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CLINICAL RESEARCH

New insertable cardiac monitors show high diagnostic yield and good safety profile in real-world clinical practice: results from the international prospective observational SMART Registry

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Aims

Insertable cardiac monitors (ICMs) are indicated for long-term monitoring of unexplained syncope or palpitations, and for detection of bradycardia, ventricular tachycardia, and/or atrial fibrillation (AF). The aim of our study was to evaluate the safety and clinical value associated with a new generation ICM (Confirm Rx™, Abbott, Illinois, USA), featuring a new remote monitoring system based on smartphone patient applications.

Methods and results

The SMART Registry is an international prospective observational study. The main endpoints were ICM safety (incidence of serious adverse device and procedure-related events (SADEs) at 1 month), ICM clinical value (incidence of device-detected true arrhythmias and of clinical diagnoses and interventions), and patient-reported experience measurements (PREMs). A total of 1400 subjects were enrolled. ICM indications included syncope (49.1%), AF (18.8%), unexplained palpitations (13.6%), risk of ventricular arrhythmia (6.6%), and cryptogenic stroke (6.0%). Freedom from SADEs at 1 month was 99.4% (95% Confidence Interval: 98.8–99.7%). In the 6-month monitoring period, the ICM detected true cardiac arrhythmias in 45.7% of patients and led to clinical interventions in a relevant proportion of patients; in particular, a pacemaker implant was performed after bradycardia detection in 8.9% of subjects who received an ICM for syncope and oral anticoagulation therapy was indicated after AF detection in 15.7% of subjects with cryptogenic stroke. PREMs showed that 78.2% of subjects were satisfied with the remote monitoring patient app.

Conclusion

The evaluated ICM is associated with an excellent safety profile and high diagnostic yield. Patients reported positive experiences associated with the use of their smartphone for the device remote monitoring.

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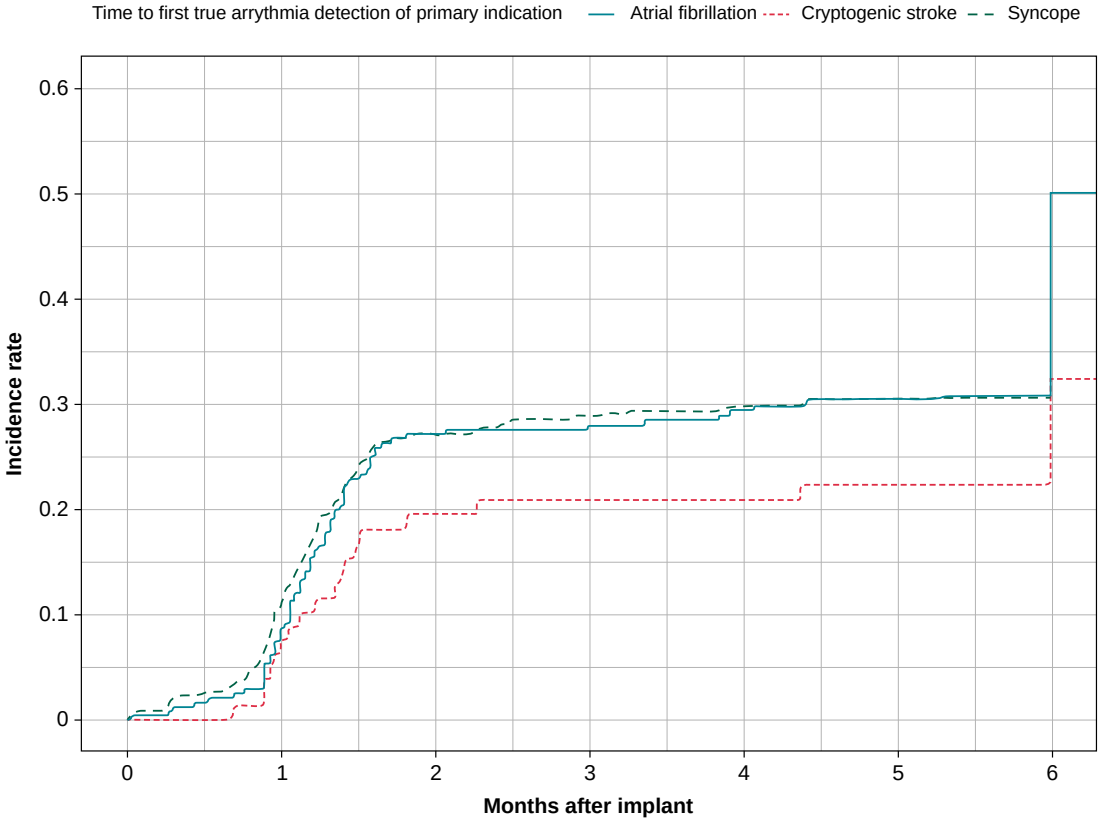
Graphical Abstract



Number at risk

Atrial fibrillation	256	220	171	161	150	145	133
Cryptogenic stroke	83	73	58	56	53	49	39
Syncope	688	579	465	437	413	382	360

Keywords Cardiac monitoring • Syncope • Cardiac arrhythmias • Atrial fibrillation • Cryptogenic stroke

What's new?

- Our large multicentre international study brings new clinical evidence on the safety profile, detection yield, clinical value, and patient acceptance of a new generation of loop recorders implanted for the monitoring of cardiac arrhythmias.
- The novelty of these monitors is that for the first time, the remote monitoring communication with the hospital staff is based on Bluetooth technology and smartphone patient applications, which allow faster and more complete data transmission.
- Detection yield was high; in just 6 months of follow-up, insertable cardiac monitors detected true cardiac arrhythmias in about 45% of patients.
- The clinical value of cardiac monitoring strategy was confirmed by the observation that a new clinical diagnosis was obtained in 27% of patients and this led to clinical interventions in a relevant proportion of these patients.
- Safety was very good; device-related or procedure-related adverse events occurred in only 0.7% of patients at 1-month post-implant.
- Patients' acceptance was also good, with about 80% of patients reporting positive experiences about the use of the smartphone application and the remote monitoring system.

Introduction

Several studies[1–3] have proven the efficacy and safety of insertable cardiac monitors (ICMs) as diagnostic tools in patients with recurrent suspected neurally mediated syncope. As a consequence, ICMs have become the standard of care for long-term monitoring of unexplained syncope.[4,5]

In the last two decades, the use of ICMs has been expanded to patients, with unexplained symptoms, who are at risk for cardiac arrhythmias, to patients with cryptogenic stroke, and to patients who, after atrial fibrillation (AF) ablation, need long-term monitoring of AF.[6–8]

New generation ICMs have small dimensions, are minimally invasive, feature specialized detection algorithms, and allow patients to send scheduled diagnostics data transmissions and to activate the recording of the cardiac rhythm using smartphone applications and Bluetooth-enabled on-time data transmission for efficient clinician remote review.

