RESEARCH **Open Access**



Application of insertable cardiac monitors in the real world: an observational cohort study in China

Beibing Di^{1†}, Lifeng Liang^{1†}, Wangyang Yang¹, Nixiao Zhang¹, Xiaona Liu², Hui Peng^{1*} and Zhijun Sun^{1*}

Abstract

Background Insertable cardiac monitors (ICMs) are increasingly used for long-term electrocardiographic monitoring. However, the data on ICMs remains limited in China.

Methods In this retrospective observational study, we evaluated the real-world use and outcomes of patients consecutively receiving Reveal LINQ (Medtronic Ltd, Minneapolis, MN) devices from 2020 to 2022 at the Cardiovascular Center of Beijing Friendship Hospital. Patient characteristics, ECG parameters, ICM indications and follow-up data were collected. The outcomes including symptom documentation, arrhythmia detection and ICMguided interventions were identified.

Results A total of 200 patients (age 64 ± 14 years; 52% males) receiving ICMs were enrolled (134 syncopes, 59 unexplained palpitations, 7 cryptogenic strokes). During median follow-up of 28 months, 98 patients (49%) had documented clinically significant arrhythmia. After ICM diagnosis, 89 (44.5%) of patients had ICM-quided actionable events. Pacemaker/defibrillator implantation (48, 24%), catheter ablation (27, 13.5%) and mediation management (11, 5.5%) were the majority of ICM-derived management. For syncope, age > 65 years (HR 1.032, p = 0.017), asymptomatic sinus bradycardia (45–55 beats / min) (HR 2.106, p = 0.043) and RR interval exceeding 2 s (HR 3.625, p < 0.001) were significantly associated with actionable events. The risk of arrhythmia requiring management changes was significantly stepwise higher with the prevalence of more risk factors (P < 0.001 by log-rank).

Conclusions ICM utilization is associated with high efficacy in diagnoses and triggers important and optimal management in China. Age > 65 years, asymptomatic sinus bradycardia (45–55 beats / min) and RR interval exceeding 2 s are independent clinical predictors of ICM-guided clinical management for syncope.

Keywords Arrhythmia, Syncope, Palpitation, Cryptogenic stroke, Insertable cardiac monitor

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Introduction

Arrhythmia disease is a challenging condition characterized by variable presentations and a paroxysmal nature, often making diagnosis elusive even after extensive evaluation. Establishing a direct correlation between the episodic symptoms and the electrocardiogram is necessary for teasing out infrequent rhythm-related causes. Insertable cardiac monitors (ICMs) [1–3], small subcutaneous devices for long-term electrocardiographic monitoring of heart rhythms, may have a role in correlating symptoms and suspected arrhythmias.

Previous studies have demonstrated the usefulness of ICM as a major diagnostic tool for arrhythmias [1, 4, 5]. Recent guidelines have significantly expanded the accepted indications where ICMs may be deployed, including recurrent unexplained syncope (US), atrial fibrillation (AF) management, cryptogenic stroke, unexplained palpitations, suspected but unproven epilepsy, unexplained falls, and primary cardiomyopathy or inheritable arrhythmogenic disorders who are at low risk of sudden cardiac death [3, 6, 7]. Effective diagnosis of these conditions may have the potential to alter clinical management and improve quality of life.

Although the diagnostic capability of ICMs is well established, the application of ICMs is still in its initial stages in China [7], and evidence demonstrating their ability to improve patient outcomes is limited. Meanwhile, if an arrhythmia is assumed to be the cause of US, an early use of ICMs is strongly recommended [6]. Although some clinical characteristics related to arrhythmia were identified in the past [8–10], data on ICMs are still limited and studies that examined predictors of arrhythmias are sparse in China.

Thus, we sought to evaluate the real-world usage and diagnostic yield of ICMs in China, and investigate whether ICM implantation leads to changes in patient management to address the gap in the current literature. Furthermore, we examined the association of patient-specific factors with ICM-guided management following the detection of arrhythmias in patients with syncope.

Methods

Study population

Consecutive patients who received a Reveal LINQ (Medtronic Ltd, Minneapolis, MN) device from December 2020 to June 2022 at the Cardiovascular Center of Beijing Friendship Hospital were included. The Institutional Ethics Committee of the Beijing Friendship Hospital affiliated with Capital Medical University (Number MR-11-24-033754) approved the study protocol. Written informed consent from the patients was unnecessary due to the retrospective nature of the study.

