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Holding Area LINQ Trial (HALT)

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ABSTRACT

Background: Recent studies have shown that insertable cardiac monitors (ICMs) can be implanted out of the traditional hospital setting and efforts are being made to explore the feasibility of implanting these devices in a specific standardized location other than the operating room or a cardiac catherization/electrophysiology lab.

Methods: This was a prospective, non-randomized, single center post-market clinical trial designed to occur in the holding area of a hospital operating room or cardiac catheterization/electrophysiology laboratory. The Medtronic Reveal LINQ ICM was implanted and patients were followed for 90 days post implant. This study was designed to observe any procedure related adverse events stemming from the holding area implantation.

Results: Twenty patients were implanted at our hospital in a holding room not traditionally associated with the electrophysiology/cardiac/operatory labs. One patient was lost to the 90-day follow up. In one case, ICM implantation led to diagnosis requiring removal of ICM before the 90 day follow up and insertion of a biventricular implantable cardioverter defibrillator (ICD). In the remaining 18 patients, there were no serious complications such as minor skin infections, systemic infections or procedure-related adverse events requiring device explant.

Conclusion: When following a standardized protocol with attention to sterile technique, it is feasible to implant ICMs in a holding area with no procedure related adverse events (AE).

1. Introduction

Insertable cardiac monitors (ICM) have been traditionally used as a diagnostic tool to evaluate possible cardiac etiologies for recurrent unexplained episodes of syncope or palpitations [1–5]. With the advancement in technology, these devices have reduced in size and grown in diagnostic capability, which now includes long-term surveillance of patients at risk for or with documented atrial fibrillation.

These devices have been traditionally implanted in a hospital setting, utilizing resources traditionally reserved for invasive cardiac device implants such as implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices. While these invasive cardiac device implants have inherent need for an advanced level of anesthesia and transvenous leads along with fluoroscopy, ICMs are minimally invasive and require only a small subcutaneous incision of approximately 1 cm in length [6–9]. Because the sensing electrodes are self-contained on the surface of the device, these devices do not require cardiac leads, facilitating the possibility of transitioning the procedure to an outpatient setting [10] such as in the office, clinic setting or holding area of an operating, electrophysiology, or catheterization lab.

Previous studies have shown that the implant procedure itself for the predicate devices is relatively safe with implantation related infection rate at 2–4% [11–13]. Comparatively, in-hospital ICMs implant complications are low (LINQ ICM related infection rate is 1.6% and a procedure-related serious AE rate is 1.6%) [22] and less than pacemaker implant complications [11–14] The most important and relevant complications associated with ICM implantation are those which require surgical intervention to re-open or drain the device pocket. These events not only have the greatest impact on patient health and recovery, but in many cases require removal of the device.

The literature does not provide data regarding the timing of post-implant ICM complications; however, data from other implantable cardiac devices suggests that the majority of pocket

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hematomas and infections will occur within several days of the procedure and that 90 days is an established time frame for monitoring pocket infections [14,19–21].

In this Holding Area LINQ Trial (HALT), the Reveal LINQ cardiac device implantation in a holding area is evaluated as a possible alternative to traditional electrophysiology/cardiac/operatory labs. The primary objective was to characterize the rate of procedure-related complications within 90 days of the implant procedure, which require resolution by surgical intervention. Secondary objectives included evaluating for time and resource utilization, techniques and procedures utilized during LINQ ICM holding area implants, as well as the device functionality at the 90 day follow up.

2. Methods

2.1. Ethics statement

The study protocol and informed consent was approved by the Western Institutional Review Board, Olympia WA. All patients were provided with and signed the IRB approved written informed consent.

2.2. Study overview

The HALT is a prospective, non-randomized, single center post-market clinical trial designed to occur in the holding area of a hospital operating room or cardiac catheterization/electrophysiology laboratory. The Medtronic Reveal LINQ ICM was implanted by experienced electrophysiologists at this institution in adult, non-pregnant subjects with appropriate clinical indications using standard of care techniques and procedures. Twenty (20) patients with established clinical indications for the LINQ cardiac monitoring were implanted using standard of care techniques and procedures; all patients, who were consecutively offered of a device implant in the holding area, gave consent for the procedure. There were no refusals to participate in the protocol. Patients were excluded from the study if they had other cardiac monitoring devices (such as a pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy), coagulopathy (INR greater than 3.0), active infection (within previous 30 days), reduced immune function or otherwise at high risk for infection, life expectancy of less than 12 months, or unusual thoracic anatomy or scarring at the implant site.

