A NOVEL ENTIRELY EXTRACARDIAC TEMPORARY PACING SYSTEM WITHOUT POST-PROCEDURAL BEDREST RESTRICTIONS

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ABSTRACT

Background

Patient immobilization imposed with temporary intracardiac pacing can result in clinical complications and economic burden. A completely extracardiac temporary pacing lead may provide an alternative pacing modality that does not require patient immobilization or bed rest restrictions.

Objective

The purpose of this study was to evaluate the effects of posture and in-hospital ambulation tests during temporary pacing with a novel, completely extracardiac lead.

Methods

In this prospective single-center study, patients who underwent a permanent pacemaker implant or replacement were simultaneously implanted with the extracardiac temporary pacing system. The effects of posture (i.e. supine, left/right lateral decubitus and upright) on electrical performance and appropriate pacing/sensing during in-hospital ambulation tests were evaluated 1- and 2-days post-implant.

Results

Eleven patients (64% male, 67.7 ± 9.4 years, BMI 25.9 ± 3.5 kg/m2) were successfully implanted with cardiac capture on Day 0. Cardiac capture was possible in all postures in 10 out of 11 patients on Day 1 and Day 2. Failure to capture occurred in one patient due to presumed lead dislodgement. Changes in posture did not affect mean pacing thresholds by more than 1.6 V on Day 1 and 1.9 V on Day 2. Appropriate sensing and pacing were also observed during in-hospital activity in all patients undergoing ambulation tests.

Conclusions

Temporary pacing performance using a completely extracardiac lead was minimally impacted by post-procedural posture changes and in-hospital ambulation. These results suggest that bedrest restrictions and patient immobilization may not be necessary with an extracardiac pacing lead.

Disclosures: **W. van der Stuijt**: None **A.F. Quast**: None. **N.E.G. Beurskens**: None. **M.C. Burke**: Boston Scientific Corp., AtaCor Medical, Inc., Medtronic, Inc., St. Jude Medical. **A. Ebner**: None. **M. Husby**: AtaCor Medical, Inc. **A. Marcovecchio**: AtaCor Medical, Inc. **R. Sanghera**: AtaCor Medical, Inc. **R.E. Knops**: Boston Scientific Corp., Medtronic, Inc., St. Jude Medical.

INTRODUCTION

Patient immobilization associated with temporary intracardiac pacing can result in clinical complications and economic burden. The AtaCor EV Temporary Pacing System (AtaCor Medical, San Clemente, CA) is a completely extracardiac temporary pacing system that provides potential clinical advantages over existing temporary pacing alternatives that require intravascular, endocardial or epicardial contact. Included in these potential clinical advantages are the avoidance of risk historically associated with temporary pacing (systemic infection, thrombo-embolism, cardiac perforation, pericardial effusion and tamponade) and, importantly, the elimination of bedrest restrictions while the temporary lead is inserted.

The Subcostal Temporary Extracardiac Pacing (STEP) Study (n=12) represents the first human data collected with development versions of the AtaCor Medical custom extracardiac temporary pacing lead ("StealthTrac Lead") and delivery tool ("MACH I Delivery Tool").

METHODS

Subjects undergoing a standard-of-care procedure provided written informed consent in order to participate in the study. All subjects were required to have a market-released pacing lead (e.g., transvenous) to provide clinically necessary temporary pacing during a clinically necessary procedure. Following the procedure, subjects were not restricted to bedrest while the StealthTrac Lead remained implanted.

As shown in **Figure 1**, the extracardiac lead was placed with a custom delivery tool inserted through an intercostal space near the sternal margin, accessed through a 2-3 cm skin incision. Once the delivery tool tips were advanced through the intercostal muscle into the anterior mediastinum, the extracardiac lead was advanced into position by squeezing the delivery tool actuator and the delivery tool was subsequently removed.

