Real-world comparison of in-hospital Reveal LINQ insertable cardiac monitor insertion inside and outside of the cardiac catheterization or electrophysiology laboratory

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Background Traditionally, insertable cardiac monitor (ICM) procedures have been performed in the cardiac catheterization (CATH) or electrophysiology (EP) laboratory. The introduction of the miniaturized Reveal LINQ ICM has led to simplified and less invasive procedures, affording hospitals flexibility in planning where these procedures occur without compromising patient safety or outcomes.

Methods The present analysis of the ongoing, prospective, observational, multicenter Reveal LINQ Registry sought to provide real-world feasibility and safety data regarding the ICM procedure performed in the CATH/EP lab or operating room and to compare it with insertions performed outside of these traditional hospital settings. Patients included had at least a 30-day period after the procedure to account for any adverse events.

Results We analyzed 1222 patients (58.1% male, age 61.0 ± 17.1 years) enrolled at 18 centers in the US, 17 centers in Middle East/Asia, and 15 centers in Europe. Patients were categorized into 2 cohorts according to the location of the procedure: in-lab (CATH lab, EP lab, or operating room) (n = 820, 67.1%) and out-of-lab (n = 402, 32.9%). Several differences were observed regarding baseline and procedure characteristics. However, no significant differences in the occurrence of procedure-related adverse events (AEs) were found; of 19 ICM/procedure-related AEs reported in 17 patients (1.4%), 11 occurred in the in-lab group (1.3%) and 6 in the out-of-lab group (1.5%) (P = .80).

Conclusions This real-world analysis demonstrates the feasibility of performing Reveal LINQ ICM insertion procedures outside of the traditional hospital settings without increasing the risk of infection or other adverse events. (Am Heart J 2019;207:76-82.)

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The use of insertable cardiac monitors (ICMs) for long-term continuous monitoring of infrequent cardiac arrhythmias has increased during the past decade. As a result of accumulating evidence, current guidelines recommend the use of ICMs for the evaluation of selected patients with recurrent unexplained syncope (Class I, level of evidence A)[1]; unexplained falls (Class IIb, level of evidence B)[1]; selected patients with suspected or certain reflex syncope (Class IIa, level of evidence B)[1]; atrial fibrillation detection after stroke (Class IIa, level of evidence B)[2] and cryptogenic stroke (Class IIa, level of evidence C)[3]; and for patients in whom epilepsy was suspected but treatment has proven ineffective (Class IIb, level of evidence B).[1]

Historically, ICM insertions have been performed in the cardiac catheterization (CATH) or electrophysiology (EP) lab. This practice made sense due to the larger size of the original ICMs and invasiveness of the insertion procedure. However, the introduction of the miniaturized Reveal LINQ ICM has led to simplified and less invasive insertion procedures, affording hospitals flexibility in planning where these procedures occur within the hospital without compromising patient safety or outcomes.[4-9] Indeed, infection rates reported for the miniaturized ICM are lower (0–1.6%)[4,6-8,10,11] than for previous models (2.0%-4.3%).[12-16] Furthermore, performing ICM procedures outside of the traditional settings can reduce costs,[4,5,9] increase lab efficiency by allocating staff and laboratory resources to more invasive procedures,[4-6,8,9] and improve patient experience.[5,9,10]

The purpose of the present analysis of the ongoing Reveal LINQ Registry is to provide real-world procedure characteristics and safety data regarding the ICM insertion procedure performed in the CATH/EP lab or operating room and compare it with insertions performed outside the traditional settings within the hospital.

Methods

Study overview

The Reveal LINQ Registry is an ongoing, nonrandomized, observational, multi-center, global study (ClinicalTrials.gov, NCT02746471). Its purpose is to generate reliable long-term "real-world" data of product performance, economic valuation, site-of-service procedural information and to identify the value of the Reveal LINQ ICM (Medtronic Inc., Minneapolis, USA) in the care pathway. In total, 1613 patients monitored with the ICM have been enrolled and will be followed prospectively from insertion for up to 3 years. Follow-up visits are scheduled every 6 months post-device insertion, while real time reporting is required for adverse events that are potentially system related or procedure related as well as stroke, TIA, bleeding events, and ablation-related events. Patients were eligible for the study if they received an ICM for any of the approved indications including: clinical syndromes or situations at increased risk of cardiac arrhythmias, as well as transient symptoms suggesting a cardiac arrhythmia, such as dizziness, palpitations, syncope, or chest pain. The study was designed and is being conducted in accordance with the declaration of Helsinki. The local Institutional Review Boards or Ethics committees have approved the study protocol at each participating center, and all patients have provided written informed consent.

