Analysis of the determining factors of detectable P-wave and amplitude of QRS complex sensed by implantable loop recorder

Jang Ho Ahn¹ | Hyunho Ryu¹ | Il-Young Oh MD, PhD¹² | Youngjin Cho MD² | Ji Hyun Lee MD, PhD²

¹College of Medicine, Seoul National University, Seoul, South Korea
²Division of Cardiology, Department of Internal Medicine, Seoul National University Bundang Hospital, Seongnam, South Korea

Correspondence
Il-Young Oh, Division of Cardiology, Department of Internal Medicine, Seoul National University Bundang Hospital, 82 Gumi-ro 173beongil, Bundang-gu, Seongnam 13620, South Korea. Email: ilyoung.oh@snubh.org

Abstract
Background: Determining factors for sufficient QRS amplitude and discernible P-wave sensing in implantable loop recorder (ILR) are unknown. We aimed to investigate determining factors and ILR implantation angle that may improve QRS complex and P-wave sensing in ILR.

Methods: We retrospectively reviewed 220 patients who underwent ILR implantation or follow-up analysis. Patient demographic, clinical, echocardiography, electrocardiography, heart angle, and ILR angle data were collected as predictor variables. Associations between ILR QRS amplitude/P-wave detectability and each predictor variable were investigated.

Results: Univariate linear regression showed that ILR QRS amplitude was significantly associated with age, height, ILR angle, and QRS amplitudes of 12-lead electrocardiogram (ECG) (lead I, II, aVR [inverted aVR], aVF, V1–V6) and Holter ECG (lead V3, V5). Among discrete variables, only left ventricular hypertrophy (LVH) affected ILR QRS amplitude (P = .016). A multivariate linear regression analysis revealed that ILR angle (β = −0.008, P < .001), lead aVR amplitude (β = 0.469, P = .003), Holter lead V5 amplitude (β = 0.116, P = .049), Age (β = −0.005, P = .014), and LVH (β = 0.213, P = .031) were independent determinants of ILR QRS amplitude. Logistic regression revealed that heart angle significantly affected ILR P-wave detectability (β = 0.12, P = .008). Multiple logistic regression revealed that heart angle (β = 0.121, P = .013) and lead V1 amplitude (β = 28.1, P = .034) were independent determinants of ILR P-wave detectability.

Conclusion: ILR insertion angle, lead aVR QRS amplitude, Holter lead V5 QRS amplitude, age, and LVH are determinants of ILR QRS amplitude. Heart angle and lead V1 P-wave amplitude of 12-lead ECG are determinants of ILR P-wave detectability.

Keywords
ECG monitoring, implantable loop recorder, P-wave detection, QRS amplitude
1 | INTRODUCTION

Implantable loop recorders (ILRs) are used in patients who require long-term cardiac monitoring. Established indications for ILR include recurrent unexplained syncope and palpitations.\(^1,2\) ILR monitoring has also been shown to be effective in detecting atrial fibrillation (AF) after cryptogenic stroke, compared with conventional 24 h electrocardiogram (ECG) monitoring.\(^3\) Other rare indications for the ILR include rhythm monitoring after myocardial infarction, valve implantation, and AF ablation.\(^4\)

QRS complex and P-wave detection are the major issues regarding the analysis of ILR records. A prior study reported that P-wave undersensing in ILR hindered the differentiation between a fine F wave in AF with slow ventricular response and a small P-wave with a paroxysmal AV block.\(^2\) Moreover, AF detection in ILR is based on the absence of a single P-wave between two R-waves, in addition to the incoherence of R–R intervals over a certain period.\(^5\) Therefore, ILR needs to record discernible P-waves. QRS complex undersensing may lead to false bradycardia detection.\(^6\) False detection of bradyarrhythmias may increase time required for data review. Hence, ILR needs to record QRS complexes with amplitudes above a certain threshold. A previous study found relationships between ILR QRS complex undersensing and age, sex, and body mass index (BMI).\(^7\) However, other characteristics including patient history, Holter ECG, and 12-lead ECG data are yet to be investigated. In addition, the optimal conditions for recording discernible P-waves are unknown.