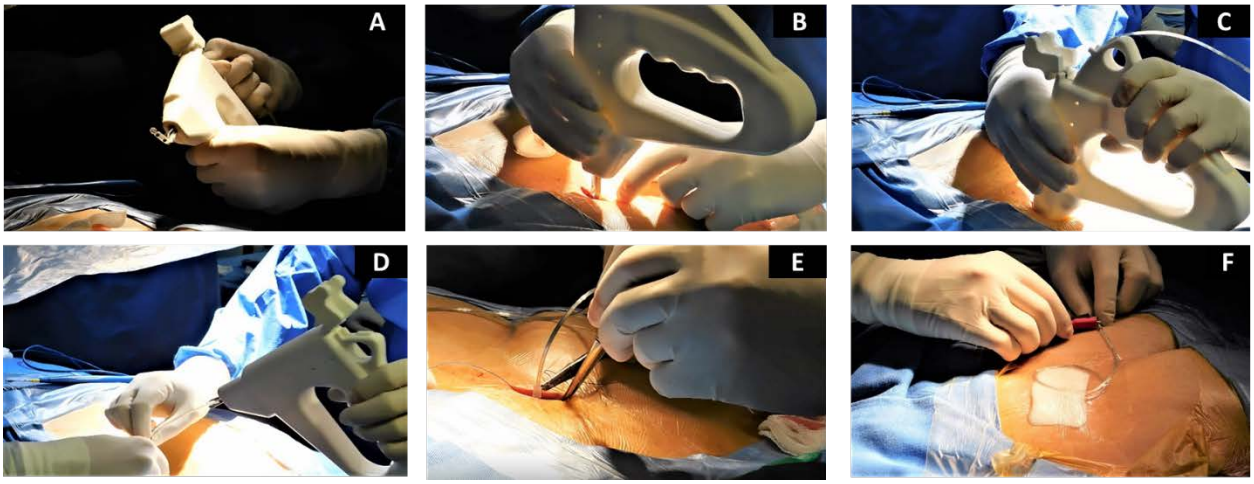

FIGURE 1: ***(A)*** *Loading the StealthTrac Lead into the Mach I Delivery Tool (AtaCor Medical, San Clemente, CA);* ***(B)*** *The Mach I Delivery Tool tips inserted through a 2-3 cm skin incision;* ***(C)*** *The Mach I Delivery Tool tips inserted through the intercostal muscle to access the mediastinal space;* ***(D)*** *Removal of the MACH I Delivery Tool over the proximal end of the StealthTrac Lead;* ***(E)*** *Fixation of the StealthTrac Lead with a suture sleeve;* ***(F)*** *Connection between the terminal pin of the StealthTrac Lead to an external pacing system analyzer.*

The extracardiac pacing lead was tested by connecting a pacing system analyzer or temporary pacemaker to the electrical contacts on the proximal end of the lead. Leads were fixed in place using a suture sleeve and suture materials. Following fixation, fluoroscopic imaging was performed to verify the position of the distal end of the pacing lead within the extracardiac tissue in the region of the cardiac notch of the left lung near the pericardium.

One (1) day and two (2) days after the procedure, pacing capture thresholds, pacing impedance and R-wave amplitudes were assessed in multiple postures. Additionally, Holter ECG recordings were obtained during periods of pacing and sensing with the StealthTrac Lead (See **Figures 2 and 3)**.

FIGURE 2: *A STEP Study subject performing a short walk during periods of extracardiac pacing and sensing with the StealthTrac Lead*

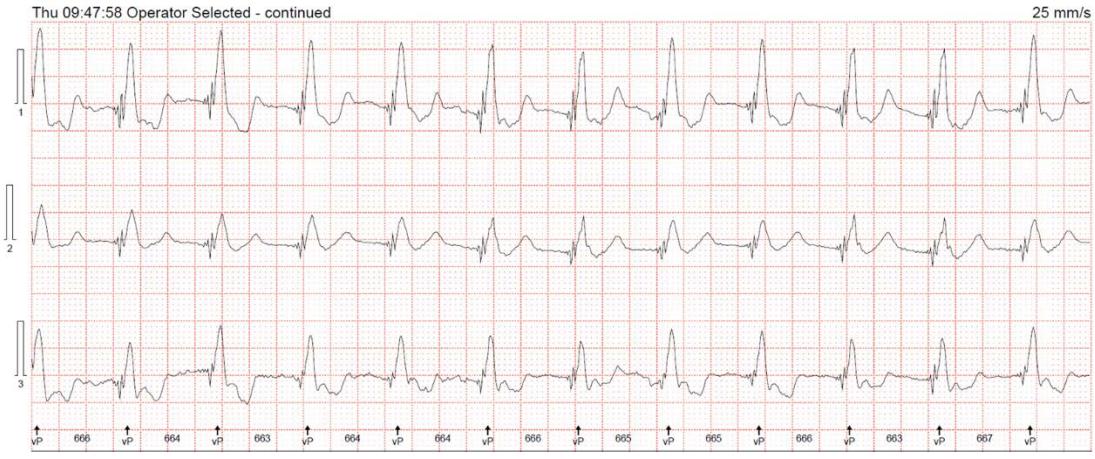

FIGURE 3*: Example Holter ECG recording made during extracardiac pacing with the StealthTrac Lead during a short walk*

Paced beats and sensing intervals from the Holter ECG recordings were scored for pacing capture and appropriate sensing by the StealthTrac Lead.

RESULTS

Twelve (12) subjects were enrolled at Sanatorio Italiano in Asuncion, Paraguay (Adrian Ebner, MD, Principal Investigator) and inserted with the StealthTrac Lead on 27-Aug-2019 and 08-Oct-2019.

Eleven (11) subjects underwent a successful procedure to place a market-released transvenous pacing lead. One (1) subject was withdrawn due to pericardial tamponade caused by the market-released transvenous lead, which precluded any attempt to insert the StealthTrac Lead.

