



Insertion of miniaturized cardiac monitors outside the catheter operating room: experience and practical advice

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Received 28 May 2016; accepted after revision 30 August 2016; online publish-ahead-of-print 17 March 2017

Minor surgical procedures are increasingly being performed as outpatient procedures in settings outside hospital operating rooms (ORs). In electrophysiology, the recent miniaturization of insertable cardiac monitors (ICMs) has enabled the routine insertion of the device as a minimally invasive procedure without the need of a catheter OR. However, a shift to office-based environments for minor surgical procedures is associated with some concerns, particularly with respect to patient- and procedure-related safety in the new setting. In the present document, the authors provide practical advice on facilities, practices, and adaptations necessary when performing ICM insertions in office settings, based on available recommendations as well as their own experience with the use of the novel Reveal LINQ ICM. The main differences from in-hospital implant settings are simplified requirements of room, equipment, and insertion procedures, while ensuring and maintaining an adequate, sterile environment. Patient selection is important: certain groups of patients are recommended to be treated in the catheter OR (e.g. those at increased risk for bleeding or very frail elderly individuals). Insertion in alternative positions, as is sometimes performed for cosmetic reasons, should be referred to dedicated hospitals. Quality assurance and internal quality control are critical in the new procedural landscape, and it is important not to trivialize minor surgical procedures. Operators' sharing of experiences and lessons learned, e.g. in the form of registries, should be encouraged.

Keywords

Insertable loop recorder • Outpatient surgery • Quality control

Introduction

Over the last decades, there has been a shift from performing minor surgical procedures in hospital operating rooms (ORs) to physicians' offices. This development towards increased use of less resource-intensive settings and outpatient procedures continues across a range of clinical areas, including otolaryngology, ophthalmology, gynaecology, dermatology, general surgery, gastroenterology, oral surgery, urology, vascular and plastic surgery.¹ Multiple factors are driving the shift, including improvements in anaesthesia, simpler and safer technologies, greater patient acceptance and a need for more efficient use of surgical, human, and financial resources.

In electrophysiology, a more efficient use of resources is seen in the use of ambulatory settings with same-day discharge for a number of procedures. For patients receiving a pacemaker, same-day implantation has long been recognized as a safe way to

reduce resource use and costs for the intervention.² Same-day discharge is also increasingly common with implantable cardioverter-defibrillators^{3,4} although these procedures are still performed in the hospital cardiac catheter laboratory or OR. Until recently, this was also true for insertable cardiac monitors (ICMs, or implantable loop recorders, ILRs), small subcutaneous devices that continuously monitor the heart rhythm and record events over a timeframe of up to several years. Insertable cardiac monitors are commonly used to monitor patients with syncope or stroke of unknown origin for infrequent rhythm abnormalities, as well as for long-term monitoring of atrial fibrillation post ablation.^{5–7}

Although the feasibility of moving ICM implantation outside the catheter laboratory setting was explored a few years ago with promising results,⁸ the implantation of first-generation ICMs was typically performed in the catheter laboratory or OR to allow for a sterile aseptic procedure with local anaesthesia and mild sedation as necessary.

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What's new?

- Available data and experience suggest that a new miniaturized insertable cardiac monitor (ICM) can safely be implanted in an office-based environment.
- However, to ensure optimal patient safety, several aspects need to be carefully observed, including maintenance of sterility, patient selection, and internal quality control.
- The current document provides the authors' experience and gives some practical advice for safe implantation of ICM out of the catheter lab operating room.

The introduction of the miniaturized Reveal LINQ™ ICM⁹ (Medtronic plc, Dublin, Ireland) in 2014 represented a fundamental change in the design of ICMs and the conditions associated with its insertion and use. Measuring only 7 × 45 × 4 mm, Reveal LINQ is ~1 cm³ in volume, one-third the size of an AAA battery (Figure 1). The small size and uncomplicated insertion procedure of the device enable its routine insertion as a minimally invasive procedure without the need of a catheter OR.⁷

The move to increased use of office-based procedures is associated with some concerns, however, particularly regarding the level of patient and procedure-related safety in the new setting. Guidelines on topics, such as minimizing surgical site infection¹⁰, typically focus less on the actual conditions under which minor surgical procedures should take place.¹¹

