Expert opinion of the Heart Rhythm Association of the Polish Cardiac Society and the Polish Neurological Society on evidence-driven implementation of implantable loop recorders in Poland

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ABSTRACT

Implantable loop recorders (ILR) are considered increasingly helpful in diagnosing cardio-neurological conditions, especially if arrhythmic events are of high clinical importance but are unlikely to be captured by standard methods of electrocardiogram recording due to the low frequency of events and short duration of a single event. The compelling evidence from randomized trials and observational studies strongly supports ILR utilization in patients after cryptogenic stroke or transient ischemic attack and in patients with recurrent transient loss of consciousness of unknown origin. These two groups of patients are expected to gain the most from initiating ILR-driven clinically effective management strategies. Stroke or transient ischemic attack survivors with detected subclinical atrial fibrillation can be switched from antiplatelets to anticoagulants, whilst patients with recurrent syncope may avoid severe injuries and/or substantial impairment of their quality of life. This joint opinion of the Heart Rhythm Association of the Polish Cardiac Society and experts from the Polish Neurological Society summarizes the up-to-date rationale for using ILR in everyday clinical practice and describes the road map for implementing this technology in Poland. Special emphasis is placed on the most recent guidelines issued by both cardiological and neurological scientific societies.

Key words: acute ischemic stroke, atrial fibrillation, COVID-19, ECG monitoring, embolic stroke of undetermined source, syncope

INTRODUCTION

Implantable loop recorders (ILR), also known as insertable cardiac monitors, have been developed to enable long-term continuous cardiac rhythm monitoring [1, 2]. Over the past three decades, ILR technology has substantially advanced, leading to enhanced quality of recorded electrocardiograms (ECG) and improved reliability of automated algorithms. These have been accompanied by appropriate miniaturization of the device and its lifespan of 18 to 36 months [2].

ILRs are considered particularly useful in patients who experience clinically significant but infrequent arrhythmia-related symptoms of short duration that are unlikely to be recorded by conventional 12-lead ECG or the standard Holter-type monitoring [1]. This is particularly relevant if the correct diagnosis of the underlying cardio-neurological condition opens a pathway for a specific evidence-based management strategy that improves prognosis [1–3].

This expert opinion represents a joint viewpoint of the Heart Rhythm Association of the Polish Cardiac Society and experts from the Polish Neurological Society on the optimal use of ILRs in Poland. Special emphasis is placed on (1) the growing support for this technology in clinical guidelines issued by various scientific societies and (2) the current implementation status in European countries.

The primary focus is on neurological patients who are at high risk of ischemic stroke caused by untreated subclinical atrial fibrillation (AF). Namely, the patients shortly after cryptogenic stroke or cryptogenic transient ischemic attack (TIA). The article also addresses another important cardio-neurological entity, recurrent transient loss of consciousness (TLoC).

GUIDELINE-BASED INDICATIONS FOR ILR AFTER ISCHEMIC STROKE

Despite significant progress in stroke prevention, acute treatment, and rehabilitation, stroke continues to be one of the leading causes of mortality and long-term disability in adults. Each year there are over 12 million new cases worldwide [4]. In Poland, in 2022, there were over 84 000 acute stroke admissions, including approximately 74 000 cases of ischemic stroke [5]. An additional 24 000 patients were admitted for TIA [5].

Ischemic stroke and TIA are conditions of marked etiological heterogeneity. Therefore, to implement optimal secondary prevention, it is essential to identify the most likely cause of stroke/TIA in each patient.

According to the TOAST (Trial of Org 10172 in Acute Stroke Treatment) classification, the major causes of ischemic stroke are as follows [6]:

- Large artery atherosclerosis (about 18%–25% of ischemic strokes) [7, 8];
- Cardiac embolism (about 20%–28% of ischemic strokes) [7, 8];
- Small vessel disease (about 12%–25% of ischemic strokes) [7, 8];
- Other determined causes (about 4%–5% of ischemic strokes) [7, 8];
- Cryptogenic (i.e. with no clear cause or more than one probable cause; about 25%–39% of ischemic strokes) [7, 8].

Furthermore, a significant proportion of cryptogenic strokes fall under the category of embolic strokes of an undetermined source (ESUS) [7, 8]. For the diagnosis of ESUS, it is necessary to [7]:

- Identify a non-lacunar ischemic brain lesion responsible for the symptoms;
- Exclude ≥50% stenosis of extra- or intracranial arteries supplying the ischemic area;
- Exclude the presence of any classic source of cardiac embolism using 12-lead ECG, at least 24-hour Holter ECG monitoring, and echocardiography.

