Implantable Loop Recorder – A Good Opportunity to Diagnose Unexplained Syncope

Predrag Cvetković, Zoran Perisić, Tomislav Kostić, Aleksandar Stojković, Miroslav Krstić, Nenad Bozinović, Bratislav Kirčanski, Mima Keković

1Pacemaker Center, Clinical Centre Niš, Niš, Serbia
2Pacemaker Center, Clinical Centar of Serbia, Belgrade, Serbia
3General Hospital Prokuplje, Prokuplje, Serbia

SUMMARY

Implantable loop recorder (ILR) is a method in cardiology, which is used for the diagnosis of unexplained syncope in patients who were not treated successfully using standard methods. Implantable loop recorder is a diagnostic device that is surgically implanted under the skin of the chest area. This device does not have the endovenous implantation of electrodes; instead, electrodes are attached to the machine housing. The device records the heart rhythm continuously, up to 14 months, and stores data outside the activator whenever symptoms appear, or by the automatic activation of the predefined program for bradycardia, asystole, and tachycardia. The aim of this paper was to describe the method for the detection of cardiac syncope with the use of implantable loop recorder.

Key words: implantable loop recorder, cardiac syncope

Corresponding author:
Predrag Cvetković
e-mail: drpedjac@yahoo.com

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INTRODUCTION

Syncope is a condition of sudden brief loss of consciousness caused by insufficient blood supply to the brain. Cardiac syncope accounts for 10% of all syncope cases. Mortality of patients with this type of syncope is 20% -30% annually (1). Cardiac syncope is caused by a significant reduction in stroke volume of the heart, which may be due to mechanical obstruction or heart rhythm disorders. As for the mechanical causes of syncope, the most often recorded are aortic stenosis, hypertrophic cardiomyopathy, mitral stenosis, left atrial tumors, cardiac tamponade.

Causes of cardiac syncope vary from arrhythmias and conduction system disorders to the most common with sinus bradycardia below 50 min, AV blocks of the second and third degree, frequent ventricular rhythm disorders, arrhythmogenic right ventricular dysplasia, pacing-induced syncope and pharmacologically induced syncope (2).

Implantable loop recorder (ILR) is a method in cardiology for the diagnosis of unexplained syncope, which has recently become more acceptable in our country. Implantable loop recorder is a diagnostic device that is surgically implanted under the skin of the chest area. This device does not have the endovenous implantation of electrodes; instead, electrodes are attached to the machine housing. The device records the heart rhythm continuously, up to 14 months. Repeated unexplained syncope represents a significant worldwide, and studies showed that in the USA one million new patients are registered annually (1, 3). After the administration of former diagnostic methods, about 35% of syncope cases remain unexplained, which poses a problem, because patients with syncope cannot perform certain types of jobs (driving cars, motorcycles, etc.) (4).

For patients with unexplained syncope, when their cardiac etiology is suspected, following the diagnostic methodological approach is essential: the standard 12-lead ECG monitoring, continuous ECG holter monitoring from 24 to 168 hours and the provocative, so-called head-up tilt test. In some patients, an additional non-invasive treatment is necessary, like echocardiography or an exercise testing, while in others invasive treatment like cardiac catheterization is also required. Given the unpredictable nature of syncope, conventional methods of continuous ECG monitoring proved to be of little diagnostic value, regardless of numerous repetitions (2, 5, 6). According to some research results, using these methods, a syncope was registered in 1.6% of patients, while dizziness was registered in 14.5% of patients (1, 7). Tilt tests and electrophysiologic tests were an attempt to provoke symptoms under controlled conditions, by means of which their cause and origin may be presumed, but they may give negative results regardless of recurrent symptoms.

AIM

The aim of this paper was to describe the implantable loop recorder as a method of choice for the diagnosis of unexplained syncope.

METHODS

Chronologically, the concept of ambulatory monitoring was gradually developed from a 24-hour ECG monitoring through the outer loop recorder (where the patient himself/herself attaches and activates it when the symptoms appear) to the development of the holter within the permanent pacemaker, early in the eighties of the 20th century, when the idea was born to use it for diagnostic purposes. The first pilot study with implantable loop recorder was carried out in 1992, including 26 patients (8, 9). Patients included in this study were those with unexplained syncope, whereby all the classic invasive and non-invasive tests had previously been performed and proved negative.

It is a device with the size and shape of a standard pacemaker, with two electrodes placed on the outside of the box that did not require endovenous lead implantation (Figure 1).

![Figure 1. The prototype of a temporary pacemaker](image)

It was the prototype of today's ILR that was able to record seven and a half or 15 minutes of ECG recording which was frozen by the magnet. On that
occassion, the correlation between symptoms and ECG rhythm was found in 88% of patients within 5.1 ± 4.8 months of surveillance. This study obtained the encouraging results that led to further improvement of ILR, so that today a device with the size of USB is available on the market with a battery that can be used up to 14 months of monitoring, and the possibility of keeping a taped ECG signal for 21 minutes of uncompressed and 42 min of compressed records (10, 11). At the Clinic for Cardiovascular Diseases, Clinical Centre Niš we use: Medtronic Reveal Plus9526 and LINQ Reveal Loop Recorder, the controller Medtronic 2090 (Figure 2, 3).

