

Comparing patient and family usability of insertable cardiac monitors in a pediatric cohort: Patient external activator versus smartphone transmission



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Introduction

Insertable cardiac monitors (ICMs) are subcutaneous cardiac devices that monitor heart rates and rhythms and store several minutes' worth of data in a looped fashion.¹ With a battery life of at least 3 years for newer devices, ICMs provide data over longer periods of time compared to Holter monitors and external event monitors.² ICMs have increasing indications in children,³ with a growing scope of diagnostic utility.⁴ There are currently 2 methods of ICM data collection: on-demand tracings during symptomatic events and device autodetected events based on provider-set parameters.

ICM transmitter system technology is rapidly evolving.⁵ The Reveal LINQ (Medtronic, Minneapolis, MN) ICM uses an external patient activator carried by the patient to initiate recordings of symptomatic events.⁶ To transmit the tracings from the device, the LINQ connects to a proprietary patient monitor connected via cellular/wireless signal to transmit data to the medical care team. Conversely, the CONFIRM Rx ICM (Abbott Laboratories, Chicago, IL) uses an application (app) to transmit data wirelessly via the patient's own smartphone.⁷ Once the app is opened, the user follows instructions to initiate a symptomatic event transmission. Using Bluetooth technology, the app transmits both symptomatic and autodetected events to the medical team.⁸

The aim of this study is to assess the patient and family usability of the CONFIRM ICM and LINQ ICM remote monitoring systems in the pediatric population. Specifically, we were interested in whether the availability of a monitor

that connects via a smartphone would be perceived as more or less usable when compared to connection via a custom proprietary transmitter.

Methods

A retrospective chart review was performed to identify patients who had CONFIRM and LINQ ICMs implanted at St. Louis Children's Hospital from 2014 to 2019. The study protocol and telephone consent/assents surveying patients and their families were approved by the Institutional Review Board at Washington University in St. Louis.

All patients with CONFIRM devices implanted during this time were enrolled; a LINQ patient group was subsequently enrolled by matching CONFIRM patients in a 2:1 ratio by age within 2 years, sex, and primary indication for implantation. One of the following primary indications for implantation was identified for each patient: known channelopathy, known supraventricular tachycardia without channelopathy, syncope, or palpitations. A 12-question survey was administered to patients and guardians electronically or via telephone. All patients who opted to complete the telephone surveys were surveyed by a single investigator, not well known to the patients/families. Results were collected using a 5-point Likert-based scale for responses and later collated into a 3-point Likert-based scale for statistical analysis. The research reported in this study was conducted according to principles of the Declaration of Helsinki.

Statistical analysis

Descriptive statistics are presented as percentages and categorical variables as means with standard deviations. Comparison of percentages/proportions were performed via z-test; 95% confidence intervals for proportions were also calculated. A *P* value of <.05 was considered statistically significant.

KEYWORDS Arrhythmias; Insertable cardiac monitor; Palpitations; Patient activator; Pediatric electrophysiology; Syncope; Usability (Heart Rhythm O² 2021;2:201–204)

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KEY FINDINGS

- There were no differences in ease of use between insertable cardiac monitors (ICMs) using external patient activation transmission systems and smartphone application-based transmission.
- Patients/guardians report high levels of convenience and confidence that their transmissions were reaching the medical team, regardless of ICM transmission type.
- ICMs are perceived by pediatric patients and their guardians to have a positive impact on guiding medical management.

Results

Demographics

Eleven patients were implanted with CONFIRM ICMs from 2018 to 2019 and were matched to 22 patients with LINQ ICMs implanted between 2014 and 2019 (Table 1). The 2 groups had similar ages at implantation (LINQ 12.9 ± 5.4 years, CONFIRM 13.8 ± 5.4 years, $P = .65$), ages at survey (LINQ 16.4 ± 5.2 years, CONFIRM 14.9 ± 5.4 years, $P = .45$), and distribution of sex and race. There was a difference between the 2 groups in time from implantation to completion of the survey (LINQ 3.6 ± 1.9 years, CONFIRM 1.1 ± 0.4 years, $P = .0002$).

Survey results

The survey response rate was 100% of enrolled patients. Eighty-six percent of LINQ patients responded that their transmission system was easy to use, compared with 64% of CONFIRM patients (LINQ, $n = 19$; CONFIRM, $n = 7$, $P = .15$). Similar proportions of patients reported their transmission system was convenient (LINQ 90% [$n = 20$], CONFIRM 82% [$n = 9$], $P = .46$) and reported high levels of confidence that their transmissions were received by the medical team (LINQ 82% [$n = 18$], CONFIRM 82% [$n = 9$], $P = 1$). Both groups answered that their devices were useful in guiding their medical management (LINQ 86% [$n = 19$], CONFIRM 82% [$n = 9$],

$P = .73$). Ninety-one percent of LINQ patients said they would recommend their transmitting system to others, compared with 82% of CONFIRM patients (LINQ, $n = 20$; CONFIRM, $n = 9$, $P = .46$) (Figure 1). Other survey questions included the following: the transmitting system was easy to connect to the ICM (agree/strongly agree, LINQ 95% [$n = 21$], CONFIRM 72% [$n = 8$], $P = .06$); instructions were easy to follow (agree/strongly agree, LINQ 91% [$n = 20$], CONFIRM 91% [$n = 10$], $P = 1$). For the remaining questions, which focused on resource availability and impact of transmissions on daily life, analysis was not possible given high nonresponse rate to these questions.

