CRT 21 Virtual

A Novel Extravascular Temporary Pacing Lead System

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Disclosures

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Stockholder:

AtaCor Medical

Speaking Honoraria and Research Support:

Boston Scientific

Biosense Webster

Consultant:

Abbott

Boston Scientific

AtaCor Medical

Disclosures

Gary Gershony, MD

I have the following relevant relationships as it pertains to this presentation:

Minor Shareholder: AtaCor Medical

Scientific Advisory Board: AtaCor Medical

Current Approaches to Temporary Pacing

Existing methods used to treat transitory cardiac arrhythmias are associated with numerous disadvantages.[1-3]

TRANSVENOUS PACING

- Fluoroscopic imaging requirements may delay therapy
- Bedrest restrictions can lengthen recovery time and increase procedure costs
- Intra- and post-operative complications are common[3]

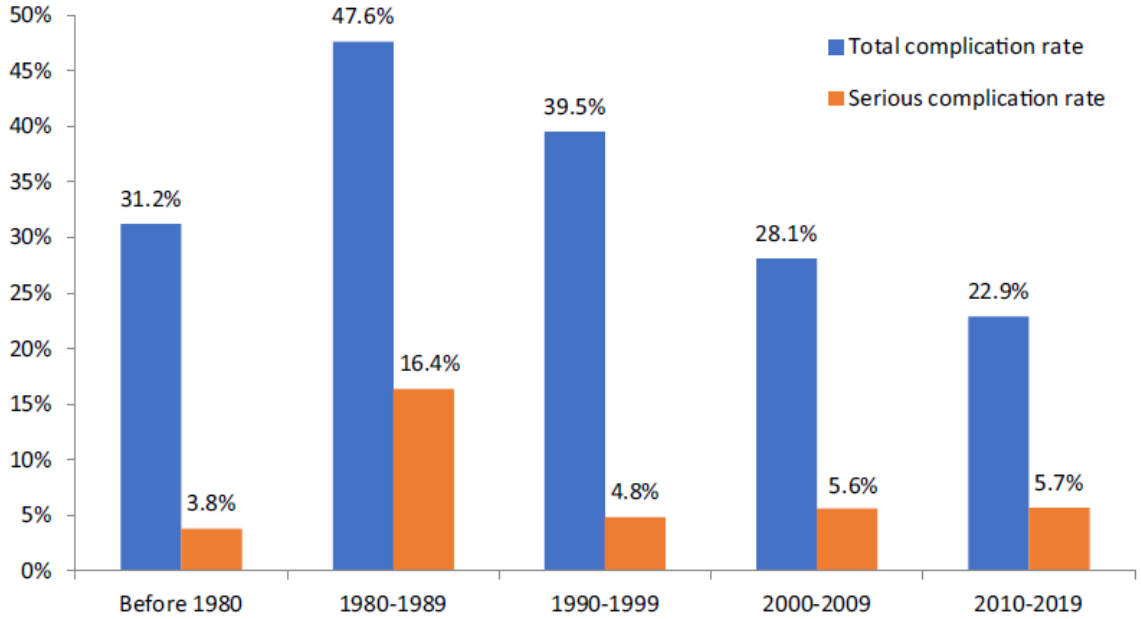
EXTERNAL (TRANSCUTANEOUS) PACING

- Ineffective
- Cutaneous electrodes stimulate skeletal muscle, causing significant patient discomfort[2]
- Intended for emergent situations

1. López AJ, Villuendas SR, García GC, et al. Temporary pacemakers: current use and complications. *Rev Esp Cardiol.* 2004;57:1045-1052.
2. Doukky R, Bargout R, Kelly RF, Calvin JE. Using transcutaneous cardiac pacing to best advantage: How to ensure successful capture and avoid complications. *J Crit Illn.* 2003;18(5):219-225.
3. Tjong, F. V. Y., U. W. de Ruijter, N. E. G. Beurskens and R. E. Knops. "A comprehensive scoping review on transvenous temporary pacing therapy." *Neth Heart J*. 2019 Oct;27(10):462-47

