Boston Scientific

CLINICAL SUMMARY

LONGITUDINAL SURVEILLANCE REGISTRY OF ACUITY™ SPIRAL LEAD

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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POST APPROVAL STUDY – SUMMARY OF LONGITUDINAL SURVEILLANCE REGISTRY OF ACUITY SPIRAL LEAD

The Longitudinal Surveillance Registry of ACUITY Spiral Lead (hereafter referred to as LSR of ACUITY Spiral) was a post approval study designed to prospectively evaluate and report on the long-term reliability and clinical performance of the ACUITY Spiral Left Ventricular (LV) Lead – a coronary venous pace / sense lead that provides chronic LV unipolar pacing and unipolar sensing.

STUDY DESIGN

The LSR of ACUITY Spiral was designed as a prospective, non-randomized, multi-center post approval registry of patients implanted with the ACUITY Spiral Lead conducted within the United States. The study was designed as a one-armed observational study, rather than a randomized study that compared the ACUITY Spiral Lead to an alternate lead. The expected performance and safety of LV leads have been well established; thereby, permitting comparison to a pre-defined performance standard instead of an active control group.

METHODS

The LSR of ACUITY Spiral collected product status information, device system- and procedure-related events, and withdrawal data. Subjects were evaluated in-clinic with a full device evaluation one-month post implant and approximately every 9 months thereafter. Boston Scientific allowed use of the LATITUDE Patient Management System to collect the latest in clinic lead measurements data. Subjects were followed until they completed 5 years of follow-up from implant or until death, withdrawal, or closure of the registry.

Study Patient Population

The registry was designed to enroll patients receiving the ACUITY Spiral Lead for Cardiac Resynchronization Therapy (CRT), without targeting specific subpopulations.

LSR of ACUITY Spiral Study Endpoints

The Primary Endpoint of the LSR of ACUITY Spiral evaluated the chronic LV lead-related complication-free rate over a 5-year follow-up period. The primary endpoint analysis included confirmed chronic LV lead-related complications that resulted in permanent loss of therapy, invasive intervention, injury, or death as adjudicated by an independent group of physicians as attributed to structural lead failure.

The LSR of ACUITY Spiral also evaluated a Modified Composite Endpoint chronic complication-free rate, which included events that occurred ≥30 days post implant resulting in a complication (defined as permanent loss of therapy, invasive intervention, injury, or death) including: dislodgement, LV performance measurements (e.g., elevated threshold, loss of capture), diaphragmatic stimulation, and all LV lead-related perforations.

RESULTS

Subject Demographics

During the registry, 94 sites enrolled 1308 subjects with 1297 successfully receiving a ACUITY Spiral Lead implant (5 subjects withdrew prior to the procedure and 6 had unsuccessful implant attempts). Figure 1 summarizes the subjects enrolled. The median patient follow-up time was 34 months. Table 1 summarizes LSR of ACUITY Spiral subject demographics. For categorical variables, the number in parentheses represent percentages.