These characteristics likely improve ICM's clinical utility and long-term safety profile; in particular, miniaturization of ICMs is expected to improve their safety profile,[9] and remote monitoring can significantly shorten the time to diagnosis and targeted treatment.[10]

With the SMART Registry (ClinicalTrials.gov Identifier: NCT03505801), we aimed to perform an international prospective observational study in patients indicated to ICM to evaluate the safety and clinical value of a new generation ICM (Confirm Rx™, Abbott, Illinois, USA). The study is ongoing. This manuscript reports on clinical outcomes through a 6-month post-implant.

Methods

Study design

The SMART Registry is an ongoing international prospective single-arm observational study, on patients indicated to ICM implant according to international guidelines,[4–7] performed in the USA, Canada, Argentina, South Africa, Saudi Arabia, Kuwait, India, Japan, South Korea, the UK, and eight European countries. The purpose of the study is to assess the safety, electrical performances, and clinical value of the Confirm Rx™ ICM in a large international multicentre real-world setting.

The study complies with the Good Clinical Practices and the Declaration of Helsinki. The Institutional Review Board or Ethic Committee of each centre approved the study protocol. All patients signed written informed consent. The study has been registered on the ClinicalTrials.gov website.

Device description

The Confirm Rx™ Model DM3500 ICM is a minimally invasive, insertable diagnostic monitoring device with subcutaneous electrodes, looping memory, and automatic as well as patient-activated electrogram (EGM) storage capability. This ICM has been built improving a previous generation device, in particular downsizing dimensions from 6.5 to 1.4 cc, in order to facilitate the insertion procedure, adding an improved detection algorithm (SharpSense™) and adding Bluetooth communication capabilities to connect the device with the patient smartphone application (myMerlin™ Mobile App) and with the Merlin.net Patient Care Network (PCN) to enable physician remote follow-up.

Patients were informed about the fact that their ICM continuously monitors their heart rhythm and were instructed on how to download and install the myMerlin™ app; how to pair their ICM to the myMerlin™ app; how to record their symptoms, if any; and how to react to notifications aiming to improve connectivity. Patients were provided with guidance about several actions, such as keeping the myMerlin™ app open, keeping their smartphones connected to the internet using Wi-Fi or cellular data, keeping their phone near (within 1.5 m) overnight and as much as possible throughout the day, and about keeping Bluetooth on (https://www.cardiovascular.abbott/content/dam/bss/divisionalsites/cv/pdf/guides/crm-mymerlin-support-guide-android-english-int.pdf).

The device has 2-year longevity and MR conditional labelling. The device technical characteristics and its safety and electrical performances have been already described.[11,12] Specific features include automated storage of EGM data when tachycardia, bradycardia, pauses, or AF is detected or when patients have symptoms and trigger data storage to allow their physicians to associate EGM characteristics with their symptoms.

The Confirm Rx™ ICM received CE mark approval in December 2016 and FDA clearance in September 2017.

The device can be implanted via a minimally invasive insertion procedure through a small skin incision that can be closed using surgical glue, surgical tape, stitches, or staples.[11,12]

Some aspects of ICM programming were recommended, such as minimum AF detection duration at 2 min, and maximal ventricular sensitivity was set at 0.15 mV for R-wave amplitude ≥ 0.45 mV but could be adjusted at 0.1 mV if R-wave amplitude was lower than 0.45 mV. Other parameters were programmable and up to the investigator's discretion. Typically, arrhythmic events were defined as pause (≥ 3 s), bradycardia [heart rate ≤ 40 beats per minute (b.p.m.)], tachycardia (heart rate ≥ 150 bpm), and AF (episodes lasting at least 2 min).

Follow-up

Subjects were followed per the standard of care at their institution for up to a 12-month post-insertion, with scheduled in-clinic follow-up visits at 1 month, in-clinic or remote follow-up visits at 6 months and in-clinic follow-up visits at 12 months. Unscheduled visits, either remote or in-clinic, related to the device were allowed at any time throughout the course of the study. At each scheduled follow-up visit and any unscheduled visits, all new Confirm Rx™ ICM EGM-associated episodes were adjudicated by qualified clinicians at the study site. Any new diagnoses and subsequent clinical outcomes based on device-detected episodes were collected at each follow-up.

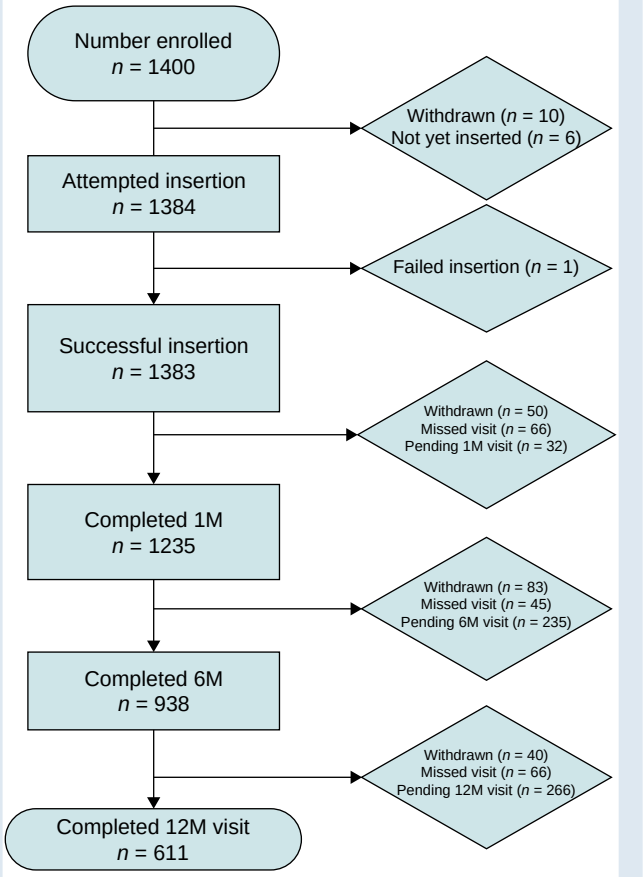


Figure 1 Subject disposition at the time of the analyses. Note that subjects who missed one visit but made subsequent visits are included in the totals. As such, the number of subjects completing each follow-up may not equal the number of subjects who missed, withdrew, or are pending the associated follow-up.

