Australasian Medical Journal 2010, 1, 1, 23-27

A Clinical Review of Implantable Cardioverter Defibrillators and Bi-Ventricular Pacemakers at one Institute

Ahmad Nasir[1], Ravinder Batra[2], Rohan Jayasinghe[3]

[1]Gold Coast Hospital, Southport, [2]Griffith University School of Medicine, Queensland, Australia

CLINICAL AUDIT

Please cite this paper as: Nasir A, Batra R and Jayasingle R. A Clinical Review of Implantable Cardioverter Defibrillators and Bi-Ventricular Pacemakers at one Institute. AMJ 2010, 1, 1, 23-27 Doi 10.4066/AMJ.2010.129

Corresponding Author:
Ahmad Nasir
Gold Coast Hospital
Southport
radhiahmad@hotmail.com

Abstract

Background: ICD/BVP indications are expanding. They are expensive devices and historically, morbidities associated with their use were high. The starting experience at the Gold Coast Hospital is being reviewed.

Methods: A retrospective chart review of all the ICD/BVPs implanted in the Gold Coast Hospital from 06/07/2007 – 17/06/2008, with special emphasis on device indications and complications.

Results: Devices implanted were (31). Primary prevention devices (67%), secondary prevention devices (33%). Indications were; Non-ischemic Dilated Cardiomyopathy (35%), Out-of-hospital Cardiac Arrest (26%), Conscious VT (13%), Ischemic Dilated Cardiomyopathy (10%), In-hospital Cardiac Arrest (6%), Long-QT Syndrome (6%) and Catecholamine-related Polymorphic VT (3%). Major complications reported; lung contusion (1), left haemothorax (1), failed coronary sinus lead positioning (2), lead re-positioning (2), atrial lead removal (1), left subclavian vein thrombosis (1), lead malfunction leading to VT under sensing and syncope (1). Device-administered therapies were eight; Inappropriate discharges (5), Appropriate discharges (1), successful Anti-tachycardia Pacing (2).

Conclusions: We believe that ICDs are very effective life-saving devices but unfortunately they still are very expensive and their use can be associated with significant morbidities especially during the learning curve.

Introduction

ICDs are very effective in the secondary prevention of sudden cardiac death; their effectiveness over placebo and anti-arrhythmic drugs has been demonstrated in major multi-centre randomised controlled trials (6, 7, 8, and 9). The indications for the implantation of ICDs have quickly expanded from the secondary prevention of sudden cardiac death in persons who suffered a VT/ VF cardiac arrest to be used more in the primary prevention of sudden cardiac death in persons at risk of arrhythmic cardiac death after their effectiveness was shown in big trials (6,10,11,12,13) the factor which had the largest impact on the increase in their use in recent years, the benefit is claimed to be a 20–30% relative reduction in mortality at one year, which is maintained over 3–5 years of follow-up, the absolute mortality benefit was approximately 1–3% per year compared to standard medical treatment (1). BVPs is another area of device therapy which is quickly developing; BVPs reduce symptoms and frequency of hospitalisation when carried out in patients with symptomatic dilated CHF and prolonged QRS duration. A recent study has also demonstrated a mortality benefit of BVPs in patients with heart failure (1, 13). We wanted to present our own registry in the first year of our institute's experience with ICD/BVPs implantation, looking mainly at the implantation indications and all complications that we could trace.

Methods

A list of all ICDs and BVPs was taken from the catheter laboratory at the Gold Coast Hospital from the start of the program with the first ICD implanted on 6th July 2007 till the end of analysis period on the 17th July 2008 which included a total of thirty one devices, charts were requested and reviewed. Excel tables were created with the patients' characteristics, device indications, device type by function, device manufacturer, device cost, procedure time, hospital stay, use of antibiotics, use of chest x-ray to check for device position and procedure complication, device check by manufacturer, documented immediate complications, follow up including all device related re-admissions, device check-up and all adjustments, referrals to another institute and their outcomes.

Results

A total of 31 devices in 31 patients were implanted (25 male, 6 female), Mean patient's age was 58 years (20-75 years), and mean follow-up period was 9 months (3-15 months). Primary prevention devices were 21 (67%), secondary prevention devices were 10 (33%), the commonest single indication in our series was non-ischemic dilated cardiomyopathy (11 patients 35%), the second most common indication was out-of-hospital cardiac arrest which occurred in 8 patients (26%) while conscious VT was next (4 patients 13%), ischemic dilated cardiomyopathy 3 patients (10%), 2 patients (6%) had in-hospital-cardiac arrest, 2 patients had congenital long QT syndrome (6%) and 1 patient had catecholamine-related polymorphic VT (3%), table (1) .

