





ORIGINAL ARTICLE

Factors affecting signal quality in implantable cardiac monitors with long sensing vector

Giovanni B. Forleo MD, PhD¹  | Claudia Amellone MD² | Riccardo Sacchi MD³ |
 Leonida Lombardi MD¹ | Maria Teresa Lucciola MD² | Valentina Scotti MD³ |
 Maurizio Viecca MD¹ | Marco Schiavone MD¹  | Daniele Giacomelli MSc^{4,5}  |
 Massimo Giammaria MD² 

¹Cardiology Unit, ASST-Fatebenefratelli Sacco, Luigi Sacco University Hospital, Milan, Italy

²Cardiology Unit, Ospedale Maria Vittoria, Turin, Italy

³Cardiology Unit, Ospedale di Vimercate, Vimercate, Milan, Italy

⁴Clinical Research Unit, BIOTRONIK Italia, Vimodrone, Milan, Italy

⁵Department of Cardiac, Thoracic, Vascular Sciences & Public Health, Padova, Italy

Correspondence

Marco Schiavone, ASST-Fatebenefratelli Sacco, Luigi Sacco University Hospital, Via G.B. Grassi, 74 - 20157, Milan, Italy.
 Email: marco.schiavone11@gmail.com

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Abstract

Purpose: Electrical artefacts are frequent in implantable cardiac monitors (ICMs). We analyzed the subcutaneous electrogram (sECG) provided by an ICM with a long sensing vector and factors potentially affecting its quality.

Methods: Consecutive ICM recipients underwent a follow-up where demographics, body mass index (BMI), implant location, and surface ECG were collected. The sECG was then analyzed in terms of R-wave amplitude and P-wave visibility.

Results: A total of 84 patients (43% female, median age 68 [58-76] years) were enrolled at 3 sites. ICMs were positioned with intermediate inclination (n = 44, 52%), parallel (n = 35, 43%), or perpendicular (n = 5, 6%) to the sternum. The median R-wave amplitude was 1.10 (0.72-1.48) mV with P waves readily visible in 69.2% [95% confidence interval, CI: 57.8%-79.2%], partially visible in 23.1% [95% CI: 14.3%-34.0%], and never visible in 7.7% [95% CI: 2.9%-16.0%] of patients. Men had higher R-wave amplitudes compared to women (1.40 [0.96-1.80] mV vs 1.00 [0.60-1.20] mV, $P = .001$), while obese people tended to have lower values (0.80 [0.62-1.28] mV vs 1.10 [0.90-1.50] mV, $P = .074$). The P-wave visibility reached 86.2% [95% CI: 68.3%-96.1%] in patients with high-voltage P waves (≥ 0.2 mV) at surface ECG. The sECG quality was not affected by implant site.

Conclusion: In ordinary clinical practice, ICMs with long sensing vector provided median R-wave amplitude above 1 mV and reliable P-wave visibility of nearly 70%, regardless of the position of the device. Women and obese patients showed lower but still very good signal quality.

KEYWORDS

implantable cardiac monitor, implantable loop recorder, long sensing vector, P-wave visibility, R-wave amplitude

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1 | INTRODUCTION

Implantable cardiac monitors (ICMs) provide continuous heart rhythm monitoring and their use is steadily increasing in clinical practice. The main indications are unexplained syncope or palpitations, cryptogenic stroke, and atrial fibrillation (AF) detection and management.¹⁻³ ICMs record subcutaneous electrogram (sECG) snapshots obtained by a sensing dipole and as the ICM electrodes are positioned under the skin, at a short distance from the heart, electrical interference and artefacts are not unexpected.⁴ Therefore, the most important goal of these devices is to obtain a clear and accurate sECG and to minimize false-positive or -negative arrhythmic episodes caused by artefacts, oversensing, or undersensing of electric potentials.⁵ The use of a long sensing vector has been proposed to increase the amplitude of the detected sECG.^{6,7} Along with the design of the devices, several additional factors may significantly affect ICM signal quality, such as patient sex and weight or implant location, but data that may provide useful information to optimize sensing capability of ICMs are still scant.

2 | METHODS

This was a retrospective, multicenter study conducted in 3 Italian sites, designed to assess the sECG provided by ICMs characterized by a long sensing vector (*BioMonitor 2, Berlin, Germany*) and to investigate potential factors that may influence the signal quality in terms of R-wave amplitude and P-wave visibility. All patients gave written informed consent for the analysis of data provided by remote monitoring. The study was conducted in accordance with the Declaration of Helsinki, applicable local law, and the European directive for data protection (General Data Protection Regulation).

