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ORIGINAL ARTICLE

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Detection of arrhythmias in adult congenital heart disease patients with LINQ™ implantable loop recorder

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Abstract

Background: Rhythm disorders are the leading cause of morbidity and mortality in adults with congenital heart disease (ACHD). Infrequent or asymptomatic arrhythmias may not be detected by routine monitoring. Implantable loop recorders (ILRs), such as the Reveal LINQ™, have been useful in long-term monitoring for arrhythmias in adults with cryptogenic stroke.

Objective: We propose the Reveal LINQ™ will detect arrhythmias, not documented by other monitoring modalities, resulting in change in management in ACHD patients.

Methods: This is a single center retrospective review of Reveal LINQ™ use in ACHD patients from 2014-2017. Medical records were reviewed to determine cardiac diagnosis, indication for implant, ILR findings, and changes in management.

Results: Twenty-two patients, median age 25 years, underwent ILR implantation. ILR findings resulted in change in management in nine (41%) patients. One-third (3/9) of the patients with clinically relevant events were asymptomatic. Patients with Fontan palliation had the highest number of pertinent positive events (57%). ACHD physiologic class D patients were more likely to have a positive finding (P = .034) compared to other physiologic classes. Majority (75%) of patients with positive events had arrhythmias documented on ILR which were not demonstrated on prior Holter/event monitors. Pertinent negative event occurred in one patient with Fontan palliation (5%) who had syncope corresponding to sinus rhythm.

Conclusion: ILRs are a useful adjunct for arrhythmia monitoring in the ACHD population with clinically relevant events in 41% of patients. A special consideration for ILRs could be made for high-risk asymptomatic patients.

KEYWORDS

adult congenital heart disease, arrhythmia, Fontan, implantable loop recorder, LINQ™

1 | INTRODUCTION

Rhythm disorders are the leading cause of morbidity, mortality, and impaired quality of life in the adult congenital heart disease (ACHD) population.[1] Arrhythmias are a frequent cause for hospitalizations in ACHD patients and increase in prevalence with age.[2,3] Intermittent surveillance using short-term monitors may detect arrhythmias but will miss infrequent or rare arrhythmias. There is a clinical need for long-term, real-time, arrhythmia monitoring in ACHD patients.

Abbreviations: ACHD, adult congenital heart disease; AF, atrial fibrillation; CHD, congenital heart disease; EPS, electrophysiology study; ICD, implantable cardioverter-defibrillator; ILR, implantable loop recorder; IQR, interquartile range; LOE, level of evidence; TOF, Tetralogy of Fallot.

New generation implantable loop recorders (ILRs) such as the Reveal LINQ™ (Medtronic) are useful in diagnosing occult arrhythmias in cases of unexplained syncope and cryptogenic ischemic stroke in adults.[4] The LINQ™ ILR has a rate-based algorithm that monitors heart rate, mean ventricular rate, and heart rate variability, which was FDA approved in February 2017 for arrhythmia monitoring in symptomatic patients at high risk for arrhythmias but has not been approved for use in pediatrics or congenital heart disease. Data demonstrates ILRs are useful for arrhythmia monitoring in adult patients with known AF as well as symptomatic patients without confirmed arrhythmia. Older generation ILRs have been reported in CHD; however, there is little data on the efficacy of new generation ILRs for arrhythmia detection in the ACHD population.[4,5] Two single center retrospective studies have reported the utility of prior generation ILRs in patients with CHD but were limited.[6,7] The newer generation Reveal LINQ™ has automated transmissions that occur monthly or more frequently for programmed events. Reveal LINQ™ vs Reveal XT has shorter procedure time, recovery and return to activity time.[8] We propose that new generation ILRs can be used in ACHD patients for improved arrhythmia detection and monitoring.

2 | METHODS

This is a single center retrospective chart review done from December 2014 to December 2017. Nationwide Children's Hospital Institutional Review Board approved this study and the requirement for informed consent was waived. The study sample consisted of patients with CHD age 18 years and over at time of ILR implantation who were followed at Nationwide Children's Hospital during the study period. ACHD patients with ILRs followed at an outside institution were excluded.

