Implantable Loop Recorder Allows an Etiologic Diagnosis in One-Third of Patients
– Results of the Spanish Reveal Registry –

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**Background:** The implantable loop recorder (ILR) is a useful tool for diagnosing paroxysmal conditions potentially related to arrhythmias. Most investigations have focused on selected clinical studies or high-volume centers. The aim of this study was to evaluate the indications and outcomes of the ILR in real clinical practice.

**Methods and Results:** This was a prospective, multicenter registry of patients undergoing ILR implantation for clinical indications (April 2006–December 2008). Clinical characteristics (symptoms, arrhythmias, treatments) were recorded in a database. Follow-up data at 1 year or after the occurrence of the first episode were also recorded. Total enrollment: 743 patients (male, 413, 55.6%; 64.9±16 years); 228 (30.7%) had structural heart disease (SHD), and 183 (24.6%), bundle branch block (BBB). Recurrent syncope (76.4%) was the most common indication for implantation. Complete follow-up was obtained for 680 patients (91.5%). Three hundred and twenty-five patients (48%) presented 414 events, with a final diagnosis in 230 patients (70.8% of patients with events; 33.1% of patients with follow-up). Syncope secondary to bradyarrhythmia was the most frequent diagnosis. Similar rates of final diagnoses were noted in subgroups of SHD, BBB and normal heart. Regarding the cause of implantation, higher event rates were registered among patients with recurrent syncope.

**Conclusions:** One-third of patients obtained a final diagnosis with the ILR, independent of the baseline characteristics. Only the cause of implantation provided different rates of final diagnosis.  

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**Key Words:** Bundle branch block; Implantable loop recorder; Registry; Structural heart disease; Syncope

The implantable loop recorder (ILR) is a valuable tool for the diagnosis of paroxysmal conditions related to arrhythmic events. The ILR is easy to implant, which has expanded its use by cardiologists, including use as a first-line tool for diagnosing syncope or other symptoms in centers without access to specific tests such as tilt testing or invasive electrophysiology. Since the first report of its implementation in 1998,1 numerous studies have documented the role of ILR in the investigation of syncopal episodes, palpitations,2 and atrial fibrillation,3 as well as risk stratification after myocardial infarction.4 The vast majority of these studies, however, were designed as clinical trials with rigid inclusion criteria and selected patients, or came from tertiary referral centers with a selected patient group and high degree of expertise, possibly resulting in a selection bias.

To date there have been few investigations of the outcomes of the device in real life practice. Recent data from the PICTURE registry suggest that the results of ILR use may differ in some aspects from those obtained in clinical studies.5 The aim of the present study was to evaluate the indications and outcomes of an ILR system in non-selected patients with a clinical indication for the device.
This study was designed as an observational, prospective, multicenter national registry. All centers in Spain known to perform ILR implants were invited to participate in the registry (Spanish Reveal Registry). All consecutive patients in whom an ILR Reveal Plus® or Reveal XT-DX® device was implanted between April 2006 and December 2008 were included. No exclusion criteria were applied. The recording parameters were programmed according to each operator/center preference.

Symptoms that led to implantation were classified as recurrent syncope, single syncope, presyncope (both recurrent and single), palpitations, and other (including chest pain, abnormal electrocardiogram [ECG] without symptoms and suspected but not definite loss of consciousness). Structural heart disease (SHD) was defined as the presence of heart disease known to increase the risk of ventricular arrhythmia, such as documented coronary artery disease, cardiomyopathy, or significant valvular heart disease. Bundle branch block (BBB) was defined as the presence of any type of intraventricular conduction delay with QRS duration >100 ms, as in previous studies.6 For subgroup analysis, patients were divided into 3 categories: patients with BBB, patients with SHD (excluding those with BBB), and patients with normal heart (NH), defined as absence of prior SHD, channelopathy, or BBB. Groups were defined according to similar previous studies.5–8

Follow-up data regarding the interpretation of clinical symptoms, recorded electrograms, final diagnosis, and treatment were included in the database as provided by the corresponding local investigator. An event was defined as an occurrence of syncope, presyncope, or palpitation reproducing the clinical complaints of the patient or the presence of a significant arrhythmia detected by the device, as defined by established guidelines.9 A diagnostic event was defined as the occurrence of any event considered significant by the referring investigator and leading to a final diagnosis. Several events could occur in the same patient, but only 1 diagnostic event and 1 final diagnosis per patient were allowed.

