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BIOIMPEDANCE ANALYSIS IS SAFE IN PATIENTS WITH IMPLANTED CARDIAC ELECTRONIC DEVICES

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7 **ABSTRACT**

8 **Background and Aims.** There are an increase in the number of patients worldwide with
9 cardiac implantable electronic devices (CIEDs). Current medical practice guidelines warn
10 against performing bioimpedance analysis (BIA) in this group of patients in order to avoid
11 any electromagnetic interference. These recommendations restrict using the BIA in patients
12 undergoing heart failure or with nutrition disorders in whom BIA could be of major interest in
13 detecting peripheral congestion and to help guide treatment. The present study was conducted
14 to evaluate whether BIA caused electromagnetic interference in patients having CIEDs.

15 **Methods.** Patient enrollment was conducted during routine face-to-face consultations for
16 scheduled CIEDs interrogations. Device battery voltage, lead impedance, pacing thresholds
17 and device electrograms were recorded before and after each BIA measurement to detect any
18 electromagnetic interference or oversensing.

19 **Results.** A total of 200 patients were enrolled. During BIA, no significant changes in battery
20 voltage, lead impedance or pacing thresholds were detected, nor were there any inappropriate
21 over- or undersensing observed in intracardiac electrograms. Furthermore, 6- and 12-month
22 follow-up did not reveal any changes in CIEDs.

23 **Conclusions.** This study shows no interference in patients equipped with CIEDs and suggests
24 that BIA can be securely performed in these patients.

25 **Keywords:** Bioimpedance analysis, pacemakers, implantable cardioverter-defibrillator,
26 device interference

27 INTRODUCTION

28 Current medical guidelines have prompted the implantation of an increasing number of
29 cardiac implantable electronic devices (CIEDs) such as pacemakers (PM) and implantable
30 cardioverter defibrillators (ICDs) [1]. A large survey in 2009 revealed worldwide
31 implantation of 300 000 ICDs and over 1 million of PM [2]. These CIEDs rely on complex
32 microcircuitry and are susceptible to interact with electromagnetic interference produced by
33 medical equipment such as magnetic resonance imaging, electrosurgery and bioelectrical
34 impedance [3][4].

35 Bioimpedance analysis (BIA) has been highly valued for its noninvasiveness, safety, low cost,
36 ease of use and is widely used for measurements of the body composition [5][6]. BIA
37 methodology allows the assessment of fat-free mass (FFM) and total body water (TBW). The
38 analysis of body composition by BIA has gained increasing recognition in numerous
39 biomedical applications, including nutrition, hemodialysis for the estimation of hydration
40 state and sports medicine [7][8][9][10]. It is also applied in disease diagnosis such as late-
41 stage lung cancer and pulmonary edema, as well as in gastrointestinal and cardiovascular
42 diseases[11][12][13][14][15]. In particular, thoracic BIA has been applied for diagnostic,
43 therapeutic and prognostic purposes in patients with heart failure, those waiting for heart
44 transplantation and patients with hypertension[14][16][17].

45 While it is poorly acknowledged that BIA actually interferes with CIEDs function, guidelines
46 and manufacturers recommend not performing BIA in patients with CIEDs, since it may
47 cause inappropriate shocks or pacing inhibition (Nutriguard-MS: instructions for use.
48 http://www.data-input.de/media/pdf_english_2014/instructions-for-use-nutriguard-ms.pdf.
49 Accessed May 5th, 2017), [6]. These recommendations restrict performing BIA in many
50 patients with cardiovascular diseases. Therefore, the present study aimed to assess whether

51 BIA caused electromagnetic interference in patients with CIEDs during a BIA test, including
52 over a follow-up of 12 months.

53 **METHODS**

54

55 **Study population**

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

68

69 **Bioimpedance analysis (BIA) principles**

70 Principles of BIA have been illustrated by applying the cylinder model to illustrate the
71 relationship between impedance and geometry, an assumption made by considering the shape
72 of the body as five tubes, namely two arms, two legs and a trunk, connected in electrical
73 series. A whole body BIA measurement or the body segment BIA technique can either be
74 performed. Measurement of whole body BIA by applying the hand to foot method is the most
75 frequently used [18][19]. This method primarily assesses limb compartments and does not
76 accurately predict the trunk water compartments ,which is estimated around 50% of the body