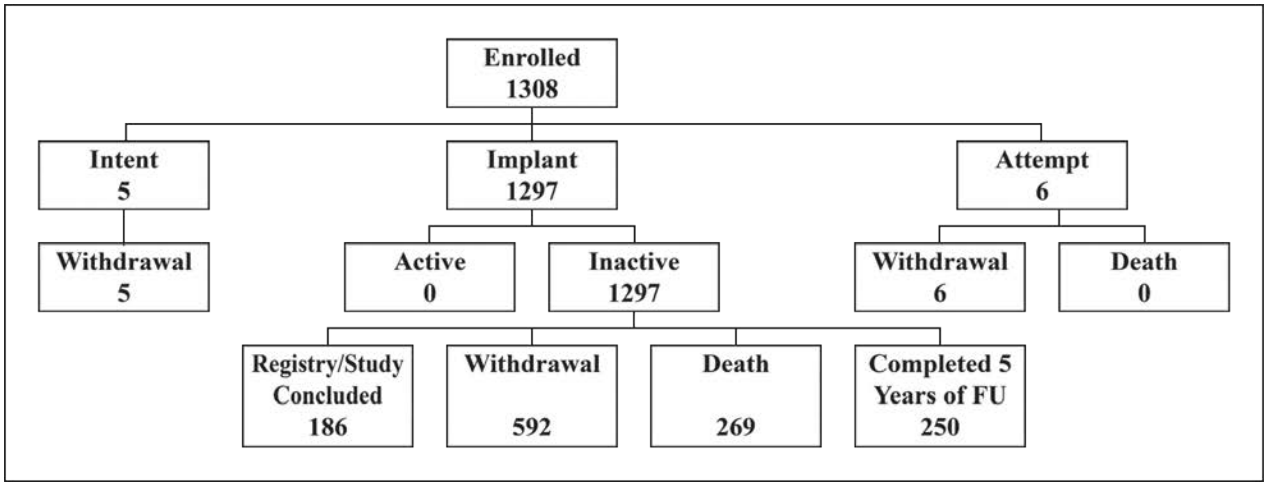

Figure 1. Status of enrolled subjects.

Table 1. Subject Demographics at Enrollment.

Characteristic	Measurement	All Subjects (N = 1308)
Age (years)	N	1308
	Mean ± SD	69.2 ± 10.8
	Range	26.0–94.0
Gender [N (%)]	Female	357 (27)
	Male	951 (73)
Race [N (%)]	White, not of Hispanic Origin	1068 (82)
	Black or African American	126 (10)
	Hispanic or Latino	52 (4)
	Other	62 (5)
NYHA Class [N (%)]	I	18 (1)
	II	176 (13)
	III	931 (71)
	IV	39 (3)
	Unknown	143 (11)
LVEF (%)	N	1282
	Mean ± SD	26.8 ± 7.9
	Range	10.0–71.0
	LVEF % not available	25 (2)
QRS Duration (ms)	N	1255
	Mean ± SD	150 ± 31
	Range	12–500
	QRS Duration not available.	48 (4)

Characteristic	Measurement	All Subjects (N = 1308)
PR Interval (ms)	N	959
	Mean ± SD	183 ± 55
	Range	16–959
	PR Interval not available.	284 (3)
Arrhythmia/Conduction Disorder [N (%)]	Left Bundle Branch Block	691 (54)
	None	140 (11)
	Nonspecific Intraventricular Delay	228 (18)
	Right Bundle Branch Block	149 (12)
	Unknown	77 (6)
HF Etiology [N (%)]	Ischemic	765 (59)
	Nonischemic	535 (41)

Adverse Events Reported

The study protocol defined adverse events as inappropriate performance of the PG or lead that resulted in an undesirable or unanticipated procedure or clinical occurrence. There were 373 adverse events reported by the centers during the study. The most common adverse event was Extracardiac Stimulation (phrenic/diaphragm) (N = 93) due to the LV lead. Adverse events reported during the registry are summarized in Table 2.

For LSR of ACUITY Spiral, an independent group of 3 physicians adjudicated all LV lead-related events. Of the events adjudicated, none were attributed to being related to the Primary Endpoint for chronic LV lead performance.

Table 2. Summary of Reported Adverse Events.

		< 30 Days PI*		30–45 Days PI*		> 45 Days PI*					
Adverse Event by Type	Adverse Event Classification	Events [N(% of Event Type)]	Pts with Events [N(% of Enrolled Pts)]	Events [N(% of Event Type)]	Pts with Events [N(% of Enrolled Pts)]	Events [N(% of Event Type)]	Pts with Events [N(% of Enrolled Pts)]	N Total Adverse Events	N Events Adjud-icated	N Events Counting Against the Endpoint	N Events Counting Against Modified Endpoint
Left ventricular lead	Elevated thresholds	10 (12.5)	10 (0.76)	2 (12.5)	2 (0.15)	19 (20)	15 (1.15)	31	31	0	6
	Lead migration/ dislodgement	6 (7.5)	6 (0.46)	4 (25)	4 (0.31)	20 (21.05)	19 (1.45)	30	30	0	22
	Loss of capture	5 (6.25)	5 (0.38)	0 (0)	0 (0)	16 (16.84)	14 (1.07)	21	21	0	12
	Undersensing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.05)	1 (0.08)	1	1	0	0
	Extracardiac Stim (phrenic/ diaphragm)	51 (63.75)	50 (3.82)	7 (43.75)	7 (0.54)	35 (36.84)	28 (2.14)	93	93	0	8
	Oversensing/ Multiple counting	1 (1.25)	1 (0.08)	0 (0)	0 (0)	0 (0)	0 (0)	1	1	0	0