Follow-up visits were scheduled according to the investigators’ preference. For study purposes, follow-up ended after the occurrence of a diagnostic event or at the end of the study period. For patients without diagnostic events, a minimum follow-up of 12 months was required.

Data collection was performed using a questionnaire delivered to all participating centers in 2 formats: electronically through a website to be completed online, or printed upon request. The recorded electrograms could be sent to the steering committee via the Internet for discussion if deemed necessary by the investigator.

Data were prospective and collected in a dedicated MS Access database (Microsoft Corporation, 2003). Anomalous or inconsistent data were requested for reanalysis.

### Table 1. Baseline Characteristics and Tests

<table>
<thead>
<tr>
<th></th>
<th>Total patients</th>
<th>Group SHD</th>
<th>Group BBB</th>
<th>Group NH</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>743 (100)</td>
<td>157 (21.6)</td>
<td>183 (25.2)</td>
<td>387 (53.2)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>69.5±16.1</td>
<td>71.1±12.5</td>
<td>74.4±13.5</td>
<td>66.5±17.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>413 (55.6)</td>
<td>110 (70.1)</td>
<td>125 (68.3)</td>
<td>173 (44.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>352 (47.4)</td>
<td>87 (56.5)</td>
<td>107 (60.8)</td>
<td>156 (41.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>119 (16.0)</td>
<td>36 (23.8)</td>
<td>35 (20.7)</td>
<td>46 (12.3)</td>
<td>0.002</td>
</tr>
<tr>
<td>Anomalous ECG</td>
<td>245 (32.9)</td>
<td>31 (19.7)</td>
<td>183 (100)</td>
<td>15 (3.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LVEF &gt;55%</td>
<td>527 (70.9)</td>
<td>86 (54.9)</td>
<td>122 (66.7)</td>
<td>306 (79.1)</td>
<td></td>
</tr>
<tr>
<td>LVEF 35–55%</td>
<td>85 (11.4)</td>
<td>48 (30.6)</td>
<td>32 (17.5)</td>
<td>5 (1.3)</td>
<td></td>
</tr>
<tr>
<td>LVEF &lt;35%</td>
<td>8 (1.1)</td>
<td>3 (1.9)</td>
<td>5 (2.7)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>No data</td>
<td>123 (16.6)</td>
<td>20 (12.7)</td>
<td>24 (13.1)</td>
<td>76 (19.6)</td>
<td></td>
</tr>
<tr>
<td>Reveal Plus</td>
<td>514 (69.2)</td>
<td>111 (70.7)</td>
<td>136 (74.3)</td>
<td>257 (66.4)</td>
<td>0.147</td>
</tr>
<tr>
<td>EPS Normal</td>
<td>258 (34.7)</td>
<td>70 (44.6)</td>
<td>95 (51.9)</td>
<td>86 (22.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>EPS Pathological</td>
<td>53 (7.1)</td>
<td>10 (6.4)</td>
<td>21 (11.5)</td>
<td>22 (5.7)</td>
<td></td>
</tr>
<tr>
<td>EPS Not performed</td>
<td>432 (58.1)</td>
<td>77 (49.0)</td>
<td>67 (36.8)</td>
<td>279 (72.1)</td>
<td></td>
</tr>
<tr>
<td>HUT Positive</td>
<td>82 (11.0)</td>
<td>12 (7.6)</td>
<td>14 (7.7)</td>
<td>52 (13.4)</td>
<td></td>
</tr>
<tr>
<td>HUT Negative</td>
<td>149 (20.1)</td>
<td>21 (13.4)</td>
<td>37 (20.2)</td>
<td>88 (22.7)</td>
<td></td>
</tr>
<tr>
<td>HUT Not performed</td>
<td>512 (68.9)</td>
<td>124 (78.9)</td>
<td>132 (72.1)</td>
<td>247 (63.8)</td>
<td></td>
</tr>
<tr>
<td>Cause of implant</td>
<td>Single syncope</td>
<td>107 (14.4)</td>
<td>29 (18.5)</td>
<td>32 (17.6)</td>
<td>44 (11.4)</td>
</tr>
<tr>
<td>Cause of implant</td>
<td>Recurrent syncope</td>
<td>568 (76.4)</td>
<td>109 (69.4)</td>
<td>137 (75.3)</td>
<td>313 (80.9)</td>
</tr>
<tr>
<td>Cause of implant</td>
<td>Presyncope</td>
<td>43 (5.8)</td>
<td>16 (10.2)</td>
<td>9 (4.9)</td>
<td>16 (4.1)</td>
</tr>
<tr>
<td>Cause of implant</td>
<td>Other</td>
<td>25 (3.4)</td>
<td>3 (1.9)</td>
<td>4 (2.2)</td>
<td>14 (3.6)</td>
</tr>
<tr>
<td>Cause of implant</td>
<td>Lost to follow-up</td>
<td>63 (8.5)</td>
<td>15 (9.6)</td>
<td>19 (10.4)</td>
<td>27 (7.0)</td>
</tr>
</tbody>
</table>