Various protocols exist for the ILR implantation. ILR is recommended to be inserted at 45° or vertical angle within second to fourth intercostal space, 2 cm from the left border of the sternum.\(^8,9\) However, there is no evidence that the position or angle of insertion in the given protocol maximizes QRS complex or P-wave amplitude for ILR recording.

We aimed to investigate the patient characteristics and ILR implantation angle that may increase QRS amplitude and P-wave detectability sensed by ILR.

2 | METHODS

2.1 | Study population

A total of 220 patients who had undergone ILR implantation or follow-up after implantation at Seoul National University Bundang Hospital, Seongnam, South Korea, from September 2015 to November 2020 were retrospectively reviewed. Patients were included regardless of ILR models (201 Reveal LINQs [Medtronic, Dublin, Ireland], 14 Confirm Rx ICMs [Abbott, Abbott Park, Illinois, USA], 3 Confirm DM2102s [Abbott, Abbott Park, Illinois, USA], 1 reveals DX [Medtronic, Dublin, Ireland], 1 Reveal XT [Medtronic, Dublin, Ireland]). The ILRs were initially inserted at 45° in the fourth intercostal space and were reinserted between 0° and 90°, depending on the operator’s decision, when the QRS amplitude was less than 0.3 mV. In the P-wave analysis, patients who did not have any ILR events (n = 55; rhythm strips recorded by ILR as tachycardia, bradycardia, atrial fibrillation, noise, or symptoms), patients who only had ILR events during which the P-wave was supposed to be absent (n = 13), and patients who had less than two P-wave detected events and less than two P-wave undetected events (n = 72) were excluded. In QRS complex analysis, patients without any QRS amplitude records were excluded (n = 40). Finally, 80 patients were included in the P-wave analysis, and 180 were included in the QRS complex analysis (Figure 1).

The Institutional Review Board Committee of Seoul National University Bundang Hospital approved this retrospective study (B-2011/651-104) and waived the need for informed consent for access to electronic medical records (EMR). The study was performed in accordance with the tenets of the Declaration of Helsinki.

2.2 | Definitions

Age was defined as the patient age at which the ILR was implanted. BMI was calculated by dividing the weight of the patient (kg) by the square of the height (m). The patient history including hypertension, diabetes mellitus, hyperlipidemia, smoking, stroke, congestive heart failure, acute myocardial infarction, peripheral artery disease, hypertrophic cardiomyopathy (HCMP), and patent foramen ovale, was collected from EMR. The ILR model of each patient, whether or not the model is Reveal LINQ, was collected from EMR. Clinical indications, including cryptogenic stroke, syncope, and palpitations, were also obtained from EMR. Left atrial (LA) anteroposterior diameter, LA volume index (LAVI), left ventricular (LV) mass, and LV mass index (LVMII) were measured during routine echocardiography, from which the time interval to ILR implantation was less than 6 months and was the shortest among patients.

FIGURE 1  Data selection prior to analysis. AF: atrial fibrillation; ILR: implantable loop recorder; VT: ventricular tachycardia
all routine echocardiography analyses within the same patient. The LA volume was measured using the Simpson method in apical four-chamber and apical two-chamber views at ventricular end-systole. The LA volume index (LAVI) was calculated as the LA volume in milliliters divided by the body surface area in square meters. The LV mass was determined by the Devereux formula, and LV mass index was calculated by dividing the LV mass by the body surface area. Heart angle and ILR angle were manually measured in a chest posteroanterior X-ray image, from which the time interval to ILR implantation was less than 6 months and was the shortest among all chest posteroanterior X-ray images within the same patient. The chest X-ray image was taken at a standing position. The heart angle was defined as the angle between the horizontal line and the line dividing the ventricular area symmetrically via the apex. The ILR angle was similarly defined (Figure 2A). P-wave vector, QRS vector, and P-wave/QRS amplitudes of 12 leads were collected using IntelliSpace ECG (Philips, Eindhoven, the Netherlands) Standard 12-lead Report and Morphology Analysis Report of the 12-lead ECG record, from which the time interval to ILR implant was less than 6 months and was the shortest among all ECG records within the same patient. Each amplitude was defined as the greater value between positive and negative amplitudes, both of which were written in the Morphology Analysis Report. The P-ILR angle and QRS-ILR angle were defined as the acute angles between the ILR angle and P-wave vector and QRS vector, respectively. Left ventricular hypertrophy (LVH) was defined as a Romhilt-Estes score ≥4 in the Standard 12-lead Report, which is the criteria used in Seoul National University Bundang Hospital. Holter lead V1/V3/V5 P-wave/QRS amplitudes were measured from routine Holter monitoring records, from which the time interval to ILR implantation was less than 6 months and was the shortest among all Holter monitoring records within the same patient. Each amplitude was defined as a greater value between positive and negative amplitudes, which would be 0.83 mV in this example. Examples of discernible P-waves (red arrows above) and indiscernible P-waves (below) in ILR events. 2.3 | Statistical analysis