Before considering ICM implantation, all patients underwent a basic pre-evaluation which included

medical history review, physical examination, 12-lead electrocardiography (ECG), Holter monitoring, echocardiography and, if appropriate, coronary angiography, cardiac stress testing, and neurological examinations with electroencephalograph, computed tomography or magnetic resonance imaging of the head. An extended diagnostic assessment including head up-tilt test (HUTT) or electrophysiological (EP) studies were performed, when indicated.

Data collection

The ICM was positioned subcutaneously in the left pectoral region under local anesthesia with small incision or it was injected. ICM diagnostic parameters were programmed according to 'reason for monitoring' information: bradycardia, a ventricular rate < 40 beats/min (4 consecutive beats); pause, a ventricular pause of > 3 s; and tachycardia, a ventricular rate > 150 beats/min (16 consecutive beats). Automatic algorithms for detection of AF were activated. An automatically detected episode was triggered when it met the ICM diagnostic parameter for that episode type. Patients were also instructed to activate the ICM manually in response to symptom occurrence (patient activation). Complications related to the operation and postoperation were assessed.

All patients underwent routine post-implant 3-day follow-up for wound. Thereafter ICMs were interrogated every 2–3 months, in addition to unscheduled visit if a patient-triggered event occurred. Auto triggered and patient-triggered events were analyzed, and the association with or without a concomitant arrhythmic finding was recorded for each patient symptom episode. Patients were followed up until June 2024, or ended follow-up at the latest ICM check because of battery depletion.

Data were collected from medical records and device interrogations. ICMs were considered diagnostic if they helped confirm or rule out arrhythmias as the underlying cause of the symptoms. The time to significant findings was defined as the duration between the date of ICM implant to the date of conclusive diagnosis. Clinically significant arrhythmias were defined as (1) sick sinus syndrome (SSS, including sinus bradycardia or asystole or significant pause exceeding 3s); (2) atrioventricular block (AVB, including 3rd degree AVB or 2nd degree AVB Mobitz type)); (3) ventricular arrhythmia other than premature ventricular contractions or ventricular couplets; (4) supraventricular tachycardia (atrioventricular reentry tachycardia or atrioventricular nodal reentry tachycardia) and (5) AF.

If the detected arrhythmia led directly to a change of medical or device therapy, this was deemed as actionable events. ICM-guided therapy was classified into (1) permanent pacemaker (PPM) implantation; (2) implantable cardioverter defibrillator (ICD) implantation; (3) catheter Di et al. BMC Cardiovascular Disorders (2025) 25:267 Page 3 of 9

ablation and (4) medication addition or change in dosage. These actionable events were based on current guidelines [11–14]. The ICM remained being implanted until battery depletion. Patients were given the option to have the device explanted with or without implantation of a replacement ICMs after battery depletion.

Study endpoints

The primary endpoint of this study was clinically significant arrhythmias defined as any of the followings: (1) sick sinus syndrome (SSS, including sinus bradycardia or asystole or significant pause); (2) atrioventricular block (AVB, including 3rd degree AVB or 2nd degree AVB Mobitz type)); (3) ventricular arrhythmia other than premature ventricular contractions or ventricular couplets; (4) supraventricular tachycardia (atrioventricular reentry tachycardia or atrioventricular nodal reentry tachycardia) and (5) AF.

The secondary outcome was the implementation of ICM-guided therapy concerned with the syncope subgroup, which was defined as (1) permanent pacemaker (PPM) implantation; (2) implantable cardioverter defibrillator (ICD) implantation; (3) catheter ablation and (4) medication addition or change in dosage."

Statistical analyses

We present continuous variables as means (SDs) or medians (interquartile ranges [IQRs]) and categorical variables as numbers (percentages). Continuous variables were compared with student's t-test or Mann-Whitney test on the basis of the distribution. Categorical variables were compared with the $\chi 2$ or Fisher's exact test. All significant variables in Table 2 were evaluated for the

secondary study endpoint in a univariate Cox proportional hazard model, then the variables with a significant association were entered into a multivariate Cox model to identify independent predictors of clinically significant arrhythmia and the likelihood of management change in the syncope subgroup. Syncopal patients were classified into different risk groups according to the prevalence of independent predictors, then clinically significant arrhythmia requiring management was analyzed by the Kaplan-Meier method, and hazard ratios were determined using the log-rank test. Analyses were performed using SPSS Statistics version 27.0 (IBM Corp, Armonk, NY), and a two-sided P-value < 0.05 was considered statistically significant.

Results

Study population

There were 200 patients in the cohort study. Mean age was 64 ± 14 years and 52% were males. The indications of ICM implantation were syncope (134; 67%), unexplained palpitations (59; 29.5%), and cryptogenic stroke (7; 3.5%) (see Fig. 1). Trend lines for the number of ICM implantation over time are detailed in Fig. 2. The number of implantation increased significantly since 2021.

