ORIGINAL RESEARCH

Impact of Device Miniaturization on Insertable Cardiac Monitor Use in the Pediatric Population: An Analysis of the MarketScan Commercial and Medicaid Databases

Dustin Nash (D, MD; Hannah Katcoff, MPH; Jennifer Faerber (D, PhD; V. Ramesh Iyer, MD; Maully J. Shah, MBBS; Michael L. O'Byrne (D, MD, MSCE*; Christopher Janson (D, MD*

BACKGROUND: Insertable cardiac monitors (ICMs) are effective in the detection of paroxysmal arrhythmias. In 2014, the first miniaturized ICM was introduced with a less invasive implant technique. The impact of this technology on ICM use in pediatric patients has not been evaluated. We hypothesized an increase in annual pediatric ICM implants starting in 2014 attributable to device miniaturization.

METHODS AND RESULTS: A retrospective observational study was conducted using administrative claims from MarketScan Medicaid and commercial insurance claims databases. Use of ICM between January 2013 and December 2018 was measured (normalized to the total enrolled population \leq 18 years) and compared with balancing measures (Holter ambulatory monitors, cardiac event monitors, encounters with syncope diagnosis, implantation of implantable cardioverter-defibrillator/ pacemaker). Secondary analyses included evaluations of subsequent interventions and complications. The study cohort included 33 532 185 individual subjects, of which 769 (0.002%) underwent ICM implantation. Subjects who underwent ICM implantation were 52% male sex, with a median age of 16 years (interquartile range, 10–17 years). A history of syncope was present in 71%, palpitations in 43%, and congenital heart disease in 28%. Following release of the miniaturized ICM, use of ICMs increased from 5 procedures per million enrollees in 2013 to 11 per million between 2015 and 2018 (*P*<0.001), while balancing measures remained static. Of 394 subjects with \geq 1 year of follow-up after implantation, interventions included catheter ablation in 24 (6%), pacemaker implantation in 15 (4%), and implantable cardioverter-defibrillator implantation in 7 (2%).

CONCLUSIONS: Introduction of the miniaturized ICM was followed by a rapid increase in pediatric use. The effects on outcomes and value deserve further attention.

Key Words: database
device miniaturization
insertable cardiac monitor
pediatrics
utilization

The Insertable cardiac monitor (ICM) is a valuable tool in the evaluation of syncope and palpitations when ambulatory noninvasive rhythm monitoring has not provided a definitive diagnosis. Efficacy of this method in the pediatric population has been established in prior studies.^{1,2} Significant progress has been made to make ICMs smaller to allow the procedure to be less invasive and less morbid. In February 2014,

Correspondence to: Dustin Nash, MD, 3401 Civic Center Boulevard, Philadelphia, PA 19104. Email: nashdb@chop.edu

*M. L. O'Byrne and C. Janson are co-senior authors.

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CLINICAL PERSPECTIVE

What Is New?

• This study demonstrates the rapid increase in use of insertable cardiac monitors among pediatric patients after introduction of the first miniaturized insertable cardiac monitors in 2014.

What Are the Clinical Implications?

- While use has increased, overall number of implants and complications remains relatively low.
- The effects of increased use on outcomes and value deserve further attention.

Nonstandard Abbreviations and Acronyms

ICM insertable cardiac monitor

the Reveal LINQ (Medtronic INC., Minneapolis, MN) received US Food and Drug Administration approval. With a volume of 1.18 mL, this device was 87% smaller than its predecessor, the Reveal XT at $9 \, \text{mL}$,³ promising shorter procedure and recovery times, as well as expansion of eligible recipients to smaller and younger patients.^{4,5}

The impact of miniaturization on real-world use of ICMs in pediatric patients has, to our knowledge, not been evaluated. To provide an estimate of use in the United States, we analyzed data from an insurance claims database that included recipients of both commercial and public coverage for the years 2013 to 2018. We hypothesized that the rate of ICM implantation would increase following LINQ release in February of 2014. Furthermore, we sought to describe the characteristics of pediatric patients undergoing ICM implantation, as well as report device complications and subsequent therapeutic interventions.