2.3. Study procedures

Implants were required to take place in a hospital holding area rather than the traditional facility locations such as the hospital operating room, cardiac catheterization lab, or electrophysiology lab. The holding area was a small patient examination room separated from other patient exam bay by walls and a door, resembling an outpatient clinical exam room (Fig. 1). There was a sink in the patient exam room, laminate flooring, ceiling A/C vent, wall mounted hemodynamic monitoring equipment, and wall mounted oxygen/suction lines. Patient sedation was limited to local anesthetics and/or oral anti-anxiety medications. Intravenous access was only considered in an emergent resuscitation situation. Follow-up visits occurred at 7–14 and 90-days post-implant to identify any adverse events related to the implant procedure. Lastly, device functionality was assessed by collection of the R-wave amplitudes as recorded at the time of implant and subsequent follow up visits.

2.4. Data analysis

All procedure-related adverse events (AE) were collected throughout the study duration. Before the enrollment, the principal investigator defined and categorized adverse events into serious or not serious, procedure-related, and implant site infection related. Serious adverse events were prospectively defined as any event that led to death or to a serious deterioration in the health of the patient that resulted in a life-threatening illness or injury, permanent impairment of a body structure or body function, in-patient hospitalization, or in medical or surgical intervention to prevent permanent impairment. Procedure related events were prospectively defined as adverse events that occurred due to any procedure related to the implantation or surgical modification of the device. Implant site infection adverse events were required to meet one of the following criteria: purulent drainage from the incision, positive culture, diagnosis of implant site infection by the surgeon or attending physicians based on clinical evidence including; pain or tenderness, localized swelling, erythema, warmth, wound dehiscence, or erosion.

3. Results

Twenty patients were enrolled as targeted; the first patient was enrolled on June 19th, 2015 and the last patient was enrolled on November 9th, 2015. Baseline characteristics of the study patients are delineated on Table 1. The average age of study participants was 66 ± 15 years old. Twelve (60%) percent of the study participants were male and fifteen (75%) of enrolled patients were Caucasians. Only four patients (20%) had previous history of coronary artery disease while only one patient (5%) had history of cardiomyopathy. Nine devices (45%) were inserted for the management of known atrial tachycardia or fibrillation, eight devices (40%) were used for the diagnosis of unexplained syncope, two devices (10%) were used for the diagnosis of cryptogenic stroke, while one device (5%) was used for the long term cardiac monitoring post atrial fibrillation ablation. All patients were implanted with Reveal LINQ.

Two board certified electrophysiologists performed the implants in a designated holding room. One physician placed seventeen (85%) of ICMs while the other implanted three (15%) of ICMs. All twenty patients (100%) completed the 7–14 day follow up and nineteen patients (95%) completed the 90 day follow up. One patient was lost to follow up after his initial 14 day follow up. One patient completed the 90 day follow up; however, he received a diagnosis during the 90 days of follow-up based on the ICM data (34 days after implantation) and received biventricular ICD. This patient receive the ICD before the 90 day follow up, but his ICM was not explanted and he completed his ICM 90 day follow up. The last enrolled patient completed the entire 90 day follow up on March 14th, 2016.

The patient and physician preparation was left up to the discretion of the investigator and described in Table 2. However, all patient preparation was done in the designated holding area. Out of all implantations, twenty patients (100%) were prepped with a topical disinfectant agent (chlorhexidine) and twenty patients (100%) were prepped with sterile drape after sterilization of the patient. All patients were given head mask and face mask. All preparation work was done following standard sterile techniques. Local anesthetic was achieved with a subcutaneous analgesic agent. The provider wore sterile gowns, gloves, face mask, and head cover in all cases. In only five cases (25%), the physician used wet scrub technique, while the other fifteen cases (75%) were done after using dry scrub technique. No patient required anxiolytics. No patient was given preoperative or postoperative antibiotics. The most commonly employed closure technique was two interrupted staples for skin closure.

The total procedure time was 60 ± 23 min from the time the patient was brought into the holding area to the time the patient

Fig. 1. Holding area.

Table 1
Patient demographics.