The baseline clinical characteristics of the study cohort are outlined in Table 1. The basic pre-evaluation diagnostic workups were performed before ICM implantation in all patients. 10 (5%) patients had a HUTT, and 17 (8.5%) patients had EP study.

Median follow-up time was 28 months (IQR, 26–33). No patients were lost. There was no local pain or infection post ICM implantation. In 17 (8.5%) patients the

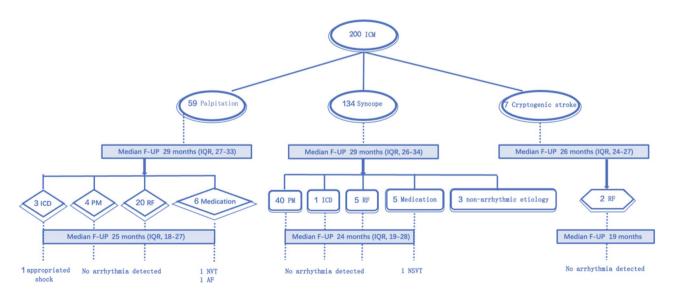


Fig. 1 Indications for ICM implantation and follow-up events. F-UP=follow-up; ICD=implantable cardioverter-defibrillator; ICM=Insertable cardiac monitors; PM=pacemaker; RF=radiofrequency ablation; NSVT=nonsustained supraventricular tachycardia; NVT=nonsustained ventricular tachycardia; AF=atrial fibrillation; Appropriated shock=appropriate ICD intervention on ventricular tachycardia/ventricular fibrillation

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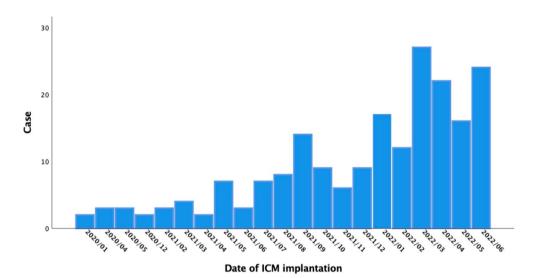


Fig. 2 ICM Implantation trend

Table 1 Patient baseline characteristics by indication for ICM implantations

Baseline	All	Indication for ICMs		
characteristics	patients (N=200)	Syncope (N=134)	Palpitation (N=59)	Crypto- genic stroke (N=7)
Age(y): mean (sd)	64.1(14.4)	65.6(14.3)	61.3(11.2)	60.3 (5.2)
Male, n(%)	105(52.5)	76 (56.7)	26 (44.1)	3 (42.9)
Body Mass Index (kg/m ²): mean (sd)	25.2(4.1)	25.3 (4.3)	25.1(4.0)	24.7(3.5)
EF%: mean (sd)	64.2(7.5)	64.8(6.5)	62.9 (9.5)	65.5(5.8)
EF% < 50%, n(%) Medical history, n(%)	10 (5.0)	5 (3.7)	5 (8.5)	0 (0)
Coronary artery disease	81(40.5)	57 (42.5)	24 (40.7)	0 (0)
Myocardial infarction	9 (4.5)	5 (3.7)	4 (6.8)	0 (0)
Hypertension	130(65.0)	92 (68.7)	32 (54.2)	6 (85.7)
Diabetes mellitus	61 (30.5)	36 (26.9)	20 (33.9)	5 (71.4)
Laboratory test				
NT-proBNP, median (IQR), pg/mL	191(64.1, 365.5)	188(67.5, 296.0)	259(56.7, 485.0)	45.0 (31.7, 53.1)
C-reactive protein (CRP), median (IQR), mg/dl	1.1 (0.6, 4.3)	1.1 (0.6, 4.4)	1.3 (0.8, 3.3)	0.7 (0.5, 17.0)
Thyrotropin (TSH), median (IQR), mU/L	0.4 (0.2, 0.6)	0.4 (0.2, 0.6)	0.3(0.2,0.4)	0.3 (0.2, 0.40)
HbA1c(%):mean (sd)	6.1(1.1)	6.3(1.2)	6.3(1.0)	5.84(0.85)
Creatinine, median (IQR), µmol/L	74.2 (64.0, 90.3)	75.2 (64.9, 93.1)	72.9 (58.9, 83.3)	69.4 (42.6, 71.5)
LDL-C(mmol/L): mean (sd)	2.5(0.7)	2.5(0.7)	2.7 (0.7)	2.0(0.9)
K ⁺ (mmol/L): mean (sd)	4.0(0.4)	4.1(0.4)	4.0(0.4)	3.8(0.3)

ICM, insertable cardiac monitors; IQR, interquartile ranges; EF, ejection fraction, LDL-C, Low density lipoprotein cholesterol; HbA1c, glycosylated hemoglobin

device was explanted due to battery depletion (with subsequent replacement in 1).

