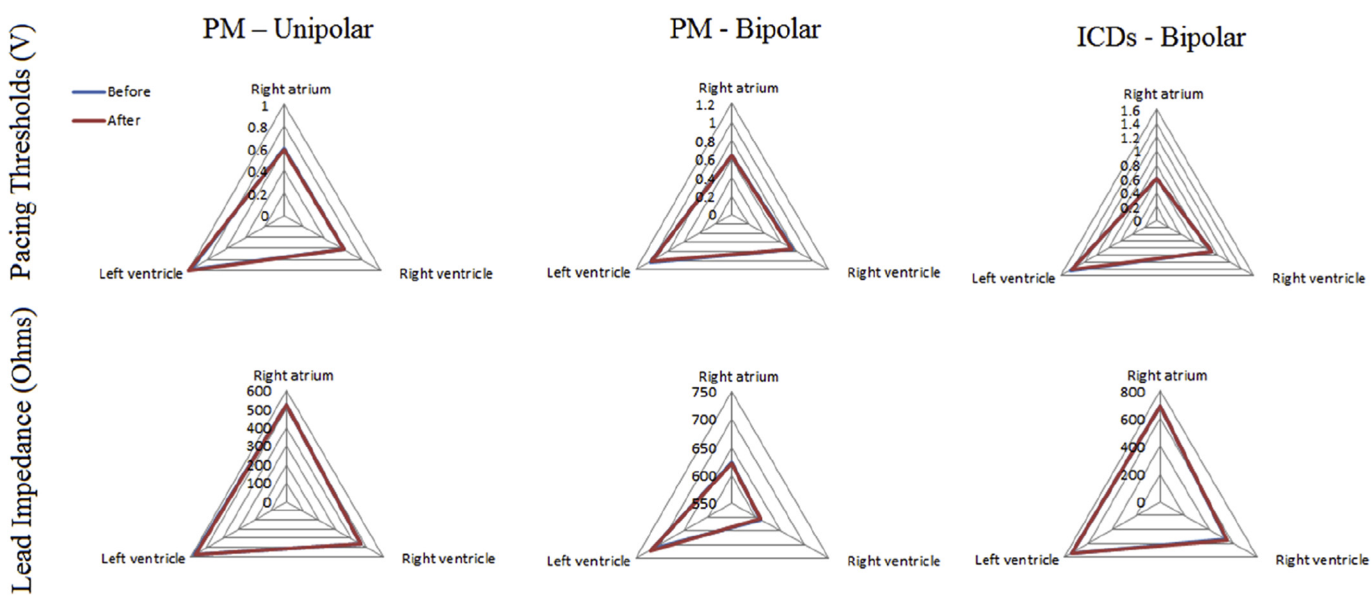


**Fig. 3.** *Evolution of devices parameters before and after BIA.* No differences in unipolar and bipolar measurements were observed in PM and ICDs concerning leads impedance and pacing thresholds, before and after BIA.

No interaction, including increase in threshold, modification of lead impedance, abnormal decrease in battery voltage, or under-/oversensing, was observed during this follow-up for PM and ICDs.

## 4. Discussion

Manufacturers and clinical practice guidelines do not recommend whole body BIA in patients with cardiac implantable electronic devices because of possible electromagnetic interferences, although literature data regarding its safety is rarely encountered. Hence, BIA has not been widely used to date in this group of patients, regardless of its non-invasive nature. The present work demonstrates the absence of alterations in the functioning of CIEDs (PM and ICDs) during the use of BIA. In our cohort of 200 patients with CIEDs, we did not detect any signal over-, undersensing or pacing inhibition, as well as no changes in device battery voltage, lead impedance and pacing thresholds, thus suggesting the safety of using BIA in this specific population. As a result, patients with PM or ICD are not at risk of putative complications under BIA.

A consequence of the electrical current is over-sensing which can induce resistance-wave oversensing leading to inhibition of ventricular pacing in pacing-dependent patients, and/or inappropriate shock in patients with ICD devices and alterations in the device programmer.

All devices are programmed based on the endogenous heart rates and to detect cardiac signals between 10 and 70 Hz [24]. Consequently, all signals outside of these ranges are not captured by cardiac devices. For BIA assessments herein, the conductance of the electrical current was measured at three frequencies, namely 5, 50 and 100 kHz, a range outside the detected field by CIEDs.