2.1 | Long sensing vector ICM

The *BioMonitor 2* is an ICM designed to automatically record the occurrence of arrhythmias or it can be activated by the patient during symptomatic episodes. It is a leadless device typically inserted under the skin, in the left side of the chest, which uses two electrodes placed on the body of the device to continuously monitor the patient's sECG. Recommended locations from manufacturer are those areas close to the heart where the ICM will be exposed to minimal movement from body positional changes. The *BioMonitor 2* is characterized by a long distance (88 mm) between the electrodes that is obtained via a 5-mm-long case and a flexible antenna with an electrode on the top. This long sensing vector has been designed to improve the quality and amplitude of the sensed sECG. The implantation is performed under local anesthesia using specific insertion tools and without sensing mapping before the procedure. The device continuously analyses the heart rate to start recording immediately

if the set detection criteria are met. The provided sECG has a sampling rate of 128 Hz and an 8-bit amplitude resolution. It is displayed in the so-called "Full Morphology," which is determined by a 0.5-40 Hz bandpass filter, while the hidden "Sensing" signal that is used to isolate and detect QRS complexes is obtained using a 10-40 Hz bandpass filter.

2.2 | Data collection

Consecutive patients in sinus rhythm who were already implanted with the ICM underwent a single in-hospital study follow-up. Demographic characteristics were collected, and the implantation site of the device was classified by skin palpation. The device inclination was assessed using the midline of the sternum as reference and defined as perpendicular to sternum ($0^\circ \leq \text{angle } \alpha \leq 20^\circ$), with intermediate inclination ($20^\circ < \text{angle } \alpha \leq 60^\circ$), or parallel to sternum ($60^\circ < \text{angle } \alpha \leq 90^\circ$) as shown in Figure 1. Intercostal spaces were used to indicate its cranial/caudal location. Body mass index (BMI) was calculated for all patients and a BMI over 30 Kg/m^2 was used to indicate obesity. A standard 12-lead ECG was performed to measure the maximum voltage of the QRS and P waves. The ICM was then interrogated to collect R-wave amplitude on the displayed sECG as the average of 3 different QRS complexes measurements using the automatic markers of the ICM; an example is depicted in Figure 2. A 10 s sECG snapshot was then printed to assess the P-wave visibility as "readily visible," "partially visible" (ie, not visible in all available beats), or "never visible." These measurements were repeated for supine and standing position of the patient. P-wave visibility was assessed by two independent electrophysiologists. In the event of disagreement, a third independent adjudicator was assigned and adjudication was reached by majority vote. The primary endpoint of the analysis was the evaluation of the R-wave amplitude. Secondary endpoint was the P-wave visibility at ICM signal. The "noise burden" defined as the percentage of the time during which the patients' rhythm cannot be assessed owing to artefacts was also collected from the device diagnostics.

2.3 | Statistical analysis

Data were reported as number (percentage) for categorical variables or median (interquartile range [IQR]) for continuous variables. The proportion of patients with visible P wave was expressed along with the 95% confidence interval (CI). The R-wave amplitude was compared between subgroups with the Mann-Whitney test or the Kruskal-Wallis test in case of more than 2 subgroups, while differences between supine and standing positions were analyzed with the Wilcoxon matched-pairs test. P-wave visibility was compared with the Pearson's χ^2 . Statistical significance was defined as $P < .05$. All statistical analyses were performed using STATA (version 11E, StataCorp LP, College Station, TX, USA).

FIGURE 1 Implantation site of the device: the inclination was assessed using the midline of the sternum as reference and defined as perpendicular to sternum ($0^\circ \leq \text{angle } \alpha \leq 20^\circ$), with intermediate inclination ($20^\circ < \text{angle } \alpha \leq 60^\circ$), or parallel to sternum ($60^\circ < \text{angle } \alpha \leq 90^\circ$), while intercostal spaces were used to indicate its cranial/caudal location. Number of patients, median R-wave amplitude (interquartile range), and proportion of patients with readily visible P waves (95% confidence interval) are reported in the text box for each device inclination