Cohort diagnoses and management decisions

Ninety-eight(49%) patients were diagnosed with a clinically significant arrhythmia or had arrhythmia excluded as the cause of their symptoms. The most clinically significant arrhythmias were bradyarrhythmias (51, 25.5%). Median time to diagnosis was 3months (IQR, 1–11). Of all diagnostic ICM events, 50% were detected within 3 months, 75% were detected within 11 months, and 95% were detected within 28 months. Arrhythmia was precluded in 3 (1.5%) patients.

A diagnosis that altered management was made in 89 (89/200, 44.5%) patients. PPM or ICD implantation was performed in 48 (24%) patients. Catheter ablation was administered in 27 (13.5%) patients. Antiarrhythmic medications were started in 11 (5.5%) patients. Alternative management was taken in 3 (1.5%) patients with nonarrhythmic etiology, wherein two patients were finally diagnosed with epilepsy and received anti-epileptic drug treatment, and one patient had an unclear cause of syncope with no further syncope occurring during the follow-up period. Six (3%) patients refused the intervention. After receiving drug therapy (amiodarone 200 mg once daily), one patient had appropriate ICD intervention on ventricular tachycardia/ventricular fibrillation, and three patients experienced nonsustained supraventricular or ventricular tachycardia during a median follow-up of 24 months (IQR, 19-27). The therapeutic decisions resulting from ICM data are summarized in Fig. 3.

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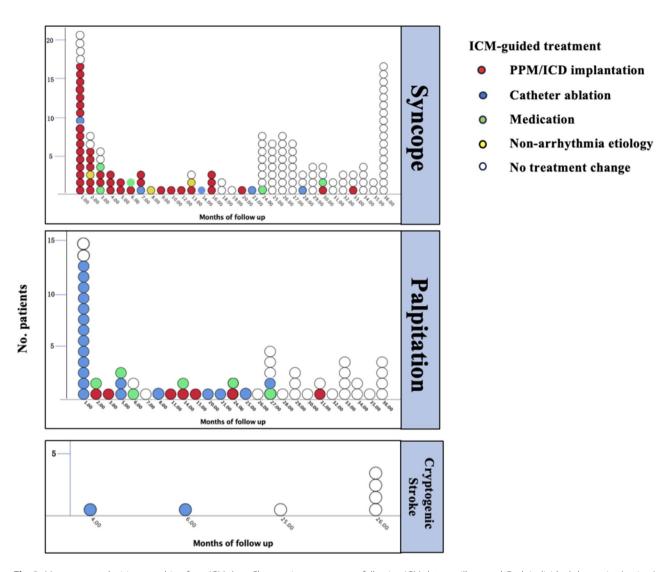


Fig. 3 Management decisions resulting from ICM data. Changes in management following ICM data are illustrated. Each individual data point (patient) is represented as a circle, and is grouped into columns by months of follow-up. Colours represent final treatment. Data are stratified by ICM indication. PPM = permanent pacemaker; ICD = implantable cardioverter-defibrillator

Diagnoses and management decisions by indication

Patients with syncope

Of the 134 patients with US, the average number of syncope episodes was 3.5 before ICM insertion. During follow-up, 57 (57/134, 42.5%) patients had correlation with a clinically significant arrhythmia. Three patients (3/134, 2.2%) had an exclusion diagnosis of arrhythmia based on normal ICM recordings when syncope reoccurred, and were finally diagnosed with epilepsy. The diagnostic yield was 44.8% (60/134) by ICM monitoring for US. Median time to diagnosis was 3 months (IQR, 1–13). The most common bradyarrhythmic finding associated with syncope was SSS due to asystole or sinus pauses (35/64, 54.7%), followed by AVB (9/64, 14.1%), and AF with slow ventricular response (heart rate lower than 50 beats per minute) (3/64, 4.7%). 41(41/134, 30.6%) patients

underwent ICM-directed PPM or ICD implantation, and 6 patients refused the device therapy. Ten (10/134, 7.5%) patients suffered from recurrent syncope due to fast supraventricular or ventricular tachycardia, and underwent an ICM-directed catheter ablation procedure or were administered antiarrhythmic medications. Recordings and the corresponding clinical management were summarized in Fig. 1.

