

R-wave amplitude changes with posture and physical activity over time in an insertable cardiac monitor



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BACKGROUND Insertable cardiac monitors (ICMs) are accepted tools in cardiac arrhythmia management. Consistent R-wave amplitude (RWA) is essential for optimal detection.

OBJECTIVES Assess RWAs with posture/activities at insertion and at 30 days.

METHODS Participants (n = 90) with Confirm Rx™ ICM had RWAs measured in different postures (supine, right-side [RS], left-side [LS], sitting, and standing) and defined physical activities (including isometric push [IPUSH] and pull) at 2 time points. ICMs were inserted in 45° to sternum and parasternal orientations.

RESULTS There were significant reductions at insertion with RS, LS, sitting, or standing vs supine (reference position) (all $P < .05$). At 30 days, significant changes only occurred with LS and sitting ($P < .05$). Sex had an effect on RWAs, with females having significant variability at insertion (supine vs RS, LS, sitting, standing, and IPUSH; all $P < .05$). Males showed large RWA interpatient variabilities but minimal differences between positions vs supine.

At 30 days, RS, LS, and sitting positions remained significant for females ($P < .05$), while in males RWAs were higher than at insertion for most postures and activities. The orientation 45° to sternum had consistently higher RWAs vs parasternal orientation at both time points ($P < .0001$). In females, ICM orientation had no significant effect on RWAs; however, in males the 45° to sternum produced higher RWAs. ICM movement from the insertion site showed no correlation with RWA changes.

CONCLUSION The mean RWAs were higher at 30 days with less interparticipant and interpostural variability; males had higher RWAs compared to females; 45° to sternum orientation had higher RWAs; and ICM migration from the insertion site did not affect RWAs.

KEYWORDS Insertable cardiac monitors; Sex; Posture; R-wave amplitude; Device orientation

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Introduction

Implantable cardiac monitors (ICMs), also known as insertable cardiac monitors or implantable loop recorders, are small devices implanted subcutaneously to provide long-term monitoring and automatic recording of cardiac rhythms. While medical indications for the device vary worldwide and applications of the technology are ever expanding, it has been successfully used to detect arrhythmias such as bradycardia, atrial fibrillation, and asystole. ICMs are also used to identify rhythm disorders in patients with unexplained syncope or

cryptogenic stroke and for rhythm monitoring following catheter ablations.^{1–7}

ICMs have been shown to be more effective in the management of syncope compared to conventional evaluations such as 24-hour Holter monitoring, carotid sinus massage, echocardiography, exercise testing, head-up tilt test, and electrophysiological studies.^{8,9} Diagnostic yield was greater and time to treatment was significantly lower in ICM-implanted patients.⁹ ICMs not only have a very low incidence of adverse events with its relatively simple insertion procedure but are also cost effective in the assessment of syncope, as demonstrated by an approximate cost reduction of 26% per diagnosis.^{10–13}

ICMs such as Confirm Rx from Abbott detect arrhythmias by sensing changes in R-R interval and by evaluating R-wave

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KEY FINDINGS

- The R-wave amplitudes (RWAs) were higher after 30 days compared to immediately after insertion of the insertable cardiac monitors (ICMs).
- There was also less interpostural variability in the RWAs when compared to supine posture after 30 days.
- The RWAs in male participants were higher with less interpostural variability at 30 days compared to female participants.
- RWAs were higher in the 45° to sternum position compared to parasternal positioning at both time points.
- There were no association between ICM migration and changes in RWAs.

amplitudes (RWAs) in the electrocardiogram signal. However, there is paucity of data regarding changes in RWAs with variations in body posture, physical activity, and device movements that could potentially have effects on electrogram signal and thus event detection. This study was designed to characterize the safety and performance of the Confirm Rx ICM in relation to physical activity and posture in participants who have a clinical indication for the device.

Methods

Study details

This single-arm, nonrandomized, multicenter, open-label study of 100 participants was designed to assess variations in RWAs in the Confirm Rx device (Abbott, Sylmar, CA) during defined physical activities and specific postures in participants with a clinical indication for Confirm Rx. Participants greater than 18 years of age, with life expectancy of greater than 12 months, and with no previous ICM inserted or existing cardiac implantable electronic device were included in the study. Baseline characteristics, procedural data, complications, and RWAs at different postures/activities were collected at insertion and 30 days post-procedure. The study was approved by local human ethics committees from 8 participating centers in Australia and all participants provided written informed consent. The study was designed in accordance with the Declaration of Helsinki as revised in 2013 and is registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (Trial ID NCT03803969). [Supplemental Figure 1](#) illustrates the study flow chart.

Index procedure and 30 day follow-up

Insertion procedure

The device was inserted as per manufacturer's instructions. Briefly, the procedure was performed using sterile techniques either under local anesthesia or under other sedation at investigator's discretion. The device was inserted at the left fourth

intercostal space in 1 of 2 orientations: (1) parasternal or (2) 45° to the sternum. A 10 mm skin incision was made by pulling back the skin and using the incision tool (DM3520) supplied with the device. The preloaded ICM was then injected into the pocket created by the introducer end of the insertion tool. The incision was sealed with either a suture, surgical glue, or steri-strip and dressing. Antibiotics were given at clinical investigator's discretion.

Posture and activity measurements

RWAs were measured immediately post-insertion in various postures (supine, lying on right side [RS], lying on left side [LS], sitting, standing) and activities (ballottement of device, chest-thumping, arm flaps, isometric push [IPUSH], isometric pull, left handshake, brisk walk, and pressure on the device [tip, middle, base of the device]). These assessments were also performed 30 days post-procedure. Gross migration/movement of the device was quantified by 3 measurements: distance of the (1) incision/scar relative from left lateral sternal border (LLS), (2) tip of the device from the LLS border, and (3) tip of the device to the incision/scar.

