Participant Flow

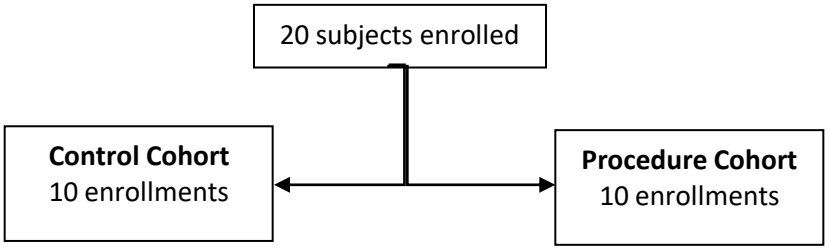

Table 1: Baseline Demographics

Subject Characteristics	All Subjects (n=20)	No Procedure (n=10)	Procedure (n=10)
Sex (n,%)			
Male	14 (70%)	6 (60%)	8 (80%)
Female	6 (30%)	4 (40%)	2 (20%)
Age (years)			
Mean ± Standard Deviation	64.7 ± 13.7	68.9 ± 10.4	60.5 ± 15.7
Median	64.5	70.0	62.0
Minimum-Maximum	37 - 86	53 - 81	37 - 86

Table 2: Physical Exam Findings

Subject Characteristics	All Subjects (n=20)	No Procedure (n=10)	Procedure (n=10)
Weight (lb)			
Mean ± Standard Deviation	206.7 ± 60.0	222.0 ± 65.8	191.4 ± 52.3
Median	207.5	221.0	195.0
Minimum-Maximum	112 - 356	140 - 356	112 - 272
Height (in)			
Mean ± Standard Deviation	67.4 ± 3.4	67.6 ± 3.2	67.2 ± 3.8
Median	68.0	68.0	67.3
Minimum-Maximum	59 – 72	63 – 72	59 – 72
LVEF (%)			
Mean ± Standard Deviation	28.2 ± 8.1	27.6 ± 6.7	28.7 ± 9.6
Median	28.0	25.5	30.0
Minimum-Maximum	15 – 45	15 – 40	15 – 45

OUTCOME MEASURES

1.1. Results and Tabulations of Individual Subject Data

In total, 20 patients were enrolled in the study at one center. 10 subjects under the control group and 10 subjects under the procedure group.

1.1.1. Primary objective

The average and median number of paced beats after ultrasonic pacing stimuli were delivered to at least one pacing location were 81.2 and 79, respectively. A successful pacing outcome of at least three consecutive paced beats was observed in 7 of the 10 procedure subjects. The following table lists the total number of paced beats for each subject in the procedure group.

Table 3: Number of paced beats for each Procedure cohort subject

Subject ID	Total number of paced beats	Successful pacing outcome of 3 consecutive paced beats
M1003300001	73	NO
M1003300005	109	YES
M1003300006	149	YES
M1003300007	19	YES
M1003300008	155	YES
M1003300009	79	YES
M1003300010	123	YES
M1003300011	13	NO
M1003300012	13	NO
M1003300015	79	YES

1.1.2. Secondary objective: Cardiac Resynchronization Feasibility

A successful resynchronization outcome, defined by an improvement in QRS or ED index immediately after an ultrasound pacing stimulus was delivered to at least one pacing location for at least one AV delay, was observed in 7 of the 7 procedure subjects who demonstrated a successful pacing outcome as defined in 1.2.1. The following table lists the improvement in QRS and SDAT after an ultrasound pacing stimulus was delivered for each subject who met a successful pacing outcome.

Table 4: Improvement in QRS width and SDAT value (ED index) at one pacing location at one AV delay for each Procedure cohort subject who met a successful pacing outcome

Subject ID	QRS at baseline	SDAT at baseline	AV delay during ultrasound pacing stimulus	QRS after ultrasound pacing stimulus	SDAT after ultrasound pacing stimulus	% change QRS	% change in SDAT	Successful resynchronization
M1003300005	170 ms	42.2	130 ms	130 ms	35.0	-24%	-18%	YES
M1003300006	165 ms	47.5	90 ms	145 ms	32.0	-12%	-33%	YES
M1003300007	170 ms	48.0	130 ms	115 ms	25.4	-32%	-47%	YES
M1003300008	130 ms	39.4	110 ms	110 ms	31.5	-15%	-20%	YES
M1003300009	115 ms	31.2	90 ms	85 ms	25.1	-26%	-20%	YES
M1003300010	135 ms	36.3	160 ms	120 ms	18.2	-11%	-50%	YES
M1003300015	150 ms	27.4	90 ms	120 ms	20.67	-20%	-25%	YES

1.1.3. Secondary objective: Characterization of Troponin I Level

Table 16 lists the troponin values at baseline (1st measurement), and at follow-up 4 to 8 hours after baseline (2nd measurement) and 24 to 48 hours after baseline (3rd measurement). There was no difference between the procedure and control groups for the change in troponin over time: '2nd measurement-baseline', '3rd measurement-baseline' or 'peak-baseline troponin values' (P-value = 0.373, 0.843 and 0.509, respectively) (Table 17).

Table 5: Troponin Summary

Group	1st Measurement	2nd Measurement	3rd Measurement
No procedure (n=10)			
Mean (SD)	0.065 (0.125)	0.338 (0.335)	0.264 (0.148)
Median (IQR)	0.020 (0.020-0.030)	0.155 (0.120-0.420)	0.230 (0.150-0.380)
Range	0.020-0.420	0.090-1.120	0.090-0.500
Procedure (n=10)			
Mean (SD)	0.032 (0.024)	0.196 (0.111)	0.218 (0.167)
Median (IQR)	0.020 (0.020-0.030)	0.160 (0.130-0.250)	0.150 (0.090-0.320)
Range	0.020-0.090	0.030-0.390	0.060-0.580

Table 6: Difference from Baseline Comparisons

Group	2nd Measurement-1st Measurement	3rd Measurement-1st Measurement	Peak measurement-1st Measurement
No procedure (n=10)			
Mean (SD)	0.273 (0.351)	0.199 (0.134)	0.324 (0.326)
Median (IQR)	0.120 (0.060-0.400)	0.160 (0.080-0.300)	0.200 (0.120-0.400)
Range			

	0.000-1.100	0.050-0.440	0.060-1.100
Procedure (n=10)			
Mean (SD)	0.164 (0.121)	0.186 (0.154)	0.248 (0.135)
Median (IQR)	0.140 (0.070-0.230)	0.130 (0.070-0.300)	0.225 (0.130-0.320)
Range	0.010-0.370	0.040-0.520	0.060-0.520
P-value (t-test)	0.373	0.843	0.509

Adverse Events

There were no reported adverse events associated with this trial.