Boston Scientific

CLINICAL SUMMARY

COGNATE 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.

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TABLE OF CONTENTS

CLINICAL STUDY - SUMMARY OF COGNATE STUDY

SUMMARY

The COGNATE study was designed to confirm that the newly integrated hardware upgrades to the INGENIO device function as intended to support the Right Ventricular Automatic Capture feature performance

The COGNATE study was designed to collect human data on the unipolar configuration of the Auto Gain Control (AGC) feature in the right atrium (RA) and right ventricle (RV).

STUDY DESIGN

COGNATE was an acute, confirmatory, prospective, multi-center study designed to gather data on dual chamber pacemaker and Cardiac Resynchronization Therapy Pacemaker (CRT-P) indicated patients, with no restrictions on the type or brand of RA and RV leads. This study enrolled 80 patients at 5 centers.

Inclusion Criteria

Patients who were scheduled to receive either a dual chamber pacemaker or a CRT-P device were included.

Objectives

The COGNATE study was intended to:

- Confirm that the Right Ventricular Autothreshold measurements, in the Automatic Capture feature, were accurate using the INGENIO hardware platform
- Characterize the sensitivity and the positive predictive value of the unipolar RV and RA Auto Gain Control

Study Progress

Five centers enrolled 80 patients of whom 73 underwent the COGNATE testing and completed the study. Of the 80 patients, three had unsuccessful testing attempts

(attempt status) and four had no test attempted (intent status). There were no deaths associated with the study. Table 1 includes details on the study progress.

Table 1. Study Summary

Data Item	Result			
Number of enrolled patients	80			
Number of withdrawn patients	7			
Number of patients tested with Acute Study System	73			
Number of patients included in Right Ventricular Automatic Threshold (RVAT) analyses (Unipolar/Bipolar)	66/63			
Number of patients included in DCS analyses (RA/RV)	64/66			
Testing phase*	November 20, 2009 - June 2, 2010			
Number of centers	5			
Patient Demographics				
Mean age at time of consent	73.1 ± 11.2 years			
Gender	64% male		36% female	
Adverse Events	**I**	**II**	**III**	**IV**
Observations	0	0	1	0
Complications	3	0	0	0
* Testing phase consists of time elapsed between testing procedures performed on the first and last patients.				

STUDY RESULTS

RVAT Test Accuracy Results

Table 2 presents the accuracy of the reported RVAT tests. Each RVAT test resulted in either a device-determined threshold or an error code. Expected error codes were obtained when the test was run under unfavorable conditions which include the starting amplitude being lower than the pacing threshold as an example. The

accuracy of each test result was assessed by reviewing the surface ECG obtained during the RVAT test. An accurate test was defined as:

1. A test that resulted in a commanded threshold equal to the threshold as determined by the surface ECG, or

2. A test that resulted in an appropriate error code as determined by the surface ECG.

Table 2. RVAT Accuracy

Configuration	RVAT Result	Tests Performed	Tests Resulting in Accurate RVAT Performance
Bipolar	Test Ended in a Threshold	60	59 (98.3%)
	Test Ended in an Error Code	3	3 (100.0%)
	Total	**63**	**62 (98.4%)**
Unipolar	Test Ended in a Threshold	66	66 (100.0%)
	Total	**66**	**66 (100.0%)**

A total of 63 commanded bipolar and 66 commanded unipolar tests were considered for analysis. The accuracy of the RVAT bipolar and unipolar tests were 98.4% and 100.0%, respectively.

AGC Test Accuracy Results

The number of appropriately sensed (true positive), undersensed (false negative) and oversensed (false positive) beats for RA and RV sensing at each test scenario and the accumulated total is listed below in Table 3.

Table 3. AGC Accuracy

				Inappropriately Sensed Beats			
	Scenario	**Patients**	**Appro-priately Sensed Beats**	**Under-sensed Beats**	**Over-sensed Beats**	**Sensitivity**	**Positive Predictive Value**
Right Atrial Channel	AP/VP	59	6692	20	400	99.7%	94.4%
	AP/VS	42	3819	2	1819	99.9%	67.7%
	AS/VP	57	5195	27	690	99.5%	88.3%
	AS/VS	55	4283	12	1601	99.7%	72.8%
	TOTAL	**64**	**19989**	**61**	**4510**	**99.7%**	**81.6%**
Right Ventricu-lar Channel	AP/VP	59	6468	0	0	100.0%	100.0%
	AP/VS	42	3739	0	0	100.0%	100.0%
	AS/VP	59	5173	0	0	100.0%	100.0%
	AS/VS	56	3821	5	0	99.9%	100.0%
	TOTAL	**66**	**19201**	**5**	**0**	**>99.9%**	**100.0%**

The sensitivity and positive predictive value of the AGC algorithm were 99.7% and 81.6% in the RA channel and, >99.9% and 100.0%, in the RV channel. Most of the FN (undersensed) events occurred as a result of cross channel blanking after pacing. There were no oversensed events in the RV resulting in the PPV score of 100%. The RA PPV was lower than RV PPV due to oversensed large amplitude far field R-wave.

Conclusion

The data show that the COGNATE objectives were met in evaluating the compatibility of AGC with unipolar right atrial and right ventricular sensing, and in obtaining human evoked response data to assist with evaluation of the right ventricular automatic capture (RVAC) performance on the new INGENIO hardware platform.

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