Continuous variables are shown as mean ± standard deviation and categorical variables are presented as frequencies and percentages. The Kolmogorov–Smirnov test was used to analyze the distribution of continuous variables. On that basis, continuous variables between the two groups were compared by Student’s t test and discrete variables by $\chi^2$ test or Fisher’s exact test. One-way ANOVA
and Bonferroni post-hoc analyses were used to compare continuous variables among the three groups. Correlation between ILR QRS amplitude and each continuous predictor variable was assessed by univariate linear regression. Patient characteristics and ECG QRS amplitudes with P value of < .05, and ILR models were included in a forward stepwise multivariate model to determine factors that are independently associated with ILR QRS amplitude (dummy variables were used for discrete variables). For QRS amplitudes, the leads with the smallest P value or the greatest correlation coefficient among all ECG leads (12-lead and Holter) were included in the multivariate model in order to avoid collinearity. The correlation between ILR P-wave detectability and each continuous predictor variable was assessed using univariate logistic regression. Patient characteristics and ECG P-wave amplitudes with P value of < .05, and ILR models were included in a multivariate model to determine factors that were independently associated with ILR P-wave detectability (dummy variables were used for discrete variables). For P-wave amplitudes, only the lead with the smallest P value among all ECG leads (12-lead and Holter) was included in the multivariate model to avoid collinearity. Statistical analysis was performed using R statistics (R Core Team, Vienna, Austria).

3 | RESULTS

3.1 | Patient characteristics

Among the 220 patients, 138 (62.7%) were males. The mean ages of male and female patients were 61.3 ± 15.9 years and 67.9 ± 12.9 years, respectively (Table 1). The ECG characteristics of the 220 patients are shown in Table 2 and Data S1. For the 220 patients, the mean time evaluation of ECG and Holter ECG from ILR implantation were 34.6 and 34.5 days respectively. For the P-wave analysis, 47 and 33 patients were classified into detectable and undetectable groups, respectively. Baseline characteristics of 180 included in the QRS complex analysis and 80 patients included in the P-wave analysis and are shown in Data S2 and S3.

3.2 | Determining factors of the ILR QRS amplitude

Univariate linear regression showed that ILR QRS amplitude was associated with age, height, ILR angle, and QRS amplitudes of 12-lead ECG (lead I, II, aVR [inverted aVR], aVF, V1-V6) and Holter ECG (lead V3, V5) (Figure 3, Table 3, Data S4). Lead aVR of the 12-lead ECG had the most significant P value (P = 5.56 × 10−5) and lead V5 of Holter ECG (r = .41, P < .0001) had the greatest correlation coefficient among all ECG leads (Figure 3). Student’s t test revealed that among discrete variables, only LVH affected ILR QRS amplitude (P = .016). A forward stepwise multivariate linear regression analysis revealed that ILR angle (β = −0.008, P < .001), lead aVR amplitude (β = 0.469, P = .003), Holter lead V5 amplitude (β = 0.116, P = .049), Age (β = −0.005, P = .014), and LVH (β = 0.213, P = .031) were the independent determinants of ILR QRS amplitude (adjusted r² = 0.425, F = 17.3, P < .001) (Table 3).