		< 30 Days PI*		30–45 Days PI*		> 45 Days PI*					
Adverse Event by Type	**Adverse Event Classification**	**Events [N(% of Event Type)]**	**Pts with Events [N(% of Enrolled Pts)]**	**Events [N(% of Event Type)]**	**Pts with Events [N(% of Enrolled Pts)]**	**Events [N(% of Event Type)]**	**Pts with Events [N(% of Enrolled Pts)]**	**N Total Adverse Events**	**N Events Adjud-icated**	**N Events Counting Against the Endpoint**	**N Events Counting Against Modified Endpoint**
	High pacing lead impedance	0 (0)	0 (0)	1 (6.25)	1 (0.08)	0 (0)	0 (0)	1	1	0	0
	High amplitude	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.05)	1 (0.08)	1	1	0	0
	Other	7 (8.75)	7 (0.54)	2 (12.5)	2 (0.15)	3 (3.16)	3 (0.23)	12	12	0	1
	Subtotal	**80**	**76 (5.81)**	**16**	**16 (1.22)**	**95**	**76 (5.81)**	**191**	**191**	**0**	**49**
Device/PG	Inability to defibrillate or pace	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.19)	1 (0.08)	1	0	0	0
	Inappropriate therapy (e.g., shock)	1 (4.55)	1 (0.08)	1 (100)	1 (0.08)	38 (45.24)	27 (2.06)	40	0	0	0
	Migration of device	1 (4.55)	1 (0.08)	0 (0)	0 (0)	3 (3.57)	2 (0.15)	4	1	0	1
	Possible malfunction	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.19)	1 (0.08)	1	0	0	0
	Accelerated ventricular arrhythmia	0 (0)	0 (0)	0 (0)	0 (0)	10 (11.9)	10 (0.76)	10	0	0	0
	Skin erosion	1 (4.55)	1 (0.08)	0 (0)	0 (0)	4 (4.76)	4 (0.31)	5	0	0	0
	Other	19 (86.36)	19 (1.45)	0 (0)	0 (0)	27 (32.14)	27 (2.06)	46	1	0	1
	Subtotal	**22**	**22 (1.68)**	**1**	**1 (0.08)**	**84**	**69 (5.28)**	**107**	**2**	**0**	**2**
Atrial lead	Lead migration/ dislodgement	5 (41.67)	5 (0.38)	0 (0)	0 (0)	3 (27.27)	3 (0.23)	8	0	0	0
	Lead insulation breakage or abrasion	0 (0)	0 (0)	0 (0)	0 (0)	1 (9.09)	1 (0.08)	1	0	0	0
	Loss of capture	3 (25)	3 (0.23)	0 (0)	0 (0)	0 (0)	0 (0)	3	0	0	0
	Undersensing	2 (16.67)	2 (0.15)	0 (0)	0 (0)	1 (9.09)	1 (0.08)	3	0	0	0
	Oversensing/ Multiple counting	0 (0)	0 (0)	0 (0)	0 (0)	4 (36.36)	4 (0.31)	4	0	0	0
	High pacing lead impedance	2 (16.67)	2 (0.15)	0 (0)	0 (0)	0 (0)	0 (0)	2	0	0	0
	Other	0 (0)	0 (0)	0 (0)	0 (0)	2 (18.18)	2 (0.15)	2	0	0	0
	Subtotal	**12**	**12 (0.92)**	**0**	**0 (0)**	**11**	**11 (0.84)**	**23**	**0**	**0**	**0**

