Boston Scientific

CLINICAL SUMMARY

INSIGNIA I ULTRA STUDY

CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

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CLINICAL STUDY - SUMMARY OF INSIGNIA I ULTRA

STUDY DESIGN

This clinical study was a prospective, multi-center, randomized test order within patient, clinical evaluation to document appropriate system performance of the INSIGNIA I Ultra pacemaker system in humans. Patients implanted with the INSIGNIA I Ultra pacemaker were followed through pre-discharge, 1-month and 3-month follow-ups. The purpose of this clinical study was to support safety and effectiveness of the Guidant INSIGNIA I Ultra pacemaker system.

Patient Demographics

The patients who participated in this study were from each investigator's general patient population which met indications for use and had no contraindications of the INSIGNIA I Ultra system. There were 105 patients enrolled in this clinical study; 101 that were implanted with the pacemaker system and followed through three months. Four patients were enrolled but did not undergo an implant procedure (intent). There were no patients attempted but not implanted.

The mean age of patients implanted with an INSIGNIA I Ultra was 69.5 years. The INSIGNIA I Ultra clinical study consisted of 62 males and 39 females. The predominant pacemaker indications were 3rd degree AV block, sinus bradycardia and sinus node dysfunction. These indications are typical of dual chamber pacemaker implants.

Commanded Autothreshold versus Manual Threshold Test

The accuracy of the Autothreshold test performed by the device was evaluated by comparing the threshold test results obtained by using the device commanded Autothreshold feature to those of manual threshold testing in the ventricle of the same patient at the same pulse width (0.4ms). The manual threshold and commanded Autothreshold algorithms decrements by a resolution of 0.2 V. The Autothreshold was evaluated at pre-discharge, one and three month follow-ups in all patients. The order of the threshold tests (commanded/manual or manual/commanded) was randomized at pre-discharge and that order was followed also at the one and three month follow-ups. Refer to Table 1.

Table 1. Commanded Autothreshold Performance

Threshold Test	n	mean ± std	Range	p-value
Commanded test	296	0.652 ± 0.335	[0.200–2.100]	-
Manual test	300	0.651 ± 0.335	[0.200–2.200]	-
Paired Difference	296	-0.001 ± 0.049	[-0.300–0.300]	<0.0001[a]

a. Paired comparison for equivalence. Small p-value supported the alternative hypothesis that the means are equivalent.

Ventricular Lead Mix

The Automatic Capture feature is designed to work with any ventricular lead. The INSIGNIA I Ultra clinical study allowed for any type of leads chosen by physicians without excluding any specific lead.

The following lead manufacturers leads were used: APC, Biotronik, Ela, Guidant, Intermedics, Medtronic, St. Jude, Sorin, Teletronics, and Vitatron. There were 31 different types of ventricular leads in the INSIGNIA I Ultra clinical study:

- Polarity: 11% unipolar 89% bipolar
- Fixation: 45% passive 55% active
- Impedance: 17% normal 83% high
- Steroid: 14% non-steroid 86% steroid

The data indicates that the Commanded Autothreshold test accurately determines the ventricular pacing threshold using any ventricular lead.

Complication Free Rate

The complication free rate was observed from all scheduled and unscheduled follow-up visits through the patient's three-month follow-up period. A complication is defined as a clinical event that results in invasive intervention, injury, or death (e.g., surgical evacuation of a hematoma, lead dislodgment requiring invasive lead repositioning, pulse generator replacement). The complication free rate was 93.1%; this met the goal of ≥ 90% (by equivalent test, $p < 0.0001$). There were no

complications related to the Automatic Capture and AutoLifestyle features, which were required to be turned “ON” throughout the study.

Delivery of the Backup Pulse

The Automatic Capture feature backup pulse delivery was evaluated at the 3-month visit in 83 patients. These patients had the Automatic Capture feature turned “ON” and were in beat-to-beat capture verification mode. Patients underwent 24-hour Holter monitoring and analysis. During beat-to-beat capture verification mode, the device determines if a pacing pulse captured the heart and, if a loss of capture is determined, delivers a back-up pulse.

Table 2. Loss of Capture without Back-up Pulse Events

Number of Patients Evaluated[a]	Number of Events
83	0

a. Eleven patients did not require a Holter, five patients did not have valid Trending Data Exports disk, and one patient did not have a valid Holter.

This data indicates that the Automatic Capture feature during beat-to-beat capture verification mode appropriately determines if the primary pacing pulse captured the ventricle and delivers a back-up pacing pulse when needed.

Evaluation of Ambulatory Autothreshold

The ability of the Ambulatory Autothreshold test to determine the ventricular threshold overall was 97.1% (n=3746 tests). The primary reason for unsuccessful Ambulatory Autothreshold tests was that the pacemaker initiated an ATR mode switch during the ambulatory threshold test.

The data indicates that the Ambulatory Autothreshold test accurately determines the ventricular pacing threshold on any lead.

AutoLifestyle Feature

This endpoint evaluated the ability of the AutoLifestyle feature to increase or decrease the MV max Long Term resulting from daily activities and/or a maximal exercise test. The AutoLifestyle feature was evaluated at the one and three-month follow-up in all patients. At the one-month visit the first 60 patients with a minimum of 15 valid tests from each group (AutoLifestyle "ON"/"4 -minute fast walk within 30

minutes" and AutoLifestyle "ON") participated in a maximal exercise test (Borg Scale value 15-20 on a scale 6-20). All patients were to have the AutoLifestyle feature on throughout the entire evaluation period.

The feature was evaluated by verifying data from the activity log of the device for no inappropriate response. The activity log records the time, date, MV Response Factor and MV max with the change in the MV max Long Term invoked by the AutoLifestyle feature.

All patients were evaluated at the 1-month and 3-month follow-up visits. There was no incidence of inappropriate response per the predefined criteria at either the 1-month or 3-month follow-ups.

STUDY RESULTS

Conclusions

The objective of this study was to provide clinical information to support the complication free rate and to assess the effectiveness of the INSIGNIA I Ultra pacemaker system. The following conclusions can be made from this study:

- The data indicates that the Commanded Autothreshold test accurately determines the ventricular pacing threshold on any lead.
- This data provides reasonable assurance the INSIGNIA I Ultra pacemaker system is safe.
- The Automatic Capture feature during beat-to-beat capture verification mode appropriately determines if the primary pacing pulse captured the ventricle and delivers a back-up pacing pulse when needed.
- The data indicates that the Ambulatory Autothreshold test accurately determines the ventricular pacing threshold on any lead.

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