Syncopal patients with actionable events were older (70.96 \pm 12.38 years vs. 64.27 \pm 14.03 years, p = 0.006). They more frequently had hypertension (82.3% vs. 60.2% p = 0.008) while other important characteristics were similar. Likewise, baseline ECG and 24-h Holter monitoring before ICM implantation showed differences. Asymptomatic sinus bradycardia (45–55/min), first degree AV block with normal sinus rate and RR interval exceeding

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Table 2 Syncopal patient baseline characteristics by change in management

Baseline characteristics Patients with a change in clinical management (n=51) Patients without a change in clinical management (n=83) Policy (n=83) Age > 65years: n(%) 47 (92.2) 37(32.5) 0.006 Male, n(%) 27 (52.9) 49 (59.0) 0.49 Syncopal episodes in lifetimes, median (IQR) 2.0 (2.0, 3.0) 2.0 (2.0, 4.0) 0.22 Trauma secondary to syncope, n(%) 3 (5.9) 2 (2.4) 0.37 Hypertension, n(%) 42 (82.3) 50 (60.2) 0.008 Coronary artery disease, n(%) 23 (45.1) 34 (41.0) 0.72 EF %: mean (sd) 64.2 (7.2) 65.1 (6.1) 0.46 EF %<50%, n(%) 3 (5.9) 2 (2.4) 0.37 ECG/Holter findings (n,%) 11 (21.6) 7 (8.4) 0.03 Sinus bradycar-dia(45-55 bpm) 14 (27.5) 9 (10.8) 0.02 first degree AV block (normal sinus rate) 8 (15.7) 9 (10.8) 0.43 Bundle branch block 24 (47.1) 5 (6.0) < 0.001	management			
Male, n(%) 27 (52.9) 49 (59.0) 0.49 Syncopal episodes in lifetimes, median (IQR) 2.0 (2.0, 3.0) 2.0 (2.0, 4.0) 0.22 Trauma secondary to syncope, n(%) 3 (5.9) 2 (2.4) 0.37 Hypertension, n(%) 42 (82.3) 50 (60.2) 0.008 Coronary artery disease, n(%) 23 (45.1) 34 (41.0) 0.72 EF %: mean (sd) 64.2 (7.2) 65.1 (6.1) 0.46 EF %<50%, n(%) 3 (5.9) 2 (2.4) 0.37 ECG/Holter findings (n,%) 11 (21.6) 7 (8.4) 0.03 Sinus bradycar-dia(45-55 bpm) 14 (27.5) 9 (10.8) 0.02 block (normal sinus rate) 8 (15.7) 9 (10.8) 0.43		change in clini- cal management	change in clinical management	P value
Syncopal episodes in lifetimes, median (IQR) 2.0 (2.0, 3.0) 2.0 (2.0, 4.0) 0.22 Trauma secondary to syncope, n(%) 3 (5.9) 2 (2.4) 0.37 Hypertension, n(%) 42 (82.3) 50 (60.2) 0.008 Coronary artery disease, n(%) 23 (45.1) 34 (41.0) 0.72 EF %: mean (sd) 64.2 (7.2) 65.1 (6.1) 0.46 EF %<50%, n(%)	Age > 65 years: n(%)	47 (92.2)	37(32.5)	0.006
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to syncope, n(%) Hypertension, n(%) 42 (82.3) 50 (60.2) Coronary artery 23 (45.1) 34 (41.0) EF %: mean (sd) 64.2 (7.2) 65.1 (6.1) EF %<50%, n(%) 3 (5.9) 2 (2.4) Sinus bradycar- dia(45-55 bpm) first degree AV 14 (27.5) 9 (10.8) Bundle branch 8 (15.7) 9 (10.8) 0.008 0.008 0.009 0.008 0.019 0.020 0.019 0.020 0.030 0	in lifetimes, median	2.0 (2.0, 3.0)	2.0 (2.0, 4.0)	0.22
Coronary artery disease, n(%) EF %: mean (sd) 64.2 (7.2) 65.1(6.1) 0.46 EF %<50%, n(%) 3 (5.9) 2 (2.4) 0.37 ECG/Holter findings (n,%) Sinus bradycardia(45-55 bpm) first degree AV 14 (27.5) 9 (10.8) 0.02 block (normal sinus rate) Bundle branch 8 (15.7) 9 (10.8) 0.43 block	· · · · · · · · · · · · · · · · · · ·	3 (5.9)	2 (2.4)	0.37
disease, n(%) EF %: mean (sd) 64.2 (7.2) 65.1(6.1) 0.46 EF %<50%, n(%)	Hypertension, n(%)	42 (82.3)	50 (60.2)	800.0
EF %<50%, n(%) 3 (5.9) 2 (2.4) 0.37 ECG/Holter findings (n,%) Sinus bradycar- 11 (21.6) 7 (8.4) 0.03 dia(45-55 bpm) first degree AV 14 (27.5) 9 (10.8) 0.02 block (normal sinus rate) Bundle branch 8 (15.7) 9 (10.8) 0.43 block	, ,	23 (45.1)	34 (41.0)	0.72
ECG/Holter findings (n,%) Sinus bradycar- dia(45-55 bpm) first degree AV block (normal sinus rate) Bundle branch block 11 (21.6) 7 (8.4) 0.03 0.02 0.02 0.02 0.02 0.03 0.03 0.043	EF %: mean (sd)	64.2 (7.2)	65.1(6.1)	0.46
dia(45-55 bpm) first degree AV 14 (27.5) 9 (10.8) block (normal sinus rate) Bundle branch 8 (15.7) 9 (10.8) 0.43 block	ECG/Holter findings	3 (5.9)	2 (2.4)	0.37
block (normal sinus rate) Bundle branch 8 (15.7) 9 (10.8) 0.43 block	,	11 (21.6)	7 (8.4)	0.03
block	block (normal sinus	14 (27.5)	9 (10.8)	0.02
RR interval over 2 s 24 (47.1) 5 (6.0) < 0.001		8 (15.7)	9 (10.8)	0.43
	RR interval over 2 s	24 (47.1)	5 (6.0)	< 0.001

