

Real-world battery longevity of Implantable Loop Recorders implanted for Unexplained Syncope: results from a large single center registry

L. Duvillier¹, A. Demolder¹, S. Van Renterghem¹, C. De Mey¹, F. West¹, and Jan De Pooter¹

¹Universitair Ziekenhuis Gent Hartcentrum

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Abstract

Background/Purpose Implantable loop recorders (ILR) are increasingly used in cardiac rhythm monitoring and diagnostic work-up of unexplained syncope. ILR battery longevity according to manufacturers' product performance specifications typically ranges between two to four years, but real-world data in this population are lacking. **Methods** This monocentric, prospective, observational study included consecutive patients with unexplained syncope undergoing ILR implantation between 10/2007 and 10/2019. The main purpose was to determine real-world battery longevity of ILR. Diagnostic yield and relationship between arrhythmogenic diagnosis and duration of ILR-monitoring was explored. **Results** The study included 309 patients (59 years [38-73], 49% female) with ILR implantation for unexplained syncope. Median battery longevity was 42 [40-45] months. 99.5% of ILR reached prespecified battery longevity. The time to end-of-life varied by up to 33 months among the same ILR models. Overall arrhythmogenic diagnostic yield counted 27% (73% sick sinus syndrome, 20% atrioventricular block and 7% ventricular tachycardia). Median time to diagnosis was 10 [2-25] months, with the latest event at 43 months. The cumulative diagnostic yield for arrhythmogenic event was 15.7%, 22.9%, 34.9%, 54.2%, 72.3% and 100% at 1, 2, 6, 12, 24 and 48 months respectively. In univariate analysis, 1st degree AV-block and prolonged HV time on EP study were predictors of diagnosis, while QRS duration abnormality borderline missed significance. **Conclusions** Real-world battery longevity of ILRs matched industry projected longevity in 99.5% of patients implanted with ILR for unexplained syncope. A battery longevity of minimum 3.5 years is recommended to maximize the diagnostic yield in this population.

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diagnostic yield counted 27% (73% sick sinus syndrome, 20% atrioventricular block and 7% ventricular tachycardia). Median time to diagnosis was 10 [2-25] months, with the latest event at 43 months. The cumulative diagnostic yield for arrhythmogenic event was 15.7%, 22.9%, 34.9% , 54.2%, 72.3% and 100% at 1, 2, 6, 12, 24 and 48 months respectively. In univariate analysis, 1st degree AV-block and prolonged HV time on EP study were predictors of diagnosis, while QRS duration abnormality borderline missed significance.

Conclusions

Real-world battery longevity of ILRs matched industry projected longevity in 99.5% of patients implanted with ILR for unexplained syncope. A battery longevity of minimum 3.5 years is recommended to maximize the diagnostic yield in this population.

Keywords: Implantable loop recorder; Battery longevity; Home monitoring

Introduction

Syncope is a form of non-traumatic, transient loss of consciousness due to hypoperfusion of the brain and can further be divided in cardiac syncope, reflex syncope or syncope due to orthostatic hypotension (1). It is a common condition (30-40% life time prevalence) (2, 3), with around 6 cases per 1000 person-years (4) and has a high rate of recurrence within the same year (up to 43%)(5). Conventional diagnostic work-up results in 30% of syncope cases remaining unexplained (2, 6), with an increased risk of recurrence and therefore trauma, or fatalities (2, 7). Digital wearables are increasingly used by patients, but are expensive (8). Diagnostic yield of Holter monitoring in patients with infrequent symptoms, is low (9). Therefore the early use of an Implantable Loop Recorder (ILR) in the diagnostic work-up of unexplained syncope, thought to be of cardiac etiology, is strongly recommended (1, 10-12). ILRs allow long-term surveillance of a single lead ECG and have been shown to be an effective tool in detecting clinically relevant arrhythmias (13-17), thereby leading to an earlier diagnosis. This early diagnosis results in less burden of further syncope (18), reduction in additional investigations, fewer hospitalization days and significant healthcare cost reduction (13, 19, 20). In a meta-analysis of five randomized controlled trials (RCTs) (660 patients), ILR implantation was 3.7 more probable of finding a diagnosis, compared to the conventional work-up (Holter, tilt testing, EP study) (13-17, 21). This way, ILR have a positive impact on survival of these patients, likely to the higher rate of device therapy (22). The median time to diagnosis, found in a large meta-analysis, is approximately 4 months (23). However, it remains unclear up to what point in time relevant arrhythmogenic diagnoses can be detected. Manufacturers of the latest generation of ILRs claim a minimum battery longevity between 2 and 4 years, but real-world data about ILR battery longevity are lacking. This study explores the battery longevity and the time relationship with the diagnostic yield of ILR implanted for unexplained syncope.

