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Comparison of the Implantable Cardiac Monitor Reveal LINQ Versus Reveal XT in Young Patients

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KEYWORSDS

SUMMARY

We aimed to compare procedure feasibility, complications, recovery time and length of stay, and the clinical impact of the new-generation cardiac implantable loop recorder Reveal® LINQ with a previous-generation implantable loop recorder Reveal® XT. We also compared the mean time to the first event detection after implantation.

We report on a prospective, single-centre, non-randomized, observational experience of consecutive Reveal® LINQ and Reveal® XT implantations in the sterile operating room between September 2014 and April 2018. In all patients, the indications included recurrent syncope of presumed cardiac origin or recurrent unexplained palpitations. All implants were performed in the modified manufacturer method. No significant difference was detectable in baseline characteristics between patients who underwent LINQ (n = 15) or XT (n = 93) device implantation. The procedural time was 11 minutes in Reveal® LINQ vs 20 minutes in Reveal® XT (p< .001) with shorter surgery room occupation time (30 vs 40 minutes) (p< 0.001). The hospitalization time (day hospital) was 6 vs 7.5 hours (p< 0.01). During a mean one-year follow-up, a diagnosis was made in 103 (95.4%) patients and in 73 (70.8%) one or more therapeutic interventions were established following recording of arrhythmias. Theremain pts (4.6%) had normal sinus rhythm during symptom episodes. The mean time from device implantation and the event detection was 3.8 months in Reveal LINQ vs 5.7 months in Reveal XT (p<.001). Complications occurred in 5 (5.38%) patients of XT group and in no patients of LINQ group (p<.001). Reveal® LINQ and Reveal® XT were comparable in identifying the presence or absence of an arrhythmia during syncope and palpitations in young patients with and without structural heart disease and inconclusive conventional diagnostic testing. Noteworthy, LINQ offered shorter procedural time compared with XT and no patients had complications. The earlier diagnosis should be related by the remote monitoring capability of LINQ.

INTRODUCTION

Recurrent syncope and palpitations are common symptoms prompting cardiac valuation in the young populations. Incidence of syncope is difficult to determine accurately as many cases remain unreported. Literature reports a 6-month mortality of 10%, which can go up to 30% if cardiac syncope is untreated [1-7]. The Task Force for the diagnosis and management of syncope of the European Society of Cardiology published guidelines for the diagnosis and management of syncope [8] and the Heart Rhythm Society, the European Heart Rhythm Association and the European Society of Cardiology (HRS/EHRA/ESC) guidelines recommended the criteria for Implanted Loop Recorder (ILR) implantation [9]. In subjects with recurrent unexplained palpitations ILRs is a safe and more

cost-effective diagnostic approach than conventional strategy [10]. The ILRs are devices implanted to aid in the management of syncope and palpitations in young people [4-6]. These devices can be used to record symptom events or auto-record events that meet programmed tachycardia and bradycardia criteria. ILR technology advanced significantly until 2014 with the Reveal LINQ (LINQ) (Medtronic Inc, Minneapolis, Minnesota) with a smaller size than its predecessor, the Reveal XT (XT) (Medtronic Inc, Minneapolis, Minnesota) [11-16]. It needs to be activated either by the patient or a bystander after a syncopal attack. The principle is the same as that of Holter ECG monitoring. ILR have a loop memory that continuously records and deletes electrocardiogram (ECG). There are two ways the cardiac monitor stores to review later: ECG recording stored when the patient or caregiver use the Patient Assistant or automatic ECG recordings based on how the doctor has programmed the cardiac monitor. The device can store up to 30 min of recordings from patient activated episodes, 27 min of automatically detected arrhythmias. On the contrary of the predecessor the LINQ is now capable of wireless telemetry for remote monitoring to a cellular-based Care Link bedside monitor (Medtronic Inc, Minneapolis, Minnesota). The LINQ is small enough that it can be inserted in a minimally invasive fashion using the supplied insertion kit in the outpatient setting. [7,12,14]. The use of LINQ has been widely adopted in the pediatric population given the small size [15-17]. Nevertheless it has been demonstrated that the LINQ implantations is simpler and faster [18-20] but it has also suggested that the LINQ's position in the subcutaneous tissue might be prone to device injury and erosion in active children [21-22]. Our study aimed to assess the characteristics of procedure, recovery, hospitalization times, mean time from implantation to the first event detection, and complications associated with the LINQ device compared with a historic XT group.