Statistical analysis

Data has been represented as mean \pm SD or mean \pm SEM. GraphPad Prism version 8.0.0 (GraphPad Software, San Diego, CA) and IBM SPSS Statistics version 26.0 (IBM Corp, Armonk, NY) were used for statistical analysis. Statistical tests were 2-sided with a level of significance at P values $< .05$.

Results

A total of 100 participants were recruited for the study. However, 1 participant withdrew from the study after receiving a pacemaker implant before the scheduled Confirm Rx insertion. Four additional participants had the ICM device explanted before the 30 day follow-up, as they received either a pacemaker or an implantable cardioverter-defibrillator based on Confirm Rx findings, and 5 other participants had incomplete follow-up. Therefore, all analyses were restricted to 90 participants with paired data available at both baseline and 30 day follow-up. Baseline participant characteristics are shown in [Table 1](#). The mean age for this cohort was 66.4 ± 13.0 years with almost equal distribution across both sexes (54% female and 46% male).

Procedural characteristics

The mean procedure time from skin incision to closure was 5.77 ± 3.84 minutes. Forty-four (48.9%) participants were inserted with the device in the left parasternal orientation and 46 (51.1%) participants had the device inserted 45° to the sternum. Several closure methods were utilized based on investigator preference ([Table 2](#)).

R-wave amplitude changes associated with posture and physical activities

The mean RWA in the supine position at insertion was 0.62 ± 0.29 mV. Although interpostural RWAs did not fluctuate overtly at insertion, when the subject changed posture

Table 1 Patient characteristics (paired analysis)

Patient Characteristics	N = 90
Age, y (mean ± SD)	66.4 ± 13.1
Sex, female, n (%)	49 (54.4)
BMI, kg/m ² (mean ± SD)	27.6 ± 5.2
Medical history, n (%)	
CAD	19 (21.1)
MI	4 (4.4)
Angina	3 (3.3)
CABG	4 (4.4)
PTCA	10 (11.1)
NYHA class	
Class I	69 (76.7)
Class II	15 (16.7)
Class III	0
Class IV	0
Unknown/none	6 (6.7)
Hypertension	43 (47.8)
Hypercholesterolemia	34 (37.8)
Diabetes	9 (10.0)
COPD	6 (6.7)
Renal disease	5 (5.6)
Smoking status	
Active smoker	2 (2.2)
Ex-smoker	23 (25.6)
Chronic anemia	4 (4.4)
Stroke	7 (7.8)
Peripheral artery disease	1 (1)
Cryptogenic stroke	8 (8.9)
Thyroid dysfunction	9 (10.0)

BMI = body mass index; CABG = coronary artery bypass graft; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

from supine to RS, LS, sitting, or standing positions a significant reduction was observed (0.45 ± 0.27 mV, 0.45 ± 0.28 mV, 0.49 ± 0.25 mV, and 0.52 ± 0.26 mV, respectively; $P < .05$). At 30 days, the difference in RWAs remained significant in the LS and sitting positions (0.50 ± 0.30 mV and 0.50 ± 0.25 mV; $P < .05$), as shown in [Figure 1A](#) and [1B](#). Assessment of RWAs across these defined postures and activities at the 30 day follow-up period demonstrated that there was a significant increase in RWAs in the RS and LS positions compared to insertion (0.45 ± 0.27 mV vs 0.51 ± 0.30 mV and 0.45 ± 0.28 mV vs 0.50 ± 0.29 mV for RS and LS, respectively; $P < .05$), also shown in [Figure 1A](#) and [1B](#).

Table 2 Procedure characteristics and outcomes (paired analysis)

Characteristic	Outcome
Successful implantation, n (%)	90 (100)
Procedure time, minutes (mean ± SD)	5.77 ± 3.84
Device orientation, n (%)	
45° to sternum	46 (51.1)
Parasternal	44 (49.9)
Closure method, n (%)	
Glue only	15 (16.7)
Suture only	17 (18.9)
Steri strip/dressing only	35 (38.9)
Combination of 2 closure methods	23 (25.6)
Antibiotics (cefazolin)	21 (23.3)

Sex-based variations in RWA

At insertion female participants demonstrated significant decrease in RWAs when body posture changed from supine to RS, LS, sitting, or standing positions or when performing the IPUSH maneuver (supine 0.650 ± 0.28 mV changed to 0.40 ± 0.22 (RS); 0.42 ± 0.26 (LS); 0.49 ± 0.21 (sitting); 0.52 ± 0.21 mV (standing); 0.53 ± 0.24 mV (IPUSH); $P < .05$). At 30 day follow-up, although there was an increase in RWAs seen across the aforementioned movements, the changes noted in RS, LS, and sitting positions remained significant 30 days post insertion when compared to supine ($P < .05$), shown in [Figure 2A](#) and [2B](#). Interestingly, in males there were no significant variations identified across different body postures or physical activities at insertion or at 30 days. There was, however, an overall increase in RWAs in all the positions and movements when comparing 30 days to insertion ($P < .05$), shown in [Figure 2C](#) and [2D](#).