Materials and methods

Study population

This observational, prospective, single center study included all consecutive patients with unexplained syncope in whom an ILR was implanted in the period of 10/2007 – 10/2019 at the Ghent University hospital, Belgium. Inclusion was halted in 2019, since the main goal of this study was to focus on battery longevity. Patients were implanted with an ILR if syncope was suspected to be of cardiac origin and remained unexplained after a conventional diagnostic workup, in accordance with recent guidelines. (1).

ILR of different brands (Medtronic, Abbott and Biotronik) were implanted according to the preference of the referring or implanting physician. Programming of ILR was tailored to the individual patient. All ILRs were implanted in a dedicated electrophysiology lab. History, clinical information concerning the syncope event, comorbidities, ECG and laboratory results were retrieved from the electronic patient file. The study was approved by the local Ethics committee.

Follow-up and endpoints

All ILR patients underwent follow-up by remote home monitoring and regular clinical follow-up at 1 and 6 months after implant. After this initial period, the frequency of in-clinic follow-up varied between 6 to 12

months, depending on physician preference. History, clinical examination and interrogation of the ILR were routinely performed at each of the clinical follow-up consultations.

Remote monitoring alerts were checked five days a week by dedicated staff members experienced in device interrogation and follow-up. All arrhythmogenic events, potentially cause related with syncope, such as prolonged pauses (>3 seconds), type 2 2nd degree atrioventricular (AV) block or 3rd degree AV-block as well as fast supraventricular tachycardia (SVT) or ventricular tachycardia (VT) were registered and adjudicated by an electrophysiologist. Appropriate therapy was guided by the nature of the arrhythmogenic event in relation the presence or absence of symptoms. Indications for pacemaker or implantable cardioverter-defibrillator (ICD) implantation were guided by international guidelines (1, 10). Remote monitoring was also used to detect the end-of-life (EOL) status of the ILR.

Statistical analysis

Categorical variables are presented as absolute numbers (percentage). Continuous variables are expressed as mean \pm standard deviation in case of Gaussian distribution or median [1st,3rd quartile] in case of non-Gaussian distribution. Normality was tested using the Shapiro-Wilk test. To compare means and medians of continuous variables among groups, the independent Student's t-test and Mann-Whitney U test were used, respectively. In case of >2 groups, the one-way ANOVA or Kruskal-Wallis test was used where appropriate. Categorical variables were compared among groups using the Chi Squared test. Statistical significance was set at a 2-tailed probability level of <0.05. All statistical analyses were performed using SPSS software (version 28.0, IBM, Armonk, NY, US).

Results

3.1 Baseline patient characteristics and ILR implants in follow-up

The study included 348 patients who were implanted with an ILR for unexplained syncope. Follow-up data were available in 309 patients (88% out of total implanted patients), figure 1. The mean age was 59 years (range 4-93 years), 49% was female. The median number of syncope was 3 [1-3]. Baseline patient and electrocardiographic findings are summarized in table 1. Baseline conduction abnormalities on ECG were present in 13% of the patients. 8.7% had a first degree atrioventricular block, 2.3% left bundle branch block (LBBB), 7.4% right bundle branch block (RBBB), 2.3% bifascicular block and 0.6% had a trifascicular block. During work-up for syncope, all of the patients had a negative 24h Holter monitoring, and 46% underwent head up tilt testing, which was negative. Electrophysiologic (EP) study was performed in 59% of the patients (and negative), before implantation of the ILR. Numbers of patients implanted with different ILR models and according to different manufacturers are specified in figure 2. Two out of three patients (67%) received an ILR manufactured by Medtronic, 29% Abbott and 3% Biotronik.

3.2 Battery longevity

During follow-up, 206 (59%) of patients reached ILR EOL (Table 2), with precise longevity determined in 1175 of these cases. Overall, the median battery longevity measured 42 [40-45] months with minimum and maximum battery longevity spanning a range of 24-72 months among patients. Battery longevity according to ILR model and manufacturer is displayed in figure 2.