Data given as n (%) or mean±SD. Patients with channelopathies (n=16) were excluded from the 3 predefined subgroups (SHD, BBB and NH). BBB, bundle branch block; ECG, electrocardiogram; EPS, electrophysiological study; HUT, head up tilt test; LVEF, left ventricular ejection fraction; NH, normal heart; SHD, structural heart disease.

### Methods

Continuous variables are presented as mean±SD or median (range) when the distribution was not normal. Qualitative vari-
One-third of the patients had SHD (for study purposes, those with BBB or conduction disease were included in the group of BBB for analysis): 132 patients had ischemic heart disease, 24 had dilated cardiomyopathy, 28 had hypertrophic cardiomyopathy, 28 had valvular disease, 9 had congenital disease and 9 had other diagnosis. Left ventricular ejection fraction (LVEF) was normal in the majority of the patients, although it was moderately depressed (35–55%) in 85 patients (12%) and <35% in 8 patients (1.1%).

BBB was present in 183 patients (24.6%), with left BBB (LBBB) being most common (n=64, 8.6%; right BBB [RBBB], n=46, 6.2%). Other ECG anomalies were reported in 62 patients (8.3%), mainly atrial fibrillation (n=16, 2%) and first-degree atrioventricular (AV) block (n=16, 2%). ECG was compatible with a channelopathy in 16 patients (2%; long QT interval, n=8; Brugada patterns, n=8, according to ECG criteria).  

### Diagnostic Tests
Carotid sinus massage (CSM) was performed in 364 patients...
(n=107, 14.4%), presyncope (n=43, 5.8%), and other (n=25, 3.2%), which included palpitation (n=12) and other causes of implant. Six hundred and forty-four devices (86.6%) were implanted by a cardiologist, and the rest were implanted by intensive care unit physicians. There were only 3 cases of minor complications related to the implant: 1 case of subcutaneous emphysema, 1 of minor bleeding, and 1 of wound dehiscence.

Follow-up
All follow-up results refer to the patients with available follow-up data (680 patients, 91.5%; Table 2). Baseline characteristics for the 63 patients without follow-up did not differ from those in the overall group. The mean follow-up duration was 10.6 ± 6.0 months (range, 0–31.6 months). There were 414 events recorded in 325 patients (47.8%); patients with events had a mean of 1.3 episodes. The most prevalent event was syncope (238 episodes; 57.5% of events), followed by presyncope (102 episodes; 24.6%) and palpitation (30 episodes; 7.2%). Asymptomatic automatic activations of the device were recorded in 35 episodes. Two hundred and thirty patients (33.8%) had diagnostic events. The median time to diagnosis was 176 days (range, 0–842 days; Figure 1). A definitive diagnosis of arrhythmic symptoms based on a significant arrhythmia detected by the device was made by the corresponding investigator in 176 patients (25.9%). The most common rhythm during the episodes was sinus arrest (73 episodes), followed by AV block (68 episodes), supraventricular tachycardia (18 cases), ventricular tachycardia (14 cases), and atrial fibrillation (13 cases). Additionally, 39 patients were regarded as having neuromediated syncope, with a significant sinus arrest recorded in 8 of them. The rate of diagnosis increased according to the severity of the symptoms described during the event (syncope, 74%; presyncope, 62%; palpitations, 35%; P<0.05; Table 3). No differences in the rate of final diagnosis were obtained between the patients with RBBB and LBBB (32.6% vs. 32.8%).

Two hundred and thirty patients (33.8%) had diagnostic events. The median time to diagnosis was 176 days (range, 0–842 days; Figure 1). A definitive diagnosis of arrhythmic symptoms based on a significant arrhythmia detected by the device was made by the corresponding investigator in 176 patients (25.9%). The most common rhythm during the episodes was sinus arrest (73 episodes), followed by AV block (68 episodes), supraventricular tachycardia (18 cases), ventricular tachycardia (14 cases), and atrial fibrillation (13 cases). Additionally, 39 patients were regarded as having neuromediated syncope, with a significant sinus arrest recorded in 8 of them. The rate of diagnosis increased according to the severity of the symptoms described during the event (syncope, 74%; presyncope, 62%; palpitations, 35%; P<0.05; Table 3). No differences in the rate of final diagnosis were obtained between the patients with RBBB and LBBB (32.6% vs. 32.8%).

