Miniaturized Reveal LINQ insertable cardiac monitoring system: First-in-human experience

Helmut Pürerfellner, MD, FHRS,[*] Prashanthan Sanders, MBBS, PhD, FHRS,[†]
Evgeny Pokushalov, MD,[‡] Marco Di Bacco, PharmD,[§] Tracy Bergemann, PhD,[‖]
Lukas R.C. Dekker, MD, PhD,[¶] for the Reveal LINQ Usability Study Investigators

From the [*]Department of Cardiology, Elisabethinen University Teaching Hospital, Linz, Austria, [†]Centre for
Heart Rhythm Disorders, South Australian Health and Medical Research Institute, University of Adelaide and
Royal Adelaide Hospital, Adelaide, Australia, [‡]Arrhythmia Department, State Research Institute of Circulation
Pathology, Novosibirsk, Russia, [§]Medtronic Bakken Research Center BV, Maastricht, the Netherlands, [‖]Medtronic,
Inc, Minneapolis, Minnesota, and [¶]Department of Cardiology, Catharina Hospital, Eindhoven, the Netherlands.

BACKGROUND The Reveal LINQ is a miniaturized insertable cardiac monitor (ICM) with wireless telemetry for remote monitoring of patients with suspected arrhythmias.

OBJECTIVE The primary objective of this study was to evaluate the functionality of the Reveal LINQ system by measuring R-wave sensing and data transmission.

METHODS The Reveal LINQ Usability Study was a nonrandomized, prospective, multicenter trial. The study enrolled 30 patients with any indication for an ICM. Data were collected at baseline, implantation, and 1-month follow-up visits and through daily wireless transmissions.

RESULTS Thirty patients were enrolled and had a Reveal LINQ device implanted. The mean age was 55 ± 15 years. All patients had successful implantation of the ICM in one of the recommended locations. Ease of implantation procedure was rated as easy or very easy for 90% of implantations. R-wave amplitudes were 0.584 ± 0.325 mV at implantation and 0.596 ± 0.336 mV at 1 month ($P = .8$). Automatic transmissions were successful 79.5% (69.5%–86.9%) of the time. Transmission failures that caused a delay in data transfer occurred because of incomplete data reception or patients being out of range in 45% and 42% of instances, respectively. For all patients, transmission failures were followed by successful automated or manual transmission of information on a subsequent day. The devices stored 217 arrhythmic episodes during 30 days of follow-up, identified as atrial fibrillation (n = 111), asystole (n = 95), bradycardia (n = 4), fast ventricular tachycardia (n = 1), and ventricular tachycardia (n = 6). No serious procedure- or system-related adverse events occurred during the 1-month follow-up period.

CONCLUSION The miniaturized Reveal LINQ ICM supports arrhythmia detection and monitoring, achieving adequate sensing performance without safety issues.

CLINICAL TRIAL REGISTRATION URL: http://www.clinicaltrials.gov. Unique identifier: NCT01965899.

KEYWORDS Arrhythmia; Atrial fibrillation; Syncope; Remote monitoring

ABBREVIATIONS AF = atrial fibrillation; **CI** = confidence interval; **ECG** = electrocardiogram; **ICM** = insertable cardiac monitor

(Heart Rhythm 2015;12:1113–1119) © 2015 Heart Rhythm Society. Open access under CC BY-NC-ND license.

Introduction

Insertable cardiac monitors (ICMs) have been introduced into clinical practice to assist physicians in diagnosing patients with syncope or the detection of arrhythmias. Their utility and cost-effectiveness in the evaluation of syncope have been proven such that recent guidelines have advocated early use of these devices.[1–3] ICMs are considered the reference standard in the analysis of syncope after the exclusion of high-risk patients.[4] Current guidelines have also extended these indications to highlight their utility in the investigation of patients with infrequent but recurrent palpitations. In addition, there is growing interest in the use of such monitoring in arrhythmia detection after cryptogenic stroke and after ablation of atrial fibrillation (AF).[5–9] The Medtronic Reveal LINQ (Medtronic, Minneapolis,

