Original Article

Facts and Factors about Permanent Pacemakers Lead Displacement

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Abstract

Objective: To share the authors' clinical experience with lead displacement in permanent pacemakers, identify the potential causes of this issue, and explore how these causes can be avoided to improve patient outcomes.

Methodology: For all those patients who presented with a displacement of lead, a detailed history was obtained, and their permanent pacemaker's implantation procedure record was re-examined for the possible causes of lead displacement. Site of device explored and the lead's integrity checked and readjusted. If the adjustment was not possible, then the lead was extracted, and the screwing system of the lead was examined outside the patient's body, and the new lead was implanted. All the data so collected was analyzed on SPSS version 22.

Results: Total 1670 procedure were retrospectively analyzed critically. There were 47 patients with lead displacement. Atrial lead displacement was documented in 10 cases. Ventricular lead was displaced in 37 patients. All patients with ventricular lead displacement had their initial placement of lead at the right ventricle apex. 20 lead were readjusted and 20 replaced. In 7 cases the old lead was nor extractible neither repositionable.

Conclusion: lead displacement in permanent pacemakers is one of the common complications which can best be minimized by taking care of all the responsible factors for lead displacement at the time of implantation.

Keywords: Artificial cardiac pacemaker, Cardiac resynchronization devices, Complications, Lead displacement, Pacemaker implantation

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Introduction

Lead displacement is one of the common complications in the implantation of cardiac implantable electronic devices (CEID).[1] It is defined as the change in the position of lead, which may or may not affect the function of the device. However, it becomes significant clinically only when it affects the function of the device.[2] It increases the cost and complications of the redo procedure. The redo procedure is cumbersome for the patient and prone to infection.[3]

Lead displacement is one of the most frequently reported complications following pacemaker implantation. It can occur early, within the first weeks post-implantation, or later due to physiological or mechanical reasons. Early lead displacement is often attributed to insufficient lead fixation or patient activity shortly after implantation, while late displacement may result from myocardial changes, device erosion, or mechanical lead failure. Both forms of displacement can compromise the pacing function and lead to adverse clinical outcomes, including symptomatic bradycardia, syncope, and even life-threatening arrhythmias.[4]

Globally, research has highlighted various factors associated with lead displacement. These include procedural factors such as suboptimal lead positioning, patient-specific characteristics such as age and comorbidities, and external influences like physical activity post-surgery. International literature has also described unique complications such as Twiddler's syndrome and Reel syndrome, where device manipulation can lead to lead displacement and malfunction.[5,6]

Beside its cost and pain, in permanent pacemakers lead displacement may immediately endanger the life of the patient and then, it will demand urgent intervention.[3] Patient with displaced lead can present with dizziness, near syncope, syncope, lethal arrhythmia.[2] It can lead to sudden death without any prior warning.[7]

It may be an incidental finding at time of routine check up and programming of the device. In these cases, mostly the patients are not fully dependent on pacemakers, or the patient's escape rhythm is such that it will be helping the patient hemodynamically, and he is either asymptomatic or complaining of mild dizziness.[2]

Patient electrocardiography (ECG) will show inappropriate pacing spikes that are under sense without being captured.[2] The displaced lead may be appreciated in a chest x-ray. In these cases patient needs both Posterior- Anterior- (PA) view and lateral view.[2] On programming of the device, the impedance of the lead is increased but either the pacing threshold is very high or it is not capturing at all.[8] Sometime the lead on Roentgenogram looks normal in position and the impedance is within normal range but the device fails to capture. These are called micro dislodgment.[2] Mostly, the displacement is confirmed under fluoroscopy.

While international studies provide valuable insights into the mechanisms and management of pacemaker lead displacement, these findings may not be entirely generalizable to the Pakistani population due to differences in healthcare infrastructure, patient demographics, and clinical practices. Recent international literature, including studies conducted over the last decade, has provided robust data on preventive strategies, such as lead anchoring techniques and early post-operative monitoring.[9] However, there is a lack of complementary national data to contextualize these findings within Pakistan's unique healthcare environment.

However if it is the atrial lead which is displaced, the patient may be asymptomatic at all or will present with pacemaker's syndrome.[3,10] Patients with ventricular lead displacement need urgent replacement. Since the rhythm of these patients with ventricular lead displacement is not reliable, even if the patient is not symptomatic, therefore they should have temporary pacemaker implantation immediately and then can be scheduled for readjustment.[11]

In this study, we share our experience of this important issue in device implantation and try to find the possible causes that can best be avoided.