Clinical endpoints

Clinical endpoints comprised incidence of device-detected arrhythmias, diagnosis yield for each arrhythmia and for each ICM indication, and clinical decisions and interventions resulting from device detection and following diagnosis.

Safety endpoints

The primary safety endpoint of the SMART Registry was the freedom from serious adverse device and procedure-related effects (SADEs) through a 1-month post-insertion procedure. The safety performance goal was set at 90%, based on the Confirm IDE study (NCT03505801) where the SADE rate (excluding battery depletion) was 97.3% [95% confidence interval (CI): 90.7%, 99.7%]. According to the SMART Registry statistical plan, the null hypothesis could be rejected if the 95% lower confidence bound of *P*, calculated using the Clopper–Pearson exact method for binomial distributions, will result in >90%. In recent prospective trials on ICMs, the SADE rate observed through a 1-month post-insertion procedure was 1.1%, and the adverse event (AE) rate was 4%.[9]

The secondary safety endpoint was freedom from SADEs through a 12-month observation.

Technical endpoints

The technical endpoints comprised R-wave amplitude at scheduled in-clinic follow-ups through a 12-month observation and insertion procedure times.

Physicians reported experiences

Using a Likert scale of 1 to 5, physicians were asked to rank their satisfaction (1 being very dissatisfied, 5 being very satisfied), with the Confirm Rx incision and insertion tools, and to rank their overall insertion procedure.

Patient-reported experience measurements (PREMS)

Subjects were asked to report on their experience with the myMerlin™ app at the 1-month and 12-month follow-up. The quality of life of subjects was self-recorded at enrolment, 1-month follow-up, and 12-month follow-up using the EQ-5D-3L questionnaire.

Statistical analysis

For continuous variables, the results were summarized with the number of observations and with mean and standard deviation or with median and interquartile range (IQR), as appropriate. For categorical variables, the results were summarized with subject count, percentage/rate, and event count if applicable. Survival analysis or analysis of incidence was conducted to analyze the time-to-event data including incidence of device-detected arrhythmias, incidence of clinical diagnosis, or freedom from SADE endpoints. Survival curves were constructed using Kaplan–Meier estimates using Greenwood's formula for variance. Subjects without events were censored at their last known event-free follow-up time.

Results

Fourteen hundred subjects were enrolled into the SMART Registry across 91 different sites, globally. *Figure 1* shows the subject disposition. Out of 1384 attempted insertions, 1383 (99.9%) were successful. A total of 1235 subjects completed the 1-month follow-up visit, 938 subjects completed the 6-month follow-up, and, finally, 611 subjects completed the 12-month visit. Subjects who may have missed some study visits but were able to complete other study visits were included in the totals.

The main baseline demographics and primary indications for ICM implant for 1384 patients with attempted implant are shown in *Table 1*. The average age of subjects was 60 ± 16 years. The most common ICM indications were syncope for 688/1384 (49.7%) subjects and AF monitoring for 256/1384 (18.5%) subjects. In particular, 83 patients (6.0%) had cryptogenic stroke.

Table 1 Baseline demographics and ICM implant primary indications

Characteristics	Subjects with attempted implant (N = 1384)
Age, mean ± SD (*n*)	60 ± 16 (1384)
Female, % (*n*/*N*)	43.8% (606/1384)
NYHA class (%, *n*/*N*)	
I	36.1% (499/1384)
II	9.8% (136/1384)
III	2.2% (30/1384)
IV	0.1% (2/1384)
Unknown/not applicable	51.8% (717/1384)
LVEF Mean ± SD (*n*)	59 ± 8 (909)
LVEF ≤ 30% (%, *n*/*N*)	0.8% (7/909)
LVEF 31–40% (%, *n*/*N*)	3.0% (27/909)
LVEF > 40% (%, *n*/*N*)	96.3% (875/909)
ICM indication[a]	
Syncope (%, *n*/*N*)	49.7% (688/1384)
Atrial fibrillation (%, *n*/*N*)	18.5% (256/1384)
Palpitations (%, *n*/*N*)	13.4% (186/134)
Risk for cardiac arrhythmias (%, *n*/*N*)	6.5% (90/1384)
Dizziness (%, *n*/*N*)	6.5% (90/1384)
Cryptogenic stroke (%, *n*/*N*)	6.0% (83/1384)
Chest pain (%, *n*/*N*)	1.5% (21/1384)
Shortness of breath (%, *n*/*N*)	1.0% (14/1384)

[a]Study investigators were allowed to select more than one ICM indication (e.g. in the case of ICM implanted for AF monitoring in cryptogenic stroke patients, they may have described ICM indication with both 'atrial fibrillation' and 'cryptogenic stroke'); therefore, the sum of the number of indications is >1384.

Clinical endpoints—device detections

Kaplan–Meier estimated incidence of device-detected true cardiac arrhythmias at 6 months was 45.7%, as shown in *Figure 2*. The trend of device-detected cardiac arrhythmias and clinical diagnoses, in *Figures 2–5*, shows steeper patterns at 1 month and at 6 months, due to the fact that these were the scheduled times for follow-up visits. In total, the ICM detected true arrhythmias in 554 subjects [40.0% of all subjects (1384) with an attempted implant]. As shown in *Figure 3*, Kaplan–Meier estimated incidence of device-detected true arrhythmias was documented within the first 6 months of ICM monitoring in 44.6% of subjects indicated for syncope, in 50.0% of subjects indicated for AF, and in 32.3% of subjects indicated for cryptogenic stroke. In particular, in the cryptogenic stroke cohort, a total of 13 patients had true device-detected AF episodes within the first 6 months of ICM monitoring with a Kaplan–Meier estimated AF incidence of 19.2% (95% CI: 11.5–31.2%) (*Figure 4*). Within this cohort of cryptogenic stroke patients, the analysis of the AF episodes stored in the device diagnostics showed that the median AF episode duration was 7 min [IQR: (3.7, 14.8)].

The time to first device-detected true cardiac arrhythmia was 85 ± 74 days; when stratified by indication, this time was 81 ± 73 days, 96 ± 79 days, and 74 ± 63 days for subjects indicated for syncope/presyncope, AF, or cryptogenic stroke, respectively.

