


ORIGINAL ARTICLE

Investigation on the optimal implantation site and setting of Reveal LINQ[®] avoiding interference with performance of transthoracic echocardiography

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Abstract

Background: The optimal implantation site of a new implantable cardiac monitor (ICM) named Reveal LINQ[®] may be limited based on a sufficient amplitude of R wave potential (AEP) acquisition because it is the same anatomic area used for transthoracic echocardiography (TTE).

Methods: Among 18 healthy volunteers, we assessed AEPs in 3 combinations through parasternal placement of 2 electrodes, (i) in the 4th intercostal space (ICS; site A/setting a; A/a), (ii) the same setting in the 5th ICS (site B/setting a; B/a), and (iii) in a sagittal plane relative to the left sternal border at the 4th ICS (site A/setting b; A/b), and further measured AFPs in several body positions in all site-setting combinations: supine, left and right lateral decubitus, sitting, and standing. The degree of interference with TTE performance was assessed by placement of an imitation ICM in setting a at both sites A and B.

Results: Only the AEPs in A/a and B/a met the criteria ($AEP \geq 0.3$ mV) in all positions. The AEPs in the supine position with all combinations were higher than those achieved in other positions ($P < .001$). The imitation interfered with TTE performance at site A among 78% of subjects, but only 17% at site B ($P = .0006$). The end-diastolic dimension of the left ventricle at site A was decreased after the imitation placement ($P = .028$). At site B, all female subjects complained of discomfort because their brassieres overlaid the imitation.

Conclusion: The B/a combination is optimal; however, the personal discomfort related to brassieres should be considered.

KEYWORDS

devices, female, human, implantable loop recorder, transthoracic echocardiography

1 | INTRODUCTION

The implantable loop recorder is a useful device to investigate potential cause(s) of unexplained syncope,^{1,2} or undiagnosed arrhythmias,³⁻⁵ but challenges include patient discomfort and infectious risks.⁶ Very recently, a smaller sized implantable loop recorder could be commercially available for clinical use named Reveal LINQ[®] (implantable cardiac monitoring [ICM] system) from Medtronic (Minneapolis, MN, USA). The reduced size simplifies the implantation procedure and has been associated with a decrease in patient discomfort.⁶ The manufacturer's recommended implantation site is identical to that used to obtain optimal transthoracic echocardiography (TTE) windows. However, depending upon its size, the optimal implantation site is anatomically restricted due to the importance of acquiring a sufficient amplitude of electrical potential (AEP) of the R wave. Because the ICM may remain implanted for several months or even years, the decrement in TTE quality as a result of the ICM has the potential to impact clinical care and patient outcomes during the period of implantation. Thus, we investigated 3 research questions with important clinical implications: (i) assessment of the optimal insertion sites and settings to achieve sufficient AEPs; (ii) whether the presence of an imitation ICM impacts TTE performance; and (iii) whether the quality of TTE data was different before and after placing the imitation ICM.

2 | METHODS

2.1 | Subjects

We enrolled 18 healthy volunteers (10 male, 8 female) from age 23 to 63 (mean 45.3 ± 13.6 years) at the Hokkaido Cardiovascular Hospital through advertisements. The study was conducted from May 8, 2017, to June 9, 2017. Written informed consent was obtained before commencement of the study.

2.2 | Measurements of R wave AEPs

As actual implantation was not permissible, we attached the thoracic electrodes to our subjects, distancing (37.7 mm) them proximal to the location in which an actual ICM would be implanted to create a clinically plausible simulation. Initially, 2 small electrodes were attached in the 4th intercostal space (ICS) positioned similarly to precordial leads V2 and V3 2 cm lateral to the left sternal border (Figure 1A: site A/setting a; A/a, the site and settings recommended by the manufacturer). To ascertain outcomes and TTE performance during implantation at alternative sites, we moved the electrodes caudally to the 5th ICS in the previously described parasternal position (Figure 1B: site B/setting a; B/a). Finally, we attached the electrodes superiorly in a sagittal plane relative to the left sternal border at the 4th ICS 2 cm lateral to the left sternal border (Figure 1C: site A/setting b; A/b, an alternative site recommended by the manufacturer). We measured the AEPs as follows:

1. Two small electrodes were attached in the way described above using a special measure (Figure 2), based on the actual site of the ICM.
2. Both electrodes were connected to a pacemaker programmer 2090W (Medtronic) with electrical cables (Figure 3); then, AEPs were measured based on the site-setting combinations described above.
3. The AEPs in all sites/settings were measured in supine, left lateral decubitus, right lateral decubitus, sitting, and standing positions.
4. We defined a sufficient AEP based on a clinically significant R wave of ≥ 0.3 mV, and an AEP twice the amplitude of the T wave and P wave.

