Real-World Incidence of Pacemaker and Defibrillator Implantation Following Diagnostic Monitoring With an Insertable Cardiac Monitor

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Insertable cardiac monitors (ICM) are used in patients with suspected or known cardiac arrhythmias; the resulting diagnosis can lead to therapeutic interventions such as a pacemaker (PPM) or defibrillator (ICD) implant. We investigated the incidence of these implants in a large, real-world, cohort of ICM patients. The Optum© EHR de-identified database was used to identify patients with cardiovascular diseases, an ICM implant, ≥180 days of follow-up before and after ICM implant, and no previous history of a PPM or ICD. The Kaplan-Meier (KM) incidence estimates for device implants following an ICM implant were determined. A total of 19,173 patients with an ICM implant were identified. During a mean follow-up of 40 months, either a PPM or ICD was implanted in 21% of patients. A device was implanted in 25% of patients with history of syncope compared with 15% in patients with another indication for ICM implant (p <0.001). There was a significantly greater number of PPM implants following an ICM in patients with history of syncope compared with another indication for ICM implant (23% vs 13% p <0.001); in contrast, there was no difference in ICD implants between the 2 groups (3% in both groups, p = 0.84). In conclusion, a PPM or ICD was ultimately implanted in 21% of ICM patients. Pacemaker implant rates varied significantly with indication for ICM implant, whereas ICD implants rates were similar. In particular, patients with history of syncope had the greatest likelihood of needing a PPM during follow-up. **(Am J Cardiol 2019;123:1967−1971)**

Subcutaneous insertable cardiac monitors[1−2] (ICM) are most often used to diagnose a cause for unexplained syncope,[3−10] to monitor for recurrent atrial fibrillation (AF) after surgical and catheter ablation of AF,[11−14] catheter ablation of atrial flutter,[15] and in patients with history of cryptogenic stroke.[16,17] Continuous long-term ECG monitoring using ICMs improves the ability to diagnose a cardiac arrhythmia compared with intermittent, external, ECG tools such as Holter and event monitors[5,11,18] or reliance on patient symptoms alone.[19] Multiple studies have shown that ICM-based monitoring strategies have higher diagnostic yield and lead to more appropriate therapeutic interventions, like a pacemaker (PPM) or defibrillator (ICD) implant, compared with standard of care.[4−10] The main objective of this study was to evaluate, using a large database of patients in the United States, the real-world incidence of PPM and ICM implants in patients who underwent ECG monitoring using an ICM.

Methods

The study cohort used the Optum© EHR de-identified database, which contained de-identified data from patients collected in electronic health record systems during 2007 to 2016 from multiple hospital systems across United States. We included patients if they had a cardiovascular diagnosis code in their medical records or they had a cardiovascular-related procedure performed during the data collection period. In this study, an analysis cohort was formed, which included patients with ICM implant and at least 180 days of follow-up before and after implant of ICM. Patients were excluded if they had a history of PPM or ICD device before the ICM implant. Within the analysis cohort, patients were further subdivided into 2 cohorts, one with history of syncope and the other with no history of syncope.

Procedure and diagnosis codes for insertable cardiac monitor implants were identified in the de-identified EHR database using the CPT codes shown in Table 1. The earliest date of either implant or follow-up CPT code was used as the date of implant to include patients with ICM implants outside the health systems in the database but with follow-up within health systems in the database. Patients with only removal code were excluded from the data cohort. Pacemaker and defibrillator implants were identified in the de-identified EHR database using CPT codes as well the ICD-9 or ICD-10 hospital codes as shown in Table 1. A few rules were used to resolve conflicting information in EHR data. In case of presence of PPM and ICD procedure codes over same period of time, the device type with higher number of procedure codes was assigned as the device. In case

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Table 1
CPT, ICD-9, and ICD-10 codes used for identification of patients with insertable cardiac monitors, pacemaker, and defibrillators from EHR data