Clinical endpoints—new arrhythmia diagnosis

During the first 6 months of ICM monitoring, 332/1384 (17.6%) of patients received a new clinical diagnosis based on device-detected arrhythmias. Kaplan–Meier estimation of a 6-month incidence of a new clinical diagnosis was 27.1% for all patients, 29.9% for syncope subjects, 25.6% for AF subjects, and 20.9% for cryptogenic stroke subjects, as shown in *Figure 5*.

Clinical endpoints—clinical interventions

During the first 6 months of ICM monitoring, a total of 70 subjects received a therapeutic device implant such as a pacemaker, ICD, or CRT-D, resulting in a Kaplan–Meier estimated incidence of 5.5% interventions at 6 months. In particular, 56 of the 688 subjects indicated for syncope ended up with a pacemaker, resulting in a cumulative Kaplan–Meier incidence of 8.9% at 6 months. Of the 256 subjects indicated for

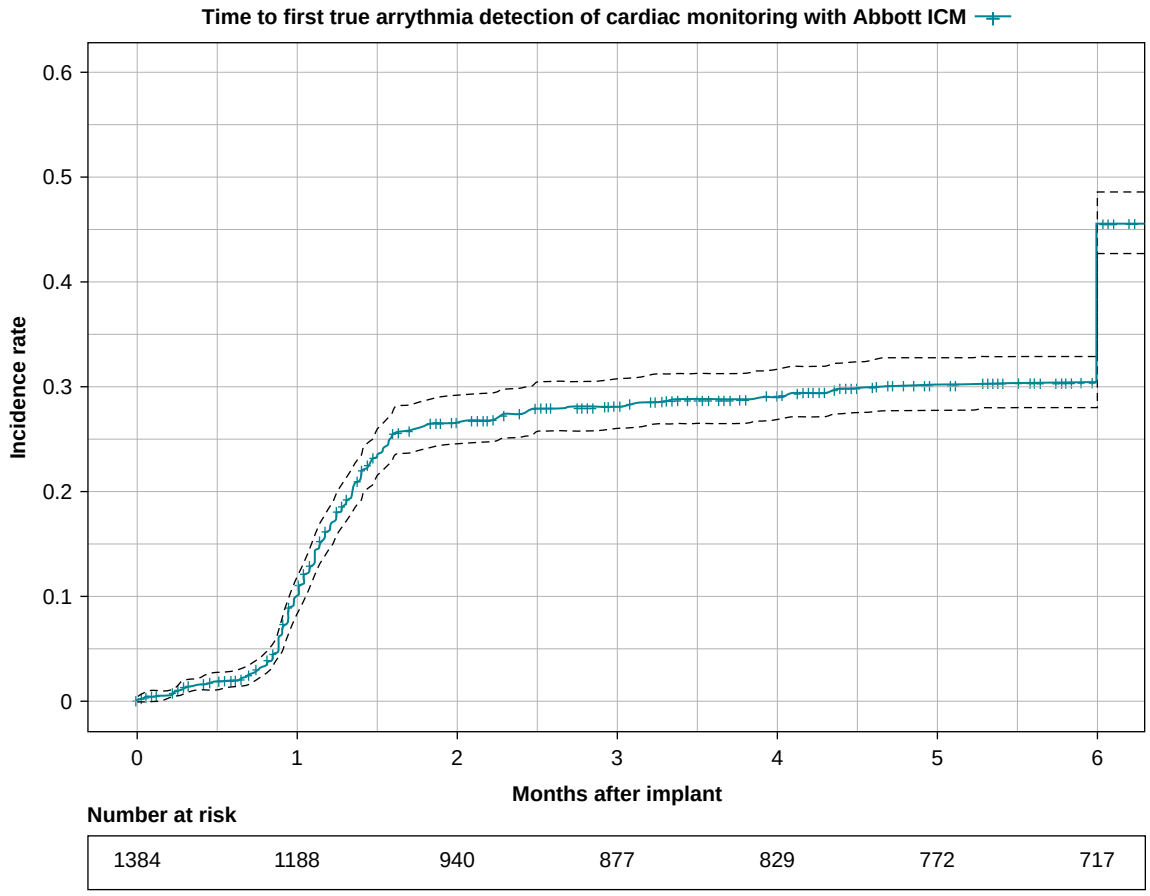


Figure 2 Incidence of true device-detected arrhythmias through 6 months of cardiac monitoring.

AF, 2 patients received a pacemaker for prolonged ventricular or low rate during AF, resulting in an estimated Kaplan–Meier incidence of 0.9% at 6 months.

A total of 29 subjects received an ablation during the first 6 months of monitoring.

Moreover, 116/1184 (9.8%) subjects had 133 drug therapy changes, as a result of ICM-detected cardiac arrhythmias. In particular, oral anticoagulation therapy was indicated in 13 (15.7%) cryptogenic stroke patients after device-detected AF.

Primary safety results

The primary endpoint of freedom from SADEs through a 1-month post-insertion was analysed in 1242 subjects, in particular 1235 who completed the first month follow-up visit and 7 subjects who had withdrawn prior to their first month follow-up visit due to a SADE. A total of nine events occurred within the first month of implant. The nine events included post-procedure infection, pain at the surgical site, device dislocation, erosion, extrusion, anxiety, and false detection/undersensing. As shown in *Figure 6*, freedom from SADEs at 1 month was 99.3% (95% CI: 98.6–99.7%).

Technical endpoints

The median ICM insertion time was 7 min [IQR: (4, 11)]. The primary closure technique during the insertion procedure was reported in 181, and it was sutures (70.7%, 128/181), while other physicians used Steri-Strip (14.9%, 27/181), Dermabond (8.8%, 16/181), and other techniques (5.5%, 10/181).

At the end of 6 months, the ICM remained inserted in 98.1% of patients.

The mean R-wave amplitude measured at implant in 1381 subjects was 0.59 ± 0.29 mV (95% CI: 0.58–0.61 mV, min value 0.1 mV, max value 3.0 mV), and, measured at 1-month follow-up in 1149 subjects, was at 0.58 ± 0.29 mV (95% CI: 0.57–0.60 mV; min value = 0.07, max value 2.07 mV). The R-wave amplitude, when measured in 434 subjects who reached a 12-month follow-up, was 0.62 ± 0.31 mV (95% CI: 0.59–0.65; min value 0.07 mV, max value 2.07 mV).

Physician-reported experiences

One hundred eighty-one implanters shared their level of satisfaction about the implant procedure, the incision tool, and the insertion tool, as described in *Table 2*. Eighty-nine investigators also completed the survey to report on their satisfaction with remote follow-up (also reported in *Table 2*).

