An Anatomic-Based Approach for the Placement of Implantable Loop Recorders

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Introduction: Placement of the Reveal implantable loop recorder (ILR; Medtronic Inc., Minneapolis, MN, USA) has previously involved preoperative cutaneous mapping to determine the optimal location. We describe an anatomic-based approach to ILR placement that does not require cutaneous mapping.

Method: A total of 63 patients (40 women, 23 men, mean age 38 ± 15 years) were included in the study. Each underwent implantation of a Reveal ILR in the left upper chest area midway between the supraclavicular notch and the left breast area. Thirty-two patients received a Medtronic Reveal DX ILR and 31 received Reveal XT device.

Results: In all 62 patients, adequate electrocardiographic tracings were obtained at implant without the need for preoperative cutaneous mapping, and all were followed for a period of 10 ± 4 months afterwards. The mean P wave amplitude was 0.12 ± 0.20 mV at implant and at follow-up (6–14 months postimplant); the amplitude was 0.11 ± 0.19 mV. The peak-to-peak QRS amplitude was 0.48 ± 0.15 mV at implant and 0.44 ± 0.16 mV at a follow-up of 6–14 months. The P waves were not detected in two patients at follow-up. In one patient, decreased amplitude of QRS complex resulted in the autoactivation of the device and in one other patient noise was inappropriately oversensed and recorded.

Conclusion: A simple anatomic approach can be used for reveal ILR placement. (PACE 2010; 1–4)

Introduction

The implantable loop recorder (ILR) has become a valuable tool in the diagnostic evaluation of patients suffering from recurrent unexplained episodes of syncope. A variety of different placement sites have been proposed, usually requiring time-consuming cutaneous mapping techniques to determine optimal positioning and signal strength. We describe a simple straightforward anatomic-based approach for the placement of Reveal ILRs (Medtronic Inc., Minneapolis, MN, USA) that does not require preoperative mapping. The selection of the implant site was based on both our own previous experience with ILR placement combined with results from previously published data.

Method

A total of 63 patients (40 women, 23 men, mean age 38 ± 15 years) were evaluated in the current study, which was approved by our Institutional Review Board. A Reveal DX model 9528 was implanted in 32 patients and Reveal XT model 9529 in 31 patients. Each patient had suffered from recurrent unexplained syncope of more than 1-year duration and had suffered at least three syncopal episodes in the preceding 6 months prior to implant. All 63 patients had been previously seen and evaluated in our institution’s Syncope and Autonomic Disorders clinic. After an overnight fast, patients were taken to the pacemaker laboratory. In each patient, an imaginary line was drawn between the suprasternal notch and the approximate area of left nipple (Fig. 1). An area in the inferior middle one-third of the line was prepared and draped in usual surgical fashion and a 1% xylocaine solution was infiltrated for local anesthesia. A 2.0-cm incision was then made in the skin using a number 15 surgical scalpel at the lower one-third of the aforementioned imaginary line. Blunt dissection was then employed to create a 6-cm subcutaneous pocket. The Reveal (DX and XT) ILR is a rectangular device measuring 62 × 19 × 8 mm and weighs 15 grams. A pair of sensing electrodes on its surface records a single lead bipolar electrogram. The battery has a projected duration of 36 months. The device was inserted into the subcutaneous pocket and adequate signal strength and size were then analyzed using a telemetry wand (in a sterile cover) attached to a standard portable device programmer.
The pocket was then irrigated with an antibiotic solution. The deep dermal layer was then closed with a 2.0 absorbable braided suture placed in a continuous fashion. The subdermal layer was closed using an absorbable 3.0 monofilament suture placed in an interrupted fashion. The wound surface was then sealed with a tissue adhesive (2-octyl-cyanoacrylate) and dressed with a non-adherent dressing and covered with a transparent film dressing. All patients were discharged 2 hours postprocedure. Patients were seen in the Syncope Clinic 1 week postimplant and downloads of information from the device were made every month either by a transtelephonic monitor or in the clinic. P- and R-wave amplitude (peak-to-peak) was calculated at the time of implant and at a follow-up of 10 ± 4 months. As was noted earlier, 32 patients received a Reveal DX ILR (Model #9528) and 31 patients received a reveal XT (Model #9529).