METHODS

We report on a prospective, single-centre, non-randomized, observational experience of consecutive young patients with recurrent syncope or palpitations who underwent Reveal LINQ or Reveal XT implantation in the operating room between September 2014 and April 2018. The study population enrolled 15 Reveal LINQ (9 males and 6 females, median age 14 years) and 93 Reveal XT (70 males and 23 females, median age 12 years) patients. Enrolled patients did not receive any study related compensation. Written informed consent was obtained from patients or their families with assent obtained from younger older than 14 years of age. Six patients were submitted previously to cardiac surgery for treatment of congenital cardiac diseases (3 in LINQ group and 3 in XT group). All the younger patient were previously submitted on conventional strategy:

echocardiography, ECG, Holter ECG monitoring, tilt table test, exercise stress test. In addition to the first-tier investigation, other tests performed prior to the receipt of an ILR were brain computed tomography (n=5), electroencephalography (n=6) and electrophysiological study (n=2).

REVEAL XT

Reveal XT implantation was performed in the operating room using sterile techniques under moderate sedation and local anesthesia. IV antibiotics (either cefazolin or vancomycin) were given prior (before 1 h) to skin incision to all patients. A one small incision was made in the left 5th intercostal space and a linear pocket was created to accommodate the device. After obtaining hemostasis, the pocket was irrigated with antibiotic solution and device was secured to the pocket floor. Closure practice later evolved to closing the incision with CT-1 interrupted absorbable sutures (Vicryl Plus antibacterial; Ethicon Inc, Cincinnati, Ohio) prior to applying monofilament polyglytone topical absorbable suture 3-0 Caprosyn (Covidien - Medtronic Inc, Minneapolis, Minnesota). An occlusive dressing was then applied to the site. Post procedural antibiotics were prescribed for all patients for a minimum of 3 days. Patients were recommended to keep the incision dry and avoid a shower for a minimum of 5 days. All patients were regularly followed in the clinic every 3–6 months.

REVEAL LINQ

Patients LINQ were admitted to the surgery area the day of the procedure where they received anesthesia evaluations. Patients were then taken to the surgery room for the procedure and returned to the recovery area to recover from anesthesia effects. All pts were discharged home the same day. All implants were performed in the sterile operating room using the provided toolkit according to the modified recommended manufacturer method [23]. Location for device insertion was practitioner dependent with some devices implanted in a para-sternal or pre-pectoral location (between the 3rd and 5th intercostal space). Before wound closure, the device-recorded QRS amplitude was tested, and if sensing was insufficient (≤ 0.2 mV), one or more device repositions were performed. Patients received either single dose of IV antibiotic during the early implantation period (either cefazolin or vancomycin) prior (before 1 h) to the procedure during the late implantation period. There were no difference in the antiseptic precautions, including use of sterile gloves and mask, by all the personnel involved in the insertion procedure, skin preparation which included use of chlorhexidine-alcohol swabs and the draping technique that were used between the patients. The implantation including the skin preparation is being performed by the electrophysiologist only, with assistance from

