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ORIGINAL ARTICLE

Feasibility of an Entirely Extracardiac, Minimally Invasive,Temporary Pacing System

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BACKGROUND: A completely extracardiac pacing system provides the potential for clinical advantages over existing device alternatives that require intravascular, endocardial, or epicardial contact. Preliminary studies evaluating the feasibility of cardiac pacing with a lead in the anterior mediastinum, outside the pericardium and circulatory system have been completed. These studies examined (1) the anatomic access route, (2) the usability of a delivery tool to facilitate lead placement, and (3) the pacing performance of the extracardiac lead.

METHODS: Feasibility evaluations included (1) a retrospective computed tomography analysis to characterize anatomic variations related to lead access, (2) accessing the anterior mediastinum in cadavers and human subjects using a custom delivery tool, and (3) acute clinical pacing performance.

RESULTS: Major findings: (1) A total of 166 (95%) out of 174 patients had a viable lead access path through the fourth, fifth, or sixth intercostal space. (2) Access to the targeted implant location using a delivery tool was successful in all 5 cadavers and 3 humans without use of fluoroscopy and with an average lead delivery time of 121±52 s. No damage to the lung, pericardium, heart, or internal thoracic vessels occurred. (3) Pacing performance was tested in 6 human subjects showing a threshold voltage of 4.7 V (2.7–6.7), threshold pulse width of 1.8 ms (1.0–2.5), and an impedance of 1205 Ω (894–1786). R-wave amplitudes measured 9.6 mV (5.6–12.0).

CONCLUSIONS: Results support the feasibility for this completely extracardiac pacing method in a heterogeneous patient population, using a minimally invasive, parasternal, delivery approach and with adequate sensing and thresholds suited for temporary pacing.

VISUAL OVERVIEW: A visual overview is available for this article.

*Drs Quast and Beurskens are joint first authors

Key Words: bradycardia ■ cadaver ■ extra-cardiac pacing ■ pacemaker ■ pericardium ■ temporary pacing

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WHAT IS KNOWN?

- The current standard of care for extracardiac pacing uses cutaneous electrodes at energies that cause severe discomfort due to skeletal muscle stimulation.
- Temporary intracardiac pacing is limited by the need for fluoroscopy for placement and poor ambulation due to complication risks.
- Minimally invasive cardiac interventions are increasing the need for subacute pacing solutions that reduce risk.

WHAT THE STUDY ADDS?

- Establishes the feasibility of a completely extracardiac pacing lead to provide temporary bradycardia pacing without skeletal muscle stimulation.
- Introduces the concept that an application-specific delivery tool can deliver and pace an extracardiac lead without fluoroscopic guidance or clinical adverse event.
- In-depth analysis of thoracic computed tomography images supports the anatomic feasibility of this concept in a broad patient population.

Permanent transvenous pacemaker systems involve the placement of ≥1 leads in or on the heart, which are connected to an implantable pulse generator. Although these systems provide an important life-sustaining therapy for patients with bradycardia, they are not without risk. Lead and pocket issues result in relevant complication rates in conventional pacemaker recipients.[1] Recently, leadless pacemaker therapy has been introduced as a therapeutic alternative to avoid these well-known complications of conventional pacemaker therapy.[2,3] Despite promising results, important challenges remain with leadless pacemaker therapy, such as the optimal end-of-life strategy and the occurrence of life-threatening cardiac perforations.[4,5]

Temporary transvenous cardiac pacing therapy is widely used to correct compromising or life-threatening arrhythmias in acute settings. Yet, complications are common in patients treated with transvenous temporary pacing and have remained high since its introduction 6 decades ago.[6–8]

A novel, completely extracardiac pacing system is being developed that can deliver bradycardia pacing therapy while avoiding risks and complications associated with pacing systems that require intravascular, endocardial, or epicardial contact. Such an extracardiac pacing system (Atacor Medical, Inc, San Clemente, CA [AtaCor]) includes a lead within the anterior mediastinum through an intercostal space (ICS) over the cardiac notch of the left lung, using a custom developed delivery tool, which can be attached to an external or permanent pulse generator system (Figure 1). This novel approach has the potential to become a viable pacing option in challenging clinical situations, such as acute temporary pacing, device infection, children, congenital heart disease, and venous obstruction. This approach may also provide a favorable alternative for patients in whom transient or permanent pacing needs develop as a result of other interventions (eg, transcatheter aortic valve replacement) or emergent cardiovascular circumstances where time is essential and fluoroscopy is not.