	Procedure codes		
	CPT device implant-removal codes	CPT device follow-up codes	ICD-9/ICD-10 hospital codes
Insertable cardiac monitor	33282, 33284	93285, 93291, 93298	–
Pacemakers	33206, 33207, 33208, 33227, 33228, 33214, 33212, 33213, 33,229	93280, 93279, 93288, 93281	00.50, 00.53, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 0JH604Z, 0JH634Z, 0JH804Z, 0JH834Z, 0JH605Z, 0JH635Z, 0JH805Z, 0JH835Z, 0JH606Z, 0JH636Z, 0JH806Z, 0JH836Z, 0JH607Z, 0JH637Z, 0JH807Z, 0JH837Z
Defibrillators	33249, 33240, 33230, 33231, 33262, 33263, 33264, 33270	93289, 93282, 93283, 93284, 93641	00.51, 00.54, 37.94, 37.96, 37.98, 0JH608Z, 0JH609Z, 0JH808Z, 0JH809Z, 0JH638Z, 0JH639Z, 0JH838Z, 0JH839Z

CPT, current procedural terminology; EHR, electronic health data; ICD, International Statistical Classification of Diseases and Related Health Problems.

of equal number of procedures, then it was considered a PPM as that is what is considered more likely in these patients. Patients with only information regarding the removal of PPM or ICD were excluded. History of syncope as well as other disease states as well as cardiac arrhythmias were identified using ICD-9 or ICD-10 codes as shown in Table 2.

History of hypertension, coronary artery disease, diabetes, heart failure, atrial fibrillation, ischemic stroke/transient ischemic attack (TIA) before ICM implant are reported for the entire cohort as well as for patients with history of syncope and no history of syncope. Baseline variables were compared using the Student t test for continuous variables and the χ^2 test for categorical variables. The Kaplan-Meier (KM) estimates for PPM or ICD device implants following ICM implants are reported for the entire cohort as well as for patients with history of syncope. Comparisons of KM curves between history of syncope and no history of syncope were done using the log-rank test, and hazard ratios were computed using the Cox proportional hazards model.

Results

A total of 32,778 ICMs were identified, of which 19,173 met inclusion criteria of ≥180 days of follow-up before and after ICM implant and no previous PPM or ICD implant. A total of 11,672 (36%), 1,510 (5%), and 423 (1%) patients were excluded due to lack of 180 days of follow-up before or after ICM implant, PPM/ICD before ICM implant, and only ICM removal evidence respectively. The average follow-up duration for patients after ICM implant was 2.1 ± 1.5 years. The baseline demographics of the patient population are shown in Table 3. During follow-up, a PPM or ICD was ultimately implanted in 2,667 (14%) and 385 (2%)

Table 2
ICD-9 and ICD-10 diagnosis codes used to determine history of different diseases before ICM implant

Disease state	ICD-9 or ICD-10 diagnosis codes
Syncope	780.2, R55
Hypertension	401.X, 402.X, 404.X, 403.X, 405.X, I10.X, I11.X, I12.X, I13.X, I15.X
Coronary artery disease	410.X, 411.X, 412.X, 413.X, 414.0X, 414.2, 414.3, 414.4, 414.8, 414.9 I20.X, I21.X, I22.X, I23.X, I25.1X, I25.2, I25.5, I25.6, I25.7, I25.8, I25.9
Diabetes	250.X0, 250.X2, E11.X, 250.X1, 250.X3, E10.X
Heart failure	428.X, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, I50.X, I11.0, I13.0, I13.2
Ischemic stroke	433.X, 434.X, 436.X, I63.X, I65.X, I66.X
TIA	435.X, G45.0, G45.1, G45.2, G45.8, G45.9
Atrial fibrillation	427.31, I48.0, I48.1, I48.2, I48.91
Atrial flutter	427.32, I48.3, I48.4, I48.92
Supraventricular tachycardia	427.0, I47.1
AV block	426.0, 426.1, 426.10, 426.11, 426.12, 426.13, 426.54, I44.0, I44.1, I44.2, I44.3X, I45.3
Bradycardia and sinus node dysfunction	427.89, R00.1, 427.81, I49.5
Ventricular tachyarrhythmia	427.4X, 427.1, I49.0X, I47.2
Premature depolarizations	427.60, 427.61, 427.69, I49.1, I49.2, I49.3, I49.4X
Ventricular block (LBBB, RBBB, fascicular block)	426.2, 426.3, 426.4, 426.5X, I44.4, I44.5, I44.6X, I44.7, I45.0, I45.1X, I45.2, I45.3, I45.4