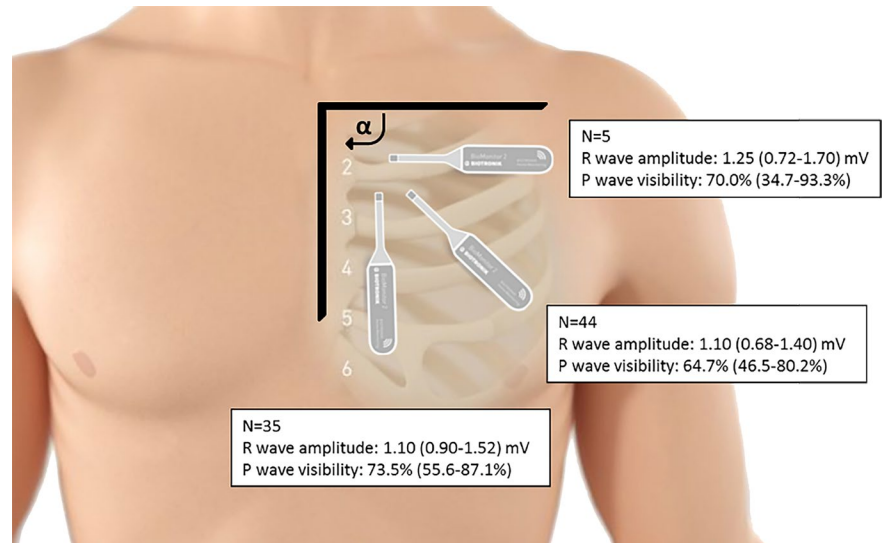


FIGURE 2 Example of Implantable cardiac monitor interrogation and sECG (blue signal) measurements: P-wave visibility was assessed as “readily visible”, ie, visible in all beats (red arrows), while the peak-to-peak R-wave amplitude was measured positioning the automatic dotted vertical lines on 3 different QRS complexes (2 pictured). The amplitude is reported in the red rectangle

3 | RESULTS

3.1 | Study population and implantation site

A total of 84 patients with ICM were enrolled at 3 sites and completed the study follow-up. The median time between ICM implant and the in-hospital study follow-up was 204 (101-414) days. Baseline demographics and locations of device positioning are summarized in Table 1. Thirty-six (43%) patients were female, median age was 68 (58-76) years, and median body mass index (BMI) was 24.6 (22.3-29.0) Kg/m². The primary indication for ICM implantation was unexplained syncope (43%), followed by cryptogenic stroke (36%), palpitations (14%), AF burden monitoring (6%), or sudden cardiac death risk stratification (1%). ICMs were more frequently positioned with an inclination of approximately 45° (52%) or were parallel (43%) to the midline of the sternum. Only five patients (6%) had the device

positioned perpendicular to the sternum. Half of the ICM sensing vector included the first or second intercostal space and were classified as having cranial position. The 12-lead ECG showed sinus rhythm with visible P waves for all patients. QRS wave had maximum ECG voltage >1 mV for 30% of patients, while P waves had ≥ 0.2 mV for 34% of patients.

3.2 | Primary endpoint

At device interrogation, the R-wave amplitude was 1.10 (IQR: 0.72-1.48) mV in supine position and 0.90 (0.60-1.40) mV in standing position ($P < .001$). These values had a strong positive correlation with the R-wave amplitude provided by the remote monitoring system which is continuously measured and displayed as an average value; details are provided in Table 2 and Figure 3. The results of the subgroup analysis for the R-wave amplitude are summarized in Figure 4. Men had significantly higher values compared to women (IQR: 1.40 [0.96-1.80] mV vs 1.00 [IQR: 0.60-1.20] mV, $P = .001$), while obese patients tended to have lower amplitudes compared to normal or underweight subjects (0.80 [IQR: 0.62-1.28] mV vs 1.10 [IQR: 0.90-1.50] mV, $P = .074$). No differences were found according to implant location (inclination and cranial/caudal position) and surface ECG maximum voltage.

3.3 | Secondary endpoint

The P wave was defined as “readily visible” in 69.2% (95% CI: 57.8%-79.2%) of patients, “partially visible” (ie, not visible in all available beats) in 23.1% [95% CI: 14.3%-34.0%], and “never visible” in 7.7% [95% CI: 2.9%-16.0%]. These observations were similar in supine and standing position, as shown in Figure 5.

