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Use of an implantable loop recorder in different age groups to identify the cause of unexplained syncope

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A – Study Design, **B** – Data Collection, **C** – Statistical Analysis, **D** – Data Interpretation, **E** – Manuscript Preparation, **F** – Literature Search, **G** – Funds Collection

Summary **Background.** An implantable loop recorder (ILR) is a small subcutaneous electrocardiogram monitoring device that may be useful in the diagnosis of patients with recurrent syncope or palpitations, while initial examination is not diagnostic.
Objectives. To analyze the use of an ILR in different age groups and identify its effectiveness in determining the cause of syncope.
Material and methods. This single-center retrospective study included 51 patients who underwent ILR implantation at the Hospital of the Lithuanian University of Health Sciences Kaunas Clinics due to unexplained syncope between January 2015 and July 2022. Patients were divided into two groups according to age: younger (< 50 years, *n* = 26) and older (≥ 50 years, *n* = 25).
Results. The mean duration to diagnosis of arrhythmia-related syncope was 219 [105–995] days in the younger patients and 141 [30–452] days in the older patients ($p = 0.28$). In younger patients, the diagnoses were sinus node dysfunction (SND) (*n* = 3), complete atrioventricular (AV) block (*n* = 1), and ventricular tachycardia (VT) (*n* = 1), while in older patients – SND (*n* = 4), complete AV block (*n* = 2), fast supraventricular tachycardia (SVT) (*n* = 1), and VT (*n* = 1). In younger patients, 4 (80%) were offered a pacemaker and 1 (20%) an implantable cardioverter-defibrillator implantation, while in older patients, the recommendations were more heterogeneous: 6 (75%) were offered a pacemaker, 1 (12.5%) an catheter ablation, and 1 (12.5%) an electrophysiological study. The documented incidence of arrhythmia-related syncope was not statistically significant different between the groups (19.2% vs 32.0%, $p = 0.30$).
Conclusions. An ILR is a useful instrument in determining the causes of recurrent unexplained syncope in different age groups.
Key words: cardiac arrhythmias, syncope, cardiovascular diagnostic techniques.

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Background

Ambulatory electrocardiogram (ECG) monitoring is a beneficial instrument used to record the electrical activity of the heart for a longer period of time and to determine a precise diagnosis in patients with certain symptoms, such as unexplained syncope or palpitations [1]. Possible ambulatory ECG monitoring methods include Holter monitoring (HM), wearable cardiac event monitors, external loop recorders, and implantable loop recorders (ILRs), and the selection of the proper device should be determined by the frequency of the patient's symptoms and predicted monitoring duration [2]. HM allows one to record continuous ECG, usually up to 7 days; therefore, it is more suitable for patients with more frequent symptoms [3]. While symptoms occur less often, devices with a longer possible follow-up duration should be selected, such as external loop recorders or ILRs [2].

An ILR, also called an insertable cardiac monitor (ICM), is a small subcutaneous cardiac rhythm-monitoring device used for diagnosing cardiac arrhythmias and allows for recording of ECG for up to 3 years [4, 5]. The use of an ILR is appropriate in patients who experience recurrent symptoms but which are too rare (i.e. less than monthly or several times per year) to be recorded using traditional monitoring methods [1, 6].

Syncope is a transient loss of consciousness, caused by global cerebral hypoperfusion, and is characterized by a rapid beginning, short duration and typically quick complete recovery time [4, 5]. Syncope is a sign of various underlying conditions that can range from relatively non-malignant issues to life threatening problems [6]. ILR use is a method of choice in patients with recurrent unexplained syncope if the findings of a primary examination (clinical evaluation, medical history, ECG, HM, or other conventional investigations) did not help to establish a diagnosis [4]. The use of ILRs is beneficial for an early diagnosis and notably improves the diagnosis rate, as well as grants relevant data about the mechanism of syncope and appropriate management strategy [7].

Objectives

The aim of this study was to analyze the use of ILRs in different patient age groups and identify the effectiveness in determining the cause of syncope at the Hospital of the Lithuanian University of Health Sciences Kaunas Clinics over the period from January 2015 and July 2022.