AV, atrioventricular; ICD, International Statistical Classification of Diseases and Related Health Problems; ICM, insertable cardiac monitor; LBBB, left bundle branch block; RBBB, right bundle branch block; TIA, transient ischemic attack.

Table 3
Baseline demographics of the study population

Variable	All Patients (n = 19,173)	History of syncope		p Value
		Yes (n = 10,346)	No (n = 8,827)	
Age (years)	63 ± 16	63 ± 18	63 ± 15	0.092
Men	9,245 (48%)	4,740 (46%)	4,505 (51%)	<0.001
Coronary artery disease	7,255 (38%)	4,186 (40%)	3,069 (35%)	<0.001
Diabetes	4,855 (25%)	2,670 (26%)	2,185 (25%)	0.095
Heart failure	2,752 (14%)	1,569 (15%)	1,183 (13%)	<0.001
Hypertension	13,664 (71%)	7,399 (72%)	6,265 (71%)	0.410
Ischemic stroke/transient ischemic attack	2,289 (12%)	643 (6%)	1,646 (19%)	<0.001
Atrial fibrillation	7,017 (37%)	2,914 (28%)	4,103 (46%)	<0.001
Atrial flutter	1,688 (9%)	618 (6%)	1,070 (12%)	<0.001
Supraventricular tachycardia	2,515 (13%)	1,296 (13%)	1,219 (14%)	0.009
AV block	1,656 (9%)	1,011 (10%)	645 (7%)	<0.001
Bradycardia and sinus node dysfunction	7,489 (39%)	4,488 (43%)	3,001 (34%)	<0.001
Ventricular tachyarrhythmia	1,817 (9%)	1,060 (10%)	757 (9%)	<0.001
Premature depolarizations	3,357 (18%)	1,897 (18%)	1,460 (17%)	0.001
Ventricular block: LBBB, RBBB, fascicular block	2,127 (11%)	1,349 (13%)	778 (9%)	<0.001

AV, atrioventricular; LBBB, left bundle branch block; RBBB, right bundle branch block.

patients, respectively, with an ICM. At 40 months after ICM implant, the KM estimate of implant of a PPM, ICD or either device was 18%, 3%, and 21%, respectively.

An ICM was implanted for evaluation of syncope in 10,346 patients (54%). A comparison of the baseline demographics of patients with and without syncope as the indication for ICM implantation is shown in Table 3. Not surprisingly, patients without syncope were more likely to have history of stroke/TIA; these are considered indications in themselves for long-term ECG monitoring using an ICM.[11–17] Patients with syncope were more likely to have bradycardia and sinus node dysfunction. A PPM or ICD was implanted in 25% of patients with history of syncope compared with 15% in patients with another indication for ICM implants (p <0.001).

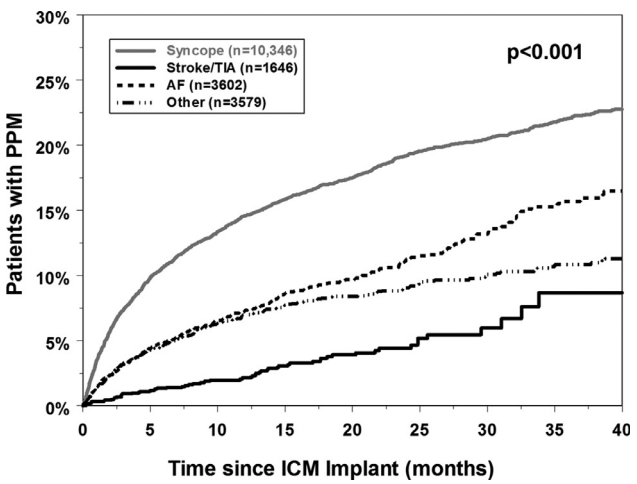

Figure 1. Kaplan-Meier estimates for pacemaker (PPM) implants following insertable cardiac monitor (ICM) implant in patients with history of syncope, stroke/transient ischemic attack (TIA), atrial fibrillation (AF), and other indication.