The results of the subgroup analysis for the P-wave visibility are summarized in Figure 6. Patients with higher P-waves voltage at surface ECG (≥ 0.2 mV) have higher chances to have a well-visible P

TABLE 1 Patient demographics and implantation sites of ICM

| | |
|--|------------------|
| Number of patients | 84 |
| Gender (female) | 36 (43%) |
| Age, y | 68 (58-76) |
| BMI, Kg/m ² | 24.6 (22.3-29.0) |
| Obese (BMI>30 Kg/m ²) | 17 (20%) |
| Indication for ICM | |
| Unexplained syncope | 36 (43%) |
| Stroke | 30 (36%) |
| Palpitations | 12 (14%) |
| AF burden monitoring | 5 (6%) |
| Sudden cardiac death risk stratification | 1 (1%) |
| Implantation site | |
| Parallel to sternum (60°<angle α \leq 90°) | 35 (43%) |
| Intermediate inclination (20°<angle α \leq 60°) | 44 (52%) |
| Perpendicular to sternum (0° \leq angle α \leq 20°) | 5 (6%) |
| Cranial/caudal location | |
| High intercostal space delimiting the device | |
| 1st | 6 (7%) |
| 2th | 36 (43%) |
| 3th | 25 (30%) |
| 4th | 12 (14%) |
| 5th | 5 (6%) |
| Low intercostal space delimiting the device | |
| 3th | 2 (2%) |
| 4th | 22 (26%) |
| 5th | 60 (71%) |

Note: Data presented as number (percentage) or median (interquartile range).

Abbreviations: BMI, body mass index; ICM, implantable cardiac monitor; AF, atrial fibrillation.

wave at ICM signal (86.2% [68.3%-96.1%] vs 59.2% [44.2%-73.0%], $P = .012$). Patient sex, implant location, and BMI did not affect P-wave visibility.

The mean noise burden retrieved from the device diagnostics was 0.15% (0%-1.75%) without significant differences among subgroups.

TABLE 2 Correlation between the average R-wave amplitude manually measured on the displayed sECG in supine and standing position and the value automatically provided by the remote monitoring system

| | Supine position | Standing position | Home monitoring | Spearman coefficient | P^a |
|-----------------------|-----------------|-------------------|-----------------|---|---|
| R-wave amplitude (mV) | 1.1 (0.7, 1.5) | 0.9 (0.6-1.4) | 0.8 (0.6-1.2) | 0.85 ^b 0.71 ^c 0.78 ^d | <0.001 ^b <0.001 ^c <0.001 ^d |

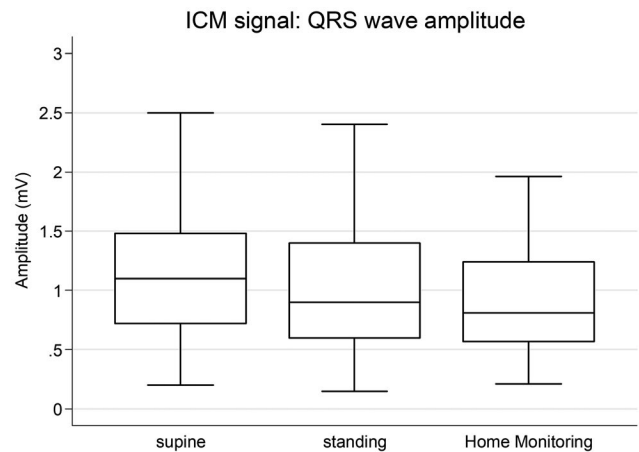
Note: Data are expressed as median (Interquartile range) or n (%).

^aTest of H₀: supine and standing are independent from Bonferroni correction.

^bSupine vs Standing.

^cSupine vs Home Monitoring.

^dStanding vs Home Monitoring.

**FIGURE 3** Comparison between the average R-wave amplitude manually measured on the displayed sECG in supine and standing position and the value automatically provided by the remote monitoring system. $P > .05$ for each paired comparison with Bonferroni correction

4 | DISCUSSION

In the present study, we observed that ICMs with a long sensing vector provided a median value of R-wave amplitude above 1 mV that resulted higher in males than in females and was not affected by implant location and surface ECG voltage. Conversely, obese patients showed the lowest R-wave amplitude values (median 0.80 mV). Additionally, P waves were readily visible in around 70% of patients and their visibility was not influenced by patient sex, weight, or implant location. As expected, patients with higher P-wave voltage at surface ECG (≥ 0.2 mV) have higher chances to have a well-visible P wave at ICM signal. The above findings confirmed on a large and multicenter population the excellent sensing performance of the long vector ICM already found in previous smaller and single-center experiences.⁸⁻¹² In addition, as a novelty, we explored subgroups of patients where there are concerns about ICM signal quality, such as females and obese subjects. The association between signal and implant site was also analyzed, ICMs were mostly inserted with an intermediate inclination of approximately 45° or parallel to the midline of the sternum, but neither the R-wave amplitude nor the P-wave visibility was influenced by the device positioning in the different sites.