Patient-reported experience measurements

At their 1-month follow-up visit, subjects were asked to report on their experience with the myMerlin™ application. Out of 1177 subjects who completed the survey, 975 (82.8%) subjects found the overall instructions on the myMerlin™ to be easy or very easy to interpret or follow. In addition, 921 (78.2%) subjects were satisfied or very satisfied with their overall experience with the myMerlin™ application.

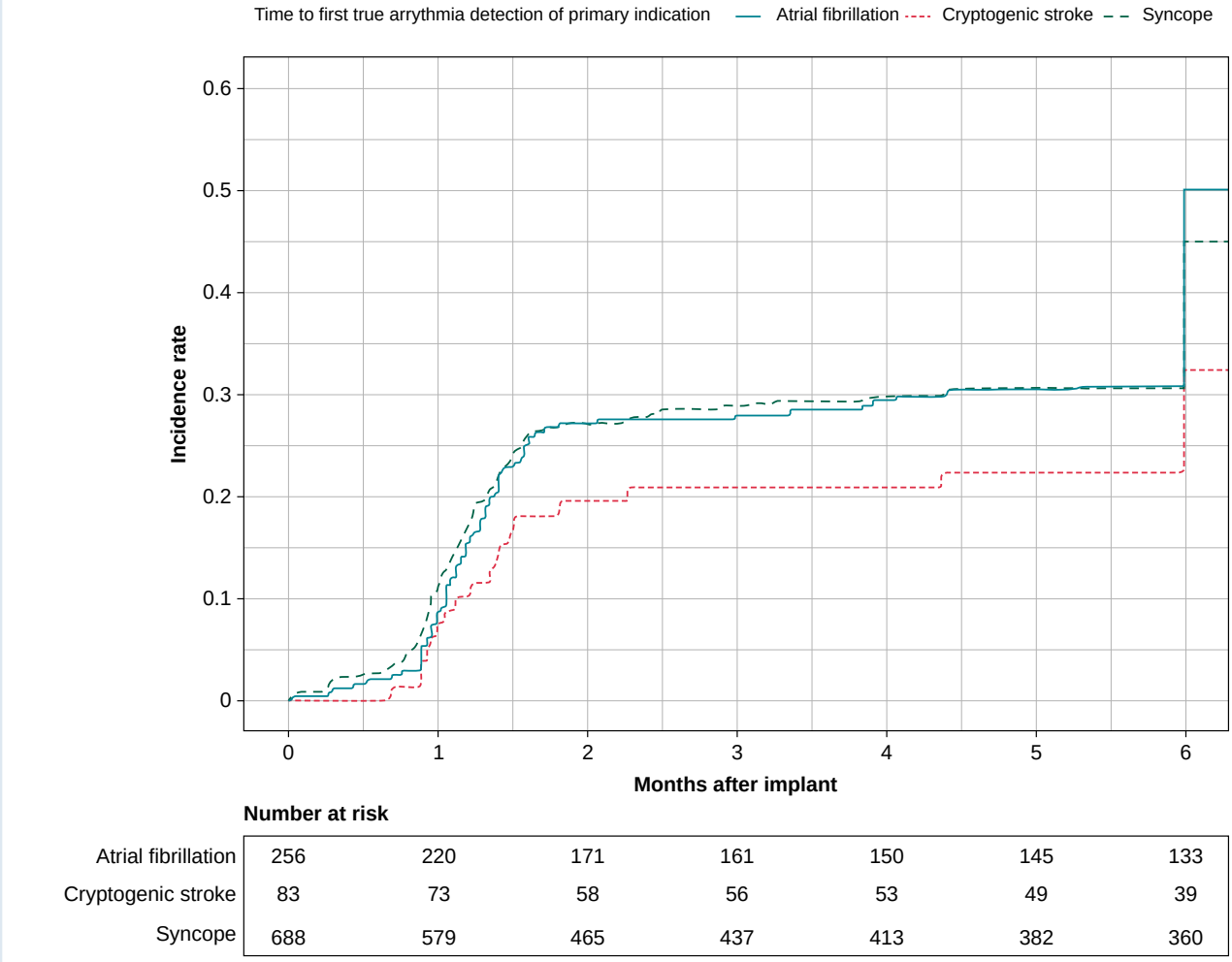


Figure 3 Incidence of first true arrhythmia detection for subjects stratified by indication.

Discussion

Our large international multicentre study brings new clinical evidence on the safety and clinical value of ICM for the monitoring of cardiac arrhythmias. This is particularly relevant in view of the involved geographies (USA, Canada, Latin America, Europe, Middle East, Africa, and Asia), the number of implanting sites (91), and the large number of patients (1400).

New arrhythmia detection

In this study, within the first 6 months of observation, ICMs detected true new arrhythmias in 45.7% of subjects (*Figure 2*) confirming the clinical value of the ICM diagnostic strategy.

Almost half of the subjects included in the registry had an ICM indication due to unexplained syncope, the ICM detected true arrhythmias in 44.6% of these patients (*Figure 3*), and this led to new diagnoses in 30% of patients (*Figure 5*). These proportions compare favourably with previous findings.[3,4] In the PICTURE observational registry, for example, the percentage of patients with syncopal events where the evaluated ICM played a role in the diagnosis was 20% within 180 days. The role of ICM for improving the diagnostic yield in patients with unexplained syncope has been clearly demonstrated.[3,4]

Recent ESC Guidelines for the diagnosis and management of syncope[5] have upgraded the use of ICMs to Class I/level of evidence recommendation in an early phase of evaluation in patients with recurrent syncope of uncertain origin, outlining that patients monitored with ICMs are 3.6 times more likely to receive a diagnosis for syncope. High diagnosis yield in patients with unexplained syncope is very important; a recent German longitudinal study[13] has found that patients with ICM, compared with patients treated with other diagnostics tools, are associated with better prognosis. The authors stated that the risk of death is reduced by a factor 2, and patients live longer, likely because of an improved detection of arrhythmias, resulting in a 4 × higher indication for active cardiac devices.