During 40 months of follow-up, 23% patients with syncope required PPM implantation; the lowest risk of PPM implantation was seen in patients with stroke/TIA as indication for ICM (Figure 1). In patients who received a PPM implant, the median time to PPM implant was 4.5, 9.4, 6.8, and 5.4 months in patients with syncope, stroke/TIA, AF, or other indication. The characteristics of patients with or without PPM implant following ICM implant are shown in Table 4. Patients with history of syncope were 2 times more likely to receive a PPM compared with patients with no history of syncope (HR 2.18, 95% confidence interval [CI] 2.00 to 2.37, p <0.001), which is the most significant predictor of PPM implant in the multivariable model (Table 4). In contrast, only 3% patients with syncope or without syncope (p = 0.84) ultimately required an ICD. There was no difference in need for an ICD implant in patients with syncope, stroke/TIA, AF, or other indication for ICM implantation (Figure 2), with median time to ICD implant being 8.8, 5.2, 8.5, and 6.4 months, respectively.

Discussion

Use of a de-identified electronic health records database facilitated an analysis of a very large cohort of patients with an ICM. The principal findings of the study are the following: (1) syncope is the indication for ICM in 54% of patients; (2) during follow-up, 18% of patients underwent PPM implantation and 3% of patients underwent ICD implantation; (3) patients with syncope had a twofold greater likelihood of needing a PPM compared with patients with another indication for the ICM; and (4) the likelihood of needing an ICD was low, irrespective of indication for the ICM.

In this study, we were able to confirm that the largest indication for an ICM was evaluation of unexplained syncope. In the remaining patients, the most common other defined indications for an ICM were evaluation and management of AF and stroke or TIA. However, there is great

Table 4
Characteristics of patients with and without pacemaker (PPM) implant following ICM implant

Variable	PPM Implant (n = 2,667)	No PPM implant (n = 16,506)	Multivariable predictors of PPM implant	
			Hazard ratio (95% CI)	p Value
Age (years)	69 (15)	62 (16)	1.03 (1.02-1.03)	<0.001
Men	1,338 (50%)	7,907 (48%)	–	NS
Syncope	1,922 (72%)	8,424 (51%)	2.06 (1.89-2.25)	<0.001
Coronary artery disease	1,191 (45%)	6,064 (37%)	–	NS
Diabetes	728 (27%)	4,127 (25%)	–	NS
Heart failure	434 (16%)	2,318 (14%)	–	NS
Hypertension	2,040 (76%)	11,624 (70%)	–	NS
Atrial fibrillation	1,052 (39%)	5,965 (36%)	1.13 (1.04-1.22)	0.004
AV block	402 (15%)	1,254 (8%)	1.53 (1.37-1.71)	<0.001
Bradycardia and sinus node dysfunction	1,283 (48%)	6,206 (38%)	1.30 (1.20-1.40)	<0.001
Ventricular block: LBBB, RBBB, fascicular block	437 (16%)	1,690 (10%)	1.23 (1.11-1.37)	<0.001

AV, atrioventricular; LBBB, left bundle branch block; NS: not significant in multivariate model after forward selection; RBBB, right bundle branch block.

need to understand how use of ICMs influences subsequent management of patients. To that end, some of these patients require a therapeutic intervention such as PPM or ICD implantation. To date, the need for these therapies has been defined only by very small studies and most have focused only on patients with syncope.

