Effectiveness of remote monitoring in the management of syncope and palpitations

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Aims
Recently, the remote transmission of data detected by implantable loop recorders (ILRs) has become available. The aim of this study was to evaluate effectiveness and acceptance of remote monitoring in the clinical management of syncope and palpitations in patients with ILR.

Methods and results
Consecutive patients implanted with ILR (Reveal DX/XT Medtronic, Inc.) and followed up by means of remote monitoring (CareLink⁶) were included. The patients were requested to transmit the data stored in the ILR every week, via the CareLink system, or more frequently during the first period. Patient acceptance of ILR was evaluated by means of a questionnaire concerning physical and mental components. Forty-seven patients (27 males, average age 64 ± 19 years) were enrolled and followed up for 20 ± 13 weeks. Thirty-two patients (68%) had at least one ECG recording of a true relevant event. The mean time from ILR implantation to the first true relevant ECG was 28 ± 49 days, which was 71 ± 17 days less than in the clinical practice of 3-monthly in-office follow-up examinations. Thirty-eight patients (81%) had at least one false arrhythmic event, mainly false asystole and false fast ventricular tachycardia. In the absence of Carelink transmission, at least one episode of memory saturation of ILR would have occurred in 21 patients (45%) that would have limited the diagnostic yield. Patient compliance was good even though one-fifth had some minor psychological concern regarding the ILR implant. CareLink was well accepted and judged easy to use.

Conclusion
Remote monitoring enhances the diagnostic effectiveness of Reveal, limiting the risk of memory saturation due to the high number of false detections and reducing the time to diagnosis. Both ILR and CareLink were well accepted and well tolerated by the patients, as they were considered useful.

Keywords
Prolonged ECG monitoring • Implantable loop recorder • Syncope • Palpitation • Remote monitoring

Introduction
The implantable loop recorder (ILR) is an effective tool in the diagnosis of unexplained syncope and palpitations.¹⁻² Implantable loop recorder-based specific therapies have proved effective in patients with syncope.¹⁻³ Recently, remote transmission of data detected by ILR has become available. While some studies have reported the effectiveness of the remote monitoring of implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices,⁴⁻⁷ limited data are available on ILR. A recent study⁸ has shown that automatic ILR recording and wireless transmissions are feasible for remote ECG monitoring, but is hampered by an excessive ECG burden of false detections. Moreover, little is known about the quality of life of patients with syncope who receive ILR. Farwell et al.⁹,¹⁰ found that the quality of life of ILR recipients was better than that of patients on conventional management, mainly because the time to diagnosis could be shortened by ILR. However, these authors did not evaluate the additive impact of the remote monitoring system. The aims of this study were: (i) to evaluate the effectiveness of remote monitoring in patients with ILR for syncope and palpitations and (ii) to evaluate patients’ physical and mental acceptance of ILR and remote transmission.

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**Methods**

This prospective four-centre study enrolled consecutive subjects aged >18 years who had had two or more episodes of unexplained palpitations and/or syncope before hospital examination. All patients received an ILR (Reveal DX/XT) and an external remote monitoring device (CareLink Monitor), both from Medtronic Inc. Minneapolis, MN, USA, in order to perform home interrogations and transmissions. The ILR was implanted by means of the standard technique.

The patients were requested to transmit the data stored in the ILR every week, via the CareLink system, or more frequently during the first period. If symptoms recurred, patients were instructed to activate the ILR, in order to record the cardiac rhythm and to transmit these data during the same day. Moreover, in-office follow-up examinations were scheduled every 3 months, in accordance with the usual practice of the hospitals participating in the study.

We evaluated total ECG events transmitted, frequency of transmissions, numbers and types of true and false events, theoretical memory saturation, frequency of reprogramming of ILR parameters, and patient compliance. True relevant events were defined as: (i) manual activation during a recurrence of index (pre)syncope or palpitation, with or without arrhythmic events or (ii) automatic activation with true relevant arrhythmias [i.e. type 1, 2, and 4 of the ISSUE classification (1–3)]. False events were defined as automatic registrations without arrhythmic events (artefacts).

Finally, we evaluated patients’ acceptance of ILR implantation and CareLink transmissions. These were evaluated by means of a specific questionnaire (see below) during an outpatient examination, which was performed a mean of 23 ± 18 weeks after implantation.