For patient's characteristics, co-morbidities and medications refer to tables (2, 3, 4)

21 devices (70%) were single chamber ICDs with a single right ventricular sensing pacing and defibrillating lead, 4 devices (13%) were double chamber ICDs with an additional atrial sensing and pacing lead as well, 5 devices (16%) were BVPs with the addition of a coronary sinus lead to the double chamber ICD to pace the left ventricle to achieve cardiac re-synchronization function and finally, one patient had an ICD pulse generator replaced only (because of battery run out).

Devices manufacturers were; St. Jude Medical 17 devices (55%), Medtronic 11 devices (35%) and Guidant 3 devices (10%).

All devices were implanted subcutaneously in the left pectoral area; all patients had prophylactic antibiotics intra-operatively with intra-venous Cephazolin plus intra-venous Gentamycin in selected patients. All patients had prophylactic oral antibiotics with Cephalexin for 5 days post-procedure. All patients in our series had a check chest X-ray the first post-procedure day, all devices were checked by manufacturer, all patients had device check at 6 weeks and then at 6 monthly intervals thereafter except one patient.

The majority of the devices were implanted in a day procedure, 18 (58%), 8 patients (26%) had a hospital stay from 2-7 days, of them 3 patients had a conscious VT within the same hospital admission and 5 patients (16%) had a hospital stay of more than 7 days all of them had a cardiac arrest within the same hospital admission and a prolonged intensive care unit stay prior to the implantation procedure. Procedure duration was properly documented in 25 patients (80%), in the majority it was less than 90 minutes (17 procedures 54%), only 4 (13%) procedures lasted longer than 180 minutes and they were all BVPs.

Twenty one patients (67%) in our series had reported some complications, ten had reported none, and around thirty complication occurrences were documented. These were procedure related or device related. Procedural complications were; significant pain requiring narcotic analgesics in six patients, significant bleeding from implantation wound which required local pressure in two patients plus intra-venous desmopressin infusion in one patient, local hematoma in one patient which happened on the 8th post-procedure day secondary to minor trauma, minor haemoptysis on the 3rd post-procedure day in one patient (CT scan of the chest confirmed lung contusion which was managed conservatively) and one patient was admitted with left sided haemothorax on the 14th post-procedure day despite the fact that chest X-ray taken on the 1st post-procedure day was normal, required two inter-costal chest drains and video-assisted thoracoscopic procedure to stop the bleeding, two patients failed coronary sinus lead positioning for BVP, one patient eventually had an epicardial lead placed on mini-thoracotomy at another hospital to achieve BV pacing, the other was changed to single chamber ICD mode and the atrial lead was retrieved at a later date because that patient developed atrial fibrillation and failed cardio-version, one patient developed left subclavian vein thrombosis on the 10th post-procedure day, one patient developed persistent left shoulder and ICD pocket pain and was referred to another hospital to consider sub-muscular implantation of the ICD.

As far as the device complications are concerned, Inappropriate discharges occurred in four patients, in the first patient it was for a supraventricular tachycardia falling in the VT detection zone for that the ICD was re-programmed, in the second patient it was for a non-sustained VT after anti-tachycardia pacing mode failure secondary to under-rate detection for which ICD was re-programmed but inappropriate discharge recurred for a non-sustained VT as well which failed to respond to anti-tachycardia pacing therapy appropriately delivered by the device this patient was started on treatment with amiodarone to suppress the non-sustained VTs, in a third patient it was for an atrial flutter falling in the VT detection zone in whom a trial of radiofrequency catheter ablation of the atrial flutter was attempted but failed and both atrial flutter and inappropriate discharge of the ICD recurred, the patient was eventually referred to another hospital to attempt atrial flutter ablation with a thermo-cool catheter and 3D mapping, and in the last patient it was for over-sensing noise caused by ICD pocket manipulation, in this patient the right ventricular lead was unscrewed and re-inserted at the ICD pocket. One patient received an appropriate discharge which was for VF properly sensed and terminated. Other therapies administered were anti-tachycardia pacing which successfully terminated sustained VT in two patients.

Lead related complications occurred in five patients; coronary sinus lead needed to be repositioned in one patient because of diaphragmatic stimulation on the 22nd post-implantation day, right ventricular lead had to be repositioned into right ventricular apex in one patient on the 5th post-implantation day as was under-sensing, atrial lead had to be removed on the 10th post-implantation day in one patient as it was not in place and the patient developed atrial fibrillation which persisted after a trial of electric cardio-version, right ventricular lead had to be repositioned in one patient because of high threshold on the 29th post-implantation day and lastly one patient needed a special right ventricular lead to replace the original lead which was done in a different hospital because of VT un-detection leading to a syncopal event which happened on day 144 post-implantation. 44 of re-admission days directly related to ICD problems happened because of these complications, and a total of 4 patients had to be referred to another institute to deal with these complications as outlined above as our institute lacked the technology or the personnel to deal with those complications. For a summary of device complication refer to (table-5).