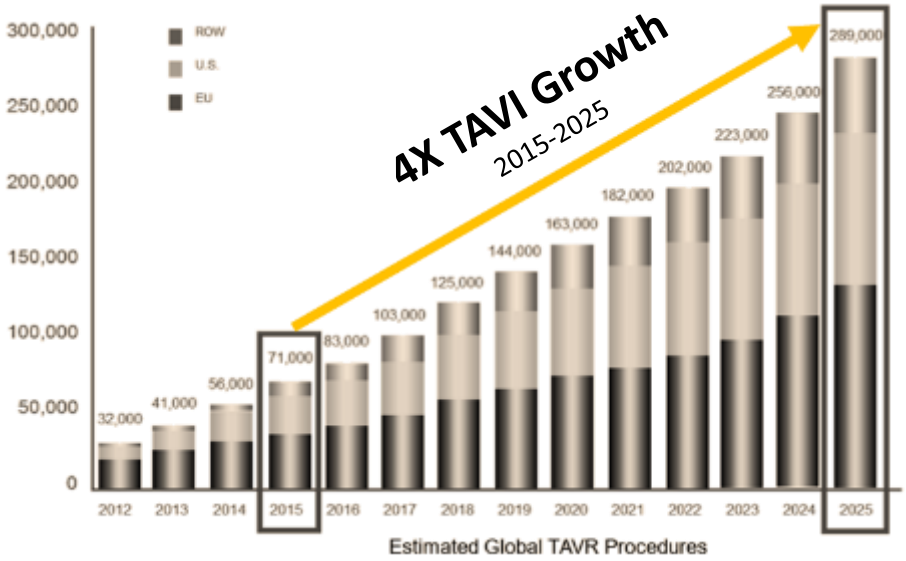
Temporary Pacing Complication Rates

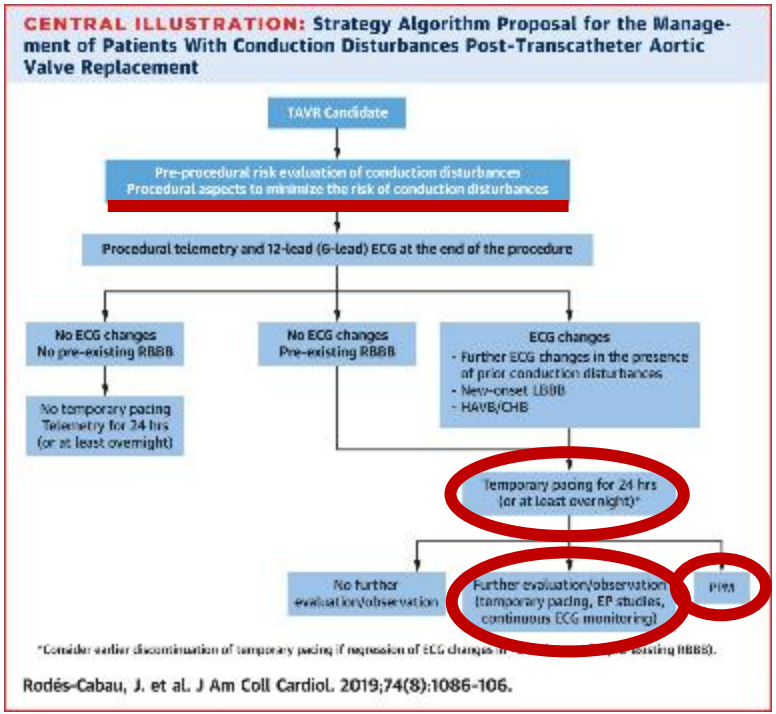
Comprehensive Literature Review, Tjong, F.V.Y. et al.



Tjong, F. V. Y., et al. (2019). Neth Heart J. 2019 Oct;27(10):462-473

As TAVI Grows, Need for Pacing Grows





Rodés-Cabau, J. et al. J Am Coll Cardiol. 2019;74(8):1086-106.

Pacing After TAVI

Data Demonstrate Need for Interim Pacing Solution

RESULTS:
13.1% of patients received a PPM after within 10 days after TAVR.

CONCLUSION:
"Fewer than half of patients who receive a new PPM following TAVR are pacemaker dependent at early follow-up (<30 days). The use of self-expanding valves and post-balloon dilation are associated with a markedly increased risk of PPM dependency."

DECEMBER, 2018

RESULTS:
16.2% of patients received a PPM after after TAVR.

CONCLUSION:
"Specific situations of conduction disturbance lead to different prognosis and should be managed specifically. After 3 months most patients implanted with PPM have recovered a spontaneous AV conduction, with a low ventricular pacing rate."