The Nationwide Children's Hospital patient database was queried for all ILR implantations in ACHD patients. A retrospective chart review was performed to collect demographic data, underlying cardiac diagnosis, presence of symptoms, indication for ILR implantation, previous arrhythmia monitoring (24 hour ambulatory Holter monitor and/or 30 day event monitor) and changes in management. The Medtronic Carelink system was reviewed for ILR programming data and all transmissions made by the patients. All tachycardia, bradycardia, pause, and symptomatic events were reviewed by two independent reviewers. No additional transmissions were required for this study. Device programming was at the discretion of the implanting electrophysiologist in collaboration with the patient's primary cardiologist.

The primary outcome measure was the incidence of clinically relevant events defined as ILR findings resulting in change in management; further classified as pertinent positive and pertinent negative events. Pertinent positive events were defined as arrhythmias detected that changed management, including initiation or adjustment of medication, cardioversion, electrophysiology study (EPS), ablation, or implantation of a cardiovascular implantable electronic device. Pertinent negative events were defined as symptoms consistent with indication for implantation which did not correlate with an arrhythmia on ILR.

Data were summarized using frequency with percentage for categorical variables and median with interquartile range (IQR) for continuous variables. Data were also analyzed to compare the differences between patient groups using chi-square and Fisher's exact tests. Analysis was performed using Graph Pad Prism v.7.03. Statistical significance was achieved with a two-sided P value < .05.

3 | RESULTS

Fifty-six Reveal LINQ™ ILRs were placed at our institution of which 22 patients met the inclusion criteria for our study with median age 25 years (IQR 23-37) and were followed for an average of 23 ± 13 months (Table 1). The most common patient diagnoses were Fontan palliation (32%) and Tetralogy of Fallot (TOF) (32%) (Figure 1). Reasons for implant were prior history of arrhythmia, palpitations, dizziness, and syncope with several patients having multiple reasons for

TABLE 1 Patient demographics

Patient characteristic	Frequency, n (%) N = 22
Age (years)[a]	25 (23-37)
Male gender	11(50)
Indication for implant[b]	
Syncope	9 (41)
Palpitations	16 (73)
Dizziness	10 (45)
Prior history of arrhythmia	16 (72)
Routine monitoring	
Routine Holter/EM	21 (96)
Positive finding on prior Holter/EM	16 (73)
CHD complexity[c]	
Simple	2 (9)
Moderate	11 (50)
Complex	9 (41)
Underlying diagnosis	
Fontan	7 (32)
TOF	7 (32)
Other	8 (36)
ACHD physiologic class	
Class A	0
Class B	4 (18)
Class C	13 (59)
Class D	5 (22)

Abbreviation: CHD, congenital heart disease.
[a]Median interquartile range.
[b]Patients may have more than one indication for implantation.
[c]As per the American College of Cardiology Task Force 1 of the 32nd Bethesda Conference Classification of Congenital Heart Disease.