METHODS

Data Source

The Truven Health MarketScan Claims and Encounter Database (Truven Health Analytics, IBM Watson Health, Ann Arbor, MI)⁶ is an insurance claims database with modules containing data from commercial insurers and Medicaid programs.^{6–15} The database contains longitudinal deidentified health care reimbursement data, spanning the continuum of care (inpatient, outpatient, emergency department, and pharmacy encounters). It provides one of the largest sources of patient-level geographically representative data in children. It represents a large convenience sample of the population within the United States. As the data are deidentified, the study was exempt from review by The Children's Hospital of Philadelphia Institutional Review Board according to the Common Rule. Data sharing is prohibited by our data use agreement with Truven Analytics. Methods and statistical code will be shared upon request.

Study Design and Measures

Eligible subjects were children and adolescents (0-18 years) who underwent ICM insertion and with data in the MarketScan commercial and/or Medicaid databases between January 1, 2013, and December 31, 2018. These subjects were identified by guerying available encounters in the database for an International Classification of Diseases (ICD), Ninth Revision (ICD-9) or Tenth Revision (ICD-10) code or Current Procedural Terminology code consistent with ICM insertion (Table S1). Subject characteristics recorded were age, sex, race or ethnicity, insurance class (Medicaid versus commercial), and census region. Race and ethnicity are available only as a single variable for recipients of Medicaid, while census region is available only in recipients of commercial insurance. The presence of ICD codes for arrhythmias or arrhythmia-associated conditions, including congenital heart disease, cardiomyopathy, long QT syndrome, or Wolff-Parkinson-White syndrome, among patients who underwent ICM implantation were recorded in a non-mutually exclusive manner. Associated encounter diagnoses such as syncope and palpitations were also recorded. ICM complications including infection, erosion, and pain were identified by the presence of associated ICD codes. Additionally, postimplantation procedures such as cardioversion, electrophysiology study, catheter ablation, implantable cardioverter-defibrillator or pacemaker insertion, and removal of ICM were recorded. ICD/ Current Procedural Terminology codes for variables included in this analysis are available upon request.

Statistical Analysis

Descriptive statistics were calculated for the demographics and clinical characteristics of the cohort. We first analyzed the rate of implants by quarter year, with rates expressed as the number of ICMs implanted per million unique enrollees. Expressing rates as a percentage of total enrollees mitigates potential bias attributable to changes in the total number of enrollees over time. To ensure that observed changes in ICM rates reflected changes in ICM-specific practice, we also used the following events/diagnoses as balancing measures: (1) encounters with a diagnosis of syncope, the most common indication for ICM, (2) Holter monitor, the most common noninvasive ambulatory rhythm monitor; (3) cardiac event monitors, including mobile cardiac outpatient telemetry as longer duration noninvasive monitoring modalities and potential alternatives to ICM; and (4) a composite of invasive electrophysiologic procedures, specifically pacemaker implantation, implantable cardioverter-defibrillator implantation, and electrophysiology study (representative of invasive pediatric electrophysiologic volume in the cohort). We hypothesized that the rates for these balancing measures would not change meaningfully over the study period (in contrast to the rate of ICM use, which we expected to increase).

Before analysis, we visually evaluated the changes in ICM use. Based on these results, we compared data before release of miniaturized devices (2013) with data after release (2015-2018) via the chi-square test, with a threshold for significance set at P<0.05. Implants from 2014 were not included to allow for adoption and stabilization. The proportion of procedures that were performed in an inpatient versus outpatient setting were recorded. The median ages of ICM recipients before release of miniaturized devices (2013) and after release (2015-2018) were compared by Wilcoxon rank-sum test. Given the potential for patient flux into and out of the database with insurance changes, we compared characteristics of patients with <1 year of follow-up and those with at least 1 year of follow-up; we then evaluated complications and subsequent invasive electrophysiologic procedures performed among those patients with at least 1 year of follow-up.