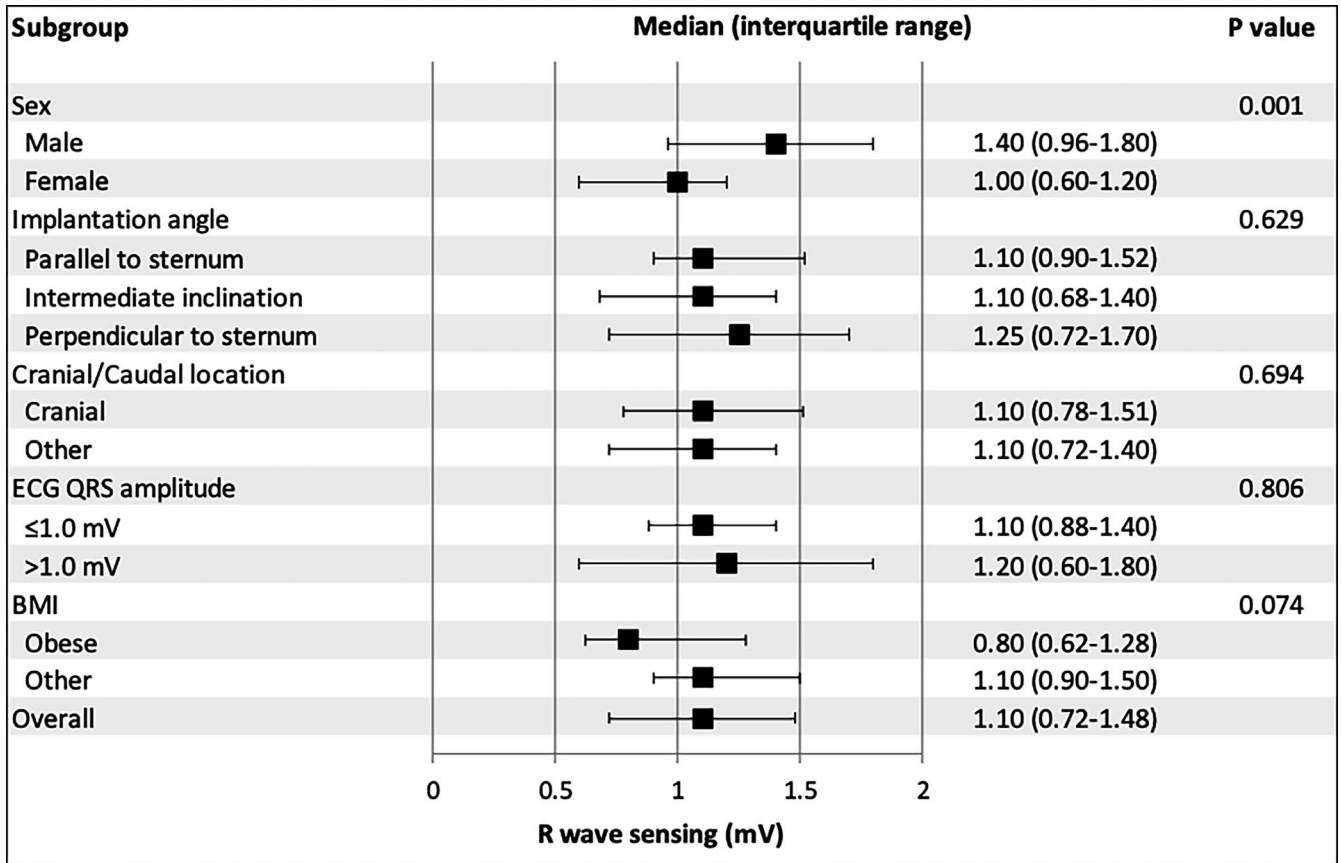


FIGURE 4 Subgroup analysis of the median R-wave amplitude on ICM signal

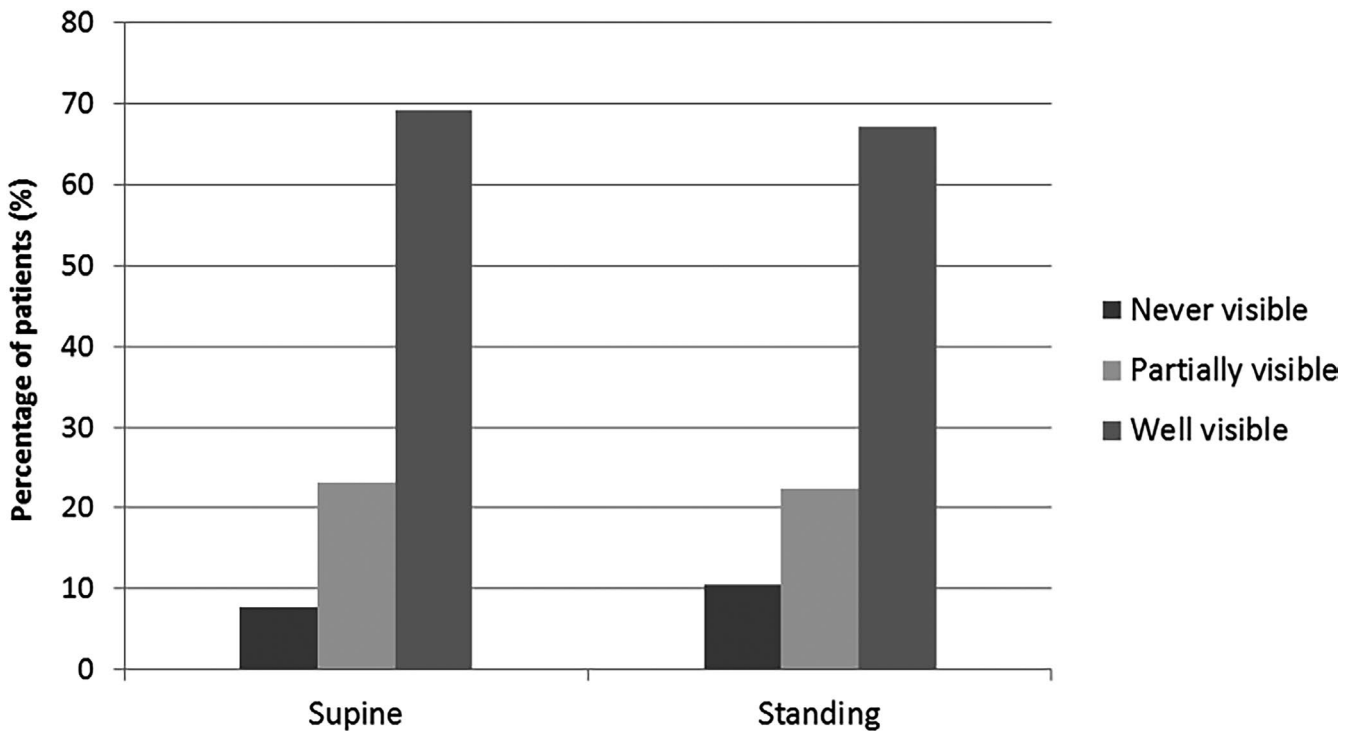


FIGURE 5 P-wave visibility on ICM signal with supine and standing position

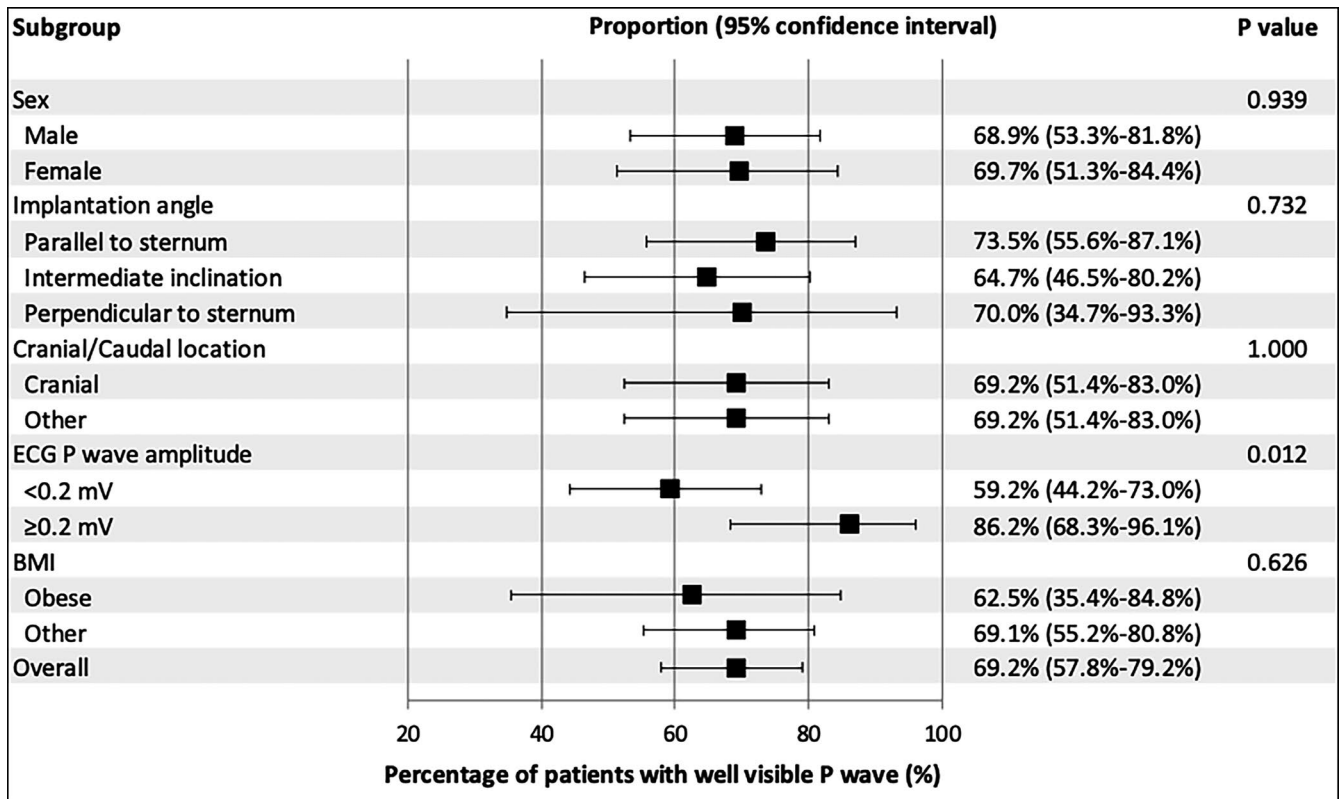


FIGURE 6 Subgroup analysis of P-wave visibility on ICM signal. Abbreviations: ECG: electrocardiogram; ICM: implantable cardiac monitor

4.1 | R-wave amplitude

Sensing issues are often present in ICM recordings and can hamper the clinical value of these devices, potentially leading to frequent nondiagnostic follow-up, loss of information as a result of memory overflow, or increased workload when devices are followed remotely. The R-wave undersensing leading to asystole/bradycardia inappropriate detection is the most frequent issue, with an incidence ranging from 20% to 69% at 2 years.^{5,13} R-wave undersensing can be caused either by premature ventricular contractions or intrinsic beat-to-beat variability of sECG signal during sinus rhythm, so that adequate R-wave amplitude and detection are crucial to