Permanent Pacemaker Implantation in Ibn - Al Nafees Hospital; Indications and Early Complications

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ABSTRACT:

BACKGROUND:

A pacemakers is a small device that is placed in the chest to help control abnormal heart rhythms and prevent bradycardia.

OBJECTIVE:

To evaluate the practice of permanent pacemaker implantation including indications and early complications.

PAT IENTS AND METHODS:

This is a retrospective study in 90 patients over 2.5 years (from June 2013 to January 2016). The case sheets of patients were studied carefully including history, clinical examination, ECG findings, echocardiographic Study and cardiac catheterization. In addition, the reports of the first follow up visit around two weeks after implantation were studied.

RESULTS:

The females (61.2%) more than males, syncope (44.4%) and dizziness (33.3%) were the most common presentations, most of patients (87 patients) represented in class I indication for pacemaker implantation, CHB (72.2%) was the most common ECG finding, the most common causes of heart block were unspecified (55%) and post MI (27.7%), the most common pacing mode was VVI mode (43.3%). The complications of pacemaker implantation were 11.1% and the infections represent 3.1%, In older age group and in diabetic patients the infection incidence increased. The indication of temporary pacemaker prior to permanent pacemaker implantation was (22.2%), and post-acute MI and hemodynamically unstable patients were the most common causes (8 patients) and (7 patients) respectively .

CONCLUSION:

implantation of permanent pacemaker is a save and could be life saving in significant bradycardia, and complete heart block was the most common cause of pacemaker implantation

KEYWORDS: permanent, pacemaker, implantation

INTRODUCTION:

The heart's "natural" pacemaker is called the sinoatrial (SA) node or sinus node. It's a small mass of specialized cells in the top of the heart's right atrium (upper chamber). It makes the electrical impulses that cause your heart to beat., The natural pacemaker may be defective, causing the heartbeat to be too fast, too slow or irregular. The heart's electrical pathways also may be blocked,[1] "artificial pacemaker" is a small, battery-operated device that helps the heart beat in a regular rhythm. Some are permanent (internal) and some are temporary (external) it uses batteries to send electrical heart impulse to help pump correctly. An electrode is placed in the chest wall and its lead inserted in the heart[2]

it can be observed that the development of electro-therapy usually preceded the understanding of what was actually occurring within the heart. Over the last fifty years or so, electro-therapy has shown a very rapid, almost explosive, development[3]

As implantable arrhythmia control devices are continually improved and as new indications are discovered the rate of implantation increased further well over 2 million pacemakers have been implanted worldwide since 1960.[4,5,6]

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Temporary cardiac pacing is indicated for the acute management of serious Brady arrhythmias that are refractory to medical therapy7[7]. All leads today are steroid –eluting leads, which decreases the acute to chronic threshold rise seen in non-steroidal leads due to the inflammatory process.

The fifth position (V) of the code is now used to indicate whether multi-site pacing is present in "O" None of the cardiac chambers," A" one or both atria, "V" one or both ventricles, or "D" any combination of atria and ventricles. To describe a patient with a DDDR pacemaker with bi-ventricular stimulation, the code would be DDDRV. [8]

Depending on the patient condition, one of the following types of pacemakers can be implant. [9]

- **Single chamber pacemaker.** which carries electrical impulses to the right ventricle of the heart.
- **Dual chamber pacemaker.** which carries electrical impulses to the right ventricle and the right atrium of the hart.
- **Biventricular pacemaker.**
- Biventricular pacing, also called cardiac resynchronization therapy, is for people with heart failure with abnormal electrical systems. This type of pacemaker stimulates the lower chambers of the heart (the right and left ventricles) to make the heart beat more efficiently.

In 2013, multiple firms announced devices that could be inserted via a leg catheter rather than invasive surgery. The devices are roughly the size and shape of a pill, much smaller than the size of a traditional pacemaker. Once implanted, the device's prongs contact the muscle and stabilize heartbeats.

Engineers and scientists are currently working on this type of device.[10] The Nanostim leadless pacing technology announced In 2014 by St. Jude Medical Inc. The Nanostim pacemaker received CE marking and the post-approval implants have occurred in Europe [11]

But this therapy is still not approved by the FDA in the United States[12]

While the Medtronic Micra and St Jude Nanostim are just single-chamber pacemakers, leadless dual-chamber pacing will become possible with further development for patients with atrioventricular block[13]

THE AIM OF STUDY:

The aim of the study is to evaluate the indications for pacemaker implantation and to assess the practice of pacemaker implantation and short term complications of implantation (2 weeks after implantation).

PATIENTS AND METHODS:

Over period of 2.5 years (from June 2013 to January 2016), a retrospective study was conducted at Ibn-Al Nafees center for thoracic and cardiovascular surgery in Baghdad.. The study included a total number of 90 patients who underwent permanent pacemaker implantation. Case sheets of all patients were studied carefully including history, clinical examination, electrocardiography traces, chest x-rays, echocardiography reports, laboratory investigations and cardiac catheterization reports whenever available.