		< 30 Days PI*		30–45 Days PI*		> 45 Days PI*					
Adverse Event by Type	**Adverse Event Classification**	**Events [N(% of Event Type)]**	**Pts with Events [N(% of Enrolled Pts)]**	**Events [N(% of Event Type)]**	**Pts with Events [N(% of Enrolled Pts)]**	**Events [N(% of Event Type)]**	**Pts with Events [N(% of Enrolled Pts)]**	**N Total Adverse Events**	**N Events Adjud-icated**	**N Events Counting Against the Endpoint**	**N Events Counting Against Modified Endpoint**
Right ventricular lead	Elevated thresholds	2 (25)	2 (0.15)	0 (0)	0 (0)	3 (6.82)	3 (0.23)	5	0	0	0
	Lead migration/ dislodgement	3 (37.5)	3 (0.23)	0 (0)	0 (0)	2 (4.55)	2 (0.15)	5	0	0	0
	Loss of capture	1 (12.5)	1 (0.08)	0 (0)	0 (0)	3 (6.82)	3 (0.23)	4	0	0	0
	Undersensing	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.27)	1 (0.08)	1	0	0	0
	Inappropriate shock due to oversensing	0 (0)	0 (0)	0 (0)	0 (0)	6 (13.64)	6 (0.46)	6	0	0	0
	Oversensing/ Multiple counting	1 (12.5)	1 (0.08)	0 (0)	0 (0)	4 (9.09)	4 (0.31)	5	0	0	0
	High pacing lead impedance	0 (0)	0 (0)	0 (0)	0 (0)	2 (4.55)	2 (0.15)	2	0	0	0
	High amplitude	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.27)	1 (0.08)	1	0	0	0
	High shock lead impedance	0 (0)	0 (0)	0 (0)	0 (0)	14 (31.82)	7 (0.54)	14	0	0	0
	Low shock impedance	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.27)	1 (0.08)	1	0	0	0
	Cardiac Perforation	1 (12.5)	1 (0.08)	0 (0)	0 (0)	0 (0)	0 (0)	1	0	0	0
	Other	0 (0)	0 (0)	0 (0)	0 (0)	7 (15.91)	7 (0.54)	7	0	0	0
	Subtotal	**8**	**7 (0.54)**	**0**	**0 (0)**	**44**	**35 (2.68)**	**52**	**0**	**0**	**0**
Total	**Total**	**122**	**108 (8.26)**	**17**	**17 (1.3)**	**234**	**169 (12.92)**	**373**	**193**	**0**	**51**

*PI = post-implant
Note: patients may have multiple adverse events of different types; therefore the patient totals may not be the sum of the patient rows

Study Endpoint Results

Data collected during LSR of ACUITY Spiral demonstrated that the ACUITY Spiral Lead is safe and performs as expected in a chronic clinical setting. Based on these data, the Primary Endpoint passed the complication-free rate at 100% (Figure 2), with no events adjudicated as related to structural lead failure. In addition, the Modified Composite Endpoint showed a complication-free rate of 95.3%, with lower one-sided 95% confidence bound of 94.0%, which exceeded the passing criteria of 92.5% (Figure 3).

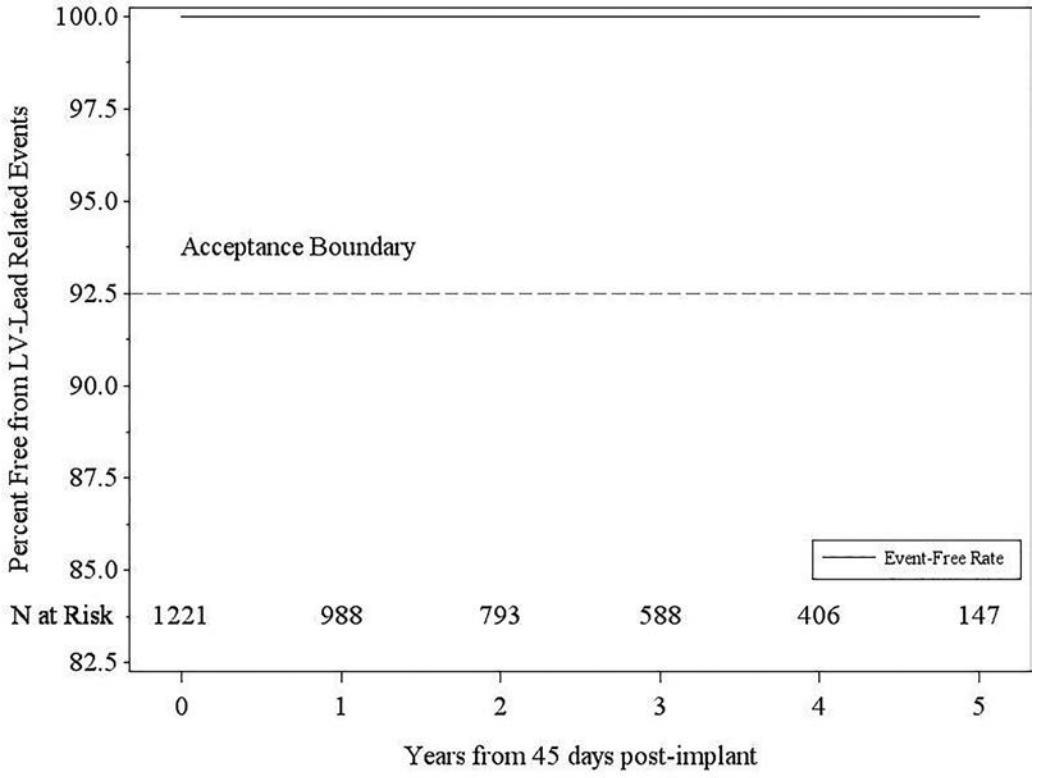

Figure 2. Primary Endpoint ACUITY Spiral-related chronic complication-free rate.