Material and methods

Patients and data collection

This single-center, retrospective study included 51 patients who had an ILR implanted at the Hospital of the Lithuanian Uni-

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versity of Health Sciences Kaunas Clinics due to unexplained syncope between January 2015 and July 2022. Patients were divided into two different groups according to age: younger (less than 50 years) and older (50 years or older).

Study data was collected from medical records, including medical history (pre-existing diseases, used medications, history of smoking, head trauma), physical examination, clinical investigations that were performed before ILR implantation (laboratory tests, electrocardiography (ECG), echocardiography, HM, coronary angiography (CAG), tilt table test, electrophysiological (EP) studies, exercise tolerance test, active standing test, 24-hour ambulatory blood pressure (BP) monitoring, routine electroencephalography (EEG), sleep EEG, brain computed tomography, brain magnetic resonance imaging, carotid duplex ultrasound), ILR findings, determined diagnosis, and treatment strategy.

Research was approved by the Bioethics Center of the Lithuanian University of Health Sciences (No. BEC-MF-227, 2023-02-08).

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) version 27.0 software was used for statistical analysis. Categorical data was expressed as frequency and percentage. The normality of data was assessed with the Kolmogorov-Smirnov test. Continuous data that had normal distribution was expressed as mean ± standard deviation (SD), while data following non-normal distribution was represented as median (minimum and maximum values).

ILR implantation and follow up

The implantation procedure was performed by an electrophysiologist in an EP lab. A minor surgical cut was made in the parasternal area. The ILR was inserted under the skin into a prepared pocket, and the wound was closed. After implantation, the device was activated and programmed.

In the outpatient clinic, ILR interrogation was performed regularly every 3–6 months. If the patient developed cardiac symptoms such as palpitations, dizziness, or syncope, ILR interrogation was performed immediately. ILR interrogation was performed by an electrophysiologist.

Results

Demographic and clinical characteristics of the patients

Patients were divided into two different age groups: in the first group, patients were younger than 50 years old (n = 26), and in the second group, patients were 50 years or older (n = 25). In the first group, the median age was 40 [18–49] years, while in the second group, the median age was 60 [50–84] years.

Younger subjects were more frequently smokers. On the contrary, older subjects had more pre-existing diseases and used more medications. According to the medical history, two comorbidities were statistically significantly more prevalent in older patients: arterial hypertension and dyslipidemia.

During physical examination, systolic and diastolic BP were statistically significantly higher in older patients, while heart rate at rest did not differ between the groups. Baseline characteristics are presented in Table 1.

Clinical investigations performed before an implantable loop recorder

Some laboratory and instrumental examinations were performed in patients before ILR implantation. These findings of the subjects are represented in Table 2.

Table 1. Demographic and clinical characteristics of the patients

Variables	Younger patients < 50 years old (n = 26)	Older patients ≥ 50 years old (n = 25)	p
Men	11 (42.3%)	12 (48.0%)	p = 0.68
Comorbidities			
Ischemic heart disease	2 (7.7)	5 (20.0)	p = 0.20
Arterial hypertension	9 (34.6)	21 (84.0)	**p < 0.001**
Dyslipidemia	4 (15.4)	13 (52.0)	**p = 0.01**
Neurological disorders	1 (3.8)	3 (12.0)	p = 0.28
Diabetes mellitus	2 (7.7)	3 (12.0)	p = 0.61
Comorbidities	0 [0–3]	2 [0–4]	**p < 0.001**
Used medications			
ACEIs/ARBs	5 (19.2)	17 (68.0)	**p < 0.001**
Beta blockers	6 (23.1)	12 (48.0)	p = 0.06
Statins	2 (7.7)	6 (24.0)	p = 0.11
CCBs	2 (7.7)	7 (28.0)	p = 0.06
Metformin	1 (3.8)	2 (8.0)	p = 0.53
Used medication, number of medications	0 [0–4]	2 [0–5]	**p < 0.001**
History of smoking	10 (38.5%)	3 (12.0%)	**p = 0.03**
History of previous head trauma	2 (7.7)	2 (8.0)	p = 0.97
Physical examination findings			
Systolic BP, mm Hg	125 [110–160]	138 [116–180]	**p = 0.003**
Diastolic BP, mm Hg	79 [57–91]	80 [70–100]	**p = 0.02**
HR, bpm	70 [47–90]	69 [56–92]	p = 0.66