This article compiles several preliminary studies demonstrating the conceptual foundation and feasibility of an innovative and radically different cardiac pacing concept and is presented in 3 sections: (1) a computed tomography (CT) evaluation of the anterior mediastinum and its parasternal access through the ICS in a large heterogeneous patient population to characterize potential candidates, (2) an evaluation of the ability to gain access and deploy a substernal lead using the delivery tool in a cadaver model and human subjects, and (3) cardiac pacing performance in the anterior mediastinum in humans.

METHODS

To evaluate feasibility of extracardiac pacing in the anterior mediastinum, 3 separate studies were performed, each designed to assess specific aspects of this novel pacing approach and system. First, parasternal access to the anterior mediastinum was analyzed in a retrospective CT study. Second, performance of the delivery tool was evaluated using both a cadaver model and human subjects. Finally, ventricular pacing capture, R-wave sensing, and muscle stimulation were tested in an acute human study. Because of the sensitive nature of the data collected for this study, requests to access the dataset from qualified researchers trained in human subject confidentiality protocols may be sent to AtaCor Medical, Inc at alan@atacor.com.

The intended implant technique of the final system envisions placement of a pacing lead through an ICS, near the left sternal margin, over the cardiac notch of the left lung (Figure 1). The distal end of the lead is equipped with a pair of closely spaced electrodes that are noncircumferential and oriented towards the heart, a design feature intended to minimize the potential for intercostal skeletal muscle stimulation. The distal end of the lead is designed to reside within the connective tissue between the posterior surface of the anterior chest wall and the pericardium. Leads will be designed for removal by direct, manual retraction force, that is, pulling the lead, similar to the method used for current subcutaneous implantable cardioverter-defibrillator (ICD) leads.

Anatomic Evaluation of the Human Anterior Mediastinum

This study was designed as a retrospective CT analysis to characterize the substernal space within the anterior mediastinum in 4 specific patient populations, namely a broad population of control patients (arm A), patients with

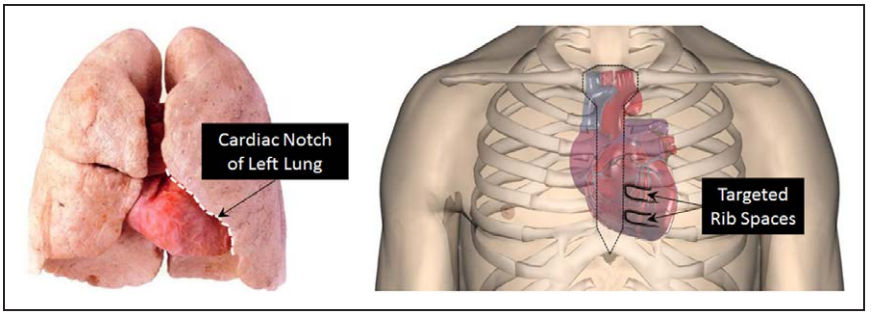

Figure 1. Anatomical considerations for extracardiac lead placement.
Left, Cardiac notch of the left lung provides left parasternal access into the anterior mediastinum towards the heart without lung obstruction. **Right**, Targeted rib spaces for lead insertion over the cardiac notch of the left lung.

pulmonary disease (arm B), patients with congenital heart disease (arm C), and patients with an implanted transvenous pacemaker or ICD system (arm D). Specifically, the substernal space of interest is defined as the portion of the anterior mediastinum between the intercostal muscle/sternum and the outer surface of the pericardium (Figure 2). Rib numbers were identified on sagittal CT views to visualize the fourth, fifth, and sixth left ICS. The path through the ICS near the left sternal margin was assessed for obstruction by the left lung. Additional CT measurements and analysis were performed to characterize the anatomy within, and adjacent to, the anterior mediastinum where the substernal pacing lead is planned to be implanted (Data Supplement).

Evaluation of the Custom Lead Delivery Tool

This analysis was designed to evaluate the ability to access the anterior mediastinum using prototype lead delivery tools (Figure 3). Initially, 3 cadavers and 3 human subjects were tested with a first-generation delivery tool prototype (Figure 3, left). Subsequently, 2 more cadavers were tested with a second-generation custom delivery tool (Figure 3 right). X-rays and CT imaging of the later unpreserved cadavers were acquired 2 days before the implant procedures and were analyzed according to the above-described methods in the CT study. Each use of the delivery tool and all implants were performed by a practicing clinical electrophysiologist. Postprocedure dissections were performed on the cadaver subjects to characterize any anatomic damage that may have resulted from the implant procedure. Additionally, the first-generation delivery tool was evaluated for safety in live subjects undergoing valve or septal defect open heart surgery. In that clinical evaluation, the custom delivery tool was used to access the anterior mediastinum before performing the median sternotomy for the patients' surgical index procedure. Damage to adjacent mediastinal tissue was also assessed poststernotomy.

