SAFETY ANALYSIS OF A NOVEL ENTIRELY EXTRACARDIAC TEMPORARY PACING SYSTEM: RESULTS OF A PILOT STUDY

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ABSTRACT

Background

Recently, a temporary extracardiac pacing system has been developed. This system uses a uniquely designed lead and delivery tool to place a pair of electrodes within the anterior mediastinum through an intercostal space. This may provide clinical advantages over existing devices that require intravascular, endocardial or epicardial contact.

Objective

In this pilot study, we aimed to evaluate the initial safety of this extracardiac pacing system.

Methods

Patients who underwent a permanent pacemaker implant or replacement simultaneously received a temporary extracardiac pacing system. Implants were performed on two separate dates on 6 and 5 subjects, facilitating learning curve analyses. Safety was evaluated by analyzing all adverse device effects (ADE) through 30 days post-removal.

Results

The extracardiac pacing system was successfully inserted in all 11 attempted patients (64% male, age 67.7 ± 9.4 years, BMI 25.9 ± 3.5 kg/m^2). First attempt success rate improved from 17% to 60% between the two implant dates. Similarly, the mean time from first incision to pacing improved from 15.8 to 9.2 min. One patient experienced failure to capture and discomfort one day post-implant, possibly related to lead dislodgement. Another patient experienced pacing-induced discomfort starting one day post-implant. The lead was successfully removed from all 11 patients without ADE through 30 days post-removal.

Conclusions

These results confirm that an entirely extracardiac pacing system can be safely used to provide temporary pacing. ADEs were limited to a potential lead dislodgement and discomfort. Results from this pilot study will guide further improvements that can be validated in subsequent studies.

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

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 risks historically associated with temporary pacing (systemic infection, thrombo-embolism, cardiac perforation, pericardial effusion and tamponade) and the elimination of bedrest restrictions while the temporary lead is inserted.

The AtaCor EV Temporary Pacing System provides temporary pacing from a lead placed in the anterior mediastinum. As shown in Figure 1, the lead is placed with a custom delivery tool that is inserted through an intercostal space near the sternal margin, which is accessed through a 2-3 cm skin incision. The delivery tool tip is advanced through the intercostal muscle into the anterior mediastinum. Squeezing the delivery tool lever advances the lead into position. The delivery tool is then removed, leaving the extracardiac lead in place.

The distal end of the pacing lead contains two electrodes that reside in the extracardiac tissue in the region of the cardiac notch of the left lung near the pericardium. The proximal end of the pacing lead, contains electrical contacts that allow for connection to a pacing system analyzer or temporary pacemaker.

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").