ACEIs/ARBs – angiotensin-converting enzyme inhibitors or angiotensin receptor blockers; CCBs – calcium channel blockers; BP – blood pressure; HR – heart rate; bpm – beats per minute. Data is presented as frequency (percentage) or mean ± standard deviation.

Table 2. Clinical investigations performed before ILR			
Variable	**Younger patients < 50 years old (*n* = 26)**	**Older patients ≥ 50 years old (*n* = 25)**	***p***
Laboratory tests			
Hemoglobin, g/l	139 [107–169]	137 [119–158]	*p* = 1.00
Potassium, mmol/l	4.30 [3.26–5.30]	4.40 [3.37–5.02]	*p* = 0.39
Sodium, mmol/l	138 [132–143]	140 [136–145]	***p* = 0.04**
Magnesium, mmol/l	0.78 [0.70–0.84]	0.87 [0.76–0.92]	***p* = 0.01**
Standard ECG	26 (100.0)	25 (100.0)	
Echocardiography	20 (76.9)	25 (100.0)	***p* = 0.01**
LVEF, %	55 [50–68]	55 [50–66]	*p* = 0.06
LVEDD, mm	48 [38–53]	46 [41–56]	*p* = 0.55
HM	23 (88.5)	23 (92.0)	*p* = 0.67
CAG	3 (11.5)	10 (40.0)	***p* = 0.02**
24-hour ambulatory BP Monitoring	0 (0.0)	1 (4.0)	*p* = 0.30
Tilt table test	8 (30.8)	13 (52.0)	*p* = 0.12
Electrophysiological studies	4 (15.4)	6 (24.0)	*p* = 0.44
Exercise tolerance test	5 (19.2)	9 (36.0)	*p* = 0.18
Active standing test	0 (0.0)	1 (4.0)	*p* = 0.30
Routine EEG	10 (38.5)	12 (48.0)	*p* = 0.49
Sleep EEG	6 (23.1)	4 (16.0)	*p* = 0.53
Brain CT	9 (34.6)	9 (36.0)	*p* = 0.92
Brain MRI	4 (15.4)	12 (48.0)	***p* = 0.01**
Carotid duplex ultrasound	4 (15.4)	10 (40.0)	*p* = 0.05
Number of examinations performed before ILR, number of tests	4 [2–8]	6 [3–9]	***p* = 0.001**

ECG – electrocardiography; HM – Holter monitoring; CAG – coronary angiography; BP – blood pressure; EEG – electroencephalography; CT – computed tomography, MRI – magnetic resonance imaging. Data is presented as frequency (percentage) or mean ± standard deviation.

Laboratory tests were within the normal limits. Hemoglobin and potassium levels were similar in both groups; however, sodium and magnesium values were higher in older people.

Cardiological examination was performed for most of the enrolled patients. Standard ECG (100%) and HM (88.5%) were the most frequently used tests in the younger patient group, while standard ECG (100%), echocardiography (100%), and HM (92%) were used in the older patient group. Echocardiography and CAG were more often performed in older patients when compared to younger patients ($p = 0.01$ and $p = 0.02$, respectively). Other tests did not statistically significantly differ between the groups.

Neurological examination was also performed in some patients. The most common tests in the older patient group were routine EEG (48%), brain MRI (48%), and carotid duplex ultrasound (40%), while in younger patients – routine EEG (38.5%) and brain CT (34.6%). Brain MRI was statistically significantly more frequently performed in older patients ($p = 0.01$).

