Case Report

Innovative Use of Biotrace Tempo Pacemaker Lead Following Cardiac Surgery

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ABSTRACT

The Tempo® Temporary Pacing Lead is a temporary, transvenous, active fixation pacemaker lead used exclusively in structural heart and electrophysiology procedures since regulatory approval in 2016. We utilized the Tempo lead for four patients undergoing redo-robotic cardiac surgery in which surgical epicardial leads could not be placed. No failure-to-pace events were encountered and patients were able to participate in various levels of physical activity without limitation.

Keywords: Active fixation pacemaker, minimally invasive cardiac surgery, robotic cardiac surgery, temporary pacemaking

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Submitted: 29-Jan-2022 **Revised:** 01-Apr-2022 **Accepted:** 05-Apr-2022 **Published:** 05-Jul-2022

INTRODUCTION

The Tempo Temporary Pacing Lead has been used in structural heart and electrophysiology procedures for temporary pacemaking since regulatory approval in 2016.[1] The lead is a temporary, transvenous, active-fixation pacemaker. The Tempo lead may have distinct advantages compared to epicardial leads traditionally used in the perioperative period for cardiac surgery, and this report is the first documented use of this device following cardiac surgery. Written HIPAA authorization was obtained for publication of this report.

CASE REPORT

A 58-year-old man with a history of mitral and aortic valve replacement presented for redo-robotic mitral valve replacement for severe prosthetic mitral stenosis. Due to prior sternotomy and robotic approach, surgical exposure for placement of a traditional right ventricular epicardial pacemaker was limited; therefore, the anesthesiology team planned to place a preoperative Tempo® Temporary Pacing Lead (BioTrace Medical, Menlo Park CA, USA) for postoperative pacing. The Tempo lead is an active fixation, bipolar pacing electrode and is FDA approved for use as a temporary transvenous pacemaker.

General anesthesia was induced with standard monitors and an arterial line. Following endotracheal intubation with a 37L double lumen endotracheal tube, right internal jugular 11Fr and 9Fr sheaths were placed under continuous ultrasound guidance. A ProPledge (Edwards Life Sciences, Irvine CA, USA) percutaneous coronary sinus catheter

Access this article online	
Quick Response Code:	Website: www.annals.in
	DOI: 10.4103/aca.aca_25_22

How to cite this article: Goldhammer JE, Linganna RE, Pfeil DS, Witzeling SD, Vishnevsky A, Ruggiero NJ, *et al*. Innovative use of biotrace tempo pacemaker lead following cardiac surgery. Ann Card Anaesth 2022;25:362-5.

was positioned in the coronary sinus via the 11Fr sheath using fluoroscopy and transesophageal echocardiography; pulmonary EndoVent (Edwards Life Sciences, Irvine CA, USA) was positioned in the main pulmonary artery via the 9 Fr sheath. Left internal jugular vein was accessed with a 7Fr sheath with ultrasound guidance. The Tempo lead was advanced via the 7Fr sheath into the apex of the right ventricle with fluoroscopic guidance. Following fluoroscopic confirmation of position, the balloon at the tip of the lead was inflated, forcing apposition of the tip of the lead to the apical ventricular septum. Stabilizer loops were then released to anchor the lead to the endocardium [Figure 1] and the balloon deflated. The Tempo lead was tested and captured successfully at 0.8 mA.

Cardiopulmonary bypass (CPB) was initiated with percutaneous femoral arterial and bicaval cannulation. Cross-clamp of the ascending aorta was applied using the IntraClude (Edwards Life Sciences, Irvine CA, USA) endovascular aortic cross-clamp. Delnido cardioplegia was delivered in antegrade and retrograde fashion using both the Intraclude and Propledge devices. Robotic mitral valve replacement with #31 bioprosthetic valve was performed without complication via three 8 mm ports in the right thorax. The patient was weaned from CPB in sinus rhythm; total CPB time and cross-clamp time were 179 and 91 minutes, respectively. The patient was transitioned to the ICU in sinus rhythm on epinephrine 0.06 mcg/kg/min, phenylephrine 1.5 mcg/kg/min, and vasopressin 0.04 units/min. Tempo pacemaker was set to VVI at 50 beats per minute (bpm) for backup pacemaking in the event of bradycardia or complete heart block. The patient was extubated on postoperative day (POD) 0.

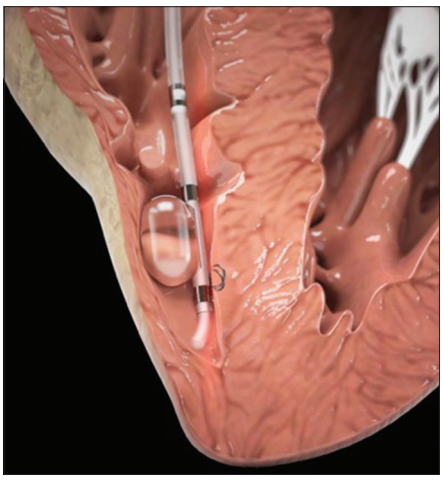

Figure 1: Air-filled balloon ensures Tempo lead tip is apposed to septal wall in the right ventricular apex. Stabilizer loops are deployed to provide active lead fixation to the endocardium

Early on POD #1 he was out of bed to chair. The patient required intermittent pacing using the Tempo lead at 80 bpm for hypotension. The patient was able to walk with assistance with indwelling Tempo lead. On POD #2 he was hemodynamically stable, in sinus rhythm, and the Tempo lead was removed at the bedside. The stabilizer loops were retracted and the lead removed with gentle traction through the vascular sheath [Figure 2].