77 mass [20][21][22]. The segmental BIA allows a better assessment of skeletal muscle mass in
78 comparison to whole body BIA and was introduced to circumvent trunk resistance [7]. In
79 practice, we applied tetrapolar electrodes placed on hands and feet which consist on driving
80 electricity into the body (two current electrodes) and detecting the impedance (two detection
81 electrodes). These measurements are based on considering the body as a cylinder, provide
82 reproducible results and allowed us to established an empirical relationship between the water
83 volume and the square height to resistance ratio (height^2/R) [5][23]. In essence, the body
84 reacts to the electrical current by providing two types of resistance: capacitance or reactance
85 arising from the opposition of a condenser such as cell membranes, and resistance from the
86 opposition of a conductor like extra- and intracellular fluid. The impedance is the combination
87 of the two reactance and resistance parameters. All these measurements may vary according
88 to several clinical and biological factors including weight, height, length, age, patient posture,
89 body temperature, intra- and extracellular electrolyte concentration, dehydration and
90 inflammation. In addition, the various tissues of the human body are characterized by
91 different electrical resistance values. For example, adipose tissue and bones are poor electrical
92 conductors (with high impedance), while blood and muscles are better conductors due to their
93 high content in water and electrolytes (with low impedance) [18].

94

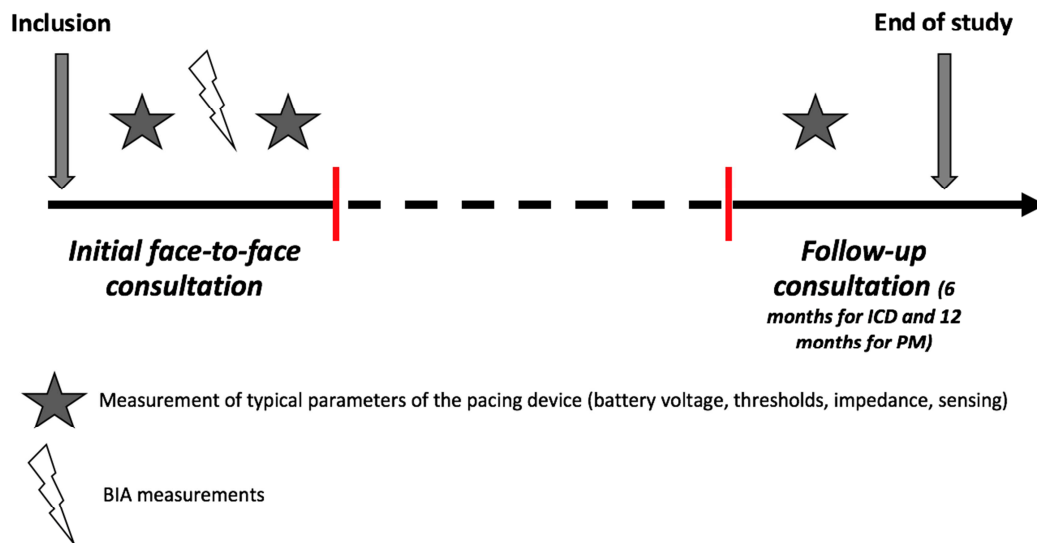
95 **Protocol and Data collection**

96 Both clinical history and physical examination including device type implant time and
97 programmed device parameters were recorded. Capture and sensing thresholds were assessed
98 in all leads. These diagnostics included impedance trends, oversensing measurements and
99 spontaneous activity recordings (**Figure 1**). The bioimpedance analysis was performed with
100 the Nutriguard-MS (München, Germany), in which sensing electrodes were placed at the
101 upper limbs and in the opposite side of the device, and impedance measured at 5, 50 and 100

102 kHz (**Figure 2**). All patients were at rest for at least 10 minutes before proceeding with the
 103 BIA. The device's battery voltage, leads impedance and pacing thresholds were recorded
 104 between each BIA measurement by a cardiac rhythm management specialist. The devices
 105 implanted in these patients were from five different manufacturers at the time in France
 106 (Biotronik, Boston Scientific, Medtronic, St Jude Medical and Sorin Group).

107 The measuring voltage depends on the R-value of the patient and is totally independently of
 108 the battery voltage. At this measurement method, a constant current flow called a “patient
 109 helpcurrent” with 0,8 mA (=800 uA) via the electrodes through the human body. For the
 110 measurement that means for patients with $R < 1000$ Ohms the measurement current expected
 111 is about $U < 1$ volt effective.