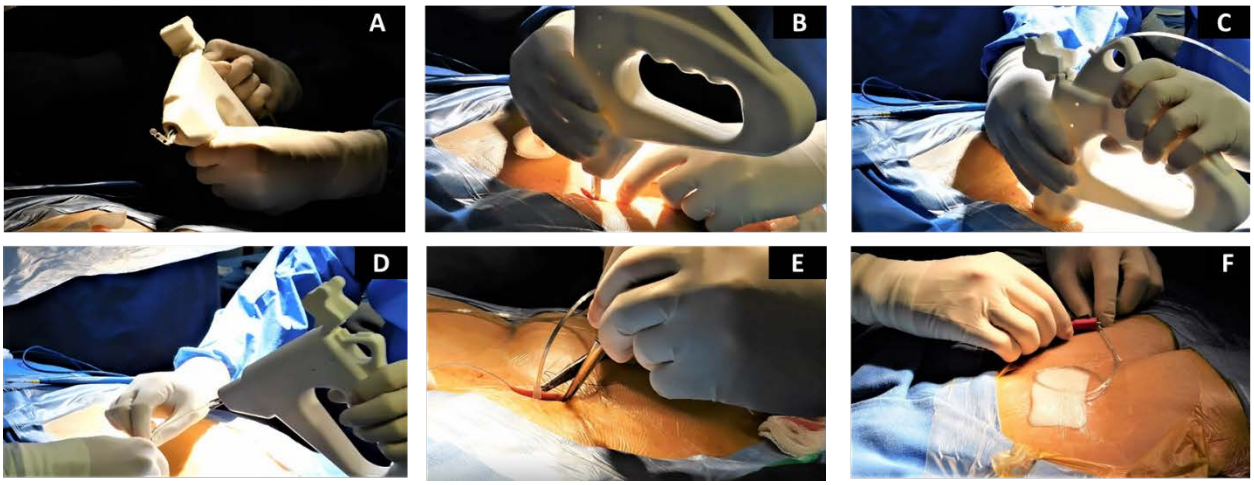

FIGURE 1: ***(A)*** *Loading the StealthTrac Lead into the Mach I Delivery Tool (AtaCor Medical, San Clemente, CA);* ***(B)*** *The Mach I Delivery Tool tips inserted through a 2-3 cm skin incision;* ***(C)*** *The Mach I Delivery Tool tips inserted through the intercostal muscle to access the mediastinal 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.*

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. Protocol testing performed during the study is summarized below in Figure 2.

Safety was evaluated through an analysis of all Clinical Events throughout the study period, including a 30-day post-removal follow-up, which was intended to identify any latent events. A final follow-up was performed 25-30 days after removal to identify any latent adverse events before the subject exits the study.

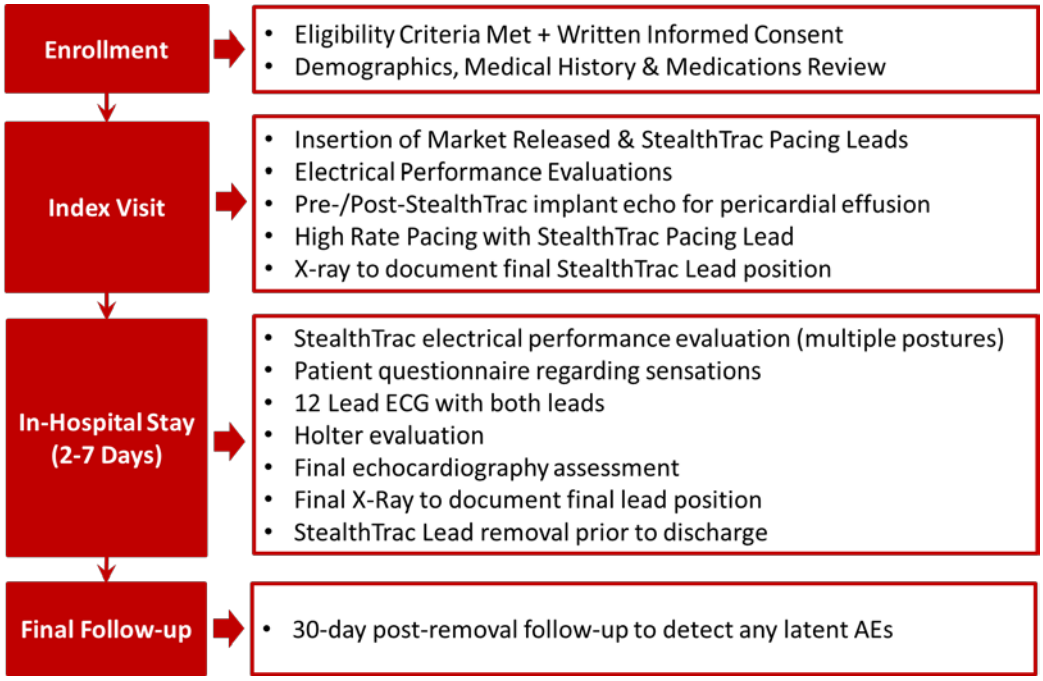

FIGURE 2: *Subcostal Temporary Extracardiac Pacing (STEP) Study design*

RESULTS

Twelve (12) subjects were enrolled and followed at Sanatorio Italiano in Asuncion, Paraguay (Adrian Ebner, MD, Principal Investigator) from 26-Aug-2019 to 07-Nov-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. One (1) additional subject experienced a dislodgement of the market-released transvenous lead following placement of the lead and pocket closure. The market-released transvenous pacing lead was revised and the subject remained in the study. 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 StealthTrac Lead was successfully inserted using the MACH I Delivery Tool in all eleven (11) Subjects under conscious sedation. There were no pericardial effusions caused by the StealthTrac Lead, as confirmed by echocardiography.