Discussion

This study compared the usability of 2 types of ICM transmitting systems in a pediatric cohort. Pediatric patients reported high rates of easy utility with both types of transmitting system. Additionally, pediatric patients with an external patient activator (LINQ) reported similar ease of transmitting data, convenience of use, and perception of successful transmission to those with a smartphone app-based system (CONFIRM).

While ICMs were initially developed and targeted for adults with recurrent syncope,⁹ the utility of ICMs has expanded and now includes pediatric patients with a variety of indications for implantation. This study importantly demonstrates that pediatric patients have very high rates of utility across the metrics of ease of use, convenience of transmission, and confidence that transmissions reach the medical team. Greater than 80% of each group reported that their device and transmitting system positively affected their medical care. Notably, the majority of patients in each group would recommend their device/transmitting system to others.

Smartphone adoption in the United States is high, with a rate of 84% among American teens in 2019.¹⁰ Despite increasing reliance on smartphone apps and most patients' comfort and familiarity with these devices, pediatric patients with proprietary external patient activation systems reported similar ease of use to patients with smartphone app-based transmission.¹¹ Some CONFIRM respondents cited

Table 1 Demographics

	Medtronic Reveal LINQ (n = 22)	St. Jude CONFIRM Rx (n = 11)	P value
Demographics			
Age at implantation (years)	12.9 ± 5.4	13.8 ± 5.4	N.S.
Age at time of survey (years)	16.4 ± 5.2	14.9 ± 5.4	N.S.
Time from implant to survey (years)	3.6 ± 1.9	1.1 ± 0.4	.0002
Sex	36% female (n = 8)	36% female (n = 4)	N.S.
Race	95% white (n = 21)	91% white (n = 10)	N.S.
Indications for ILR placement			
Syncope	55% (n = 12)	55% (n = 6)	N.S.
Channelopathies	18% (n = 4)	18% (n = 2)	N.S.
Supraventricular tachycardia	18% (n = 4)	18% (n = 2)	N.S.
Palpitations	9% (n = 2)	9% (n = 1)	N.S.

Data are presented as means with standard deviations or as percentages.
ILR = implantable loop recorder; N.S. = no significance.

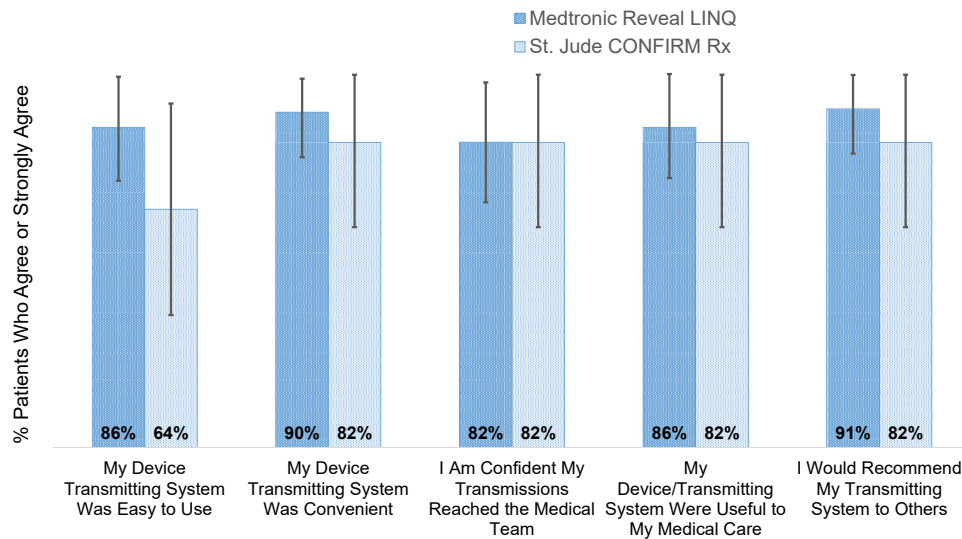


Figure 1 Bar graphs demonstrating the percentage of patients who “agreed” or “strongly agreed” with the survey questions/statements. Error bars denote 95% confidence interval.

problems with Bluetooth connections and software updating problems, which also have been reported in other studies of smartphone app technology.¹² Notwithstanding the seeming convenience associated with smartphone apps, the proportion of patients reporting that their transmission system was convenient was similar.¹³ LINQ and CONFIRM patients also reported similar rates of confidence that transmissions were reaching the medical team despite the differences in transmitting system interface.

