Reveal LINQ Versus Reveal XT Implantable Loop Recorders: Intra- and Post-Procedural Comparison

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Objectives To compare the procedure, recovery, hospitalization times, and costs along with patient/parent satisfaction after newer-generation cardiac implantable loop recorder (Reveal LINQ; Medtronic Inc, Minneapolis, Minnesota) and previous-generation implantable loop recorder (Reveal XT; Medtronic Inc).

Study design A prospective study of patients undergoing LINQ implantations between April 2014 and October 2015 was performed. Retrospective chart review of patients undergoing XT implantations was performed for comparison.

Results Thirty-one patients received LINQ and 15 patients received XT. Indications included syncope/palpitations (28/46, 61%), history of arrhythmias (9/46, 20%), arrhythmia burden in congenital heart disease (5/46, 10%), and monitoring in channelopathies (4/46, 9%). The LINQ group underwent more conscious sedation procedures than the XT group (8/31 vs 0/15, $P = .04$) with shorter procedural time (9 vs 34 minutes, $P < .001$), room occupation time (38 vs 81 minutes, $P < .001$), recovery time (21 vs 67 minutes, $P < .001$), and total hospital time (214 vs 264 minutes, $P = .046$). The LINQ group also had shorter return to activity time (2 vs 5 days, $P = 1$). Three device erosions in the LINQ group required reintervention. The LINQ group had fewer body image issues than the XT group (1/26 vs 5/14, $P = .01$) with both groups scoring 5/5 overall patient/parent satisfaction score at follow-up. Both groups had comparable total direct hospital costs (US $5905 vs $5438, $P = .8$).

Conclusions LINQ offers better procedural and recovery time compared with XT. LINQ implantations under conscious sedation reduce total hospitalization time. *(J Pediatr 2017;187:290-4).*

Cardiac implantable loop recorders (ILRs) are devices implanted to aid in the diagnosis of infrequent arrhythmia and unexplained syncope in pediatrics.[1-3] These devices can be used to record symptom events or auto-record events that meet programmed tachycardia and bradycardia criteria. More recent indications have expanded to include the diagnosis of recurrent palpitations, detection of atrial fibrillation, and monitoring of arrhythmia burden in patients with genetic arrhythmia syndromes.[4-6]

ILR technology advanced significantly with the Reveal LINQ (LINQ) (Medtronic Inc, Minneapolis, Minnesota) with an 88% smaller size than its predecessor, the Reveal XT (XT) (Medtronic Inc, Minneapolis, Minnesota).[7] Implantation of an XT in pediatrics typically requires general anesthesia, careful skin incision closure with sutures, and insertion in a sterile environment (ie, electrophysiology laboratory or operating room). Conversely, the LINQ is small enough that it can be inserted in a minimally invasive fashion using the supplied insertion kit in the outpatient setting.[8-10] LINQ implantations have also been shown to be simpler and faster than other ILRs in adults.[6] These characteristics may lead to healthcare cost savings and better user satisfaction.[6,10,11] However, the LINQ has also been shown to carry a higher risk of procedural complications such as pocket infections.[12]

The use of LINQ ILRs has been widely adopted in the pediatric population given the small size, ease of insertion, and diagnostic data quality. However, empiric observations have also suggested that the LINQ's position in the subcutaneous tissue might be prone to device injury and erosion in active children. This study aimed to assess changes in procedure characteristics, including procedure, recovery, and hospitalization times, healthcare costs, and patient/parent satisfaction associated with the LINQ device compared with a historic XT ILR cohort at 2 pediatric electrophysiology centers in the US.

Methods

We performed a 2-center prospective observational study evaluating procedure characteristics and patient and parent satisfaction of pediatric patients undergoing LINQ implantations from April 2014 to October 2015 at St. Louis Children's

ILRs	Implantable loop recorders
LINQ	Reveal LINQ
XT	Reveal XT

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Hospital and University of Iowa Stead Family Children's Hospital. Retrospective chart review of patients undergoing XT implantations was also performed for comparison. Institutional review board approval was obtained at both Washington University in St. Louis School of Medicine and the University of Iowa Carver School of Medicine.