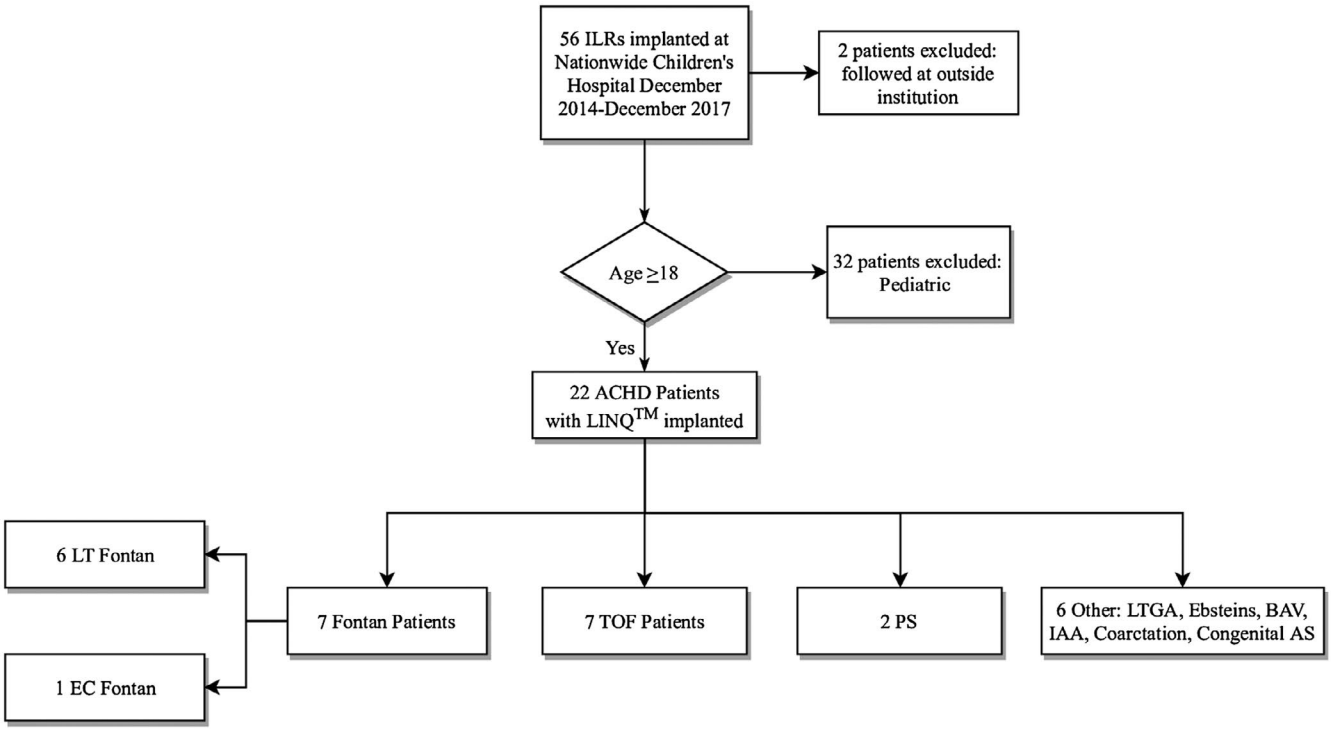

FIGURE 1 Patient screening and selection. Flowchart depicts patient screening and selection. Among the 56 ILRs placed from 2014 to 2017 there were 22 ACHD patients. Abbreviations: ACHD, adult congenital heart disease; AS, aortic stenosis; BAV, bicuspid aortic valve; EC, extracardiac; IAA, interrupted aortic arch; LT, lateral tunnel; LTGA, L-transposition of the great arteries; PS, pulmonary stenosis; TOF, Tetralogy of Fallot

implant. Almost all patients, 21/22 (96%), had appropriate noninvasive arrhythmia monitoring with 24 hour ambulatory Holter monitor or 30 day event monitor prior to ILR implantation. The majority of patients were NYHA Functional Class II (45%) or III (32%). Patients were also categorized based on their ACHD Physiologic class as defined in the recent ACHD management guidelines[9] excluding arrhythmia burden; the majority of patients were ACHD physiologic class C (59%) followed by D (23%). Patient-specific data are included in Table 2.

Clinically relevant events were detected in almost half of patients 9/22 (41%) during the study period (Figure 2). Pertinent positive events were documented in eight (36%) patients. These included four patients with atrial tachyarrhythmia: two atrial flutter, one atrial fibrillation, one ectopic atrial tachycardia; and two patients had ventricular tachycardia. Two patients had pauses that prompted change in management (Figure 2). Change in therapy included medication change, implantable cardioverter-defibrillator (ICD) implantation, pacemaker implantation, electrophysiology study (EPS) andcardioversion. Underlying diagnoses among the eight patients with pertinent positive events were: Fontan (4/8, 50%), TOF (1/8, 12%), Ebstein's anomaly (1/8, 12%), interrupted aortic arch (1/8, 12%), and congenital aortic stenosis (1/8, 12%). The majority of patients with pertinent positive events, 6/8 (75%), had arrhythmias documented which were not demonstrated on prior Holter/event monitors or were different from known arrhythmias. A pertinent negative event occurred in one patient with Fontan palliation (5%) who had syncope corresponding to sinus rhythm. The average time from implant to intervention for positive finding was 284 ± 256 days. In our cohort, three patients had ILR implantation for monitoring of antiarrhythmic effectiveness due to high suspicion for recurrent arrhythmia. All three patients had a change in management based on arrhythmia detected by the ILR. Among these three patients, one had an ICD implantation, one was started on an antiarrhythmic therapy, and one was started on anticoagulation for recurrent atrial fibrillation.