Methodology

The study was conducted at the Electrophysiology Department of Hayat Abad Medical Complex, Peshawar, Pakistan, from June 2010 to April 2021. Informed consent was obtained from all patients presenting with lead displacement.

All patients with lead displacement underwent a detailed history-taking regarding their permanent pacemaker implantation procedure. The hospital records of the procedure, the implanting interventionist, and the follow-up records were re-examined to identify potential causes and the timing of lead displacement.

Routine baseline investigations were performed, including virology testing, complete blood count with erythrocyte sedimentation rate (ESR), and random blood sugar. A temporary pacemaker was implanted during the procedure. Patients were started on broad-spectrum antibiotics 24 hours before the procedure, per the hospital protocol. If required, the chest was shaved, and the area was painted with pyridine the night before the procedure.

Under fluoroscopy, the lead and device were examined, and the device was assessed using a telemetry programmer. The patient was then scrubbed and draped. The site of the device was explored, and the device was retrieved and detached from the lead. The lead was then made free from any surrounding adhesions and fibrosis.

In this study, we prioritized several variables considered crucial in influencing lead displacement out-

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comes. These variables included patient demographics (age, sex), lead type (screw or tine), implantation site, operator experience, and device type (single or dual chamber). These variables were selected by a thorough review of the literature, clinical relevance, and observational insights gathered during the study period. Additionally, procedural factors such as duration, post-implantation protocols, and patient comorbidities, including diabetes and hypertension, were examined for their potential impact on lead stability. Data analysis focused on evaluating the interplay between these variables and lead displacement through statistical models, including chi-square tests and regression analyses. This comprehensive approach was intended to provide a nuanced understanding of the factors contributing to lead displacement, thereby aiding in targeted preventive strategies.

The integrity of the lead was checked, and an attempt was made to readjust it. If readjustment was not possible, the old lead was extracted, and the screwing system of the lead was examined outside the body. If necessary, a new lead was implanted. In some cases, the old lead was not extractable due to heavy fibrosis within the heart; in such cases, the lead was capped and buried in the pocket, and a new lead was implanted following a venogram.

The threshold of the new lead was checked, and if the device life was deemed reasonable (i.e., greater than two years), the same device was reattached. If the device's lifespan was less than two years, a new device was implanted. The wound was closed in layers.

Data were collected using a pre-formed Performa, and all collected data were analyzed using SPSS version 22 for frequency, mean, and mode.

Table 1. Frequency of etiology and percentages of lead displacement

Diagnosis	Frequency	Percent (%)
Blocks	1454	87.1
Battery Depleted	70	4.2
Hypertrophic Cardiomyopathy (HCM)	1	0.1
Near Erosion	1	0.1
Syncope	1	0.1
Heart Failure (HF)	53	3.2
Arrhythmia	34	2.0
Infected & Erosion	10	0.6
Lead Fracture	4	0.2
RV Perforation	1	0.1
Lead Displacement	41	2.5
Total	1670	100.0

Table 2. Complications during the procedure

Complication	Frequency	Percent (%)
Lead Displacement	6	0.4
Failed	3	0.2
SVC Dissection	2	0.1
Mild Pericardial Effusion	1	0.1
Hematoma	3	0.2
Infection	3	0.2
Pneumothorax	16	1.0
Lead Damage	3	0.2
No Complication	1633	97.8
Total	1670	100.0

Results

A total of 1670 procedures were retrospectively analyzed critically. The results of the study are tabulated in Table 1 and Table 2, and ventricular lead displacement, respectively. Among the procedures, there were 1030 (61.7%) single-chamber pacemakers and 535 (32%) dual-chamber pacemakers. Male patients in the study were 962, and female patients were 708. The mean age of the patients was 60.47 ± 16.35 years. Other devices included Cardiac Resynchronization Therapy (CRT) devices, Automatic Implantable Cardioverter Defibrillators (AICD), and loop recorders. A total of 1592 screwing leads, 28 tine leads, 49 screwing and tine leads, and one leadless device were used. The maximum age of a patient in the study was 100 years, and the minimum was 10 years.

The results of patients diagnosed with lead displacement at presentation to the outpatient department (OPD) are shown in Table 1. The results of complications during or soon after the procedure during the patient's index stay are shown in Table 2. A total of 47 patients with lead displacement presented during the study period. Among these, 41 (87.23%) cases presented to the OPD in the follow-up clinic, with or without symptoms (see Table 1), and 6 (12.77%) cases were identified as complications of the implantation procedure during their hospital stay after primary implantation.