Figure 2. Sagittal computed tomography view with targeted location, the anterior mediastinum within the cardiac notch, for pacing.

Study Devices

The first- and second-generation delivery tools are both equipped with a pair of blunt, separating access tips which are used to access the anterior mediastinum. The delivery tools are intended to be directed along the surface of the sternum from the midline to the left sternal margin until they are pushed into the anterior mediastinum adjacent to the sternal margin via the target rib space. The access tips are then separated using a built-in lever, creating an access channel within which a substernal lead is inserted. The delivery tools are then removed, leaving the substernal lead in place (Figure 4). Detailed description of the delivery tools is provided in the Data Supplement.

Study Procedure

The delivery tool is intended to be positioned using anatomic landmarks, without the need for fluoroscopic guidance to locate a suitable entry point into the anterior mediastinum. Once access is gained, the delivery tool is used to deploy a preloaded substernal lead into position.

Human Feasibility Study for Anterior Mediastinum Cardiac Pacing

This study was designed to evaluate cardiac pacing thresholds while pacing intraoperatively using a substernal lead. In addition, the study was designed to characterize the degree of skeletal muscle stimulation while pacing over a range of voltage and pulse widths outputs with a substernal lead. A 3-axis accelerometer was placed within a sterile sleeve and adhered to the surface of the anterior chest wall. The accelerometer was sufficiently sensitive to detect mechanical deflections

Figure 3. First (left) and second (right) generation delivery tools to facilitate lead placement into the anterior mediastinum.

resulting from intrinsic cardiac contractions, a phenomenon that could be visually observed in the accelerometer signals recorded during baseline intrinsic activity. Transcutaneous pacing was then delivered as it is a pacing modality known to elicit substantial skeletal muscle stimulation. Accelerometer signals recorded during transcutaneous pacing clearly demonstrated the skeletal muscle contractions on all 3 accelerometer axis signals coincident with delivery of transcutaneous pacing stimuli. To demonstrate concept feasibility, noncircumferential electrodes from commercially available pacing leads were utilized. Two separate leads were equipped with 1 electrode positioned at the distal end of each lead so that they may be oriented towards the heart. Electrodes were placed in close proximity to each other to facilitate bipolar pacing and sensing. Leads were either manually manipulated with the assistance of a sterile L-shaped bracket or positioned through an early prototype of a custom delivery tool. The study was approved by a reviewing ethics committee for the investigational site. Eligible subjects providing written informed consent were enrolled in the study. All protocol testing occurred intraoperatively. No chronic follow-up visits were required other than to identify any latent clinically adverse events that may have occurred after hospital discharge before study exit. For safety purposes, all clinically adverse events were required to be reported. From an effectiveness perspective, targeted ICS were identified via palpation and confirmed with fluoroscopy. Baseline data, consisting of ECG and 3-axis accelerometer signals were recorded before the delivery of any pacing. Signals were collected while delivering 200 mA transcutaneous pacing across the thorax, a control and standard of care known to elicit substantial skeletal muscle stimulation. Substernal leads were placed via (1) a sternal opening, poststernotomy under the targeted ICS or (2) directly through the intercostal muscles of the targeted ICS (Figure 5). Skeletal muscle stimulation tests were then repeated to characterize the degree of skeletal muscle stimulation that occurred in response to substernal compared with cutaneous pacing. Pacing was delivered between 2 hemispherical electrodes placed in the connective tissue between the sternum and pericardium and oriented towards the heart. Cardiac pacing thresholds were identified and pacing at the threshold voltages, 2× threshold voltage, and at 18 V was delivered to measure and record the degree of any concomitant skeletal muscle stimulation.

Statistical Analysis

Continuous variables were tested for normality. Values are presented as means with SDs or median with interquartile ranges. Dichotomous data are presented as proportions.