We measured AEPs in an apical position among an initial analysis of 3 subjects, but we opted to exclude further measurements in this position because of an inability to measure AEPs.

2.3 | Interference with TTE performance due to the presence of the imitation ICM

To estimate the impact of ICM implantation on TTE performance, we conducted a pre-post pilot study based on our mock thoracic ICM implantation. Due to insufficient AEP acquisition in setting b, we did not investigate interference in this setting. Initially, we obtained adequate echocardiographic images from the parasternal long- and short-axis views using a Vivid E9 with M5Sc-D transducer (GE Healthcare, Little Chalfont, UK). We marked the site at which we obtained optimal TTE images. The end-diastolic and end-systolic dimensions of the left ventricle and left atrium were measured via the long-axis view. We derived the spherical index (%) of the left ventricle based on the short-axis view, calculated as the short axis length divided by the long axis length.

The imitation ICM was then placed on the thorax at either site A or B (Figure 4). Following this, we repeated the TTE at the marked sites, attempting to replicate the images before placement of the imitation ICM, during which time the examiner subjectively evaluated the extent of interference. The definition of interference is as follows: a TTE transducer overlays greater than 1/2 of the ICM (grade 2); a TTE transducer overlays less than 1/2 of the ICM (grade 1); and a TTE transducer does not overlay the ICM at all (grade 0). The differences in echocardiographic data before and after imitation ICM placement at both sites were evaluated.

2.4 | Statistical analyses

We compared AEPs and echocardiographic data before and after imitation ICM placement using a paired *t* test. We also compared AEPs between those achieved in the supine position relative to other positions using a paired *t* test. The difference in AEPs in the 3 site-setting combinations was analyzed by repeated-measures ANOVA. If a significant difference was observed, we performed a paired *t* test with the Bonferroni correction. We compared the

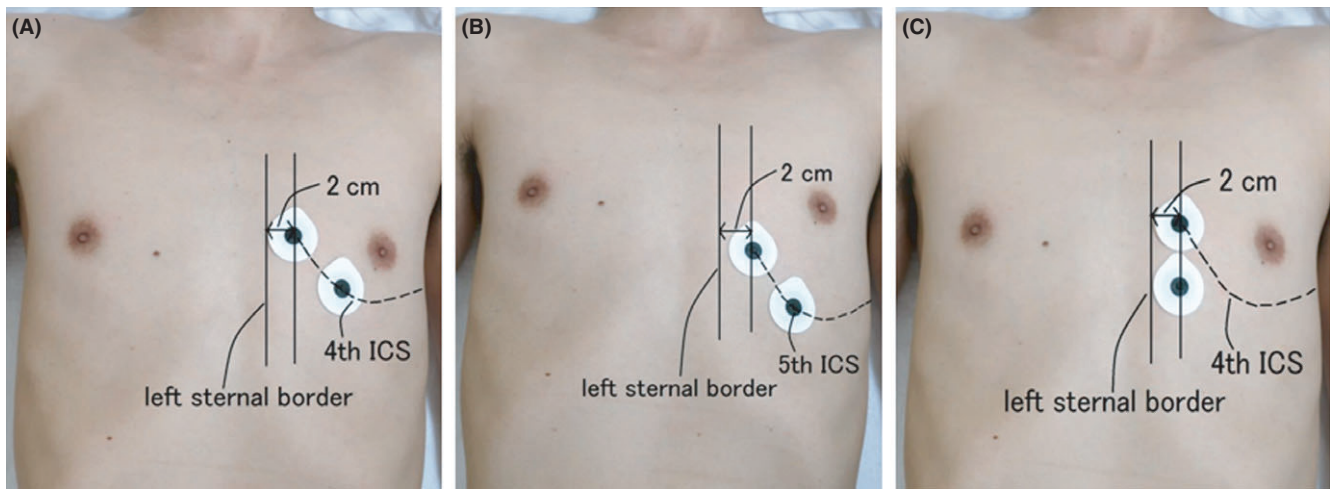


FIGURE 1 Measurements of the amplitude of electrical potential as measured by the R wave. Two small electrodes were attached parasternally in the 4th intercostal space (ICS) in positions similar to those of ECG precordial leads V2 and V3 2 cm lateral of the left sternal border (A). They were then moved to the 5th ICS, again placed in a parasternal position (B). Finally, they were attached superiorly in a sagittal plane relative to the left sternal border at the 4th ICS in the same parasternal position (C)



