A Novel Extravascular Temporary Pacing Lead System

Gary Gershony, MD and Martin Burke, DO
Disclosures

Martin Burke, DO

Stockholder:
  AtaCor Medical

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  Boston Scientific
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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 common³

**EXTERNAL (TRANSCUTANEOUS) PACING**

- Ineffective
- Cutaneous electrodes stimulate skeletal muscle, causing significant patient discomfort²
- Intended for emergent situations

Temporary Pacing Complication Rates

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

As TAVI Grows, Need for Pacing Grows
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."

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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."

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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)

CAUTION -
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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

94% Procedure Success in first 34 subjects

97% Freedom from Serious Complications in first 34 subjects
  - One (1) pericardial effusion of unknown origin following placement of TV and EV pacing leads

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.

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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

Novel Extravascular Pacing

Technology Development

**PHASE 1**
TEMPORARY PACING
- Delivery Tool
- Custom Extracardiac Lead
- Connection to commercial external temporary pacemakers

**PHASE 2**
INTERIM PACING
- Delivery Tool
- Custom Extracardiac Lead
- Connection to cutaneous 30-day pacemaker

**PHASE 3**
PERMANENT PACING
- Delivery Tool
- Custom Extracardiac Lead
- Connection to commercially available implantable pacemaker

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