There is some reported evidence of electromagnetic interference between cardiac pacemakers and cellular telephones/media players, preventing the PM from functioning properly and causing inhibition of pacing or resulting in painful inappropriate shocks [25,26]. Others have identified electromagnetic interference between digital music players and PM/CDs, however with no effect on intrinsic device function [27].

Recent studies have shown the safety of using bioimpedance vector analysis (BIVA) in patients with CIEDs. BIVA is another method for interpreting bioimpedance information by plotting impedance as a bivariate vector based on its resistance (on the X axis) and capacitive reactance (on the Y axis) components. In a study by Buch et al. evaluating a cohort of 20 subjects with chronic heart failure and implanted ICDs, the authors did not observe any effects of BIVA on intracardiac electrograms or surface electrocardiograms from any lead, whether atrial or ventricular, in patients with cardiac resynchronization therapy [28]. In addition, no inappropriate sensing in device marker channels as well as no telemetric interference was observed between BIVA and the CIEDs. Another study conducted in 21 patients with acute heart failure decompensation showed no changes with regard to device function and leads, or alterations in wire parameters or inappropriate sensing in channels during BIVA [29].

In a recent study, 63 patients implanted with various single-chamber, dual-chamber and biventricular ICDs from different manufacturers underwent BIA measurements in concomitance with routine ICD controls [30]. The study revealed no electromagnetic interferences or artifacts during real-time electrocardiogram recordings using an electrical current of 0.8 m Amp at frequencies from 5 to 100 kHz.

The above-mentioned studies are however limited to small sample sizes, no long-term follow-up and/or to a restricted brand of cardiac devices. In addition, patients implanted with PM have been analyzed in only one study where the authors investigated the function of only 13 PM devices.

In the present study involving a large number of enrolled subjects with PM and ICDs, we performed BIA and analyzed for any occurrence of electromagnetic interference. Indeed, as previous studies, our results showed no effect on device function or lead parameters. To our knowledge, this data shows for the first time the long term safety of using BIA in a larger cohort of patients with CIEDs.

There are several reasons to perform BIA in patients with chronic heart failure. In this population, overweight and obese subjects are at lower risk of death than patients with normal body weight, suggesting an association between higher body mass index (BMI) levels and survival [31]. Also, BIA can be used to facilitate the earlier recognition of cachexia, a poor prognostic sign, in chronic heart failure patients [32]. Furthermore, it has been shown that involuntary weight loss and malnutrition continue to be prevalent among hospitalized patients [33]. Therefore, the outcome of BIA measurements such as the resistance and reactance is of interest to determine nutritional risk and to be predictive for prognosis in various diseases [34,35].

The BIA method has also been validated for quantifying the amount of fluid retention and accumulation in acute decompensated heart failure patients and to provide a useful support for the management of these subjects especially those hospitalized in an acute care unit [36]. Moreover, BIA has been accurately used for diagnosis and guidance of treatment in acute decompensated heart failure patients [37]. Hence, the current guideline against using BIA in patients with PM and ICDs will ultimately exclude a considerable percentage of these patients with chronic heart failure from this valuable analysis.

### 4.1. Study limitations

Despite the advantages of the BIA method and its ability to be used in a population of patients with PM and CDs, it should not be performed on subjects with extremely low (<25 kg) or high (>220 kg) body weight. Secondly, the measurements using the Nutriguard-MS herein were made with frequencies from 5 to 100 kHz. It is not excluded that other BIA systems using different frequencies (up to 500 kHz) may interfere with the CIEDs. Although pacing-dependent patients have not been included (due to ethical considerations) in the present analysis, our results as well as previous reported data discussed above are in agreement with recommending BIA in all CIEDs patients regardless of pacing-dependent status.

## 5. Conclusion

BIA could provide a useful insight in patients implanted with PM and ICDs. The present findings show that the use of BIA in this group of patients is safe and is without risk with regard to the function of these CIEDs. Current recommendations cited by manufacturers and guidelines by international societies should be reviewed and adapted accordingly.

## Statement for authorship

XC, BP, FJ, RE have participated to the preparation of the design of the study. All authors have materially participated in the article preparation (XC, OL, AM, PB, FJ, EF, GM, MA, GS, SP, YB, RR, BC, JRL, TG, BP, PM, GC, RE).

All authors have approved the final article.

## Conflict of interest

None.

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