The present analysis included patients enrolled before or on the day of ICM insertion and who had the procedure performed at least 30 days before the database freeze cutoff date. This was to provide an opportunity to report any early procedure-related adverse events (AEs).

Study procedures

The ICM insertion procedure for this registry has been previously described.[17,18] The procedure was performed following the standard insertion practice at each center. In particular, the choice of procedure site of service, use of intravenous moderate sedation, wound closure method, use of antibiotics, and ICM fixation (use of sutures to hold the device in place) were performed at physician discretion. For this analysis, the site of service defined as "in-lab" included cardiac catheterization (CATH) lab, electrophysiology (EP) lab, and operating room, whereas "out-of-lab" referred to other locations within the hospital, such as procedure room, clean room, and room adjacent to an electrophysiology lab (EP lab holding area).

Definition of ICM/procedure-related adverse events

An ICM- or procedure-related adverse event (AE) was defined as a clinical sign, symptom, or health condition that was causally related to the device or the insertion procedure.[18] An AE was considered serious (SAE) if it led to device explant; resulted in death or serious deterioration in health as indicated by a life-threatening illness or injury, permanent impairment of body function, or damage; or led to inpatient prolonged hospitalization, a medical or surgical intervention to prevent life-threatening illness, or an injury or permanent impairment to a body structure or body function.[18] AEs were reported upon occurrence and defined by the investigators based on their clinical acumen.

Data analysis

Patients were categorized into 2 arms based on the site of service of the procedure within the hospital (in- and out-of-lab). Comparisons of the in-lab and out-of-lab groups were performed using either the 2-sample t test or Fisher exact test. Patient baseline characteristics were obtained and summarized using descriptive statistics (SAS software, version 9.4, SAS Institute, Cary, NC). A sensitivity analysis was performed to assess the baseline characteristics and adverse event rates at the 14 sites that performed both in and out of lab insertion procedures.

Table I. Baseline characteristics

Patient characteristics	Total (N = 1222)	In-lab (n = 820)	Out-of-lab (n = 402)	*P*
Age, mean (range)	61.0 ± 17.1 (1-92)	59.4 ± 17.9 (1-92)	64.2 ± 14.6 (15-90)	**<.0001**
Male, n (%)	710 (58.1%)	463 (56.5%)	247 (61.4%)	.11
BMI, mean (range) [number of patients with available BMI]	27.9 ± 6.5 (10-61) [n = 1100]	27.7 ± 6.6 (10-57) [n = 743]	28.2 ± 6.2 (16-61) [n = 357]	.25
Primary indication for ICM, n (%)				**<.0001**
Syncope	370 (30.3%)	295 (36.0%)	75 (18.7%)	
Cryptogenic stroke	224 (18.3%)	144 (17.6%)	80 (19.9%)	
Suspected AF	149 (12.2%)	103 (12.6%)	46 (11.4%)	
Palpitations	140 (11.5%)	101 (12.3%)	39 (9.7%)	
AF management	139 (11.4%)	65 (7.9%)	74 (18.4%)	
Post-AF ablation monitoring	56 (4.6%)	24 (2.9%)	32 (8.0%)	
Ventricular tachycardia	47 (3.8%)	17 (2.1%)	30 (7.5%)	
Pre-AF Ablation monitoring	26 (2.1%)	22 (2.7%)	4 (1.0%)	
Transient ischemic attack (TIA)	19 (1.6%)	14 (1.7%)	5 (1.2%)	
Seizures	2 (0.2%)	1 (0.1%)	1 (0.3%)	
Other	50 (4.1%)	34 (4.2%)	16 (4.0%)	
History of COPD, n (%)	55 (4.5%)	40 (4.9%)	15 (3.7%)	.46
History of Cancer, n (%)	119 (9.7%)	83 (10.1%)	36 (9.0%)	.54
Diabetes, n (%)	181 (14.8%)	122 (14.9%)	59 (14.7%)	1.00
Congestive heart failure, n (%)	69 (5.6%)	42 (5.1%)	27 (6.7%)	.29
Peripheral vascular disease, n (%)	44 (3.6%)	25 (3.1%)	19 (4.7%)	.14
History of TIA/stroke, n (%)	380 (31.1%)	255 (31.1%)	125 (31.1%)	1.00
Baseline OAC, n (%)	363/1211 (30.0%)	224/812 (27.6%)	139/399 (34.8%)	**.01**
Baseline antiplatelets, n (%)	474/1208 (39.2%)	318/808 (39.4%)	156/400 (39.0%)	.95

Statistical tests used were: *t* test to compare numeric averages between the 2 groups (age and BMI) and Fisher exact test to compare categorical variables between the 2 groups. Abbreviations: COPD, chronic obstructive pulmonary disease; TIA, transient ischemic attack; OAC, oral anticoagulation.