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the nurse who was trained in the insertion procedures. All patients were given moderate sedation and local anesthetic at the implantation site. The steps of insertion were in accordance with the manufacturer recommendations as outlined in the LINQ manual except for the modifications described as below: 1. Use of regular scalpel number 11, instead of insertion tool provided by the manufacturer. 2. After obtaining hemostasis, the pocket was irrigated with antibiotic solution and device was secured to the pocket floor. 3. Use of closure practice later evolved to closing the incision with 1-2 interrupted absorbable sutures prior to applying topical absorbable suture material. 4. Post procedural antibiotics were prescribed for all patients for a minimum of 3 days. At device insertion tool was advanced through the incision into the subcutaneous tissue at an angle of 45° to make some space in the dense subcutaneous tissue. The insertion is pre-loaded with the device and which is then "injected" in the subcutaneous tissue. Subsequent to device insertion the tool is withdrawn leaving the device in place. After obtaining hemostasis, the pocket was irrigated with antibiotic solution and device was secured to the pocket floor. Closure practice later evolved to closing the incision with CT-1 interrupted absorbable sutures (Vicryl Plus antibacterial; Ethicon Inc, Cincinnati, Ohio) prior to applying monofilament polyglytone topical absorbable suture 3-0 Caprosyn (Covidien - Medtronic Inc, Minneapolis, Minnesota). An sterile dressing was then applied to the site. Post procedural antibiotics were prescribed for all patients for a minimum of 3 days. Patients were recommended to keep the incision dry and avoid a shower for a minimum of 5 days. All patients were regularly followed in the clinic every 3–6 months and received at the discharge cellular-based CareLink bedside monitor. The LINQ is capable of wireless communication to a cellular-based (provided to the patient). This technology allows for daily downloads of alerts that have been triggered in the LINQ monitor. These alerts are programmed by the implanting physician and may be tailored to the individual patients needs. This alert notification allows physicians to be notified when an alert has been triggered, instead of waiting until the patient has symptoms or at the time of a monthly interrogation, as was the practice in previous generations of the device. The LINQ were programmed postimplantation and patients along with parents were educated in event recording, using the external remote control. They were advised to attend as soon as possible after a symptomatic recurrence.

POPULATION

All 108 patients details the comparison of the various times associated with the ILR implant procedure. Total in-hospital time was defined as the time from initial admission to the surgery room recovery area to time of discharge. Surgery room occupation time was defined as the time when the patient entered the room to the time the patient left the room. Procedure time was defined as the time from skin incision to the time of dressing. Finally, recovery time was defined as the time from dressing the incision to the time of being awake and fully conversational. We sought to evaluate the peri-procedural complications of ILR and compared the outcomes of LINQ with XT device. All patients underwent incision evaluation in the clinic at 7 days post-implantation. Patients were diagnosed to have "complications related to ILR implantation" if they develop any below mentioned complication: device infection, device hematoma, non-closure of the incision with device protrusion.

STATISTICAL ANALYSES

Categorical summary data are presented as frequency with percentage. Continuous data are not normally distributed and, therefore, presented as median with interquartile range (IQR). Descriptive statistics were used to analyze the survey responses. Differences between the group of subjects who received LINQ and those who received XT devices were compared using the Fisher exact test and nonparametric Mann-Whitney U test. Analysis was performed using SPSS statistical software v. 23.0 (IBM Corporation, Armonk, New York). A p value ≤ .05 was considered statistically significant.

RESULTS

No statistical significant difference was detectable in the demographic and clinical data between the LINQ and XT groups (Table 1).

Table 1: Patient Characteristics.

Patient characteristics	XT (number = 93)	LINQ (number =15)	P value
Age (y)	14 [8-16]	12 [8-14	n.s.
Weight (kg)	49.3 [32.6-63.5]	45.5 [36.9-56.4]	n.s.
Female patients	23 (24.7%)	6 (40.0%)	0.05
Indications for ILR			
Syncope	65 (69.8%)	13 (86.6%)	n.s.
Palpitations	28 (30.2%)	2 (13.3%)	0.05

Data are expressed as median [interquartile range] or absolute number (percentage)

