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Research Article

IMPLANTATION EXPERIENCE OF DEFIBRILLATORS AND CARDIAC RESYNCHRONIZATION THERAPY: THE NATIONAL INSTITUTE OF CARDIOVASCULAR DISEASES (NICVD), DEVICE REGISTRY 2017-18

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Abstract:

Introduction: The incidence of heart failure and sudden cardiac death is increasing at an alarming rate all around the globe and same is the case of Pakistan. The leading cause is ischemic heart disease but non-ischemic cardiomyopathies are also playing its part. It has increased the rate of heart failure, arrhythmia, and sudden cardiac death, morbidity and mortality have also been increased resulting in frequent emergency department visits.

Sudden cardiac death (SCD) is an important cause of death in adult and young patients. Over the past years, the rate of implantable cardiac defibrillator (ICD) implantation is increased dramatically all over the world. with advances in technology and improved training, techniques of implantation are improving, resulting in better outcomes in term of device-related infections, ICD therapy, lead problems, and generator issues, during and after implantation.

The National Institute of Cardiovascular Diseases (NICVD) cardiac resynchronization therapy (CRT) and ICD registry provides a real-time picture of the need for ICDs and CRT devices in clinical practice across Pakistan. NICVD, Karachi is the largest cardiac institute of Pakistan, which provides all cardiac services under one roof. And it receives patients from all over the country. Therefore, it is the recommended center to see the incidence of high energy devices in the Pakistani population.

Methods: This is a single center registry of NICVD, Karachi includes patients from May 2017 to June 2018, admitted through emergency or outpatient department and were diagnosed as a case of heart failure, survival of sudden cardiac death or cardiomyopathies. All cases are included on the base of ACC/AHA guidelines of device-based therapy.

All procedures were performed by experienced operators together with fellows in training under close supervision. Patients' characteristics, diagnoses, procedural details, and indication for placement of ICD were taken from history and hospital records. Complications related to implantation and adverse events occurring during follow-up were also extracted from hospital emergency or outpatient department.

Results: A total of 930 patient were included in this registry. Out of this biventricular pacing devices, CRTD were 216 (28.0%) and CRT P were 54(5.8%). Single ICD were 422(45.0%) and dual ICD were 238(25.0%).

Majority of patients were of ischemic cardiomyopathy that comes up to 726(78.06%) and non-ischemic cardiomyopathy were 204(21.93 %). Primary prevention, 704 (75.698%), were more than secondary prevention, 226 (24.30%). This also showed that male received more devices than female (730 (78.49%) vs. 140 (15.05%) patients. Diabetic were 499 (48.27%) and hypertensive were 475 (51.07%) among all patients. Hypertrophic cardiomyopathy (HCM) was in 16 (1.72%) and arrhythmogenic right ventricular dysplasia (ARVD) was in 10 (1.075%) also included are those who have high-risk feature or secondary prevention.

Conclusion: This report gives an overview of the clinical practice and device implantation. Heart failure patients are increased over the period of time, and the common cause according to this report is ischemic cardiomyopathy. Biventricular pacing therapy is also increased and CRT D were used more than CRT P. Gender difference was noted for device therapy as male received more high energy devices. High energy devices were used more for primary prevention.

Keywords: Heart Failure, Sudden Cardiac Death, ICD, CRT P, Cardiomyopathy

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INTRODUCTION:

The incidence of heart failure and sudden cardiac death is increasing at an alarming rate all around the globe and same is the case of Pakistan. The leading cause is ischemic heart disease but non-ischemic cardiomyopathies are also playing its part. [1] It has increased the rate of heart failure, arrhythmia, and sudden cardiac death. Morbidity has also increased resulting in frequent emergency department visits. [2-3]

Sudden cardiac death (SCD) is one of important cause of death in both adult and young patients. [4] Over the past years, the rate of implantable cardiac defibrillator (ICD) implantation is increased all over the world [5] as more and more patients are surviving from heart failure. [6-7] Implantable defibrillators (ICD) have proven mortality benefit in patients suffering from unstable ventricular arrhythmias. [8] With modern technology and improved training, techniques of implantation are improving day by day, resulting in better outcomes in term of ICD therapy, lead problems, and generator issues, device-related infections, during and after procedure. [9-10]