		Total (N = 20)
Age		65.75 ± 15 (range 44–97)
Male sex		12 (60%)
Race	White or Caucasian	15 (75%)
	Black or African American	2 (10%)
	Hispanic or Latino	3 (15%)
Weight (kg)		83.1 ± 22.1
BMI		26 ± 5.66
Hypertension		15 (75%)
Diabetes mellitus		3 (15%)
Hyperlipidemia		15 (75%)
Coronary artery disease		4 (20%)
History of syncope		7 (35%)
History of cerebrovascular accident		3 (15%)
History of atrial fibrillation		12 (60%)
Indications		
Management for known atrial fibrillation		9 (45%)
Diagnosis of unexplained syncope		8 (40%)
Cryptogenic stroke		2 (10%)
Long term cardiac monitoring post atrial fibrillation ablation		1 (5%)

Table 2
Implant preparation.

		Total (N = 20)
Patient preparation		
Topic disinfectant		20 (100%)
Sterile drape		20 (100%)
Mask		20 (100%)
Subcutaneous analgesic		20 (100%)
Physician preparation		
Sterile gloves		20 (100%)
Mask		20 (100%)
Sterile gown		20 (100%)
Wet scrub		5 (25%)
Dry scrub		15 (75%)
Closing technique		
Staple	1	1 (5%)
	2	14 (70%)
	3	3 (15%)
Dermabond		1 (5%)
Suture	1	1 (5%)

was transferred out of the holding area. The implant procedures typically involved one physician and one registered nurse. Patient education followed each procedure and this time was accounted into the total procedure time. Moreover, physician waiting time was also included in this total procedure time.

These study patients tolerated the ICM implantation well in the holding area. Out of eighteen patients, excluding one lost to follow up and one device upgrade, there were no adverse events. There were no procedure related adverse events requiring surgical intervention within 90 days of the implant procedure. There were no serious adverse events or non-serious adverse events requiring explant. Lastly, none of the enrolled patients required antibiotics for infection related adverse events. There were no minor skin infections, systemic infections or deaths.

Only sixteen (80%) R wave amplitudes were available at the 90 day follow up with an average of 0.431 ± 0.216 V. No device required relocation due to poor R wave sensing.

4. Discussion

This study confirms other previous trials' findings that an ICM can be implanted in a non-surgical setting [10], more specifically in a holding area of an operating room, cardiac catherization lab, or electrophysiology lab. In this trial, non-operative setting was carefully selected and there were no adverse events of any kind, presumably owing to adherence to basic sterile patient/physician preparation techniques. This trial demonstrates that an ICM can be implanted in a holding area outside of the traditional in-hospital procedure room when following standard sterile techniques.

Numerous procedures in different medical specialties have evolved out of the in-hospital setting to a less resource intensive setting [15–18]: invasive cardiac implantable electronic devices such as pacemakers and defibrillators transitioned from surgical operating rooms to cardiac catherization or electrophysiology suites, with comparative complications rates [19–21]. When ICMs were first introduced, the same approach was taken to minimize bacterial contamination and infection [10]. However, ICM implantation is minimally invasive and does not require available resources in a cardiac catherization or electrophysiology lab. Therefore, the migration of such procedure from a hospital setting to a holding area or even outpatient environment should be cost effective and will allow hospitals to better utilize their resources for more appropriate complex cardiac procedures.

The major question that needs to be addressed before the complete transition would be the cost effectiveness of such migration as well as possibilities of limiting cost intensive complications. Overall, implanting these devices out of the operating room or cardiac catherization/electrophysiology lab can be economical to patients and for the medical centers as it allows appropriate allocation of resources [23]. Additionally, this study along with other preceding studies demonstrated that outpatient procedure related adverse events requiring surgical intervention was at least comparable if not superior to reported in-hospital ICM implantation complication rates [10,22]. Although, this pilot study looked at a small sample size, it demonstrated that with adherence to standard sterile techniques, the rate of infection related adverse events were nonexistent in our study of 18 patients who completed the 90 day follow up, further supporting an effort to establish an ICM implantation in a non-surgical room setting.

4.1. Study limitation

While the holding area was designed to resemble an outpatient clinical room, it was not distinctly separate from the hospital. Using this study as bridging evidence to implant ICMs in outpatient settings, future studies should be conducted in various office settings. Additionally, this was a non-randomized study with a small sample size.

5. Conclusion

This study successfully demonstrates that the ICMs can be inserted in a non-surgical setting such as a holding area of an operating room, cardiac catheterization lab, or electrophysiology lab. When following standard sterile techniques, it is feasible to implant ICMs in a holding area. This manuscript serves as an initial investigation regarding feasibility of implanting the ICM in a non-electrophysiology/cardiac catheterization lab setting. A larger study is needed to demonstrate that this procedure can be translated to a complete outpatient setting such as an office based location.

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