112 Thus, an output voltage of 1V and a power of $1V \times 0.8mA = 0.8mW$ is applied; and this at all
 113 frequencies 5, 50, and 100 KHz. The output is on average between 0,3 – 0,8 V, always below
 114 1 V.
 115



116

117

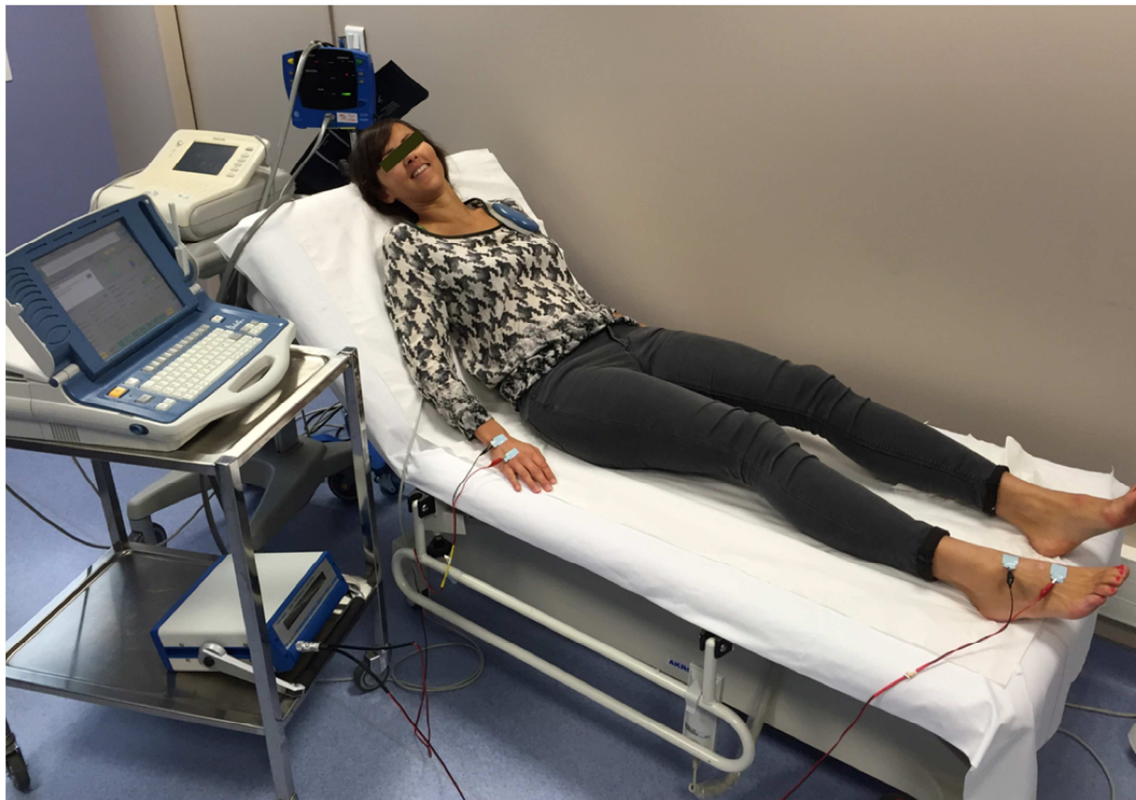
Figure 1: Flow diagram of the study design.

118

119 For PM devices, measurements were performed in both bipolar and unipolar conditions, after
 120 which the PM was reset to its initial program. For the entire duration of the BIA, telemetry

121 was sustained between device and programmer, from which continuous printing of the
122 intracardiac electrograms was collected. The latter were then analyzed for any indication of
123 interference between the Nutriguard-MS (München, Germany) and the PM or ICDs leads and
124 device programmer.

125



126

127

Figure 2: Patient installation.

128

129 **Statistical analysis**

130 Sample size was established on the estimation of the incidence of electromagnetic
131 interference between BIA and CIEDs, and its 95% confidence interval (CI). On the hypothesis
132 that no event will occur, we needed 200 subjects in order to have an upper bound of the 95%
133 CI at 1.5% considering Hanley 3/N formulae. No differences were expected between PM

134 and ICDs to the BIA application, the reason for which we worked with a single group of
135 patients (100 subjects with PM and 100 with ICDs).

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

147

148

149 **RESULTS**

150 We enrolled 200 patients with CIEDs in the study between March 2014 and August 2015,
 151 comprising 100 subjects with PM and 100 patients with ICDs. Characteristics of patient are
 152 reported in Table 1. The majority of subjects implanted with PM were male and the mean age
 153 was 79.5 ± 11.7 years. For this group of patients, 25% had single-chamber ventricular pacing,
 154 73% had a dual-chamber and 2% had a cardiac resynchronization therapy device. In patients
 155 with ICDs, the majority were male with an average age of 65.1 ± 13.3 years. Single-chamber
 156 models were recorded in 57% of subjects, dual-chamber models in 20%, and a cardiac
 157 resynchronization therapy device in 23% of patients (Table 1). The diagnosis leading to CIED
 158 implantation is reported in Table 1. Prior to BIA, all batteries and leads displayed normal
 159 function.
 160