ICM insertion orientation and changes in RWA

The device was inserted in the parasternal position in 44 participants and 46 others received the device in the 45° to sternum orientation. The latter orientation consistently had higher RWAs compared to the parasternal position at both insertion and 30 days post insertion ($P < .0001$ for both time points) and, although not statistically significant, there was a numerical improvement noticed in RWAs at 30 days in the 45° to sternum orientation. While the parasternal orientation resulted in lower RWAs, there was less variability in RWA with changes in posture and physical activities assessed. The average standard error of the mean in the parasternal orientation ([Figure 3A](#) and [3B](#)) was significantly lower than in the 45° to sternum orientation at both insertion (0.032 vs 0.048 , respectively, $P = .0003$) and 30 day follow-up (0.034 vs 0.052 , respectively, $P < .0001$).

Further analysis of the data from both sex and device orientation indicated that in females the orientation of the Confirm Rx device did not have any significant effect on RWAs and that there was also no change in RWA for each postural or activity at insertion and 30 days post insertion ([Figure 4A](#)). The variability in RWA between supine and other postural activities ($P \leq .005$ for RS and LS, $P < .05$ for Sit for parasternal; $P = .003$ for RS, $P \leq .005$ for LS, and $P < .05$ for 45° to sternum) was evident in both device orientations at insertion. However, at 30 day follow-up this effect was less marked in the parasternal orientation and was no longer significant in the 45° to sternum position. In males, the 45° to sternum orientation produced higher RWAs overall compared to the parasternal position, with statistical significance evident in supine and RS positions at 30 days post insertion (0.51 ± 0.20 mV in supine position at 30 days in parasternal vs 0.72 ± 0.38 mV in the 45° to sternum orientation; 0.46 ± 0.18 mV in RS position at 30 days in parasternal vs 0.70 ± 0.39 mV in the 45° to sternum orientation; $P < .05$), shown in [Figure 4B](#). Of note males with ICMs in the 45° to sternum orientation were observed with significant improvements in RWAs 30 days post procedure in the