Patients who came to the OPD and were diagnosed with lead displacement had their devices implanted either at our center or at other centers, sometimes years after the initial implantation. The rate of acute displacement as a complication during the first month post-procedure was very low at our center, approximately 6 cases (0.4%), and all of these were atrial lead displacements. A total of 10 atrial lead displacements were documented, with 9 leads successfully re-implanted. In one case, the lead was left in place as the patient was asymptomatic and unwilling to undergo a redo procedure.

Ventricular lead displacement occurred in 37 patients, with 4 tine leads displaced and the remainder being screwing leads. All patients with ventricular lead displacement had their initial lead placement in the right ventricle apex. Of these, 20 leads were readjusted, 7 could not be retrieved and were capped and left in situ, while new leads were implanted. In 10 cases, the old leads were successfully mobilized but could not be repositioned, so they were explanted and replaced with new leads.

Discussion

Lead displacement is one of the common complication of PPM.[1] The reported incidence of this complication is 5% to 13% in different studies.[2] In one large registry of 1929 patients from Dutch high-volume teaching hospital the reported incidence was 4.4% for lead dislodgement from January 2010 to December 2011.[12] Lead displacement is divided into two groups: early occurs within the first six weeks of implantation, and late displacements occurring after six weeks.[2] The rate of early dislodgment for VVI pacemakers reported up to 1 % and more than 5% for dual chamber pacemakers.[2] So obviously it is the atrial lead which dislodges more frequently. The reported acceptable rates is less than 1 percent for ventricular leads and about 2% to 3% for atrial leads.[2] however in biventricular pacing devices, the coronary sinus lead displacement, is about 2% to 10.6%.[13]

When we compare our own data with the international reported lead displacement, among 1670 patients in our study with different type of CIED, we came across total 47 (2.9%) lead dislodgments. Six (0.4%) leads displacements were observed in the hospital stay after first implantation and 41 (2.5%) cases presented after discharge of the patients from the hospital. These patients either came to emergency room with symptoms or were picked during routine follow up and were asymptomatic.

There were 4 cases of right ventricle tine lead dislodgment, and all were in the early period. As tine leads are stabilized by tiny prongs made of the same material as that of covering insulation of the lead, typically silicone rubber. These prongs protrude backward from the base of the distal tip. Their orientation is designed to allow advancement of the lead for initial implantation but to prevent retraction and dislodgement by engaging the myocardial trabeculae of the right atrial appendage and right ventricular apex. Later on there is inflammatory reaction which induce fibrosis and adhesion and hold it in place. In the early period when there is no fibrosis they can easily dislodged. Tine leads are no more in practice at our center.

The lead dislodgment in CRT-P[13] and AICD[14] remain 4.3% in our study closely in the range of other studies.[15] These displacements were also mostly in the early period of implantation. These were left ventricular (LV) leads which displaced. As the LV leads are placed in the coronary sinus without any anchoring mechanism so these are very prone to dislodgment.

There were 41 cases of RV lead displacement with screwing leads. Of these, there were 37 cases of lead displacement in the single chamber pacemakers. The reported data of lead displacement is controversial for dual chamber vs. single chamber pacemaker's devices. Some data report more displacement in dual chambers devices,[2] while other documented more displacement in single chambers devices.[16] The possible explanation for this controversy is the implantation rate of single vs. dual chambers devices and experience of the operator.[16] Most of our device implantation is non-insured at our center, therefore mostly VVI is implanted

and most of VVI are implanted by relatively less experienced operator, therefore, the rate of displacement is more in VVI in our study. The devices are implanted under fluoroscopy. The two-dimensional picture of the heart by fluoroscopy will easily detract the less experienced operator.[17] These operators mostly fixed the leads in chordate, which may displace easily.

In a few cases, we note a piece of cardiac tissue in the screwing coil when the displaced lead was examined outside the body. This was the cause of failure of repositioning. The tissue was neither allowing the de-screwing mechanism nor allowing re-fixing of the lead in cardiac chambers.

We observed that inexperienced operator repeatedly screws and unscrews the lead to adjust the position. This will damage the screwing system and the lead will loosely hang in cardiac tissue and the operators will not be appreciating the stability so the lead will dislodged later on. Most of the time they either under screw the lead, so the lead fail to fix or over screw the system and will damage the screwing system.