Two hundred and eleven patients (31.0%) received treatment according to the ILR findings. A pacemaker implant was the most common therapy (n=145; 5 patients with diagnosis of neurocardiogenic syncope). Other treatments included ICDs in 11 patients, ablation in 11 patients, drugs in 25 patients, and other therapies in 39 patients (counseling, anti-epileptic medication, psychiatric medication etc.).

Eighteen deaths (2.6%) were confirmed during follow-up (55.5% men; mean age, 72±8.5 years). Ten of these patients (55.5%) had SHD, and 7 patients (38.9%) presented abnormal baseline ECG (BBB, n=4). LVEF was normal in 10 patients (55.5%), moderately depressed in 3 patients (16.6%), and there were no data for the remaining patients. Only 3 patients were

Table 3. Presence of Events vs. Final Diagnosis

<table>
<thead>
<tr>
<th>Final diagnosis</th>
<th>Patients with events (n=325)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Syncope n=187</td>
</tr>
<tr>
<td>Bradycardia (n=144)</td>
<td>95 (50.8)</td>
</tr>
<tr>
<td>Tachycardia (n=32)</td>
<td>7 (3.7)</td>
</tr>
<tr>
<td>Neuromediated (n=39)</td>
<td>29 (15.5)</td>
</tr>
<tr>
<td>Other diagnosis (n=15)</td>
<td>8 (4.3)</td>
</tr>
<tr>
<td>Non-diagnostic (n=95)</td>
<td>48 (25.7)</td>
</tr>
</tbody>
</table>

Data given as n (%). Data refer to the first diagnostic event. If all the events were non-diagnostic, only the first event was considered. Note the higher rate of final diagnosis obtained when the event was syncope as compared with presyncope or palpitations.

Documented Arrhythmia
Arrhythmia had been previously documented in 233 patients (31.4%): atrial fibrillation in 91 patients (12%), first- or second-degree AV block in 53 patients (7%), sinus node dysfunction in 9 patients, induction of ventricular tachycardia in 9 patients, supraventricular tachycardia in 15 patients, and first- or second-degree nodal AV block in 16 patients.

Indication and Implant Procedure
Patients were classified into 4 categories according to the cause of implant: recurrent syncope (n=568, 76.4%), single syncope (n=107, 14.4%), presyncope (n=43, 5.8%), and other (n=25, 3.2%), which included palpitation (n=12) and other causes of implant.
under age 60, and 2 of them had previous severe concomitant conditions (1 with dilated cardiomyopathy and another with liver cirrhosis). In 2 patients the death was related to ischemic cause, in 1 it was secondary to hepatic failure, and in 1 it presented as sudden death (a 71-year-old patient with a previous cardiac transplant). It was impossible to identify the cause of death in the rest of the cases.

The rate of complications with the device was low; there were no major events during the implant process. Thirteen patients (1.7%), however, presented some complications during follow-up: 8 cases of erosion (2 with concomitant infection), 6 cases of infection, and 1 case of device malfunction. Only in 1 case a new device was implanted.

Subgroup Analysis
We studied the outcomes of the device in the subgroups of patients with BBB, SHD, and NH. The baseline patient characteristics and tests performed in these groups are listed in Table 1. As expected, we detected between-group differences in baseline characteristics.

Patients with NH were younger, more frequently women, and had lower prevalences of hypertension and diabetes. EPS prior to implantation was performed less frequently in the NH group, while HUT was performed more frequently. Finally, the SHD group had proportionally fewer patients with recurrent syncope but a higher rate of presyncope as the cause for implantation; in contrast, the NH group had a lower rate of single syncope.

The diagnostic rate was similar among the 3 groups, as was the rate of final treatment (Table 2; Figure 2). No differences were found in the type of final diagnosis, with similar rates of bradycardia, tachycardia, and neuromediated events in the 3 groups.

Regarding the rate of final diagnosis in the total patient group according to the cause of implant, significant differences were found when the patients were divided according to recurrent syncope, single syncope, and presyncope groups, with higher rates in the recurrent syncope group (Table 4). Similar results were obtained in the NH group, but when the same analysis was performed for the SHD and BBB subgroups, no significant differences in the rate of final diagnosis were found, probably due to the small sample size.