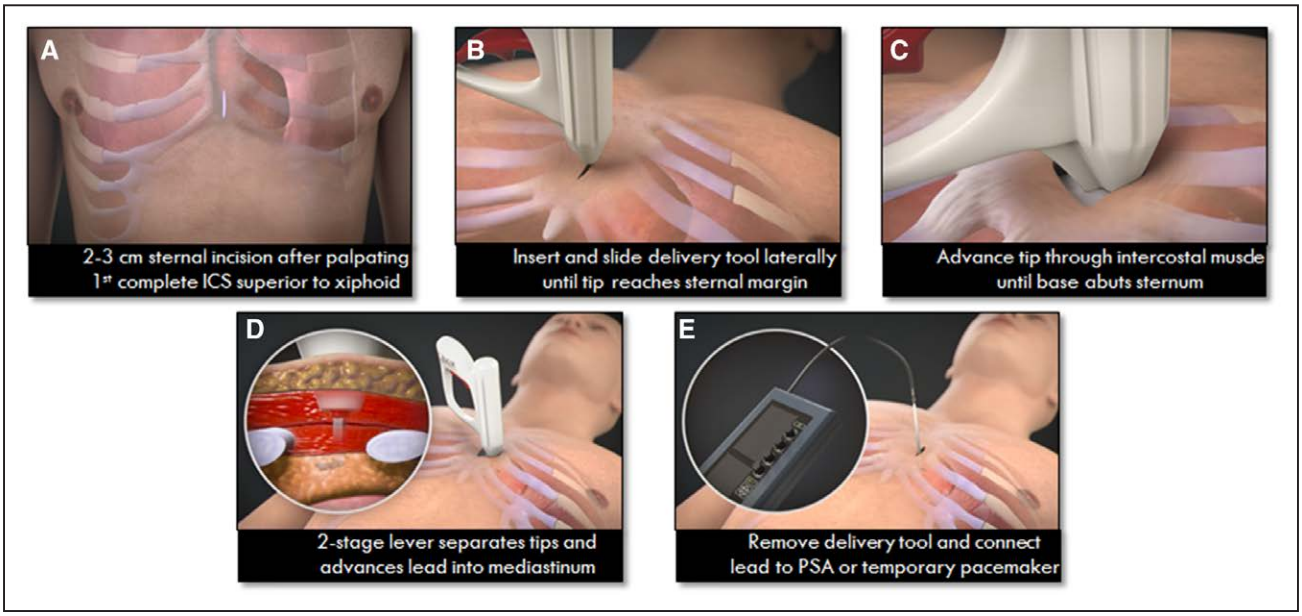

Figure 4. A, Access to the anterior mediastinum is gained over the cardiac notch of the left lung near the sternal margin through intercostal spaces (ICS) 4, 5, or 6.

B and **C**, The delivery tool is applied to the surface of the sternum through a 2–3 cm skin incision and then moved laterally to find the sternal margin. The delivery tooltip is then advanced through the intercostal muscle into the anterior mediastinum. **D**, Squeezing the delivery tool lever advances the substernal lead into position. **E**, The delivery tool is removed, leaving the substernal lead in place which can be attached to a temporary or permanent pacing system. PSA indicates pacing system analyzer.

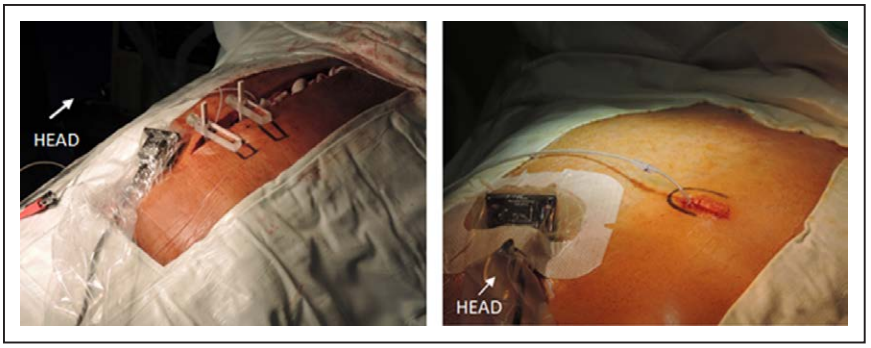

Figure 5. Subject with 2 substernal leads placed through a sternotomy opening (left) and a different subject (right) with 1 substernal lead placed using the delivery tool after identifying a targeted intercostal space via palpation (without fluoroscopy).

RESULTS

Anatomic Evaluation of the Human Anterior Mediastinum

A total of 174 patients were enrolled in the anatomy study. Arms A, B, and D each included 50 patients, and 35 patients were included in arm C. Eleven patients were patients with pacemaker devices and with a history of pulmonary disease; therefore, these patients were included both in arm B and D for analysis. Baseline characteristics are described in Table.