JANUARY, 2019

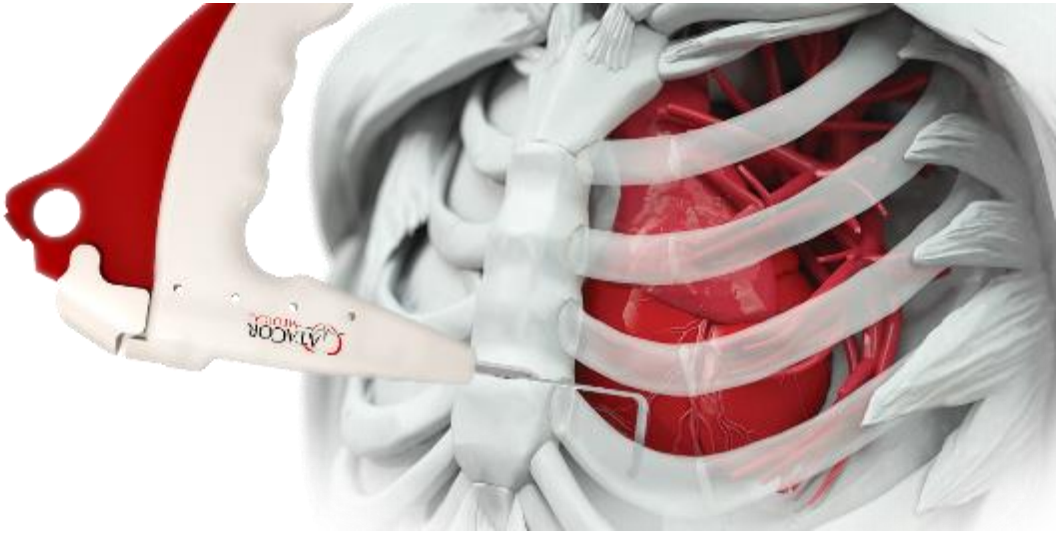
Novel Extravascular Pacing Under Development

EXTRAVASCULAR (EV) PACING

Pacing lead inserted parasternally over the right ventricle

DESIGNED FOR:

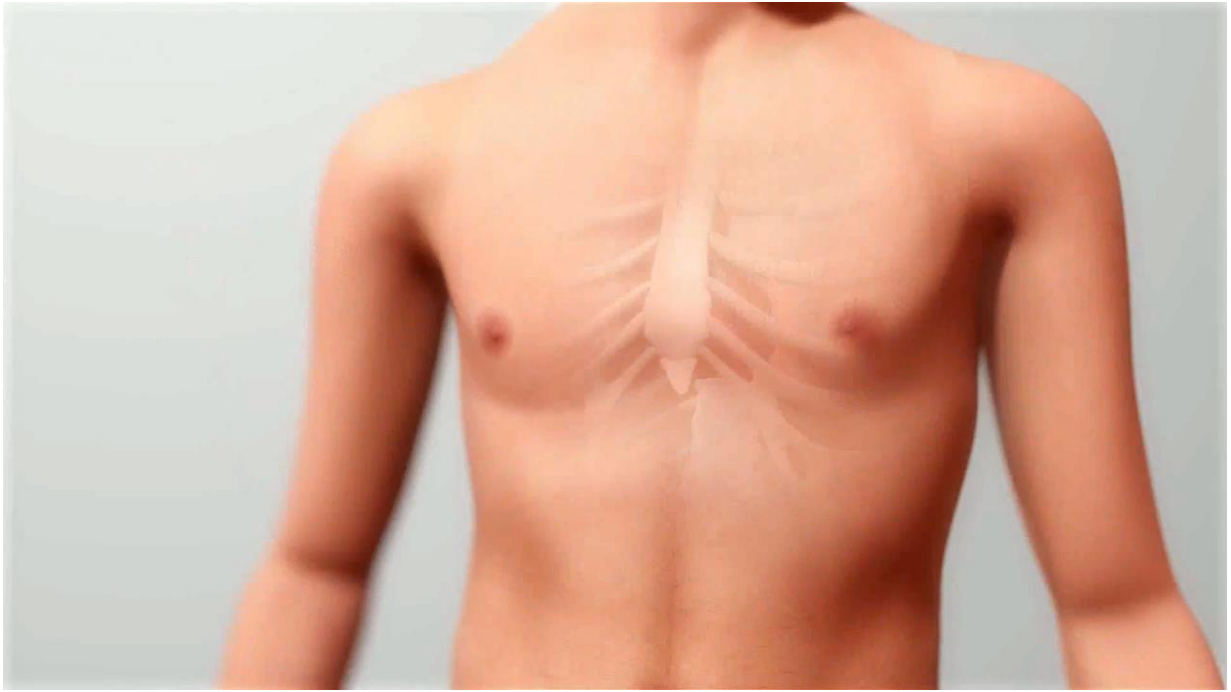
- Efficient deployment w/o advanced catheter skills
- Rapid initiation of pacing suitable for emergency situations
- Avoidance of cardiovascular complications
- Positional stability, even while patients are mobile



EXTRAVASCULAR TEMPORARY PACING LEAD SYSTEM WITH PARASTERNAL ACCESS
(AtaCor Medical, Inc.; San Clemente, CA)

CAUTION - Investigational device. Limited by Federal law (USA) to investigational use. Exclusively for clinical investigation.