Minnesota) is a novel ICM. It is much smaller than its predecessor, uses wireless telemetry for remote monitoring of patients (including nightly automated transmissions), and features the addition of a new P-wave filter to further refine the performance of the AF algorithm.[10] These improvements aim to simplify the implantation procedure, increase patient acceptance, and enhance the device's AF detection capabilities. In this clinical context, the current usability study of the Reveal LINQ system evaluated both ease and efficiency of the insertion procedure and overall functioning of the remote monitoring system.

Methods
Study design
The LINQ Usability Study was a prospective, multicenter, single-arm clinical study assessing first-in-human usability of the new device, its implantation procedure, and its monitoring system. The study was prospectively designed and conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent to the study protocol that was reviewed and approved by the human research ethics committee of each participating institution.

Study population
In this initial experience, a total of 30 patients undergoing ICM implantation were recruited. Indications for ICM implantation reflected current guidelines and local physician practices. The following exclusions were used: age < 18 years; inability to provide consent; pregnancy; an already active implanted cardiac device; and a life expectancy of < 18 months.

Device
The Reveal LINQ ICM system includes an implantation kit, the Reveal LINQ device, and the home monitoring equipment. With a volume of only 1.18 mL, the Reveal LINQ is 87% smaller than its predecessor, the Medtronic Reveal XT (Online Supplemental Figure 1). The device transmits data to Medtronic's CareLink network automatically on a daily basis. There are no triggers required before the transmission. In addition, CareAlerts are sent from CareLink to physicians when 1 of the following conditions is detected: patient-activated episodes, including episodes that occur within 20 minutes of a device-detected episode; device-detected tachycardia, asystole, bradycardia, and AF; AF burden above a threshold determined by the clinician; ventricular rates (with or without ventricular fibrillation) above a threshold set by the clinician; low battery; and electrical reset. The storage capacity of the device allows for up to 59 minutes of electrocardiogram (ECG) recordings from patient-activated episodes and automatically detected arrhythmias. The study required all implanted devices to be programmed at nominal settings.

Implantation procedure
On the basis of previous testing with ECG body surface mapping to determine the optimal implantation location, 2 thoracic anatomic locations were recommended for implantation over the fourth intercostal space on the left hemithorax: 45° ("best") and parallel ("good") relative to the sternal border. No other implantation locations were compared or evaluated. An incision tool and an insertion tool are provided by Medtronic to execute the device implantation. The incision tool safely creates the minimal opening in the skin necessary to place the Reveal LINQ. The insertion tool assists in the placement of the device in the subcutaneous tissue.

During implantation, data on R waves were collected from the value reported on-screen by the programmer. On the day of implantation, the patient received the home monitoring device, as well as instructions about its use for nightly automated transmissions and weekly manual transmissions.

Follow-up
Patients were followed up until 1 month after implantation for the study objectives. Data were collected at baseline, implantation, and the 1-month follow-up visit. Automatic device transmissions were sent nightly to the Medtronic CareLink network with key ECG data, and additional manual transmissions were sent on a weekly basis with full ECG data. Adverse events were collected throughout follow-up. All of the adverse events were adjudicated by an independent committee. Device interrogations and chest radiography were performed, and patient surveys were collected after implantation and at the 1-month follow-up visit. Patient surveys, physician procedure, and CareLink surveys assessing overall patient and physician satisfaction with the Reveal LINQ system were collected. Physician surveys were administered after implantation for each patient. Finally, physician CareLink surveys were completed by hospital staff at the 1-month follow-up visit and at any additional time point needed, for example, when CareAlerts were reviewed.

