

One-Year Experience of Cardiac Devices Implantation in Baghdad Teaching Hospital and Review of Their Indications and Related Early Complications

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ABSTRACT

Background: Arrhythmias can cause a range of problems for patients, from palpitations and dizzy spells, to blackouts and sudden cardiac arrest. Cardiac rhythm management including device implantation is the treatment for special type of arrhythmias.

Objective: To evaluate the practice of trans-venous permanent devices (pacemaker single ventricle, biventricular and intra-cardiac defibrillator) implantation.

Methods: A group of 150 patients with different indications for permanent pacemaker and intra-cardiac defibrillator implantation who were referred to Baghdad Teaching Hospital - catheterization unit during the period from December 2016 to December 2017 were enrolled in this study. Case sheets of all patients were studied carefully and their indications for devices implantation were re-evaluated. The implantation procedures log were reviewed and short-term complications (within two weeks of the implantation) were studied.

Results: The mean age of the enrolled patients was 62 ± 3 years. The most common presentation were dizziness (62%) syncope (36.6%) and the least common presentation was disturbed level of consciousness. Complete heart block was the most common ECG finding (30.6%). Left bundle branch block was (23.3%) and ventricular tachycardia was (8%). The indications for devices implantation were compatible with American 2012 guidelines for (single or bi ventricular pacing and intra-cardiac defibrillator implantation). The single ventricle lead pacemaker mode was (20.66%), while dual leads pacemaker mode was (36.66%). Defibrillator lead device was implanted in 49 patients (32.66%) and biventricular pacing implanted in 15 patient (10%). Total complications occurred in (2.6%) of the all procedures. Hypertension and ischemic heart diseases appeared to be the strongest associated factor (68.6%) in this study.

Conclusion: Dizziness and syncope were the main presentation. Hypertension and ischemic heart diseases are main associate factors, minimal complication were reported in the current study and most of them were transient.

Keywords: Pacemaker, Arrhythmia, Syncope.

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The term 'CRM' is conventionally used to describe treatments based on implanted electronic devices such as pacemakers and defibrillators. Involvement of physicians (device specialists, imaging and heart failure specialists), physiologists, specialist nurses (arrhythmia and heart failure) to aid in suitability for devices, device selection, optimization and follow up leads to improved patient outcomes⁽¹⁾.

Current pacemakers have a much smaller size, longer battery life, multiple pacing and sensing modalities, and therapeutic capabilities in the form of detecting and treating tachy-arrhythmias as well improving the contractility of a failing heart⁽²⁾. Medical practice guidelines represent the cumulative effort of patients, clinicians, scientists, and statisticians striving to guide patient care on the basis of the best clinical trial science available⁽³⁻⁸⁾.

The aim of this study is to assess the practice of transvenous devices implantation in a cardiac unit in teaching hospital and to evaluate the indications for

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implantation and short term complications (within two weeks).

Methods

Over a period of one years (from December 2016 to December 2017), an observational case series study was conducted at Baghdad teaching Hospital-catheterization unit. A total 161 patients who enrolled in the study, only 150 patients fulfilled inclusion criteria according to 2008 ACC/AHA guideline⁽⁹⁾ for devices implantation (permanent pacemaker either single ventricle or bi ventricular and intra-cardiac defibrillator). Those were done by an expert operator (according to training requirement for device implantation) in left sided subclavian vein approach was used in 145 procedures under local anesthesia while those who failed to get access were replaced by right sided subclavian vein approach (used in 5 procedures). Data collected included information about mode of presentation and duration, associated comorbidities, ECG, Echocardiography, Holter study, electrophysiological study and cardiac catheterization reports whenever

available, with review of their medications. Follow up those patients were done, by history, examination, chest x-ray, ECG and Holter study if indicated. Within two weeks review and follow up included look for complications, optimization and programming according to type of device implanted. All data were collected from patients himself or their relative.

An approval for study was taken from the Ethical committee of Baghdad College of Medicine and informed consent was taken from each candidate before enrollment in the study. The statistical analysis was conducted by using statistical package for social sciences (SPSS) version 23, multiple contingency tables were performed.

Results

One hundred fifty patients had been studied; 98 of them were male (65.3%), 52 were female (34.7%); mean age: 62±3 years. Among all candidates, hypertension was present in 103 patients (68.66%), diabetic patients were 38 (25.33%) and ischemic heart diseases 47 patients (31.33%), (Table 1).

Table 1: Baseline characteristics of patients who underwent device implantation.

| Character | Value No. (%) |
|------------------------------------|---------------|
| Number of patients | 150 |
| Number of procedures | 150 |
| Mean age (years ±SD) | 62±3 |
| Male number (%) | 98(65.3) |
| Female number (%) | 52(34.7) |
| Hypertension number (%) | 103(68.66) |
| Diabetes mellitus number (%) | 38 (25.33) |
| Ischemic heart diseases number (%) | 47(31.33) |

Table 2 describes the variable mode of presentation, mainly recurrent dizziness (62%), shortness of breath (38.6%), syncope (36.6%) and palpitation (26.6%). The distribution of patients according to the ECG findings is shown in table (3) as following: Complete AV block (CHB) was the most common ECG finding, represented in 46 patients (30.6%), while left bundle branch block 35 patients (23.3%), sinus nodal dysfunction 23 patients (15.3%), symptomatic 1st degree

heart block 13 patients (8.6%), 2nd degree heart block 12 patients (8%), atrial fibrillation 8 patients (5.3%) and ventricular tachycardia 12 patients (8%).