3.1 | Implantable loop recorders in Fontan patients

There were seven patients with Fontan palliation with an ILR implanted for symptoms of syncope (3/7, 43%), palpitations (6/7, 86%), dizziness (5/7, 72%), and/or documented arrhythmia (2/7, 29%). Median age at implant of the Fontan patients was 25.6 years (IQR 23-31) with 57% (4/7) males. Four of seven Fontan patients (57%) had pertinent positive events which resulted in cardioversion, EPS, ICD placement, or initiation of anti-arrhythmic medication. Three (43%) of the Fontan patients had prior history of atrial tachyarrhythmia and ILR was implanted for arrhythmia monitoring among which two had changes in medical management based on arrhythmias detected by the ILR. All four Fontan patients with clinically relevant events had tachyarrhythmia: two with non-sustained ventricular tachycardia and two with supraventricular tachycardia. Among the Fontan patents with pertinent positive events, we found no association with systemic ventricular systolic dysfunction or degree of atrioventricular valve regurgitation to predict those with positive ILR

TABLE 2 Patient clinical history

Patient	Age (y)	Diagnosis	Indication for ILR	ACHD PC	Prior arrhythmia	Finding on ILR	Management
1	24	PS	Palpitation and dizziness	B	None	None	
2	21	EC Fontan	Palpitation, dizziness, and arrhythmia	D	Atrial Tachycardia	VT	Sotalol
3	24	BAV s/p AVR	Arrhythmia	C	NSVT	None	
4	51	TOF	Palpitations and arrhythmia	C	NSVT	Sinus tachycardia	
5	20	TOF	Syncope, dizziness, and arrhythmia	B	Sinus bradycardia	Syncope with sinus pause	Pacemaker
6	24	LT Fontan	Syncope, palpitations, and dizziness	C	None	Sinus bradycardia	
7	28	LT Fontan	Palpitations, dizziness, and arrhythmia	C	NSVT	SVT	EPS
8	23	TOF s/p PVR	Palpitations, dizziness, and arrhythmia	C	NSVT	Sinus bradycardia	
9	22	LT Fontan	Palpitations, dizziness, and arrhythmia	D	NSVT	NSVT	ICD
10	39	LTGA	Syncope, palpitations, and arrhythmia	C	NSVT	Sinus tachycardia	
11	30	TOF s/p PVR	Syncope, palpitations, and dizziness	C	None	Tachycardia due to oversensing	
12	24	LT Fontan	Syncope with negative EPS palpitations, dizziness, and arrhythmia	C	Atrial Tachycardia	Syncope with Sinus tachycardia	
13	22	TOF s/p PVR	Arrhythmia	C	NSVT	Sinus tachycardia	
14	25	ASD, PS	Syncope	B	None	None	
15	39	IAA, BAV	Palpitations and arrhythmia	C	AF	AF	Pradexa
16	25	TOF s/p PVR	Palpitations and arrhythmia	B	PVCs	Sinus tachycardia	
17	40	Ebsteins	Syncope, palpitations, and arrhythmia	D	SVT	Afl	Amiodarone
18	44	LT Fontan	Palpitations and dizziness	D	None	Afl	Cardioversion
19	27	LT Fontan	Syncope, palpitations, and arrhythmia	D	NSVT	Sinus tachycardia	
20	38	TOF	Syncope	C	None	Sinus tachycardia	
21	21	AS s/p AVR	Arrhythmia	C	VT (declined ICD)	Pause	Adjusted Sotalol
22	31	CoA, VSD	Arrhythmia	C	Afl	None	

Abbreviations: ACHD PC, adult congenital heart disease physiologic class; AF, atrial fibrillation; Afl, atrial flutter; AS, aortic stenosis; ASD; atrial septal defect; AVR, aortic valve replacement; BAV, bicuspid aortic valve; CoA, coarctation of aorta; EC, extracardiac; EPS, electrophysiology study; IAA, interrupted aortic arch; ICD, implantable cardioverter-defibrillator; ILR, implantable loop recorder; LT, lateral tunnel; LTGA, L-transposition of the great arteries; NSVT, non-sustained ventricular tachycardia; PS, pulmonary stenosis; PVCs, premature ventricular contractions; PVR, pulmonary valve replacement; s/p, status post; SVT, supraventricular tachycardia; TOF, Tetralogy of Fallot; VSD, ventricular septal defect; VT, ventricular tachycardia.

events. Although three of seven Fontan patients had history of syncope as an indication for ILR implantation, none of the patients with pertinent positive events had syncope during the study period.

