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AN EXPERIENCE WITH IMPLANTATION OF DDDR PERMANENT PACEMAKER (PASSIVE FIXATION) TECHNIQUE AT ARMY CARDIAC CENTRE LAHORE AND EXPLORING THE ASSOCIATION OF AGGRAVATION OF PROCEDURE WITH GENDER AND DIABETES

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Abstract :

Background *: The number of permanent pacemaker insertions in the Pakistan has been steadily increasing. The study aims to curtail the complications of dual chamber pacemaker implantation in heart block patients through the use of passive fixation technique. Complications being displacement, cardiac perforation and wound infection which elevate morbidity and mortality.*

Method*: A series of 150 consecutive patients were implanted permanent pacemakers for either complete heart block (CHB) or Sick Sinus Syndrome (SSS) at Army Cardiac Centre Lahore from January 2014 to June 2017.A retrospective study was carried out to determine the results of Passive Fixation Technique using Steroid Eluting Tined Leads in both Right Ventricle (RV) as well as Right Atrium (RA).*

Results*: The Findings of this study indicated that out of 150 patients that were followed up after implantation not even a single patient had lead dislodgement or Cardiac Chamber Perforation. It was observed that only four patients reported with superficial wound infection which was managed successfully through appropriate antibiotics whereas only one with deep wound infection for which pacemaker was explanted and replaced successfully. Male patients having diabetes had a greater risk of developing complications with the procedure.*

Conclusion: *This study showed that implantation of Dual Chamber (DDDR) permanent pacemaker using Passive Fixation Technique is feasible and safe with minimum rate of complications that include lead displacement, cardiac perforation and pocket wound infections in patients with complete heart block and sick sinus syndrome. There is highly significant positive association of diabetes and male gender with aggravations of the procedure, p value < 0.001(0.000).*

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INTRODUCTION:

Cardiac Pacemaker is a Medical device which provides support to the pace generating system of heart in case of inadequate functioning of the conducting system of heart. The Implantation of Permanent Pacemaker is a lifesaving intervention in patients suffering from complete heart block or sinus nodal dysfunction. From 2014 onwards Dual Chamber (DDDR) permanent pacemakers using Passive Fixation Technique have been routinely used at Army Cardiac Centre Lahore.

First Permanent Pacemaker was implanted in 1960 however, a major development, evolving in the 1970`s, was the trans venous lead for permanent pacemakers which eliminated the need to open the chest and sew an electrode into myocardium. Instead, an electrode could be passed through a vein under the clavicle and into the right ventricular chamber, eliminating the need for cardiac surgery. However, there had been a number of setbacks associated with the procedure as well.

Chronologically speaking, there are early displacements, which occur within the first six weeks after implantation, and late displacements, after this period of time. Early displacements are more frequent than late displacements and they usually affect atrial leads. The incidence of early displacements is 1% in VVI pacemakers and 5.2% in DDD pacemakers (3.8% of the cases affecting atrial leads and 1.4% ventricular leads).These values are higher in biventricular pacing devices, related to coronary sinus lead displacement. Early lead displacements are the most frequent cause of re-intervention, involving atrial leads in the majority of cases.

Lead Dislodgement and Displacement is a relatively common problem and can occur in 5-10% of the patients [1].
Atrial Lead Dislodgement is slightly more common than it is for ventricular leads. Acceptable dislodgement rates should be probably less than 1% for ventricular leads and no more than 2-3% for Atrial leads.

Passive Fixation leads are stable in the atrial appendage and Active Fixation leads are necessary to prevent dislodgement in patients with prior cardiac surgery, the use of which is associated with higher rate of Cardiac Chamber Perforation.

STUDY MATERIAL AND METHOD:

A descriptive study carried out at Army Cardiac Centre Lahore to study the results of Passive fixation Technique while implanting Dual Chamber permanent pacemakers (DDDR).The study Population comprised of 150 consecutive patients presented in the Department of Cardiology at Army Cardiac Centre Lahore from January 2014 to June 2017.This study included patients who underwent permanent pacemakers (DDDR) implantation due to complete heart block, sick sinus syndrome or symptomatic bradycardia. These patients were followed up in the outdoor department of Cardiology at ACC Lahore and outcomes were collected.

RESULTS:

Table 1: shows number of implantations done from January 2014 to June 2017.

YEAR	NO OF DDDR
2014	41
2015	46
2016	40
2017 (30th June)	23
Total	150

Table 2: shows total number of associated complications following the implantation procedure from January 2014 to June 2017.