During a mean follow-up of over a year in all young people, a diagnosis was made in 103 (95.4%) (14/15, 93.3% LINQ and 89/93, 95.6% XT, n.s.) patients and in 73 (70.8%) (13/15, 86.6% LINQ and 60/93, 64.5% XT p < .001) one or more than one therapeutic intervention was established following recording of arrhythmias. The remain pts (4, 6%) had normal sinus rhythm during symptom episodes. The following ar-

rhythmias were recorded during syncope or palpitations: SVT (supraventricular tachycardia (n = 30/103, 41, 1%) sinus arrest of 2.5 sec (n= 21/103, 28,8%) type II atrioventricular (AV) block (n= 19/103, 26%) and monomorphic ventricular tachycardia (n= 3/103, 4,1%). The mean time from device implantation and the event detection was 3.8 months in Reveal LINQ vs 5.7 months in Reveal XT (p< .001). The procedural workflow was similar in both groups. The LINQ group had significantly shorter times associated with the device implant procedures (Table 2). Of the 15 LINQ patients, 10 (66.5%) were implanted in the prepectoral location, 5 (33.5%) were implanted in the parasternal location.

Table 2: Comparison of times associated with ILR implant procedures between the LINQ and XT group.

Implant procedures	XT	LINQ	P value
Procedure time (min)	20 [15-25]	11 [7-15]	< .001
Room time (min)	40 [32-47]	30 [28-33]	< .001
Recovery time (hours)	7.5 [5-8]	6 [4-9]	< .05

Data are expressed as median [interquartile range]

All XT were implanted in the left sub clavicular pocket. Lastly, the mean procedural time was 11 minutes in LINQ vs 20 minutes in XT (p< .001) with shorter surgery room occupation time (30 vs 40 minutes, p<.001). The recovery times was 6 hours vs 7.5 hours (p< .05) (Table 2). In Reveal XT group 5 complications (5.37%) occurred, namely 3 dehiscence with device protrusions requiring reintervention, 1 superficial infection, 1 hematoma with continued soreness. The complications rate constant during the overall period is 1,5%/year. No patient of LINQ group suffered complication (Table 3).

Table 3: Comparison of procedural characteristics and complications between XT and LINQ groups.

Procedural characteristics	XT group	LINQ group	p-value
Intravenous antibiotic use (%)	93 (100%)	15 (100%)	n.s.
Sutures placed (%)	93 (100%)	15 (100%)	n.s.
Wound dehiscence with			
device protrusion (%)	3 (3.22%)	0	0.05
Infection (%)	1 (0.93%)	0	n.s.
Hematoma (%)	1 (0.93%)	0	n.s.
Cumulative complications (%)	5 (5.38%)	0	0.001

Data are expressed as absolute number (percentage).