The results showed that the anterior mediastinum could be accessed in 166 (94%) of 174 subjects through at least 1 parasternal point of entry at the level of the fourth, fifth or sixth ICS, without contacting the left lung or internal thoracic vein/artery. Eight subjects with chronic obstructive pulmonary disease appeared to have a lung-obstructed path through all 3 of the evaluated ICSs; however, 84% of chronic obstructive pulmonary disease subjects had ≥1 viable paths through the fourth, fifth, or sixth ICS (Table). The distance between the posterior sternum and pericardium, which is highlighted in Figure 2, was measured in all subjects (Table). Additional measurements of the area of interest are reported in the Data Supplement.

Evaluation of the Custom Delivery Tools

First-generation delivery tool usage was evaluated in 3 cadavers, followed by 3 male clinical subjects, aged 19 to 61 years (body mass index, 23.2–27.6 m/kg^2), for safety, lead placement, and lead delivery time. Lead placement into the anterior mediastinum using the delivery tool without fluoroscopy was successful in all cadavers and subjects. Access to the anterior mediastinum was gained parasternally via the fourth, fifth, or sixth left ICS. There were no instances of damage to the lung, pericardium, heart, internal thoracic vessels, or other anatomic structures during postprocedural cadaver assessment, and there were no clinically adverse events related to the device or implant procedure. Lead tips were over the right ventricle in all cases and mean lead delivery time was 121±52 s, ranging from 42 s to 3 minutes and 38 s in the human subjects. Second-generation delivery tool usage was evaluated in 2 cadavers with successful access to the anterior mediastinum in both cases without the use of fluoroscopic guidance. There was no evidence of damage to the lung, pericardium, heart, internal thoracic vessels, or other anatomic structures.

Substernal Cardiac Pacing Results

Six males (19 to 68 years, body mass index, 23.2–34.9 kg/m^2) were evaluated during valve or septal defect sternotomy surgery. Cardiac capture with substernal leads placed in the anterior mediastinum was achieved in all subjects without any adverse events. The mean and range for threshold voltage, threshold pulse width, impedance, and current were 4.7 V (2.7–6.7), 1.8 ms (1.0–2.5), 1205 Ω (894–1786), and 4.4 mA (1.7–7.3). Mean and range for R-wave amplitudes were 9.6 (5.6–12.0 mV; Figure 6). Observations from accelerometer recordings and a concomitantly recorded ECG signal clearly demonstrated that there was no change in the morphology of any of the 3 accelerometer axis signals. This lack of change, independent of pacing with the evaluated lead, supports that pacing did not result in concomitant skeletal muscle stimulation. Skeletal muscle stimulation was clearly detected while delivering transcutaneous pacing. While delivering substernal pacing, no skeletal muscle stimulation was measured over the entire range of electrical outputs (Figure 7). Additionally, palpation of the thorax confirmed the absence of skeletal muscle stimulation while pacing via the substernal leads. In the current studies, which were all acute studies, lead removal was performed with direct retraction without any damage to surrounding tissue.

DISCUSSION

Major Findings

This collection of feasibility studies describes a novel pacing system that provides cardiac pacing without entering the vascular or pericardial space. Analysis of

Table. Baseline Characteristics and Results of CT Anatomy Study

	Arm A (n=50)	Arm B (Lung; n=50)	Arm C (CHD; n=35)	Arm D (DEVICE; n=50)
Baseline characteristics				
Age, y	65.6±11.1	70.7±7.5	40.5±13.6	74.7±7.5
Male, n	25 (50%)	26 (52%)	17 (49%)	24 (48%)
BMI, kg/m^2	29.0±6.3	28.5±8.4	25.9±5.3	28.0±7.2
Device type				
DDD-PM				32 (64%)
CRT-D				5 (10%)
CRT-P				5 (10%)
DR-ICD				4 (8%)
VR-ICD				2 (4%)
VVI-PM				2 (4%)
Congenital heart defect				
Left-sided lesions			14 (40%)	
TGA			9 (26%)	
Tetralogy of Fallot			6 (17%)	
Other			5 (14%)	
Fontan circulation			1 (3%)	
Lung disease				
COPD		(66%)		
Asthma		(16%)		
Emphysema		(8%)		
Sarcoidosis		(6%)		
CT analysis results				
Unobstructed path to the anterior mediastinum				
Fourth ICS	40 (80%)	27 (54%)	30 (86%)	40 (80%)
Fifth ICS	49 (98%)	35 (70%)	35 (100%)	45 (90%)
Sixth ICS	50 (100%)	42 (84%)	35 (100%)	48 (96%)
Unobstructed Path to the anterior mediastinum through any ICS	100%	42 (84%)	35 (100%)	48 (96%)
Distance posterior sternum to pericardium, mm				
Fourth ICS	5.4±2.5	11.3±8.9	4.6±4.4	6.1±4.3
Fifth ICS	5.4±3.4	9.2±8.2	3.6±1.5	5.0±2.9
Sixth ICS	5.9±7.6	9.6±8.1	4.3±2.3	5.2±3.3

