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Original Article

Post procedural complications of cardiac implants done in a resource limited setting under 'C' arm: A single centre experience

Lt Col A. Jayachandra^a, Lt Col Vivek Aggarwal^b, Maj Sandeep Kumar^{c,*}, Col I.V. Nagesh^d

^a Classified Specialist (Medicine) & Cardiologist, Command Hospital (Northern Command), Udhampur, India

^b Assistant Professor, Department of Medicine, Armed Forces Medical College, Pune 411040, India

^c Graded Specialist (Medicine), Base Hospital, Delhi Cantt, India

^d Associate Professor, Department of Medicine, Armed Forces Medical College, Pune 411040, India

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ABSTRACT

Background: Cardiology interventions in peripheral hospitals is a challenging task where cardiologist have to fight against time and limited resources. Most of the sudden cardiac deaths occur due to arrhythmia and heart blocks/sinus node dysfunction. Our study is a single peripheral center experience of cardiac devices implantation using a 'C' Arm. The aim of this study was to post procedural complications of cardiac implants done in a resource limited setting under 'C' arm.

Methods: This study is done at a peripheral cardiology center with no cardiac catheterization laboratory (CCL) facilities. Consecutive patients reporting to cardiology center, between Jan 2015 and Oct 2016, with a definite indication for cardiac device implant were included in the study. All the procedure of implantation was done in the operation theatre under 'C' arm under local anesthesia with continuous cardiac monitoring and critical care back up.

Results: Total 58 device implantations were done from Jan 2015 to Oct 2016. The mean age of the patients was 67.15 ± 10.85 years. Males constituted almost two third (68.9%) of patients. The commonest indication for device implantation was sinus node dysfunction in 60.34% followed by complete heart block in 25.86% and ventricular tachycardia in 12.06%. No post procedure infection was observed in our study.

Conclusion: Device implantation constitute a major group of life saving interventions in cardiology practice. Our study has emphasised that when appropriate aseptic measures are taken during device implantation at peripheral centres, the complications rate are comparable to interventions done at advance cardiac centres.

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* Corresponding author.

E-mail address: sandeep.sapehia@gmail.com (S. Kumar).

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Introduction

Practice of cardiology in a peripheral setup without a catheterization laboratory is a big challenge. Most of the patients who require acute cardiac interventions initially report to peripheral centres for emergency care. Timely cardiac interventions are of paramount importance for optimal patient outcome. Advance cardiac care is generally centred around larger cities and most of people living in remote areas have limited accessibility to such centres.¹ Studies have demonstrated that rural population have higher mortality due to various cardiac ailments compared to urban population. Moreover, rural population have limited access to advance cardiac facilities in view of low income status, illiteracy and long travelling distances to larger cities.² Unlike other surgical interventions, cardiac device implantation is generally done in advance cardiac centres. Most of the sudden cardiac deaths (SCD) occur due to arrhythmia and heart blocks/sinus node dysfunction.³ Timely recognition of these diseases can prevent SCD in the population, but most patients are unable to reach cardiac centres for interventions. Performing the cardiac intervention in the peripheral resource limited setting is poorly studied and data available is very scarce. Timely interventions and device implantations in these patients can be life saving. Even in Indian Armed forces there is significant incidence of sudden cardiac deaths in combatants and their dependents in conflict zone and far flung areas. Similar, to national health setup, Armed Forces also have limited cardiac catheterization laboratories (CCL) for obvious reasons of economic sustainability of technology. Our study is a single peripheral centre experience of cardiac devices implantation using a 'C' Arm. Our study has demonstrated that when basic aseptic measures are taken, cardiac devices can be successfully implanted in peripheral centres. If further data is analyzed from experiences of various cardiologists, possible national policy can be framed for cardiac device implantation in peripheral hospitals. This would enable offering cardiac intervention facility to larger population within limited economic resources. The aim of the study was to study the peri and post-procedural complications including infections and outcome of cardiac devices implanted in a peripheral hospital under 'C' arm in a resource limited setting.