On Day 1 post insertion, a single subject experienced an apparent extracardiac lead dislodgement, precluding further testing. Baseline demographic characteristics of the study subjects are summarized in **Table 1**.

TABLE 1: *Demographic Characteristics*

VARIABLE	N (%) OR MEAN (SD)	RANGE (MIN, MAX)
Age (years)	67.7 (9.4)	49, 82
Female Gender	4 (36%)	.
Height (cm)	165.0 (8.8)	156, 187
Weight (kg)	69.5 (9.6)	56, 86
BMI (kg/m2)	25.9 (3.5)	21.3, 31.9

The effect of posture (supine, left/right lateral decubitus and upright) on electrical performance measurements was evaluated 1- and 2-days post-implant. Cardiac capture in all postures was possible in all subjects except for Subject 06, who exhibited failure to capture (1) day post-implant due to the previously described presumed lead dislodgment. Mean pacing capture thresholds by posture are shown below in **Table 2**.

TABLE 2*: Pacing Capture Thresholds by Posture*

	PACING CAPTURE THRESHOLD (MEAN ± SD)			
	LEFT	RIGHT	SUPINE	UPRIGHT
Day 1	5.8 ±1.0 [4.6, 7.4]	7.2 ±3.3 [4.2, 13.5]	5.6 ±2.7 [3.6, 12.6]	6.6 ±2.4 [3.8, 10.4]
Day 2	5.8 ±1.2 [3.3, 7.1]	7.2 ±2.8 [4.2, 12.6]	7.0 ±2.6 [4.1, 13.4]	7.7 ±2.9 [3.2, 11.3]

Holter ECGs recorded during periods of pacing and sensing with the StealthTrac Lead showed a high degree of appropriate pacing capture (97.8%) and sensing (98.9%) across subjects (Figure 4).

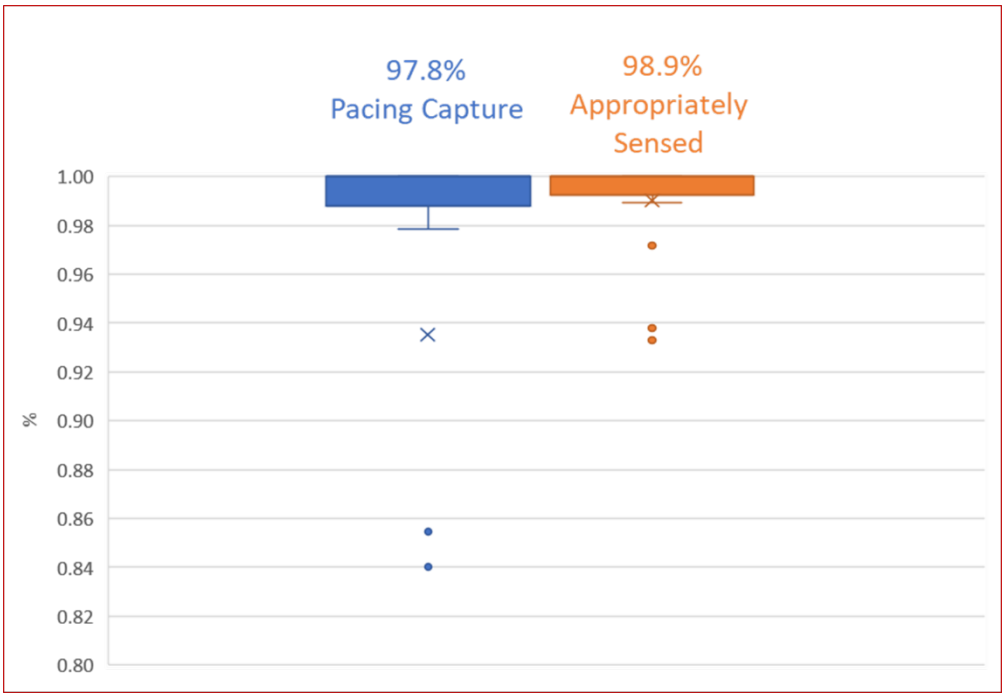

***FIGURE 4**: Proportion of appropriately captured paced events and proportion of intervals that demonstrated appropriate sensing*

CONCLUSION

These initial results confirm that development versions of the StealthTrac Lead can provide consistent pacing and sensing without fixation to the heart. The StealthTrac Lead provided consistent capture and sensing in all but a single case, where a suspected lead dislodgement prevented capture.

Notably, appropriate sensing and pacing were demonstrated during protocol-guided walks over two (2) days during which time subjects had no bedrest restrictions. There were no adverse events related to posture testing or activities performed during Holter recordings.

Learnings from this pilot study are being used to guide improvements in extracardiac lead electrical performance through iterative device designs, new accessories and improved instructions for use.

The STEP Study underscores the potential of the AtaCor EV Temporary Pacing System, which provides a completely extravascular/extracardiac approach to rapid initiation of temporary pacing without bed rest restrictions.