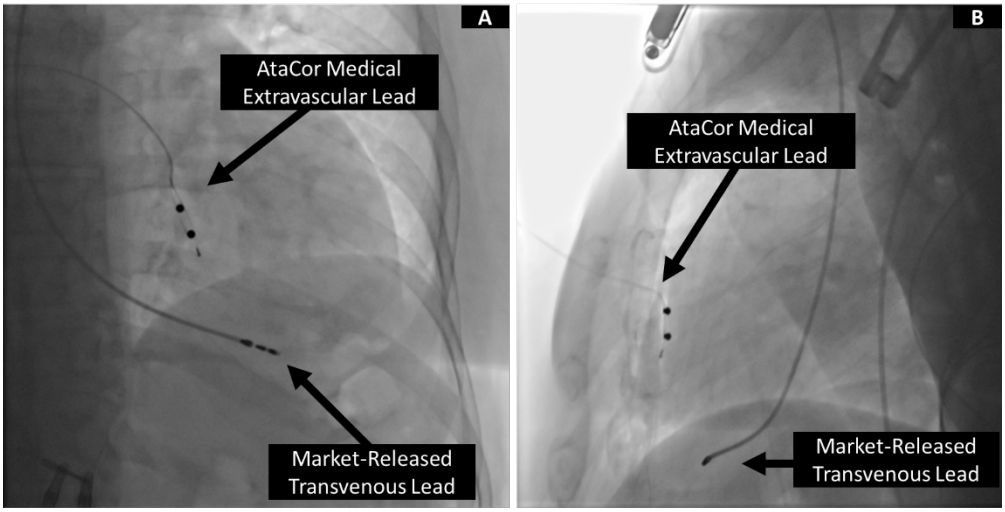

FIGURE 3: *Example lead position images in AP (A) and lateral (B) orientations*

Improvements in first attempt success, insertion success within 2 attempts and time from incision to pacing were noted between the first six (6) insertions performed on 27-Aug-2019 and the last five (5) procedures performed on 08-Oct-2019, where improved techniques were implemented relating to the choice of rib space, consistent use of a vertical incision and lead deployment direction

Table 2: *Insertion procedure metrics*

	27-AUG-2019 PROCEDURES (N = 6)	8-OCT-2019 PROCEDURES (N = 5)
First Attempt Success, N (%)	1 (17%)	3 (60%)
Insertion Success within 2 Attempts, N (%)	2 (33%)	5 (100%)
Time to Pacing (minutes), Mean [min, max]	15.8, [6, 46]	9.2, [4, 18]

All eleven (11) subjects underwent study follow-ups one (1) and two (2) days following StealthTrac Lead insertion. There were no adverse events related to the placement of subjects in different postures for electrical performance measurements or related to short walks with the StealthTrac Lead active (pacing and sensing).

To summarize the safety observations, two (2) Subjects experienced three (3) non-serious Adverse Events related to the AtaCor Temporary Pacing System:

- One subject experienced a suspected lead dislodgement on the day following lead insertion, which resulted in the inability to capture and pain while attempting to obtain capture;
- One subject experienced pain while pacing in some postures using an increased output voltage in response to elevated thresholds.

Additionally, two (2) subjects experienced one (1) serious and one (1) non-serious Adverse Event related to the market-released pacemaker system.

- One subject experienced a dislodgement of the market-released transvenous lead following placement of the lead and pocket closure;
- One subject experienced pericardial tamponade. Following discovery of the tamponade on fluoroscopic imaging, pericardiocentesis was performed, followed by monitoring in the ICU. The subject was withdrawn from the study and discharged the following day.

CONCLUSION

The STEP Study represents the first human use of development versions of the StealthTrac Lead and MACH I Delivery Tool, custom devices intended to provide extravascular/extracardiac temporary pacing when connected to an external pacemaker.

These results confirm that the StealthTrac Lead can be safely inserted within the anterior mediastinum using the MACH I Delivery Tool in patients under conscious sedation. The StealthTrac Lead provides temporary pacing without bedrest restrictions. Additionally, the StealthTrac Lead can be safety removed using local anesthetic.

Results from this study will be used to guide improvements to the device design, instructions for use, and the design of subsequent clinical investigations of the AtaCor Temporary Pacing System. The STEP Study underscores the clinical potential of the AtaCor EV Temporary Pacing System, which provides a completely extravascular/extracardiac approach to rapid initiation of temporary pacing without intraprocedural fluoroscopy or bed rest restrictions.