Discussion

ICD/BVPs are very effective life-saving devices that are also very costly which is an important limitation to their use; device only cost in our registry was 425950 Australian Dollars. In addition their use can be associated

with a lot of complications that can affect patients' quality of life quite adversely; these complications make the second important limitation to the expansion in their use. The incidence of ICD complications is difficult to determine due to inconsistent definitions and the lack of mandatory reporting. Information comes from annual reports filed with the United States Food and Drug Administration, by companies that make devices and from voluntary registries (2). Approximately 50% of patients experience an adverse event within the first year after ICD implantation (2, 3). The rate of freedom from any adverse event at 1, 3, and 12 months was 79, 68, and 51 percent, respectively as was illustrated in a prospective study of 778 patients receiving a trans-venous ICD (2,3). Among the complications that occurred, 60 % were due to the ICD system, 29 % were related to the implantation procedure and 11 % were not device-related (2). As far as procedural complications are concerned, a peri-procedural mortality of 0-0.8 % has been reported (2), incidence of severe bleeding was 1.5%, and infection of the generator pocket or leads has been reported in up to 7%. ICD system problems included lead failure; the estimated lead survival rates at 5 and 8 years are 85% and 60% respectively. The annual defect rate increases with time and reaches 20% in 10-year-old leads (5) mainly due to lead dislodgement, fracture, and insulation defects (2, 5). The other common complication is inappropriate shocks which occurred in 20-25% of ICD patients the main cause being supra-ventricular tachy-arrhythmias including sinus tachycardia, atrial fibrillation, and the other important cause is non-sustained VT (2).

In conclusion, we believe that ICDs are very effective life-saving devices but unfortunately they still are very expensive and their use can be associated with significant morbidities especially during the learning curve. We appreciate the limitation of our data and that generalisation is difficult because our sample size is quite small, and it early experience in a single public hospital with a relatively low volume of device implantation basically led by one cardiologist. But we believe that it represents the experience of many programs on a learning curve and we present our experience to help those planning to start a similar program.

Reference

1) Guidelines for the prevention, detection and management of chronic heart failure in Australia, 2006 (National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand)

2) Morton F Arnsdorf, MD, MACCLeonard I Ganz, MD, UpToDate.com®: article on (Implantable cardioverter-defibrillators: Complications).

3) Rosenqvist, M, Beyer, T, Block, M, et al on behalf of the European 7219 Jewel ICD Investigators. Adverse events with transvenous implantable cardioverter-defibrillators: A prospective multicenter study. Circulation 1998; 98:663.

4) Kleemann, T, Becker, T, Doenges, K, et al. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of>10 years. Circulation 2007; 115:2474.

5) Eckstein, J, Koller, MT, Zabel, M, et al. Necessity for surgical revision of defibrillator leads implanted long-term: causes and management. Circulation 2008; 117:2727.

6) DiMarco, JP. Implantable cardioverter-defibrillators. New England Journal of Medicine 2003; 349:1836.

7) The Antiarrhythmic versus Implantable Defibrillators (AVID) Investigators. A Comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. New England Journal of Medicine 1997;337:1576-83.

8) Connolly SJ, Gent M, Roberts RS, et al.Canadian Implantable Defibrillator Study (CIDS): a randomized trial of the implantable cardioverter defibrillator against amiodarone. Circulation 2000;101:1297-302.

9) Kuck KH, Cappato R, Siebels J, Ruppel R. Randomized comparison of Antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest: the Cardiac Arrest Study Hamburg (CASH). Circulation 2000;102:748-54.

10) Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implantable defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. New England Journal of Medicine 1996;335:1933-40.

11) Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. New England Journal of Medicine 2002;346:877-83.

12) Bigger JT Jr. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. New England Journal of Medicine1997; 337:1569-75.

13) Bänsch D, Antz M, Boczor S, et al. Primary prevention of sudden death in Idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). Circulation 2002; 105:1453-8.

13) Gervais R, Leclercq C, Shankar A, Jacobs S, Eiskjær H, Johannessen A, Freemantle N, Cleland JG, Tavazzi L, Daubert C; on behalf of the CARE-HF investigators. European Journal of Heart Failure. 2009 Jul; 11(7):699-705. Epub 2009 Jun 7.

PEER REVIEW
Not commissioned; externally peer reviewed

CONFLICT OF INTEREST
The authors declare that they have no competing interests.