BMI indicates body mass index; CHD, congenital heart disease; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy–defibrillator; CRT-P, cardiac resynchronization therapy–pacemaker; CT, computed tomography; DDD-PM, dual chamber pacemaker; DR-ICD, dual chamber ICD; ICD, implantable cardioverter-defibrillator; ICS, intercostal space; PM, pacemaker; TGA, transposition of great arteries; VR-ICD, single chamber ICD; and VVI-PM, single chamber pacemaker.

CT images provided evidence that substernal pacemaker lead placement is applicable for a large range of anatomic variations and medical histories, including patients with pulmonary disease, congenital heart disease, and pacemaker and ICD recipients. In addition, substernal leads can be placed safely and efficiently into the anterior mediastinum in rapid sequence using a custom delivery tool without fluoroscopy. Furthermore, the acute human study demonstrated that substernal pacing was possible without inducing concomitant skeletal muscle stimulation in all subjects. The intention for this novel technology is to first develop a system that can provide temporary pacing in a manner that does not require placement of any devices within the circulatory system.

Analysis of the 174 CT images show that the thickness of the connective tissue in the anterior mediastinum varies, and the average thickness is ≈5 and 10 mm in subjects without and with a history of lung disease, respectively. Available clinical data is limited (N=6), and quantitative analysis of the connective tissue thickness and pacing thresholds is not available. However, it was possible to position substernal pacing leads in all clinical subjects with thresholds that were substantially lower

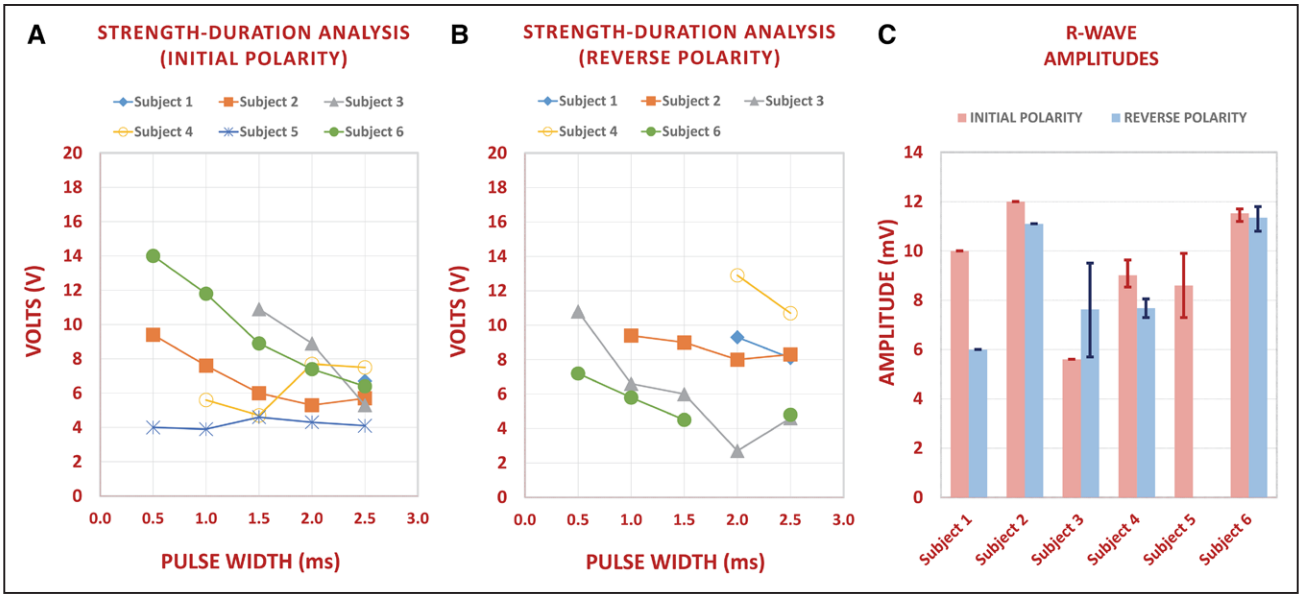

Figure 6. Acute clinical pacing performance.
A, Strength-duration relationships: initial polarity. **B**, Strength-duration relationships: reverse polarity. **C**, Measured R-wave amplitudes. Error bars=minimum/maximum.

than the maximum output of commercially available temporary pacemakers.