The relationship between AF and ischemic stroke is complex. In patients with ESUS, the embolic material is expected to originate from the left atrial appendage, with paroxysmal atrial fibrillation as the underlying pathology. However, three large clinical trials (NAVIGATE ESUS, RESPECT ESUS, and ATTICUS) have failed to show the superiority of non-vitamin K antagonist oral anticoagulant over aspirin in unselected ESUS patients [9, 10]. In the future, imaging and electrocardiographic biomarkers of atrial cardiomyopathy may prove to be reliable enough for risk stratification and guide treatment decisions even in the absence of AF [11, 12]

Presently, the formal diagnosis of AF remains critical for the initiation of highly effective oral anticoagulant therapy. Therefore, the high-risk ESUS patients are likely to gain the most from intensified diagnostic workup. The use of ESUS to drive further intensive ECG monitoring seems practical. Its diagnostic criteria impose several additional tests to be performed before excluding other types of stroke, which increases the likelihood of subclinical atrial fibrillation [7]. This holds particular importance for patients who have experienced TIA, as proper treatment may prevent their first-ever stroke and avert the associated risk of mortality and disability.

The standard diagnostic workup conducted in the stroke unit and post-stroke outpatient setting allows the detection of previously unrecognized AF in over 20% of patients [12]. A recent meta-analysis of randomized trials indicates that stroke survivors scheduled for ILR implantation have an almost 6-fold increase in AF detection compared to standard outpatient monitoring (13% vs. 2.4% at 12 months) [13]. From the public health perspective, adopting such an approach is expected to yield a substantial reduction in the long-term burden of recurrent cardioembolic strokes in high-risk patients [3, 14, 15].

Professional guidelines issued by prominent cardiological and neurological societies (European Society of Cardiology [ESC], European Stroke Organization, Polish Neurological Society) endorse the implementation of extended ECG monitoring in patients recovering from an

Table 1. Recommended use of implantable loop recorders after ischemic stroke or TIA

ESO 2022 guidelines [9]		PNS 2019 guidelines [17]	ESC 2020 guidelines [16]
In patients with acute ischemic stroke or TIA			
		PNS recommends ECG monitoring for at least 22 hours to detect AF QoE: moderate; Strength: strong	1. ESC recommends using short-term ECG recording for at least the first 24 h, followed by continuous ECG monitoring for at least 72 h whenever possible. Class I, LoE: B 2. In selected[a] stroke patients without previously known AF, additional ECG monitoring using long-term non-invasive ECG monitors or insertable cardiac monitors should be considered to detect AF. Class IIa, LoE: B [a]Not all stroke patients would benefit from prolonged ECG monitoring; those deemed at risk of developing AF (e.g. the elderly, with cardiovascular risk factors or comorbidities, indices of LA remodeling, high C2HEST score, etc.) or those with cryptogenic stroke and stroke characteristics suggestive of an embolic stroke should be scheduled for prolonged ECG monitoring
In adult patients with ischemic stroke or TIA of undetermined origin			
1. ESO recommends prolonged cardiac monitoring instead of standard 24-hour monitoring to increase detection of subclinical AF. QoE: moderate; Strength: strong 2. ESO suggests the use of additional outpatient monitoring compared with in-hospital cardiac rhythm monitoring alone to increase the detection of subclinical AF. QoE: very low; Strength: weak 3. ESO suggests the use of implantable devices for cardiac monitoring instead of non-implantable devices to increase detection of subclinical AF.QoE: low; Strength: strong 4. There is continued uncertainty over the advantages of the use of blood, echocardiographic, ECG, or heart or brain imaging biomarkers to increase the detection of subclinical AF	1. ESO suggests prolonged cardiac rhythm monitoring for AF for more than 48 h 2. ESO suggests initiating ECG monitoring as early as possible during the in-hospital stay to increase the rate of AF detection 3. The presence of potential blood, echocardiographic, ECG, or brain imaging biomarkers might increase the probability of AF detection but given the limited current evidence, ESO suggest avoiding their use for excluding patients from long-term ECG monitoring	1. 1. Extension of Holter-type cardiac rhythm monitoring for more than 24 hours may be considered, including the use of invasive telemetric methods. QoE: moderate; Strength: strong 2. It is justified to prolong the time of cardiac rhythm monitoring to identify patients requiring oral anticoagulants, also with the use of ILRs (stated in the text, not a direct guideline)	
In adult patients with ischemic stroke or TIA of undetermined origin and PFO			
1. There is continued uncertainty over the risks and benefits of the use of implantable monitor devices over any non-implantable external monitor devices to increase detection of subclinical AF	1. ESO suggests prolonged cardiac rhythm monitoring for AF for more than 48 h in patients older than 55 years to increase the detection of subclinical AF 2. ESO suggests prolonged cardiac rhythm monitoring for AF to increase the rate of anticoagulation or reduce unnecessary PFO occluder implantations in patients with cryptogenic stroke and PFO older than 55 years 3. ESO suggests using implantable monitoring devices, compared to any non-implantable external monitoring device, to detect paroxysmal AF in patients with cryptogenic stroke and PFO older than 55 years 4. In patients younger than 55 years with undetermined stroke and PFO, we suggest that basic cardiac monitoring during 24 h by telemetry or Holter-ECG could be enough to rule out subclinical AF, but clinical, stroke and PFO characteristics should be taken into account	This subgroup of patients was not addressed directly in the guidelines. However, cases with <7 points in RoPE score are not considered to be at high risk of paradoxical embolism and may be classified as cryptogenic	This subgroup of patients was not addressed directly in the guidelines. However, it is included in the abovementioned population of patients with ischemic stroke or TIA without previously known AF

