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Case Report

Successful Leadless Pacemaker Implantation- A Remarkable Solution for the Recurrent Pacemaker Leads Infection

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Abstract

In current healthcare scenario, pacemaker infections are one of the leading causes of many fatal complications in the patients. Pacemaker leads, especially those which are placed with in the venous system and chambers of the heart, are at higher risk of getting colonized with micro-organisms because of their sizeable extent and the nature of their external materials which are most often exposed (usually silicone or polyurethane). Leadless pacemakers, in comparison to the traditional Trans venous pacemaker, have specific features that decrease the risk of infection because of a smaller surface area, a metal only exposed surface, no communication with the heart valves, and no component that is close to the skin surface. Our case report is small contribution to add on the evidences that the leadless pacemakers are nothing but phenomenal advancements in interventional cardiology that aim at preventing lead and pocket-related complications thus causing marked reduction in morbidity and mortality in patients, eventually decreasing the financial burden on the patient by also reducing the hospital stay.

Keywords: Leadless pacemaker; Trans venous pacing; complete heart block; Trans catheter approach; recurrent pacemaker infections.

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Introduction

As per medical literature available, over one million pacemakers are inserted annually all over the world [1]. If we talk about interventional cardiology, pacemaker lead infection is one of the paramount causes of morbidity and mortality and is primarily troublesome in pacemaker-dependent patients. Sohail and colleagues [2] found that there was a considerable rise in mortality following septicaemia induced infection of cardiovascular implantable electronic devices. In another set of patients, Johansen and colleagues [3] brought up in their retrospective study that the risk of infection and septicaemia after 1-2 years of pacemaker implant could reach up to approximately 9.5%. Kirkfeldt and colleague's [4] retrospective study showed that the risk of infection in the case of device replacement and revision is sky high than the actual risk which is seen post initial pacemaker implantation. A leadless pacemaker which is an intra-cardiac medical device is known to sense cardiac activity from multiple heart chambers and applies cardiac stimulation to at least one cardiac chamber and produces a cardiac diagnostic indication. The leadless device can also be implanted in one cardiac chamber (e.g., the right ventricle) and can detect near-field signals from that chamber as well as far field signals from the nearby cardiac chamber (e.g., the right atrium). Leadless pacemaker systems needless to say have a specialised self-contained system which includes both pulse generator and electrode assembled with in a single functioning unit and is safely guided into the Right Ventricle via well-known Trans venous approach. Only one leadless pacemaker (Micra [Medtronic PLC; Minneapolis, MN]) has been approved by the US Food and Drug Administration for use in the United States; a second (Nanostim [Abbott Laboratories; Abbott Park, IL]) is pending approval. Micra attaches to the right ventricle myocardium via four linear self-expanding nitinol tines. Nanostim attaches via an active screw-in helix and secondarily via three nitinol tines angled perpendicularly to the helix [5]. Although, traditional Trans venous pacemakers are supposed to have an infection rate scaling from 0.77% to 2.08%, current clinical trials which were done enrolling more than 3000 patients have reported no cases of leadless pacemaker infection [6]. Leadless pacemaker clinical trials reported a remarkable observation which was the absence of the pacemaker site infections, in the setting of ongoing bacteraemia in the patient [7]. No wonder future innovations will certainly promote leadless pacemakers which can execute biventricular pacing profitably in needy patients. Present case was the first of its kind in our institute and successfully demonstrates how introduction of leadless pacemakers can be used to reduce infections and associated complications in high-risk patient population.

Case Report

A case of 80 years old female is k/c/o diabetes and hypertension, triple vessel disease on medical management and underwent permanent pacemaker insertion for complete heart block in 2011. The patient was allergic to penicillin and sulpha containing drugs. Patient was CRE (COLISTIN RESISTANT

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ENTEROCOCCUS) POSITIVE. 2d echo showed ejection fraction of 50%. Patient underwent replacement of Left side Pacemaker in Nov 2018, which got infected with pus collection so was changed to right side on 06 DEC 2018. On 12 DEC 2018, presented to EMS with c/o fever with chills high grade for 3-4 days, poor appetite, and altered sensorium for 3 days. She was admitted to other private hospital with above mentioned complaints. She was hypotensive, drowsy, was started on vasopressor support and IV antibiotics and was shifted to H N reliance hospital for further management. On Arrival to emergency room, she was on vasopressor support, disoriented. Wound culture and blood culture were sent and she was shifted to ICU for further management. Culture of klebsiella pneumonia was documented. Patient was in sepsis with infected right side permanent pacemaker which was removed on admission and was put on temporary pacemaker (Femoral Transvenous pacemaker) and was started on higher antibiotics for treatment of sepsis. After previous wound healing patient underwent Thoracotomy and Epicardial Pacemaker Insertion on 01/2020. Repeated admissions for abdominal wound at pace maker insertion site were treated conservatively with antibiotics and dressing. But on 02/2020 she was admitted again with pain and gaping of wound from the abdominal pacemaker site with exposure of the lead wire. Wound closure done after treating infection with antibiotics for 4-5 days. During the stay in hospital, patient had alleged history of fall in bathroom followed by intertrochanteric fracture. Pre op investigations were performed in which all routine blood investigations were normal, chest x-ray and ECG were also normal. 2D ECHO showed- S/P Permanent pacemaker implantation, Normal sized LV with and good contractility, LVEF: 55%. No e/o LV regional wall motion abnormality. Grade three LV diastolic dysfunction, (E/E': 16), Mild mitral annular calcification, Trivial MR, mildly scleroses aortic valve with adequate opening, Trivial AR. Patient was taken up for the surgery and administration of regional anaesthesia was planned. Open reduction internal fixation done under subarachnoid block, recovery uneventful with temporary pacemaker in situ, and without any complications. Patient again admitted with pacemaker site wound infection on 30/08/2020 and was started on antibiotics for treating the same. As patient had Recurrent Pacemaker Site Infection with Pacemaker Prolapse-Implantation of Dual chamber permanent pacemaker (LEADLESS) was planned. On 02/09/2020- patient was taken in cathlab for the leadless pacemaker implantation. Well informed, written detailed consent was taken for the procedure. Patient and relatives were counselled about post op ICU stay, ionotropic support and pacemaker malfunction. Multidisciplinary approach was adopted. Case was discussed in detail with the cardiologists and ICU team. Our primary plan was to offer the patient safe monitored anaesthesia care and general anaesthesia in case of emergency. All emergency drugs were kept ready. Difficult airway cart was prepared and kept stand by. Pacing pads were attached to the patient. Difibrillator machine was checked and kept ready for unexpected arrythmias. All standard ASA monitors were attached. Oxygen @ 4l/minute by nasal prongs was being administered to the patient. Before start of the procedure vitals noted