RESULTS

Demographics

The study cohort included 33532185 individual subjects, of which 769 (23 per million individuals) underwent ICM implantation (Table 1). Forty-nine subjects had implantation of 2 ICMs during the study period for a total of 818 implants. Among individuals undergoing ICM implantation, 402 (52%) were male subjects, with a median age at procedure of 16 years (interquartile range [IQR], 10–17). Medicaid insurance was the primary payer for 308 (40%). The most common associated condition was congenital heart disease (28%), followed by cardiomyopathy (12%), long QT syndrome (9%), and Wolff-Parkinson-White syndrome (4%). Syncope was present in 545 (71%) and palpitations in 333 (43%).

ICM Use

Use of ICMs increased significantly from 2013 (5 procedures/million enrollees) to the period between 2015 and 2018 (11 procedures/million enrollees; *P*<0.0001; Figure 1) with quarterly use up to 288% of the 2013 mean value. Prespecified balancing measures demonstrated fluctuations in quarterly use rates from 66% to 127% of their 2013 mean values but without consistent trend (Table S2). The proportion of ICMs performed during inpatient encounters decreased from 38% in 2013 to 7% in 2018 (Figure 2).

Age at Implantation

The median age at implantation in 2013 (pre-LINQ release) was 16 years (IQR, 11–18 years), which did not significantly differ from the median age at implantation in 2015 to 2018 of 16 years (IQR, 11–18; P=0.84).

Complications and Subsequent Procedures

A total of 394 patients (51%) had at least 1 year of follow-up. These patients were more likely to be younger, with a median age of 14 years (IQR, 8–18 years) versus median age of 18 years (IQR, 14–18) among the group with <1 year of follow-up (P<0.0001). They were also more likely to have public insurance (186 patients [47%] versus 122 patients [32%]), and to have been coded for an inpatient encounter (80 patients [20%] versus 48 patients [12%]). Of those with at least 1 year of follow-up, 25 (6%) had complications, with device infection in 14 (4%) and erosion in 5 (1%) (see Table 2). Ten of 14 (71%) infections occurred in 2015. Subsequent procedures were done on 60 (15%), including catheter ablation in 24 (6%), pacemaker implant in 15 (4%), and implantable cardioverter-defibrillator implant in 7 (2%) (Table 3).

DISCUSSION

This observational study leveraged a combined public and commercial claims database to generate a representative sample of US children and evaluate whether the introduction of a miniaturized device was associated with increased use of ICMs in children. Following the introduction of the first miniaturized ICM, there was a significant increase in ICM use among a large pediatric cohort. The uptake of this technology was rapid, occurring over a single calendar year. During the available follow-up, the increased use was sustained. These findings are consistent with the hypothesis that a smaller, less invasive device would be associated with increased use in young patients. While acknowledging that causality cannot be established with this study design, our analysis of balancing measures demonstrates that similar patterns were not seen in the most common indication for the procedure or the most common alternatives to the procedure. This suggests that the pattern observed reflects increased ICM use.

The significant increase in use of these devices raises several important questions. First, what is the biggest driver of the sustained doubling in implant rate? The database does not demonstrate an increase in encounters for syncope, suggesting that the observed