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Results

Study population

As of October 2017, 1222 patients fulfilled the inclusion criteria for this analysis. Patients were enrolled at 18 centers in the United States (58% of patients), 17 centers in Middle East/Asia (Israel, Saudi Arabia, Japan) (15%) and 15 centers in Europe (Belgium, Germany, Greece, Italy, Netherlands, Portugal, Spain, UK) (27%). The mean age was 61.0 ± 17.1 years and 58.1% were male. The most common primary indications for an ICM were syncope (30.3%), cryptogenic stroke (18.3%), suspected AF (12.2%), palpitations (11.5%), and AF management (11.4%).

The cohort was divided into 2 arms according to the site of service of the ICM insertion procedure, as described in the Methods section. Of the 1222 patients, 820 (67.1%) had procedures performed in-lab and 402 (32.9%) were out-of-lab. Several differences were observed in the baseline characteristics between the 2 groups (Table I). Patients who had the insertion procedure performed out-of-lab were older (64.2 vs 59.4 years, $P < .0001$) compared with the in-lab group. The out-of-lab group contained less patients monitored for syncope (18.7% vs 36.0%), and more patients followed for AF management (18.4% vs 7.9%), post-AF ablation monitoring (8.0% vs. 2.9%), and ventricular tachycardia (7.5% vs. 2.1%) than the in-lab group ($P < .0001$). Another baseline difference was the use of oral anticoagulation therapy, more frequent in the out-of-lab group (34.8% vs 27.6%, $P = .01$). OAC discontinuation (among 360 patients with available data) was more frequent in the in-lab (52.8%; 57 of 221) than the out-of-lab cohort (10.8%; 15 of 139).

ICM insertion procedure

Of 50 centers, 33 solely performed in-lab procedures, (n = 688), 3 solely performed out-of-lab procedures (n = 60), and 14 had a mix of service sites (n = 474). Moreover, a country-based bias was also observed, with 5 countries only performing in-lab procedures (Belgium, Germany, the Netherlands, Saudi Arabia, and the UK). The most common sites of service were EP/CATH labs for in-lab procedures and clean/procedure rooms or non-invasive laboratory for those performed out-of-lab. Insertions were mainly performed by electrophysiologists (90.5%) followed distantly by interventional (5.2%) and general cardiologists (3.9%).

Multiple procedure differences were noted based on the site of service (Table II). Intravenous moderate sedation was more commonly used in-lab (13.2% vs. 0.5% out-of-lab, $P < .0001$). Pre-procedural antibiotics

Table II. Procedure characteristics

Procedure Characteristics	In-lab (n = 820)	Out-of-lab (n = 402)	*P*
Site of service			**n/a**
CATH/EP lab/Operating Room	820 (100.0%)		
Clean/procedure room or non-invasive lab		334 (83.1%)	
Holding area		41 (10.2%)	
Cath lab recovery Room		17 (4.2%)	
Patient Room		6 (1.5%)	
Other site of service*		4 (1.0%)	
Pre-procedural antibiotics	386/812 (47.5%)	46 (11.4%)	**<.0001**
% Oral	25/814 (3.1%)	11 (2.7%)	
% IV	372/812 (45.8%)	35 (8.7%)	
Post-procedural antibiotics	155/813 (19.1%)	22 (5.5%)	**<.0001**
% Oral	82/815 (10.1%)	16 (4.0%)	
% IV	92/813 (11.3%)	7 (1.7%)	
Anesthesia			
Local	746 (91.0%)	399 (99.3%)	**<.0001**
General	18 (2.2%)	1 (0.3%)	**.007**
Intravenous moderate sedation	108 (13.2%)	2 (0.5%)	**<.0001**
Implant tools used			.56
Provided incision and insertion tools	641 (97.1%)	350 (98.9%)	
Provided insertion tool only	9 (1.4%)	3 (0.8%)	
Provided incision/insertion tools and scalpel	5 (0.8%)	1 (0.3%)	
Provided incision tool only	3 (0.5%)	0 (0.0%)	
Scalpel only	2 (0.3%)	0 (0.0%)	
Not specified	160	48	
Device fixation with sutures	142/762 (18.6%)	26/384 (6.8%)	**<.0001**
Wound closure method			
Sutures	378 (46.1%)	100 (24.9%)	**<.0001**
Staples	60 (7.3%)	128 (31.8%)	**<.0001**
Surgical glue	164 (20.0%)	140 (34.8%)	**<.0001**
Adhesive strips	396 (48.3%)	240 (59.7%)	**.0002**