Extravascular Pacing Lead Insertion (Animation)



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Case Example

First in Human Study, AtaCor Medical, Inc.

Loading the lead into the delivery tool

Delivery tool tips inserted through a 2-3 cm skin incision

Placement of delivery tool tips through the intercostal muscle to access the mediastinum

Removal of the delivery tool

Fixation of the lead

Connection to an external pacing device

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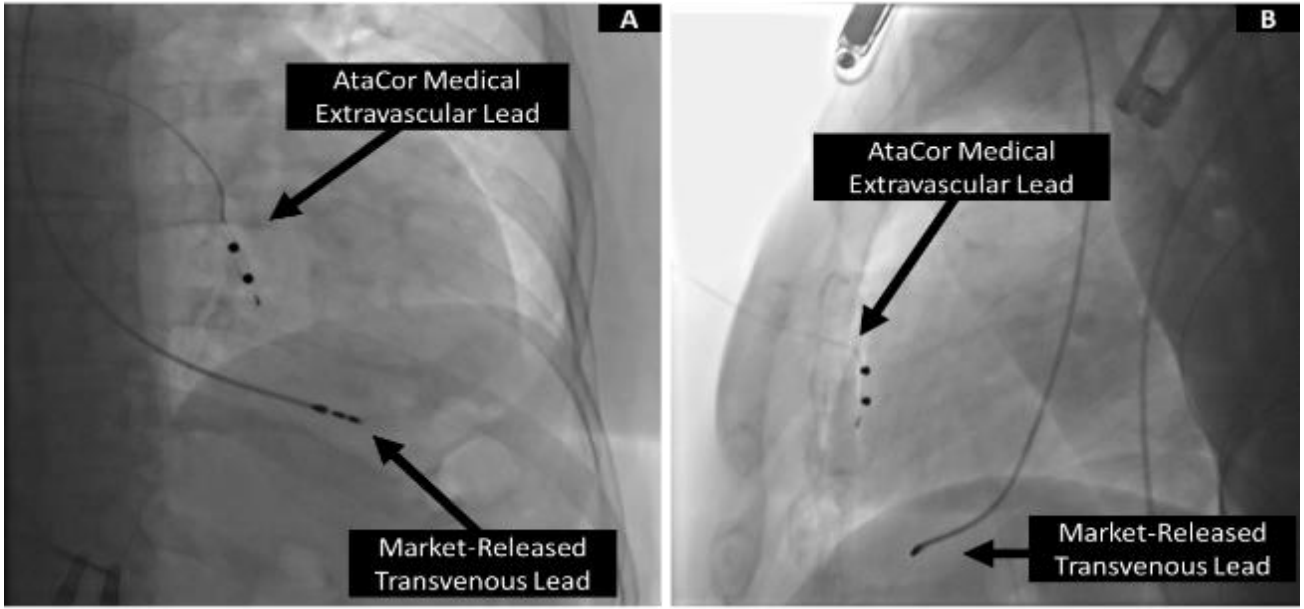
Example Images

First in Human Study, AtaCor Medical, Inc.



EXAMPLE EXTRAVASCULAR LEAD IN AP **(A)** AND LATERAL **(B)** VIEWS

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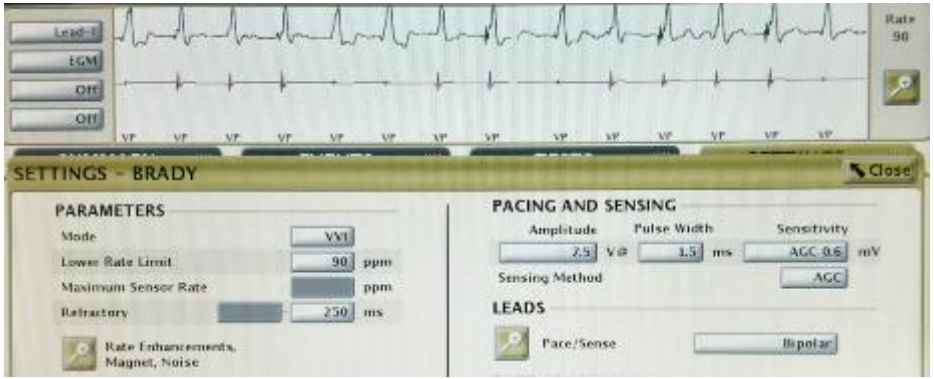
Three Pilot Studies Support Feasibility[1-3]