EF, ejection fraction; IQR, interquartile ranges; ECG, electrocardiography; AV, atrioventricular

Table 3 Cox proportional hazards regression analyses for ICM-quided management in syncopal patients

	Univariate		Multivariate	
	HR (95%CI)	P value	Adjusted HR (95%CI)	P value
Age > 65 years	1.04 (1.01, 1.06)	0.005	1.03 (1.01, 1.06)	0.02
Hypertension	0.39 (0.19, 0.80)	0.01	0.52 (0.25, 1.09)	0.08
Sinus bradycar- dia(45-55 bpm)	2.62 (1.33, 5.12)	0.005	2.11 (1.02, 4.34)	0.04
First degree AV block (normal sinus rate)	2.21 (1.19, 4.09)	0.01	1.52 (0.80, 2.88)	0.20
RR interval over 2 s	4.58 (2.62, 8.01)	< 0.001	3.63 (2.00, 6.57)	< 0.001

ICM, insertable cardiac monitors; AV, atrioventricular

2 s were more frequent in patients with actionable events (p = 0.038, p = 0.018 and p < 0.001, respectively) (Table 2).

The significant predictors for a clinically significant arrhythmia in univariate analysis were further evaluated by the method of multivariate analysis. The remaining significant independent predictive factors were age > 65 years (HR 1.032, p = 0.017), asymptomatic sinus bradycardia (45–55/min) (HR 2.106, p = 0.043) and RR interval exceeding 2 s (HR 3.625, p < 0.001) (Table 3).

Kaplan-Meier curves were generated for risk stratification based on those three independent predictors: age > 65 years, asymptomatic sinus bradycardia (45–55/min) and RR interval exceeding 2 s. As indicated by Kaplan-Meier event curves (Fig. 4), patients (41/134, 30.6%) without these risk factors had the lowest risk of clinically significant arrhythmia. The risk of clinically significant arrhythmia was significantly stepwise higher with the prevalence of more risk factors: 47.0% (63/134) for one risk factor, 18.7% (25/134) for two risk factors, and 3.7% (5/134) for three risk factors; p < 0.001 by log-rank.

Patients with palpitation

Of the 59 patients with unexplained palpitations, 33 (33/59, 55.9%) patients experienced symptoms that correlated with a clinically significant arrhythmia. Episodes of newly diagnosed AF were recorded in 13 (13/59, 22.0%) patients, who started anticoagulation. Eight of them underwent AF ablation, and the others were treated with antiarrhythmic medications. Three (3/59, 5.1%) patients experienced symptomatic episodes of fast nonsustained polymorphic VT and subsequently underwent ICD implantation. Seven (7/59, 11.9%) patients were diagnosed with nonsustained monomorphic ventricular tachycardia, wherein 6 patients received VT ablation, and 1 patient was given antiarrhythmic medications. Six (6/59, 10.1%) patients with AV node reentrant tachycardia or focal atrial tachycardia underwent catheter ablations. Four (4/59, 6.8%) patients were recorded with bradyarrhythmias, and underwent PPM implantations. Figure 1 summarizes the changes in management occurring as a result of ICM findings.