Of interest, the time to EOL range varied among patients, as displayed in figure 3: from 28 to 61 months for model Reveal 9529, 36 to 51 months for model Reveal Linq II, from 24 to 51 months for model Confirm ILR 2102 and from 24 to 41 months for model Confirm Rx 3500. As such, maximum difference in time to EOL among patients implanted with same ILR models was: 33 months for Reveal 9529, 15 months for Reveal Linq II, 27 months for Confirm ILR 2102 and 17 months for Confirm ILR.

Premature end-of-life, here defined as time to EOL less than the prespecified manufacturers battery longevity, occurred in one patient (0.5%). In this particular patient EOL was reached after 28 months, while a battery longevity of at least 36 months was guaranteed according the manufacturer product performance specifications. No clear explanation was found for this premature end-of-life. In patients exceeding the pre-

defined battery longevity, a median additional battery longevity was seen of 6 [2-9] months for the Reveal 9529, 7 [5-8] months for the Reveal Linq, 19 [16-21] months for the Confirm ILR 2102 and 1 [0-12] month for the Confirm RX DM 3500.

3.3 Diagnostic yield

Arrhythmogenic diagnosis, clinically relevant to the index syncope was diagnosed in 83 of 309 (27%) of patients (Table 2). Type of arrhythmogenic diagnosis in those patients are listed in Table 2. Sick sinus syndrome was present in 60 (72%) of these 83 patients, atrioventricular block (being Mobitz type 2 2nd degree AV block or 3rd degree AV block) in 17 patients (20%) and ventricular tachycardia in 6 (7%). Of those patients with an arrhythmogenic diagnosis, 66 patients (79%) received a pacemaker, and 7 patients (8%) an ICD. The remaining 10 patients (12%) did not receive device implantation based on clinical decision making. Besides etiologic diagnoses explaining syncope, additional diagnoses (mostly atrial fibrillation or atrial flutter) were found as well in 58 patients (18.8% of the study population).

3.4 Time relationship between arrhythmogenic diagnosis and time of monitoring

Cumulative diagnostic yield of ILR among patients with syncope is given in figure 4. The cumulative diagnostic yield for arrhythmogenic event explaining syncope was 15,7%, 22,9%, 34,9% , 54,2%, 72,3% and 100% at 1, 2, 6, 12, 24 and 48 months respectively. After 43months, a plateau in diagnostic yield could be observed, with the last arrhythmogenic diagnosis made at 43 months of follow-up. The mean time to diagnosis was 10 [2-25] months. Among patients with an arrhythmogenic diagnosis (n=83), this diagnosis was established in 15.7% of patients in the first month, 7.2% in the second month 4.8% in the third month, 8.4% in the period between 3 and 6 months, 19.2% in the period between 6 months and 1 year, 16.8% in the second year, 17.5% in the third year and finally 10.4% in the fourth year. Of all arrhythmogenic episodes, 90% were diagnosed within 3 years of ILR monitoring.

3.5 Reasons for ILR extraction before reaching EOL

Of all implanted loop recorders, 92 (30%) were extracted before reaching EOL. In 73 (24%) of patients this was due to the diagnosis of an arrhythmogenic episode requiring pacemaker or ICD implantation. In 14 patients (5%), the ILR was extracted prematurely due to the finding of an alternative diagnosis, 4 (1%) due to localized pain at the insertion place and 1 (<1%) because of skin protrusion.

Acknowledgement

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Figure legend:

Figure 1:

Patient flow chart and diagnostic yield

Figure 2:

Figure 2 summarizes the median battery longevity of every individual model, with interquartile range, as well as the manufacturer self-reporter battery longevity. Range (min – max) of battery longevity is listed too. ILR = implantable loop recorder.

Figure 3:

Figure 3 depicts the five different Implantable Loop recorder models, manufactured by three different companies, used in this trial. The blue line indicates the self-reported minimal battery longevity by Medtronic (being 3 years, or 36 months), while the red line indicates that of Abbott (St Jude Medical) (being 2 years, or 24 months). ILR = implantable loop recorder.

Figure 4:

Figure 4. In this figure a survival curve is depicted. It shows the number of arrhythmogenic diagnoses in relation to time. After 43 months no arrhythmogenic diagnoses were made.