In the present study, we provide practical advice on the facilities, practices, and adaptations necessary when performing ICM insertions in in-office settings, based on available recommendations and evidence as well as our own experiences with the use of the Reveal LINQ ICM. The primary objective is to avoid surgical site infections and to promote the safety and efficacy of the procedure. Since rules and regulations vary between centres and countries, it is

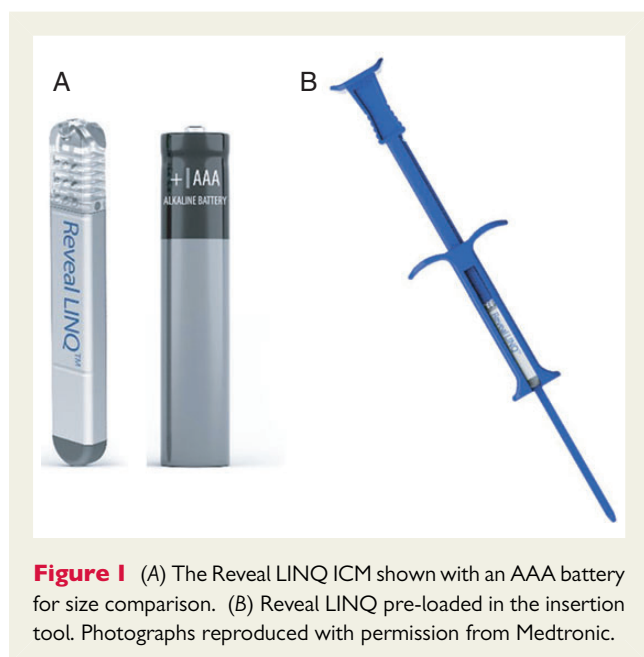


Figure 1 (A) The Reveal LINQ ICM shown with an AAA battery for size comparison. (B) Reveal LINQ pre-loaded in the insertion tool. Photographs reproduced with permission from Medtronic.

Table 1 Key points of consideration for office-based ICM insertion procedures

Facilities and resources

- Ensure there is sufficient space for staff movement in and out of sterile areas
- Provide a space for patient recovery after the procedure
- Install emergency equipment (including medication) in an accessible location on the same floor as the treatment room
- Provide sufficient personnel training and maintain high operator skills
- Ensure that a programmer from the manufacturer is available

Procedures

- Screen and select for eligible patients
- Ensure sterility at all times
- After closure, ensure the wound is clean, dry, and haemostatic
- Allow time for patient recovery after the procedure
- Review and assess the procedure and patients' satisfaction

required that any recommendation be adapted to local conditions to ensure compliance with country and institutional regulations.

Practical advice

The key points of consideration when moving from catheter OR to office-based ICM insertion procedures are summarized in Table 1.

Reveal LINQ

Reveal LINQ represents a significant miniaturization step for ICMs: with a size of 7 × 45 × 4 mm, its dimensions are 87% smaller than those of its predecessor Reveal XT. The insertion opening is as small as 8 mm. The incision is generated with a specific tool, included as part of the insertion kit, to reduce the cosmetic impact of the procedure. Reveal LINQ is delivered pre-loaded in an insertion tool which further simplifies the subcutaneous delivery of the device and ensures consistent, repeatable insertions (Figure 1). The incision is closed, using surgical tape, surgical glue, stitches, or staples.⁹

Room and equipment

The treatment room should be of sufficient size to allow all staff to move freely to and from the sterile area, and equipped with a reclining couch (in case of a vagal episode) and a washbasin for scrubbing. Each procedure requires pre-specified equipment (Table 2). The equipment suggested is divided into items needed for local anaesthesia, personal protective equipment, surgical instruments, and for closing the wound. A separate area for the lay-up of instruments is helpful, but may not be necessary. Obviously, all surgical instruments must be sterile at the point of use, and the use of the provided tools in the insertion kit is strongly recommended. In our experience, these tools, indeed, have a short-learning curve and greatly facilitate the procedure compared with alternative equipment. The insertion kit also aids in the closure of the wound by making a uniform and small incision. Once local anaesthesia has taken effect, the insertion and wound closure can be completed in only a few minutes. Emergency equipment should be located and accessible on the same floor as the treatment room. In most European countries, infection control will need to approve the room and a clinical standard operating procedure, detailing which room will be used for

the procedure and where the equipment will be stored, may be required. For minor surgical procedures, there is no specification of the rate of air changes and no positive pressure air system requirement.¹¹ Natural ventilation is acceptable, but in such cases a fly screen is mandatory. During the procedure, all doors and windows must be shut, and personnel should not be allowed to move in and out of the room.