The National Institute of Cardiovascular Diseases (NICVD), CRT and ICD registry provides a real-time picture of the need of ICDs and CRT devices in clinical practice across Pakistan. National Institute of Cardiovascular Diseases (NICVD), Karachi is the biggest cardiac institute of Pakistan, which provides all cardiac services under one roof. And it receives patient from all over the country. Therefore it is the recommended center to see the incidence of high energy devices in Pakistani population.

METHODS:**Patient population:**

This is a single center registry, from National Institute of Cardiovascular Diseases (NICVD), Karachi. Patients were included for the duration of May 2017 to June 2018 in this registry. Patient were either admitted to hospital through emergency department or

outpatient department and were diagnosed as a case of heart failure, survival of sudden cardiac death and a case cardio myopathies. All the cases are included on the base of ACC/AHA guidelines of device base therapy. The procedures included in this study were performed by experienced operators along with fellows in training under direct supervision. Patients' details like indication, diagnoses, procedural details, for the placement of ICD and CRT were recorded accordingly.

Lead data:

P wave, R wave, pacing lead sensing, lead impedance, right ventricular (RV) shock impedance, and pacing thresholds were recorded from first interrogation of device after implantation, which is usually first day after implantation, 10th day and one month.

Implantation technique:

ICD implantation was performed in the dedicated electrophysiology lab under local anesthesia. The patient is placed in supine position, External defibrillator pads were placed in conventional manner. Venous lines were routinely used.

Device implantation in (sub/supra) pectoral position:

A 5cm incision was made over the either left or right deltopectoral region. A 53 or 52 cm atrial lead if indicated and 58 or 65 cm shock lead were preferably used through axis of the subclavian vein or cephalic vein as alternative in some cases. A subcutaneous pocket was created. The ICD/ CRT device after connecting the leads into its sockets is placed in the pocket and fixed with a non-absorbable suture. The incisions were closed once the homeostasis was controlled.

Epicardial implantation of left ventricular lead (mini thoracotomy):

Epicardial lead approach was used in CRT for left ventricular lead only, were coronary sinus was

difficult to approach have an inappropriate anatomy or no adequate branches for lead placement.

Pocket hematoma and evacuation:

Hematoma and infections included were those not fixed with adequate pressure dressing and antibiotic covers, had open the wound for correction.

Follow-up:

In hospital complications (3 days) including pneumothorax, pocket hematoma infection, lead

dislodgment were recorded in this data. Regular follow up was done on first post operated day than on 10th when patient came for removal of suture

RESULTS:

The total of 930 patients included in this registry, out of this biventricular pacing devices were CRTD in 216 (28.0%) and CRT P in 54 (5.8%) of the total devices. While, SICK were 422 (45.0%) and dual ICD were 238 (25.0%). Demographic profile, indications and implanted devices are presented in Table 1.

Table 1: Demographic profile, Indications and Implanted Devices

Characteristics	Total
Total	930
Demographic Profile	
Male	790 (84.94%)
Hypertension	475 (51.1%)
Diabetes	499 (48.27%)
Hypertrophic cardiomyopathy (HCM)	16 (1.7%)
Arrhythmogenic right ventricular dysplasia (ARVD)	10 (1.1%)
Indications	
Primary	704 (75.698%)
Secondary	226 (24.30%)
Ischemic cardio myopathy (IHD)	726 (78.1%)
Non-ischemic cardiomyopathy (NIHD)	204 (21.9%)
Devises	
Cardiac resynchronization therapy (CRT) devices	216 (23.2%)
Cardiac resynchronization therapy (CRT) pacemaker	54 (5.8%)
Single implantable cardioverter defibrillator (SICK)	422 (45.4%)
Dual implantable cardioverter defibrillator (DICD)	238 (25.6%)

Majority of the patient were of ischemic cardio myopathy that come up to 726 (78.06%) and non-ischemic cardiomyopathy were 204 (21.93 %). Primary prevention 704 (75.698%) are more than secondary prevention are 226 (24.30 %). This also showed that male 790 (84.94%) received devices more than female 140 (15.05%) patients. Diabetic are 499

(48.27%) and hypertensive are 475 (51.07%) among all patients. HCM 16 (1.72%) and ARVD 10 (1.075%) also included are those who have high risk feature or secondary prevention. Demographic profile and indications by implanted devices are presented in Table 2.