Abbreviations: AF, atrial fibrillation; C2HEST, coronary artery disease or chronic obstructive pulmonary disease (C2, 1 point each), hypertension (H, 1 point), elderly (E, age ≥75 years, 2 points), systolic heart failure (S, 2 points), thyroid disease (T, hyperthyroidism, 1 point); ECG, electrocardiogram; ESC, European Society of Cardiology; ESO, European Stroke Organization; LoE, level of evidence; PFO, patent foramen ovale; PNS, Polish Neurological Society; QoE, quality of evidence; RoPE, Risk of Paradoxical Embolism Score, TIA, transient ischemic attack

ischemic stroke of unknown etiology [9, 16, 17]. While these guidelines may not be entirely uniform (see Table 1), they consistently emphasize the importance of extensive ECG monitoring after stroke to detect previously unknown AF. The emergence of over-the-counter wearable devices approved for AF detection, especially smartwatches capable of ECG recording, is anticipated to improve the diagnostic yield [18]. However, the most recent document issued by the European Stroke Organization in May 2022 strongly supports prolonged cardiac monitoring after cryptogenic strokes with special emphasis on ILRs [9]. This recommendation extends even to patients with patent foramen ovale (PFO) or patients without additional markers of subclinical AF [9].

GUIDELINE-BASED INDICATIONS FOR ILR IN SYNCOPE

Syncope is a common clinical condition that affects more than one-third of the general population over the course of life [1, 19, 20]. Its causal mechanism is often elusive and generally benign. However, approximately 14% of syncope cases syncope are considered severe, posing a high risk of

severe injuries and/or substantial impairment of the quality of life [20]. Syncope can be classified into three main groups: reflex, secondary to orthostatic hypotension, and cardiovascular syncope [1]. Differential diagnostic workup of a patient experiencing TLoC always includes seizures [1, 21]. In this respect, the presence of significant bradycardia or tachycardia, as documented by ECG recording at the time of the event, results in the diagnosis of cardiac syncope.

In patients with a diagnosis of syncope confirmed using ILR, both the diagnosis and treatment, including causal treatment, may occur more quickly [22–25]. Considering the proportion of syncope patients in whom ECG recording changed previous therapeutic management, ILR proves not only clinically effective (number needed to treat = 2.1) but also cost-effective [26]. This advantage becomes particularly evident when patients with implanted devices are monitored remotely [27].

The role of ILRs in the diagnostic workup is extensively addressed in two major up-to-date guideline documents [28, 29]. The first guidelines were released in August 2017 by the American College of Cardiology and the American Heart Association in collaboration with the Heart Rhythm Society [29]. The second were released in October 2018 by the ESC in collaboration with the European Heart Rhythm Association [28]. Both guidelines are largely complementary and support ILR utilization in selected cases [19, 28, 29]. This support is more pronounced and more precise in the ESC/European Heart Rhythm Association guidelines (Table 2).

Prospective data provide evidence that ILRs offer particular benefits in adult populations (1) with suspected epilepsy but no improvement on anti-seizure medications, (2) with unexplained falls, and (3) with loss of consciousness and coexisting cardiac conditions such as hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia, or channelopathies [28].

In the pediatric population, there are currently no clear guidelines on ILR use. Nevertheless, experimental and observational studies have demonstrated the potential for implementation in children experiencing loss of consciousness of unknown cause. The aim is to exclude or confirm potentially dangerous underlying arrhythmias [30–36].

It should be emphasized that the UK's National Institute of Health and Care Excellence (NICE) considers ILRs cost-effective [37]. As a consequence, NICE recommends using ILRs in the diagnostic workup after total loss of consciousness of unexplained or suspected arrhythmogenic etiology if the initial cardiovascular examination is inconclusive.