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were BP- 140/80 mmhg SPO2-100% HR-70 bpm paced at VVI MODE. In view of anticipated procedural complication, before shifting the patient in cathlab. Blood reservation was done in view of any intra procedural bleed. Inotropes were prepared and kept ready to overcome any hemodynamic instability during procedure. Patient was taken inside cathlab for placement of leadless pacemaker. Standard American society of anaesthesiologists monitors attached before starting the procedure. 18G IV line secured in left hand. Fluid attached for maintaining patency of IV line during the procedure. We kept communicating with the patient to calm her down and allay her anxiety. Using local anaesthesia infiltration, left femoral arterial access was obtained for arterial pressure and left femoral venous access was obtained in view of need for any inotropic support during the procedure by the cardiologist (so the central line was avoided). Moderate sedation in the form of Inj. Midazolam 1 mg, Inj. Fentanyl 50 mcgs was administered to the patient. Right femoral venous access was obtained for the implantation of the pacemaker. 27f sheath and dilator was inserted. Dilator and the wire were removed leaving the sheath in the Right atrium. Delivery device with the pacemaker were advanced through the sheath into mid septum of Right ventricle. Pacemaker check was done which was excellent and delivery device with sheath was then removed. Homeostasis of both groins achieved. Mode-VVI, with base rate -70 bpm. As all the modalities of pacing in our patient of COMPLETE HEART BLOCK failed due to complications related to traditional pacemaker, Leadless pacemaker was the only option left. Therefore, the leadless pacemaker was successfully implanted into right ventricle and pacing adjusted to 70bpm. Patient tolerated the procedure well. Shifted to ICU for one day observation. No post procedural complications seen and the patient was discharged with leadless pacemaker in situ. Successfully dual chamber leadless permanent pacemaker implantation was done with moderate sedation. No complications were noted during the procedure. Patient was hemodynamically stable throughout.

Discussion

The present leadless pacemaker devices, which is approximately 90% smaller than a regular trans venous pacemaker, is an assembly of self-contained generator and electrode system which is introduced straight into the right ventricle. The device is generally implanted through femoral vein using Trans catheter approach, also there is no need of chest incision or subcutaneous generation of pacemaker pocket. The prime advantage of a leadless pacemaker is the exclusion of several complications associated with Trans venous pacemakers and its leads. Important problems with Tran venous pace makers are pocket infections, hematoma, lead dislodgment, and lead fracture [8]. Advantages of a leadless pacemaker are as follows:

A. It is much smaller as compared to traditional pacemaker.
B. It has no part that has close proximity to the skin surface, therefore there are reduced chances of infection has no interaction with Tricuspid valves

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because Leadless pacemakers mostly become encapsulated in the cardiac tissue, like the pacing leads of traditional Trans venous pacemakers.

C. The leadless pacemaker is also cosmetically better as there is no chest incision made and also no need for the creation of any pacemaker pocket.
D. These new pacemakers are now designed with compatibility to magnetic Resonance imaging.
E. Battery life is approximately 5-15 years which is comparable to that of a Trans venous pacemaker.
F. A leadless pacemaker is always retrievable. G) One useful application may be postoperatively after performing Trans catheter aortic valve replacement.
G. A leadless pacemaker can be switched off at the end of battery life and a new leadless or traditional trans venous pacemaker can be implanted.

Complications of a leadless pacemaker are as follows-

A. Related to the use of femoral vein as access.
B. Device positioning very often.
C. High probability of cardiac perforation resulting pericardial effusion.

As our patient has h/o Recurrent Pacemaker Site Infection with Pacemaker Prolapse, Leadless pacemaker insertion was the last resort and was planned to be done via Trans femoral route. The leadless device was selected because of patients increased risk of bacteraemia and deemed high risk of conventional pacemaker placement any further. In our case leadless pace maker was the last resort to offer since patient had already suffered much in the past adding to her morbidity and frequent hospital stay straining her financially as well. We can firmly say that a multidisciplinary approach and pre op case discussion helps to carry out such cases uneventfully and offers patient safe and satisfactory perioperative care by anticipating complications in advance and also helps in faster recovery and reducing hospital stay.

Conclusion

Leadless pacing is found to be an innovative approach for cardiac pacing while reducing the pitfalls of Trans venous pacemaker. This technology had shown outstanding results in the field of cardiac pacing. The future of leadless pacemaker devices is very promising and revolutionary and will eventually lead to expanded pacing capabilities.

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