The second most common indication for ICM implant in our registry was AF, comprising 18.8% of all ICM indications, and true device-detected arrhythmias were documented in 50.0% of these subjects within the first 6 months of ICM monitoring (*Figure 3*). Clinically relevant diagnoses were derived in 20.5% of these patients (*Figure 5*). Of particular clinical importance is the subgroup of patients who received an ICM for AF monitoring after a cryptogenic stroke. In these cohorts, AF was detected in 19.2% of patients within 6 months (*Figure 4*). In the Crystal AF study,[8] which evaluated cryptogenic stroke patients, AF was detected by the ICM in 8.9% of subjects at a 6-month follow-up and 21.1% of subjects at 24 months. A recent randomized study[14] has

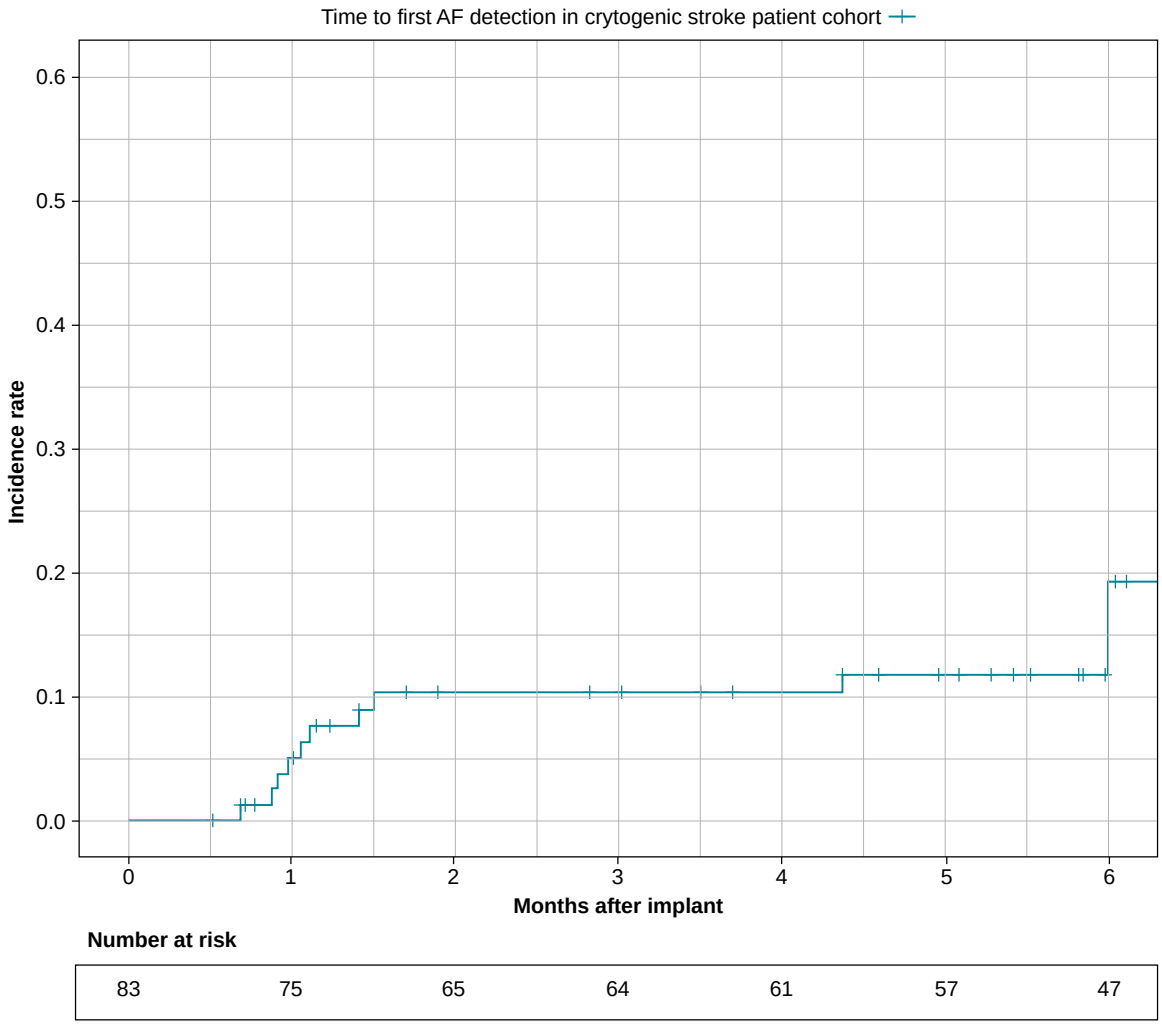


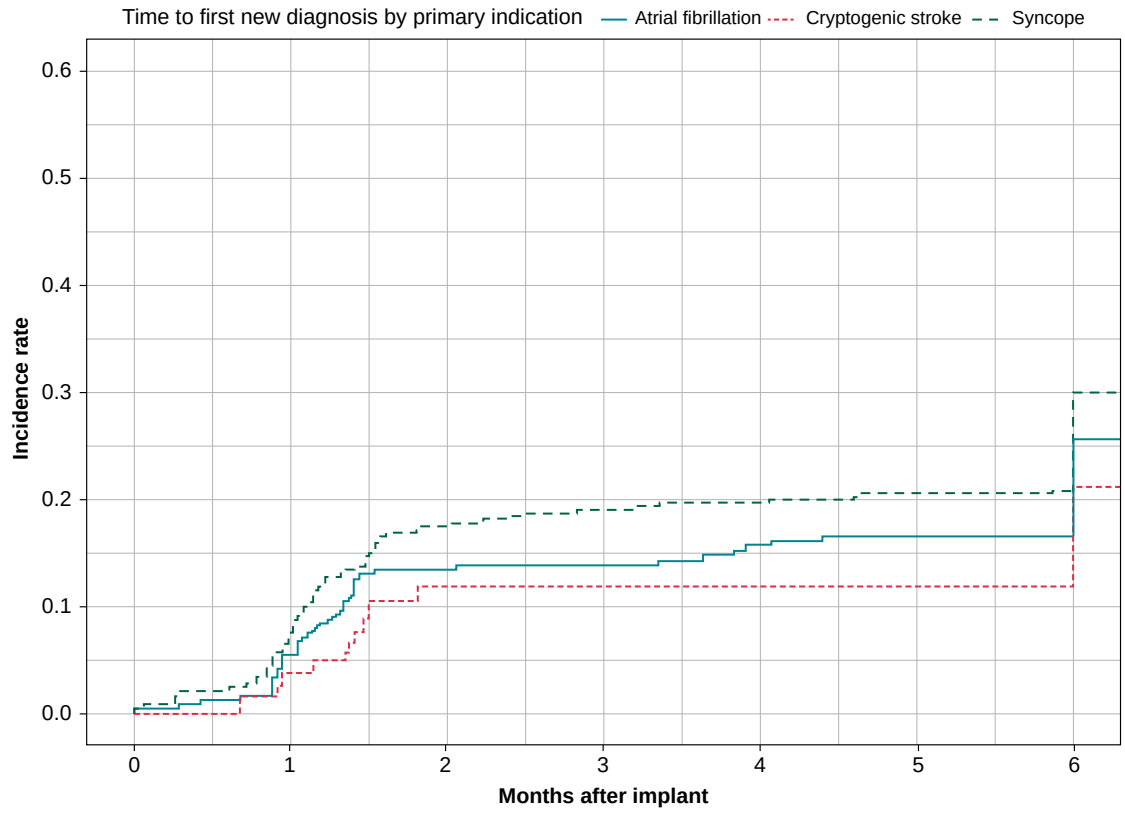
Figure 4 Time to first AF detection in cryptogenic stroke patient cohort.