Similarly, lead structure is another important factor in lead stability. Stiff PPM leads which were mostly used previously are very notorious for RV perforation on one hand[18] but soft and very flexible leads increased the rate of displacement on the other hand. Similarly coronary sinus lead, which could not be fixed, will increase the displacement ratio.[13]

Some procedurerelated factors may be responsible for lead displacement. If the lead sleeve is fixed with subcutaneous tissue, it can pull the lead. Similarly if the sleeve is not well pushed inside the muscle the lead will come out between sleeve and underlying muscle and easily will pull the lead out of the heart. Similarly if the device is not properly fixed in pocket, and if there is loose space like in elderly patients, the device can move in the pocket and can displace the lead.

At time Twiddler's syndrome[19,20] may be responsible for lead displacement. Patients intentionally or unintentionally start rotating the device manually and the, lead starts rolling around the device and displacing it. In Twiddler's syndrome, the rotation of the generator is on its long axis, which causes damage to the leads by twisting and lead needs to be prepalaced.[21] Reel's Syndrome is similar to the Twiddler's Syndrome. Reel syndrome contrary to Twiddler's syndrome, manifests with the rotation of generator on transverse axis with leads coiling around it.[21] Reel syndrome commonly occurs within a month of implantation and normally there is no damage of the leads.[21] This is the reason why normally there is no need of lead change, unlike Twiddler's syndrome where the leads are usually damaged and their replacement is almost mandatory.[22] where the patient move the device in transverse direction and so displace the lead. Similarly, Ratchet syndrome is caused by retraction and electrode dislocation with ratcheting but without coiling of the generator due to progressive displacement of the electrodes from their fixing protections.[23] These disabilities can be diagnosed on X-Ray chest. Mostly, these syndromes are prevalent in children.

Pacemakers lead displacement is more in dual chamber or biventricular pacing devices.[24] In dual chamber device it is the atrial lead which displaces more.[3] In this case the possible factor is the loop, if it is very long, it will drags the lead down and second, its hanging position, which prone it to displacement in the early period before fibrosis of the implanting area occurs.[16]

The last but not the least is the right atrial (RA) and right ventricle (RV) morphology. The right atrial appendage is often amputated at the time of cardiopulmonary bypass. Because of concerns regarding lead displacement, use of active fixation atrial leads has been recommended in patients who require permanent atrial or dual chamber pacing after open heart surgery.[25] Similarly, patients with Ebstein's anomaly present unique challenges to permanent pacing due to anatomical variations and tricuspid valve replacement.[26]

These may be not the complete list of factors responsible for lead dislodgment and careful observation may reveal more important risk factors. Therefore, to minimize the rate of dislodgment, the procedure should always be supervised by a senior fellow. Proper lead size according to the height of the patient should be selected.

The previous used hard structure leads should not be used. The loop of the lead inside the heart should be just enough so that it not put traction on lead. While fixing the lead, it should be directed posteriorly toward the septum, so to avoid hanging the lead in chordae tendineae which may lead to dislodgment.

Future work in this area should focus on exploring alternative lead and device designs with the potential to minimize displacement risks while maintaining optimal functionality. Additionally, the development and implementation of standardized training programs for operators could improve implantation practices, leading to a decrease in lead displacement rates. Moreover, future research could examine the possible benefits of advanced imaging techniques in guiding the implantation process to reduce lead displacement rates effectively.

Despite the insights gained from this study, it is not without limitations. The single-center nature of the study may limit the generalizability of findings to broader populations. Additionally, the retrospective design poses inherent challenges, such as reliance on the accuracy and completeness of recorded data. While the study provides valuable data on lead displacement, gaps remain in understanding its long-term implications, particularly in diverse patient populations and evolving device technologies. Further multi-center and longitudinal studies are needed to address these

gaps and explore innovative lead and device designs to reduce displacement rates.

Conclusion

Pacemaker's lead dislodgment is not very uncommon complication. There is no one risk factor responsible for lead displacement. However if all the factors are kept in mind at time of implantation, the rate of this complication can significantly be reduced, if not completely avoided.

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Authors' Contribution Statement

ZAK contributed to the conception, design, acquisition, analysis, interpretation of data, and drafting of the manuscript. MAK contributed to the analysis, interpretation of data, drafting of the manuscript, and final approval of the version to be published. All authors are accountable for their work and ensure the accuracy and integrity of the study.

Conflict of Interest

Authors declared no conflict on interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.