Primary objectives
There were 2 primary objectives in the study. The first primary objective was to assess the percentage of successful transmissions by the system during the first 30 days after implantation. Thirty days of follow-up was used to evaluate a consistent number of data points for each patient. A successful transmission was defined as a full packet of data to CareLink from the Reveal LINQ device. When a transmission failure was caused by patient error, it was not included in the analysis. The second primary objective characterized the R-wave amplitudes at implantation and 1 month. The R-wave amplitudes were taken from the on-screen ECG readings by the programmer.

Secondary objectives
The secondary objectives included characterizing system- and procedure-related adverse events; summarizing the

physicians' experience with implantation of the Reveal LINQ via a physician survey; summarizing the experience with CareAlerts via the physician CareLink survey; and summarizing the patients' experience with the Reveal LINQ system via a patient survey. As an additional analysis, we characterized serious adverse events. Events were considered serious when they led to a death; led to a serious deterioration in health, indicated by a life-threatening condition, a permanent impairment or damage, a hospitalization or increased length of hospitalization, or a condition that required unplanned medical intervention; or might have led to death or a serious deterioration in health had suitable intervention not taken place.

Ancillary study objectives

Ancillary objectives included quantifying device depth after implantation and device migration at the 1-month follow-up visit. The device implanter provided measurements of depth of implantation. Device migration was measured by chest radiographs and by marking the location of the incision as (1) the linear distance the device migrated relative to the incision (device migration beyond 20 mm was considered to be of clinical relevance), (2) the angular rotation toward or away from the sternum within the coronal anatomic plane, and (3) longitudinal axis rotation relative to the coronal anatomical plane.

Statistical analysis

To estimate the margin of error for the proportion of successful wireless transmissions in the study, a 95% confidence interval (CI) of a binomial proportion was calculated. The primary transmission endpoint had multiple transmissions within each study patient, and thus, a correlated data method was used. A generalized estimating equation was built, which assumed a working independence variance matrix, and robust sandwich estimators were used to estimate the standard error. A sample of 30 subjects was chosen to provide 95% CIs for the proportion of successful transmissions with a precision of at least ±9.6%. The sample size calculations assumed the standard error increased by an overdispersion factor of $[1+ \rho (n-1)]$ to account for correlated data. The correlation between measurements was assumed to be high ($\rho = 0.8$), and the proportion of successful transmissions was assumed to be 90%.

To characterize the R-wave amplitude at implantation and 1-month follow-up, summary statistics for both time points were calculated, including the mean, standard deviation, median, and interquartile range. A paired Student t test compared the amplitudes between implantation and 1 month. The proportion of R-wave amplitude values greater than or equal to 200 μV was also estimated at implantation and 1 month.[11]

All secondary and ancillary objectives were characterized with standard summary statistics. Continuous variables assessed at the baseline physical examination were summarized with means and standard deviations.

Results

Enrollment cohort

In the study, 30 patients were enrolled at 8 centers in Austria, the Netherlands, Australia, and Slovakia. All 30 patients underwent a successful implantation procedure and were discharged with the device. All remained active in the study at the time of endpoint analysis and had completed their 1-month follow-up visits. No patients exited the study before the 1-month follow-up visit (Online Supplemental Figure 2).

Baseline patient characteristics and indications for the 30 patients with an implantation of the Reveal LINQ system are summarized in Table 1 and Online Supplemental Table 1. The mean age was 55±15 years, and 63% of patients were female. The primary indications for ICM implantation were syncope (n = 19), suspected AF (n = 2), AF ablation monitoring (n = 2), AF management (n = 3), palpitations (n = 3), or cryptogenic stroke (n = 1). Follow-up was calculated as time from implantation date. Individual patient follow-up ranged from 27 to 49 days, with an average of 34.5 ± 4.7 days per patient. The total follow-up time was 1034 patient days.

