

## IMPLANTABLE LOOP RECORDER IN DIAGNOSIS OF UNEXPLAINED SYNCOPES

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Implantable loop recorder is a diagnostic method in cardiology, having a role in revealing the cause of recurrent unexplained syncope. For automatic recording, the device is equipped with bradycardia and tachycardia programmable options. Battery capacity is 14 months.

The aim of the study was to investigate the use of loop recorder in the diagnosis of unexplained syncope.

The study enrolled the patients with unexplained syncope who were consecutively referred to our Syncope Unit, either as outpatients or during hospitalization, in an 8-month period. This study included 17 patients with unexplained syncope (9 male, 8 female). Mean age range was 43±21.1 years. The first control was after 14 days, the second after 1 month, and the third control after 2 months of the study beginning. In case of symptoms appearance, the control examination was done immediately. Total follow-up period was 64±37 days. If the patients had positive finding, the implantation of permanent pace maker was done. Results: In 9 patients, the cause of syncope was verified and they received a permanent pacemaker. They had the pauses in heart action longer than 3 seconds. The shortest time to making the diagnosis was 14 days and the longest time period was 48 days. There was no severe irregular rhythm.

Loop recorder is a very important diagnostic method with a role in revealing the cause of unexplained syncope. *Acta Medica Medianae 2009;48(1): 12-14.*

**Key word:** unexplained syncope, loop recorder

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### Introduction

Syncope is a syndrome defined as a sudden, transitory loss of consciousness with incapability of retaining postural tonus that occurs due to disturbed perfusion of the brain (1). A typical clinical picture of a syncope is characterized by: hypotension, pallor, sweating, loss of consciousness, motionlessness, shallow and slow breathing, preservation of the sphincter. There is large a number of etiological factors that can cause syncope, but they are usually classified into three groups: syncopes of cardiac origin, syncopes of non-cardiac origin and syncopes of uncertain origin.

Causes of syncope	%
Unknown	35
Reflexive vascular	19
Cerebral causes and epilepsy	9
Orthostatic hypotension	7
Tachyarrhythmia	7
Bradyarrhythmia	4
Metabolic	4
Obstruction of blood flow	4
Other causes	2

Recurrent syncopes of uncertain etiology pose a big medical problem. In the USA, about a million

of patients with syncope are registered annually. Syncope is the cause of 6% of the total number of hospitalizations. In 30% of patients, syncope is recurrent. It has been estimated that even after applying the complete diagnostics, even 47% of syncopes remain of uncertain etiology.

The usual diagnostic algorithm for patients with syncope of uncertain etiology covers the standard ECG, the 24-72h holter ECG monitoring, the provocation head up tilt test (in cases when the vasovagal syncope is suspected), echocardiogram (in cases of structural heart diseases) and, potentially, electrophysiological study (EPS) (4,5). Even though it is considered that patients with negative EPS have good prognosis, they still have limiting symptoms – they cannot perform certain types of activities like driving motor vehicles; in case of frequent falls, they can sustain serious injuries and there is also a certain risk of sudden cardiac death (6).

Due to sporadic occurrence of symptoms and their unpredictability, even when there are recurrences, the usual ECG monitoring strategies are of relatively small value in diagnostics. In classic holter monitoring, syncope occurs in 1.6% of patients, and fainting in 14.5%.

Tilt tests and electrophysiological studies are attempts to provoke symptoms, on the basis of which the causes of their occurrence can be assumed, under controlled conditions. They can give negative results in spite of the recurred symptoms (7).

The ILR (implantable loop recorder) is the first implantable heart function monitoring and heart rhythm recording system. Doctors get the possibility to use the recorded information in finding possible constraints in functioning of the heart and irregularities of the heart rhythm.

The purpose of this study was to analyze the use of the ILR in syncope of uncertain etiology diagnosis in the Department of Cardiology, Clinical Center Nis, in the period 2005-2008.

### Material and methods

17 patients (9 men and 8 women) with syncope of uncertain etiology were analyzed. The mean age of the examinees was  $43 \pm 21.1$  years. Before implanting the ILR, a complete uninvase diagnostics (ECG, echocardiogram, 24<sup>h</sup> holter monitoring and complete laboratory check) was performed with each patient. The ILR implantations were performed in the catheterization theatre of the Department of Cardiology, Clinical Center Nis. All the patients had the ILR implanted under local anesthesia at the level between the 2<sup>nd</sup> and 4<sup>th</sup> intercostal spaces, depending on the preoperation signals. The first follow-up was 14 days after the implantation, followed by the next one after a month and two months afterwards. The patients immediately reported eventual occurrences of the symptoms. The total follow-up period was  $64 \pm 37$  days. In cases of positive results, the patients were given indications for the implantation of permanent pace-makers.

### Results

The obtained results showed that the use of ILR proved the cause of syncope in 9 patients and, consequently, they had permanent pace-makers implanted. It concerned pauses in heart-functioning among which the shortest one lasted for 3 seconds and the longest one lasted for 9 seconds. There were no malignant rhythm disorders. The shortest diagnostification period was after 24 days, whereas the longest one was after 48 days.

Table 1.