COMPLICATION	Rate/ Frequency
Lead Dislodgement	0
Cardiac Chamber perforation	0
Superficial wound infection	4
Deep Wound infection	1

Table 3: shows total number of males and females in the study.

Gender	frequency
Male	97
Female	53
total	150

Table 4: shows total number of diabetics and non-diabetics taking part in the study

Diabetics	111
Non diabetic patients	39
total	150

As shown in table1 there had been 41 DDDR pacemaker implantations employing passive fixation technique in 2014, 46 implantations in 2015, 40 implantations in 2016 and 23 from January till June 2017 accounting for a total of 150 implantations in which as shown in table 2 there had been 4 superficial and 1 deep wound infection whereas no perforation and dislodgement had been reported. Table 3 shows that there were 97 males and 53 females with percentage being 64.7% males and 35.3% females and 111 diagnosed diabetics as shown in table 4.

DISCUSSION:

The Implantation of Permanent Pacemaker is a lifesaving intervention in patients suffering from complete heart block or sinus nodal dysfunction. The 1st single chamber VVIR PPM was implanted on 09-09-2010 at Army cardiac Centre Lahore. From 2014 onwards Dual Chamber (DDDR) permanent pacemakers using Passive Fixation Technique are routinely used in which Steroid Eluting Tined leads (Capsure sense MRI surescan 58cm for the Right Ventricle and 53cm for the Right Atrium) were utilized and Excellent Results were obtained in terms of minimum Complications as displacement, dislodgement, perforation and infections. Study was carried out to see the results of (DDDR) PPM using Passive Fixation Technique in patients with CHB or SSS at Army Cardiac Centre Lahore which is a state of the Art Cardiac Care facility. Out of 150 patients only 4 patients reported back with superficial wound infection which were managed successfully with antibiotics and one patient landed in the emergency department with deep wound infection for which PPM was explanted and replaced. There was no RV and RA lead dislodgement in these 5 cases. `

Overview of cardiac perforation following pacemaker implantation

Acute and late complications from pacemaker implantation occur in a variable percentage of patients, ranging from 3.2% to 7.5% [2]. Cardiac perforation, which can lead to pericarditis, cardiac tamponade, or even death, is one of the important complications. The incidence of perforation after permanent pacemaker implantation is reportedly between 0.3% and 1.2% [3]. Most patients with a perforation complain of chest pain, dyspnea, and hypotension, thus making such symptoms important clues to an accurate diagnosis. Abnormal sensing or pacing parameters, and abnormal signs in chest radiography or echocardiography also indicate cardiac perforation. Almost all such instances tend to occur within 1 month after surgery, and the extraction of the lead is recommended when it is identified[4] However, some reports had also described successfully managed cases without extraction [2].

Predictors of cardiac perforation following pacemaker implantation

Multivariate analysis of 4280 permanent pacemaker implantations at the Mayo Clinic revealed that the use of a temporary pacemaker, helical screw leads, and steroids are the individual predictors of a

perforation, and elevated right ventricular systolic pressure is protective against perforation [5]. The risk of using screw-in leads has also been established in other case reports .[6] A recent review article proposed several candidates in addition to the risk factors of perforation; the type and the location of the leads, the heart muscle characteristics, anticoagulation therapy, patient age, gender, and body mass [7].

Active-fixation atrial leads

An atrial lead is essential for dual chamber pacing, but dislodgement of this lead is not uncommon. [2] In order to reduce the dislodgement rate, active fixation (screw-in) leads have been developed and have emerged in popularity because of their reliability and the relative ease of placement at sites with the optimal pacing and sensing thresholds, adding to lower dislodgement rates. However, active fixation leads are associated with rare complications, including pericarditis, atrial lead perforation, pericardial effusion with or without cardiac tamponade, and death. The leads increase the chance of perforating the thin-walled right atrium, which averages 2mm in wall thickness, compared to passive fixation [8]. Several risk factors may be responsible for the increased complication rate of screw-in leads [9]. Dissimilarity in the anatomy of the right atrium, such as an extremely thin-walled or multi-lobed atrial appendage may therefore play a role in the perforation. Previous reports have suggested that the implantation of active-fixation leads in the right atrial free wall is important risk factors responsible for increasing pericardial complications compared to the right atrial appendage. A prospective randomized study showed a similar frequency of lead tip positioning in the right atrial appendage and lateral atrial wall among patients with pericardial complications [10]. In addition, factors, such as the lead design and stiffness of the helix, skills of the operator are important. Over-screwing during atrial lead fixation, abrupt lead withdrawal without unscrewing, and distal positioning of the stylet while screwing should be avoided.

