Clinical utility of a novel wireless implantable loop recorder in the evaluation of patients with unexplained syncope

Vijayapraveena Paruchuri, MD, Mehul Adhaduk, MBBS, Naga V. Garikipati, MD, MPH, Jonathan S. Steinberg, MD, FHRS, Suneet Mittal, MD, FHRS

From the Al-Sabah Arrhythmia Institute and Division of Cardiology, The St. Luke's and Roosevelt Hospitals, Columbia University College of Physicians & Surgeons, New York, New York.

BACKGROUND The implantable loop recorder (ILR) is particularly useful for monitoring patients with syncope, given the episodic nature and unpredictable pattern of recurrent episodes. Current practice guidelines advocate ILR implantation in select patients with unexplained syncope.

OBJECTIVE The purpose of this study was to evaluate the clinical utility and potential advantages of a novel wireless ILR in a consecutive cohort of patients with unexplained syncope.

METHODS Patients with unexplained syncope despite a comprehensive evaluation who underwent implantation of a Transoma Medical Sleuth ILR were examined. ILR implantation was considered in these patients if left ventricular function was ≥40% and if syncope was recurrent, associated with trauma, and/or associated with an abnormal ECG (e.g., bifascicular block).

RESULTS The Sleuth ILR was implanted in 50 patients. During mean follow-up 293 ± 211 days, 16 (32%) patients had recurrent near-syncope or syncope. Only half of the patients self-activated the ILR; in the other half, a diagnosis was established based on autoactivation-initiated storage of a significant arrhythmia event. Overall, there were 5 patients with complete heart block, 3 with sinus node dysfunction, 3 with supraventricular tachycardia, 2 with neurally mediated syncope, and 3 with a nonarrhythmic cause of syncope. The median time from an event to physician notification was 150 minutes (interquartile range 99, 297 min). Median time from ILR implantation to final diagnosis was 71 days (interquartile range 24, 143 days; range 3–683 days).

CONCLUSION A diagnosis of syncope was ultimately made in nearly one third of patients with unexplained syncope. Patients frequently did not activate their ILR at the time of recurrent syncope. However, the wireless ILR automatically transferred ECG data to a central monitoring station within minutes to hours of the arrhythmic event, virtually eliminating the possibility of data loss, thus greatly facilitating clinical decision making.

KEYWORDS Implantable loop recorder; Syncope

ABBREVIATIONS **ECG** = electrocardiogram; **ILR** = implantable loop recorder; **IQR** = interquartile range; **PDM** = patient diagnostic manager

(Heart Rhythm 2011;8:858–863)

The implantable loop recorder (ILR), a single-lead electrocardiographic (ECG) monitor that is placed subcutaneously, is capable of storing ECG data in response to patient activation as well as automatically in response to a significant bradyarrhythmia or tachyarrhythmia and has a several-year battery longevity. It is particularly useful for monitoring patients with unexplained syncope, given the episodic nature and unpredictable pattern of recurrent episodes. Thus, current practice guidelines advocate ILR implantation in appropriate patients with unexplained syncope.[1]

Despite the apparent appeal of ILRs, technical limitations still prevent realization of their ideal potential in the diagnosis of clinically significant arrhythmias. A major limitation is potential undersensing or oversensing during sinus rhythm.[2,3] This can rapidly exhaust the storage capacity of the ILR, potentially causing an inability to record clinically significant arrhythmias. Alternatively, clinically significant arrhythmic events can be overwritten by ECG storage of events triggered by a sensing abnormality. A wireless ILR, which was briefly available in the United States, overcame this limitation by transmitting stored events almost immediately to a central recording station. Therefore, we sought to evaluate the clinical utility and potential advantages of a wireless ILR in a consecutive cohort of patients with unexplained syncope.

Methods

Study population

Consecutive patients with syncope whose diagnosis remained unexplained despite a thorough initial evaluation who underwent implantation of a Sleuth ILR (Transoma Medical, Arden Hills, MN, USA) were examined. ILR implantation was considered in these patients if left ventricular function was ≥40% and if syncope was recurrent, associ-

Dr. Mittal was a consultant to, and received research funding from, Transoma Medical. **Address reprint requests and correspondence:** Dr. Suneet Mittal, Al-Sabah Arrhythmia Institute, The St. Luke's-Roosevelt Hospitals Center, 1111 Amsterdam Avenue, New York, New York 10025. E-mail address: smittal@chpnet.org. (Received January 10, 2011; accepted January 26, 2011.)