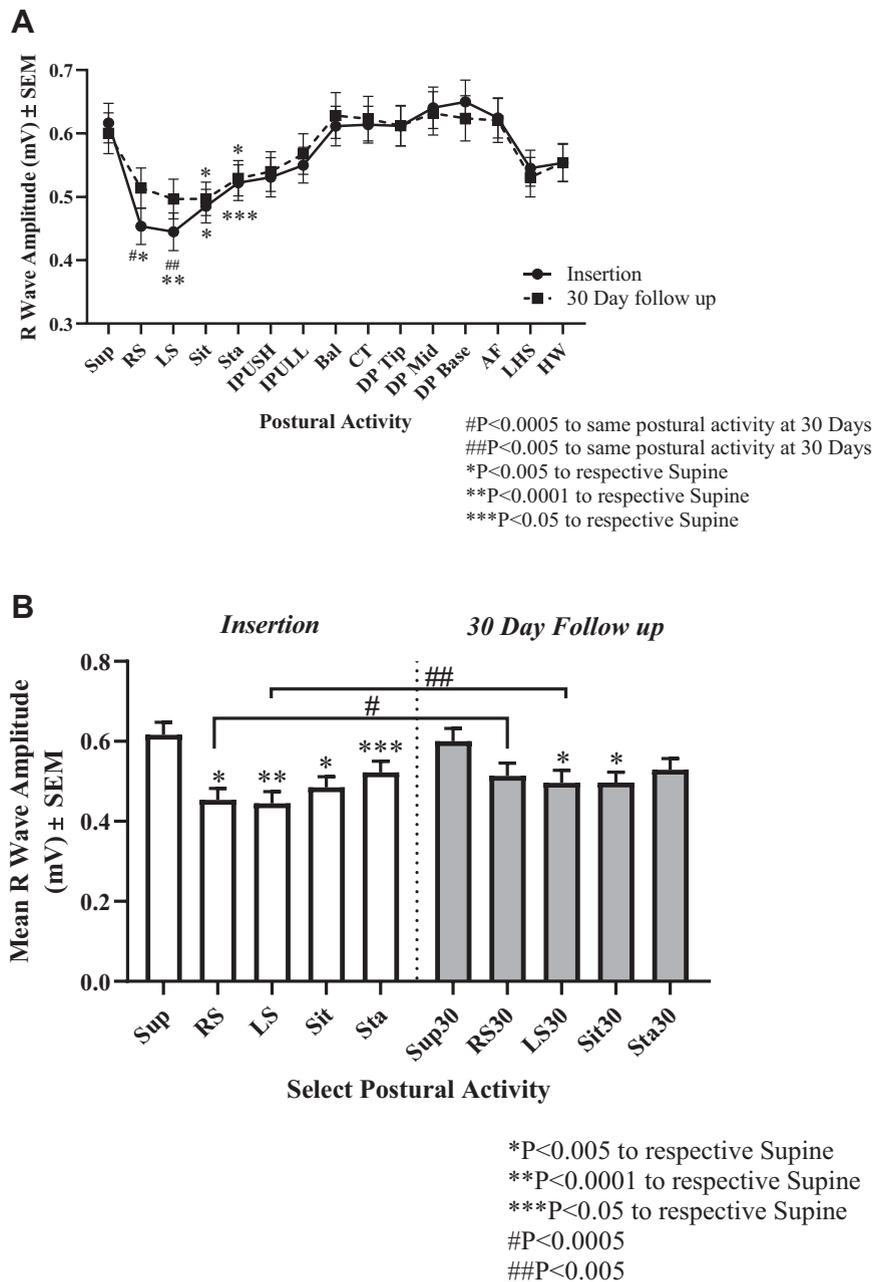


Figure 1 R-wave amplitude (RWA) at different postural activities at insertion and 30 day follow-up. **A:** The RWAs, at insertion (black circle) and 30 day follow-up (black square), were calculated for all postural activity. **B:** A more detailed look at selected postures. Data presented are the mean RWA \pm standard error of mean. * $P < .005$ to respective Supine, ** $P < .0001$ to respective Supine, *** $P < .05$ to respective Supine, # $P < .0005$ to same postural activity at 30 days, ## $P < .05$ to same postural activity at 30 days. AF = arm flaps; Bal = ballottement of device; CT = chest thumping; DP-Tip/Mid/Base = device pressure/pressure on insertable cardiac monitor at the tip, middle, or lower part; HW = brisk hall walk; IPULL = isometric pull; IPUSH = isometric push; LHS = left arm handshakes; LS = lying on the left side; RS = lying on the right side; Sit = sitting; Sta = standing; Sup = supine.

supine, RS, and LS postures compared to measurements at insertion ($P < .05$). It is marked that in male participants there was very little RWA variability between supine and other postural activities regardless of device orientation and time lapsed post-insertion.

Device migration after insertion

At the 30 day follow-up there was no change in the distance from the tip of the device to the LLS border but

there was an increase in the distance from incision/scar to the LLS border ($P = .02$) and a decrease seen in the distance from the tip of the device to the incision/scar ($P = .001$), shown in Figure 5. Further analysis revealed no correlation between changes in the measurements of scar from the LLS border and tip relative to scar and changes in RWAs (insertion vs 30 days) seen in supine, RS, LS, sitting, or standing postures ($r^2 < 0.06$), shown in Supplemental Figure 2.