**Figure 2: Medtronic Reveal Plus 9526 Loop Recorder and Reveal LINQ**

**Technique**

ILR implantation is an ambulatory surgical intervention that is performed in the operating room, i.e. the room for cardiac catheterization. The procedure of catheterization takes about 30 minutes, which is relatively short, considering that the device is placed under the skin, requiring the endovenous lead implantation of electrodes. Unlike the installing of antibradykardia pacemaker, this procedure carries less risk of further complications. The first step in preparing the operating field is washing the area with alcohol two times, then with povidone-iodine two times and covering it with sterile surgical cover sheets. Before the surgeon administers a local anesthetic, it is necessary to perform skin mapping in order to obtain the best ECG signal and determine the precise place of the local anesthetic application. Then, a surgical incision of 3 cm in length is made in order to place the device (Figure 3) (7). The best signal is obtained in the third or fourth intercostal space, where the incision is made about 2 cm to the left of the sternum.

Subcutaneous space for the device is made by blunt dissection. The device is positioned so that the circular electrodes on the body of the camera are turned downwards and then subdermal tissue and skin are sewn in the usual way. Signal is checked by telemetry connectivity checks on the programmer. Skin mapping criteria for the selection of the place for implantation are R-T peak to peak amplitude greater than 2:1 and R-T peak-to-peak greater than 5:1. After implantation, optimal signal sensing is programmed and the optimal autoactivation values are set, while the patient and his close relatives are educated on how to use an external activator for recording ECG signals (similar to the remote for car alarms) at the point of the occurrence of symptoms (12). There is no real contraindication for the implantation of ILR, unless the patient is allergic to metal; however, the presence of an active infection or a bleeding diathesis may preclude implantation. Prophylactic antibiotic therapy is the same as for post-installation of antibradycardia pacemaker.

**Monitoring of patients with implantable loop recorder**

Routine control of patients with implantable loop recorder is carried out one month after implantation and every month afterwards, or immediately after any symptoms occur, whether an external activator of recording was used, or records are read using a standard controller for pacemaker (Medtronic 2090) (Figure 3) with special software. When a patient activates the camera, recording is done continuously and the data is stored in the device memory. Recording covers the period before and after the activation of the device. A trigger to activate the device is four consecutive R-R intervals for bradycardia and 16 consecutive R-R intervals for tachycardia, which automatically activates the device without prior activation of an external device by the patient. In this way it is achieved that if the patient is not in a position to issue an order for activating, the device itself will do so (7, 9).
DISCUSSION

Studies dealing with implantable loop recorder have shown a close correlation between the occurrence of symptoms and the heart rhythm. The study RAST (Randomized Assessment of Syncope Trial) (13) compared two diagnostic approaches in patients with syncope and ejection fraction less than 35% and showed that primary implantation of loop recorder has better diagnostic value compared to conventional methods. Results in 60 patients have shown that a prolonged monitoring of patients with syncope has a better diagnostic value than conventional diagnostic methods. The mere cost of the device, with the whole procedure of implantation, patient monitoring and device explantation is less than or approximately equal to conventional methods for the diagnosis of unexplained syncope, which is one in a series of positive reasons some authors use to recommend implantable loop recorders in patients with unexplained syncope.

In the diagnostic algorithm of unexplained syncope suggested by Krahn and colleagues (1, 7, 13), a dominant place is given to ILR. Although some authors promote it as a modern method for the diagnosis of unexplained syncope, ILR implantation and head-up tilt test are the gold standard tests for the diagnosis of unexplained syncope as well as electrophysiological testing in patients with syncope and structural heart diseases.

Our opinion, based on previous experience in the diagnosis of unexplained syncope, confirms the importance of ILR in the diagnosis of unexplained syncope in properly selected patients.

CONCLUSION

Compared to standard conventional methods, implantable loop recorder is an important tool in cardiology for diagnosing unexplained syncope as it allows extended monitoring and establishing the correlations between symptoms and the time of recorded heart rate.
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Implantabilni loop rikorder – dobra mogućnost za dijagnostikovanje sinkopa nejasnog porekla

Predrag Cvetković, Zoran Perisić, Tomislav Kostić, Aleksandar Stojković, Miroslav Krstić, Nenad Bozinović, Bratislav Kirčanski, Mima Keković

1Pejsmejker centar, Klinički centar Niš, Niš, Srbija
2Pejsmejker centar, Klinički centar Srbije, Beograd, Srbija
3Opšta bolnica Prokuplje, Prokuplje, Srbija

SAŽETAK

Implantabilni loop rikorder (ILR) je metod u kardiologiji koji se koristi za dijagnostikovanje sinkopa nejasnog uzroka kod bolesnika kod kojih primenom standardnih metoda nije bilo uspeha. Implantabilni loop rikorder je dijagnostički aparat koji se hirurškim putem implantira ispod kože grudnog koša, aparat koji nema endovensko uvođenje elektroda, već su elektrode pričvršćene na kućištu aparata. Ovim aparatom se beleži ritam srca neprekidno, a najviše 14 meseća, memoriše se spoljnom aktivacijom u vreme simptoma ili automatskom aktivacijom unapred zadatim programom za bradikardiiju, asistoliju, tahikardiiju. Cilj ovog rada bio je da se opiše metod za detekciju kardijalnih sinkopa uz pomoć implantabilnog loop rikordera.

Ključne reči: implantabilni loop rikorder, kardijalna sinkopa