evaluated AF detection by continuous ICM monitoring in stroke patients according to stroke type and found that ICM detected AF within the 6-month follow-up in about 7% of subjects with large artery atherosclerosis and in 9% of subjects with small vessel disease. This study, similar to the previously described Crystal AF study,[8] also confirmed the superiority of ICM detection yield compared with standard clinical follow-up. Subclinical AF is present on average in one-third of patients with cryptogenic stroke or transient ischaemic attack (TIA) but can be much more frequent, up to three-thirds of patients who have frequent premature atrial beats, long P-wave durations, and large left atrial end-systolic volumes.[15] The results from the first 6-month analysis of this SMART Registry confirm the fact that a clinically meaningful proportion of cryptogenic stroke patients do suffer AF and may therefore be indicated to oral anticoagulation therapy. Both US and European guidelines[6,7] outline the importance of long-term cardiac monitoring and recommend ECG monitoring via ICMs, in patients with stroke of unknown origin. On the other hand, cardiac monitoring is also important to identify those cryptogenic stroke patients who do not suffer from AF and are therefore not indicated to oral anticoagulation (OAC).

We need to wait for the results of future randomized studies to understand the clinical value of AT/AF detection in cryptogenic stroke in guiding the optimization of thromboprophylaxis through OAC.

Clinical diagnoses and interventions driven by ICM detections

In our study, in the first 6 months of observation, the Kaplan–Meier estimated incidence of a new diagnosis was high—27.1% for all patients, 29.9% for syncope subjects, 25.6% for AF subjects, and 20.9% for cryptogenic stroke subjects. These data show a high diagnosis yield which confirms the clinical value of long-term ICM monitoring. A previous randomized study has shown the high detection yield of the ICM evaluated in our study, compared with another ICM.[11] As proposed by the authors, the faster detection results may be due to specific features of the Confirm Rx™ device such as the fact that it can transmit data about several arrhythmias per day and that the patient smartphone application and the Bluetooth feature allows for on-time data transmissions and may be associated with faster data transmission. The latter characteristics may also result in improved—faster and/or easier connection between patients and healthcare providers, which could enable more efficient clinical decisions. On the other hand, high diagnostic yield and transmission of all detected episodes through remote monitoring systems may cause a large volume of data to be processed. In this scenario, artificial intelligence may provide important solutions to efficiently extract value from this constantly increasing volume and variety of data and to help in its interpretation.[16]



Number at risk

Atrial fibrillation	256	228	204	195	183	176	165
Cryptogenic stroke	83	76	64	63	60	57	48
Syncope	688	603	524	494	471	444	420

Figure 5 Kaplan–Meier estimated incidence of a new diagnosis by primary indication for ICM implant after 6 months of monitoring.

Arrhythmia detection and diagnosis led to relevant clinical decisions and intervention comprising pacemaker, ICD, or CRT-D implant in 5.5% of all subjects and medication changes in 9.8% of all patients, and in particular pacemaker implant in 8.9% of patients who received an ICM for unexplained syncope and oral anticoagulation indication in 15.6% of patients who received an ICM for cryptogenic stroke. These rates of interventions, especially taking into account the short monitoring period (6 months) in which they occurred, show that ICM continuous monitoring has clinical relevance and confirms the fact that insertable and wearable cardiac monitors with single- or multiple-lead ECG technology are accepted for multiple indications in current clinical practice and triggers arrhythmia diagnosis and treatment, as shown by the recent wEHRAbles 2 survey.[17]

Safety

In our cohort, device-related and procedure-related serious adverse events were very rare, occurring at a 0.7% incidence rate at 1-month post-implant. These data favourably compare with those reported by previous studies.[8,9] In particular, Crystal AF study[8] reported that out of 208 subjects with ICMs, 5 subjects (2.4%) had their ICM removed due to infection at the insertion site or pocket erosion. In that study, the most common ICM-related adverse events were infection (1.4% of patients), pain (1.4% of patients), and irritation or inflammation (1.9% of patients) at the insertion site. In our study, the ICM remained inserted in 98.1% of patients at 6 months, and the infection rate was 0.43% (6/1384) through the first 6 months of monitoring. Previous data on new generation smaller devices, from other manufacturers, were associated with a 1.8% infection rate.[9] Our data confirm that smaller ICM dimensions are associated with lower infection rates compared with previous generations of ICM devices whose dimensions were associated with infection incidence rates as high as 2.3–4%.[8,9]

Implanter satisfaction

ICM implant is an easy procedure; out of 1384 attempted insertions, 1383 (99.9%) were successful. The majority of physicians showed satisfaction about the implant procedure, in particular, 81.8% were satisfied with the overall insertion procedure, 58.0% reported being satisfied with the incision tool, and 87.8% are satisfied with the insertion tool. Sixty-five per cent of physicians were satisfied with the remote follow-up experience. These results are comparable with reported experiences of implanters who used similar ICMs.[9,10]