Table 2: Demographic profile and indications by implanted devices

Characteristics	CRT-D	CRT-P	SICD	DICD
Total	216	54	422	238
Demographic Profile				
Male	169 (78.2%)	31 (57.4%)	399 (94.5%)	191 (80.3%)
Hypertension	113 (52.3%)	33 (61.1%)	214 (50.7%)	115 (48.3%)
Diabetes	104 (48.1%)	22 (40.7%)	160 (37.9%)	163 (68.5%)
Indications				
Primary	166 (76.9%)	54 (100%)	303 (71.8%)	181 (76.1%)
Secondary	50 (23.14%)	0 (0%)	119 (28.1%)	57 (23.9%)
Ischemic cardio myopathy (IHD)	178 (82.4%)	0 (0%)	356 (84.4%)	192 (80.7%)
Non-ischemic cardiomyopathy (NIHD)	38 (17.6%)	54 (100%)	66 (15.6%)	46 (19.3%)

Complications during implantation:

Procedure related complication, that is included pneumothorax, were observed in 8 (0.86%) of the total 930 cases. Appropriate measure were taken chest X ray were taken and chest tube was done. Six patient recovered completely and two could not survive the event.

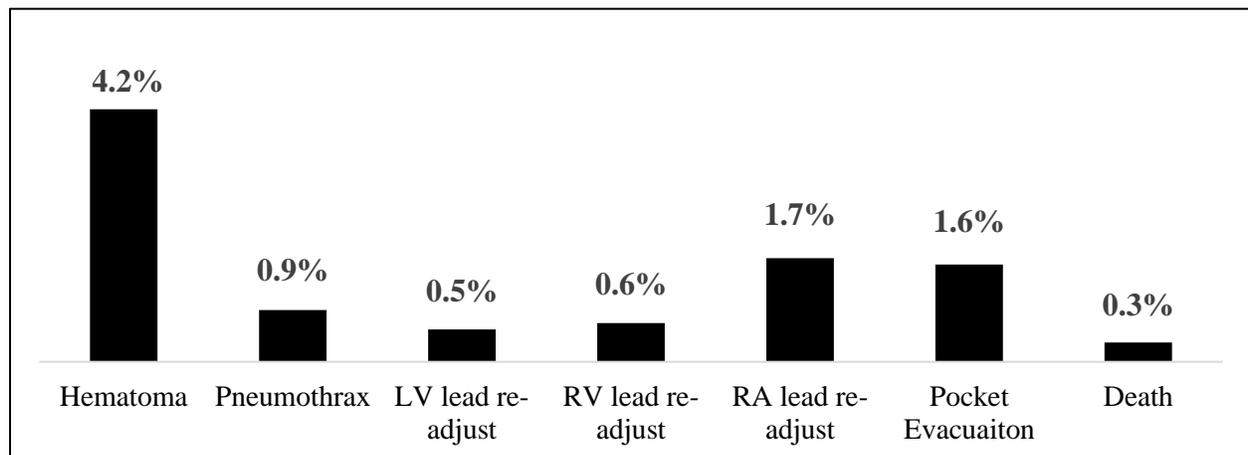
Hematoma was noted in 39 (4.1%) of patient in follow up period up to 10 days, all patient were reopened, evacuated with clotted blood and hemostasis secured. Patients were on dual antiplatelet or vitamin K antagonist that resulted in hematoma.