Device and implantation characteristics

In the majority of the patients (n = 28; 93.3%), devices were implanted at the best recommended location (within the fourth intercostal space on the left hemithorax, 45° angle relative to the sternal border), with most incisions (n = 22; 73.3%) cranial to the device. Most implantations (n = 25; 83.3%) were performed in the catheterization laboratory, and the remainder took place in a clean procedure room. All 30 implantations were successful on the first attempt. All procedures took place under local anesthesia and without the use of sutures to fixate the device. Local anesthetic drugs used were procaine (n = 5; 16.7%), lidocaine (n = 23; 76.7%), and lidocaine with adrenaline (n = 2; 6.7%). Antibiotic drugs were administered before the procedure in half of the patients (cefazolin [n = 6], ampicillin/sulbactam [n = 5], cephalexin [n = 2], and flucloxacillin [n = 2]),

Table 1 Primary indication for implantation

Patient characteristics	Phase 1 patients (n = 30)
Sex, n (%)	
Male	11 (36.7)
Female	19 (63.3)
Age, y	54.9 ± 14.8
Body mass index, n (%)	
<30 kg/m^2	24 (80.0)
>30 kg/m^2	6 (20.0)
Primary indication for implantation, n (%)	
Syncope	19 (63.3)
Palpitations	3 (10.0)
Suspected AF	2 (6.7)
AF ablation monitoring	2 (6.7)
AF management	3 (10.0)
Cryptogenic stroke	1 (3.3)

AF = atrial fibrillation.

whereas no antibiotic drugs were administered in the remaining procedures (n = 15).

The device was implanted at an average depth of 9.1 ± 6.2 mm. It was left to the discretion of the operator to use dermal adhesive or sutures to close the skin. There was minimal to no incision site bleeding reported in 28 patients (93.3%) and moderate bleeding reported during the procedures in 2 patients (6.7%). The closure methods used at the completion of the procedure varied, with sutures used in 14 cases (46.7%), adhesive strips (Steri-Strips, 3M, St. Paul, Minnesota) in 9 (30.0%), and a topical skin adhesive (Dermabond, Ethicon Inc, Somerville, New Jersey) in 4 (13.3%).

Primary objectives

For the first 30 patients, each of whom was followed up for 30 days (900 total device follow-up days), daily wireless transmissions had a success rate of 79.5% (95% CI 69.5%–86.9%) from the Reveal LINQ device to CareLink. On the basis of the predefined endpoint in the study protocol, 21 transmissions were excluded from the total expected because there were 20 days during which monitors were not plugged in by the patients and 1 day when a manual transmission interrupted a wireless transmission. Accordingly, from the 900 follow-up days, there were 879 transmissions expected, and 699 of them were successful. The majority of transmission failures occurred for 1 of 2 reasons. In 45% of transmission failures, the MyCareLink home monitor received data with errors (ie, incomplete or corrupted). In 42% of transmission failures, the patient was out of range of the MyCareLink home monitor. For all patients, transmission failures were followed by successful automated or manual transmission of information on a subsequent day. The average number of days without a transmission was 2.1 days.

Further analysis of transmission failures did not reveal any nonrecoverable loss of data attributable to lack of successful wireless transmission for 29 of the 30 patients. There was 1 patient for whom 7 episodes were not transmitted. For this patient, however, a large number of episodes were detected by the device during follow-up, consisting of both sinus pauses and AF episodes. In all other cases, despite

a failed wireless session, the subsequent successful wireless session was able to report the occurrences of episodes in a timely manner. In all cases, the data were still available in the device memory for retrieval. R-wave amplitudes were 584.0 ± 325.0 μV at implantation and 595.7 ± 336.1 μV at 1 month ($P = .81$) (Figure 1). At implantation, amplitudes were ≥200 μV in 29 of 30 patients (96.7%; 95% CI 83.3%–99.4%). At 1 month, amplitudes were ≥200 μV in 28 of 30 patients (93.3%; 95% CI 78.7%–98.2%). An example of the Reveal LINQ ECGs at implantation is shown in Figure 2.