**Implantable loop recorder**

Both Reveal DX and Reveal XT can detect bradycardia and tachycardia episodes. These ILRs can record a total of 49 min and 30 s of ECG. If the patient activates the device manually, the duration of recording is 7.5 min (6.5 min before and 1 min after activation) for a total of three episodes. A maximum of 27 automatic ECG recordings of episodes of 1 min duration are also stored and classified as asystole, bradycardia, tachycardia, or fast ventricular tachycardia; only Reveal XT is able to classify episodes of atrial fibrillation. When the ECG memory is full, the ECG of the oldest stored episode is overwritten by that of a new episode, but a minimum of three episodes for each type of arrhythmia is preserved. However, the Reveal can still keep 30 logs of deleted ECG recordings filtered as above. These episodes without ECG were counted but not considered for analysis.

**CareLink system**

The CareLink system consists of a monitor plugged into an analog telephone connection; the monitor can communicate with the implanted device by means of a wand. When the patient places the wand over the device, complete interrogation of the device is carried out and the stored data are transmitted to a secure Network Server via the telephone connection. The clinical staff can review device information on a secure website via the internet.

**Questions on compliance with implantable loop recorder and CareLink**

We asked 33 patients questions regarding the ILR and CareLink system. The ILR questionnaire included five questions concerning physical components and five questions concerning mental components. Another six questions specifically regarded CareLink transmission.

**Statistical methods**

Data were expressed as means ± standard deviations or medians with 25th and 75th percentiles, as appropriate.

The following measurements were taken:

(i) the time from ILR implantation to the first true episode documented;

(ii) the estimated reduction in the time to diagnosis of a true episode by means of weekly transmission in comparison with 3-monthly in-office follow-up examinations;

(iii) the estimated memory saturation time. Since the memory of the device is able to store a maximum of 27 ECG recordings (excluding episode logs), the estimated memory saturation time was calculated as 27 × (days of observation)/(no of episode logs).

**Results**

Forty-seven patients were enrolled and followed up for 20 ± 13 weeks. Their clinical characteristics are listed in Table 1.

**Data transmission**

Overall, the 47 patients made 1369 transmissions during 956 weeks of follow-up. On average, each patient made a median of 26 (11–38) transmissions. Data on 247 154 events with or without ECG were transmitted by 42 patients; 5 patients never had events. ECG recordings were available for 6448 of these events (2.6%); of these, 976 [median 2 (0–10) per patient] were true relevant events and 5472 [median 16 (2–109) per patient] were false events (artefacts).

Thirty-two patients (68%) had true relevant ECG (Table 2). True relevant arrhythmic events were recorded by means of automatic detection features in 14 patients (30%) and by manual activation (21 events) in three patients (6%). In addition, there were 174 symptomatic, non-arrhythmic, relevant ECG recordings in 25 patients (53%). Asystole was the most frequent true arrhythmic event (Figure 1). The mean time from ILR implantation to the first true relevant ECG was 28 ± 49 days [median 11 days [5;27]]. In comparison with our usual clinical practice, whereby an in-office follow-up examination is scheduled every 3 months, we estimated that weekly transmission would have been able to reduce the time to diagnosis by 71 ± 17 days.

**Table 1 Clinical characteristics of the patients**

| Total number | 47 |
| Mean age, years | 64 ± 19 |
| Male gender, n (%) | 27 (55) |
| Indication for ILR |  |
| Syncope, n (%) | 41 (88) |
| Presyncope, n (%) | 3 (6) |
| Palpitations, n (%) | 3 (6) |
| Abnormal ECG, n (%) | 7 (14) |
| Coronary arterial disease, n (%) | 3 (6) |
| Reveal DX, n (%) | 44 (94) |
| Reveal XT, n (%) | 3 (6) |

ILR, implantable loop recorder; ECG, electrocardiogram
Thirty-eight patients (81%) had false arrhythmic events registered by the ILR (Table 3). Asystole and FVT were the most frequent false arrhythmic events (Figures 2 and 3), the cause of false detection being undersensing or noise, respectively. Table 4 shows the ratio between true and false events for each type of arrhythmia; apart from bradycardia, which was mostly true, a very high percentage of false arrhythmic events was recorded for the other arrhythmias.

During the observation period, inter-transmission ILR memory saturation was observed in 193 (14%) of 1369 transmissions. The most frequent cause was the recording of false asystole and FVT episodes. Implantable loop recorder parameters were reprogrammed in 8 patients out of 17 that needed a change in ILR setting. In four of these reprogramming was complete and appropriate, and was effective in three cases. We estimated that, if these patients had been monitored by means of 3-monthly in-office follow-up examinations, as is the usual clinical practice in our departments, instead of frequent Carelink transmissions, at least one episode of ILR memory saturation would have been observed in 21 patients (45%) within a wide range of time shown in Table 5.