3.2 | Implantable loop recorders in TOF patients

There were seven TOF patients who underwent ILR implantation, median age 25 years (IQR 12-22), with symptoms of syncope (3/7, 43%), palpitations (4/7, 57%), dizziness (3/7, 43%), and documented arrhythmia (5/7, 72%). Based on previously published TOF risk stratification for sudden cardiac death, three patients were high risk, three were intermediate risk, and one was low risk.[10] No tachyarrhythmia was documented in TOF patients with mean follow-up 24 ± 12 months. Only one of the TOF patients (14%) had positive finding which resulted in a pacemaker implantation; this patient, with an ILR implanted for a history of syncope, had a symptomatic event corresponding to a sinus pause lasting more than 10 seconds, resulting in pacemaker placement for sinus node disease. False positive tachycardia events occurred in three TOF patients, one of whom had over sensing due to QRS double counting.

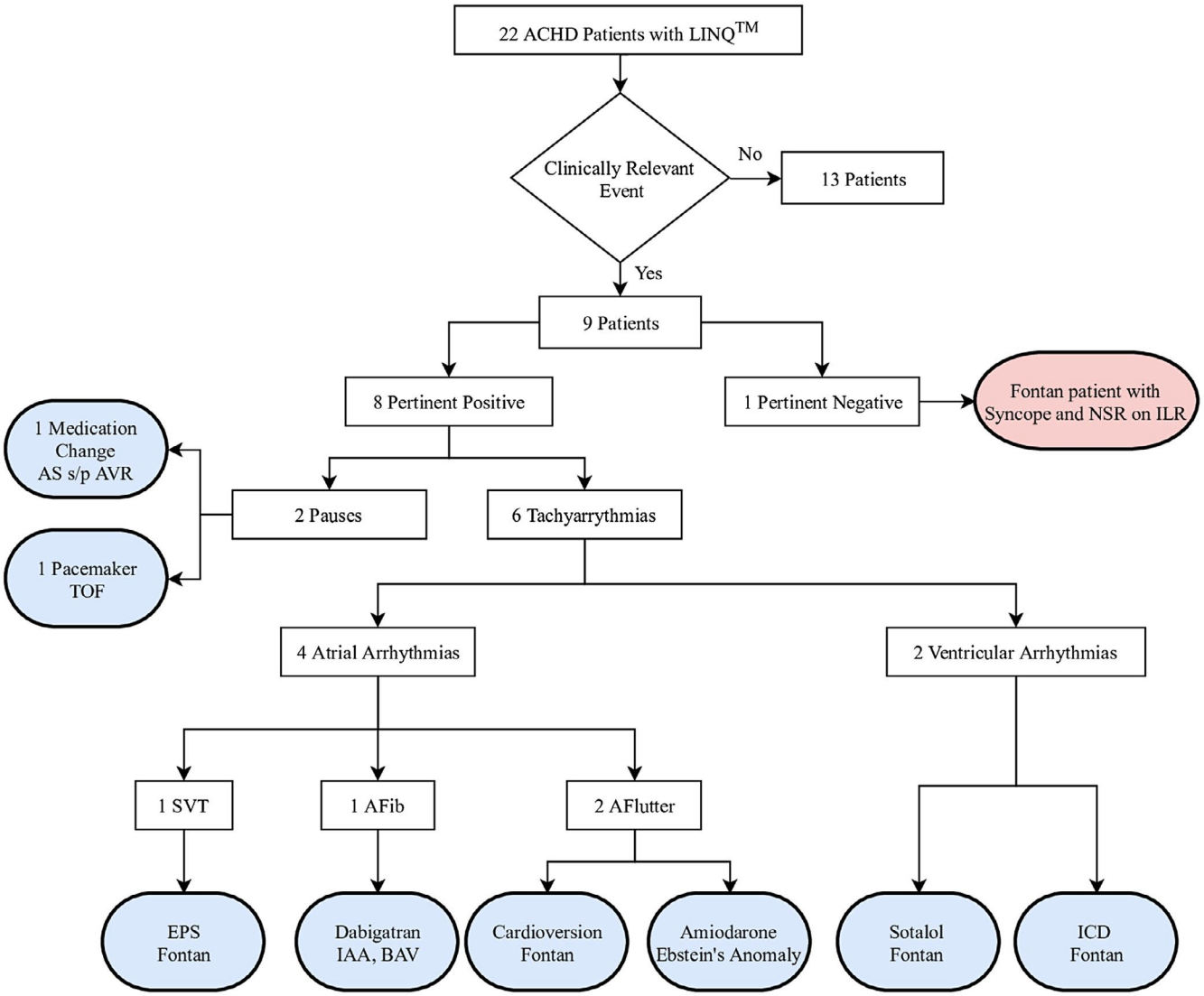

FIGURE 2 Summary of clinically relevant events detected by LINQ™. Flowchart shows the clinically relevant events detected by ILR. There were eight patients with pertinent positive events (blue) and one patient with a pertinent negative event (red). Abbreviations: ACHD, adult congenital heart disease; AFib, atrial fibrillation; AFlutter, atrial flutter; AS, aortic stenosis; AVR, aortic valve replacement; BAV, bicuspid aortic valve; IAA, interrupted aortic arch; ICD, implantable cardioverter-defibrillator; ILR, implantable loop recorder; NSR, normal sinus rhythm; SVT, supraventricular tachycardia; TOF, Tetralogy of Fallot

There was a higher prevalence of pertinent positive events with ILR in patients with Fontan palliation as compared to patients with other diagnoses, though not statistically significant (57% vs 26% $P = .34$). We compared the prevalence of positive events in patients with Fontan palliation and patients with TOF as both groups are known to have high risk of arrhythmia. The prevalence of pertinent positive events in Fontan patients was higher (57%) compared to TOF (14%) ($P = .28$, Fishers exact test).