Patients with cryptogenic stroke

Seven patients underwent ICM monitoring for suspected AF following cryptogenic stroke. ICM documented new asymptomatic AF in 2 (2/7, 28.6%) patients, leading to a decision to commence catheter ablation and anticoagulation (see Fig. 1). The median time to diagnosis was 4.5 months.

Discussion

ICMs provide the advantage of long-term continuous monitoring, which enables documentation of symptom-ECG correlation, thereby increasing the appropriate and effective therapy. This observational cohort study examines the real-world application of ICMs in Chinese patients. We found that (1) 49% patients identified a significant arrhythmic cause correlated with symptoms; (2) more importantly, ICM-guided diagnoses mostly led to clinical management for 44.5% of patients; (3) age > 65 years (p = 0.017), asymptomatic sinus bradycardia (45–55/min) (p = 0.043) and RR interval over 2 s (p < 0.001) were associated factors with clinically significant

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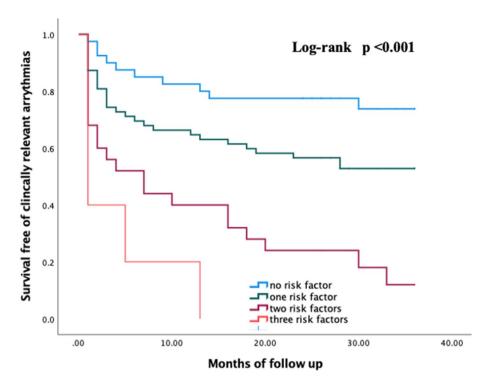


Fig. 4 Kaplan-Meier estimates the survival free of clinically relevant arrythmias. Risk model based on independent predictors (age > 65 years, asymptomatic sinus bradycardia (45–55/min) and RR interval over 2 s)

arrhythmias requiring management changes in syncopal patients.

In our center, the number of ICM implantation had increased significantly since 2021. That might be explained by changes in recommendations of guidelines. The 2018 European Society of Cardiology guideline [6] amplified the indications of the use of ICMs in patients with US. The 2020 Chinese guidelines [7] identified 2 separate class I recommendations and 5 class IIa recommendations in US, palpitation, AF management, and others. The update of the guidelines promoted the adjustment of medical insurance policy in China, which has made patients less concerned about the economic issues of ICM implantation. These factors may be the reasons for the remarkable growth of ICM applications in China. However, there remains a discrepancy between clinical practice and the indications provided by the guidelines, with the estimated indications significantly exceeding those actually implemented.

The vast majority of ICM implantation indication is still US in China [7]. It is worth noting, in our study, diagnostic yield (44.8%) by ICM monitoring for US is higher than those obtained in the PICTURE study (28%)[15] and the Spanish Reveal Registry study (30.9%)[16]. Probably because the part of the arrhythmias was diagnosed during the EP study (55%) prior to ICM implant in those studies, only 8.5% of our patients underwent an EP study. But Peter et al. [17] found that an EP study did not seem

to be sensitive enough for the diagnosis of bradycardic syncope. They reported that some patients with normal HV interval or sinus node recovery time (SNRT) by EP study showed AVB or SSS during later ICM monitoring. Additionally, approximately one-third of our patients firstly visited the neurology or emergency department, where they had been fully evaluated with various relevant examinations and were highly suspected of having an arrhythmic etiology prior to subsequent ICM implantation. Furthermore, PICTURE, REVEAL and some smaller studies [18–20] were performed in European or American populations, whereas we capture a Chinese population.

Notably, arrhythmic etiology likely underscores the high risks of US. In the selected patients, the systematic use of ICMs may provide reassurance on symptoms, and reduce the burden of psychological distress associated with device therapy. We have provided evidences that age > 65 years, asymptomatic sinus bradycardia (45–55/min) and RR interval exceeding 2 s were the strong clinical or ECG features that predicted the arrhythmic etiology of syncope requiring management changes. Additionally, the combination of these factors illustrated the increased risk of arrhythmia. These findings indicate that high-risk patients could benefit from an early ICM implantation and, if necessary, from a specific therapy and thus limiting the use of time-consuming diagnostic tests and the burden on the healthcare system [21].

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Importantly, these patient-specific factors are easy and reproducible to obtain.