Materials and methods

This study was done at a peripheral cardiology centre with no cardiac catheterization laboratory (CCL) facilities. Fluoroscopy in CCL is a standard technique used for device implantation where continuous images can be seen on a monitor and it also enables taking images in various planes. In our study the device implantation is done in a resource limited setting in routine operation theatre of a hospital under 'C' arm which does not offer advantages of fluoroscopy and CCL. Consecutive patients reporting to cardiology centre, between Jan 2015 and Oct 2016, with a definite indication for cardiac device implant were included in the study. Indications for device were based on symptoms, electrocardiography and holter monitoring. Cardiac devices used were single chamber pacemaker (VVI/VVIR), dual chamber pace maker (DDD/DDDR), automated

intracardiac cardioverter defibrillator (AICD) and implantable loop recorder (ILR). Active fixations leads were not used in our procedures due to limited fluoro time/plane and poor window quality, not allowing complete visualization of the screw. Patients who were candidates for biventricular pacing were referred to the cardiology centre with CCL facilities. All the patients who presented with cardiovascular instability underwent temporary pacemaker implantation for stabilization before the device placement was done. All the procedure of implantation was done in the operation theatre under 'C' arm under local anaesthesia with continuous cardiac monitoring and critical care back up. Left subclavian was a preferred vein for lead implantation into the right ventricular apex and/or Rt atrial appendage. The implant time for cardiac devices was 35 ± 5 min (including fluoro time of 10 ± 4 min) and 50 ± 10 min (including fluoro time 14 ± 4 min) for single and double chamber devices respectively. Prophylactic parenteral antibiotics were used in all the patients with injection teicoplanin 400 mg and Inj Amikacin 500 mg or Inj Piperacillin/Tazobactam 4.5 g 2 h before the procedure. Parenteral antibiotics were continued for five days after the procedure followed by oral antibiotics for 5 days. All the patients were monitored in ICU/HDU for 48 h post procedure. Patients were followed for 04 weeks post procedure. Radiograph of the chest was done post procedure to confirm the lead placement and for detection of pneumothorax. Immediate and late complications including the cardiovascular events were recorded. Baseline co-morbidities, indication for pacemaker implantation and post surgical site infections and haematomas were also recorded.

Results

Total 58 device implantations were done from Jan 2015 to Oct 2016. Most of the patients were in the age group of 60–79 years (77.5%) with 2 (3.4%) below 40 years and 4(6.89%) above 80 years. The mean age of the patients was 67.15 years with SD of 10.85%. Males constituted almost two third (68.9%) of patients. Hypertension was the commonest comorbidity noted in the patients with 18.96% of patients followed by respiratory diseases (15.51%), CAD (12.06%). The commonest indication for device implantation was sinus node dysfunction in 60.34% followed by complete heart block in 25.86% and ventricular tachycardia in 12.06% of the patients. One patient underwent implantable loop recorder implantation for recurrent unexplained syncope. Details are as depicted in [Table 1](#).

The commonest device implanted was single chamber pacemaker in 67.24% of the patients followed by dual chamber pacemaker in 19% patients, and AICD implantation in 12% of the patients. One patient underwent ILR implantation for recurrent syncope. Details are depicted in [Table 2](#). Immediate peri-procedural complications were noted in 12% of patients with no mortality. One patient had sudden cardiac arrest following VT within 1 h of procedure and was successfully revived. One patient each had SVC dissection, periprocedural small pneumothorax left, vasovagal episode, acute confusional state following lignocaine injection and haematoma at the implant site. One patient required lead repositioning and was shifted to cardiac catheterization centre. Details of complications are described in [Table 3](#). There was no case of post

Table 1 – Baseline characteristics.

Patient criteria	No of patients n = 58(100%)
Age	
≥80 years	4 (6.89%)
60–79 years	45(77.5%)
40–59 years	7(12.06%)
<40 years	2(3.44%)
Mean age	67.15 years (SD 10.85)
M:F ratio	2.2:1 (40:18)
Comorbidities	
Coronary artery disease	7 (12.06%)
Respiratory diseases	9 (15.51%)
Cardiomyopathies	4 (6.89%)
Chronic kidney disease	5 (8.62%)
Diabetes mellitus	6 (10.34%)
Hypertension	11 (18.96%)
Ischaemic stroke	2(3.44%)
Fracture neck of femur	2 (3.44%)
Hypothyroidism	1 (1.72%)
Indications of device implantation	
Complete heart block	15 (25.86%)
Sinus node dysfunction	35 (60.34%)
Ventricular tachycardia/fibrillation	7 (12.06%)
Unexplained recurrent syncope	1 (1.72%)

Table 2 – Types of cardiac devices implanted.

Type of device implanted	Number of patients (n = 58)	Percentage
Single chamber pacemaker (VVIR/VVI)	39/58	67.24%
Dual chamber pacemaker (DDDR/DDD)	11/58	18.96%
AICD	7/58	12.06%
ILR	1/58	1.72%
AICD, automated implantable cardiac defibrillator; ILR, implantable loop recorder.		

Table 3 – Post procedural complications.