3.3 | ACHD physiologic class

Recently published ACHD guidelines included a physiologic class based on NYHA functional class, hemodynamic or anatomic sequelae, arrhythmia burden, hypoxia, exercise capacity, and end organ dysfunction (renal/hepatic/pulmonary).[9] Patients were classified based on these guidelines independent of their arrhythmia burden. The majority of the patients in our cohort were ACHD physiologic class C (59%) followed by class D (23%); none of the patients in our study were class A. A trend test demonstrated progressively increasing incidence of pertinent positive events from Class B through D ($P = .067$). Patients in the ACHD physiologic Class D had a higher likelihood of pertinent positive events ($P = .034$) as compared to patients in the other physiologic classes (Figure 3). One third of the patients (3/9) with clinically relevant events were asymptomatic and had arrhythmias detected on their routine transmission, all of whom were physiologic Class C or D.

3.4 | Other considerations

In this cohort of 22 ACHD patients, 18 (82%) had symptomatic episodes; six of whom (33%) had associated clinically relevant event on

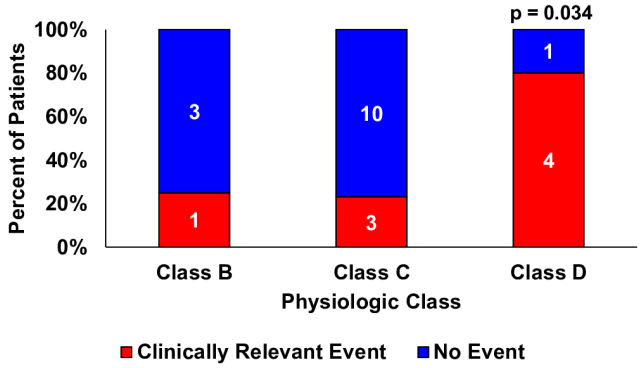

FIGURE 3 Patients with clinically relevant events in each physiologic class. Bar graph demonstrating the percent of patients in each ACHD physiologic class with clinically relevant events, with the highest percent in Class D (P = .034)

ILR. The remaining 12 patients had symptomatic events that either did correspond to indication for implant or were not reported. Events were consistent with sinus rhythm or sinus tachycardia and did not prompt further investigation. There were 13 patients with tachyarrhythmia detected (59%), 6 of whom had clinically relevant events. All others were consistent with sinus tachycardia or over sensing. ILR reprogramming was needed in two patients due to achievable sinus rate above tachycardia detection rate programmed. There were no pocket infections in our cohort. However, there was one patient in whom the device extruded due to return to exercise sooner than recommended.

