



## Research Article

# Single Center Experience on the Explantation of Insertable Cardiac Monitors Outside the Electrophysiology Lab

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### Abstract

#### Introduction

It has been shown that insertable cardiac monitor (ICM) can safely be implanted in less intensive hospital settings (LIHS). Aim of this analysis is to assess feasibility and safety of ICM explantation or replacement (EoR) procedures, when performed in a LIHS, like a room outside the Electrophysiology/Catheterization laboratory or Operating room (EP/CATH/OR).

#### Methods

We prospectively collected data of consecutive patients indicated for explanting an ICM (Reveal LINQ™-Medtronic Inc) in our center due to recommended replacement time (RRT). ICM implant indication, performed ICM diagnoses, R wave sensing amplitude and signal quality at explant and replacement (if performed), procedure times during the procedure were collected.

#### Results

From April 2020 and October 2022, 119 patients (60.4±16.9 years, 69% males) underwent a ICM EoR in our center. 60% of ICM allowed the physician to make a diagnosis during device life span. 24 (20%) of ICM were replaced by injecting the device in the same pocket where previous ICM was explanted. R-wave amplitude measured by the new ICM was not significantly different from pre-explant value (0.9±0.5 mV vs 0.8±0.4 mV; p=NS). Total procedure time was 8.5±1.0 min for explant and 9.4±1.1 for replacement procedure. No complications or infections occurred during ICM EoR procedures and at 3 months after the procedure.

#### Conclusions

The EoR of insertable cardiac monitors outside the CATH/EP laboratory can be safely performed in clinical practice. When, in about 20% of patients, physician opted to implant a new ICM, it can be easily implanted in the same pocket, getting the procedure easy and fast.

**Keywords:** Insertable Cardiac Monitor; ICM Explant; ICM Replacement; Outpatient Procedures.

## Introduction

Insertable cardiac monitors (ICM) are indicated in a variety of clinical situations when continuous cardiac monitoring over extended periods of time may be needed for proper diagnosis and treatment such as recurrent unexplained syncope, palpitations, unexplained falls or suspected epilepsy [1], management of atrial fibrillation (AF) particularly after catheter ablation [2], cryptogenic stroke [2,3], and evaluation of ventricular arrhythmias burden in patients with arrhythmic cardiomyopathies or ion channel diseases [4].

Several studies have previously shown that ICM can safely be implanted with a minimally invasive procedure (skin incision <1cm) in less intensive hospital settings (LIHS), outside the cardiac catheterization (CATH) or electrophysiology (EP) laboratory or operating room (OR), with operational benefits [5-11]. However, there are few data so far about the feasibility and safety of performing ICM extraction or replacement procedures in these less intensive hospital settings. In addition, since no guidelines are available to help physicians in the decision of replacing, instead of simply explanting, the ICM in patients without a ICM diagnosis, real world data on percentage of ICM replacements, easiness and safety of the procedure, patient acceptance and the rate of additional diagnoses could be relevant.

The aim of our work is to assess the feasibility and safety of ICM explant and replacement procedures, when performed in a LIHS, outside the EP/CATH/OR, that was, according to the clinical practice of our center (cardiology clinics of the Santa Maria del Carmine Hospital in Rovereto, Italy), a nonsterile outpatient room in the same floor of the EP lab with easy access to all emergency equipment. In addition, the percentage of ICM replacements, patient acceptance, the degree of patient pain and anxiety during the procedures and the feasibility of re-implanting the new ICM in the same sub-cutaneous pocket are also evaluated.

## Methods

We prospectively collected data of consecutive patients indicated for explanting an ICM (Reveal LINQ™ - Medtronic Inc) in our center due to recommended replacement time (RRT) notification received from the remote monitoring system. The study was conducted in accordance with the protocol of good clinical practice and the principles of the Declaration of Helsinki.

Some days before the procedure, the patient was informed about the steps of the procedure and study objectives/data collection and, if he was on warfarin or direct oral anticoagulation therapy (OAC), he was asked to not assume on the procedure day

OAC morning dose, but to postpone it after the procedure or to take only the nightly dose. The discontinuation of antiplatelet drugs on the procedure day was not requested. On the procedure day, the patient signed the informed consent to the procedure and the study, last remote ICM data transmission was checked, the reliability of signal quality and R-wave amplitude sensing were assessed using ICM programmer and following data were collected: patient demographic, initial ICM indication, list of recorded arrhythmic events and the reason for ICM explant or replacement.