Secondary objectives

Ten adverse events were reported in 9 patients during 1 month of follow-up. There were 4 procedure-related events (implantation site pain [n = 2] and wound infection [n = 2]), and 2 of these adverse events were also determined to be system-related events (implantation site pain [n = 2]). One of the implantation site pain events was treated with paracetamol/acetaminophen and resolved. The other implantation site pain event occurred when the device was pressed to the rib; no actions were taken, but it prompted the patient to request explantation 5.4 months after implantation. Both wound infections were attributed to an excessive amount of liquid bonding agent used during the procedure and resolved spontaneously by removal of a glue clot; no antibiotic drugs were used to treat the infections. There were 3 serious adverse events in 2 patients, all considered serious because the events resulted in hospital admissions (2 AF events in 1 patient and 1 palpitation event in 1 patient). An additional serious adverse event occurred after 1 month of follow-up, which was a presyncopal event in 1 patient. None of the serious adverse events were procedure or system related. There have been no deaths during the study. Table 2 summarizes all reported adverse events.

The patient survey revealed that there was no limitation in daily activities related to Reveal LINQ for any patient. One patient reported use of over-the-counter pain medications after the procedure. Overall, 76.7% of patients (n = 23) were "very satisfied" and 20.0% (n = 6) were "satisfied" with the Reveal LINQ device. For the MyCareLink home monitor,
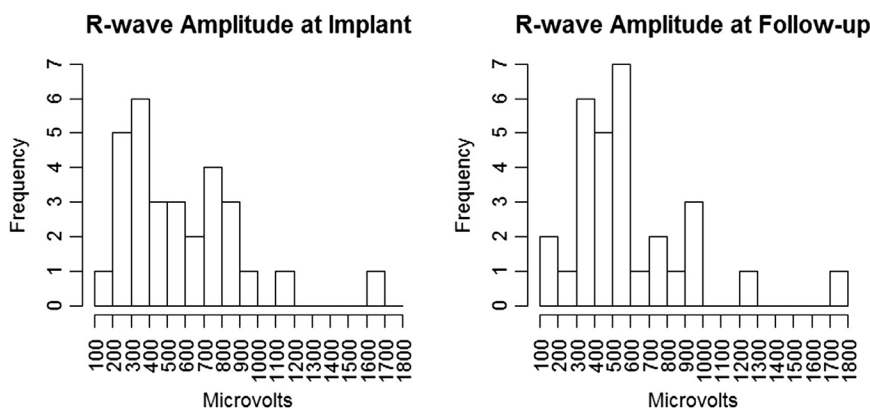

Figure 1 Histograms of R-wave amplitude at implantation and at the 1-month follow-up visit.

Figure 2   Example of an electrocardiogram (ECG) reading from the Reveal LINQ.

96.7% (or 29 patients) rated the monitor as "very easy to use."

Overall physician acceptance was favorable, with the majority classifying the procedure as easy (n = 16; 53.3%) or very easy (n = 11; 36.7%). Results were also positive for the experience with CareAlerts, with 18 of 20 respondents (90.0%) classifying the reports as easy to use compared with traditional monitoring reports. Furthermore, when used for clinical decisions, the event report was classified as "very actionable, no changes needed" by 15 of 16 respondents who used the report (93.8%).

Ancillary objectives

The implanted device depth, as defined by the implanting physician, was 9.1 ± 6.2 mm (n = 30). No devices migrated beyond the threshold of clinical relevance. Results for device migration in the longitudinal, lateral, and rotational directions are presented in Table 3. The average superior-to-inferior longitudinal migration distance was 2.0 ± 3.9 mm (n = 30). Examples of radiographs at implantation and at 1 month are shown in Online Supplemental Figure 3.

Detection of arrhythmias

The device detected, stored, and transmitted 217 episodes in 10 patients during the first 900 days of device follow-up (30 days after implantation for each patient). The episodes detected were AF (n = 111), asystole (n = 95), bradycardia (n = 4), fast ventricular tachycardia (n = 1), and ventricular tachycardia (n = 6). Of the detected AF episodes, 98% occurred in patients with suspected AF, AF ablation monitoring, AF management, or bradycardia by conversion of AF. The detected asystole episodes occurred in patients with syncope, suspected AF, AF ablation monitoring, AF management, or bradycardia by conversion of AF.