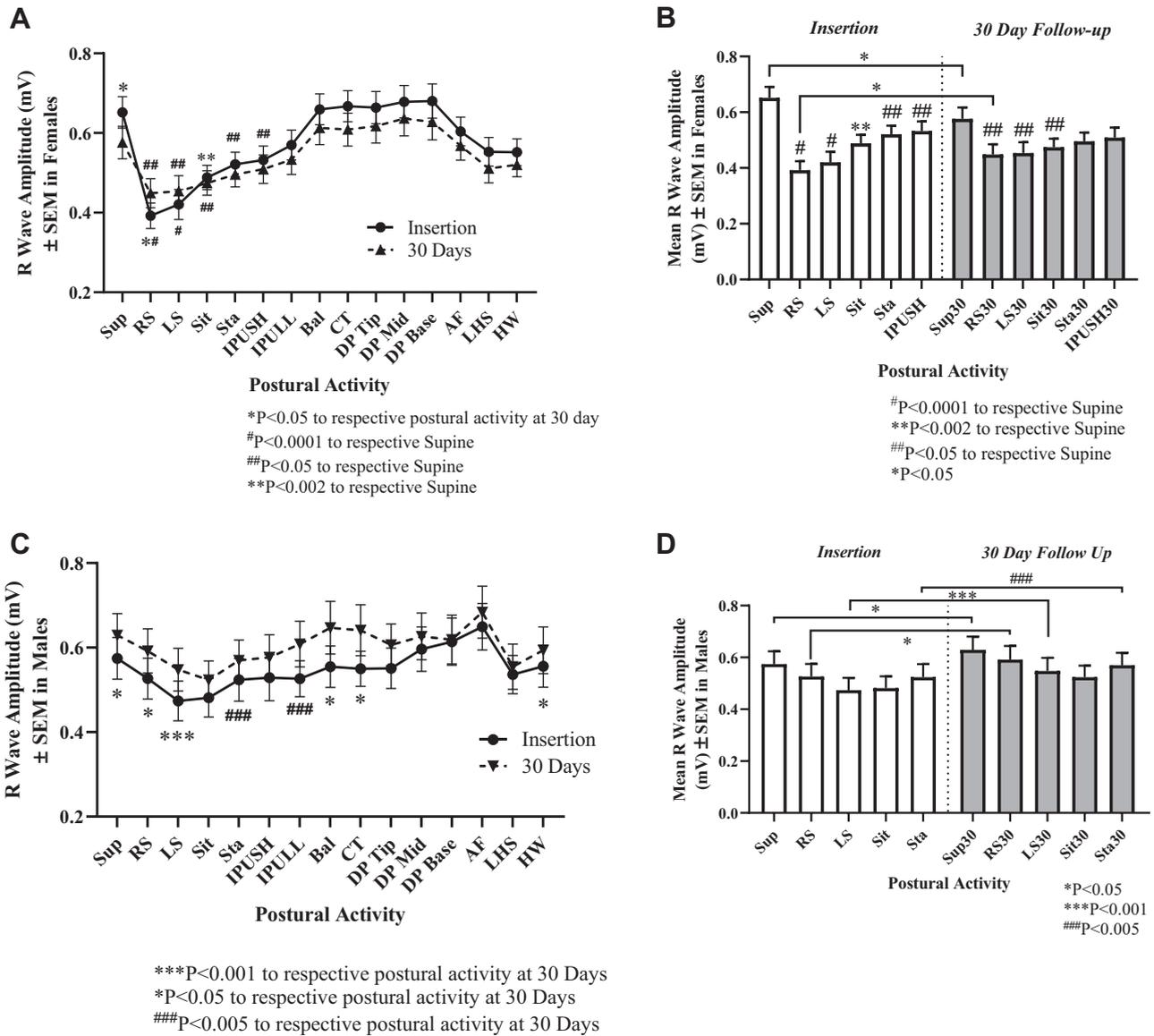


Figure 2 R-wave amplitude (RWA) of postural activities by sex. **A, B:** The RWA at insertion (black circles) and at 30 days (black triangles) for (A) all postural activities and (B) selected postures in females. **C, D:** The RWA at insertion (black circles) and at 30 days (black triangles) for (C) all postural activities and (D) selected postures in males. * $P < .05$ to the respective posture at 30 days, ** $P < .002$ to respective Supine, # $P < .0001$ to respective Supine, ## $P < .05$ to the respective Supine, *** $P < .001$ to the respective posture at 30 days, ### $P < .005$ to the respective posture at 30 days. Data presented are the mean RWA ± standard error of means. AF = arm flaps; Bal = ballottement of device; CT = chest thumping; DP-Tip/Mid/Base = device pressure/pressure on insertable cardiac monitor at the tip, middle, or lower part; HW = brisk hall walk; IPULL = isometric pull; IPUSH = isometric push; LHS = left arm handshakes; LS = lying on the left side; RS = lying on the right side; Sit = sitting; Sta = standing; Sup = supine.

Discussion

The current study is the first to describe the performance of the Confirm Rx ICM following various postures and physical activities at 2 different time points in participants clinically indicated for an ICM. No complications were observed and the main findings of the study were as follows: (1) average RWAs were higher at the 30 day time point compared to RWAs at insertion, with differences evident for RS and LS postures; (2) at 30 days, less interpostural variability was observed in RWAs when compared to supine; (3) overall, RWAs in male participants were higher, with less interpostural variability at 30 days compared to female participants;

