



# Additional diagnostic value of implantable loop recorder in patients with initial diagnosis of real or apparent transient loss of consciousness of uncertain origin

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## Aims

Non-syncopal transient loss of consciousness (T-LOC) encompasses disorders that sometimes resemble syncope, and the differential diagnosis with true syncope may be challenging. The implantable loop recorder (ILR) is potentially useful, but has never been systematically assessed. The aim of the study is to evaluate the diagnostic value of ILR in distinguishing syncope from non-syncopal forms of T-LOC.

## Methods and results

We implanted an ILR in 58 patients (mean age  $71 \pm 17$  years, 25 males) who had had  $4.6 \pm 2.3$  episodes of real or apparent T-LOC, in order to distinguish epilepsy from syncope (#28), unexplained fall from syncope (#29), or functional pseudo-syncope from syncope (#1). During  $20 \pm 13$  months of follow-up, 33 patients (57%) had a spontaneous event documented by ILR. A diagnosis of syncope was established by ILR documentation of an arrhythmia in 15 (26%) patients: an asystole of 6 s (IQR 4–10 s) duration was documented at the time of the spontaneous event in seven patients with initial suspicion of epilepsy and in five patients with unexplained fall; atrial tachyarrhythmia was documented at the time of the spontaneous event in 1 and 1 patient, respectively, and ventricular tachycardia in 1 patient with unexplained fall. Conversely, in another 18 patients, ILR monitoring documented no significant rhythm abnormalities at the time of T-LOC recurrence, thus excluding an arrhythmic syncope. Finally, ILR was unable to document any syncopal episode in 25 (43%) patients. Among the 15 patients with an established diagnosis of arrhythmic syncope, syncope recurred during follow-up in 2 of 11 patients who were on pacemaker therapy and in 3 of 4 patients who were on other therapies.

## Conclusion

Implantable loop recorder monitoring provides additional diagnostic value in 'difficult' patients with an initial diagnosis of non-syncopal real or apparent T-LOC.

## Keywords

Syncope • Implantable loop recorder • Non-syncopal transient loss of consciousness

Non-syncopal transient loss of consciousness (T-LOC) encompasses disorders that sometimes resemble syncope.<sup>1</sup> Among these, falls and epilepsy are two common causes of non-syncopal real or apparent T-LOC in which a differential diagnosis with syncope may be challenging. Conventional investigations, including tilt table testing, carotid sinus massage, electroencephalography, cerebral computed tomography, and Holter monitoring, are often inconclusive in

these settings.<sup>2,3</sup> As the implantable loop recorder (ILR) is able to provide electrocardiogram (ECG) monitoring for up to 3 years, it is potentially useful in documenting a spontaneous attack. Nevertheless, as the literature data on ILR in this setting are limited to case reports and small series,<sup>4–10</sup> the diagnostic role of the ILR is still unclear. Consequently, guideline recommendations are also scarce. In the 2009 version of the guidelines on syncope of the European

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### What's new?

- Literature data on implantable loop recorder (ILR) in patients with non-syncopal transient loss of consciousness (T-LOC) are limited to case reports and small series and the diagnostic role of the ILR is still unclear.
- Our data suggest that ILR monitoring provides additional diagnostic value in a minority of 'difficult' patients with an initial diagnosis of non-syncopal T-LOC.

Society of Cardiology, non-syncopal T-LOC is not considered a definite indication for ILR<sup>1</sup> and in the 2009 EHRA position paper of the European Heart Rhythm Association,<sup>11</sup> the indication for ILR for the differential diagnosis between syncopal and non-syncopal T-LOC is a class IIb recommendation.

The aim of this study was to evaluate the diagnostic value of ILR in definitely confirming/excluding an arrhythmic mechanism, thus helping to distinguish between syncope and epilepsy and between syncope and falls.