P values are based on Fisher exact test.
*Other out-of-lab sites of service included: nursery room, infirmary, outpatient clinic, and one unknown.

were used more often in the in-lab group (47.5% compared with 11.4% in the out-of-lab group, $P < .0001$). When used, the route of pre-procedural antibiotic administration was mainly intravenous for both types of settings. Post-procedural antibiotics were overall less used. Of the 177 patients who received post-operative antibiotics, 80.2% also received them pre-operatively.

The incision and insertion tools provided with the insertion kit were frequently used in both types of settings (97.1% in-lab vs 98.9% out-of-lab). Device fixation with sutures was performed in 14.7% of patients and more often in-lab than out-of-lab (18.6% vs 6.8%, $P < .0001$). Finally, the preferred methods of wound closure in-lab were adhesive strips (48.3%) and sutures (46.1%), whereas adhesive strips (59.7%), surgical glue (34.8%), and staples (31.8%) were predominantly used out-of-lab.

ICM/procedure-related adverse events

The mean follow-up period was 10.4 months (0.0-35.6). Implants were included until one month prior to visit cut-off date to allow time for reporting adverse events. Overall, 19 ICM/procedure-related adverse events (AEs) were reported in 17 patients (1.4%). The event rate per subject was 1.3% in patients from the in-lab group (n = 11) and 1.5% in patients from the out-of-lab group (n = 6). No statistically significant difference ($P = .80$) was observed in the occurrence of AEs between the 2 arms (Table III). AEs in 10 of these patients were classified as serious (SAEs) because they resulted in repositioning or removal of the ICM (2 infections, 4 pocket erosions, 2 implant site pains, 1 implant site bleeding, 2 device extrusions, and 1 migration within the body) (Table IV).

AEs in the other 7 patients were not serious and consisted of: 5 minor infections (treated with oral antibiotics), 1 skin abrasion (treated with topical cortisone), and 1 implant site pain (accompanied by some drainage following removal of the surgical glue by the patient; the wound was reclosed, and oral pain medication and antibiotics were prescribed). Of the 7 patients with infections, 4 were from the in-lab group and had received pre-procedural antibiotics, whereas 3 had the insertion performed out-of-lab and did not receive antibiotics. The overall infection rate in the cohort was 0.6%.

A sensitivity analysis was performed considering the 14 centers where the procedure took place in both sites of service (n = 474; 132 in-lab and 342 out-of-lab). It did not show any statistically significant differences between the

Table III. ICM/procedure-related adverse event rate per subject

	All Adverse Events			Serious Adverse Events		
AEs	In-lab (820)	Out-of-Lab (402)	*P*	In-lab (820)	Out-of-Lab (402)	*P*
Infection	4 (0.5%)	3 (0.7%)	.69	2 (0.2%)	0 (0.0%)	1.00
Device Extrusion	2 (0.2%)	0 (0.0%)	1.00	2 (0.2%)	0 (0.0%)	1.00
Implant Site Bleeding	1 (0.1%)	0 (0.0%)	1.00	1 (0.1%)	0 (0.0%)	1.00
Implant Site Pain	2 (0.2%)	1 (0.2%)	1.00	1 (0.1%)	1 (0.2%)	.55
Pocket Erosion	2 (0.2%)	1 (0.2%)	1.00	2 (0.2%)	1 (0.2%)	1.00
Migration	1 (0.1%)	0 (0.0%)	1.00	1 (0.1%)	0 (0.0%)	1.00
Skin Abrasion	0 (0.0%)	1 (0.2%)	.33	0 (0.0%)	0 (0.0%)	-
TOTAL	11 (1.3%)	6 (1.5%)	.80	8 (1.0%)	2 (0.5%)	.51

AE, procedure-related adverse event; SAE, serious procedure-related adverse event. SAEs are a subset of AEs.
Note: Number of patients with at least one occurrence of AE (%) are presented. Categories are not mutually exclusive, so the total is not necessarily the sum of the categories.