FIGURE 2 The specific measure indicating the actual electrode sites of the Reveal LINQ®

extent of interference in TTE performance at sites A and B with Fisher's exact test. In this analysis, we specified grade 1 or 2 as the presence of significant interference, and grade 0 as the absence of significant interference. Statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL, USA), specifying statistical significance as $P < .05$.

3 | RESULTS

3.1 | Subjects' characteristics

Table 1 shows subjects' demographic and physical characteristics. One subject had a BMI < 18.5 , and 3 subjects had a BMI > 25 (mean BMI 22.6 ± 3.0). All other study subjects' BMIs stayed within the normal range.

3.2 | AEP acquisition

Table 2 shows the AEPs at the 3 site-setting combinations in several positions, as is described above. Sufficient AEPs were obtained with combinations A/a and B/a in all positions, but not in any positions with the A/b combination ($P < .001$). The AEPs in the supine position with all combinations were higher than those in the other positions. They were lower in the lateral decubitus positions with the A/a and A/b combinations ($P < .001$), and further decreased in sitting and standing positions with all combinations ($P < .001$). However, the AEPs with the A/a and B/a combinations still met the criteria for clinical use in all positions, while 4 subjects (22%) with the A/b combination did not meet criteria in the supine position and 12 subjects (67%) in the standing position. In all subjects achieving a sufficient AEP, we observed AEPs at least twice as high relative to the amplitude of the T and P waves. Finally, we analyzed the relationship AEPs achieved and BMI, but did not observe any significant modifications.

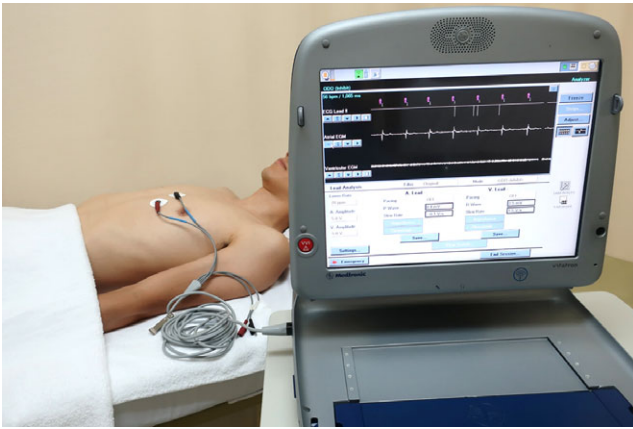


FIGURE 3 Measurements of the amplitude of electrical potential based on the R wave ascertained after connection of the electrodes with a pacemaker programmer 2090W (Medtronic)

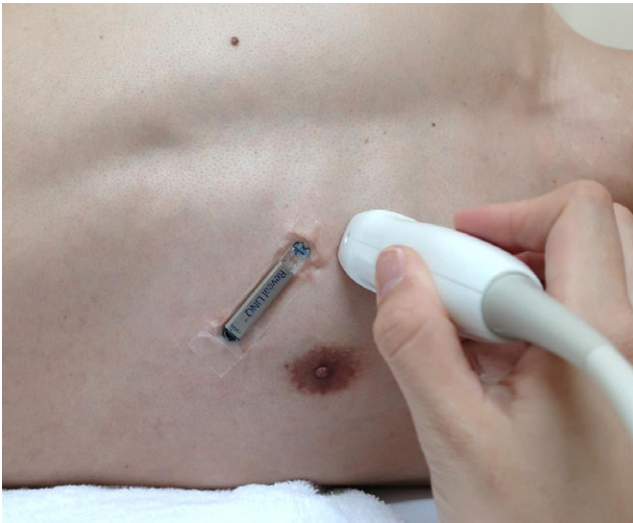


FIGURE 4 The figure shows that an assessment method of grading interference with transthoracic echocardiography performance upon placement of an imitation Reveal LINQ® in the 4th intercostal space

3.3 | Interference with TTE performance due to the presence of the imitation ICM

Table 3 shows the grade of interference with TTE performance after placement of the imitation ICM in setting a, according to site. At site A, there was significant interference ($P = .0006$) in 14 of the 18 subjects (78%), but at site B in only 3 subjects (17%).