Table 2   Adverse events (n = 10) through 1 month of follow-up

Key term	Procedure related	System related	Serious (Y/N)	Days after baseline visit
Cardiac arrest	Not related	Not related	N	0
Wound infection	Related	Not related	N	4
Palpitations	Not related	Not related	Y	3
Wound infection	Related	Not related	N	15
Atrial fibrillation	Not related	Not related	Y	7
Palpitations	Not related	Not related	N	22
Implantation site pain	Related	Related	N	33
Atrial fibrillation	Not related	Not related	Y	24
Angina pectoris	Not related	Not related	N	28
Implantation site pain	Related	Related	N	0

Table 3   Device migration measurements summary

Device migration metrics	From implantation to 1-month follow-up, n = 30 (100%)
Superior-to-inferior longitudinal migration distance, mm	
Mean ± SD	2.0 ± 3.9
Median	0.0
25th–75th percentile	0–0
Minimum–maximum	0–10
Inferior-to-superior longitudinal migration distance, mm	
Mean ± SD	1.7 ± 3.6
Median	0.0
25th–75th percentile	0–0
Minimum–maximum	0–10
Left-to-right lateral migration distance, mm	
Mean ± SD	0.3 ± 1.8
Median	0.0
25th–75th percentile	0–0
Minimum–maximum	0–10
Angular rotation relative to original device implant orientation, n (%)	
0°	27 (90)
0°–25°	3 (10)
Longitudinal axis rotation relative to original device implant orientation, n (%)	
0°	28 (93)
90°	2 (7)

Discussion

This study describes the first clinical experience with the miniaturized Reveal LINQ. We report positive results with regard to (1) ease of implantation, (2) quality of ECGs obtained, (3) remote monitoring as assessed by daily transmissions, (4) absence of major complications, and (5) no significant device migration after a follow-up of 1 month.

The sensing performance in this study was excellent, and the data collected indicate high-quality R-wave amplitude signals compared with a benchmark of at least 200 μV and excellent ECG recordings from the device. Daily wireless transmissions had a success rate of 79.5% (95% CI 69.5%–86.9%) from the Reveal LINQ device to CareLink. The reasons for the majority of transmission failures fell into 2 main categories: either the data were received by the monitor but were incomplete, or the patient was out of range of the monitor.

The device detected 217 episodes in 10 patients during 1 month of follow-up. Although the evaluation of detection performance for atrial arrhythmias via adjudication or other monitoring systems was not within the scope of this report, findings from a recently published study applying the P-SENSE algorithm of the Reveal LINQ device showed improved detection capabilities for atrial arrhythmias, particularly with regard to reducing the number of false-positive events.[10] On the basis of the clinical results obtained, this novel miniaturized device may further expand the indications for clinical use (eg, cryptogenic stroke, monitoring efficacy of rhythm control strategies).

The major limitation of this study is that the follow-up time was relatively short. In addition, the patient cohort was still small. With regard to AF detection, dependence on the ventricular ECG for detection of atrial arrhythmias remains a limiting factor. Results for detection performance are still pending; however, the novel P-SENSE algorithm used has already shown a significant performance improvement in a recent study.[10]

Conclusions

The Reveal LINQ system is functional and safe in patients for whom ICM implantation is indicated. Device miniaturization in combination with technological advances may further enhance its use in daily cardiac care, as well as in clinical research.

Acknowledgments

Appendix
Supplementary data

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.hrthm.2015.02.030.