Potential Clinical Use as a Temporary Pacing System

Currently available devices for temporary transvenous pacing expose patients to a high risk of complications besides restricting patients in their mobility.[6–8] With the increasing number of procedures, such as transcatheter aortic valve replacement requiring temporary pacing for a certain time in frail patients, the limitations of current temporary pacing leads has become increasingly visible in clinics around the world.[9] Temporary transvenous pacing is associated with specific problems including lead instability, infection, hemorrhage, pneumothorax, patient discomfort, and complication rates have not changed over time.[6–8] A reasonable interpretation of the persisting high complication rates is that the concept of temporary transvenous pacing has not changed considerably since its introduction. The current guidelines acknowledge the risks associated with temporary transvenous pacing and stress that it should be applied as briefly as possible.[10] These findings underline the necessity for alternative treatments for patients requiring temporary pacing. New technologies, such as the AtaCor extracardiac pacing system, may provide an alternative for patients who require temporary bradycardia pacing. We demonstrated here that placement of substernal pacing leads was feasible and did not result in iatrogen-

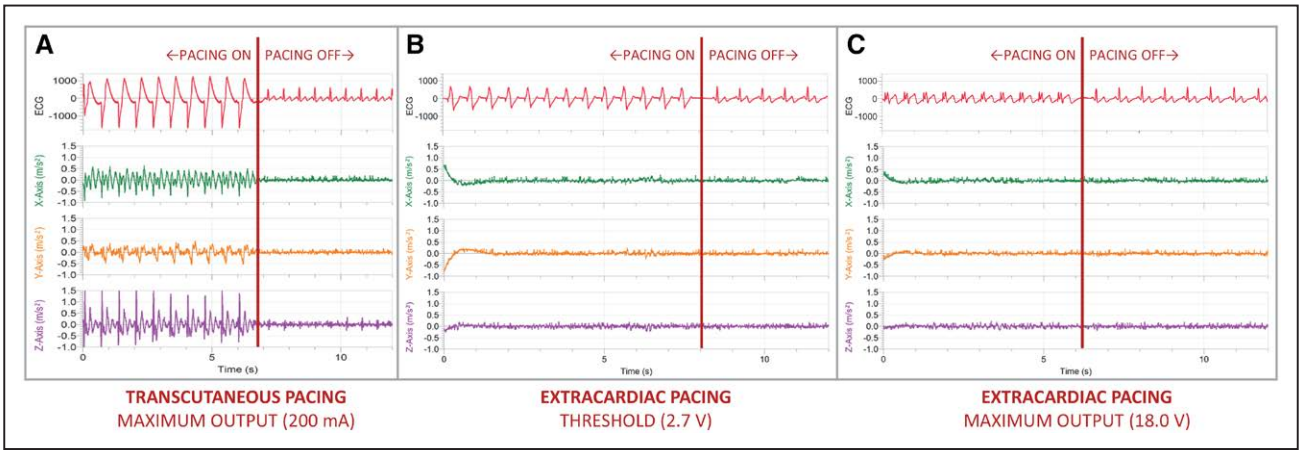

Figure 7. Accelerometer tracings illustrate that extracardiac pacing does not result in skeletal muscle stimulation.
Top tracings in all panels are ECG signals. Lower 3 signals in all panels are *x*, *y*, and *z* axes of an accelerometer placed on the surface of the chest. **A**, Skeletal muscle stimulation is clearly apparent for the initial 8 s of transcutaneous pacing at 200 mA, after which pacing is turned off. **B**, No skeletal muscle contraction/movement occurred while pacing with the extracardiac lead at 2.7 V. This is supported by the unchanging accelerometer signals before and after pacing is delivered. **C**, Extracardiac lead pacing at maximum output also resulted in the absence of skeletal muscle contraction/movement, which is supported by the unchanging accelerometer signals before and after pacing is delivered.

ic complications, such as damage to lung, pericardium, heart, internal thoracic vessels, or other anatomic structures in these patients. Given that the current pacing thresholds are higher than in general accepted permanent pacing, this extracardiac pacing system currently seems a viable option for temporary pacing. The high thresholds currently limit the routine use of this pacing system as an alternative for permanent pacing. However, permanent pacing may also be achieved if lead optimization efforts in future developments would be able to reduce these pacing thresholds. High pacing thresholds were accepted at the onset of new therapies, such as left ventricular pacing in the past as the trade-off for the potential benefit may be valuable, in the correct patient population. This may be the case for the AtaCor permanent pacing option as well. In some patients, we may accept shorter battery longevity to provide pacing without entering the vasculature.