## Methods

The patients included in this study had initially undergone evaluation for T-LOC of uncertain cause (suspected epilepsy or unexplained fall) by other specialists (i.e. neurologists, geriatrists, internists) who raised the suspicion of an alternative diagnosis of arrhythmic syncope and referred to our Syncope Units for ILR implantation aimed at obtaining electrocardiographic documentation of a spontaneous event. After ILR implantation, patients were monitored every 3 months by means of in-hospital visits or remote monitoring until a recurrence of the spontaneous event was recorded, the ILR was explanted or the study ended.

## Results

Of the 309 patients who received ILRs between January 2003 and August 2012, 251 had a syncopal T-LOC. In the other 58 (19%) patients, the mechanism of T-LOC was uncertain and ILRs were implanted in order to distinguish epilepsy from syncope (#28), unexplained fall from syncope (#29), or functional pseudo-syncope from

syncope (#1). These patients formed the population of this study. The patients' clinical characteristics are listed in Table 1. The reason for re-appraisal of the initial diagnosis of epilepsy were initial diagnosis of epilepsy which was judged unresponsive to antiepileptic drug therapy by referring neurologist (# 14 cases) and/or the presence of contrasting historical features and objective signs, e.g. myoclonic jerks or tonic-clonic activity mimicking generalized epilepsy or prolonged post-critical confusion in absence of precise epileptic features (# 14 cases); in addition in 14 patients (50%) competing abnormalities/diagnoses were present which made an alternative diagnosis of syncope possible. The reason for re-appraisal of the initial diagnosis of unexplained fall in 29 patients was a history characterized by: recurrent unintentional falls to the ground or to a lower level occurring without prodromes in absence of accidental situations, i.e. slip or trip or environmental hazards; the patients denied loss of consciousness but were unable to remember precisely the event. In 15 patients (52%) competing abnormalities (Table 1) suggested an alternative diagnosis of unexplained syncope.

## Diagnostic yield

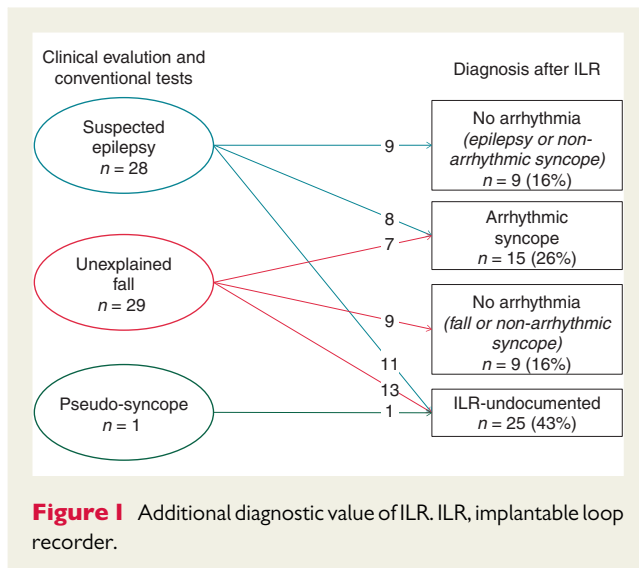
During  $20 \pm 13$  months of follow-up, 34 (59%) patients had event recurrence; 33 of these (57%) had a spontaneous event documented by ILR: asystole in 12 (20%) patients, tachyarrhythmia in 3 (5%), no arrhythmia in 18 (31%).

The diagnosis of syncope was established by ILR documentation of an arrhythmia in 15 (26%) patients: asystole was documented at the time of the spontaneous event in seven patients with initial suspicion of epilepsy and in five patients with unexplained fall; tachyarrhythmia was documented at the time of the spontaneous event in 1 and 2 patients, respectively (Figure 1). Asystole was of 6 s (IQR 4–10) duration and was due to sinus arrest in 11 patients and to AV block in one patient. Tachyarrhythmias were ectopic atrial tachycardia in one patient, atrial fibrillation in one patient, and ventricular tachycardia in one patient. Conversely, in the other 18 patients, ILR documented no significant rhythm abnormalities at the time of syncopal recurrence, thus excluding an arrhythmic syncope; however, a non-arrhythmic cause of syncope still remained possible as an alternative to the initial diagnosis of epilepsy or fall, especially in five patients who had a positive hypotensive response during tilt table testing or carotid sinus massage, suggesting a reflex mechanism. Finally, ILR was unable