QRS amplitude values below the recommended threshold value were observed. The recommended minimum threshold of QRS amplitude is 0.3 mV for Reveal LINQ. Among 163 patients who were included in ILR QRS complex analysis and whose ILR model was Reveal LINQ, seven patients (4.3%) had maximum QRS amplitude greater than or equal to 0.3 mV and minimum QRS amplitude less than 0.3 mV. For these seven patients, there was no apparent difference in EMR records between the minimum- and maximum-recorded situations. A total of six patients had a mean ILR QRS amplitude less than 0.3 mV. However, there were no clinical characteristics of the six patients that were significantly different from those of the other patients (Data S4).

3.3 | Determining factors of the ILR P-wave detectability

Logistic regression revealed that among continuous variables, only heart angle significantly affected ILR P-wave detectability (β = 0.12, P = .008). Lead aVF of 12-lead ECG had the most significant P value among all ECG leads (Data S5). There were no discrete variables affecting ILR P-wave detectability according to the χ² or Fisher’s exact test analysis (Data S6). Multiple logistic regression analysis revealed that heart angle (β = 0.110, P = .019) and lead V1 amplitude (β = 28.1, P = .034) were the independent determinants of ILR P-wave detectability (Data S5).

4 | DISCUSSION

In the present study, we demonstrated that (i) decreased ILR angle, increased lead aVR QRS amplitude, increased Holter lead V5 QRS amplitude, younger age, and LVH led to increased ILR QRS amplitude, and (ii) steeper heart angle and increased lead V1 P-wave amplitude of 12-lead ECG led to better ILR P-wave detectability.

Previous studies have established relationships between 12-lead QRS amplitude and patient characteristics. Females had smaller precordial QRS amplitude. The findings in the present study support their findings. Females had smaller ILR QRS amplitude (male: 0.78 mV vs. female: 0.69 mV [P = .058]) although not statistically significant (Table 3). A previous study established the relationship between QRS complex amplitude undersensing of ILR and various characteristics. The study revealed that age did not affect the sensed QRS amplitude of ILR, which contradicts our result (Table 3). However, the study population was smaller (n = 32) than that in our study (n = 180). A study discovered that specific positions and implantation angles yielded ILR QRS amplitude greater than the manufacturer-recommended value of 0.3 mV. Another study showed that insertion in V2-V3 at a 45° angle yielded maximum QRS amplitude. However, the sample size in both these studies was small (n = 15 and 41, respectively), subjects were all male in the former study, and the angle options were limited to 0°, 45°, 90°, and
135° from the horizontal line. Our study is the first to demonstrate a linear correlation between the ILR implant angle and QRS amplitude.

One the basis of our results, higher QRS amplitude and distinctive P-wave of ILR are expected in patients with greater lead aVR QRS amplitude and lead V1 P-wave amplitude of 12-lead ECG, greater lead V5 QRS amplitude of Holter ECG, younger age, LVH, and steeper heart angle. For patients without optimal conditions, decreasing the ILR insertion angle may yield greater ILR QRS amplitude. Moreover, ILRs of longer lengths should be manufactured. The direction of ILR and Holter V5 lead are grossly similar, and there