	Total	2013 (n=84)	2014 (n=135)	2015+ (n=550)	P value
Male sex, n (%)	402 (52)	45 (54)	76 (56)	281 (51)	0.42
Age at procedure, median (IQR)	16 (11–17)	16 (11–18)	16 (9–18)	16 (11–18)	0.84
Race or ethnicity (available for 258)		Available for 19	Available for 42	Available for 197	0.95
White, n (%)	180 (70)	13 (68)	28 (67)	139 (71)	
Black, n (%)	61 (24)	5 (26)	12 (29)	44 (22)	
Hispanic, n (%)	11 (4)	1 (5)	1 (2)	9 (5)	
Other, n (%)	6 (2)	0 (0)	1 (2)	5 (2)	
Insurance class, n (%)					0.003
Medicaid insurance	308 (40)	22 (26)	50 (37)	236 (43)	
Commercial insurance	461 (60)	62 (74)	85 (63)	314 (57)	
Region (available for 458, only commercial insurance)		Available for 62	Available for 84	Available for 313	0.31
Northeast, n (%)	75 (16)	8 (13)	16 (19)	51 (16)	
North Central, n (%)	113 (25)	16 (26)	24 (28)	73 (23)	
South, n (%)	203 (44)	23 (37)	33 (39)	148 (47)	
West, n (%)	67 (14)	15 (24)	11 (13)	41 (13)	
Encounter coding for ICM implantation, n (%)					<0.0001
Inpatient encounter	127 (17)	31 (37)	29 (21)	68 (12)	
Outpatient encounter	642 (83)	53 (63)	106 (79)	482 (88)	
Preoperative diagnoses, n (%)					
Any congenital heart disease	218 (28)	30 (36)	42 (31)	146 (27)	0.06
Tetralogy of Fallot	13 (2)	0 (0)	2 (1)	11 (2)	0.20
Single ventricle	9 (3)	1 (2)	2 (1)	6 (3)	0.96
Ebstein anomaly	5 (1)	0 (0)	0 (0)	5 (1)	0.20
Cardiomyopathy	93 (12)	12 (14)	23 (17)	58 (11)	0.09
Long QT syndrome	73 (9)	8 (10)	19 (14)	46 (8)	0.26
Wolff-Parkinson-White syndrome	31 (4)	3 (4)	5 (4)	23 (4)	0.74
Symptoms,† n (%)					
Syncope	545 (71)	58 (69)	94 (70)	393 (71)	0.59
Palpitations	333 (43)	24 (29)	52 (39)	257 (47)	0.0007
Tachycardia, unspecified	231 (30)	12 (15)	40 (30)	179 (33)	0.003
Bradycardia, unspecified	70 (9)	0 (0)	0 (0)	70 (13)	<0.0001
Abnormal electrocardiogram	227 (29)	26 (31)	37 (27)	164 (30)	0.94

Table 1.	Characteristics of Individuals Undergo	ing ICM Implantation b	v Year of Implant (n=769)
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ICM indicates insertable cardiac monitor; and IQR, interquartile range. [†]Note that patients may have more than one initial presenting symptom.

change reflects an increased likelihood of using ICM for evaluation of syncope. At the same time, the age at ICM implantation did not change significantly over time, suggesting that expanding implantation into younger patients does not explain the observed increase. Absence of a change in age may reflect the epidemiology of syncope, which is much more common in older children and adolescents. Patient and family preference may play a role, as they may be more interested in pursuing an ICM with a less invasive implant technique. Nguyen et al described a better cosmetic perception in pediatric patients with the LINQ device compared with Reveal XT.³ Physicians may also be more comfortable in referring for miniaturized ICM because of ease of implantation procedures, which can

potentially be performed in an outpatient setting, with lower perceived procedural risk and rapid recovery. In support of this, we observed a commensurate trend from ICM implantation during inpatient encounters to outpatient encounters during the study period.

Although we hypothesize that device miniaturization is the biggest factor, there are other factors that may drive increased ICM use, including improved remote monitoring capabilities, greater availability with multiple device manufacturers, increased physician familiarity with the technology, and decreasing confidence in alternative diagnostic modalities, such as tilt-table testing. Another potential driver of increased pediatric ICM use is increasing diagnosis of patients with inherited arrhythmia syndromes through cascade

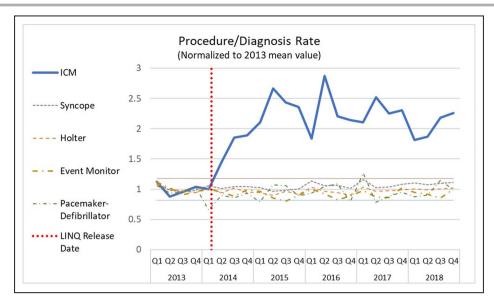


Figure 1. Effect of ICM miniaturization on use as compared with balancing measures. ICM implantation trends and balancing measures over the study period. The graph displays quarterly rates of ICM implant and balancing measures normalized to the 2013 mean value. ICM indicates insertable cardiac monitor.

screening, as ICMs have been proposed as useful surveillance for certain conditions.¹⁶ Another important recent trend is the increased use by both patients and providers of wearables as a surrogate for cardiac monitors¹⁷; while this may have a downstream impact on ICM use, this could not be evaluated in the current study. Important questions to answer include whether the increased use of ICM results in better outcomes (ie, more successful identification of arrhythmias in atrisk populations) or more definitive documentation of nonarrhythmic events (reassuring the "worried well"),

and what balance of these end points represents highvalue care (cost-effective compared with alternatives).