Table IV. Characterization of ICM/procedure-related serious adverse events

SAEs	Type	Time to SAE (days)	Treatment	Implant settings	IV Proph. Abx	Closure method	Age	Medical Hx
SAE 1	Infection	15	Explant/NR	In-lab	Yes	Strip	55	-
SAE 2	Infection	11	Explant/NR	In-lab	Yes	Strip, Glue	42	DM, HTN
SAE 3	Pocket Erosion	20	Explant/NR	In-lab	No	Glue	78	CAD
SAE 4	Pocket Erosion	134	Repositioned	In-lab	No	Strip	75	HTN
SAE 5*	Pocket Erosion	39	Repositioned Explant/NR	Out-of-lab	No	Glue	62	-
SAE 6*	Pocket Erosion	182						
SAE 7	Implant site pain	27	Explant/NR	Out-of-lab	No	Strip, Staple	88	DM, HTN, CAD, stroke/TIA
SAE 8	Implant site pain	1	Explant/ICM	In-lab	No	Suture, Glue	33	-
SAE 9**	Implant Site Bleeding	7	Surgery	In-lab	Yes	Glue	78	HTN
SAE 10**	Device Extrusion	29	Explant/NR					
SAE 11	Device Extrusion	2	Explant/NR	In-lab	Yes	Strip	60	HTN
SAE 12	Migration	392	Explant/NR	In-lab	Yes	Strip	71	HTN. RD, COPD

Abbreviations: IV Proph Abx, intravenous prophylactic antibiotics; Hx, history; Strip, adhesive strip; Glue, surgical glue; Explant/NR, ICM explanted and not replaced; Explant/ICM, ICM explanted and replaced with a new ICM; DM, diabetes mellitus; CAD, coronary artery disease; HTN, hypertension; TIA, transient ischemic attack; RD, renal dysfunction; COPD, chronic obstructive pulmonary disease.
*Two erosions were reported at different times in the same patient; the first occurred at 39 days and the device was repositioned; the second at 182 days and the device was explanted and not replaced.
**Two AEs were reported in the same patient: the first was an implant site bleeding at 7 days resolved by suturing the implant site; the second was a spontaneous device extrusion at 29 days; the device was explanted and not replaced.

cohorts in terms of their baseline characteristics (same as Table I) or their adverse event rates.

Discussion

We provide real-world evidence that Reveal LINQ ICM insertions performed outside the traditional settings within the hospital are feasible, safe and comparable with insertions performed in the traditional settings. Of the 17 patients with ICM/procedure-related adverse events (1.4%), 11 (1.3%) were observed in the in-lab group (EP/CATH lab/operating room or in-lab) and 6 (1.5%) occurred in the out-of-lab group (procedure/clean room or EP lab holding area). There was no statistically significant difference in the number of infections according to procedure settings (P = .69). The overall event rates were 1.4% AEs, 0.8% SAEs, and 0.6% infections. To our knowledge, this is the second largest prospective analysis, assessing the safety of performing Reveal LINQ ICM insertions outside of the traditional hospital settings in 50 international centers.

The LOOP trial is the largest study reporting on procedure complications related to the Reveal LINQ ICM, with 1420 patients inserted in an EP lab (47%) or an outpatient procedure room (53%) at four different centers. Some of their results are comparable to the present study: AE rate of 1.7%, SAE rate of 0.6% (requiring device explant), and infection rate of 0.9%.[7] In contrast, LOOP found a higher infection rate in the group receiving the ICM in outpatient procedure rooms compared to the EP lab (1.6 vs 0.1%, P = .004) despite administration of pre-procedural antibiotics in over 95% of patients. LOOP recorded more adverse events requiring explant among insertions performed by physicians in training than by senior cardiologists and a reduction of this rate over time, showing a decrease in risk as experience is gained.

LOOP and the present study showed some differences when comparing the frequency of wound closure

methods. Whereas LOOP reported use of one or a combination of adhesive strips (89%), sutures (29%) and surgical glue (22%), the Reveal LINQ Registry used adhesive strips (52%), sutures (39%), surgical glue (25%), and also included staples (15%). Another difference was that we observed less serious adverse events (requiring explant) when sutures were used, compared with other wound closure methods. However, the sample size of patients with these events was too small to reach any conclusions. In this regard, LOOP found a similar proportion of SAEs when sutures were used vs. not.