Differences among atrial lead types

Several types of atrial leads have been available; Active-fixation leads have multiple pros and cons. However, there is limited data to compare the atrial leads for the choice of fixation (passive or active) or lead shape (J-shape or straight) [11]. A randomized comparison between 2 active-fixation, steroid-eluting, and polyurethane insulated, bipolar atrial lead models that differed only in shape (J-shape or straight) showed equally favorable performance profiles for 1 year of follow-up. Dislodgments were only reported in the straight lead group in 5.9% of cases, while no dislodgments occurred in the J. shaped lead group. The rates of exit block and lead malfunction proved to be higher in the J-shaped group. Pericardial complications occurred in both groups in 1% of cases [12]. Lead macro dislodgment occurred in the straight lead group in another 1.9% of cases during the additional follow-up, and lead malfunction and excessive pacing thresholds without dislodgment occurred in the J-shaped lead group in 10.7% of cases and 3.8%in the straight lead group [13]. A prospective randomized comparison of the performance of J-shaped atrial leads with or without active-fixation revealed significantly lower pacing thresholds in the passive-fixation group at implantation, and this difference persisted at 1-year follow-up. The duration of fluoroscopy during the implantation procedure was significantly shorter in the passive-fixation group. Dislodgments were only reported in the passive-fixation group in 2% of cases, while pericardial complications occurred only in the active-fixation group in 6% of cases.[10] Another report also showed early dislodgment requiring subsequent lead repositioning to occur in 2.4% of passive-fixation leads, but in none of the active-fixation leads. The incidence of pericarditis following implantation of J-shaped active-fixation leads was 5% [14]. Passive-fixation leads are reported to have an excellent reliability and a very low incidence of atrial lead perforation [15]. While no difference in the J-shaped leads and straight leads in passive-fixation was demonstrated

Late lead perforation following pacemaker implantation

Late complications of pacemaker implantation that are well recognized include infection, failure of the atrial or ventricular lead to pace or sense appropriately, erosion of the pulse generator, and subclavian vein thrombosis. Delayed lead perforation has been defined as migration and perforation after one month of implantation. This complication has been reported to occur in 0.1-0.8% of pacemaker and 0.6-5.2% of implantable cardioverter defibrillator implantations.[4]However recent progress in diagnostic imaging has increased the number of case reports on late lead perforation. A retrospective investigation of 100 consecutive patients with permanent pacemakers or implantable cardiac defibrillators ,who underwent multidetector computed tomography revealed that 15% of patients had a lead perforation, and the perforation rate of active- and passive-fixation atrial leads were 12% and 25%, respectively.[8] This common phenomenon was confirmed by an autopsy study in which Myocardial perforation or penetration by an electrode was recognized in 5.3% of 111 autopsy cases of patients 60 years of age or over with

an implanted pacemaker. The perforation rate was 27.3% in active fixation atrial leads, and 0% in 10 passive leads. All the atrial leads perforated through the right atrial appendage but did not reach the outside of the pericardium in the diagnosis of delayed lead perforation, failure of pacing or sensing of the lead is an important clue. A recent report revealed that detection of lead dysfunction by an automatic home-monitoring system had fast and possibly life-saving capabilities for severe lead perforation [16]. Usually, the lead parameters, in particular the pacing threshold, will show a significant change following lead perforation, while many reports have demonstrated normal electrophysiological parameters. It was found that perforated leads did not show significant difference from non-perforated leads in the impedance, and the pacing threshold of all the perforated leads except for one was categorized as low [8]. A larger part of the electrode may have been in contact with the atrial myocardium, resulting in a lack of change in the lead parameters. Therefore, we should be aware that pacemaker malfunction may indicate perforation, but normal parameters do not exclude a perforation. Risk factors for late perforation have not yet been fully defined, although a research suggested that active fixation leads and anticoagulation therapy may represent predictors for the long-term development of a perforation [17]. Freedom from symptoms also does not exclude the possibility of there being a perforation, as almost all of the patients were asymptomatic. Interestingly, late lead perforation is characterized by a low rate of tamponade or death, although the mechanism underlying subclinical late perforation has not been elucidated[4]. Pacing or sensing failure requires lead repositioning or a new lead insertion for appropriate functioning of the pacemaker.

CONCLUSION:

This study confirms that Passive Fixation Technique during Dual Chamber Permanent Pacemakers has been found successful and feasible in terms of minimal rate of complication such as Lead dislodgment, Cardiac Perforation and pocket wound infection. The percentage of male patients having diabetes had a greater risk of aggravation of the procedure with highly significant positive p value <0.001(p=0.000)

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