In evaluating threshold for ICM at the individual patient level, one must weigh the benefits in terms of improved sensitivity in identifying pathology against the procedural risks and device-related complications. In the current data set, there is insufficient data to evaluate whether ICM use identified otherwise undiagnosed pathology, compared with an alternative strategy. The efficacy and safety of miniaturized ICMs in the pediatric and congenital heart disease populations have been previously

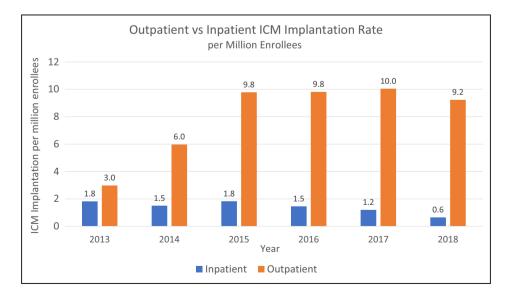


Figure 2. Proportion of inpatient ICMs by year. Balance of coding encounters for ICM implantation for outpatient or inpatient over the study period. ICM indicates insertable cardiac monitor.

Table 2. Complications Among Patients With at Least 1 Year of Follow-Up

	Year of ICM implant, n (%)						
	2013	2014	2015	2016	2017	Total	
No.	54	69	96	97	77	393	
Infection	2 (4)	2 (2)	10 (10)	0 (0)	0 (0)	14 (4)	
Erosion	0 (0)	5 (7)	0 (0)	0 (0)	0 (0)	5 (1)	
Other*	2 (4)	4 (6)	0 (0)	0 (0)	0 (0)	6 (2)	

ICM indicates insertable cardiac monitor.

* Includes pain, hemorrhage, and complications not otherwise specified.

described in single-center studies. Bezzerides and colleagues⁶ reported outcomes in a retrospective cohort of 133 pediatric patients and patients with congenital heart disease who underwent miniaturized ICM implantations: during a median follow-up of 11 months, 78 (59%) had diagnostic transmissions with a positive diagnosis in 31 (40%). A cohort from Italy of 21 patients aged <6 years demonstrated a total diagnostic yield of 47%.⁵ Adverse events such as infection and erosion among these cohorts ranged from 4% to 9.5%, which are in line with our observations. In their study of 31 patients with the LINQ device and 15 patients with the Reveal XT, Nguyen found a higher rate of erosions in the LINQ cohort.³ In another study by Gunda et al¹⁹ of 112 adult patients who underwent LINQ placement, pocket closure without sutures was associated with a significantly increased risk of infection (12% versus 0%). In the current study, the highest infection rate was seen in 2015. This temporally corresponds to the era when miniaturized ICMs had been adopted, but the practice of suture closure techniques was likely still developing. Further investigations are needed to compare complication rates of miniaturized ICMs to predecessors.⁵

At the population level, a cost-benefit analysis would best address the issue of threshold for ICM. This analysis is beyond the scope of the current report. It has been suggested by prior reports that a change in procedure location from a catheterization laboratory to a procedure room translates to fewer staff and equipment and lower costs.⁵ However, other studies have

described higher cost with the miniaturized ICM, in part because of the cost of the device itself.²⁰ Further investigation is needed to evaluate outcomes and value of the miniaturized ICM in this patient population, especially as newer generations of miniaturized ICMs are released with improved battery longevity and better patient interfaces.²¹

Limitations

There are several additional limitations we acknowledge. Most importantly, the data set had only 1 year of prerelease data available to establish a baseline implant rate. It is possible that other trends are missed because of this. One could even speculate that providers delayed ICM implant in 2013 in anticipation of the miniaturized device release. However, we feel that the data are consistent with our hypothesis. Figure 1 demonstrates 5 guarters of steady implant rate before release, followed by a gradual increase in implant rate, and finally settling into a new baseline rate. The assumption is that ICMs placed in 2015 and beyond represent miniaturized devices, but this cannot be confirmed. The database also cannot offer insight into ICM use by manufacturer or specific model. Because of the nature of the database, it is difficult to ascertain the primary indication for ICM. The database does not contain sufficient detail to further differentiate the nature of inpatient and outpatient encounters, and the observed trends may represent changes in coding practice alone.