Pocket infection noted in 15 (1.61%) patient. In all patients transesophageal echocardiography was performed and blood cultures were sent to rule out infective endocarditis (IE). They received appropriate

antibiotic treatment for 2–4 weeks, and if not cured all system including battery and leads were replaced with new one on the contralateral side.

Left ventricular lead dislodgement was noted in 5 (0.53%) of biventricular pacemaker during follow up of 10 days and one month. In these patient coronary sinus lead repositioning was done.

Lead dislodgement is noted in 24 (2.5%) of patient that includes both right atrial and right ventricular leads. All leads were dislodge within one month of implantation were repositioned. Complications noted during follow-up period of one month after implantation are presented in Figure 1.

Figure 1: Complications noted during follow-up period of one month after implantation

DISCUSSION:

This report is a single center study. Cases of cardiac disease are drastically increase in our population. Number of devices implanted in a year has jumped high. Total high energy devices implanted are up to 930, and count is on the raise. The number of devices in the same period of time is much higher than Sweden and European registries. [11-8]

In Europe society the implantation rate for pacemaker in 2011 was 604 units per million inhabitants, with a marked heterogeneity between countries. [12] Data from the Swedish Pacemaker Registry is same as that of European average, shows pacemaker implantation rate in Sweden of 697 units per million inhabitants in 2012. [11] As regards ICDs, the mean implantation rate in Europe was 103 per million inhabitants in 2011. [12] In line with 2012 data from the Swedish ICD Registry (136 ICD implants per million inhabitants). Number of CRT-P implanted in Sweden is higher than Europe. 19 CRT-P implants per million in Europe in 2011 as compare to Forty-one (41) CRT-P implants per million in Sweden in 2012, with a lower ratio of CRT-D/CRT-P implants (on average 60% in Sweden vs. 80% in Europe). This high rate of CRT-P may reflect the opinion of the key opinion leaders that CRT-P is good enough or may reflect the somewhat lower costs and lower complication rate of CRT-P compared with CRT-D. [11]

Data from our study showed that the majority of patients receiving a high energy device are men. In particular, women represent only 140 (15.05%) and men are 790 (84.94%) of total ICD and CRT-D patients which comparable with the Swedish data where 80% are male. [11-13] Similar gender differences were seen in ICD therapy of sudden cardiac death for secondary or primary prevention as shown by previous studies. More patients were hypertensive 475 (51.1%) as compare to diabetic 499 (48.27%). CRT D were higher than CRT P in heart failure and NYHA III, IV and needed device base therapy. Single ICD are higher than dual ICD.

Our data showed that patient receiving high energy devices are mostly ischemic cardiomyopathy 726 (78.1%) than for any other cause. Devices are used more in primary prevention 704 (75.69%) than in secondary prevention 226 (24.30%). As compare to 41% of secondary prevention in Swedish registry. [11]

The complication rate noted in this Registry on ICD, and CRT were in line with previously reported data. [14] Complication rates was higher in ICDs with or

without CRT properties than for CRT alone. Re-intervention was done for lead-related complications, in particular lead dislodgment and hematoma. Notably, LV lead displacement rates 5 (0.53%) were quite low compared with earlier findings. Lead infection incidence is low. Death noted are only 3 (0.32%) in the mention duration out of which two were secondary to pneumothorax and one was due to tamponade as a coronary sinus cannulation complication.

LIMITATIONS:

The study is a single center national institute of cardiovascular disease descriptive report of data collection of deceive registry. Further investigation is required to analyze factors potentially influencing regional and global device implantation rates were out of the aim of this report. Phrenic nerve stimulation, left ventricular ejection fraction and NYHA class information were not available in the study. Clinical and echocardiographic and clinical response was not assessed for CRT patients.

CONCLUSION:

This report gives an over view about the clinical practice and device implantation. Heart failure patients are increased over the period of time, and the common cause according to this report is ischemic cardiomyopathy. Biventricular pacing therapy is also increased and CRT D were used more than CRT P. Gender difference was noted for device therapy as male received more high energy devices. High energy device were used more for primary prevention.

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