References

1. Krahn AD, Klein GJ, Yee R, Takle-Newhouse T, Norris C; for the Reveal Investigators. Use of an extended monitoring strategy in patients with problematic syncope. Circulation 1999;99:406–410.
2. Krahn AD, Klein GJ, Yee R, Skanes AC. Randomized assessment of syncope trial: conventional diagnostic testing versus a prolonged monitoring strategy. Circulation 2001;104:46–51.
3. Krahn AD, Klein GJ, Yee R, Hoch JS, Skanes AC. Cost implications of testing strategy in patients with syncope: randomized assessment of syncope trial. J Am Coll Cardiol 2003;42:495–501.
4. Brignole M, Vardas P, Hoffman E, et al. Indications for the use of diagnostic implantable and external ECG loop recorders [published correction appears in Europace 2009;11:836]. Europace 2009;11:671–687.
5. Sanna T, Diener HC, Passman RS, Di Lazzaro V, Bernstein RA, Morillo CA, Rymer MM, Thijs V, Rogers T, Beckers F, Lindborg K, Brachmann J; for the CRYSTAL AF Investigators. Cryptogenic stroke and underlying atrial fibrillation. N Engl J Med 2014;370:2478–2486.
6. Etgen T, Hochreiter M, Mundel M, Freudenberger T. Insertable cardiac event recorder in detection of atrial fibrillation after cryptogenic stroke: an audit report. Stroke 2013;44:2007–2009.
7. Healey JS, Connolly SJ, Gold MR, et al; for the ASSERT Investigators. Subclinical atrial fibrillation and the risk of stroke. N Engl J Med 2012;366:120–129.
8. Ziegler PD, Glotzer TV, Daoud EG, Singer DE, Ezekowitz MD, Hoyt RH, Koehler JL, Coles J Jr, Wyse DG. Detection of previously undiagnosed atrial fibrillation in patients with stroke risk factors and usefulness of continuous monitoring in primary stroke prevention. Am J Cardiol 2012;110:1309–1314.
9. Glotzer TV, Daoud EG, Wyse DG, Singer DE, Ezekowitz MD, Hilker C, Miller C, Qi D, Ziegler PD. The relationship between daily atrial tachyarrhythmia burden from implantable device diagnostics and stroke risk: the TRENDS study. Circ Arrhythm Electrophysiol 2009;2:474–480.
10. Pürerfellner H, Pokushalov E, Sarkar S, Koehler J, Zhou R, Urban L, Hindricks G. P-wave evidence as a method for improving algorithm to detect atrial fibrillation in insertable cardiac monitors. Heart Rhythm 2014;11:1575–1583.
11. Krahn AD, Pickett RA, Sakaguchi S, Shaik N, Cao J, Norman HS, Guerrero P. R-wave sensing in an implantable cardiac monitor without ECG-based preimplant mapping: results from a multicenter clinical trial. Pacing Clin Electrophysiol 2014;37:505–511.

CLINICAL PERSPECTIVES

ICMs have been introduced into daily clinical routine to assist in diagnosing patients with syncope or the detection of clinically significant but infrequent arrhythmias, and they are well represented in current guidelines for such indications. However, there is still an unmet need to better characterize the occurrence and burden of AF in certain patient groups, such as patients with a cryptogenic stroke or patients undergoing AF ablation. In addition, limitations of earlier generations of loop recorders include the need for surgical insertion, patient discomfort, cosmetic concerns, and the quality of the ECG being dependent on the placement technique. Moreover, artifact recording, misclassification of false-positive episodes (supraventricular ectopy labeled as AF), and notification of events that occurs only in the office after a delay are still an issue. This article introduces a new miniaturized ICM with wireless telemetry that was tested in a multicenter clinical trial for remote monitoring of patients with suspected arrhythmias. The new system demonstrated both its functionality (by measuring R-wave sensing and data transmission) and its safety. Compared with the previous generation of implantable monitors, the Reveal LINQ supports improvements in various dimensions: ease of implantation, ECG quality, and remote monitoring. Safety is corroborated by the absence of both major complications and significant device migration. The new ICM has a potential for broadening the current indications for insertable continuous monitoring, for example, in patients with stroke of cryptogenic origin.