**Patient compliance**

Regarding physical components (Table 6), in general, ILR did not impair quality of life, though it was perceived as harmful (score 4 or 5) by 6–9% of patients with regard to different items. Regarding mental components, 94% of patients were not worried about ILR and 70% felt safer because they were constantly checked. However, one-fifth of patients reported feeling sicker and feeling their privacy invaded. Specific questions concerning patient compliance with Carelink transmission are summarized in Table 7. All patients judged the Carelink monitor very easy (48%) or easy (52%) to use and almost all were able to transmit in <10 min. All patients would recommend the use of Carelink to other patients.
The main results of the study are that remote monitoring enhances the diagnostic effectiveness of Reveal by bringing forward the documentation of relevant ECGs and limiting the risk of memory saturation due to the high number of false detections. Both ILR and CareLink were well accepted by the patients, as they were considered useful and were well tolerated.

In this study, in which data were transmitted weekly on average, we were able to detect true relevant ECGs in 28 days, which was 71 days less than in the clinical practice of 3-monthly in-office follow-up examinations in use in our departments. In addition, in most patients, we were able to detect multiple episodes [median

### Table 4: Rate of true episodes for each type of arrhythmia

| Type of Arrhythmia | True | False | % True |
|-------------------|------|-------|--------|
| Symptom           | 195  | 0     | 100    |
| Fast ventricular tachycardia | 4   | 1391  | 0.3    |
| Ventricular tachycardia     | 15  | 86    | 14.9   |
| Asystole           | 120  | 3671  | 3.2    |
| Bradycardia        | 582a | 251   | 69.9   |
| Atrial fibrillation| 60   | 73    | 45.1   |
| Total              | 976  | 5472  | 15.1   |

*aThis number includes 560 episodes of bradycardia which occurred in one single patient; a total of 22 episodes occurred in the other 31 patients.

### Table 5: Cumulative estimated memory saturation depending on frequency of transmission

| Frequency of Transmission | Number of Patients with Memory Saturation (%) |
|---------------------------|---------------------------------------------|
| Every day                 | 7 (15%)                                     |
| Every 7 days              | 11 (23%)                                    |
| Every 15 days             | 12 (25%)                                    |
| Every 30 days             | 14 (30%)                                    |
| Every 60 days             | 21 (45%)                                    |

**Discussion**

The main results of the study are that remote monitoring enhances the diagnostic effectiveness of Reveal by bringing forward the documentation of relevant ECGs and limiting the risk of memory saturation due to the high number of false detections. Both ILR and CareLink were well accepted by the patients, as they were considered useful and were well tolerated.

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Figure 3 A case of a false arrhythmic episode due to noise recording, misinterpreted by the Reveal as an episode of fast ventricular tachycardia (FVT detected). The noise, probably due to contractions of the muscles surrounding the ILR pocket, caused false detections of tachyarrhythmias (TS and FS labels), a situation resembling fast ventricular tachycardia (FVT). A normal sinus rhythm (labelled with arrows) continued throughout the episode, which confirms the diagnosis of false detection. This was the second most frequent type of false episode recorded in the study.
manifestations of the disease are more frequent than symptomatic events. By comparison, in most ILR studies without remote monitoring, the time to diagnosis was much longer and multiple events were only seldom recorded. For example, in the pioneering study by Krahn et al., the mean time to diagnosis was 5.1 ± 4.8 months. In three studies which used manual and automatic activation in a heterogeneous population of patients affected by unexplained syncope, the mean time to diagnosis was 109 ± 120 days, 71 ± 79 days (2.3 ± 2.6 months), and 5.4 ± 4.6 months. In patients with recurrent reflex syncope, a syncopal relapse was documented after 3 months (interquartile range 1–7). In patients with structural heart disease and negative work-up, a syncopal relapse was documented after 6 ± 5 months. In patients with bundle branch block, the time to diagnosis was a median of 48 days (16–100). Finally, in patients with unexplained palpitations, the time to diagnosis was 279 ± 228 days.