The patient selection for this study was based on the CONFIRM ICMs that had been placed. These devices had been predominantly implanted in older children and teenagers. The population had a male predominance of 64% as well, and there was very little racial diversity in the groups. Further studies could evaluate the differences in usability between different demographic populations. These data do not distinguish between guardians or patients answering survey questions or guardians/patients being primarily responsible for the transmissions from the device. Potential differences in guardian vs patient usage of the transmitting systems may exist, though these were not explored in this study.

These data suggest that ICM placement is perceived as a positive diagnostic tool by pediatric patients and their guardians. When selecting an ICM and transmitting system for a patient, a variety of factors should be considered, including Bluetooth availability to the patient, internet connection in the patients’ area of residence, and patient preference.

Limitations

Limitations of this study include its small sample size owing to the number of CONFIRM ICMs implanted at this single institution, resulting in low power for detecting differences. The difference in time from implantation to survey between the 2 groups may introduce recall bias in the LINQ group. The person responsible for performing transmissions was not explicitly asked during surveying of patients/families.

Additionally, there may be differences in ICM usability for younger patients that these patient cohorts did not show.

Conclusion

Although smartphones make several daily activities convenient, initial ICM usability data from this pediatric cohort suggest external patient-activated transmission systems have similar ease of use and convenience to smartphone app-based transmissions. Both transmission systems have high rates of satisfaction in pediatric patients and families. The transmission system is one of several factors that should be considered when selecting an ICM for patients and families. Future studies may evaluate the ease of use between transmission systems in younger age groups, in more diverse populations (both sex and race), and among different implant indications.

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Disclosures

The authors have no conflicts to disclose.

Authorship

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

Patient Consent

All patients or their guardians provided telephone consent for participation in this study.

Ethics Statement

The study protocol and telephone consent/assents surveying patients and their families were approved by the Institutional Review Board at Washington University in St. Louis. The research reported in this study was conducted according to principles of the Declaration of Helsinki.

Disclaimer

Given her role as Section Editor, Jennifer N. Avari Silva had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Editors Ulrika Birgersdotter-Green and Jeanne E. Poole.

References

1. Bisignani A, De Bonis S, Mancuso L, Ceravolo G, Bisignani G. Implantable loop recorder in clinical practice. *J Arrhythm* 2018;35:25–32.
2. Rossano J, Bloemers B, Sreeram N, Balaji S, Shah MJ. Efficacy of implantable loop recorders in establishing symptom-rhythm correlation in young patients with syncope and palpitations. *Pediatrics* 2003;112:e228–e233.
3. Bezzerides VJ, Walsh A, Martuscello M, et al. The real-world utility of the LINQ implantable loop recorder in pediatric and adult congenital heart patients. *JACC Clin Electrophysiol* 2019;5:245–251.
4. Avari Silva JN, Bromberg BI, Emge FK, Bowman TM, Van Hare GF. Implantable loop recorder monitoring for refining management of children with inherited arrhythmia syndromes. *J Am Heart Assoc* 2016;5:e003632.
5. Tomson TT, Passman R. The Reveal LINQ insertable cardiac monitor. *Expert Rev Med Devices* 2015;12:7–18.
6. Medtronic. (n.d.). Heart Monitors - Reveal LINQ ICM System. Retrieved October 26, 2020, from <https://www.medtronic.com/us-en/patients/treatments-therapies/heart-monitors/our-monitors/reveal-linq-icm.html>.
7. Kilinc OU, Shivapour JKL, Snyder CS. Confirm RX™ cardiac monitor placement in a pediatric patient. *J Innov Card Rhythm Manag* 2018;9:3315–3316.
8. Abbott. (n.d.). Living with Confirm Rx Insertable Cardiac Monitor: Abbott. Retrieved October 26, 2020, from <https://www.cardiovascular.abbott/us/en/patients/living-with-your-device/arrhythmias/insertable-cardiac-monitor/confirm-rx-icm.html>.
9. Krahn AD, Klein GJ, Yee R. Recurrent syncope. Experience with an implantable loop recorder. *Cardiol Clin* 1997;15:313–326.
10. Rideout V, Robb MB. The Common Sense Census: Media Use by Tweens and Teens, 2019. San Francisco, CA: Common Sense Media; 2019.
11. Pevnick JM, Birkeland K, Zimmer R, Elad Y, Kedan I. Wearable technology for cardiology: An update and framework for the future. *Trends Cardiovasc Med* 2018;28:144–150.
12. Shabaan M, Arshid K, Yaqub M, et al. Survey: smartphone-based assessment of cardiovascular diseases using ECG and PPG analysis. *BMC Med Inform Decis Mak* 2020;20:177.
13. Moreno MA, Kerr BR, Jenkins M, Lam E, Malik FS. Perspectives on smartphone ownership and use by early adolescents. *J Adolesc Health* 2019;64:437–442.