**Table 1 Patient characteristics**

	Total patients (n = 58)	Suspected epilepsy <sup>a</sup> (n = 28)	Unexplained falls (n = 29)
Mean age (years)	71 ± 17	64 ± 18	78 ± 8
Male	25 (43%)	17 (63%)	7 (25%)
Median number of T-LOC before implantation	4.6 ± 2.3	3.7 ± 2.1	5.5 ± 3.3
Competing abnormalities/diagnoses:	29 (50%)	14 (50%)	15 (52%)
Structural heart disease	16 (28%)	5 (18%)	11 (38%)
Bundle branch block	10 (17%)	4 (14%)	6 (20%)
Positive tilt testing	10/41 (17%)	8 (29%)	2 (7%)
Carotid sinus hypersensitivity	6/49 (10%)	2 (7%)	4 (14%)

<sup>a</sup>Fourteen patients on treatment with antiepileptic drugs.



to document any syncopal episode in 25 (43%) patients; in 16 of these, ILR monitoring is still on-going.

The probability of ILR documentation of a diagnostic event was similar in patients with associated competing clinical abnormalities/diagnoses and in those without [15/29 (52%) vs. 13/24 (54%)  $P = 1.0$ ].

## Treatment

A specific ILR-guided therapy was administered in the 15 patients with arrhythmic syncope: pacemaker in 11, antiarrhythmic drugs in three patients and reduction of hypotensive drugs in one patient. These patients were followed up for  $22 \pm 20$  months: syncope recurred in 2/11 patients on pacemaker therapy and in 3/4 patients on other therapies. Antiepileptic drugs were continued in six patients and epileptic attacks recurred in three of these. A reappraisal of one of the two patients who had a syncopal recurrence after pacemaker therapy suggested that both asystolic events and epilepsy coexisted in the same patient; antiepileptic drug therapy was therefore added, and no episodes recurred during the following 4 years.

## Discussion

Among the various causes of real or apparent T-LOC,<sup>1</sup> in this study epilepsy and unexplained falls were those that were considered most suitable for ILR recording and diagnosis. The main finding of our study was that 57% of patients with an initial diagnosis of either likely epilepsy or unexplained fall had ILR documentation of a relapse of their index attack and that, in about a quarter of patients, the final diagnosis was of arrhythmic syncope. Moreover, in the other patients, in whom no arrhythmia was documented at the time of a spontaneous attack, ILR monitoring definitely excluded an arrhythmic cause. Interestingly, syncope and epilepsy coexisted in 1 patient. A recent case report<sup>12</sup> has described this association between two different conditions which have traditionally been considered unable to coexist in the same patient. Finally, many patients had no recurrence of real or apparent T-LOC during ILR monitoring. In some of these, ECG monitoring is still ongoing after 20 months of follow-up. This finding underlines the fact that, when an ILR strategy is

decided upon, physicians should be prepared to wait even for some years before obtaining ECG documentation of a spontaneous attack.<sup>13</sup> This study suggests that ILR monitoring provides additional diagnostic value, in that it can confirm/exclude an arrhythmic mechanism, thus helping to distinguish between syncope and non-syncopal causes of T-LOC.

However, in order to put the results of this study into a correct clinical perspective, it must be underlined that the study population was a very selected group of 'difficult' cases in whom the aspecific presentation (and the lack of historical information due to retrograde amnesia) of the episodes or the presence of competing abnormalities/diagnoses make differential diagnosis challenging. This is not the case of the majority of patients affected by epilepsy and fall, in whom ILR monitoring is unnecessary.