Patient visit protocol

The main concerns during an ICM insertion procedure performed outside the catheter OR resemble those during similar procedures, e.g. contraceptive implants in general practitioners' offices (Figure 2).

Table 2 Necessary equipment for insertion of the Reveal LINQ miniaturized ICM when performed outside the catheter operating room

Equipment	Details
Local anaesthesia	Syringe, sufficiently long needle for insertion length, anaesthetics
Incision site preparation	Antiseptic solution (i.e. chlorhexidine, betadine)
Personal protective equipment ^a	Sterile gloves, gown, hat, mask
Surgical instruments	Trolley with sterile disposable drapes Sterile drape with a chest hole Manufacturer's implantation kit Surgical marker pen
Device programmer and sterile wand cover	
Emergency equipment within close proximity	
Reclining couch	
Material for skin closure	Surgical glue, surgical tape, stitches, or staples

^aWhen available, the selection of personal protective equipment and anaesthesia should follow institutional recommendations.

It is important to have appropriate patient selection and to adhere strictly to a sterile and clean environment. Operator training remains of paramount importance: the temptation must be resisted to relax demands on operators or to delegate the insertion to inexperienced operators. As with all new procedures, there is a learning curve and the simplification of ICM insertion achieved with the Reveal LINQ system must not lead to a relaxation of quality standards.

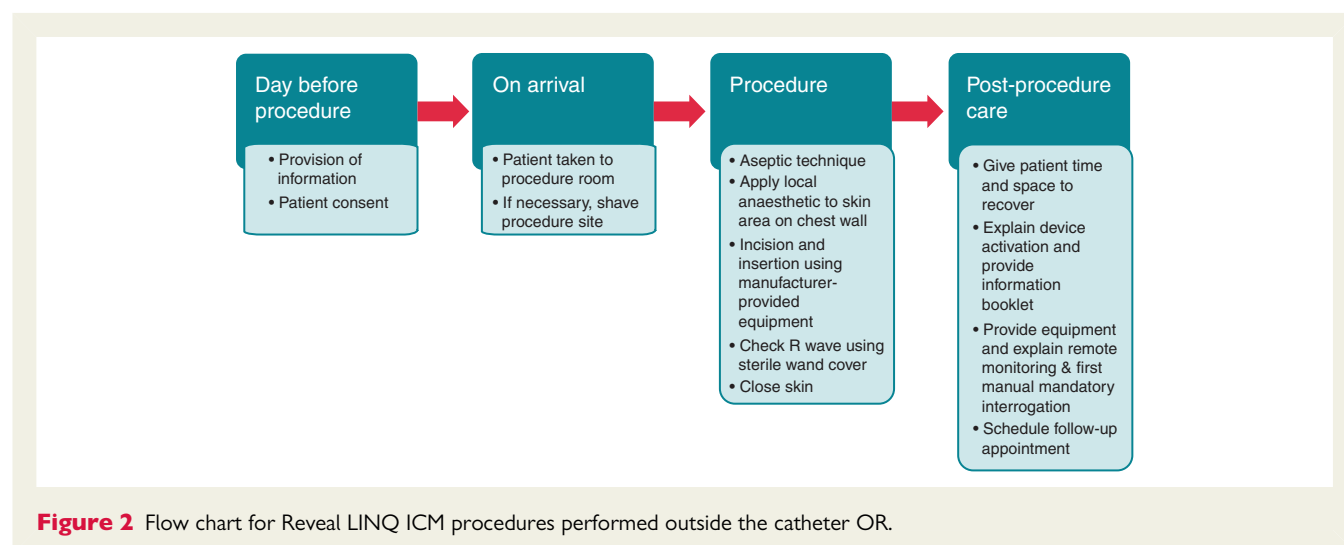
Pre-operative assessment

The decision to perform an LINQ insertion outside the catheter OR should be based on a review and assessment of each individual patient's history and physical status prior to deciding on the appropriate procedure. Patients in whom procedures should not be performed in office include those requiring general anaesthetics or sedation, patients on dual anticoagulation or with a known propensity for bleeding (haemophilia), and those at increased risk of infection (e.g. immunosuppressed patients). Such patient groups may need more dedicated care than is possible in an office setting. Patients with an allergy to local anaesthetics or latex, very frail elderly individuals, patients with dementia, or learning difficulties may also not be suitable.