In our clinical practice, ICM explant or replacement procedure was performed in a procedure room outside the EP laboratory by an EP specialist, assisted by a specialist nurse. The EP specialist and the nurse washed his/her hands with antiseptic solution, wore surgical cap and mask, sterile gloves and gown. Patient was required to wear head covers and masks as well. The incision site was shaved, washed, draped in a sterile fashion utilizing a fenestrated sterile drape and prepared with a local antiseptic solution. Local anesthesia was obtained with 2% 10cc mepivacaine. No antibiotics were administered. Explant procedure was performed by accessing the device through an incision superior to the device. The device was retrieved using a standard anatomical forceps. In case of ICM replacement, when pre-procedure R-wave sensing was optimal (>0.3 mV) the new device was implanted in the same pocket and the sensing recorded by the new device was verified. Wound closure was accomplished with single absorbable suture and a dressing was applied. During the procedure, total procedure time (from skin incision to wound closure), patient preparation and anesthesia time, ICM explant time (from skin incision to ICM out of the pocket) and re-implantation time (from ICM injection to new ICM wound closure) were collected. Immediately after the procedure we asked the patient to report his pain during the procedure (on a scale of 1 to 5) and his anxiety during the procedure (on a scale of 1 to 5). After the procedure, the patient was asked to stay in the waiting room for 15-20 minutes to monitor clinical status. New ICM was programmed, the patient was assigned with a new remote monitor and he was trained on calling the cardiology department in case of complications at home (hematoma, redness or bleeding at the incision site, ICM decubitus).

## Statistical analysis

Continuous variables with a normal distribution were expressed as mean and standard deviation, while categorical variables were expressed as counts and percentages.

Pre- and post-procedural R-wave amplitude sensing were compared using two-tailed T-student test. Statistical test deemed statistically significant if  $p < 0.05$ . All analyses were performed using SAS 9.4 version software (SAS Institute Inc., Cary, NC, U.S.)

## Results

From 27 April 2020 to 30 October 2022, 119 consecutive patients underwent a ICM explant or replacement in our center due to reached RRT. Patient characteristics, ICM indications and performed diagnoses before explant are reported in Table 1. The average age of the population was  $60.4 \pm 16.9$  years, 82 (69 %) were males. Main indications for the implanted ICM were atrial fibrillation (AF) monitoring (N=34, 29%) and recurrent syncope of presumed cardiac origin (N=27; 23%). Other indications were suspected or high risk of ventricular arrhythmias (N=24; 20%), cryptogenic stroke (N=22; 18%) and palpitations (N=12; 10%). Fourteen (12%) patients were on warfarin and 16 (13%) on direct oral anticoagulation therapy.

Characteristic	Total (N=119)
Male sex (N/%)	82 (69%)
Age (mean $\pm$ STD), years	$60.4 \pm 16.9$
Indications for implanted ICM (N/%)	
• recurrent syncope	27 (23%)
• palpitations	12 (10%)
• suspected ventricular arrhythmias	24 (20%)
• cryptogenic stroke	22 (18%)
• atrial fibrillation monitoring	34 (29%)
ICM diagnosis (N/%)	71 (60%)
• atrial fibrillation	38 (32%)
• pathological pauses	6 (5%)
• atrioventricular block	9 (8%)
• episode of ventricular tachycardia	8 (7%)
• paroxysmal supraventricular tachycardia	10 (8%)

**Table 1:** Demographic at ICM explant

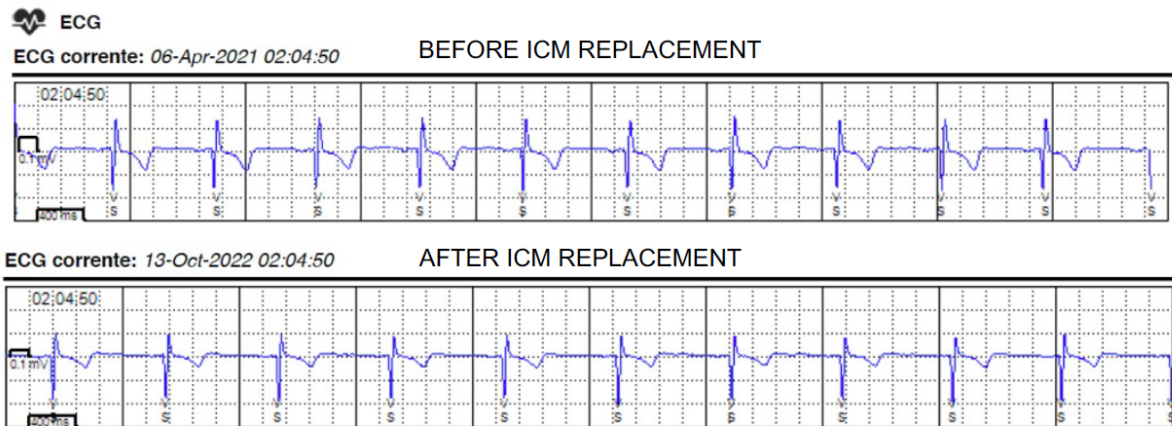
Explant procedure was performed at an average of  $44.1 \pm 10.8$  months from implantation. At that time 48 patients (40%) have not had a diagnosis, while in 71 (60%) patients ICM allowed the physician to make a diagnosis on average after  $18.7 \pm 10.1$  months from implantation. In details, ICM allowed to detect atrial fibrillation (N=38; 32%), pathological pauses (N=6; 5%), atrioventricular block (N=9, 8%), episode of ventricular tachycardia (N=8; 7%) and paroxysmal supraventricular tachycardia PSVT) (N=10; 8%).