and (4) RWAs were larger in the 45° to sternum position compared to parasternal positioning (at both time points), with ICM migration revealing no association with changes in RWAs.

A novel finding of our study was the differences in RWAs as attributed to sex. At insertion and at 30 day follow-up, RS, LS, and sitting positions showed clear differences in RWAs in comparison to supine in both sexes. Further, in female participants, this difference was significant at both time points compared to the respective supine RWA (RS: 0.39 ± 0.22 mV and 0.45 ± 0.26 mV; LS: 0.42 ± 0.26 mV and 0.45 ± 0.27 mV; Sit: 0.49 ± 0.21 mV and 0.48 ± 0.22 mV at

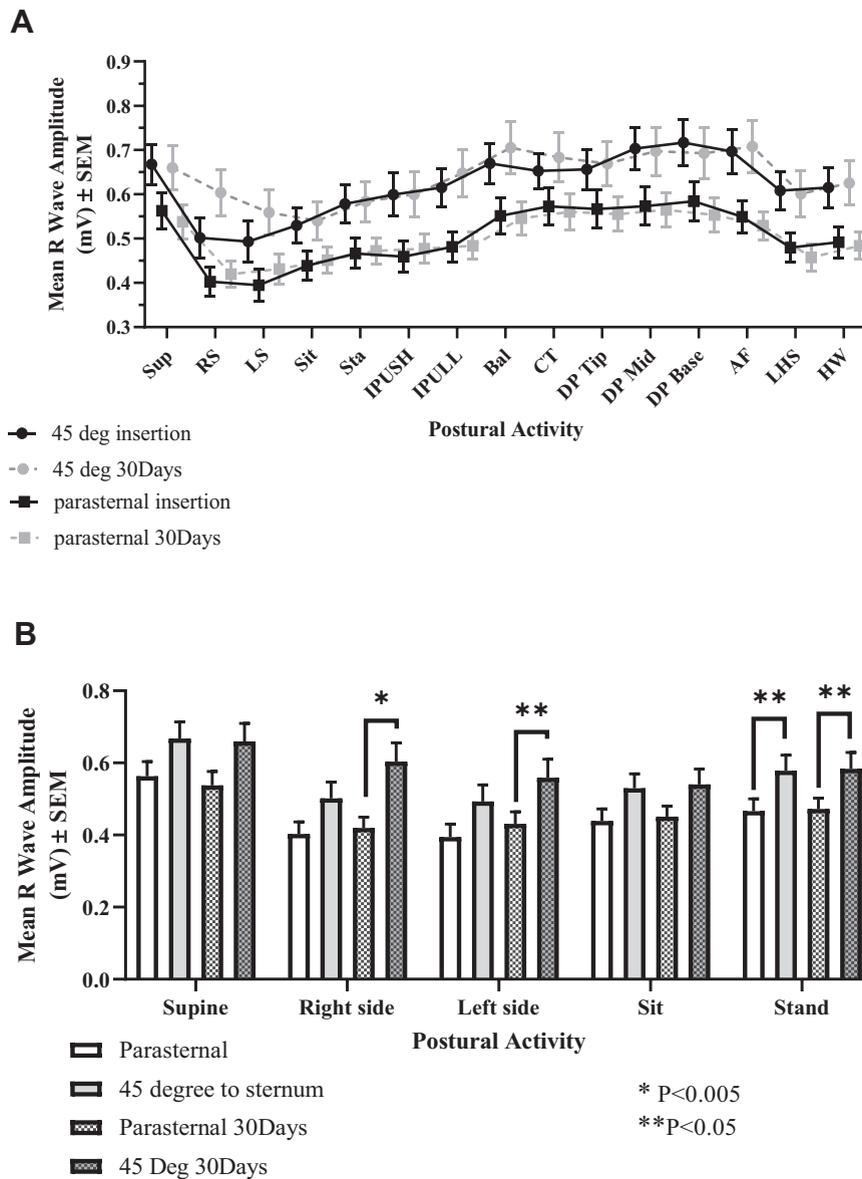


Figure 3 R-wave amplitude (RWA) at different postural activities dependent on device orientation. **A, B:** The mean RWA at (A) all postural activities (45° to sternum: *black circle*, insertion; *gray circle*, 30 days; and parasternal: *black square*, insertion; *gray square*, 30 days) and (B) selected postures at the different device orientation. * $P < .005$, ** $P < .05$. Data presented are the mean RWA \pm standard error of the means (SEM). AF = arm flaps; Bal = ballottement of device; CT = chest thumping; DP-Tip/Mid/Base = device pressure/pressure on insertable cardiac monitor at the tip, middle, or lower part; HW = brisk hall walk; IPULL = isometric pull; IPUSH = isometric push; LHS = left arm handshakes; LS = lying on the left side; RS = lying on the right side; Sit = sitting; Sta = standing; Sup = supine.