3.4 | Influence on echocardiographic data after placement of the imitation ICM

Table 4 exhibits the echocardiographic data before and after placement of the imitation ICM. The end-diastolic dimension of the left ventricle was significantly decreased at site A, but not site B ($P = .028$). The end-systolic dimension, the spherical index of the left

ventricle, and the left atrial dimension were not altered by placement of the imitation ICM at either site.

3.5 | Patient discomfort

All the female subjects complained of discomfort after the imitation ICM was placed at site B, but not site A, likely related to the presence of a brassiere, the wire of which overlaid the imitation ICM.

4 | DISCUSSION

We obtained 3 important conclusions regarding the ideal implantation site and setting for ICM placement. First, the sham ICM implantation revealed that the B/a combination is optimal in both achieving a sufficient AEP in all positions and avoiding interference with TTE performance. Second, placement at site B created discomfort among female subjects due to the presence of a brassiere. Finally, setting b should not be used due to insufficient AEP acquisition.

Very recently, a smaller sized implantable loop recorder may be commercially available for clinical use named Reveal LINQ® from Medtronic to minimize patient discomfort and employment of a less invasive implantation process.⁶ As size creates restrictions regarding the optimal implantation site(s) at which sufficient AEPs can be acquired, this development may have important clinical implications. An important challenge of optimizing ICM implantation is the anatomic overlap with the location for obtaining data while conducting echocardiographic examinations during the period of implantation. As ICMs often remain implanted for several months or years, interference with TTE performance is a potentially important demerit for patients during the period of implantation.

As the AEPs with the A/b combination were insufficient in all positions, the A/b combination should be avoided. The AEPs with the A/a and B/a combinations were sufficient for clinical use in all positions, although significant reduction in AEPs was observed in right and left lateral decubitus with A/a combination, and in sitting or upright position with A/a and B/a combinations. Furthermore, the relative lack of interference with TTE performance with B/a was significantly favorable relative to that with A/a. As previously discussed, such interference would be unfavorable for evaluation of cardiac function and cardiac disease(s) during the period of implantation. Furthermore, the significant decrease in estimation of the left ventricular end-diastolic dimension with A/a leads to an underestimation of the ejection fraction, which may have deleterious effects on patient care and, thus, outcomes. Thus, we concluded that B/a was the optimal combination for ICM implantation among males, but perhaps not females who wear a brassiere or corset due to patient discomfort. Wearing a brassiere during a trial placement of an imitation ICM prior to actual implantation may facilitate decision making for female patients to minimize the risk-benefit ratio of implantation sites. In summary, measurement of AEPs in setting a at either site A or B and assessment of TTE performance after the placement of an imitation ICM before actual ICM implantation may improve clinical

TABLE 1 Age, gender, height, weight, and BMI of all enrolled subjects

No.	Age (years)	Gender	Height (cm)	Weight (kg)	BMI
1.	23	M	168.0	54.9	19.5
2.	27	M	179.6	75.0	23.3
3.	29	F	175.0	64.0	20.9
4.	31	M	169.9	51.0	17.7
5.	35	M	174.9	78.0	25.5
6.	37	F	161.7	60.0	23.0
7.	41	M	170.0	81.0	28.0
8.	43	F	169.1	83.6	29.2
9.	48	F	173.0	65.0	21.7
10.	51	M	156.5	58.7	24.0
11.	51	M	155.6	60.7	25.1
12.	52	F	163.0	55.0	20.7
13.	52	F	160.0	56.6	22.1
14.	58	F	158.8	57.3	22.7
15.	59	M	157.5	49.0	19.8
16.	62	M	151.0	44.2	19.4
17.	67	F	155.0	54.5	22.7
18.	71	M	156.2	53.0	21.7
Average	45.3 ± 13.6		164.2 ± 8.4	61.2 ± 11.3	22.6 ± 3.0

TABLE 2 The amplitude of electrical potential of the R wave with the 3 site-setting combinations in each position among all enrolled subjects

Position	A/a	B/a	A/b
Supine	0.84 ± 0.28	0.73 ± 0.36	0.33 ± 0.19***
Right lateral decubitus	0.63 ± 0.32***	0.70 ± 0.39	0.23 ± 0.18*****
Left lateral decubitus	0.64 ± 0.27***	0.64 ± 0.37	0.22 ± 0.21*****
Sitting	0.55 ± 0.31***	0.52 ± 0.36***	0.19 ± 0.17*****
Standing	0.57 ± 0.31***	0.56 ± 0.40***	0.18 ± 0.20*****

* $P < .001$; this indicates a significant difference between A/a and A/b in each position.