avoid undersensing. As ICMs have a dynamic sensing threshold, which is automatically adjusted after each sensed R wave, higher amplitudes of sensed R waves could reduce the risk of oversensing of P waves, T waves, and noise, while ensuring a reliable and stable sensing of the following R wave. Additionally, higher R-wave amplitude can allow for a more aggressive sensing threshold decay to avoid R-wave undersensing potentially caused by the intrinsic beat-to-beat amplitude variability.

To date, there are no data showing that a large electrogram of ICM is independently associated with a clinical benefit in patients' management. However, it should be noted that a high prevalence of sensing issues has been reported in studies that used standard length dipole (<50 mm) ICMs. Afzal MR et al on a cohort of 559 patients implanted with a miniaturized ICM found an incidence of bradyarrhythmia false positives during remote monitoring ranging from

46% to 86%.¹⁴ Since the mean R-wave amplitude reported for devices with standard length dipole ranged from 0.45 to 0.59 mV,^{15,16} a potential correlation between signal amplitude and burden of undersensing episodes may be assumed. An improved signal amplitude may lead to a reduction in false-positive arrhythmic episodes and related review workload, but this hypothesis needs to be tested in a further controlled study.

It has been observed that there is a strong positive correlation between electrode distance and ECG signal amplitude¹⁷ and the use of long sensing vector (>70 mm) ICMs was shown to increase these values significantly, with values of R-wave amplitude ranging from 0.73 to 1.02 mV.⁸⁻¹² Our results are slightly above the overall mean, but still within the range shown by previous reports. Several reasons could explain the variability observed among studies, such as different characteristics of the study cohort (age, gender, and BMI), different implant location of the device, and different patient position during measurement (supine/standing). Unfortunately, not all these confounding covariates that could affect the outcome are reported in previous studies making direct comparison of the results difficult.