| Characteristics                  | Total (n = 220) | Male (n = 138) | Female (n = 82) |
|----------------------------------|----------------|---------------|-----------------|
| Age (years)                      | 63.7 ± 15.2    | 61.3 ± 15.9   | 67.9 ± 12.9     |
| Weight (kg)                      | 65.4 ± 11.6    | 70.6 ± 10.3   | 56.8 ± 8.1      |
| Height (cm)                      | 163.3 ± 9.4    | 168.6 ± 6.2   | 154.5 ± 7.0     |
| BMI (kg/m^2)                     | 24.4 ± 3.0     | 24.8 ± 2.9    | 23.8 ± 3.0      |
| **Echocardiography**             |                |               |                 |
| LA diameter^a (mm)               | 36.4 ± 6.0     | 36.7 ± 6.0    | 36.0 ± 6.0      |
| Mean LAVI^a (ml/m^2)             | 35.8 ± 12.1    | 35.0 ± 9.8    | 37.0 ± 15.3     |
| LV mass^a (g)                    | 157.8 ± 58.4   | 168.2 ± 64.6  | 139.9 ± 40.5    |
| LVMI^a (g/m^2)                   | 91.8 ± 30.1    | 93.1 ± 32.6   | 89.7 ± 25.5     |
| **Medical history**              |                |               |                 |
| Left ventricular hypertrophy     | 20 (9.1)       | 11 (8.0)      | 9 (11.0)        |
| Hypertension                     | 113 (51.4)     | 75 (54.3)     | 38 (46.3)       |
| Diabetes mellitus                | 52 (23.6)      | 36 (26.1)     | 16 (19.5)       |
| Hyperlipidemia                   | 100 (45.5)     | 65 (47.1)     | 35 (42.7)       |
| Smoking                          | 55 (25.0)      | 54 (39.1)     | 1 (1.2)         |
| Stroke                           | 166 (75.5)     | 108 (78.3)    | 58 (70.7)       |
| Congestive heart failure         | 7 (3.2)        | 3 (2.2)       | 4 (4.9)         |
| History of acute myocardial infarction | 6 (2.7) | 4 (2.9) | 2 (2.4) |
| Peripheral artery disease        | 44 (20.0)      | 27 (19.6)     | 17 (20.7)       |
| Hypertrophic cardiomyopathy      | 9 (4.1)        | 4 (2.9)       | 5 (6.1)         |
| Patent foramen ovale             | 39 (22.2)      | 24 (21.2)     | 15 (23.8)       |
| Reveal LINQ                       | 201 (91.4)     | 128 (92.8)    | 73 (89.0)       |
| **Type of index event**          |                |               |                 |
| Cryptogenic stroke               | 156 (70.9)     | 105 (76.1)    | 51 (62.2)       |
| Syncope                          | 61 (27.7)      | 31 (22.5)     | 30 (36.6)       |
| Palpitation                      | 3 (1.4)        | 2 (1.4)       | 1 (1.2)         |
| **P-wave detectability in ILR**  |                |               |                 |
| Unknown                          | 140 (63.6)     | 89 (64.5)     | 51 (62.2)       |
| Detectable                       | 47 (21.4)      | 29 (21.0)     | 18 (22.0)       |
| Undetectable                     | 33 (15.0)      | 20 (14.5)     | 13 (15.9)       |
| ILR QRS amplitude^a (mV)         | 0.745 ± 0.360  | 0.778 ± 0.411 | 0.686 ± 0.240   |
| **Chest PA angle (degree)**      |                |               |                 |
| Heart axis                       | 31.3 ± 7.7     | 30.8 ± 7.2    | 32.0 ± 8.4      |
| ILR                              | 45.0 ± 17.5    | 40.3 ± 16.0   | 52.5 ± 17.2     |

Note: Results are expressed as mean ± standard deviation or number (%).

Abbreviations: BMI, body mass index; ILR, implantable loop recorder; LA, left atrial; LAVI, left atrial volume index; LV, left ventricular; LVMI, left ventricular mass index; PA, posteroanterior.

^a Mean LA diameter: total number 215, male 135, and female 80; mean LAVI: total number 207, male 128, and female 79; mean LV mass: total number 211, male 131, female 80; mean LVMI: total number 211, male 131, female 80; patent foramen ovale: total number 113, male 113, and female 63; ILR QRS amplitude: total number 180, male 115, and female 65; chest PA angle: total number 155, male 95, and female 60 due to missing data.
was a strong positive correlation between Holter Lead V5 QRS amplitude and ILR QRS amplitude ($r = .41$, $P < .001$; Table 3). Therefore, we can assume that Holter lead V5 is analogous to an ILR lead with an extended length. Paired t test results showed that the difference between Holter lead V5 and ILR QRS amplitude was, on average, 0.54 mV within the same patient ($P < .001$). In order to yield greater QRS amplitude, extending ILR lead up to Holter lead V5 position would be necessary. This suggestion is also supported by a previous study, which showed a positive correlation between ILR QRS amplitude and electrode spacing distance. Our results can be applied to the use of wearable ECG monitoring patch that obtains ECG signals from sites similar to that of ILRs. The patch leads can be attached horizontally if the expected QRS amplitude is small. Longer length between the patch leads would also be recommended. Lead aVR QRS amplitude as a determinant of ILR QRS amplitude might imply that aligning the ILR parallel to the QRS axis may increase ILR QRS amplitude. In this study, the average ILR implant angle was $44.5 \pm 16.5^\circ$ among patients in whom ILR QRS complexes were analyzed, which is close to aVR direction (opposite to lead aVR direction) of $30^\circ$, further supporting this hypothesis. In addition, a previous study showed that orienting the ILR parallel to the QRS electrical axis led to larger ILR signals. However, linear regression between ILR QRS amplitude and the QRS-ILR angle (defined above as the absolute difference between ILR angle and QRS axis) proved that the aforementioned hypothesis is unlikely to be true ($P = 0.476$) (Table 3).