In addition, by limiting the negative impact of memory saturation, Carelink potentially increases the diagnostic yield of ILR. Indeed, in previous studies without remote transmission, the diagnostic yield of ILR was hampered by the failure to document a syncopal relapse in 5–9% of the patients (16% of events), owing to their inability to perform manual activation and to memory saturation, which prevented automatic recording. False arrhythmia storage in ILRs includes undersensing related to sudden reductions in R-wave signal amplitude during both normal sinus rhythm and arrhythmias, and undersensing due to transient loss of the ECG signal because of device amplifier saturation, T-wave, and myopotential. In this study, false arrhythmic episodes were much more frequent than those

### Table 6: Total patient compliance with Reveal in 33 patients

| Physical components | Score 0–1 | Score 2–3 | Score 4–5 | No answer |
|---------------------|-----------|-----------|-----------|-----------|
| Did Reveal cause... | Little    | ↔         | Much      |           |
| 1. Pain?            | 29 (88%)  | 1 (3%)    | 3 (9%)    | 0 (0%)    |
| 2. Skin irritation? | 29 (88%)  | 2 (6%)    | 2 (6%)    | 0 (0%)    |
| 3. Tingling?        | 28 (85%)  | 2 (6%)    | 2 (6%)    | 1 (3%)    |
| 4. Restriction of movements? | 27 (82%) | 4(12%)    | 2 (6%)    | 0 (0%)    |
| 5. Limitation of daily activities? | 31 (94%) | 0 (0%)    | 2 (6%)    | 0 (0%)    |
| Mental components   | No        | ↔         | Yes       |           |
| Did Reveal...       |           |           |           |           |
| 6. Cause you any concern? | 31 (94%) | 0 (0%)    | 1 (3%)    | 1 (3%)    |
| 7. Make you feel safer because constantly checked? | 5 (15%) | 3 (9%)    | 23 (70%)  | 2 (6%)    |
| 8. Make you feel sicker? | 20 (61%) | 1 (3%)    | 7 (21%)   | 5 (15%)   |
| 9. Seem to be an invasion of your privacy? | 22 (67%) | 1 (3%)    | 7 (21%)   | 3 (9%)    |
| 10. Increase your symptoms during monitoring? | 20 (61%) | 2 (6%)    | 6 (18%)   | 5 (15%)   |

### Table 7: Feedback on CareLink transmission in 33 patients

| 1. How long do you take to make a transmission on average? |
|----------------------------------------------------------|
| <5 min                                                   | 15 (45%) |
| 6–10 min                                                 | 17 (52%) |
| >10 min                                                  | 1 (3%)   |
| 2. How would you describe the use of the Carelink monitor? |
| Very easy                                                | 16 (48%) |
| Easy                                                     | 17 (52%) |
| Difficult                                                | 0 (0%)   |
| Very difficult                                           | 0 (0%)   |
| 3. Have you ever failed to make a transmission?          |
| Never                                                    | 25 (76%) |
| Sometimes                                                | 8 (24%)  |
| 4. Would you recommend the use of Carelink monitoring to other patients implanted with ILR? |
| Yes                                                      | 33 (100%)|
| No                                                       | 0 (0%)   |
| 5. How did you feel during the monitoring period when you used the remote control? |
| Reassured                                                | 25 (76%) |
| Not reassured                                            | 1 (3%)   |
| No difference                                            | 6 (18%)  |
| 6. Is the use of Carelink monitoring a cause of anxiety for you? |
| Yes                                                      | 1 (3%)   |
| No                                                       | 32 (97%) |
reported for other implantable devices, especially ICDs with the same remote monitoring system. The reason for this is that the ILR has no lead system and detects the surface ECG rather than the intracavitary signal. The avoidance of misdetection is clearly a priority of research. In our study, these false episodes caused some memory saturation in about half of the patients, decreasing the possibility to detect true episodes. With CareLink, it was possible to identify these patients and take corrective action (i.e., reprogramming the ILR, optimizing the transmission interval, and bringing forward follow-up visits). The results would probably have been even better if ILR had been appropriately reprogrammed. While reprogramming was successfully done in only three patients, we estimated that it would have been useful in 17 patients.