TABLES

Table (1) Number of patients for each device indication

Device indication	Number of patients (%)
Primary prevention of SCD	21 (67%)
Ischemic DCM	3 (10%)
Non-ischemic DCM	11 (35%)
Conscious VT (LV scar tissue)	4 (13%)
LQTS	2 (6%)
CPVT	1 (3%)
Secondary prevention of SCD	10 (33%)
Out-of-hospital cardiac arrest	8 (26%)
Ischemic DCM	3 (10%)
IHD (LV scar tissue)	3 (10%)
IHD (LV aneurysm)	1 (3%)
LQTS	1 (3%)
In-hospital cardiac arrest	2 (6%)
Ischemic DCM	1 (3%)
IHD (LV aneurysm)	1 (3%)

Table key words: SCD (sudden cardiac death), LV (left ventricle), LQTS (long QT syndrome), CPVT (catechol-related polymorphic VT), DCM (dilated cardiomyopathy), IHD (ischemic heart disease).

Table (2) Patient characteristics

Patient's characteristics	Number of patients (%)
Echocardiography:	
Left ventricular dilatation	22 (70%)
Significant left ventricular	13 (60%)
dilatation (LVEDD > 60 mm)	26 (83%)
Reduced Left Ventricular EF (<	6 (23%)
50%)	5 (19%)
Mild LVSD (EF 40-49%)	15 (58%)
Moderate LVSD (EF 30-39%)	15 (50%)
Severe LVSD (EF < 30%)	13 (42%)
Regional wall motion	
abnormality (hypo/akinesia)	22 (71%)
Global left ventricular	11 (50%)
hypokinesis	10 (32%)
	1 (3%)
Coronary angiography:	
Normal coronaries	
Stable coronary artery disease	
(no intervention)	27 (87%)
Coronary artery disease	4 (13%)
requiring intervention (stent)	12 (38%)
	13 (42%)
Electrocardiography:	10 (32%)
Rhythm	2 (6%)
Sinus	1 (3%)
Atrial Fibrillation/ Flutter	15 (48%)
Pathological Q- waves	
Wide QRS complex	
LBBB pattern	
RBBB pattern	
NIVCD pattern	
Non-specific T wave changes	

Table key word: LVEDD (left ventricle end-diastolic dimension), EF (ejection fraction), LVSD (left ventricular systolic dysfunction), LBBB (left bundle branch block), RBBB (right bundle branch block), NIVCD (non-specific intra-ventricular conduction delay).

Table (3) Patients' co-morbidities

Co-morbidities:	Number of patients (%)
Ischemic heart disease:	17(55%)
Acute myocardial	11(33%)
infarction history	7 (22%)
CABG surgery	7 (22%)
PCI/ stents	
	27 (78%)
Heart failure:	21 (77%)
NYHA class 1-2	6 (23%)
NYHA class 3-4	
	7 (22%)
Atrial Fibrillation/ Flutter:	
	5 (16%)
Diabetes Mellitus:	
	16 (51%)
Hypertension:	
	2 (6%)
Aortic valve replacement:	
	7 (22%)
Alcohol abuse:	
	9 (29%)
Dys-lipidemia:	
	4 (13%)
Cerebro-vascular accidents/	
Transient ischemic attacks:	
	2 (6%)
Chronic obstructive airway	
disease:	4 (13%)
	2 (6%)
Thyroid disorders:	2 (6%)
Hyperthyroidism	
Hypothyroidism	3 (10%)
Chronic liver disease:	2 (6%)
Chronic renal failure:	

Table key words: CABG (coronary artery bypass graft), PCI (percutaneous coronary intervention), NYHA (New York Heart Association).

Table (4) Medications taken by patients

Medication	Number of patients (%)
Beta- blockers	30 (96%)
Carvedilol	13 (42%)
Bisoprolol	7 (22%)
Metoprolol	5 (16%)
Atenolol	4 (13%)
Sotalol	1 (3%)
Angiotensin Converting Enzyme	24 (77%)
Inhibitors /Angiotensin 2	
Antagonists	
	18 (58%)
Statins	
	12 (38%)
Aldosterone antagonists	11 (35%)
Spironolactone	1 (3%)
Epleronone	
	23 (74%)
anti-platelets/ anti-coagulants	18 (58%)
Aspirin	7 (22%)
Clopidogrel	6 (19%)
Warfarin	
	8 (25%)
Amiodarone	
	16 (52%)
Diuretics	14 (45%)
Frusemide	2 (6%)
Thiazide	
	7 (22%)
Digoxine	

Table (5) Device Complications

Complication	Number of patients
Procedure related	
Pain	6
Bleeding	2
Haematoma	1
Lung contusion	1
Haemothorax	1
Subclavian vein thrombosis	1
Failed coronary sinus lead positioning	2
Persistent shoulder and ICD pocket	1
pain	
Device/ lead related	4
Inappropriate discharges	1
Coronary sinus lead repositioning	2
Right ventricular lead repositioning	1
Atrial lead removal	1
Right ventricular lead replacement	