The results presented here are comparable with those reported by the Reveal LINQ™ in-Office 2 (RIO 2) randomized trial. In that study, the safety of the Reveal LINQ insertion was compared in-office outside the walls of the hospital vs in-hospital locations in 482 subjects. The procedure location for the in-hospital arm in their study was equivalent to the in-lab group in this analysis (EP/CATH lab/operating room). Their results showed <1% of procedure-related complications for both arms and no infections.[10] Some of the differences between this real-world registry, where procedures were performed at the physician's discretion, and the RIO 2 controlled trial include the requirement for physicians to use the provided insertion/incision tools, a LINQ supply kit and to meet sterility standards for a surgical procedure (use of surgical hand antiseptic before the procedure, gloves, gown, mask and have all patients draped or wearing a mask). Despite these differences, results showed that the complication rate associated with the Reveal LINQ procedure was low among both types of practice environments. In addition, several single-center studies have reported on adverse events related to procedures outside the traditional hospital settings within the hospital, demonstrating SAE and infection rates ranging from 0 to 1.1%.[4,6,8,11,19]

By its nature and purpose, the Reveal LINQ Registry reflects real-world practice of the ICM insertion procedure in a multitude of international sites. It shows significant differences in some patient baseline characteristics (age, primary indication for ICM and oral anticoagulation therapy) and with respect to how the procedure is performed in-lab vs out-of-lab (use of prophylactic antibiotics and route of administration, intravenous moderate sedation, use of provided implant tools, device fixation with sutures, and wound closure methods). However, because procedures performed in- and out-of-lab were highly correlated to country and center, the differences found do not necessarily reflect differences between in- and out-of-lab populations, but instead may be confounded by other factors. One of the differences was that patients in the out-of-lab cohort were older and more likely to be on oral anticoagulation therapy, conferring them a higher risk of infection. Moreover, OAC discontinuation was more frequently observed in the in-lab cohort. Despite this, the infection rate was comparable and low for both groups. Overall, the fact that the differences observed had no apparent effect on the occurrence of AEs suggests that, by following conventional sterile techniques, the insertion of the miniaturized ICM can be performed safely outside the traditional hospital settings.

The reduction in size of the Reveal LINQ ICM has led to changes in the procedure when compared to previous iterations of the device. In general, previous ICM models were implanted in-lab; the patient generally received prophylactic antibiotics; the formation of the subcutaneous pocket was done manually; and sutures were generally used for active fixation of the device and for incision closure.[12-16,20,21] Conversely, miniaturization of the ICM is leading to an increasing number of procedures performed out-of-lab, both within this registry and as shown by other studies.[4,6-9,11,19]

Another trend observed was a reduction in the use of antibiotic prophylaxis. Since the first interim report of this registry (including 122 patients)[18] the use of pre-procedural antibiotics decreased from 42% to 35%, with no effect on the infection rate which has remained low (1.6% and 0.8%, respectively). Moreover, the use of prophylactic antibiotics was only 14% in the out-of-lab group. These variations can be partly explained by the fact that many US clinicians are moving away from administrating antibiotics for clean procedures.[17,22] Another reason may be that the preferred route of antibiotic administration observed in this registry has been intravenous, and this method is less practical in out-of-lab settings.

Other aspects of the procedure that have become simplified because of the smaller size of the device are: its insertion with the provided syringe-like tool, which forms a tight subcutaneous pocket around the device; the absence of device fixation with sutures; and wound closure, traditionally performed with sutures, is also including other methods such as staples, surgical glue, and adhesive strips.[4,6,8-10,19]

Limitations

One of the limitations of this registry is that it does not collect detailed information on procedural aspects related to sterility, namely prepping, draping, use of surgical mask, gown, and gloves. However, the low infection rate reported supports the assumption that conventional best practices were followed regardless of the site of service. Another limitation encountered has been collecting data for the type of anesthetic used. Although it was possible to select multiple options in the case report form (including local anesthesia, intravenous moderate sedation, and general anesthesia), local anesthesia use was lower than the expected 100%, suggesting that this option was not selected when intravenous moderate sedation was administered. A third limitation is that this is a post-market observational registry and patients were

enrolled in the real-world settings without randomization. Therefore, differences between in- and out-of-lab populations are confounded by other factors, such as center and country. In this regard, most centers performed only in-lab procedures and these included more than half of patients.

Conclusion

In summary, this analysis shows that performing the ICM procedure outside of the CATH/EP lab or operating room within the hospital is possible without increasing the risk of infection or complications. However, it is of great importance that the implanting physicians use best surgical practices, regardless of the site of service.

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