It is recommended to provide patients well in advance with procedure information and information on what to expect during the procedure. Written informed consent is required prior to the insertion procedure.

Hygiene and skin preparation

Although the Reveal LINQ insertion procedure needs only a minimal incision, it remains a surgical procedure, requiring effective aseptic techniques. This should be performed immediately prior to direct patient contact. Hand scrubbing according to the standard procedures and the wearing of surgical gloves, mask, gown, and cap are mandatory. Hair removal, if applicable, should be done immediately prior to the application of an antiseptic solution. The antiseptic solution should be applied liberally to the procedure site and surrounding area and allowed to dry off completely. If an operator is not familiar with performing a sterile procedure, draping, the



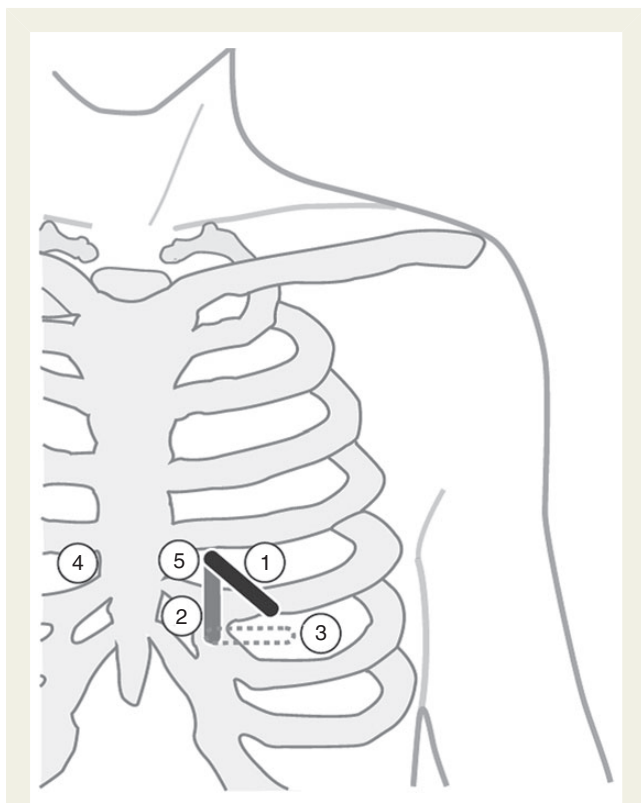


Figure 3 Insertion locations. 1, recommended location 45° relative to the sternum over the fourth intercostal space; 2, alternative position over the 4th intercostal space 2 cm parallel to the sternal border; 3, optional inframammary fold insertion location; 4, V1 ECG electrode location; 5, V2 ECG electrode location.

insertion kit or any other aspect of the operation, it is highly recommended that he or she asks for a proctor for the first cases.

Device placement

The incision and placement of the Reveal LINQ device are performed according to the manufacturer's recommendations. In most cases, the recommended location is within the fourth intercostal space on the left hemithorax at a 45° angle relative to the sternal border (Figure 3). The superior end of the device is positioned ~2 cm (± 1 cm) left lateral to the sternal border. Alternatively, the device can be positioned ~2 cm parallel to the sternal border. The incision can be made at either end of the insertion location. In special cases or for cosmetic reasons, other locations may be considered, but such patients should be referred to a dedicated hospital for the procedure. If the device is inserted in an unconventional location, it is recommended to perform surface mapping prior to the insertion. The R wave amplitude should be checked, using the sterile wand cover prior to skin closure to ensure a minimum voltage of 0.3 mV.