1547-5271/$ -see front matter doi:10.1016/j.hrthm.2011.01.039

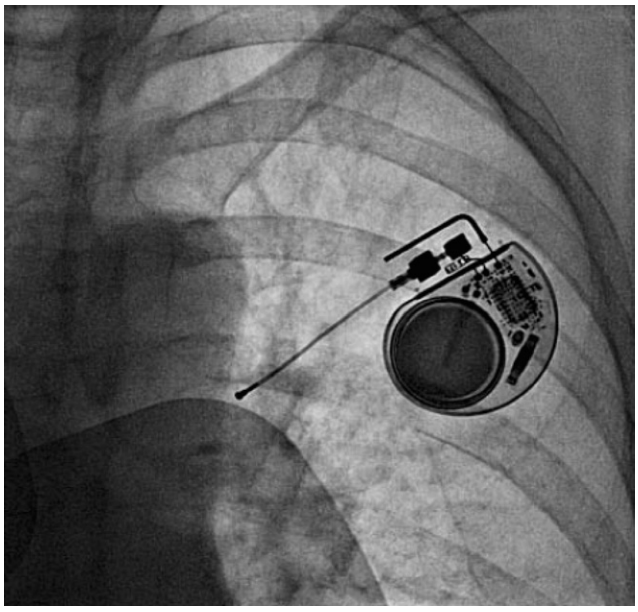

Figure 1 Fluoroscopic image of the Sleuth ILR system. The Sleuth ILR was implanted in a left infraclavicular location in all of our patients. No vector mapping was necessary prior to device implantation. Fluoroscopy was used to confirm that the antenna maintained a linear orientation. Because the device senses between the tip of the antenna and the can, keeping the antenna straight was critical to ensure adequate sensing.

ated with trauma, and/or associated with an abnormal ECG (most commonly bifascicular block).[4–6] All patients underwent a comprehensive history and physical examination, baseline 12-lead ECG, 24-hour telemetry monitoring, and echocardiography. Additional diagnostic tests including stress testing, cardiac catheterization, tilt table testing, and neurologic tests (head computed tomography or magnetic resonance imaging, electroencephalogram, carotid Doppler) were performed as clinically indicated. The study was approved by our Institutional Review Board.

Sleuth ILR

The Sleuth ILR is shaped and sized (40 × 41 × 8 mm) similar to a pacemaker generator.[7–9] It senses the ECG between the ILR and the tip of a flexible 6- or 8-cm antenna. (A 6-cm antenna was implanted in all of our patients.) The device is implanted subcutaneously in a left infraclavicular region under local anesthesia. Fluoroscopy is used to ensure that the antenna is oriented in a linear manner (Figure 1). The ILR was capable of 43 minutes of ECG storage and had a 28-month battery longevity (Figure 2).

Once implanted, the ILR automatically adjusted the gain to optimize sensing. In addition, sensing could be manually adjusted using the patient diagnostic manager (PDM). The PDM also allowed programming of bradycardia (nominal ≤40 bpm) and tachycardia (nominal ≥150 bpm) detection criteria and could be used by a patient to manually trigger ECG storage. The ILR wirelessly transmitted stored ECG data to the PDM (range 3 feet), which was capable of 630 minutes of ECG storage (Figure 2). Finally, patients were given a base station that was connected to a monitoring center (MedNet Healthcare Technologies, Ewing, NJ, USA) through the patient's landline phone connection. When the PDM was within 30 feet of the base station, stored ECG data were transmitted automatically to the monitoring center. A representative of Transoma Medical notified us if no data transmission had occurred for any 72-hour period.

The ILR was designed to maintain high sensitivity (~99.5%; Personal Communication, Brian Brockway, CEO Transoma Medical) at the expense of specificity. Specifically, a *single* beat below the low heart rate setting satisfied the bradycardia rule and *6 of 8* consecutive beats above the high heart rate setting satisfied the tachycardia rule. Events meeting these criteria were stored within the ILR; however, to prevent loss of ECG data, data were sent automatically to the PDM, which was capable of storing a large amount of data. When the data arrived at the monitoring center, it was first filtered through a proprietary offline filtering algorithm designed to exclude "false-positive" events due to noise, myopotentials, or sensing artifacts. As a final step, events still deemed to meet physician notification criteria were evaluated by a technician to determine their validity.[9] Physicians were then notified via telephone, facsimile, and/or pager of clinically significant arrhythmic events. In addition, the ECG data were posted online and available for review on an encrypted and password-protected web server. Physician notification occurred similarly for *all* patient-activated events.

Once the device was implanted in patients, regular scheduled office visits were no longer needed. Patients were contacted whenever they triggered a patient-activated event or a clinically significant bradyarrhythmic or tachyarrhythmic event was documented. Because these events were transmitted automatically, no in-office visit to clear the device's memory was needed. The primary endpoint of the study was time to diagnosis.

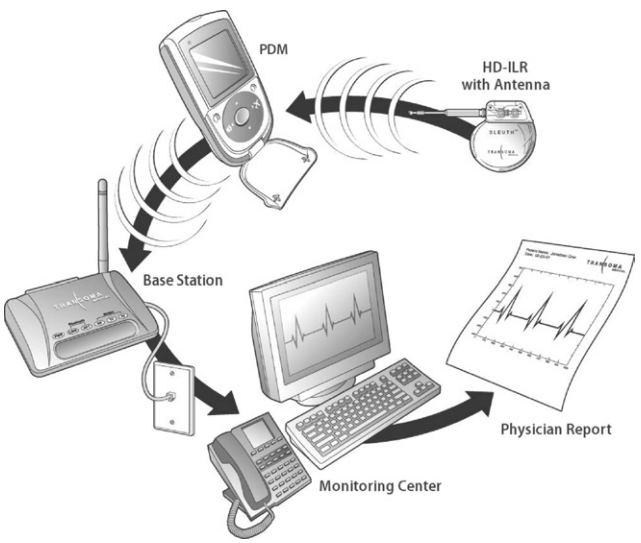

Figure 2 Schematic overview of the Sleuth ILR system. See text for discussion. ILR = implantable loop recorder; PDM = patient diagnostic manager.