**Transtelephonic Monitoring**

Data were transferred from patients implanted devices using the portable Medtronic CareLink® Network, which reads device-related data from a monitor connected to a standard phone line and physiologic data similar to the one is obtained during an in-clinic device follow-up visit. It then automatically dials a pre-programmed number to send the information to a secure Internet website (Medtronic CareLink Network) via a telephone line. The information is then available on the website and can be accessed by the physician via the Internet.

**Results**

Clearly visible P and QRS complexes were obtained in all 63 patients at implant. In no patient was any alteration of the original subcutaneous pocket necessary to obtain better recordings (Figs. 2 and 3). The mean P-wave amplitude was 0.12 ± 0.20 mV and the mean peak-to-peak QRS amplitude was 0.48 ± 0.15 mV at the time of the implant. One patient developed a subcutaneous infection requiring ILR removal.
Stability of Electrograms after Implant and at Follow-Up

Over a mean follow-up period of 10 ± 4 months, electrograms were downloaded at the follow-up and compared for signal strength obtained at the implant. All of these patients continued to have clearly visible P and QRS complexes recorded from the device, as well as diagnostic recordings of electrocardiogram (ECG) changes during syncopal events (Fig. 3). One patient complained of chronic pain at the device site; however, it was not considered significant enough to warrant device removal. P waves were seen in all 63 patients at the time of initial device implant. Two patients later noted to have a loss of P-wave sensing at follow-up. The mean P wave amplitude at implant was 0.12 ± 0.20 mV and it was 0.11 ± 0.19 mV at 6–14 month follow-up. The peak-to-peak QRS amplitude was 0.48 ± 0.15 mV at implant and 0.44 ± 0.16 mV at 6–14 month follow-up analysis.

Sensing Issues

In one patient, decreased amplitude of QRS complex resulted in the autoactivation of the device and in another signal noise was inappropriately oversensed. Both these episodes resulted in an episode of inappropriate autoactivation. Thus, in our series of patients undersensing (decreased QRS amplitude) and oversensing occurred in one patient each (1.6% each). In two patients, P wave disappeared at the follow-up (3.2%). No episode of T-wave oversensing resulting in inappropriate autoactivation was noted.

Discussion

The ILR has become a valuable tool in the diagnostic evaluation of recurrent unexplained syncope. A variety of different techniques and positions have been proposed for ILR placement, many having advocated extensive surface mapping of prospective implant sites prior to implant.3,8–10 One of the problems that have been encountered during the clinical use of these devices is undersensing either due to decreased QRS amplitude or a drift of the signal baseline.4 Both these events can trigger autoactivation of the device (which recognizes it as a pause).4 In one study, almost 50% of the patients enrolled had undersensed episodes using standard left parasternal or apical heart zone implant sites.4 We found that the aforementioned anatomic-based technique of Reveal ILR placement provided both ease of placement and an excellent recording of the ECG over prolonged periods without need for preimplant mapping of prospective sites. Each patient felt that the small residual scar was cosmetically acceptable, and the closure technique described appeared to facilitate wound healing and appearance. There were no adverse events during placement and only one patient developed a postoperative infection. While the current study was done with the
Medtronic Reveal ILRs, we have found that the technique works equally well with the St. Jude Confirm ILR. The closure technique employed was adapted from standard plastic surgical techniques to enhance wound healing and scar appearance. While a formal patient questionnaire was not employed, direct patient inquiry revealed that all but one of the patients felt that the device position was comfortable and that the subsequent scar location was cosmetically acceptable.

**Conclusion**

A simple anatomic approach can be employed for reveal ILR placement that does not require extensive pre-implant mapping. This technique allows for an efficient standardized approach to ILR placement.

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**References**