Closure

The small incision usually ensures uncomplicated wound closure, and implanters should use their preferred method, following the manufacturer's instructions. Whichever method is preferred for

closure, it is important that the insertion does not result in tension on the device which might result in the device protruding through the skin. Wounds are usually closed with polyglactin absorbable sutures and covered with a semi-permeable membrane, such as a surgical band-aid. A suture hole on the device header can be used, if necessary, to secure the ICM to the underlying tissue. Cyanoacrylate topical tissue adhesive (surgical glue) can also be used for closure. Adhesive strips are commonly used as an alternative⁹; in this case, surgical guidelines are recommended to apply a non-adhesive dressing to the dry wound for 24–48 h,¹² but in our experience a longer time period (5 days or longer with change of dressing at 4–5 days) is preferable. Caution should also be given that the wound area is clean, dry and haemostatic.

Post-procedure

The insertion procedure is usually straightforward for the patient, but sufficient time should be planned for recovery. After successful insertion of the Reveal LINQ ICM, it is suggested to have the patient sit recovering in a waiting area for a sufficient period (20–30 min). After this time, a brief check should be undertaken to review the wound and to ensure that the patient is alert and orientated. The patient is also guided through the necessary initial manual interrogation of the device. A follow-up appointment should be scheduled after 1–2 weeks, to check wound healing and to remove suture material, if necessary. Finally, it is important that before leaving the centre, patients are provided with a booklet containing information on the system, the necessary steps for wound care and a list of necessary actions, if complications occur.

Medication management

The consensus among the authors is that there is no need for the routine administration of prophylactic antibiotics when inserting ICMs outside the catheter OR as the risk of side effects would likely outweigh the risk of infection. However, local procedures may recommend differently. Currently, there is no direct evidence regarding the need for bridging of anticoagulation therapy, but based on evidence from device implantation it is not considered necessary and may even be harmful.¹³ In general, an International Normalized Ratio (INR) of 2.0–2.5 is recommended for patients on vitamin K agonist therapy. Patients on a non-vitamin K antagonist oral anticoagulants (NOACs) should withhold intake of the morning dose prior to ICM insertion, and take the dose 4–6 h after implantation if good local haemostasis is obtained.¹⁴ Single antiplatelet therapy is generally considered safe and should be continued; patients on dual antiplatelet therapy or any combination of anticoagulants (e.g. NOAC + antiplatelet; triple therapy) should not be implanted in an office setting.

Procedure evaluation

Insertable cardiac monitor insertions in an in-office setting represent a new service model. As with every new process, this should regularly be reviewed among staff and patients. Patient satisfaction and infection rates should be assessed systematically. For all practical purposes, we recommend an internal review after 3 months or 20 implants, whichever comes first, to ensure the process is working well in the new setting and identify potential needs for improvements. It is also recommended to set up a small internal

registry to monitor outcomes and possible complications for quality control purposes.

Discussion

When deciding to perform minor surgery in a setting outside the catheter OR, the guiding concern should be to expose the patient to minimal risk of surgical site infections and to maintain the safety and efficacy of the procedure. The introduction of the Reveal LINQ miniaturized ICM has made it easier for physicians to follow this lodestar when inserting a subcutaneous ECG monitor in an office setting. The practical advice in the present document is based on the manufacturer's recommendations, guidelines for minor surgical procedures, and the authors' personal experience. The main differences from in-hospital implants of earlier generations of ICMs are the simplified requirements of room, equipment, and insertion procedures.

The need for in-hospital implantation of ICMs was questioned even before the advent of the miniaturized Reveal LINQ device, as these devices are comparatively easy to handle, leadless, and do not require transvenous access.⁸ This shift has been accelerated by the availability of the miniaturized device. It should be emphasized, however, that the procedure is not suitable for all patients. Certain groups of patients should still be treated in the catheter OR, e.g. those at increased risk for bleeding or individuals needing general anaesthesia. Furthermore, although insertion in alternative positions is sometimes performed for cosmetic reasons, such procedures are not recommended in an office setting but should be referred to dedicated centres.