Table 2. Recommended use of ILRs in the diagnostic workup of cardiac syncope

ACC/AHA/HRS 2017 [29]	ESC 2018 [28]
Insertable cardiac monitors can be useful in evaluating selected ambulatory patients with syncope of suspected arrhythmic etiology Class IIa, LoE: B–R	1. ILRs are indicated in an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria[a], and a high likelihood of recurrence within the battery life of the device Class: I, LoE: A [a]Major high-risk features in patients with syncope at initial evaluation include: • New onset of chest discomfort, breathlessness, abdominal pain, or headache • Syncope during exertion or when supine • Sudden onset palpitation immediately followed by syncope • Severe structural or coronary artery disease (heart failure, low LVEF, or previous myocardial infarction) Three minor high-risk features need to be associated with structural heart disease or abnormal ECG • No warning symptoms or short (<10 s) prodrome • Family history of sudden cardiac death at a young age • Syncope in the sitting position
Candidates for ILR should present with recurrent, infrequent, unexplained syncope (or suspected atypical reflex syncope) of suspected arrhythmic cause after a nondiagnostic initial workup, with or without structural heart disease (stated in the table referring to patient selection, not a direct guideline)	2. ILR is indicated in patients with high-risk criteria in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment and who do not have conventional indications for primary prevention ICD or pacemaker indication Class: I, LoE: A 3. ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes Class: IIa, LoE: B 4. ILRs may be considered in patients in whom epilepsy was suspected, but the treatment has proven ineffective Class: IIb, LoE: B 5. ILRs may be considered in patients with unexplained falls Class: IIb, LoE: B

Abbreviations: ACC, American College of Cardiology; AHA, American Heart Association; HRS, Heart Rhythm Society; ICD, implantable cardioverter-defibrillator LVEF, left ventricular ejection fraction; other — see Table 1

COVID-19 AS A MODIFYING FACTOR

As of January 2024, it is estimated that over 702 million people worldwide have been infected with the severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) [38]. Thromboembolic episodes and arrhythmias are among the most frequent complications of coronavirus disease 2019 (COVID-19) [39]. In fact, AF diagnosed during or after SARS-CoV-2 infection is considered the second most common clinical condition, preceeded only by respiratory complications [40, 41].

The presence of newly detected AF associated with COVID-19 increases the risk of embolic complications more than 14 times and significantly worsens prognosis, nearly quadrupling mortality [42, 43].

Mechanisms such as endothelial damage, impaired microcirculation, inflammatory reaction and edema of cardiomyocytes, fibrosis, pulmonary hypertension, as well as the effect of angiotensin may contribute to a higher incidence of AF in SARS-CoV-2 positive patients. Even if the infection is clinically asymptomatic [44].

For this reason, the overall incidence of AF in the general population is probably higher than before the pandemic. Consequently, this may contribute to increased subclinical AF in patients after ESUS. Therefore, clinicians should not refrain from scheduling prolonged cardiac monitoring in

ischemic stroke patients who suffered from a stroke coinciding with COVID-19. On the contrary, it may even be justified to intensify the proactive approach to identify clinically important arrhythmias and initiate proper treatment.

It should also be noted that regular routine electrocardiograms or repeated Holter-type ECG monitoring that comprises the standard diagnostic workup typically requires the patient to travel and have direct contact with medical staff. In seasons with increased incidences of COVID-19, this approach may result in exposure to unnecessary risk of infection both among patients and healthcare professionals. Remote assessment of ECG recordings seems to be a better solution whenever possible [45]. Such functionality is provided by modern ILRs via a telemonitoring network. Through daily checks, ILRs enable prompt detection of emerging arrhythmias and, more importantly, immediate optimization of pharmacological treatment to reduce the risk of thromboembolic complications.

ILR REIMBURSEMENT ACROSS EUROPE

The utilization of ILRs is presently covered by reimbursement policies in several European countries, including Austria, Belgium, Denmark, France, Germany, Italy, Netherlands, Norway, Spain, Portugal, Sweden, Switzerland, and the United Kingdom [46]. Although the pricing and mechanisms of reimbursement may vary, it can be generally observed that countries with well-developed healthcare systems are inclined to allocate public funds for long-term ECG monitoring after ESUS and/or recurrent TLoC.