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Table 1. Relevant baseline patient characteristics

	<i>Patients, No./total No. (%)</i>
Demographics	Overall (n=309)
Age at time of implant, years	59 [38-73]
Female (%)	150 (49)
Height (cm)	170 [162-175]
Weight (kg)	72 [66-84]
BMI (kg/m ²)	25,3 [22,6-28,6]
Risk factors	
Hypertension	112 (36)

	<i>Patients, No./total No. (%)</i>
Dyslipidemia	141 (46)
Diabetes	30 (10)
Heart failure	13 (4)
Current smoker	34 (11)
Ex-smoker	49 (16)
Number of syncope	3 [1-3]
Trauma related to syncope	
Any QRS conduction abnormality	40 (13)
Head-up Tilt test	143 (46)
Holter monitoring	309 (100)
Electrophysiology study	181 (59)
Lost to follow-up during monitoring	26 (8)
Died	21 (7)
1 st degree AV block	27 (8,7)
LBBB	7 (2,3)
RBBB	23 (7,4)
Bifascular block	7 (2,3)
Trifascicular block	2 (0,6)

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unknown

Table 2. ILR follow-up and diagnostic yield

	<i>Patients, No./total No. (%)</i>
Demographics	Total number n=309
ILR follow-up	
End of battery life	206
Early extraction	92
Not yet EOL	1
Lost to follow-up	10
Arrhythmogenic diagnosis	83 (27)
Type arrhythmogenic diagnosis	
Higher degree AV block	17/83 (20)
Sick sinus syndrome	61/83 (73)
VT	6/83 (7)
Additional ILR findings	
AF/AFL/AT	58 (19)

Table 2 ILR = follow-up characteristics and types of arrhythmogenic diagnosis. EOL = End-of-life. Higher degree AV block: type 2 2nd degree AV block or 3rd degree AV block. VT = Ventricular tachycardia. AF = Atrial fibrillation. AFL = Atrial flutter. AT = Atrial tachycardia.

Table 3. Univariate analysis: predictors of syncope

Demographics	No arrhythmogenic diagnosis (n=221)	Arrhythmogenic diagnosis (n=83)	P-value
Female (%)	115 (51)	35 (42)	0.13
Age at time of implant, years	58 [36-71]	61 [46-74]	0.10
BMI (kg/m ²)	25,4 [22,3-28,7]	25,1 [22,8-28,2]	0.97
Risk factors			
Hypertension	78 (35)	34 (41)	0.34
Dyslipidemia	101 (45)	40 (48)	0.66
Diabetes	23 (10)	7 (8)	0.61
Heart failure	9 (4)	4 (5)	0.76
Current smoker	24 (11)	10 (12)	0.75
Ex-smoker	34 (15)	15 (18)	0.55
Baseline ECG characteristics			
PR interval	156 [142-176]	166 [143-202]	0.10
1 st degree AV block	14 (6)	13 (16)	0.01
QRS duration	94 [84-104]	94 [84-110]	0.80
QTc time	423 [402-440]	423 [394-441]	0.59
Any BBB	18 (8)	12 (14)	0.09
RBBB	15 (7)	8 (10)	0.39
LBBB	3 (1)	4 (5)	0.09
Any QRS conduction abnormality	24 (11)	16 (19)	0.05
RBBB	15 (7)	8 (10)	0.39
LBBB	3 (1)	4 (5)	0.09
NIVCD	6 (3)	4 (5)	0.46
Bifasc. block	5 (2)	2 (2)	1.00
Trifasc. block	1 (1)	1 (1)	0.47
Number of syncope	1 [1-3]	1[1-3]	0.37
Trauma	46 (20)	15 (18)	0.61
Traffic Accident	13 (6)	6 (7)	0.65
During sports	12 (5)	4 (5)	0.84
EP study	138 (61)	43 (51)	0.10
AH interval	110 [94-131]	116 [94-151]	0.37
HV interval	42 [38-50] N=128	46 [40-50] N=38	0.04
Abnormal HV interval (>55 ms)	8 (6)	3 (8)	0.71
SNRT	1053 [918-1250]	1170 [945-1250]	0.43
Wenckebach punt	370 [320-420]	380 [335-423]	0.81
2:1 block	320 [290-370]	330 [290-360]	0.99

Table 3. Predictors of arrhythmogenic diagnosis.