All procedures were performed in the pediatric catheterization laboratory at both St. Louis Children's Hospital and the University of Iowa Children's Hospital. All pediatric patients who were referred for LINQ implantations at either study site were enrolled from April 2014 to October 2015. Enrolled patients did not receive any study-related compensation. Written informed consent was obtained from patients or their families with assent obtained from children older than 8 years of age.

Procedural characteristics were obtained from the patients' electronic medical records and procedural logs. Financial departments at each institution provided device cost, cost of anesthesia, catheterization laboratory recovery cost, total direct cost, and total indirect hospital cost.

Once patients were sedated in the catheterization laboratory and procedural time out was performed, patients were given a single dose of intravenous antibiotics prior to insertion of the device. All LINQ devices were implanted using the provided toolkit. Location for device insertion was practitioner dependent with some devices implanted in a para-sternal, pre-pectoral, or axillary location. Closure of the incision was initially performed with manual skin approximation with Dermabond (Ethicon Inc, Cincinnati, Ohio) applied at the site. An occlusive dressing was then applied to the site. Closure practice later evolved to closing the incision with 1-2 interrupted absorbable sutures (Vicryl; Ethicon Inc, Cincinnati, Ohio) prior to applying topical Dermabond (Ethicon Inc).

Total in-hospital time was defined as the time from initial admission to the cardiac catheterization laboratory recovery area to time of discharge. Catheterization laboratory 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.

Bottom-up cost analysis to compare the costs between the 2 procedures was performed. The financial practices of cost estimation of a LINQ implantation procedure were similar at both study sites. The following cost categories are associated with the procedure: device cost, anesthesia cost, cardiac catheterization laboratory recovery cost, and total direct hospital cost. Each cost category is in turn associated with an overhead cost. The total hospital cost is the sum of the total direct hospital cost and the total hospital overhead cost. Each cost category includes, when applicable, medications cost, equipment cost, and nursing labor cost. The implanting physician's labor cost was not included in the cost estimation.

The overhead cost is the allocation of expense from non-revenue producing departments. The cost is allocated to revenue-producing departments based on their total expenses as a percentage of the total hospital expenses. That cost is then divided by the total revenue of a particular department to derive an overhead cost to charge ratio. That ratio, in turn, gets applied to every charge code the patient receives for that department. For example, a typical pediatric Heart Center will shoulder 2%-3% of the total hospital expense.

User satisfaction surveys were administered at the first follow-up visit, which usually occurred 2 weeks after the procedure. The survey consisted of 14 questions. Initial questions collected demographic data. Next, participants were asked to rate their experience with the scheduling process of the LINQ implantation procedure, anesthesia, procedure time, and time spent in the hospital for the procedure. Finally, participants were asked about the time it took to return to full activity after a LINQ insertion and whether there were any issues with the skin incision. Evaluation questions were based on a 5-point Likert scale. Patients who had previously received XT devices, who were able to be contacted, and who were willing to participate in the study were retrospectively administered the same questionnaire. The study-designed questionnaire was not validated for statistical significance.

Statistical Analyses

Summary data are presented as frequency with percentage. Continuous data are not normally distributed and, therefore, presented as median with IQR. Descriptive statistics were used to analyze the survey responses. Data were also analyzed to compare differences between the groups of users who received LINQ and those who received XT devices 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). Statistical significance was achieved with a P value of $\leq .05$.

Results

A total of 31 patients received LINQ and 15 patients received XT devices in the study. The most common indication for ILR implantation was syncope/palpitations (61%). **Table I** details the demographic and clinical data of the patient cohort. There was no statistical significance in the demographic and clinical data between the LINQ and XT groups.

Because all devices were implanted in the catheterization laboratory, the procedural workflow was similar in both groups. Patients were admitted to the cardiac catheterization laboratory recovery area the day of the procedure where they received nursing and anesthesia evaluations. Patients were then taken to the catheterization laboratory for the procedure and returned to the recovery area to recover from anesthesia effects. Most were discharged home the same day. The **Figure** details the procedure workflow of an ILR implant procedure.

Four patients in the LINQ group and 1 patient in the XT group either underwent another procedure (tilt table test, epinephrine challenge test) or were inpatient when they received the ILR. For these patients, the equivalent to the outpatient total in-hospital time was then calculated as the time the patient was admitted to the catheterization laboratory