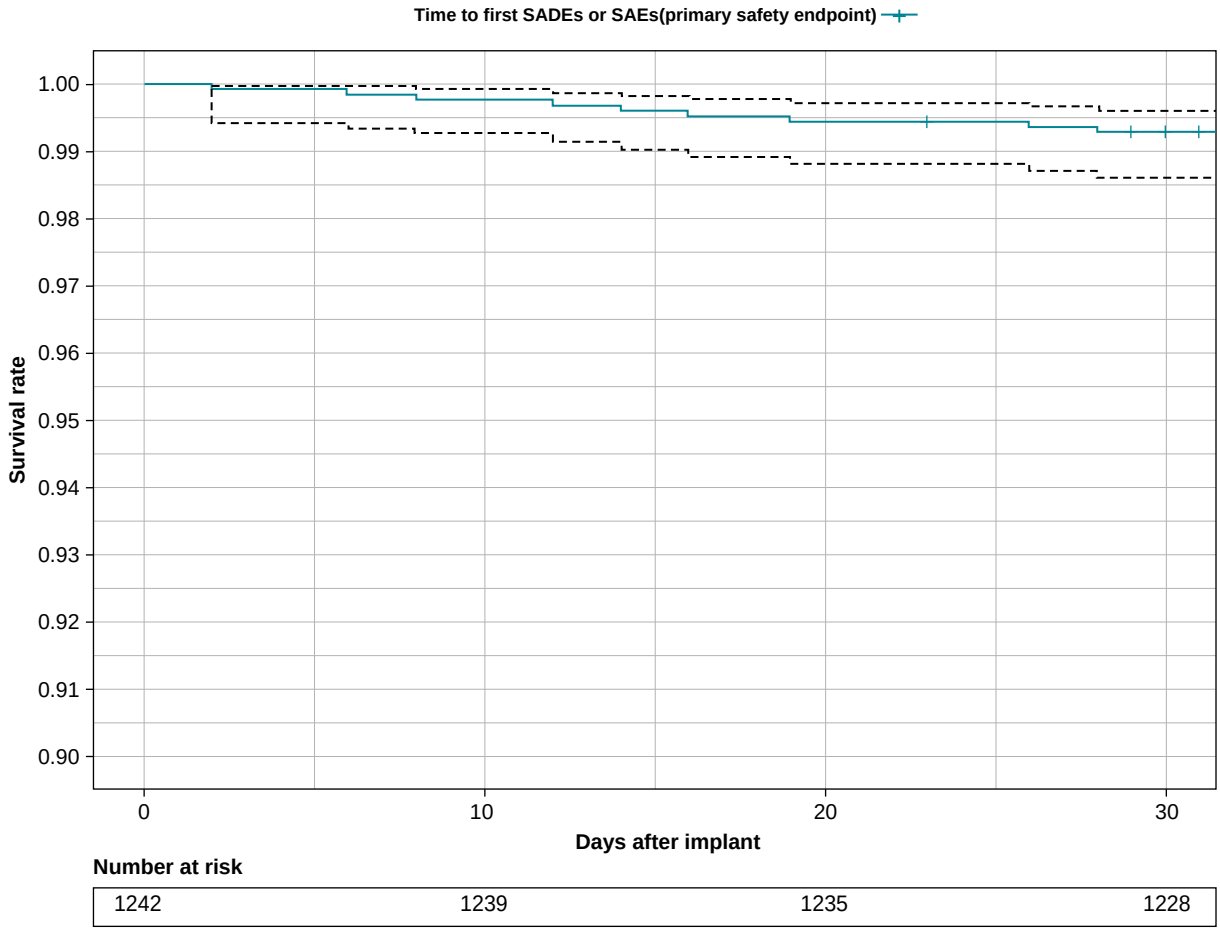


Figure 6 Freedom from SADEs at 1-month post-insertion using the Clopper–Pearson exact method.

Table 2 Physicians reported satisfaction about overall implant procedure, incision tool, insertion tool, and remote follow-up platform

Level of satisfaction Evaluated characteristic	Satisfied or very satisfied	Neither satisfied or dissatisfied	Dissatisfied
Overall implant procedure	148/181 (81.8%)	28/181 (15.5%)	5/181 (2.8%)
Incision tool	105/181 (58.0%)	33/181 (18.2%)	38/181 (21.0%)
Insertion tool	159/181 (87.8%)	18/181 (9.9%)	3/181 (1.7%)
Remote follow-up	58/89 (65.2%)	25/89 (28.1%)	6/89 (6.7%)

Patient-reported experience measurements

Out of 1177 subjects who completed the survey about the myMerlin™ app, 82.8% found the overall instructions on the to be easy or very easy to interpret or follow; also 78.2% were satisfied or very satisfied with their overall experience with the myMerlin™ application. The use of smartphone applications to enable remote monitoring is a new and innovative approach to care of patients wearing cardiac monitors. Observing such high percentages of patients who find remote monitoring smartphone applications user-friendly is re-assuring. Also, patients' satisfaction about ICM remote monitoring is fundamental for future perspectives in which not only rhythm detection will be part of ICM capabilities. The observation that about 21% were neutral or not satisfied with their experience with remote monitoring is in line with previous experiences in patients wearing implantable cardiac devices[18] and can be associated with the fact that not all the patients are technology literate and able to use, comprehend, and manage remote monitoring applications and with the fact that some patients may live in remote areas with limited smartphone connections. Most of patients in our cohort were young, with a mean age of 60 years and only a minority of patients with > 75 years. This aspect could have contributed to the high acceptance of both the remote monitoring system and the patient app. Anyhow, these systems and applications have been developed in

order to be user-friendly. A recent research,[19] on smartphone-based remote monitoring in patients with cardiac implantable devices, has shown that patients with age > 75 years, when compared with younger patients, have a similar capability of pairing smartphone applications and remote monitoring systems and of transmitting device data. We believe in the importance of insights into patient-reported experiences with smartphone applications and remote monitoring, especially because it is known that patients' perceptions do influence remote monitoring quality and outcomes.[20]

Study limitations

This is an observational study; therefore, its results should be evaluated in the context of possible biases commonly associated with observational registries such as subject selection bias or others.

The indication of ICM implant was defined by each site investigator, according to her/his interpretation of current international guidelines.[4–7] Similarly, a review of ICM detections was performed by attending cardiologists at their respective institutions; there was not a central lab or adjudication committee to review and confirm diagnoses based on ICM data. Furthermore, while pharmacological changes induced by device detection of arrhythmias were reported, specific details about these changes were not collected, and therefore any analysis on medication management could not be determined.

Our observational study aimed to evaluate the safety and clinical value of a new generation ICM in real-world clinical practice. We did not plan for measuring the device detection accuracy because it would have requested a specific process for arrhythmia episode EGM data collection and review and because other studies[11–13] have estimated the detection accuracy of this type of ICM.

Conclusion

Our large multicentre international study brings new clinical evidence on the good safety profile, high detection yield, and clinical value of implantable loop recorders for the monitoring of cardiac arrhythmias. Importantly, a large majority of implanters stated to be satisfied with the insertion tools and the overall procedure, and patients reported positive experiences associated with the use of their smartphone for the device remote monitoring.

Supplementary material

Supplementary material is available at *Europace* online.

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Conflict of interest: W.L., A.G., and C.S.H. are employees of Abbott. All remaining authors have declared no conflicts of interest.

Data availability

Data generated in the course of the study and underlying the research results may be made available; the request for data access should be submitted to the study sponsor.

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