As noted, in this study design, associations do not imply causation. As with all analyses of nonclinical data, there are limitations to the clinical detail available in claims data. As noted in other studies,^{12,14} changes from *ICD-9* to *ICD-10* in September 2015 can have significant effects on the prevalence of medical conditions, but this was not seen in the current analysis, where the point of inflection preceded the conversion to *ICD-10*. Although it has not been noted in other studies,^{13,14} it is possible that changes in insurance coverage might result in underreporting of complications and subsequent procedures.

Table 3. Invasive Electrophysiologic Procedures Among Patients With at Least 1 Year of Follow-Up

	Year of ICM implant, n (%)					
	2013	2014	2015	2016	2017	Total
No.	54	69	96	97	77	393
ICM removal	18 (33)	26 (37)	23 (24)	22 (23)	8 (10)	140 (24)
Pacemaker insertion	4 (7)	3 (4)	2 (2)	4 (4)	2 (2)	15 (4)
Implantable cardioverter-defibrillator insertion	0 (0)	2 (3)	2 (2)	3 (3)	0 (0)	7 (2)
Electrophysiology study without catheter ablation	2 (4)	2 (3)	2 (2)	6 (6)	2 (2)	14 (4)
Electrophysiology study with catheter ablation	5 (9)	4 (5)	3 (3)	8 (8)	4 (5)	24 (6)

ICM indicates insertable cardiac monitor.

CONCLUSIONS

Following introduction of the first miniaturized ICM in 2014, use significantly increased among a large pediatric population. Although the adoption of the miniaturized ICM technology was rapid, occurring over a single calendar year, the number of implants remains low. While there has been a concurrent trend toward ICM implantations occurring during outpatient encounters, the median age of implantation has not significantly changed. Future studies should address the effect of miniaturized ICMs on clinical outcomes and value.

ARTICLE INFORMATION

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Affiliations

Division of Cardiology, The Children's Hospital of Philadelphia, PA (D.N., H.K., V.R.I., M.J.S., M.L.O., C.J.); Department of Pediatrics, The Perelman School of Medicine at The University of Pennsylvania, Philadelphia, PA (D.N., H.K., V.R.I., M.J.S., M.L.O., C.J.); Data Science and Biostatistics Unit (J.F.); and Center for Pediatric Clinical Effectiveness (M.L.O.), The Children's Hospital of Philadelphia, PA; and Leonard Davis Institute and Cardiovascular Outcomes, Quality, and Evaluative Research Center, University of Pennsylvania, Philadelphia, PA (M.L.O.).

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Supplemental Material

Tables S1–S2

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SUPPLEMENTAL MATERIAL

Table S1. Procedural Code for ICM Insertion

Procedure	ICD-9	ICD-10	СРТ
Insertion of loop	37.79	0JH602Z or 0JH632Z	33282 or
recorder			33285

<u>Year</u>	2013	2014	2015	2016	2017	2018		
<u>Enrollees available</u>	n=18,141,621	n=18,603,133	n=14,205,816	n=13,754,924	n=13,339,401	n=12,348,839		
Procedure Rate per Million Enrollees: Annual Rate (% of 2013 Mean Rate)								
ICM implant	5.5 (100)	8.4 (154)	13.1 (239)	12.4 (227)	12.5 (229)	11.1 (203)		
<u>Syncope diagnoses</u>	10,083 (100)	10,477 (104)	10,028 (99)	10,791 (107)	10,829 (107)	11,064 (109)		
<u>Holter Monitor</u>	2,634 (100)	2,585 (98)	2,453 (93)	2,536 (96)	2,607 (99)	2,650 (101)		
<u>CEM/MCOT</u>	1,058 (100)	1,015 (95)	930 (88)	962 (91)	987 (93)	986 (93)		
Implantable Cardiac Defibrillator/Pacemaker insertion	21.9 (100)	18.3 (84)	20.8 (95)	21.1 (97)	21.2 (97)	21.4 (98)		

Table S2. Annual Normalized Procedural Rates