Overall, the median number of investigations before ILR implantation was 4 [2–8] tests in the younger patient group and 6 [3–9] tests in older patient group ($p = 0.001$). The results of these investigations showed no pathology, and thus ILR implantation was chosen for further investigation in these patients.

Findings of an implantable loop recorder and management

Clinically significant arrhythmia episodes were found in 13 (25.5%) patients. Syncope recurrence after ILR implantation in both groups did not differ in the younger and older patient groups (8 (30.8%) and 11 (44%) patients, respectively, $p = 0.33$). Moreover, documentation of arrhythmia-related syncope frequency did not statistically significantly differ between the groups (5 (19.2%) in the younger patient group, 8 (32%) in the older patient group, $p = 0.3$). Specific case descriptions of the confirmed arrhythmogenic cause of syncope are presented in Table 3.

Established diagnoses in both age groups are represented in Figure 1. In the younger patient group, the diagnoses were sinus node dysfunction (SND) ($n = 3$), complete atrioventricular (AV) block ($n = 1$), and ventricular tachycardia (VT) ($n = 1$), while in the older patient group – SND ($n = 4$), complete AV block ($n = 2$), supraventricular tachycardia (SVT) ($n = 1$), and VT ($n = 1$). Asystole (pause longer than 4.5 sec) was found in 5 younger patients and in 6 older patients, while duration of asystole was not statistically significantly different among the groups (9 [3 to 30] seconds in the younger patient group and 11 [5 to 23] seconds in the older patient group, $p = 0.54$).

Median follow-up duration in patients where the cause of syncope was determined was similar in the younger and older patient groups (219 [105 to 995] days and 141 [30 to 452] days, $p = 0.28$).

In the younger patient group, the recommendation after revealed ILR findings were cardiac pacemaker in 4 (80%) and implantable cardioverter-defibrillator (ICD) in 1 (20%), while in older patients, the recommendations were more variable: cardiac pacemaker in 6 (75%), ablation in 1 (12.5%), and electrophysiological (EP) study in 1 (12.5%).

Some concomitant diagnoses were confirmed during follow up in 3 enrolled patients with an implanted ILR: orthostatic hypotension and Parkinson's disease – in the older patients group, and epilepsy – in the younger patients group.

Table 3. Characteristics of patients with confirmed arrhythmogenic cause of syncope according to age						
Gender	**Age, years**	**Age at manifestation of syncope**	**Date of implantation**	**Diagnosis**	**Follow-up duration, days**	**Recommended management**
Younger than 50 years old						
Female	47	10	6/30/2016	SND	105	Pacemaker
Male	47	39	9/5/2016	SND	219	Pacemaker
Female	28	28	12/12/2016	VT	995	ICD
Male	49	47	7/17/2019	Third-degree AVB	191	Pacemaker
Female	35	17	9/14/2020	SND	275	Pacemaker
50 years and older						
Male	59	56	1/22/2015	Third-degree AVB	147	Pacemaker
Male	56	56	6/26/2019	SVT	136	Ablation
Female	73	68	10/11/2019	SND	290	Pacemaker
Male	57	57	10/14/2019	Third-degree AVB	129	Pacemaker
Male	56	48	10/8/2020	SND	30	Pacemaker
Female	72	72	4/14/2021	SND	155	Pacemaker
Female	81	76	4/29/2021	SND	452	Pacemaker
Male	59	59	6/22/2021	VT	79	EP study

CHD – coronary heart disease; AVB – atrioventricular block; SND – sinus node dysfunction; VT – ventricular tachycardia; ICD – implantable cardioverter-defibrillator; EP – electrophysiological; SVT – supraventricular tachycardia.

