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AVIER LEADLESS PACEMAKER (IMPLANTABLE PACEMAKER PULSE GENERATOR): A REVIEW

Ashok Kumar Sharma, Harshita Badoliya, Janvi Jain, Rohit Sharma, Vandana Sharma, Mukesh Sharma, Shankar Lal Soni, Vani Madaan

Arya College of Pharmacy, Kukas, Jaipur, Rajasthan, India

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Corresponding author: Ashok Kumar Sharma
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Abstract

Patients suffering from arrhythmias, bradycardia or chronic atrial arrhythmia with high degree blocks faced complications associated with transvenous pacemaker specially with old techniques which involved subcutaneous pocket, bleeding, infection and even a pneumothorax during surgical placement of pacemaker can be overcome by using leadless pacemaker. In 2013, the first leadless pacemaker was introduced in international clinical trials but removed from market due to its premature battery exhaustion. Then it redesigned with key design improvements. The leadless ll phase 2 trial then approved by FDA (Food and Drug Administration) on March 31st, 2022. In trials study included 200 subjects across 43 sites in different countries. Procedures were performed without endotracheal intubation. The objective of this study was to evaluate the success of implantation, its performance and preclinical studies. In phase ll implantation success was 98%. Unique aspects of this device were improved implant success rate and low repositioning rates. The new design of leadless pacemaker is with dual – helix fixation mechanism which is specific to right atrium anatomy. The avier leadless pacemaker contains following components:

- The avier leadless pacemaker [LSP112V]
- Avier delivery system catheter [LSCD111]
- Avier link module [Model LSL02]

It is conditionally safe for use in MRI environment by following up proper instructions. The avier leadless pacemaker met its all safety and efficacy end points. Patients who have poorly integrated hardware such as drivelines, comorbidities associated with discomfort and infection. Experts predicted that advancement in transcutaneous charging capabilities will soon render large devices which may be completely implantable.

Keyword: Pacemaker, bradycardia, implantation, femoral vein.

INTRODUCTION

A pacemaker is a small device which is implanted in the chest to control the heartbeat. It requires surgical process to get implant. It is also called as cardiac pacing device. Leadless pacemakers are used as alternative cardiac implantable devices for the treatment of bradycardia. Nearly 750000 leadless pacemakers are implanted worldwide annually. Leadless pacemakers have been designed as an alternative to transvenous systems which avoid some of the complications associated with transvenous devices.

DEVICE DESCRIPTION

Aveir leadless pacemaker system acts as a

pulse generator including batteries and electrodes provides pacing of bradycardia and get implanted in the right ventricle.

Aveir leadless system contains:

I. Aveir leadless pacemaker (LSP112V)

II. Aveir delivery system catheter (LSCD111)

III. Aveir link module (Model LSL02)

Aveir leadless pacemaker (LSP112V)

It provides intrinsic cardiac signal sensing and also delivers cardiac pacing therapy to the patients. It does not need a connector as it is a leadless device. It senses temperature of right ventricular blood which increases the pacing rate with increased metabolic demand.

To reduce inflammation, it includes single dose of dexamethasone sodium phosphate at the tip of electrode. It communicates bidirectionally via electric signals conduct between applied skin electrodes to patient's chest and electrodes connected to programmers system.

Aveir Delivery Catheter (Model LSCD111)

This delivery catheter contains an unified guiding catheter having defensive sleeve to protect electrodes and fixation helix of the leadless pacemaker , a manageable delivery catheter and a valve bypass tool which helps to facilitate the system into the femoral vein and also helps in dilating the sheath hemostasis valve of 25 Fr inner diameter.

Aveir Link Module (Model LSL02)

Aveir link module work as a communicator attached with patient cable and skin electrode to communicate with implanted aveir leadless pacemaker in the heart of the patient.

It also used to obtain ECG waves of the patients . It uses safe and high frequency electric pulses sent between the system to program and leadless pacemaker to examine the implanted leadless pacemaker.

PROCEDURE

The doctor makes a small cut (incision) in the patient's leg (femoral vein) by minor surgery and uses a delivery catheter to implant the Aveir Leadless Pacemaker into the right ventricle of the heart. After implanting the pacemaker electrodes from the Aveir Link Module are placed on the patient's skin. Then it is able to wirelessly connect to the leadless pacemaker using the link module and adjust the pacemaker's settings based on the needs of the patient. The doctor is also able to collect information about how the pacemaker is working using the link module.