## Epilepsy vs. syncope

In most cases, epilepsy is not generally difficult to diagnose and can easily be distinguished from syncope by means of the conventional evaluation.<sup>14–16</sup> Epileptic discharges arising from focal cortical disturbances, namely focal epilepsy, have a localized ictal beginning and are generally easy to distinguish from syncope, even though any partial seizure may spread to become generalized, thus leading to a secondary tonic-clonic seizure. In generalized seizures, both hemispheres are involved and consciousness is lost suddenly which may imply a differential diagnosis with convulsive syncope.<sup>17,18</sup> Electroencephalographic (EEG) findings can help to diagnose epilepsy and to distinguish between partial and generalized seizures.<sup>19</sup> Interictal EEGs tend to show localized spikes and, on occasion, associated focal slow waves in patients with partial seizures, but synchronous, high-amplitude, generalized spike-wave discharge in patients with primarily generalized seizures. In theory, only a few rare forms of epilepsy can mimic a syncopal T-LOC. Nevertheless, in clinical practice, the misdiagnosis of epilepsy is much more frequent and can occur when precise historical features are lacking or there are abnormal limb movements, such as myoclonic jerks or tonic-clonic activity mimicking generalized epilepsy.<sup>20,21</sup> It is estimated that as many as 20–40% of such patients diagnosed as epileptic actually have neurally mediated syncope with abnormal limb movements ('convulsive syncope').<sup>22</sup> An uncorrected diagnosis of epilepsy may have implications for driving, occupation, and insurance.<sup>23</sup> The best available method of investigating patients with suspected epilepsy is videotelemetry during EEG and ECG monitoring, but this examination is very costly and of limited availability.<sup>24</sup> Videotelemetry was not performed in our patients by referring neurologists who preferred to go straight to ILR implantation. Our study demonstrates the utility of ILR monitoring in such patients as an alternative or in addition to videotelemetry. Few data are available in the literature; these are summarized in Table 2. While our results are difficult to compare with those of small studies and case series, they are consistent with those of Petkar *et al.*,<sup>8</sup> who found a similarly high incidence of asystolic reflex syncope in patients with convulsive T-LOC previously suspected of being of an epileptic nature and treated with antiepileptic drugs. Although the ECG recording provided by the ILR cannot of course confirm a diagnosis of epilepsy, the registration of a spontaneous attack of tonic-clonic epilepsy can be indirectly inferred by analyzing the noise recorder in the ILR tracing. In a study by Ho *et al.*,<sup>7</sup> the EEG recordings of generalized tonic-clonic seizures were considered

**Table 2** Implantable loop recorder results in suspected epilepsy

	Number pts with ILR	ILR-documented attack	ILR-documented arrhythmias	No ILR documentation
Simpson CS <sup>6</sup>	Na	1	Na	NA
Kanjwal K <sup>5</sup>	Na	3	3	NA
Zaidi <sup>2</sup>	10	NA	2 (20%)	NA
Ho RT <sup>7</sup>	14	6 (43%)	0 (0%)	8 (57%)
Petkar S <sup>8</sup>	103	69 (67%)	28 (27%)	34 (33%)
Present study	28	16 (57%)	8 (28%)	12 (43%)
Total	159	91/145 (63%)	38/155 (25%)	54/145 (37%)

NA, not applicable.

**Table 3** Implantable loop recorder results in unexplained falls

	Number patients with ILR	ILR-documented attack	ILR-documented arrhythmias	No ILR documentation
Armstrong VL <sup>9</sup>	6 <sup>a</sup>	3 (50%) <sup>a</sup>	1 (15%)	3 (50%)
Safespace 2 <sup>10</sup>	71	48 (68%)	3 (4%)	23 (32%)
Present study	29	17 (58%)	7 (24%)	12 (41%)
Total	105	68 (65%)	11 (10%)	38 (36%)

<sup>a</sup>Three patients had isolated fall episodes and three had both syncope and fall episodes; ILR documentation was achieved in these latter cases.

identical, and revealed a tonic phase (sustained, rapid, high-frequency myopotentials) transitioning to a clonic phase (periodic bursts of high-frequency myopotentials with a decelerating burst frequency from 3–6 Hz to 1–2 Hz) prior to seizure termination. Similarly, Pektar *et al.*<sup>8</sup> found muscle artifacts suggestive of tonic-clonic seizure in 3.9% of patients' seizures, while the underlying ECG appeared normal. We did not find such features in this study.