The number of devices implanted was 150. The percentage of VVI pacemaker implanted was (20.66%). Most of VVI pacemaker mode implanted at age group (70-79 year) while DDD mode mainly at (60-69 year) age group, bi-ventricular pacing (CRT) was implanted in 10 out of 150, those suffered from heart failure, mostly at age

group (40-49 year). ICD implantation was in 49/150 patients, majority at (60-69year) age group, (Table 4).

In table 5, In general the implanted device in male more than female and DDD mode represented 24% in male vs. 12.6% in female. ICD was 20.6% in male vs. 12% in female. CRT was 9.3% in male vs. 0.6% in female. VVI was 11.3% in male while 9.3% in female.

Total complications during two weeks follow up were 2.6%, (table 6). One patient for each of followings complications; attack of sustained VT, attack of confusion, stroke and pericardial effusion. No reported cases of local hematoma or pocket infection.

From 150 devices implanted: 20% was VVI, 33% was ICD, 37% was DDD and 10% was CRT, (Figure 1).

Table 2: The distribution according to patient presentations.

| Symptoms | No. (%) |
|--|-----------|
| Dizziness | 93 (62) |
| Syncope | 55 (36.6) |
| Shortness of breath | 58 (38.6) |
| Palpitation | 40 (26.6) |
| Others (chest pain, confusion....etc.) | 4 (2.6) |

Table 3: The distribution according to the ECG findings.

| ECG findings | No. (%) |
|--|-----------|
| CHB | 46 (30.6) |
| 2 nd degree heart block | 12 (8) |
| Symptomatic 1 st degree heart block | 13 (8.6) |
| Sinus node dysfunction | 23 (15.3) |
| Atrial fibrillation | 8 (5.3) |
| LBBB | 35 (23.3) |
| VT | 12 (8) |

Table 4: The distribution according to the type of implanted devices.

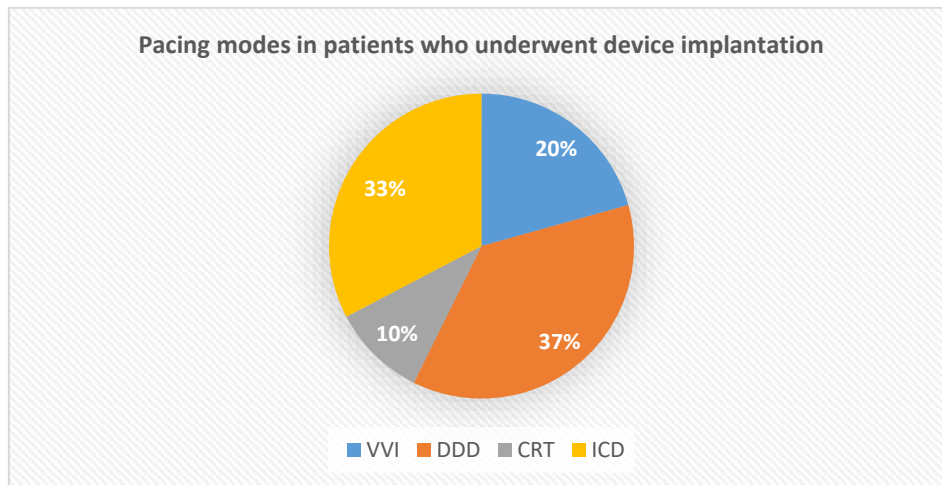
| Age group | Type of implanted device | | | | Total |
|-----------|--------------------------|---------------|---------|------------|-----------|
| | VVI Pacemaker | DDD Pacemaker | CRT | ICD | |
| 20-29 | 0 | 1 | 0 | 0 | 1 |
| 30-39 | 1 | 1 | 1 | 3 | 6 |
| 40-49 | 4 | 3 | 7 | 3 | 17 |
| 50-59 | 4 | 12 | 6 | 7 | 29 |
| 60-69 | 9 | 19 | 0 | 20 | 48 |
| 70-79 | 11 | 13 | 0 | 12 | 36 |
| 80-89 | 2 | 3 | 1 | 3 | 9 |
| 90-99 | 0 | 3 | 0 | 1 | 40 |
| Total (%) | 31 (20.66) | 55 (36.66) | 15 (10) | 49 (32.66) | 150 (100) |

Table 5: The distribution of implanted devices according to the gender.