insertion and 30 day follow-up, respectively). In considering the reasons for this disparity, we hypothesized that body mass index could impact RWAs; however, no correlation was observed between body mass index and RWAs in this relatively small cohort (r^2 ranged from 0.032 to 0.22). Another plausible reason could be anatomical differences caused by breast adiposity. Previous studies have suggested that chest contours may affect the location of the ICM electrodes relative to the heart, and this is especially pertinent in females lying on their sides, where there is both an anatomical shifting of the heart and possible movement of breast tissue.^{14,15} The results from our study corroborated with this concept, where the greatest changes from supine RWAs occurred

when female participants were lying on either side or were in the sitting position.

Beyond the sex-based differences of the participants, the study also highlighted the potential role of device positioning within the chest and the consequent sensing of RWAs for the various postures. RWAs were more pronounced for Confirm Rx ICM in the 45° to sternum orientation, showing less variability both at insertion and at 30 days post-insertion. This finding is consistent with published literature exploring the effect of ICM positioning.^{16–18} In particular, a Japan-based study investigating optimal positioning of the Reveal™ ICM demonstrated some of the positions, including 45° to sternum, had the least effect on RWAs.¹⁹ Interestingly,

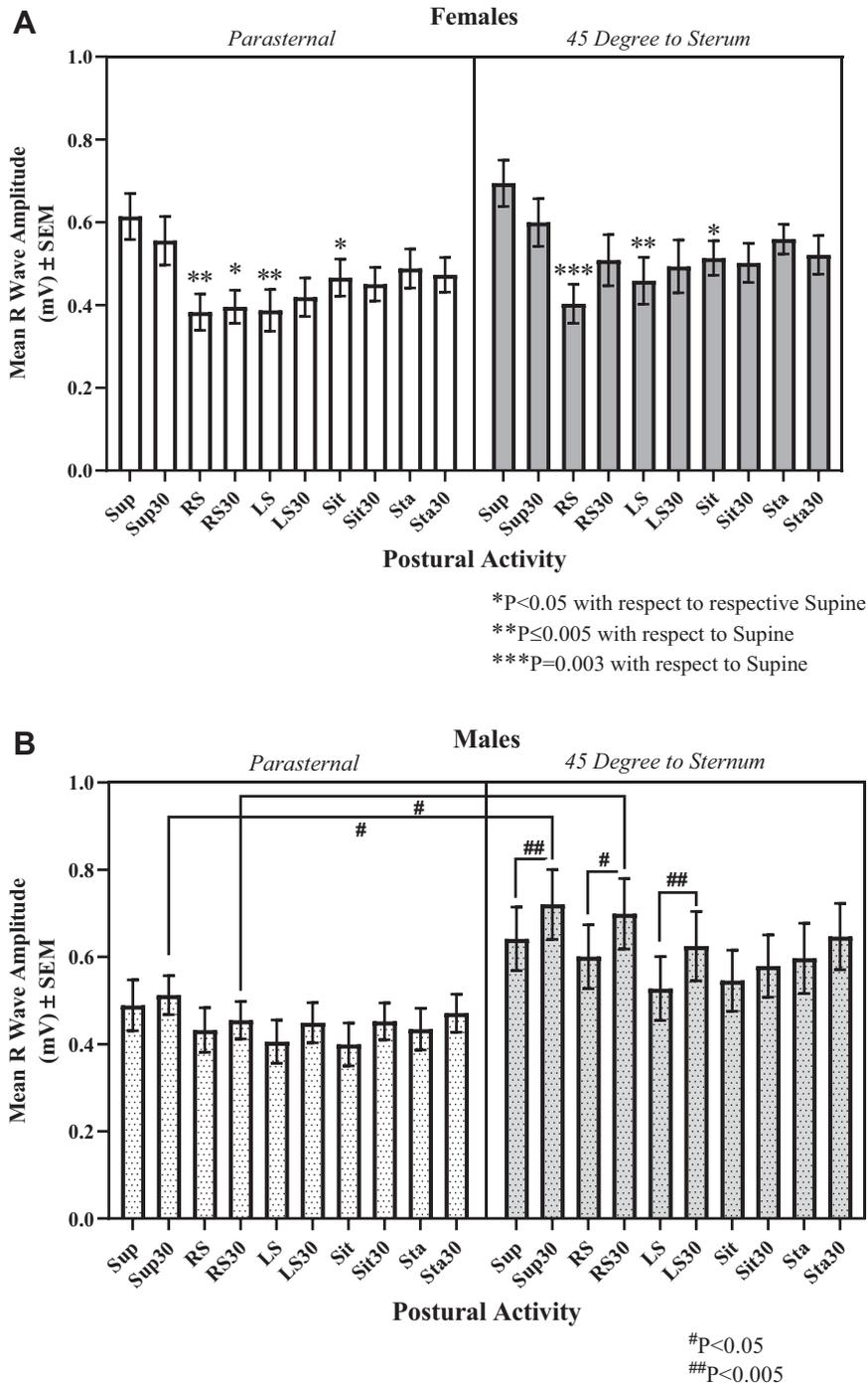


Figure 4 R-wave amplitude (RWA) evaluated on the basis of sex and device orientation. **A, B:** RWA in selected postural activities over time, separated on the basis of device orientation in (A) females and (B) males. * $P < .05$ with respect to the respective supine, ** $P \leq .005$ with respect to the respective supine, *** $P = .003$ with respect to the respective supine, # $P < .05$, and ## $P < .005$. Data presented are the mean RWA \pm standard error of the means (SEM). LS = lying on the left side at insertion; LS30 = lying on the left side at 30 days; RS = lying on the right side at insertion; RS30 = lying on the right side at 30 days; Sit = sitting at insertion; Sit30 = sitting at 30 days; Sta = standing at insertion; Sta30 = standing at 30 days; Sup = supine at insertion; Sup30 = supine at 30 days.

male participants exhibited lowest level of variability in the 45° to sternum orientation at the 30 day time point compared to female participants for the same ICM position. Largely, in female participants device orientation did not impact RWAs either at insertion or at 30 days. In both sexes, there was little change in RWA or variability, particularly in males in the parasternal orientation at insertion or after 30 days. For

both sexes, the 45° to sternum position demonstrated larger RWAs by 30 days, possibly as a result of wound healing and tightening of the skin pocket around the device allowing for better signals.

The final consideration in our study was the effect of device migration on RWAs. We hypothesized that the RWAs would progressively weaken the further the implanted ICM

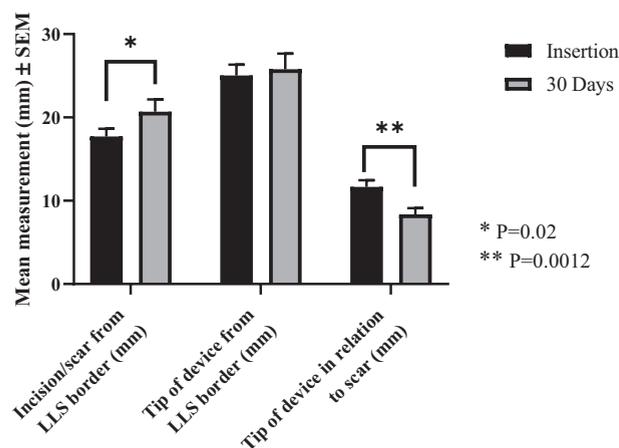


Figure 5 Device migration post-insertion. Three parameters (incision/scar relative to left lateral sternal [LLS] border, tip of the device from the LLS border, and tip of the device to the incision/scar) were measured at insertion (*black bar*) and at 30 days (*gray bar*) in order to determine device migration 30 days post-insertion. * $P = .02$, ** $P = .0012$. Data presented are the mean mm \pm standard error of the means (SEM).

migrated in relation to the heart. The ICMs were inserted subdermally, so movement from the insertion site is rare but not unexpected. We observed some ICM migration from scar tissue, and the migration seemed to be more proximal to scar tissue (initial incision) than farther away. Importantly, the migration of the ICM as measured from the left sternum was not significant from insertion to the 30 day time point and did not correlate to changes in RWAs (Figure 5). This result was suggestive of Confirm Rx ICM's ability to compensate for the effects of some internal movements on RWA detection.

Device orientation, body movements and activity can impact RWA detection.^{14,17,18,20} These factors may collectively affect the proximity and position of the ICM electrodes to the heart and thereby the ability to detect RWAs.¹⁸ Unlike other cardiac implantable electronic devices such as pacemakers and implantable cardioverter-defibrillators, the electrodes in ICMs are not in direct contact with the heart muscle and therefore can be affected by anatomical interferences and electrical noise. Inappropriate detection in addition to clinical delays result in excessive time spent by the monitoring team and valuable space in the device's limited storage capacity. Although improvements in device algorithms have advanced to help offset sensing errors, inadequate RWA detections resulting in "undersensing" or "oversensing" remain notable challenges.²¹

In addressing device sensing issues, a number of studies have demonstrated value in appropriate RWA detection.^{17,20,21} One such study was the prospective, nonrandomized multicenter study evaluating the efficacy of Biotronik's ICM, BioMonitor 2, at 3 months post-implantation.²⁰ This small study of 82 participants demonstrated an improved detection efficacy at almost 97% compared to the previous-generation BioMonitor ICM (average of 83.3%). This result is comparable to devices from other vendors, including the Confirm Rx ICM, but with some different ICM and study

design features. The defining feature of that study was the ICM's longer sensing ability coupled with strategic positioning closer to the heart, which substantially improved noise burden from 4% to 1%. The authors also speculated that the diagonal positioning of the ICM may have improved noise burden, more so than vertical positioning.²⁰ Thus, the study highlighted that positioning of the ICM could have a significant impact on R-wave sensing. However, a similar investigation into the efficacy of Confirm Rx ICM at an earlier time point (1 month) in a range of different body motions has not been performed prior to our study.