An ICM is less frequently used to elucidate the nature of palpitations compared to syncope, although the RUP study[22] has shown that that ICMs can be a cost-effective approach in comparison to a conventional strategy for patients with infrequent unexplained palpitations. Compared with previously published data22, 23, it is found that the yield of ICM-guided diagnosis for palpitations was similar. It is worth mentioning that palpitations are not usually associated with the presence of tachyarrhythmias. In our analysis, 4 patients with confirmed bradyarrhymias had only shown palpitation before ICM implantation, rather than common blackout or (pre) syncope.

The first randomized study to assess the utility of ICMs in patients with cryptogenic stroke was the CRYSTAL-AF study [4], which proved that ICM was more effective in detecting AF than the conventional follow-up. A metaanalysis [24] of 11 studies found a 5.7-fold increased detection of AF in patients who received ICMs for cryptogenic stroke compared to several intermittent monitoring strategies. Our study extends these findings by demonstrating the burden of subclinical AF in patients with no prior cause identified for cryptogenic stroke; thereafter, they received anticoagulation therapy. Nevertheless, whether the detection of AF in these patients leads to improved clinical outcomes remains to be seen. The LOOP study [25] showed a 3-fold increase in AF detection by the use of ICM and anticoagulation initiation in patients with stroke risk factors, however, there was no significant reduction in recurrent stroke during follow-up. Recently, ARTESIA trial [26] found that apixaban resulted in a lower risk of stroke or systemic embolism but a higher risk of major bleeding among patients with subclinical AF by long-term continuous monitoring. Further studies are needed to address which ICMdetected AF merits anticoagulation.

Kang et al. [27] and Ibrahim et al. [5] reported that 80% and 83.5% of ICM diagnosis were made within 6 months and 24months respectively. For patients diagnosed with Brugada syndrome, the median time from ICM implant to the occurrence of arrhythmic findings was 8.7 months (3.6–46.4) [28]. In our study, the time from ICM implant to a documentation of significant arrhythmias and change in medical care was relatively short with median times of 3 months (IQR, 1–11 months). Most of arrhythmic findings occurred in the first 12 months of monitoring. As is well known, the diagnostic yield increases as the monitoring period is increased, thus, there was a continued find rate out to almost 3 years (the average battery lifetime). Given that the majority of episodes occurred within the first 12 months, it is likely that a single ICM monitoring time of 3 years will be sufficient for majority patients. However, those patients with high-risk underlying disease may benefit from extended continuous monitoring.

Study limitations

This study has some limitations. First, relatively small sample size may have limited the detection of small variations. Second, in those patients with devices less than 3 years from implanting, ICM clinical findings and changes in management may be underestimated. Third, the particular factors predicting the probability of arrhythmias in US patients might be difficult to be ascertained by retrospective analysis, and further insight into this area is needed. Despite these limitations, the high diagnostic yield of ICMs makes them especially effective not only in patients with worrisome syncopal history but also other patient groups with unexplained palpitations and cryptogenic stroke, when an arrhythmogenic diagnosis is highly likely to change management.

Conclusion

We observed all ICM implantation at a large academic center to report on "real-world" applications in China. Our study demonstrates that ICMs have the advantage of accurate data acquisition. Documented symptom episodes lead to a high rate of diagnosis and then to targeted treatment. Patient-specific factors associated with clinically significant arrhythmia may help optimize the selection of syncopal patients for early ICMs use, which allow for more precise management and further improving outcomes.

Abbreviations

ICMs Insertable Cardiac Monitors **ECG** Electrocardiography US Unexplained Syncope ΑF Arial Fibrillation HUTT Head Up-Tilt Test FΡ Electrophysiological SSS Sick Sinus Syndrome **AVB** Atrioventricular Block PPM Permanent Pacemaker ICD Implantable Cardioverter Defibrillator

IQRs Interquartile Ranges **SNRT** Sinus Node Recovery Time

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Author contributions

Peng Hui and Sun Zhijun are responsible for the overall project design; Di Beibing, Sun Zhijun and Liang Lifeng participated in the implantation of ICM; Yang Wangyang, Liu Xiaona and Zhang Nixiao were responsible for patient follow-up and collection of clinical data; Peng Hui and Di Beibing are responsible for statistical analysis, article writing, article revision and submission.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The Institutional Ethics Committee of the Beijing Friendship Hospital affiliated with Capital Medical University (Clinical Trial Number MR-11-24-033754) approved the study protocol. We affirm that this study is in full compliance with the principles outlined in the Declaration of Helsinki. Written informed consent from the patients was unnecessary due to the retrospective nature of the study which was approved by the Ethics Committee of the Beijing Friendship Hospital affiliated with Capital Medical University.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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