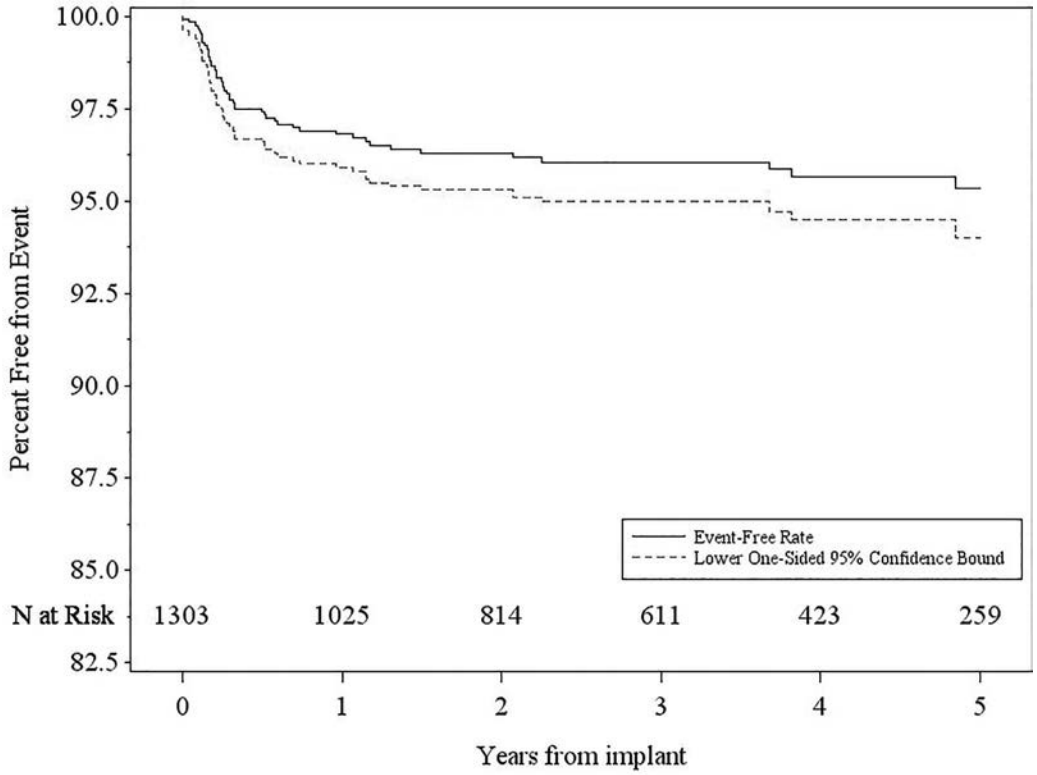

Figure 3. Modified Composite Endpoint ACUITY Spiral-related chronic complication-free rate.

STUDY STRENGTHS AND WEAKNESSES

Strengths of the LSR of ACUITY Spiral post approval study were (1) the Modified Primary Endpoint Complication-Free rate of 95.3% with a lower confidence bound of 94% exceeded the passing criteria of 92.5%, and (2) the low occurrence rate for out-of-range LV lead measurements. Weaknesses of the study were (1) the inability to enroll the minimum number of patients due to the advancement of LV lead technology and the availability of a newer generation of CRT leads during this time, and (2) a larger-than-expected rate of attrition allowing only 436 subjects to be followed through study conclusion.

CONCLUSIONS

Results from this post approval study conducted with ACUITY Spiral LV Leads demonstrated that the LSR of ACUITY Spiral endpoints were met. The Primary Endpoint passed with a complication-free rate at 100%, with no events adjudicated as related to structural lead failure. The Modified Composite Endpoint passed with a complication-free rate of 95.3%, with lower one-sided 95% confidence bound of 94.0%. In conclusion, results from this post approval study demonstrate that the ACUITY Spiral Lead is safe and performs as expected in a chronic clinical setting.

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92269560-001 en US 2018-08