Extracardiac Pacing Modalities Currently in Development

To avoid well-known complications of conventional pacemaker and ICD therapy, new extravascular device approaches are in development. Jordan et al[11] fixated standard transvenous pacing leads to the left ventricular free wall and atrial appendage using the pericardial space in 5 piglets. This approach, which was performed under thoracoscopic guidance, was feasible, yet 1 piglet developed a pneumothorax. John et al[12] successfully placed an intrapericardial lead percutaneously by a subxiphoid approach in a canine model. Clark et al[13] demonstrated a single-incision ICD lead placement to the ventricular epicardial surface in 6 piglets without complications. Bar-Cohen et al[14] presented a pericardial micropacemaker which was successfully implanted in 3 out of 6 pigs. In addition, the SPACE study (Substernal Pacing Acute Clinical Evaluation) evaluated the feasibility of pacing in the substernal anterior mediastinum by using an electrophysiology catheter placed under fluoroscopy by using a malleable stainless steel tunneling tool via a subxiphoid approach. Ventricular pacing was successful in 18 out of the 26 included patients.[15] There were 2 procedure-related adverse events. One patient suffered from incision-site pain, and 1 patient had pericardial effusion caused by the tunneling procedure. The feasibility study presented here describes a different minimally invasive approach of extracardiac pacing in the anterior mediastinum through the ICS using an easy to use custom delivery tool without the need for fluoroscopy, and without peri-procedural complications.

What Is Next

Temporary pacing is a logical initial clinical indication for this novel technology as it can leverage commercially available temporary pulse generators and is limited to in-hospital use where medical oversight exists. Preliminary work supports that this extracardiac pacing lead technology will be deployable quicker than currently available transvenous temporary pacing leads, without requiring fluoroscopy and without the risks of vascular or intracardiac placement. Additionally, the potential for increased in-hospital ambulation without the risk of dislodgement also exists and must be studied. It is expected that pacing thresholds with an extracardiac pacing lead will be greater than what is required for endocardial pacing, but this is a nonissue for externally powered temporary generators. Subacute (up to 7 days) clinical data with final lead and delivery tool devices must be generated to demonstrate safety and effectiveness for temporary pacing indications.

Additional development efforts will then be required to address permanent pacing indications. Chronic lead optimization efforts to lower pacing thresholds and novel pulse generator designs that can accommodate higher capacity batteries will help to provide adequate longevity for permanent extracardiac pacing applications, despite higher thresholds. Ultimately, an alternative permanent pacemaker option with a reduction in longevity may still be an attractive option for some if the risks associated with intravascular or endocardial device placement can be eliminated. The development of chronic clinical data will also be required to ensure that this completely extracardiac pacing approach is safe and effective for permanent pacing.

Limitations

The current study has some limitations. The number of included human patients and cadavers is limited. The CT images in the anatomy study were retrospectively assessed. Two standard transvenous pacemaker-leads, placed into the desired tissue location, were used for the evaluation of cardiac pacing performance (pacing tip-to-tip) and were not optimized for substernal pacing. Future human studies are required to evaluate the safety and efficacy of the AtaCor extracardiac pacing system for temporary and permanent pacemaker therapy in different patient groups.

Conclusions

We report the feasibility of an innovative extracardiac pacing system with leads placed parasternally through an ICS that eliminates the need to place any hardware within the vasculature, pericardium, or heart. This novel pacing approach showed to be anatomically feasible in a large heterogeneous patient population, using a minimally invasive delivery approach capable of ventricular sensing and pacing capture. The AtaCor extracardiac pacing system has the potential to provide clinically advantageous alternatives for patients requiring temporary pacing.

ARTICLE INFORMATION

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Disclosures

Dr Ebner has received research grants from AtaCor. Dr Wasley received consultancy fees from AtaCor. A. Marcovecchio and R. Sanghera are employed by AtaCor and report equity in AtaCor. Dr Knops reports consultancy fees, speaker fees, and research grants from Boston Scientific, Abbott, and Medtronic. M.C. Burke received speaking honoraria, research grants from Boston Scientific, as well as Biosense Webster and consults for Abbott, Boston Scientific, and AtaCor. M.C. Burke has equity in AtaCor. The other authors report no conflicts.

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