Our study provided further observations on factors potentially influencing sECG signal. Hence, we observed that these values were not affected by the implantation location in our cohort. Although the quality signal of the sECG did not appear to be an issue for long sensing vector devices regardless of the location of the insertion, these results should be interpreted carefully. In this study, the position of the device included the fourth or fifth intercostal space in 98% of patients. This is clearly related to the length of the dipole, but

it could be a key factor in obtaining a large signal. Our results were mainly derived from patients with vertical or diagonal position of the device. We have limited data on the insertion perpendicular to the sternum (5 cases) and, although similar results compared to more standard approaches, further results are needed to validate this position which is not currently recommended. Recently, Piorkowski and colleagues observed that the vertical tended ($P = .06$) to show a smaller amplitude than the diagonal position. This finding could be expected based on the principle that a diagonal insertion produces a vector along the long axis of the ventricle but it was not found in our study. A possible explanation could be that, since sECG signal is also negatively affected by the presence of adipose tissue, a vertical position of the device near the sternum could provide more electrically conductive tissue in contact with the electrodes. An alternative implant location was also proposed by Bisignani and associates that used an axillary approach (in 25 patients) with 45° angle relative to midaxillary line and achieved excellent R-wave amplitude which was actually slightly (not significantly) better than a standard prepectoral approach.⁸

The lowest R-wave amplitude values were found in obese patients: this is not unexpected as the adipose tissue is known to attenuate electric potentials, and it could also be a potential explanation for the lower values observed in woman compared to men. However, it should be noted that the median R-wave amplitude in obese patients was still very good (0.8 mV) and no patient showed values below 0.3 mV that is the reference recommended by manufacturers. The long sensing vector technology could, therefore, be indicated in this subgroup of patients to ensure the quality of the detected sECG and to avoid R-wave undersensing.

4.2 | P-wave visibility

Current available ICMs do not automatically mark P waves, but the opportunity to have visual evidence of the P-wave presence on the sECG could be an important additional value. We found that nearly 70% of patients had readily visible P waves on sECG. This proportion is consistent with the values reported by previous studies that investigated this aspect in standard (72% and 68%) and axillary position (65%).^{8,10} Interestingly, also these data were not affected by implant location, while almost all patients with high-voltage atrial activity at surface ECG showed visible P wave at sECG. Revealing the P wave is effective for the difference between sick sinus syndrome and heart block in bradycardia and may help predict the mechanism of re-entry in tachycardia where P-QRS relationships are diagnostic. Adequate P-wave visibility could also be of the greatest importance when ICMs are implanted for an early detection of AF to confirm the absence of atrial depolarization. Optimal detection of AF may allow an early rhythm-control strategy that recent evidence has shown to be associated with a lower risk of cardiovascular outcomes than usual care.¹⁸ Moreover, better P-wave sensing is pivotal in recognizing AF episodes, especially in asymptomatic patients who may undergo early rhythm control with drug therapy or catheter ablation, which is

known to be as safe and effective as in patients with drug refractory symptomatic AF,¹⁹ or after catheter ablation to assess recurrences and manage antiarrhythmic and anticoagulant therapy.²⁰⁻²²

5 | LIMITATIONS

The main limitation of the present analysis is its retrospective design including patients already implanted with an ICM. However, at the same time, ICMs implantations were performed in ordinary practice and reflect the routine use of ICMs in a “real-world” population. The different implantation sites were not equally represented; there were only 5 cases of ICM perpendicular to the sternum. The small sample size did not allow conclusions to be drawn on this unusual ICM location. The study design included only a single in-hospital study visit and no comparisons can be performed between short- and long-time follow-up, but previous experiences suggested stability over time of the ICM sensing performance.^{9,10} It should also be noted that a new version of the analyzed ICM (BIOMONITOR III) has been recently launched on the market.⁷ Although having a smaller case, the long sensing vector (>70 mm) design has been maintained, so that we believe that our findings may be extended also to the new devices.

6 | CONCLUSIONS

In our cohort of 84 patients implanted with an ICM with a long sensing vector, sECG provided a median R-wave amplitude above 1 mV and a P-wave visibility of nearly 70%, regardless of the inclination and the cranial/caudal position of the device. Women and obese patients showed lower but still very good signal quality.

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CONFLICT OF INTEREST

Daniele Giacomelli is employee of BIOTRONIK Italia. All the other authors have no conflicts relevant to the contents of this study to disclose.

ORCID

Giovanni B. Forleo  <https://orcid.org/0000-0001-8895-8915>
 Marco Schiavone  <https://orcid.org/0000-0003-0720-3380>
 Daniele Giacomelli  <https://orcid.org/0000-0003-1584-7944>
 Massimo Giammaria  <https://orcid.org/0000-0001-5070-7715>

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