DISCUSSION

ILR use is supported by the most recent available guidelines (Class 1 indication) in the evaluation of the syncope and palpitations patient [9]. However, LINQ has a number of revolutionary advancements and it may enable us to develop more robust care pathways for management of syncope and palpitations. In our experience during a mean follow-up of over a year, a diagnosis was made in 103 (95.3%) patients. This may somewhat be explained by the difficult in obtaining an accurate history of the exact nature of symptoms in young children. A diagnostic yeld of 50-67% in determining the etiology of syncope in young patients was reported in three retrospective studies Rossano [6] Sanatani [22] and Babikar [24]. The additional technical features of the LINQ, incorporating a remote control enhances its diagnostic yield. This is especially relevant in young patients where self activation using the remote device may be challenging. The mean time from the event detection to the next theoretical scheduled in office evaluation was 3.8 months in Reveal LINQ vs 5.7 months in Reveal XT (p< 0.001). This earlier diagnosis was facilitated by the remote monitoring capability of the LINQ and by their organizational model involving a remote monitoring team consisting of a specifically trained specialist nurse who reviewed the transmissions on a daily basis and reported significant new events to the electrophysiologist on duty. The Heart Rhythm Society consensus on remote monitoring of cardiac devices [25,26] recognized that remote monitoring of implantable loop recorders may be useful to avoid losing data may be overwritten and to facilitate early diagnosis of asymptomatic events particularly in young people with recurrent syncope of presumed cardiac origin. This results according with the study of Maines et al [27] that for patients with asymptomatic but potentially serious arrhythmias it is current practice to download and review ILR data in-office on a periodical basis (at their institution every six months). However, they conclude this practice has the potential to delay the diagnosis and might result in significant clinical consequences such as recurrent syncope or palpitations. In our single center, prospective study we found that LINQ insertion using modified manufacturer's method had no risk of complications and device infection when compared to XT device implantation. In the literature post implantation infection after ILR implantation is reported to be anywhere between 2 and 5%, despite following proper antiseptic precautions and use of pre-procedural antibiotics either, oral or IV [12,17,23,28]. However, in our study the incidence rate was only 2.7% and only in the XT group. We attribute the lower incidence of infections in our study to the implantation technique and peri-procedural management. Conventional XT devices were implanted in an operative room setting with IV antibiotics and incisions were closed with sutures. Each of these practices was similar to the novel LINQ device insertion, probably contributing to the reduced infection risk. In the LINQ group, the use of smaller incision tool or regular scalpel will increase the chance of incision to heal faster as clearly shown in modified method. Our young

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patients undergoing LINQ implantation were found to no have infections, which is in contradiction with the prior report by Gunda [23]. It is possible that with greater activity levels in younger subjects, the LINQ incision was subjected to stretch, preventing the incision from healing, exposing the device to external environment and increasing the chance of infection. In our study, there were no infections in LINQ patients who received IV antibiotics and antibiotics have been shown to be effective in decreasing the incidence of infections in patients undergoing LINQ implantation [29-30]. Our experience suggest a few modifications to LINQ insertion techniques including suture placement and longer pre-procedural and post-procedural antibiotics which may eventually decrease the incidence of device infections. Although there appears to be a concern for infection with LINQ implantations, our experience is more in line with the low level of device-related infection rates of previous multicenter studies [17-18]. LINQ implantation using the modified manufacturer's technique proposed by Gunda et al [28]23 had significantly less incidence of pocket infection compared to XT (0/15, 0% vs 5/93, 5.38%, p = 0.001) (Table 3). A previous study by Kanters et al [21] detailed the complications comparison between LINQ implant procedures in an outpatient setting and XT implant procedures were realized in a no-sterile setting laboratory. As expected, the study found that LINQ implantations in an outpatient setting are associated with a increased total complication because of the reduction in labor cost, equipment cost, overhead cost, and hospital admission cost. Our study differed from Kanters et al [21] in several aspects. In particular, both the LINQ and XT procedures in our cohort were performed in the sterile operating room. Also Babikar et al [24] with XT in a paediatric setting encountered a complication rate of 8.7%. It should also mention that current real-world practice shows that LINQ insertions are increasingly performed without the use of prophylactic antibiotics, which is associated with a very low infection rate [31- 35].

Study limitations

This is a retrospective review of ILR usage in 108 patients in a single institution. Patients selection for ILR implantation was based on clinical criteria assessed by consultant paediatric cardiologists and paediatric cardiac surgery. The study was neither randomised nor blinded. The number and extent of pre-ILR investigations were at the discretion of the clinician, all of which may have influenced the diagnostic yeld of the device.

CONCLUSIONS

The role of ILR in the investigation of syncope and palpitations should be better defined and more studies should focus on

when it should be offered in the pathway of management of syncope and palpitations also in young patients. This study demonstrates that implantation of the LINQ device has shorter procedural and recovery times. The real advantage of the LINQ is that it automatically notifies Carelink if any arrhytmias is seen, which is very advantageous for this particular type of patient. This device is ideal for close monitoring of symptomatic for syncope and palpitations yet potentially dangerous arrhythmias in young people.

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