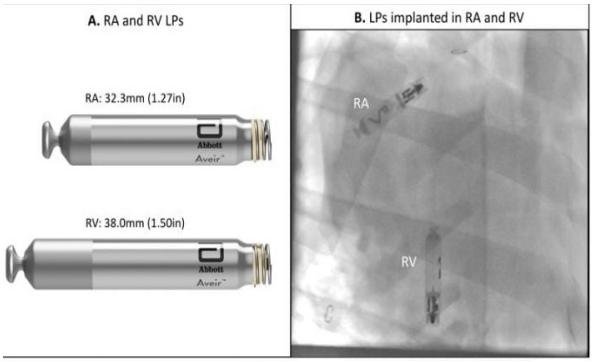

Fig A: Right Atrium and Right ventricle leadless pacemaker

Fig B: Leadless Pacemaker implanted in RA and RV

Fig C: Aveir Delivery Catheter System

Fig D: Aveir Link Module

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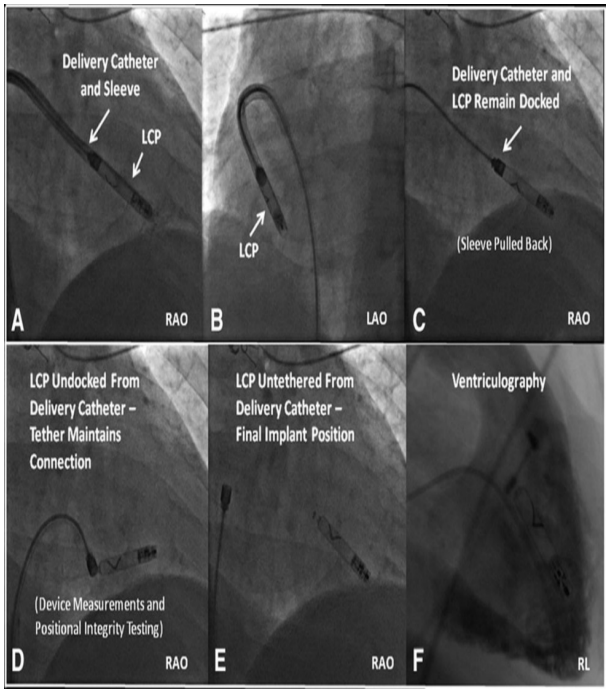

When it is used

The Aveir Leadless Pacemaker used in patients with irregular heart rhythms or in case of bradycardia who may benefit from a pacemaker system that works in one chamber of the heart (single chamber pacemaker system). This system may also be used as a replacement of traditional pacing system with leads which is hard to place.

When not to be used

The Aveir Leadless Pacemaker should not be used in patients with:

An already implanted cardioverter that detects rapid heartbeats and sends an electrical shock to correct the rhythm of the heart. A previously implanted filter to catch blood clots in one of the primary veins that carries blood to the heart (vena cava) or a mechanical valve between the heart's right lower chamber (ventricle) and the right upper chamber (atrium), called the tricuspid valve.

A known history of allergies to any of the parts or components of this device due to incompatibility.

Some features of the Aveir Leadless Pacemaker should not be used under the following conditions:

Single-chamber ventricular demand pacing should not be used mostly in case of patients who have shown worse symptoms after the pacemaker is implanted which is technically called as pacemaker syndrome.

A heart condition called as retrograde (ventricular-atrial) conduction.

In case of a person who experiences a drop in blood pressure in the arteries when pacing starts.

Adverse effects of this device

Infection, Hypotension, Valve damage, inappropriate sensor response, Pacemaker syndrome, Cardiac perforation, Death.

CLINICAL STUDIES

The first leadless cardiac pacemaker was introduced in 2013 in international clinical trials, but it was withdrawn from the market because of premature battery depletion. The redesigned Aveir, Abbott leadless pacemaker designed their improvements by the use of standard transvenous pacemaker battery containing lithium carbon-monofluoride with a 12% longer battery life having capacity of 1.1 years longer to 10.4 years. a modified form factor which was 10% shorter, 1.5-F wider, to 19.5-F, a modified docking button which enabled retrievability, a modified delivery system with an ergonomic design and a new application-specific integrated circuit (ASIC) chip designed to provide an expandable platform to support a dual-chamber pacing system. Here presenting the first-in-human experience with this novel device

This clinical trial enrolled 200 subjects across 43 sites in the United States, Canada, and Europe between November 2020 and June 2021, with a mean follow-up of 3.92 ± 1.87 subject-months. The mean age at enrollment was 75.6 ± 11.3 years, and 62.5%

of the subjects were male. Procedures were performed without endotracheal intubation. Their Implant success was 98% i.e. 196 out of 200compared with 96.3% i.e. 289 out of 300 in phase 1trial. the successful implants, 83.2% (163 of 196) did not require repositioningcompared with 70.2% (354 of 504) in phase 1.

CONCLUSION

The primary safety end point was free from complications (complication-free rate), defined serious adverse device effects in duration of 90 days. It reported the complication-free rate, based on subjects who complete their 90-day follow-up visit or drop out because of a complication. The secondary safety end point was implant success rate, defined as the percentage of subjects leaving the implant procedure with an implanted and functioning LCP device. The secondary performance end points were pacemaker performance including pacing threshold, cell voltage, R-wave amplitude, pacing percentage, and cumulative cell charge. Additionally, the leadless pacemaker performance was assessed during magnet testing (predischarge) and 6-minute walk tests (at the 2-week visit if the patient was physically capable). An independent data and safety monitoring board reviewed the safety and performance data and the aveir leadless pacemaker got FDA approved for the patients of bradyarrythmia.

RESULT

The avier leadless pacemaker met the desired goals with safety and effectiveness endpoints and get approved by FDA and PMA by following 10 years to assess long term safety and efficacy for the bradyarrythmias patients.

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