In nominal variables the Chi-Squared test was used. In continuous variables the Independent Samples Student t-test or Mann Whitney U test was used where appropriate.

BMI= body mass index. ECG: Electrocardiogram, EP study = electrophysiological study. First degree AV block = PR segment branch block. Bifascicular block = RBBB + LAFB (left anterior fascicle block). Trifascicular block = 1st degree AV block + LAFB + RBBB. NIVCD = Non-specific intraventricular conduction delay. EP study = electrophysiological study. AH interval: Atrium His interval. HV interval = His ventricle interval. SNRT = Sinus node recovery time.

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Figure 1. Patient flow chart and diagnostic yield

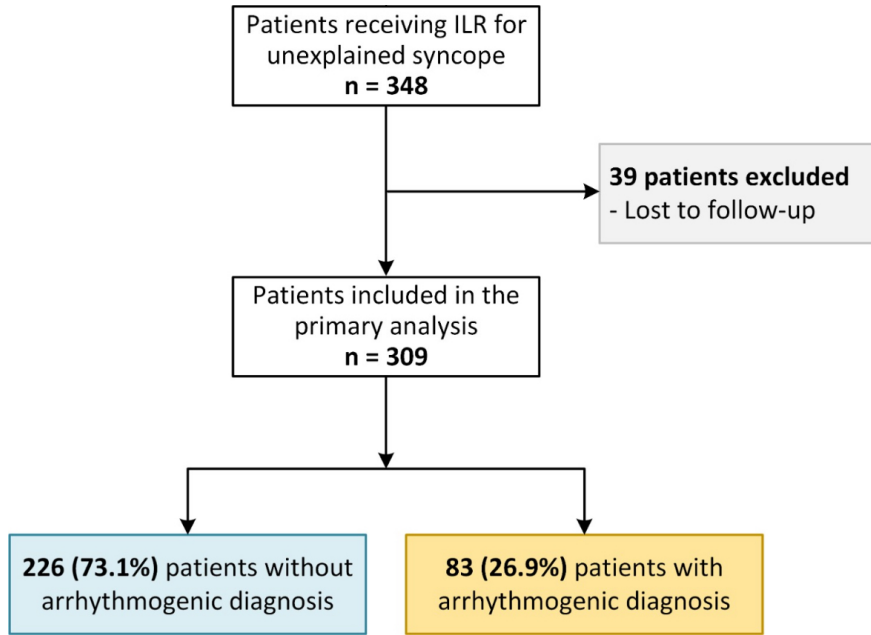


Figure 2. Comparison between ILR manufacturers

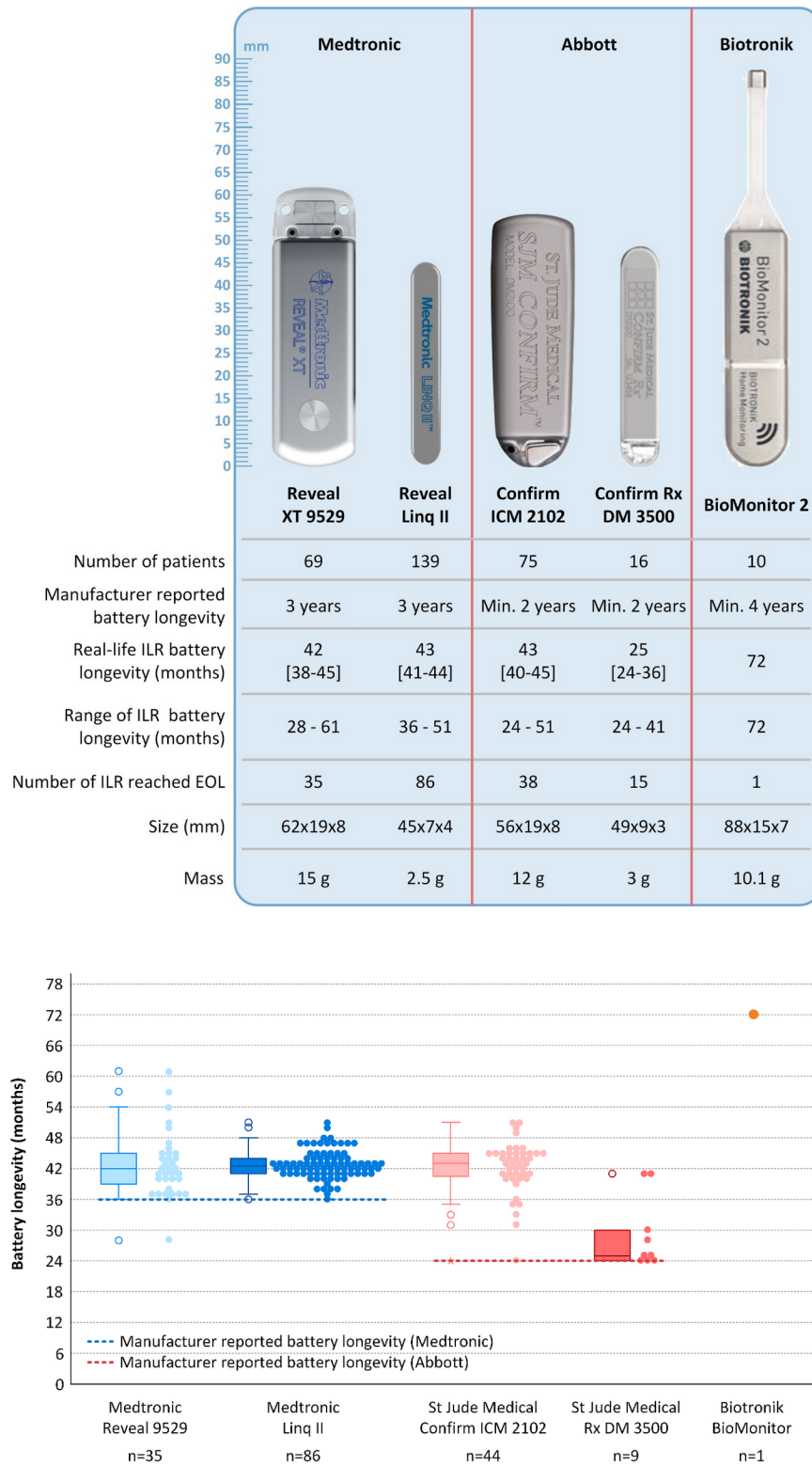


Figure 3. Battery longevity by ILR manufacturer

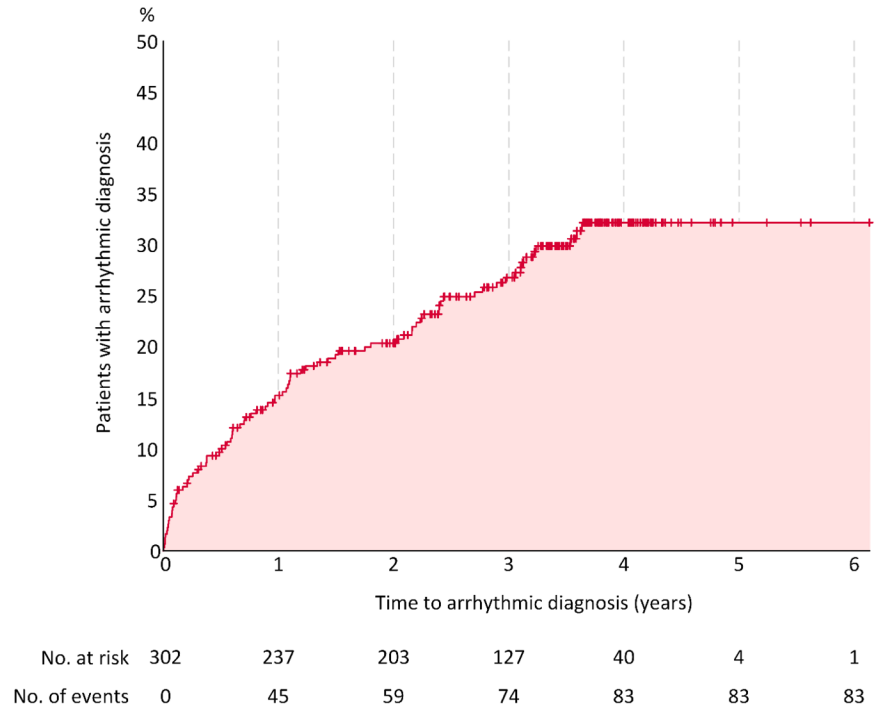


Figure 4. Cumulative diagnostic yield and time to arrhythmogenic diagnosis