This study fills a gap in knowledge on immediate efficacy features of Confirm Rx ICMs post-insertion, which may be relevant in participants who require close and accurate arrhythmia management, such as those with acute onset of arrhythmias, which may remain unresolved. The main limitations of this study are the relatively small sample size, short follow-up period, and lack of a comparison with a device from a different manufacturer. Another limitation is that the study could not distinguish whether the observed RWA variations are the result of (1) posture/activity impact on the device orientation relative to the heart, or (2) the natural autonomic nervous system response to these posture/activity changes. However, the aim of the study was to evaluate the RWA stability of the ICM, regardless of the mechanism by which posture/activity impact the RWA.

Conclusion

This multicenter investigation demonstrated that the Confirm Rx ICM insertion procedure was short and uncomplicated, with 100% technical success rate. This study showed that RWAs stabilized by 30 days and is novel in showing lesser variability in RWAs in male participants compared to female participants. The 45° to sternum orientation for the ICM may be more favorable compared to the parasternal device orientation, especially in males. This systematic evaluation of postural activity-related RWA changes at insertion and 30 days demonstrates that the Confirm Rx ICM has reliable sensing capabilities.

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Disclosures

SD, LM, and KR are employees of Abbott. All other authors have no disclosures.

Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

All patients provided written informed consent.

Ethics Statement

The authors designed the study and gathered and analyzed the data according to the Helsinki Declaration guidelines on human research. The research protocol used in this study was reviewed and approved by the institutional review board.

Acknowledgments

None.

Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.cvdhj.2021.12.002>.

References

- Brignole M, Moya A, de Lange FJ, et al; ESC Scientific Document Group. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J* 2018; 39:1883–1948.
- Cicone G, Giacomelli D, Pappone C. The role of implantable cardiac monitors in atrial fibrillation management. *J Atr Fibrillation* 2017;10:1590.
- Giancaterino S, Lupercio F, Nishimura M, Hsu JC. Current and future use of insertable cardiac monitors. *JACC Clin Electrophysiol* 2018;4:1383–1396.
- Sakhi R, Theuns D, Szili-Torok T, Yap SC. Insertable cardiac monitors: current indications and devices. *Expert Rev Med Devices* 2019;16:45–55.
- Sulke N, Sugihara C, Hong P, Patel N, Freemantle N. The benefit of a remotely monitored implantable loop recorder as a first line investigation in unexplained syncope: the EaSyAS II trial. *Europace* 2016;18:912–918.
- Pokushalov E, Romanov A, Corbucci G, et al. Ablation of paroxysmal and persistent atrial fibrillation: 1-year follow-up through continuous subcutaneous monitoring. *J Cardiovasc Electrophysiol* 2011;22:369–375.
- Brignole M, Moya A, de Lange FJ, et al. [2018 ESC Guidelines for the diagnosis and management of syncope]. *Kardiol Pol* 2018;76:1119–1198.
- Hong P, Sulke N. Implantable diagnostic monitors in the early assessment of syncope and collapse. *Prog Cardiovasc Dis* 2013;55:410–417.
- Krahn AD, Klein GJ, Yee R, Skanes AC. Randomized assessment of syncope trial: conventional diagnostic testing versus a prolonged monitoring strategy. *Circulation* 2001;104:46–51.
- Farwell DJ, Freemantle N, Sulke AN. Use of implantable loop recorders in the diagnosis and management of syncope. *Eur Heart J* 2004; 25:1257–1263.
- Krahn AD, Klein GJ, Yee R, Hoch JS, Skanes AC. Cost implications of testing strategy in patients with syncope: randomized assessment of syncope trial. *J Am Coll Cardiol* 2003;42:495–501.
- Mittal S, Sanders P, Pokushalov E, et al. Safety profile of a miniaturized insertable cardiac monitor: results from two prospective trials. *Pacing Clin Electrophysiol* 2015;38:1464–1469.
- Rogers JD, Sanders P, Piorkowski C, et al. In-office insertion of a miniaturized insertable cardiac monitor: results from the Reveal LINQ In-Office 2 randomized study. *Heart Rhythm* 2017;14:218–224.
- Sutherland DJ, McPherson DD, Spencer CA, Armstrong CS, Horacek BM, Montague TJ. Effects of posture and respiration on body surface electrocardiogram. *Am J Cardiol* 1983;52:595–600.
- van Dam P, van Groeningen C, Houben RP, Hampton DR. Improving sensing and detection performance in subcutaneous monitors. *J Electrocardiol* 2009; 42:580–583.
- Lacour P, Dang PL, Huemer M, et al. Performance of the new BioMonitor 2-AF insertable cardiac monitoring system: can better be worse? *Pacing Clin Electrophysiol* 2017;40:516–526.
- De Coster M, Demolder A, De Meyer V, Vandenbulcke F, Van Heuverswyn F, De Pooter J. Diagnostic accuracy of R-wave detection by insertable cardiac monitors. *Pacing Clin Electrophysiol* 2020;43:511–517.
- Krahn AD, Pickett RA, Sakaguchi S, et al. R-wave sensing in an implantable cardiac monitor without ECG-based preimplant mapping: results from a multicenter clinical trial. *Pacing Clin Electrophysiol* 2014;37:505–511.
- Kawashima A, Tanimoto F, Nagao T, Toyoshima T, Okuyama Y. Investigation of optimal position for implantable loop recorders by potential mapping with Reveal DX. *J Arrhythmia* 2015;31:130–136.
- Lauschke J, Busch M, Haverkamp W, et al. New implantable cardiac monitor with three-lead ECG and active noise detection. *Herz* 2017; 42:585–592.
- Passman RS, Rogers JD, Sarkar S, et al. Development and validation of a dual sensing scheme to improve accuracy of bradycardia and pause detection in an insertable cardiac monitor. *Heart Rhythm* 2017;14:1016–1023.