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 (%)		
<i>Atrial Fibrillation (SSS or slow AF)</i>	25	
<i>Atrioventricular block</i>	47	

<i>Chronotropic incompetence</i>	26	
<i>Cardiac resynchronization therapy</i>	2	22
<i>Primary Prevention</i>		
Ischemic cardiomyopathy		47
Dilated cardiomyopathy		48
<i>Secondary prevention</i>		
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)

161

162

163 **Evaluation during BIA**

164 During BIA, no changes in the devices' battery voltage, lead impedance or pacing thresholds

165 were detected (**Table 2, Figure 3**). There were no inappropriate under- or oversensing in far

166 field channels and intracardiac electrograms identified during the continuous telemetry

167 monitoring (i.e. no complete AV block, no pacing inhibition in PM, no oversensing in ICDs

168 leading to inappropriate therapy as anti-tachycardia pacing or shock). No interferences were

169 detected between the programming and cardiac devices. The different aforementioned device
 170 manufacturers were tested and no alterations were observed in the functioning of the
 171 implanted device.

172

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

174

	PM – Unipolar		p-value	PM - Bipolar		p-value	ICDs - Bipolar		p-value
	(5, 50, 100 kHz)			(5, 50, 100 kHz)			(5, 50, 100 kHz)		
	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

175

176 (CIEDs: cardiac implantable electronic devices; BIA: bioimpedance analysis; V: volt)

177

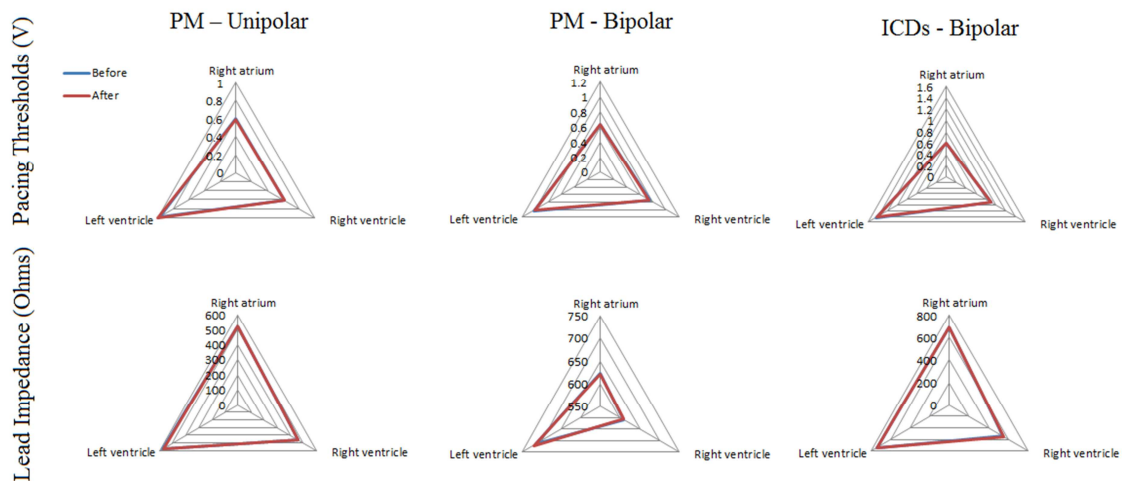
178 **Evaluation during 6-12 months follow-up**

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

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

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

190



191

192 **Figure 3: Evolution of devices parameters before and after BIA.**

193

194 **DISCUSSION**

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

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

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

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

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

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

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

239 In the present study involving a large number of enrolled subjects with PM and ICDs, we
240 performed BIA and analyzed for any occurrence of electromagnetic interference. Indeed, as
241 previous studies, our results showed no effect on device function or lead parameters. To our

242 knowledge, this data shows for the first time the long term safety of using BIA in a larger
243 cohort of patients with CIEDs.

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

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

260

261 **Study limitations**

262 Despite the advantages of the BIA method and its ability to be used in a population of patients
263 with PM and CDs, it should not be performed on subjects with extremely low (<25 kg) or
264 high (>220 kg) body weight. Secondly, the measurements using the Nutriguard-MS herein
265 were made with frequencies from 5 to 100 kHz. It is not excluded that other BIA systems
266 using different frequencies (up to 500 kHz) may interfere with the CIEDs. Although pacing-

267 dependent patients have not been included (due to ethical considerations) in the present
268 analysis, our results as well as previous reported data discussed above are in agreement with
269 recommending BIA in all CIEDs patients regardless of pacing-dependent status.

270

271 **CONCLUSION**

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

276

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282

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FIGURES LEGENDS

Figure 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.

Figure 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 minutes prior to proceeding with BIA.

Figure 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.