Discussion
Main Results
The Spanish Reveal Registry is the largest observational study to date to evaluate the use and diagnostic effectiveness of ILRs in everyday clinical practice, regardless of the clinical reasons for device implantation.

The main contribution of the study is the confirmation that patients with SHD or BBB have similar characteristics to the rest of the patients, both in the rate of diagnoses obtained as well as the type of diagnosis provided by the device. We also note that the cause of implantation may play an important role in the final diagnosis, obtaining greater rates of final diagnosis among those patients with recurrent syncope.

In the present series the patient risk profile was similar to that of previous reports, with a rate of SHD of 31%, similar to that reported by the PICTURE registry (28%). Additionally, 24.6% of the present patients had BBB.

Diagnostic Tests
As compared with the Picture registry, the rates of echocardiogram or HUT were very similar, but the rate of CSM was higher (49% vs. 36%), and much higher than the 0.4% reported in the GESINUR study. Despite the recommendation for HUT in patients with unexplained syncope and NH, only 36% of the present patients in the NH subgroup underwent this test before ILR implantation.

Regarding EPS, it is noteworthy that in 42% of patients with SHD and/or BBB and syncope, EPS was not performed before ILR implantation, despite current guideline recommendations. It is also remarkable that EPS was performed in 28% of patients with syncope and NH, a class III indication according to European guidelines. The rate of EPS was higher in the present study than in the previous registry (41.8% vs. 25%), with no data available in that study regarding the percentage of patients with BBB or SHD.

Indications
The majority of devices in the present patients were implanted due to recurrent syncope, in agreement with guidelines recommendations, but the device was also implanted in a small proportion of patients with presyncope, as in another series. Some patients with single syncope and NH, an indication not listed in the guidelines and lacking previously published data, were also included. Palpitations are a rare cause of ILR implantation, despite a previous study noting a high diagnosis rate in this setting. In patients with SHD or BBB, the device was more frequently indicated due to single syncope or presyncope than in patients with NH. This observation may be attributed to a more aggressive approach in patients with cardiac disease, when the risk of dangerous arrhythmias may motivate the investigators to implant the device with less strict criteria.

Follow-Up Results
A final diagnosis was obtained in 30.9% of the present patients. This rate is similar to those obtained in the PICTURE study (28%) and the retrospective, single-center study of Entem et al (23.6%). If we compare the present results with those obtained with external loop recorders in a similar group of 24 patients with
unexplained syncope and negative tilt table, a higher percentage of patients were diagnosed by ILR (31% vs. 13%), mainly because of infrequent syncopal events after the baseline evaluation in the external loop recorder group (21% vs. 48% in the present ILR group).

Other studies with external loop recorders noted higher rates of final diagnosis (93%), but both the patient type (64% of patients with palpitations) and the classification of the registered arrhythmias were different to the present study. Also, no data regarding the rate of diagnosis in the group of patients with syncope were reported in this study.

A small number of patients (n=12, 1.6%) had later complications that were mostly related to skin erosions. The median age of these patients was 10 years younger than the rest of the subjects, with several cases occurring in very young patients; the complications therefore were probably related to the smaller sizes of these patients, their greater physical activity, or trauma over the device. The finding of higher rates of complications in younger patients has been assessed in previous reports.

The reported mortality of the present group was relatively low (2.4%), with death occurring at a mean age of 73 years. The few deaths in the younger patients were related to severe concomitant conditions. These figures are consistent with other studies (3.9% in older patients receiving ILR, 5% in the Entem et al series), and confirm the safety of ILR implantation, even in the presence of previous concomitant disease. This fact was justified because most patients at high risk for sudden cardiac death are identified by other means (including EPS) and are not included in ILR studies. In the present study, however, the mortality of patients with SHD or BBB without EPS did not differ significantly from the rest of the sample (3.3% vs. 1.5%; P=NS). This observation may be due to the small number of fatalities as well as the patient selection criteria used by the investigators, using the ILR when the investigators assumed a low risk of fatal events. Surprisingly, the PICTURE registry does not report data on device mortality or safety.