Main characteristics of the procedures are reported in Table 2. The ICM was explanted without replacement in 95 (80%) patients, while it was replaced in 24 (20%) patients. The decision to remove or replace the ICM was made by the physician who performed the explant procedure, based on patient medical history, the absence of diagnosis or the detection of unexpected arrhythmic events with the previous ICM during its life span. Re-implanted patients were mainly those indicated to the ICM due to AF monitoring (N=10), high risk of ventricular arrhythmias (N=6) or cryptogenic stroke (N=6). Only two patients with recurrent syncope indications were replaced with a new ICM at RRT. When EP specialist decided for ICM replacement, no patients refused to receive the new device.

Total procedural time (mean $\pm$ STD), min	$8.8 \pm 1.0$
• preparation and anesthesia	$6.0 \pm 0.5$
• explant time	$2.1 \pm 0.7$
Replacements (N, %)	24 (20%)
Re-implantation time, min	$0.8 \pm 0.2$
R wave, mV	
- pre-replacement	$0.9 \pm 0.5$
- after replacement	$0.8 \pm 0.4$

**Table 2:** Explant/replacement procedure characteristics

In all patients undergoing ICM replacement, R-wave amplitude sensing before the explant was optimal (on average  $0.9 \pm 0.5$  mV) and for this reason the new ICM was injected in the existing pocket with the same orientation of initial implanted ICM using the insertion tool provided by the manufacturer. R-wave amplitude measured by the new ICM was not significantly different from pre-explant value ( $0.8 \pm 0.4$  mV;  $p=NS$ ) and the quality of the ECG signal remained optimal. A representative example of R-wave amplitude and quality of the ECG signal before and after ICM replacement is shown in (figure 1).



**Figure 1:** Representative example of R-wave amplitude and quality of the ECG signal before and after ICM replacement.

Patient-reported pain level during the procedure was  $1.2 \pm 0.4$  and the anxiety level was  $1.2 \pm 0.4$  (on a 1 to 5 scale).

Average total procedural time was  $8.8 \pm 1.0$  min ( $8.5 \pm 1.0$  min for explant and  $9.4 \pm 1.1$  for replacement procedures). In details, the preparation and anesthesia time was  $6.0 \pm 0.5$  min, the explant time (measured from skin incision to removal of the ICM) was  $2.1 \pm 0.7$  min; re-implantation time (injection of the new ICM, when performed) was  $0.8 \pm 0.2$  min.

No complications nor infections occurred during ICM explant or replacement procedures, neither any complications were reported by patients in the 3 months after the procedure. During an average monitoring period of  $16.2 \pm 9.7$  months with the 24 replaced ICMs, AF episodes were detected in 8 patients, episodes of non-sustained ventricular tachycardia in 3 patients and an asymptomatic pause lasting 4 seconds in one patient. The new ICM led to therapeutic actions in additional 4 patients: AF ablation was performed in 3 patients (in 2 patients a redo procedure was performed due to AF recurrences) and direct anticoagulation therapy was initiated in one patient after first AF diagnosis.

## Discussion

This single center analysis described the management of patients with ICM battery depletion in the clinical practice of our center.

Main findings of our experience were that: 1. the ICM was confirmed to be a valuable tool in the evaluation of arrhythmias, allowing to made a diagnosis in 60% of patients in the device life span, in accordance with previous studies [12-14], 2. ICM explant or replacement can be safely performed with short total procedure times in a less intensive hospital setting without risk of

infections and other complications [3], in clinical practice, ICM replacements were considered and performed in 20% of patients with device battery depletion, with high rate of patient acceptance and excellent patient tolerance [4], the replacement of ICM during explant procedure can easily be performed by injecting the new device in the existing pocket maintaining good R-wave sensing and quality of the signal.