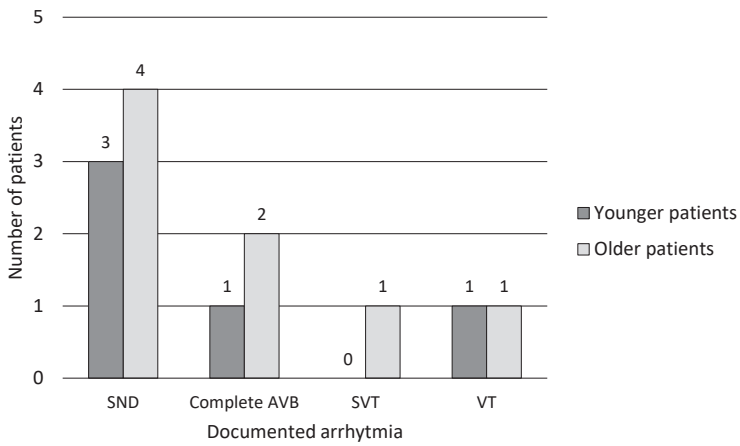

Figure 1. Findings of implantable loop recorder

SND – sinus node dysfunction; AV – atrioventricular; SVT – supraventricular tachycardia; VT – ventricular tachycardia.

Discussion

Syncope is a relatively common medical condition with a prevalence rate of 15–39% [8]. Even using many available diagnostic opportunities, the cause of syncope remains unclear in 17–37% of the cases [9]. An ILR may be beneficial for accurate diagnosis of the etiology of syncope.

The significance and value of an ILR in the diagnostics of unexplained syncope is increasing. According to the 2018 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of syncope, implantation of an ILR during the early phase of investigation is indicated in patients with recurrent syncope with unknown cause, without high-risk criteria and with a high probability of recurrence during the battery life of the device (class I, level A recommendation) [10].

The findings of our study confirm that an ILR was a helpful tool to confirm an arrhythmia-associated syncope in 13 (25.5%) of all the enrolled patients. Some researchers have reported similar diagnosis rates [11–13]; however, other studies have shown a higher probability to diagnose present arrhythmia (ranges between 46.2–55.6%) [14–15].

We found several studies analyzing different age groups when assessing the effectiveness of an ILR. Czosek et al. has shown that the most frequent ILR documented rhythm disorders in younger patients (under 21 years of age) were asystolic pauses (50%) and intermittent AV block (14%), while causative arrhythmia was confirmed in 35% of patients with syncope [16]. Vidya et al. revealed that an ILR diagnosis was established in 71.5% of young patients (mean age 31.9 ± 5.5 years old) with unexplained syncope or palpitations. Moreover, the most common detected arrhythmias were narrow complex tachycardia (30%), atrial fibrillation (20%), and ventricular premature complexes (20%) [17]. Rossano et al. found a symptom-arrhythmia correlation in 67% of 25-year-old and younger patients (mean age 12.3 ± 5.3 years old) with an implanted ILR (mean follow up duration was 8.4 ± 4.7 months) [18].

Sandgren et al. demonstrated that the most frequent rhythm disorders in older patients (mean age 66 ± 16 years) were AV block (25%) and sinus arrest (20%). A diagnosis based on ILR findings was established in 49% of patients, and the mean follow-up duration in diagnosed patients was 11 ± 10.8 months [19]. Arcinas et al. revealed that cardiac arrhythmia diagnosis was established in 44.1% of patients who were over 65 years old (mean age was 80 ± 8 years) [20].

Brignole et al. compared patients of different ages (≥ 65 years and < 65 years) and found that arrhythmias were more

likely to be the cause of recurrent syncope in the older age group compared to younger patients (44% vs 20%, $p = 0.03$) [21].

The incidence of arrhythmia-related syncope documented in our study was not statistically significantly different between different age groups (5 (19.2%) in younger patients, and 8 (32%) in older patients, $p = 0.30$). SND was the most frequent documented arrhythmia in both age groups. The median follow-up duration to diagnosis did not differ significantly (possibly due to insufficient sample size) in the younger and older patient groups (219 [105–995] days and 141 [30–452] days, $p = 0.28$).

Consequently, usage of an ILR should always be considered in patients with unexplained syncope, especially when other investigation methods do not provide a causative diagnosis.

Conclusions

The findings of our study confirm that an ILR is a beneficial tool in determining the causes of recurrent unexplained syncope in clinical practice and is similarly effective in younger and older patients.

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