In Poland in 2019, the National Consultant in Cardiology and the National Consultant in Neurology jointly applied to the Ministry of Health for qualification of monitoring for arrhythmic events with ILRs as a guaranteed hospital service for patients after cryptogenic stroke and patients having recurrent TLoC [46]. Stroke survivors were to be diagnosed with ESUS, independent in activities of daily living, and with left atrial enlargement. Patients after TLoC were supposed to have extensive diagnostic workups completed, with no clear diagnosis.

This application was preceded by extensive consultations with experts in the relevant therapeutic areas, resulting in a published consensus statement [3]. The inclusion of additional selection criteria for ESUS patients aimed to balance the expected benefit for public health and the ability to finance the service from the budget. The intention was to initiate wide implementation of a novel but costly technology by granting access to the subpopulation at the highest risk of positive yield [3].

The application was forwarded to the Agency for Health Technology Assessment and Tariff System. In March 2021, the Agency issued the report WS.420.2.2021 based on its critical appraisal and seven external expert opinions [46]. Also, in March 2021, the Transparency Council concluded that ILR use is clinically effective and probably cost-effective in detecting AF. The Council explicitly confirmed the importance of reimbursing this technology. However, it advised against reimbursement under the proposed conditions. The main points identified as suboptimal and requiring revision were: (1) the absence of provisions for outpatient implantation, (2) the lack of specification regarding outpatient follow-up, (3) the initially proposed limitation to grant access to ILRs based on the criterion of left atrial enlargement, (4) the initially proposed condition to limit access to ILRs to patients admitted to the stroke units with at least a moderate annual volume of acute stroke admissions [47].

As a result, in April 2021, the President of the Agency gave a positive recommendation for reimbursement of the intensive ILR monitoring for arrhythmic events. The recommendation specified that competent cardiology wards should be able to perform the implantation as a one-day procedure and then ensure both remote and on-site follow-up monitoring. The criterion of the minimal annual volume of acute stroke admissions has not been imposed on qualifying neurological wards [48].

In November 2023, the Minister of Health issued a regulation introducing monitoring of arrhythmic events with ILR into the basket of guaranteed hospital treatment services [49]. The possibility of one-day hospitalization in the cardiology or pediatric cardiology department for ILR implantation or ILR removal. One of the organizational requirements is to ensure follow-up visits to the cardiology center for adults or children after ILR implantation.

The service is addressed to two groups of patients [49]:

- Patients after cryptogenic stroke with negative results of standard diagnostic workup. A necessary condition is to have a formal diagnosis of cryptogenic stroke, stated directly in a discharge report from a stroke unit. The target population is estimated at 800–1521 patients per year.
- Patients after recurrent loss of consciousness in whom previous extensive diagnostic procedures have failed to identify the cause. A necessary condition is to have a formal diagnosis of ICD-10 R55 or I95.1 and the prior performance of (1) tilt test, (2) 48-hour Holter ECG, (3) ECG stress test, (4) echocardiography, (5) electrophysiological test in patients under 75 years of age, (6) psychological consultation in patients under 18 years of age. The target population is estimated at 200–800 people per year.

The decision of the President of the National Health Fund about the determination of the conditions for contracting hospital services issued at the end of December 2023 enables actual implementation of ILRs in patients after cryptogenic ischemic stroke and with recurrent syncope of unexplained etiology [50].

CONCLUSION

ILRs offer a reliable and well-tolerated method of continuous ECG monitoring for up to 36 months. This technology is particularly helpful in diagnosing cardio-neurological conditions that hold high clinical significance but are unlikely

to be captured by standard ECG recording methods due to the low frequency and short duration of a single event.

The current body of evidence, including data from randomized trials and observational studies, and guidelines issued by various scientific societies strongly support ILR use (1) in patients after cryptogenic stroke or cryptogenic TIA and (2) in patients with recurrent syncope of unknown origin. These two groups of patients are expected to gain the most from the implementation of ILR and initiation of ILR-driven clinically effective management strategies.

Stroke or TIA survivors with detected subclinical AF can be switched from antiplatelets to anticoagulants to further minimize the risk of disabling cardioembolic stroke. Similarly, patients with recurrent syncope may avoid severe injuries and/or substantial impairment of the quality of life.

The arrhythmic and thrombogenic complications associated with the COVID-19 pandemic are not expected to diminish the diagnostic yield of ILR. Moreover, remote monitoring can be more effective in detecting and managing such complications without increasing the risk of virus transmission.

The experience of other European countries clearly shows that implementing ILRs in Poland is feasible. Polish experts in the fields of neurology and cardiology believe that the adoption of ILRs will bring significant health benefits not only to individual patients but also to the general population. The implementation strategy should initially prioritize high-risk populations and ensure frequent remote monitoring to minimize delays between an arrhythmic event and the subsequent therapeutic decision.

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