The diagnostic yield of loop recorders and ICMs has been assessed in a various set of implant indications by several previous studies. In a meta-analysis of 49 studies that included 4381 patients with unexplained syncope [13], the diagnostic yield for the detection of arrhythmogenic syncope was 26.5%. The CRYSTAL-AF trial [12] revealed that the ICM can detect subclinical AF following cryptogenic stroke in 30% of patients during a 36-months follow-up after implantation. Moreover, Giada et al. [14] found that ICM allowed to make a diagnosis in 73% of patients with infrequent palpitation.

Our study showed that during a monitoring period of at least 3 years for all patients, ICM provided a diagnosis and allowed appropriate treatment in 60% of patients implanted according to current guidelines for a variety of indications.

At battery depletion, the ICM can be removed by an easy explant procedure. Our study provides real-world evidence that ICM explantation and ICM replacement are feasible and safe procedures, even when performed outside the traditional settings (EP/CATH laboratories or operating/surgery rooms), but within the hospital. Several single-center studies [5-6, 9, 15-16] and one large multi-center study [8] have already reported that the rate of adverse events related to ICM implantation procedures performed outside the traditional hospital settings, but within the

hospital, ranges from 0 to 1.1%. A randomized study [10] has also demonstrated that, when ICM implantation procedure is performed in procedure or office rooms outside the walls of the hospital, the risk of procedure-related complications is lower than 1% and no infections occurs, if physicians use the provided insertion/incision tools and 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). Recently Reveal LinQ Registry confirmed previous results in the real-world practice of a multitude of international sites, showing that out-of-lab group procedures have low infection rate (0.7%) and serious adverse event rate (0.5%), comparable with in-lab procedures [7].

However, few data are available about explantation procedure out of CATH/EP laboratory settings. A preliminary experience by Yarlagadda et al. showed that no complication occurred in 51 ICM explant procedures performed in a Cardiology clinic room [17]. In Yarlagadda's report device pocket was prepped with Chlorhexidine and a chest drape was applied. Some patient underwent a single prolene suture and no peri procedure antibiotics were used. Our study confirmed the safety of explant procedure in a procedure room outside the Cath/EP laboratory in a larger cohort of patients.

It's well known that longer cardiac rhythm monitoring allows greater number of diagnoses. In patients with syncope, 20% of recurrent syncope diagnosed with ICM occurred after 2 years (18). In cryptogenic stroke patients, 88% of patients who had AF would have been missed if only monitored for 30 days [12, 19]. However, how long to monitor has not been established yet and in clinical practice some physicians prefer to replace device at battery depletion in some patients when diagnosis was not done in device life span or in patients with atrial fibrillation when continuing rhythm monitoring can be useful for therapy management. In our experience, leaving the decision to the implanter physician based on patient needs, we found that ICM replacement was performed in 20% of patients indicated to ICM explantation and this led to therapeutic intervention in 16% of them (3 AF ablation due to AF recurrences and 1 OAC initiation due to first AF diagnosis). Although we could believe that patients are not prone to maintain the device for longtime, as reported in the TRACK AF trial [20], in our experience no patients required device explantation before RRT and, when ICM replacement was proposed, all patient accepted the procedure. Probably due to the very short procedure time (less than 10 minutes) and the out of the EP/Cath laboratory environment where the procedure was done, patient had low levels of anxiety at the explant or replacement procedure and pain was well tolerated. Reducing anxiety and pain is an important goal to improve the quality of each procedure and the patient's experience.

An additional insight from our data is that R-wave sensing amplitude is optimal even at RRT, after more than 3 years from

implant. Therefore, when ICM replacement is judged appropriate, the new ICM can be easily performed in less than 1 minute by injecting the new device in the pocket of previous device. With this procedure, R-wave sensing amplitude and the quality of the signal are maintained at optimal levels with the new device.

## Limitations

Main limitation of the study is the observational design and the lack of a control group. For this reason, it is not feasible to draw final conclusions about improvements of performing explant/replacement procedure in outpatient setting or about the optimal length of ECG monitoring. In addition, it is a single-center study with a moderate sample size with only one ICM system represented. This may have led to a selection bias. However, consecutive patients indicated for ICM explant at the site were included in the study.

## Conclusions

The explant and replacement of insertable cardiac monitors in less intensive hospital settings, outside the CATH/EP laboratory or operating room, can be easily performed in clinical practice, well accepted by the patient and safe. In our center, the decision for ICM replacement at explant has been taken in 20% of patients. In these cases, the new device was easily implanted in the same pocket, getting the procedure easy and fast.

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