### Unexplained fall vs. syncope

A significant overlap between syncope and fall has recently been recognized.<sup>25</sup> Most falls can be easily attributed to incidental (i.e. any fall related to high velocity action or sports, contact or high-risk activities, or a state of intoxication) or to accidental causes (any fall due to slipping or tripping).<sup>26</sup> Nevertheless, about 20% of falls remain unexplained after conventional investigations, and may warrant ILR implantation.<sup>27</sup> Thirty percent of elderly patients with witnessed syncope have amnesia due to loss of consciousness, and nearly two-thirds of older patients with orthostatic hypotension presenting with falls deny loss of consciousness.<sup>28</sup> For all these reasons, falls and syncope in elderly patients are often indistinguishable. Cardiovascular disorders are responsible for a significant number of patients presenting with a fall related to unexplained loss of consciousness. The cardiovascular abnormalities identified as risk factors are orthostatic hypotension, carotid sinus hypersensitivity, abnormal electrocardiogram or echocardiogram finding, history of fainting, coronary artery disease, and myocardial infarction or heart failure.<sup>29</sup>

There are very few data in the literature on ILR monitoring in patients with unexplained fall (Table 3). While ILR monitoring has been able to document an episode in a similarly high percentage of

cases in all studies, the results are somewhat contrasting with regard to the underlying mechanism. In this study, we enrolled patients who had suffered presumed falls associated to competing cardiac abnormalities/diagnoses suggesting syncope, or who were unable to explain the modality of their fall, thus arousing the suspicion of a syncopal episode. In 24% of these patients, ILR documentation of an arrhythmia was obtained. By contrast, in the randomized Safespace 2 study,<sup>10</sup> patients with established falls were enrolled on the basis of the presence of modest cardioinhibitory (mean pause 3.1 s) carotid sinus hypersensitivity, which prompted the study hypothesis that a carotid sinus syncope could have been a potential reversible cause of falling. In the ILR arm, a significant arrhythmia able to explain T-LOC was documented by ILR only in three patients. No significant reduction in falls was seen in the pacemaker arm compared with the ILR arm, thus confirming that the fall was not caused by bradycardia. Overall, the above studies suggest that patient selection is a crucial factor in determining the usefulness of ILR in patients with unexplained falls.

### Limitations

It must be remembered that the ILR can record only ECG traces and provide information on heart rhythm; it cannot provide any additional information regarding other parameters, such as blood pressure, oxygen saturation, or brain activity. Consequently, ILR monitoring was diagnostic only in 15 (26%) patients, in whom a significant arrhythmia was identified. Four ILRs needed to be implanted in order to establish a diagnosis of arrhythmic syncope. This figure is not too much lower than the 35% diagnostic yield provided by ILR in patients with unexplained syncope.<sup>11</sup> However, the diagnostic yield is likely to be dependent on the criteria used for the selection

of the patients. It is hard to define which is the population that benefits the most of this approach. In the absence of significant arrhythmia during a spontaneous attack, a non-arrhythmic cause of syncope still remained possible as an alternative to the initial diagnosis of epilepsy or fall. This was the case, for example, in five patients who had a positive response to tilt table testing and carotid sinus massage, which suggested a possible reflex hypotensive mechanism of syncope.

## Conclusions and perspectives

Implantable loop recorder monitoring provides additional diagnostic value in a minority of 'difficult' patients with an initial diagnosis of non-syncope T-LOC. Indeed, if ILR monitoring is to be useful, careful patient selection based on clinical features is essential. 'Good' ILR candidates account for a small percentage of the overall population of epileptic patients and fallers.

**Conflict of interest:** none declared.

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