** $P < .001$; this indicates a significant difference between B/a and A/b in each position.

*** $P < .001$; this indicates a significant difference in the supine position relative to all other positions. Values are expressed as mean ± standard deviation.

decisions from both the physician and patient perspectives, regardless of gender.

5 | LIMITATIONS OF THE STUDY

This study was conducted using a small number of self-selected healthy volunteers at a single institution. We obtained data based on volunteers varying widely among characteristics, including age range. Most of enrolled subjects had a BMI within the normal range. It is

TABLE 3 Grade of interference with transthoracic echocardiography (TTE) performance after placement of the imitation ICM of the Reveal LINQ[®] in setting a either at sites A or B

No.	Site A	Site B
1.	1	0
2.	1	0
3.	1	0
4.	1	0
5.	2	0
6.	1	0
7.	0	0
8.	2	0
9.	1	0
10.	0	0
11.	1	0
12.	2	2
13.	1	0
14.	0	0
15.	0	0
16.	2	2
17.	2	2
18.	2	0
Average	1.1	0.3*

Grade 2, a TTE transducer overlays $\geq 1/2$ of the imitation ICM; grade 1, a TTE transducer overlays $< 1/2$ of the imitation ICM; grade 0, a TTE transducer does not overlay the imitation ICM at all.

* $P = .0006$ vs. site A.

TABLE 4 End-diastolic dimension, end-systolic dimension and spherical index of the left ventricle, and left atrial dimension obtained by transthoracic echocardiography in setting A either at sites A or B before and after implantation of the imitation Reveal LINQ®

	Pre	Site A	Site B
Dd (mm)	45.9 ± 3.2	45.4 ± 3.2*	45.5 ± 3.0
Ds (mm)	27.7 ± 3.6	27.9 ± 3.7	28.0 ± 3.8
SI (%)	105.8 ± 9.7	106.6 ± 10.8	105.1 ± 9.8
LAD (mm)	31.6 ± 4.3	31.7 ± 3.8	31.0 ± 3.3

Dd, end-diastolic dimension of the left ventricle; Ds, end-systolic dimension of the left ventricle; SI, spherical index of the left ventricle; LAD, left atrial dimension.

Values are expressed as mean ± standard deviation.

*P = .028 vs. Dd prior to placement of imitation ICM.

possible that the results might have differed if studied among a larger group of elderly patients, or a group consisting of significant numbers of obese patients.

The ICM is usually implanted subcutaneously. As a result, mobility of the implanted ICM could influence TTE performance, but we could not assess this hypothesis because we use normal volunteers and an imitation ICM. Furthermore, we found that patient concerns regarding discomfort differed based on gender. These limitations suggest a potential benefit of conducting similar investigations on larger and more diverse populations, including elderly females who use a brassiere or corset.

6 | CONCLUSIONS

Based on our small, but rigorously conducted study, we conclude that B/a is the optimal combination for ICM implantation. In addition, we report information regarding the extent and sources of patient discomfort, mostly relevant for females. Finally, we conclude that setting b is suboptimal due to a reduced ability to acquire sufficient AEPs.

DISCLOSURES

Medtronic provided an imitation of the ICM and a special measuring device to ascertain the distance between 2 electrodes to accurately approximate the distance between electrodes of an actual ICM.

ACKNOWLEDGEMENTS

We sincerely express our gratitude to all volunteers. In addition, we thank Dr. Kenji Yamazaki for critical review and Yuki Kubota, Mai Takeshima, Haruka Haraguchi, and Ayaka Oobayashi for providing their expertise in TTE.

CONFLICT OF INTEREST

Authors declare no Conflict of Interests for this article.

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How to cite this article: Tada S, Shibata M, Ohno S, et al. Investigation on the optimal implantation site and setting of Reveal LINQ® avoiding interference with performance of transthoracic echocardiography. *J Arrhythmia*. 2018;34:261–266. <https://doi.org/10.1002/joa3.12037>