### Subgroup Analysis

Despite the differences in risk profile of the different subgroups, and the theoretically higher risk of arrhythmic cardiac events in the patients from the SHD and BBB groups, no significant differences in the rates of events or final diagnosis were seen among the 3 subgroups. Also, the type of events reported in every group is similar, with bradyarrhythmia-related events the most frequent diagnosis in all of them. More specifically, the rates of atrial fibrillation events were similar with or without SHD (Table 1). No previous comparisons of the diagnostic yield of the device in these 2 patient groups are available in the literature.

Regarding the SHD subgroup, there are discordant data among previous reports. The Entem et al study reported a rate of 30% for final diagnoses, the ISSUE2 study obtained a diagnostic rate of 40%, while Solano et al noted an increased rate of 58%, but with few tachycardia-related events (only 5%). Pezawas et al reported an even greater prevalence of recurrent symptoms (91%) but only 39.4% presented an arrhythmia during the event (mostly bradycardia), without episodes of ventricular tachycardia. We obtained a final diagnosis in 28.2% of the present group, mainly secondary to bradyarrhythmia-related events, similar to that reported by ISSUE2 and Entem et al.

One-third of the BBB cohort had a final diagnosis, with a greater rate in those patients without previous EPS, likely because some of the high-risk patients would have been previously diagnosed if the test had been performed. In 2 previous series of patients with syncope, BBB, and negative EPS, the rates of final diagnosis were 36.5% and 45%, mostly bradyarrhythmia-related events. In the present series, the rate of diagnosis was smaller, probably because fewer patients were included due to recurrent syncope.

The rate of final diagnosis in NH patients (34.2%) was similar to the other 2 groups, with bradyarrhythmia-related events as the most frequent diagnosis (64.2%) and a pacemaker implanted in 95% of cases. In a similar patient type, the ISSUE trial reported a final diagnosis in 25% of the patients. The most frequent final diagnosis, however, was neuromediated syncope, compared with only 18.2% in the present series. This observation suggests a bias among cardiologists toward an underestimation of the neurocardiogenic mechanism as the cause of severe episodic bradyarrhythmias. Further studies or new techniques could modify this observation.

Regarding the cause of implantation, the rate of final diagnosis was higher in patients receiving a device due to recurrent syncope in the total group (Table 4). This observation was expected, because the rate of final events would be greater in patients with more severe clinical presentation. Similar results were obtained in the NH group, but this finding did not reach statistical significance when the analysis was performed in the BBB and SHD subgroups, probably due to the sample size. We did not find any previous reports with which to compare regarding this issue. This finding supports the class Ia indication of ILR for recurrent syncope mentioned in the Task Force document.

As expected, the rate of diagnosis in patients with NH and presyncope was low (20%). It is noteworthy that the diagnostic yield of the device in patients with isolated syncope or presyncope and BBB is similar to that observed in patients with recurrent syncope in this subgroup. The indication for presyncope in these types of patients requires further study, because it is not referred to in the guidelines and there are few studies evaluating the utility of ILR in these patients.

### Study Limitations

The Spanish Reveal Registry was an observational registry; although the present results should be interpreted accordingly, the present information may supplement data provided by randomized, controlled studies, and may describe a more realistic clinical situation. Although it was possible to send the registered electrograms via the Web, the small number of recordings sent at the end of the study precluded their widespread use in event interpretation.

Thus, most of the final diagnoses relied on the exclusive judgment of the physician in charge of the patients. The Spanish Reveal Registry was initially designed to evaluate real clinical practice with the ILR. Although this clinical practice is expected to be based on the syncope guidelines, we did not investigate compliance with the guidelines recommendations in the present study and thus are unable to draw conclusions on this subject. Moreover, when the study was initiated in 2006, initial recommendations were made according to the 2004 ESC guidelines. Thus changes in recommendations implemented in the last published Guidelines (2009 ESC guidelines) are not reflected in this study.

Finally, we note that 9% of the present patients were lost to follow-up, which may have introduced bias into the interpretation of the results of device implantation or device safety, because some of the patients lost to follow-up could have died. The present data, however, are consistent with other similar registries, and seem to be difficult to improve in this type of study.

### Conclusion

Approximately one-third of patients receiving an ILR obtain a...
final diagnosis, mainly based on the registered arrhythmias of the device, independent of the presence of concomitant conditions such as BBB or SHD. Only the cause of implantation provide different rates of final diagnosis, in that patients with recurrent syncope had a higher rate. The use of the ILR in unselected patients seems to be a safe strategy.

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Disclosures

Natalie García-Heil belongs to the Scientific and Clinical Department of Medtronic Iberica, S.A. The other authors have no commercial associations or sources of support that might pose a conflict of interest.

References