There are several limitations to this study. First, the patient characteristics were not adjusted before analyzing their relation to ILR QRS complex or P-wave. For instance, LAVI is greater in females, older age, and hypertension patients. LA diameter is longer in higher BMI group and males. QRS axis and P axis angle are greater in patients with lower BMI and metabolic syndrome. Heart axis is greater in patients with lower BMI and younger age. However, the reference equation for adjustment was unavailable in the previous studies and our study population was too small ($n = 220$) to create a new reference equation. Second, we used ILR QRS amplitudes measured immediately after implantation (supine position) and in follow-up (sedentary position), which may vary due to postural difference. ILR QRS amplitude change due to postural change is controversial. A previous study found that posture change did not affect ILR QRS amplitude. Another study found that changes in QRS amplitude due to postural change were large enough to cause signal detection loss in ILR. Third, we included a heterogeneous group of ILR vendors and did not adjust the algorithm differences among the vendors. However, the multivariate regression models revealed that

### TABLE 2 ECG variables

| Characteristics | Total ($n = 220$) | Male ($n = 138$) | Female ($n = 82$) |
|-----------------|------------------|-----------------|------------------|
| **P-wave**      |                  |                 |                  |
| Vector$^a$ (degree) | 46 ± 26         | 47 ± 25         | 45 ± 27          |
| 12-Lead amplitude$^a$(mV) |            |                 |                  |
| Lead II       | 0.12 ± 0.04      | 0.11 ± 0.04     | 0.12 ± 0.05      |
| Lead aVF      | 0.09 ± 0.04      | 0.09 ± 0.04     | 0.10 ± 0.04      |
| Lead V1       | 0.06 ± 0.03      | 0.06 ± 0.03     | 0.06 ± 0.03      |
| **QRS complex**|                  |                 |                  |
| Vector (degree) | 32 ± 39          | 30 ± 40         | 35 ± 36          |
| 12-Lead amplitude (mV) |            |                 |                  |
| Lead II       | 0.79 ± 0.33      | 0.78 ± 0.33     | 0.80 ± 0.34      |
| Lead aVF      | 0.56 ± 0.30      | 0.55 ± 0.30     | 0.57 ± 0.31      |
| Lead V1       | 0.78 ± 0.41      | 0.79 ± 0.41     | 0.76 ± 0.40      |

Note: Values are the mean ± standard deviation or number (%). Only leads with significant associations to both implantable loop recorder (ILR) P-wave detectability and ILR QRS amplitude are shown in P-wave amplitude and QRS amplitude.

$^a$P-wave vector: total number 215, male 136, and female 79; P-wave 12-lead amplitude: total number 214, male 136, and female 78 due to missing data.

![FIGURE 3](image-url)
ILR model independently determined neither ILR QRS amplitude nor P-wave detectability (Data S5). Lastly, it is difficult to generalize our study to the whole ILR implanted population, for most of the clinical indications of ILR implantation in our study was cryptogenic stroke (156 patients, 70.9%). More ILR implanted patients with clinical indications other than cryptogenic stroke need to be investigated to generalize this study to the whole ILR implanted population.

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CONFLICT OF INTEREST
All authors declare that they have no conflict of interest.

ORCID
Il-Young Oh https://orcid.org/0000-0002-5584-605X

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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