Complication	No of patient n = 7/58(12.06%)	Type of device
Sudden cardiac arrest with in 01 h after the procedure	1/7	SCP
Lead repositioning	1/7	DCP
SVC dissection	1/7	SCP
Peri-procedural small pneumothorax Lt	1/7	AICD
Vasovagal episode	1/7	SCP
Acute confusional state after a local injection of lignocaine	1/7	AICD
Haematoma at the implant site	1/7	DCP
SCP, single chamber pacemaker; DCP, dual chamber pacemaker; AICD, automated implantable cardiac defibrillator.		

procedural surgical site wound infection or device explanation. One patient with post procedural haematoma required clot evacuation.

Discussion

Study done by Herce et al. showed that cardiac infections were noted in 1.4% of the patients with diabetes, heart failure and use of more than one lead being the independent risk factors.⁴ A recent meta-analysis has shown that the rate of infection after cardiac device implantation is on rise leading to increased health care cost and morbidity. The rate of device infection in this study was noted to be 1–1.3% with diabetes, CKD, COAD, steroid use, surgical site haematoma, heart failure and reintervention being important risk factors.⁵ Similar findings were also noted in the study done by Raad et al.⁷ However, all these studies were carried out in advance CCL with real time fluoroscopy. Extensive review of literature does not reveal any such studies done in a resource limited setting as ours. One study compared the complications rate following pacemaker implantation in smaller versus larger cardiac centres. This study revealed that there is no significant difference of complications between two centres.⁶ In our study no post procedural infections were noted, signifying importance of diligent preoperative and post operative strategies to prevent infections along with judicious use of the antibiotics. However, the number of patients in our study were small and the follow up was short. Larger multi-centric studies with stringent infection prevention guidelines are required to develop protocol based approach to prevent infections in these patients. Similar findings of proper preoperative risk assessment and close post procedural follow up were recommended in a study done by Raad et al.⁷ In another study it was noted that strict aseptic and antiseptic technique with use of double gloving and rinsing the pocket with povidone iodine along with antibiotic prophylaxis may prevent the infections after cardiac device implantation.⁷ The periprocedural complications were noted to be more common in women and elderly.^{8,9} In our study the complications were noted more in males with more than 90% of the patients being above 60 years of age. Most of the patients in our study had improvement in symptoms with improvement in the functional status. Two patients who were detected to have sinus node dysfunction during pre op evaluation of fracture neck femur were successfully operated and ambulated after the placement of PPI. Absorbable sutures were used in our study and no silk was used in order to prevent the post operative infections as silk sutures needs to be removed after 10 days with chances of suture abscess. Similar absorbable sutures were used in another study to prevent the infection.⁸ No study was found analyzing the use of cardiac implants in a peripheral set up using a 'C' Arm despite extensive literature search. In our centre too, prior to this study, the average cardiac device implant rate was 1–3 per year and limited only to emergencies. Hence, no compiled data regarding peri and post procedural data was found in the records. Limitations of the study included small number of patients with a short follow up as this is a single centre experience, vaccinations status for pneumococcal and influenza were not studied in any

patients. Our study has demonstrated that when basic aseptic measures are taken cardiac devices can be successfully implanted in peripheral centres. This would enable offering cardiac intervention facility to larger population within limited economic resources. In India about 68.8% of population reside in rural areas and significant number of population does not have easy access to bigger cities.¹⁰ Advance CCL and interventional institution are generally located in bigger cities. Poverty, illiteracy, long distances, and various socio-geographical conditions limits availability of facilities to such population. Affordability is one of the major issues with cardiac devices and any measures directed at cost cutting of cardiac devices would be a great impetus for cardiac care in country. Reuse of cardiac devices is one such measure which researchers have advocated and is being successfully practiced in western countries.^{11,12} Cardiac device implantation under 'C' arm in periphery could be major add-ons to such cost cutting measures. If cardiac devices can be implanted in peripheral health setups under 'C' arm, we would be able to offer advance cardiac interventions at point of care within available economic resources. Our study has revealed that cardiac devices can be implanted with limited complications, comparable to advance cardiac centres. This study has prospects to increase the reach of cardiac devices implantation to deprived population within available resources. If further data is analyzed from experiences of various cardiologists, possible national policy can be framed for cardiac device implantation in peripheral hospitals. However, larger such studies are desirable and the expertise needed to work in a resource limited setting should be encouraged.

Conclusions

Device implantation constitutes a major group of life saving interventions in cardiology practice. Our study has emphasized that when appropriate aseptic measures are taken during device implantation at peripheral centres, the complications rate are comparable to interventions done at advance cardiac centres.

Conflicts of interest

The authors have none to declare.

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