Since this initial clinical experience, we have used the Tempo lead in three additional patients [Table 1]. With the active-fixation lead in place, patients were able to participate in varied levels of physical activity without limitation. No complications related to perforation or tamponade have occurred in our clinical experience.

DISCUSSION

Following cardiac surgery, epicardial pacemakers are routinely placed to prevent hemodynamically significant bradycardia, complete heart block, or other rhythm disturbances. However, clinical scenarios, such as the redo-robotic surgical approach, may prohibit placement of traditional epicardial electrodes. In this setting, an alternative pacemaker option must be considered. A conventional transvenous pacemaker or a Paceport pulmonary artery catheter may act as a suitable alternative for postoperative pacemaking if epicardial access is limited; however, continuous pacemaker capture may be unreliable in large or small hearts. Electrodes may be displaced with patient movement; therefore, patient activity must be restricted with transvenous pacemaking techniques.[2,3] The

Table 1: Patient Details

Case	Surgery	Access	Removed	Out of bed with Tempo	Pacemaker related complication
1	Redo-Robotic MV Repair	Left IJ	POD 2	Yes	No
2	Redo-Robotic MV Replacement	Left IJ	POD 2	Yes	No
3	Redo-Robotic MV Repair	Right IJ	POD 1	Yes	No
4	Redo-Robotic MV Repair	Left IJ	POD 3	Yes	No

IJ=Internal jugular vein, POD=Post-operative day, MV=Mitral valve

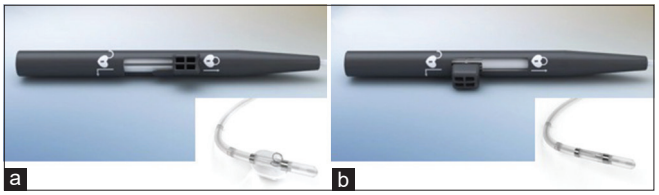

Figure 2: (a) Stabilizer loops deployed with trigger in locked position. (b) Stabilizer loops retracted with trigger in unlocked position

Tempo lead has an innovative active-fixation system which allows for reliable pacemaker capture, increased patient activity, and participation in early physical therapy. In our experience, the use of the Tempo lead has enabled early mobilization and physical therapy in a patient population that would have otherwise had activity restriction.

Cardiac tamponade is a life-threatening event occurring in 1% of patients in whom epicardial leads are removed with traction.[4] Although they may cause direct damage to heart tissue, epicardial leads are often removed in the presence of limited hemodynamic monitoring. As an alternative to removal, epicardial leads may be left *in situ* and cut at the skin. Leads remaining in the chest cavity are at risk for migration and infection. Retained epicardial leads have been localized to the aorta, pulmonary artery, esophagus, lung, colon, and soft tissue of the chest, head, and neck.[5-9] The Tempo lead is removed through the intravascular sheath when temporary pacing is no longer indicated. The stabilizer loops are retracted and the lead removed with gentle traction through the intravascular sheath. To date, no reports of perforation or myocardial injury have occurred during removal of the Tempo lead.

The Tempo lead has a soft, flexible tip designed to mitigate perforation events during lead placement. If a catastrophic event were to occur, lead placement is a relatively "safer" time for perforation compared to lead removal. During lead placement, patients are in the operating room with invasive monitoring including, arterial line, pulmonary artery catheter, and transesophageal echocardiography. In addition, a cardiac surgeon, immediately capable of relieving tamponade, is either present or immediately available. Invasive monitoring and personnel in the operative suite allow for immediate diagnosis and definitive treatment of cardiac tamponade in the rare occurrence of a perforation event.

Since regulatory approval, the Tempo lead has been used safely and effectively in structural heart procedures with zero reported occurrences of cardiac perforation, effusion, or tamponade.[10] We present the first documented use of the Tempo lead following cardiac surgery. Potential advantages of the Tempo lead, as compared to traditional epicardial leads, are: (1) Transvenous approach allows for reliable pacemaking when epicardial lead placement is challenging. (2) Active-fixation provides stability of the temporary pacemaker and allows for increased patient activity and participation in early physical therapy. (3) Reports of myocardial injury and tamponade with the Tempo lead are exceedingly rare. While perforation and tamponade are also rare with traditional epicardial leads, when they do occur, it is a life-threatening complication in a relatively unmonitored setting. Design of the Tempo lead mitigates the risk of myocardial perforation during lead placement (due to the soft, flexible tip) and at lead removal (stabilizer loops retract into the device and the lead is removed with gentle traction through the intravascular sheath). Overall, the Tempo lead platform has intriguing potential for future use to facilitate postoperative pacemaking in cardiac surgery. However, prior to widespread adoption of the Tempo platform, reliability of pace capture thresholds must be widely verified in a post-cardiotomy population.

Author contribution

Jordan E. Goldhammer, MD: This author helped with research design, clinical care, data collection, and manuscript preparation.

Regina E. Linganna, MD: This author helped with research design, clinical care, data collection, and manuscript preparation.

Douglas S. Pfiel, MD, PhD: This author helped with research design, clinical care, data collection, and manuscript preparation.

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T. Sloane Guy, MD: This author helped with research design, clinical care, and manuscript preparation.

The following manuscript has been read and approved by all authors and represents honest work, free of bias.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initial s will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

Dr. Goldhammer is a member of the medical advisory board for BioTrace Medical. The offer to join the medical advisor board of BioTrace Medical was received by Dr. Goldhammer after clinical care of all patients described in this manuscript and advanced drafting of this manuscript. BioTrace Medical provided no financial or advisory support for this manuscript. The observations provided reflect the independent views of all authors of this manuscript.

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