| Gender | Type of implanted device | | | | Total |
|--------|--------------------------|-------------------|-----------|------------|------------|
| | VVI Pacemaker (%) | DDD Pacemaker (%) | CRT (%) | ICD (%) | |
| Male | 17 (11.33) | 36 (24) | 14 (9.33) | 31 (20.66) | 98 (65.33) |
| Female | 14 (9.33) | 19 (12.66) | 1 (0.66) | 18 (12) | 52 (34.66) |
| Total | 31 (20.66) | 55 (36.66) | 15 (10) | 49 (32.66) | 150 (100) |

Table 6: Complications of implanted devices within two weeks postoperatively.

| Complication | No. (%) |
|----------------------------------|---------|
| Total number of procedures | 150 |
| Device infection number | 0 |
| Local hematoma number | 0 |
| CVA number | 1 |
| Arrhythmia (sustained VT) number | 1 |
| Pericardial effusion number | 1 |
| Apnea (drug induced) number | 0 |
| Attack of confusion number | 1 |
| Total | 4(2.6%) |

**Figure 1: distribution of devices mode implanted.**

Discussion

The current study was intended to evaluate the practice of devices implantation in Baghdad Teaching Hospital, catheterization unit. Hypertension and ischemic heart diseases were the main associated risk factors for devices implantation in this study. This agree with what is reported in a study done in 2013 by Benoit Herc  et al⁽¹⁰⁾.

Regarding gender; male was predominant (65.3%) in this study, that is similar to a survey of cardiac implantable electronic device implantation in India: from 2117 patients enrolled in that study, they reported that 64% were males⁽¹¹⁾; that might be due to the fact that male gender is one of non-modifiable risk factor for cardiovascular diseases including arrhythmias.

All patients who underwent devices implantation were symptomatic. Recurrent

dizziness, shortness of breath, syncope and palpitation were the most common reported symptoms. Asymptomatic patients were not reported in this study, that is because cardiac unit in Baghdad teaching Hospital is special unit responsible for all types of devices implantation not a general hospital and also the nature of our property of our patients who seeks medical advice only when they become symptomatic. It is worthy to mention that this unit lacks a separate electro-physiological sector.

In this study, the CHB was the most common indication for implantation of a permanent pacemaker (30,6%). While sinus node dysfunction represents (15.3%), symptomatic 1st degree heart block was (8.6%), 2nd degree heart block was (8%) and chronic AF was (5.6%). These results were similar to what found by in the Danish pacemaker registry for the year 2004, AV block was the indication in 40%, sick sinus syndrome in 35.5% and chronic atrial

fibrillation/flutter in 17.9% of patients^(12,13). The low incidence of permanent pacing for sinus node dysfunction in the present study may indicate high diagnostic threshold for sinus node dysfunction among the referring physicians and also may be due to the lack of invasive electrophysiological facilities that may diagnose sinus node dysfunction in Baghdad Teaching Hospital.

In the present study, DDD pacemaker were implanted in 24% of men, whereas 11.3% received VVI pacemaker, 9.3% BiV pacemaker. By contrast, 12.6% women received DDD pacemaker, whereas 9.4% received VVI and 0.6% received BiV pacemaker. These results were comparable with a nationwide 100,000-inpatient sample to identify permanent pacemaker implants during period from 1993 to 2009. The shift in use to dual chamber technology likely reflects improvements in lead and pacemaker design, as well as prevents pacemaker syndrome, reduces the incidence of atrial fibrillation, decreases the incidence of congestive heart failure, improves quality of life, and reduces stroke⁽¹⁴⁾.

Still we are in preliminary stage of CRT implantation whether CRT-P or CRT-D. In the current study, according to AHA-ACC guideline 2008⁽⁹⁾, only 10% of total devices implantation were CRT. The reasons for low percentage of CRT implantation in present study might be due to hesitancy of physician to send the indicated patients to specialist invasive cardiologist and the refusal of most patients to perform such procedure and they prefer to continue on medical therapy.

Forty-nine out of 150 patients were undergone ICD devices implantation in this study either for primary or secondary prevention. All of them fulfilled the criteria of AHA-ACC guideline 2008⁽⁹⁾. A study done by Al-Musawi et al⁽¹⁵⁾, registered sixty ICD implantation during 2002 till 2006, comparing to the present study, the difference in number of patients could be due to increase in physicians awareness of ICD implantation and referral to our unit and increased facilities.

In the current study; Complications were reported in 2.6% patients whom did the procedures and no mortality was encountered. In consistence with our results; Rajesh K Aggarwal et al study⁽¹⁶⁾ reported that total complications occurred in 3.5% patients. Ongoing upgrade good experiences, good preparation, sterilization and effective antibiotic cover in the cardiac unit at Baghdad teaching Hospital plays a major role in low number of complicated cases. The standards of devices implantation in Baghdad teaching Hospital approaches the international standards. Dizziness and syncope were the main presentations. Hypertension and ischemic heart diseases were the main associated factors. Minimal complications were reported in the current study and most of them were transient.

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Conflict of interest: None.

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