The TRUST Study Summary

Rationale

The number of patients with ICDs is increasing exponentially, in response to results of recent clinical studies establishing the mortality benefit of the devices in ischemic and non-ischemic cardiomyopathy patients.

The present environment imposes certain challenges for follow-up after ICD implantation. Currently, patients are seen at follow-up clinics every 3-6 months. The bulk of these routine visits involve collection of basic data only, e.g. battery status, lead impedance, and sensing function. The frequency of visits increases as a device nears its elective replacement window, which is variable and unpredictable. Intervening symptomatic events, e.g. shock therapy, may prompt interim unscheduled office or ER visits, and even hospitalization. In between scheduled follow-up visits, important diagnostic data may remain undetected.

A mechanism for performing intensive device surveillance without overburdening device clinics is desirable, but lacking. Limitations of conventional device follow-up have prompted interest in remote monitoring. Several different technologies are available, each with different capabilities. However, to date, there are limited prospective data demonstrating the feasibility and utility of these techniques.

BIOTRONIK Home Monitoring/IEGM-Online® technology utilizes automatic (wireless or landline-based) daily data transmissions, which may be reviewed on the Web. It provides salient follow-up data, e.g. battery status, lead impedance, and sensing function, as well as diagnostic data. This technology has two unique advantages: 1) data transmission requires no patient intervention, and 2) it provides automatic alerts of silent events, e.g., lead failure, onset of new AF, asymptomatic ventricular arrhythmia. Such early detection with rapid automatic notification may improve patient outcomes.

Objectives

The primary objective of this study is to demonstrate that the use of the BIOTRONIK Home Monitoring system (HM) can safely reduce the number of office visits.

Secondary objective #1 will be to compare the detection and resolution of AF, VT and VF events in both groups. It is expected that detection of events in the Home Monitoring arm will occur earlier than those in the Control group, and that these events will therefore be addressed and resolved more quickly.

In secondary objective #2, the value of Home Monitoring to triage patient initiated inquiries, such as perceived device discharges, will be assessed. The number of patient-initiated inquiries that result in ER and office visits will be compared between groups. We anticipate that the number of ER/Clinic visits will be less in the HM Group relative to the Control group, given the ability of providers to assess the device remotely in HM.

Study Design

All enrolled patients will receive a BIOTRONIK ICD with Home Monitoring/IEGM-Online® technology and will be randomized to either Group 1 (Home Monitoring (HM)) or Group 2 (No Home Monitoring) (Control) using a randomization ratio of 2:1.

Follow-ups will be scheduled for both groups at 3, 6, 9, 12 and 15 months post-implant.

Group 1 (HM)

Device evaluations for scheduled follow-ups, patient-initiated inquiries and event triggered notifications will be performed with HM/IEGM Online. Patients will be scheduled for office device interrogations only at the 3 month and 15 month follow-up points (following the HM check). At 6, 9 and 12 months a HM check will be performed first. Investigators may then elect to perform an office device interrogation if they determine that it is necessary after reviewing the HM data.

Group 2 (Control)

Patients will be evaluated using conventional, calendar-based office visits. Interim visits will be made according to physician discretion e.g. following any ICD discharges or symptoms. Home Monitoring

will be programmed OFF for the duration of the study.

HM Event Triggered Device Evaluations
Investigators with patients in Group 1 (HM) may receive HM notifications in response to pre-programmed events such as VT1 detected and SVT detected. Upon the receipt of a HM Event Notification, investigators will review the notification and the associated information on the HM/IEGM-Online website and record the type of event and what type of action, if any, was taken as a result of this notification.

Patient-Initiated Device Evaluations
Investigators may be contacted by the patient for device/arrhythmia-related care (e.g. perceived device discharge, symptoms). For patients in Group 1 (HM), investigators will triage the complaint using the Home Monitoring website. Investigators will record if the information from Home Monitoring was sufficient. For patients in Group 2 (Control), the complaint will be assessed per standard of care or normal clinic procedures.

Primary Endpoints
The purpose of primary endpoint 1 (HM efficacy) is to compare the number of in-person ICD follow-ups (HM or office) for patients in Group 1 (HM) to the conventional, calendar-based method of ICD follow-up as in Group 2 (Control).

The purpose of the primary endpoint 2 (safety) is to compare the Safety Event Rate (SER), which includes death, incidence of strokes and events requiring surgical interventions (e.g. device explants or lead revision) between the two groups.

Secondary Endpoints
The purpose of secondary endpoint 1 is to compare AF, VT and VF events between Group 1 and Group 2 in terms of the number, categories, and detection time relative to onset.

The purpose of secondary endpoint 2 is to evaluate and compare between groups the number of patient initiated inquiries that result in ER or office device interrogations.

Study-Specific Inclusion Criteria
- Implanted within the last 45 days or being considered for implant with a BIOTRONIK ICD with Home Monitoring/IEGM-Online technology
- Able to utilize the HM system throughout the study
- Ability to give informed consent
- Geographically stable and able to return for regular follow-ups for fifteen (15) months
- At least 18 years old

Study-Specific Exclusion Criteria
- Patients who do not fulfill all inclusion criteria
- Patients who are pacemaker dependent
- Currently enrolled in any other cardiac clinical investigation.

Principal Investigator
Niraj Varma, M.D., F.R.C.P.
Cardiac Pacing & Electrophysiology
Department of Cardiovascular Medicine
Cleveland Clinic
9500 Euclid Ave.
Cleveland, OH 44195

Sponsor
BIOTRONIK, Inc.
Scientific Studies Department
6024 SW Jean Road
Lake Oswego, OR 97035
Contact: Lori Gibson, D.V.M., Clinical Engineer

Study Flowchart