Number of patients	17
sex	male female
	9 8
Mean age (years)	$43 \pm 21.1$
Follow-up period (days)	$64 \pm 37$
Pause >3 seconds (%)	52.9%
VT, VF	0%
Pace-maker implanted	9 (52.9%)

### Discussion

Loop recorders owe their name to the concept of an infinite loop, the term used most frequently in programming which, in this case, stands for continual record-making while segments are kept or frozen when needed by means of a special activator. This principle is used in airplane black boxes. Encouraging results of pilot studies gave an impulse for development of the ILR. Today, it is a small device resembling a USB card, weighing 17 grams, with the battery capacity of 14 months. The device has a capability of storing recorded bipolar ECG signal lasting for 21 minutes or 42 minutes of compressed recordings in the form of a continuity or in the form of three separate segments. The recordings are made according to the principle of an infinite tape, and storing of the recordings is done by means of a non-magnetic activator activated by patients or their family members during occurrences of the symptoms. Readings of the recordings are done by

classic pace-maker programators and the recordings are in the form of ECG stripes. Implantations are performed in operation theaters or in catheterization theatres in the form of ambulance interventions. Checking the signal before implantation is of vital importance. The best signal is obtained by positioning ILR in the area between the left sternal position and the mid-clavicular line in the space between the 2<sup>nd</sup> and the 4<sup>th</sup> rib. The patient is instructed how to use the activator for recording the ECG recordings during the symptoms' occurrence. Family members should, necessarily, be acquainted with this due to the fact that the patient, during the consciousness crisis, which occurs abruptly, is usually incapable of activating the recording himself. There are no real contraindications for implantation of LOOP recorders; therefore, they are widely applied. Their interference with mobile phones has only been registered in their every day application (9). Patients with implanted recorders should not undergo magnetic-resonance diagnostics and therapies based on strong magnetic fields. DC shocks and electric shocks can cause damage to the device and disturbance of its functions. After implantation, patients are followed-up in regular time-intervals (1-2 months) and even sooner in the event of undesired occurrences (10).

There are lots of studies that point to great benefit of this method in syncope of uncertain etiology diagnostification (11). The RAST (Randomized Assessment of Syncope Trail) study compared two diagnostic approaches in syncope of uncertain etiology: the conventional diagnostic approach and implantation of the ILR. Patients with implanted ILRs were followed-up during one-year period, and the diagnosis covered finding correlations between the symptoms and the cardiac rhythm. The results have shown that monitoring with the help of the ILR implants has significantly greater diagnostic value than the conventional strategy and they are in favour of early application of the ILR (12), which has been pointed by our results as well.

The ISSUE (International Study of Syncope of Uncertain Etiology) study was performed on 111 examinees for the purpose of clarifying the syncope mechanism in tilt positive and tilt negative patients. The ILR implants were used in the estimation of correlations between the rhythm recorded during the tilt test and spontaneous rhythm disorder episodes. The results pointed to the relevant significance of the tilt test, due to the fact that the patients with positive and those with negative tests did not differ neither in clinical nor in prognostic sense, and the frequency of arrhythmia occurrence was similar. More frequent occurrence of asystolia, than it would be expected based on the previous tilt test performed on the same examinees was established, and it was been noted that bradycardia occurs more frequently in spontaneous syncopes than in those provoked by test (13).

Two groups of patients can especially benefit from the ILR: patients with cardiac disease (14,15) and negative standard tests, including a negative EPS, with a high risk of malign rhythm disorders, and patients without cardiac disease whose syncope is not clearly neuro-cardiogeneous and the cause could not be established by standard testing. The method is particularly useful when applied on children.

There are recommendations that the use of the ILR should be considered in early syncope estimation (16).

The ILR will not and cannot replace the standard tests. The tilt test remains an obligatory method in the estimation of neurocardiogeneous syncope, while the EPS is absolutely indicated method in structural cardiac diseases. Still, one should keep in mind the minimal invasiveness of the ILR implants as well as the minimal possibility of complications, although it is still a surgical intervention which forms a

small scar and there is a potential risk of it being infected.

### Conclusion

The ILR is an important diagnostic device in cardiology for syncope of uncertain etiology diagnostic. Application of the ILR is minimally invasive and safe for a patient. It is very useful when, even by the application of noninvasive methods, we cannot discover the cause of syncope.

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## IMPLANTABILNI LOOP REKORDER U DIJAGNOSTICI SINKOPA NEJASNOG POREKLA

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Implantabilni loop rekorder (ILR) predstavlja dijagnostičku metodu u kardiologiji, čija je uloga u otkrivanju sinkopa kod kojih se primenom standardnih metoda nije došlo do dijagnoze. Za automatski zapis aparat poseduje bradikardnu i tahikardnu opciju koje su programabilne. Kapacitet baterije je 14 meseci.

Cilj rada bio je da se ispita upotreba loop rekordera u dijagnozi sinkopa nejasnog porekla na Klinici za kardiologiju Kliničkog centra u Nišu.

U ispitivanju je učestvovalo 17 bolesnika sa sinkopom nejasnog porekla (9 muškaraca, 8 žena). Prosečna starost bolesnika bila je 43±21.1 godina. Prva kontrola bila je na 14 dana, zatim na mesec i na dva meseca od ugradnje. U slučaju pojave simptoma bolesnici su odmah dolazili na kontrolu. Ukupan period praćenja bio je 64±37 dana. U slučaju postojanja pozitivnog nalaza, bolesnicima je postavljana indikacija za ugradnju stalnog pejsmejke.

Kod 9 (52.9%) bolesnika dokazan je uzrok sinkopa i njima je ugrađen stalni pejsmejker. Oni su imali pauze u srčanom radu (duže od 3 sec). Najkraće vreme postavljanja dijagnoze bilo je nakon 14 dana, najduže nakon 48 dana. Malignih poremećaja ritma nije bilo.

Loop rekorder je važno dijagnostičko sredstvo u otkrivanju uzroka sinkopa nejasnog porekla. *Acta Medica Medianae* 2009;48(1):12-14.

**Cljučne reči:** sinkopa nejasnog porekla, loop rekorder