Minimizing the risk of surgical site infections is a key objective for any procedure. In this regard, ICMs have a good track record. Infection rates for in-hospital ICM insertions are in the range of 2.3–4.3%^{15–17} and rates around 6% have been reported with the placement of older generation ICMs outside the catheter OR.⁸ As Reveal LINQ requires an 0.8 cm incision, considerably smaller than the ~2 cm needed for the first-generation devices, there is no reason to expect increased infection rates with the miniaturized device. Data on in-hospital implants of Reveal LINQ from a controlled multicentre clinical study and a 'real-life' registry observed an infection rate of 1.3–1.6%¹⁸ although one individual centre has reported an infection rate of 5%.¹⁹ In our experience to date, infections have been rare (<1%). As ICM insertion involves no leads and there is no direct access to the bloodstream, any infections can be expected to be confined to the subcutaneous tissue. Such infections are easier to handle and generally have less severe consequences than infections from transvenous device implantations. An adequate assessment of patients before the procedure will also help identify and direct particular attention to the care of individuals at elevated risk for post-operative infections such as patients with diabetes.

As more reports become available with time, controversies around safety will likely resolve. The ongoing Reveal In-Office 2 (RIO 2) study (NCT02395536) is designed to provide additional data under controlled conditions. RIO 2 is a two-arm, randomized, prospective, non-blinded, multicentre, and non-significant risk study that compares the complication rate from insertion procedures performed outside the hospital OR with rates from insertions performed in the traditional hospital setting. With a target of about

500 patients and a follow-up time of 3 months, it will provide a substantial dataset for safety assessments. RIO 2 is expected to complete in early 2017.

The lower resource use associated with office-based procedures has been shown to lead to lower hospital costs: a recent health-economic analysis in three European countries (the UK, France, the Netherlands) indicated the potential for savings of €600 to €800 per ICM insertion, mostly through the need for fewer staff, less equipment, reduced overhead costs and elimination of hospital beds.²⁰ Many of the resources found in hospital cardiac catheterization or catheter ORs are not required for ICM insertion and can be freed up for more complex uses by the shift to out-of-hospital insertions. Besides the procedural advantages for healthcare providers, the reduced discomfort, inconvenience, and cosmetic impact on patients from the simplified procedure are expected to increase the acceptance of ICM insertions.

Outlook

With the continual squeeze on public resources dedicated to healthcare and the introduction of innovative and improved new treatments, there is both a push and a pull towards increased implementation of minor surgical procedures in settings outside hospitals. Doing so may be cheaper (economic push), and more patients may gain access to care and experience fewer inconveniences from the procedure (unmet-need pull). The force of these factors may lead to more minor surgical procedures taking place outside hospital catheter ORs in the future. The need to implant ICMs in such settings was questioned even before the introduction of Reveal LINQ,⁸ and the technological advancement represented by the miniaturized device has contributed to an increase in outpatient insertion of ICMs. Other ICMs entering the market in the future may well follow this trend.

Quality assurance will be important in the new procedural landscape. To ensure that standards and safety of care remain high, the implementation of uniform, patient-focused care processes will have a crucial role. It is also important not to trivialize minor surgical procedures. Diligence, compliance with standard routines, and staff competence must be maintained at all times. Furthermore, operators' sharing of experiences and lessons learned should be encouraged, particularly in the early days of procedure shifting.

Acknowledgement

The authors are grateful to Pelle Stolt for assistance with editorial matters.

Funding

Support for the development of this manuscript was provided by an unrestricted grant from Medtronic. All opinions stated are those of the authors. The sponsor had no influence on the content of the manuscript but was provided access to the final version to fact-check statements related to the Reveal LINQ ICM.

Conflict of interest: J.S. has received consultant and/or speaker fees from Amgen, Astra-Zeneca, Atricure, Bayer, Biosense Webster, Biotronik, Boehringer-Ingelheim, Boston Scientific, Bristol-Myers Squibb, Cook Medical, Daiichi Sankyo, Medtronic, Novartis, Pfizer, Roche, Sanofi-Aventis, Sorin, St Jude Medical, and Zoll; is Co-director von CorXL; and reports grant support through his institution from

Bayer Healthcare, Biosense Webster, Biotronik, Boston Scientific, Daiichi Sankyo, Medtronic, and St Jude Medical. D.J.W. has received consultancy and speaker fees from Boston Scientific, Medtronic, and St Jude Medical. H.S. has received consultancy and speaker fees from Medtronic. T.R.-F. has received consultancy payments from Medtronic and Boston Scientific. T.L. has received speaker honoraria from Biotronik, Medtronic and St Jude Medical, and research support from Biotronik and Medtronic.

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