We can compare our study with the pilot study of the Sleuth Implantable ECG Monitoring System which enrolled 40 patients and followed them up for 8.5 months. That study assessed the utility of a two-step review process: ILR transmission data were initially filtered by a central ECG monitoring facility, and the revised data were transmitted to the patient’s physician for evaluation. A total of 223 226 ECG recordings (660 per patient per month) were transmitted to the monitoring centre, but only 117 (0.005%) relevant ECGs were selected for further evaluation by the physician. One or more relevant ECGs were identified for 20 patients (50%). Thus, the study showed that sensitivity criteria for recording and transmission resulted in an excessive ECG burden of false detections, which required filtering in order to identify clinically relevant ECGs. In the present study, which had a similar total number of episodes recorded, the filtering system was different (see Methods) and ultimately 2.6% relevant ECGs were transmitted and could be analysed by the attending physician.

Both Reveal and CareLink were generally well accepted, as they were considered useful and were well tolerated. Moreover, the concerns expressed by the minority of patients mainly regarded mental rather than physical components; indeed, one-fifth of the patients reported feeling sicker and felt that their privacy had been invaded. In contrast, psychological compliance was better when Carelink was used with CRT-ICD, in that virtually no concern was reported. The difference between CRT-ICD and syncope patients in terms of their perception of the severity of the underlying disease could explain this difference. Insufficient or incomplete information provided by physicians could have contributed to this negative psychological impact in a minority of our patients. We therefore recommend that the attending physician spend more time on explanations and reassurance at the time of implantation. Our patients’ compliance with regard to the other components of quality of life was similar to that observed by other authors who evaluated the Carelink system when used with ICD or CRT. A recent study of CareLink for CRT-ICD showed good acceptance by clinicians. We did not explore this particular item, but we can assume that similar results would have emerged with regard to ILRs.

**Limitations**

The main limitation of this study is the lack of a control group of patients without CareLink. Comparison of the diagnostic yield with that of other ILR studies is difficult, owing to the different technology, methodology, patient selection, and diagnostic criteria.

However, the evaluation of the diagnostic yield was outside the scope of the present study which was aimed to effectiveness and patients’ acceptance. Finally, owing to the filtering system of Reveal, most of transmissions were without ECG. It is possible that some true arrhythmic event could have been missed. However, in general, the cause of frequent transmissions was false episodes. It is therefore likely that the episodes without ECG were the same false episodes already diagnosed by ECG.

**Clinical perspectives**

The association of ILR with remote monitoring enhances the detection of asymptomatic relevant arrhythmias much more than any other monitoring tool. The recording of a relevant arrhythmia is not necessarily equal to a diagnosis. Physicians should be aware of how to interpret correctly the ECG findings. While the correlation of symptoms with ECG is considered a strong diagnostic criterion in current guidelines, the recording of asymptomatic arrhythmias are weaker end-points with the exception of Mobitz II or III atrioventricular block or ventricular pauses >3 s, or rapid prolonged paroxysmal atrial or ventricular tachyarrhythmias. Sinus bradycardia, asymptomatic arrhythmias (other than those listed above), and pre-syncope without any relevant arrhythmia cannot be considered diagnostic per se. These findings should be interpreted in the clinical context and possibly monitoring continued until a harder endpoint is recorded.

Weekly transmission seems to be optimal for most patients in order to reduce the time to diagnosis and avoid memory saturation. However, in some patients, the frequency of transmissions should be individualized and ILRs should be reprogrammed if needed. Physicians should be aware of the importance of follow-up in order to detect false arrhythmias and adjust the features of the ILR appropriately. If the false episode rate is high, we recommend reprogramming the ILR accordingly. For example, if false FVT is the cause, the R-wave setting can be changed or FVT detection intervals and FVT number of intervals to detect (FVT NID) can be modified or even switched off. If false asystole/bradycardia is the cause, the sensing threshold should be decreased and the detection interval or duration should be changed. However, even if detection parameters are tuned, false arrhythmia rates cannot be completely eliminated in some patients. Therefore, in these cases, we recommend individualizing the transmission frequency in order to ensure that the inter-transmission time is shorter than the memory saturation time. On the basis of the theoretical memory capacity of Reveal DX/XT, we estimated the memory saturation time if the device were used without CareLink (Table 5). At one extreme, the memory would have become saturated in 1 day in 7 patients (15%); at the other, it would have been unsaturated after 60 days in 26 patients (55%).

**Conclusion**

Remote monitoring with CareLink provides an added diagnostic value to that of ILRs in patients affected by unexplained syncope and palpitations. Physicians should be aware how to interpret correctly the ECG findings of this new powerful tool. Both ILR and
CareLink are well accepted by the patients, as they are deemed useful and are well tolerated. Weekly transmission is usually optimal; however, the frequency of transmission should be individualized in some patients.

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