94% Procedure Success in first 34 subjects[1-3]

97% Freedom from Serious Complications in first 34 subjects

- One (1) pericardial effusion of unknown origin following placement of TV and EV pacing leads

LEFT: EV pacing lead connected to a commercial pacemaker



RIGHT: Programmer screen demonstrating pacing capture

CAUTION - Investigational device. Limited by Federal law (USA) to investigational use. Exclusively for clinical investigation.

1. Quast, A.F. et al. Electrical Performance of a Novel Entirely Extravascular Temporary Pacing System: Initial Pilot Study Experience. Heart Rhythm 2020, Vol. 17, Issue 5, Supp. S1-S762
2. van der Stuijt, W et al. Safety Analysis of a Novel Entirely Extracardiac Temporary Pacing System: Results of a Pilot Study
3. STEP I-III Studies,. Data on file at AtaCor Medical.

Feasibility of Ambulation

First in Human Study, AtaCor Medical, Inc.[1]

Patient ambulation with temporary pacing delivered by an EV pacing lead 1-day post-op

LEFT: Patient ambulation during EV Pacing, 1-day Post-OP

RIGHT: Holter ECG recording made while pacing with an EV lead during a short walk

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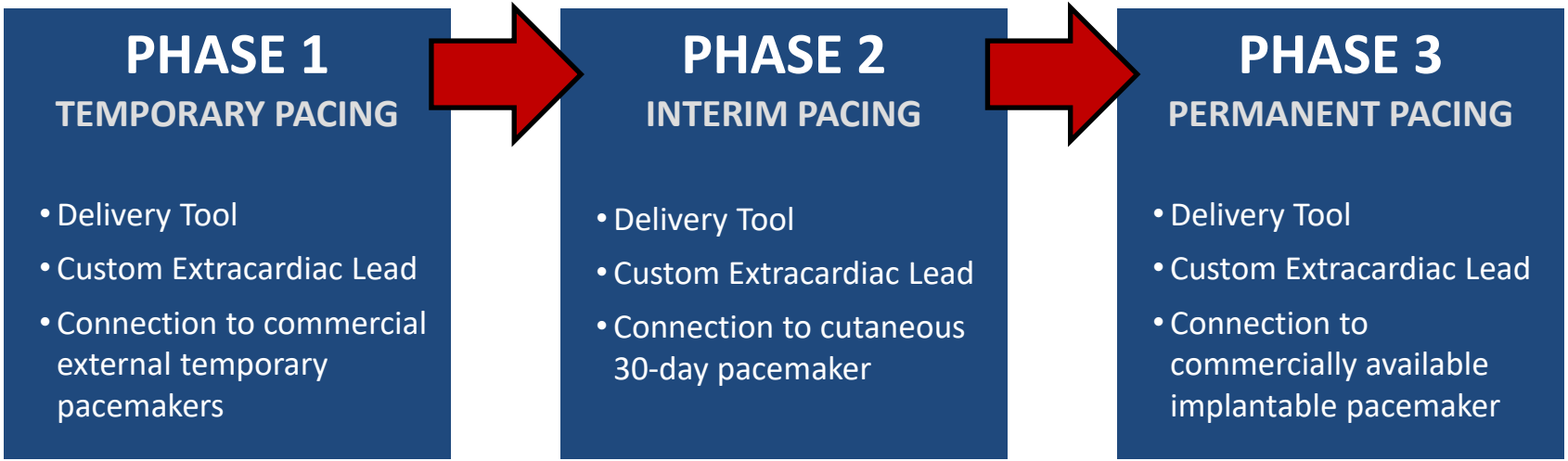
1. Beurskens et al. A Novel Entirely Extracardiac Temporary Pacing System without Post-procedural Bedrest Restrictions. Heart Rhythm 2020, Vol. 17, Issue 5, Supplement S1-S762

Novel Extravascular Pacing

Technology Development



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