4 | DISCUSSION

Arrhythmias are known to be a leading cause of mortality and morbidity in the ACHD population. The LINQ™ ILR has been useful in detection of occult atrial fibrillation in patients with cryptogenic stroke.[9] ILRs should be considered for silent atrial fibrillation in stroke patients, adults with unexplained syncope, and in symptomatic ACHD patients with high index of suspicion for a malignant arrhythmia.[1,10-12] In this single center study of LINQ™ ILR use in ACHD patients, we demonstrate a high rate of clinically relevant events (41%) in patients despite routine monitoring. Our results support a need for additional long-term monitoring in ACHD patients with high arrhythmia risk especially for patients with physiologic class D. Our data suggests patients in physiologic class D (independent of previous arrhythmias history) have the substrate for developing arrhythmias, even if asymptomatic, requiring interventions and consideration for long-term arrhythmia monitoring should be given.

It is not surprising that the majority of patients had diagnoses of Fontan palliation or repaired TOF as those lesions are known to be associated with high prevalence of arrhythmia. It is well known that patients with Fontan palliation have risk of tachyarrhythmia with estimated prevalence 60%[1] over a period of 10-15 years; however, our study identified new arrhythmias in the Fontan patients with the mean follow-up 2 years despite appropriate routine monitoring with Holter and event monitors. Though statistical analysis is limited by small numbers, the high number of pertinent positive events in Fontan patients is compelling and one must consider that long-term monitoring in this population may be warranted. It is plausible that ILR use in the Fontan population may serve to decrease presentation of acute decompensated heart failure or thrombotic events due to undiagnosed sustained tachyarrhythmia.

Surprisingly, patients with repaired TOF had a low rate of pertinent positive events, despite the fact that most (6/7) were in the intermediate or high-risk group in consideration of sudden death risk. We hypothesize that this TOF population is different than previously reported TOF cohorts in that the mean age is younger and TOF risk assessment may be more of a long-term consideration. There may be a role for long-term arrhythmia monitoring with ILR in older TOF populations.

The pertinent negative events on ILR are valuable in patients with high-risk symptoms such as syncope which may otherwise prompt more invasive work up due to concern for malignant arrhythmia. Thus minimally invasive ILR may serve a role in evaluation of syncope in the ACHD population as it may help drive clinical decision making regarding further invasive evaluation of unexplained syncope. Additionally, ILR in the ACHD population may serve as a useful tool to document effectiveness of medical management of arrhythmias. In consideration of patients for whom ILR would be useful, it is important to note that the LINQ™ ILR is a rate-based algorithm. The ability to distinguish atrial activity on tracings was variable and did not seem to be related to patient size or diagnosis. Furthermore, if a patient's known tachycardia rate was slower than achievable sinus rate, we saw a high number of false positive tachycardia events, which could be overcome with reprogramming. However, this emphasizes that slow, asymptomatic tachycardia will be difficult to detect with this device algorithm. Due to the one adult patient with device extrusion with return to sports sooner than recommended, it is now our practice to close with subcutaneous sutures as other centers have done.[13]

4.1 | Limitations

In addition to the limitations associated with the retrospective character of this study, the study is underpowered to detect potentially clinically relevant findings as statistically significant.

5 | CONCLUSION

To our knowledge, this is the first study to utilize new generation ILRs as an adjunct for arrhythmia monitoring in the ACHD population with clinically relevant events in 41% of patients. Patients with Fontan palliation and ACHD physiologic Class D had the highest prevalence of pertinent positive events despite routine Holter and event monitors. New generation ILRs may have a role in arrhythmia monitoring in asymptomatic patients at high risk, such as Fontan and patients with ACHD physiologic Class D as well as for evaluation of unexplained syncope and monitoring for antiarrhythmic treatment

efficacy in patients at high risk for recurrence. ILR is rate-based detection without morphology discrimination; therefore, programming consideration should focus on primary indication for implant and patients' underlying conduction system. Certainly, larger studies to further define new generation ILR use in ACHD population are necessary.

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CONFLICT OF INTEREST

Jassal, Thomas, Kertesz, and Kamp: None.

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AUTHOR CONTRIBUTIONS

Conception, design, analysis, and interpretation of data: Dodeja, Thomas, Daniels, Kertesz, and Kamp

Drafting of the manuscript and revising it critically for important intellectual content: Dodeja, Daniels, Kertesz, and Kamp

Final approval of the manuscript submitted: Dodeja, Thomas, Daniels, Kertesz, and Kamp

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