In this study, we found that 23% of patients with syncope required a PPM and 3% of patients required an ICD. These data are similar to what was observed in the PICTURE registry.[6] In this study, prospective, multicenter, observation European study, 570 patients with syncope were followed for a mean of 10 months after receiving an ICM. An ICM-guided diagnosis was made in 78% of patients; 3/4 of these patients had a cardiac diagnosis. A PPM was implanted in 51% of patients (15% of the overall cohort) with an ILR-guided diagnosis and an ICD was implanted in 6% of patients. However, no information is available about patients implanted for an indication other than syncope. Further, pacemaker implantation following ICM monitoring was reported in 16% in the EaSyAs study[5] over 17 months average follow-up and 22% in EaSyAs-II study[9] over 20 months average follow-up. The EaSyAs study[5] reported that ICM patients were 7.9 times more likely to receive quicker ECG-guided therapy compared with patient on conventional monitoring. Similarly, the EaSyAs-II study[9] reported that 22% of ICM patients had indication for pacing compared with only 3% in the conventional monitoring arm.

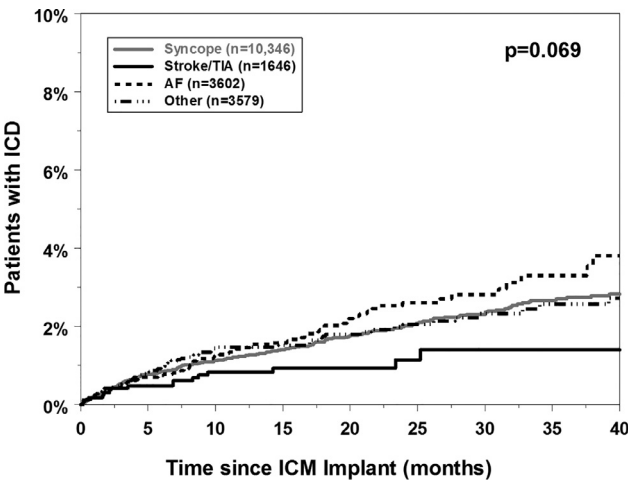

Figure 2. Kaplan-Meier estimates for defibrillator (ICD) implants following insertable cardiac monitor (ICM) implant in patients with history of syncope, stroke/transient ischemic attack (TIA), atrial fibrillation (AF), and other indication.

To our knowledge, this is the first study that compares the need for PPM or ICD implantation in patients with and without syncope as the indication for the ICM. We found that there was a significantly greater likelihood of PPM implantation in syncope patients, whereas the indication for ICM implantation did not impact need for an ICD. These data also support the utility of an ICM-guided approach in patients with syncope of unknown etiology, as most patients required neither a PPM nor an ICD during long-term follow-up.

The main limitation of the study is that the data are derived using EHR data records available for patients within the health system and thus the results are dependent on the accuracy of these data. For example, if a patient elected to undergo PPM or ICD implant outside of the health system where the ICM was implanted, then this information would not have been captured in our database. Further, in the early days of EHR systems (before 2010), there was higher likelihood of under-reporting. Hence, we may have underestimated the true incidence of device implants; however, there is no reason to believe the data would be impacted differently between patients with and without syncope. Finally, it is possible that the decision to implant a PPM or ICD was driven by data obtained from a source other than the ICM as neither the information regarding the type of ICM and information stored in the ICM device is available in this database.

Insertable cardiac monitors are being used broadly in patients with known or suspected arrhythmias. The miniaturization of these devices, incorporation of algorithms that allow for automatic detection of bradycardia, tachycardia, and atrial fibrillation events, and the ability to generate daily wireless data transmissions has made these devices an important part of patient care. However, what is lacking is

an understanding how the findings influence subsequent patient management. In this study, we provide an understanding for the first time about PPM and ICD implantation in a cohort initially managed with an ICM. Ultimately, a PPM or ICD was required in only 21% of patients, suggesting that the ICM can be used to distinguish between high- and low-risk patients and allow for a patient-tailored approach to management.

Disclosures

Dr. Mittal is a consultant for Abbott, Boston Scientific, and Medtronic; Dr. Rogers is a consultant for Medtronic; Dr. Sarkar and Ms. Koehler are employees and owner of stocks of Medtronic; Dr. Passman is a consultant for Medtronic.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.03.014.

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