The indications for pacemaker implantation were re-evaluated using the reported history and the available E.C.Gs. The implantation procedures and the mode of pacing were reviewed thoroughly and all the complications reported were studied. In addition, the reports of the first follow up visit around two weeks after implantation were studied.

The patients who underwent temporary pacemaker implantation prior to permanent pacemaker were studied.

Patients who underwent implantable cardioverter defibrillator (ICD) or a triple chamber pacemaker implantations were excluded.

Complications which occur early after implantation, were reported in the study.

RESULTS:

Over period of more than 2.5 years (from June 2013 to January 2016), 94 procedures of permanent pacemaker implantation, replacement generator and change position of generators were done for 90 patients where a mean age of 60.5± 6 years, 35 patients (38.8%) of them were males and 55 (61.2%) were females.

Among all patients, diabetes mellitus is present in 26 patients (28.8%), hypertension is present in 35 patients (38.8%) and 15 patients (16.6%) were smoker. **Table 1**.

Most common presentation was syncope which was present in 40 patients (44.4%), while 30 patients (33.3%) presented with dizziness and 25 patients (27.7%) presented with chest pain. 15 patients (16.6%) presented with shortness of breath, 5 patients (5.5%) presented with palpitation, 3 patients (3.3%) presented with cerebrovascular accident and only one patients (1.1%) presented with convulsion. **Table 2**

Among all patients, 82 patients underwent a first pacemaker implantation, 8 patients were submitted to second implantation. In those patients who underwent a second implant, most common presentation was syncope (6 patients), while the dizziness was the presenting symptom in two patients.

Complete heart block is the most common ECG finding which present in 65 patients (72.25%). Second degree heart block was in 15 patients (16.6%), sinus node dysfunction 4 patients (4.4%), bifasicular block in 3 patients (3.3%), atrial fibrillation presented in 2 patients (2.2%), and one patient (1.1%) presented with symptomatic first degree heart block, **Table 3**

In patients who underwent a second implant (8 patients), the ECG showed pacemaker malfunction (failure of capture) due to generator battery depletion.

The cause of heart block is unspecified in 50 patients (55%), ischemic in 25 patients (27.7 %), generator failure in 8 patients (3.3%), hypothyroidism and congenital causes in 2 patients (2.2%), **Table 4**.

According to the 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy, 87 patients represent CLASS I indication and 3 patients represent CLASS IIa indication,

No incidence was reported of implanting a pacemaker to a patient with CLASS IIb or III indication. **Table 5.**

The patients who underwent temporary pacemaker 20 patients (22.2%), mean age 59.8%, 7 patients (7.7%) were males and 13 patients (14.4%) were females. The most common indications for temporary pacemaker implantation were ischemic heart disease "post-acute myocardial infarction" 8 patients, and hemodynamically unstable patients "heart failure" 7 patients.

Post cardiac surgery 3 patients and two patients due to unavailability of permanent pacemaker at time being in patients with severe bradycardia, **Table 6**.

Fig. I: Pacing modes in patients underwent permanent pacemaker

Left sided subclavian vein approach was used in 82 procedures (91.1%) while a right sided subclavian vein approach was used in 8 procedures (8.8%).

Complications occurred in 10 procedures (11.1%), pacemaker infection occurred in 3 patients (3.1%), two of them responded to conservative treatment and one required change the position of generator **Table 7.**

Skin erosion occurred in 2 procedures that required changed the site of generator "new position". No attacks of bacterial endocarditis were reported due to pacemaker implantation and also no clinically evident venous thrombosis was recorded.

In comparison between those without pacemaker infection, those who develop pacemaker infection tend to be older with more incidence of diabetes mellitus.

Table I: Baseline characteristics of patients who underwent permanent pacemaker implantation

Character	No.(%)
No. of patients	90
No. of procedures	94
Mean ages(years)	60.5±6
Sex	
Male	35 (38.8)
Female	55 (61.2)
Diabetes mellitus	26 (28.8)
Hypertension	35 (38.8)
Smoking	15 (16.6)

Table 2: Clinical Presentation of patients who underwent permanent pacemaker

Presentation	NO.(%)
Syncope	40 (44.4)
Dizziness	30 (33.3)
Chest pain	25 (27.7)
S.O.B	15 (16.6)
Fatigue	11 (12.2)
Palpitation	5 (5.5)
C.V.A	3 (3.3)
Convulsion	1 (1.1)

Table 3: E.C.G findings of patients underwent permanent pacemaker

E.C.G findings	NO.(%)
C.H.B	65 (72.2)
2nd degree AV block	15 (16.6)
Sinus node dysfunction	4 (4.4)
Bifasicular block	3 (3.3)
Atrial fibrillation	2 (2.2)
Symptomatic 1st degree AV block	1 (1.1)

Table 4: Etiology of heart block

Etiology	NO.(%)
Non-specified	50 (55.5)
Ischemic (post MI)	25 (27.7)
Generator failure	8 (8.8)
Post cardiac surgery	3 (3.3)
Hypothyroidism	2 (2.2)
Congenital	2 (2.2)

Table 5: Compliance with ACC / AHA guidelines for permanent pacemaker indications

ACC / AHA class	NO. of patients
Class I (indicated)	87
Class IIa (good supportive evidence)	3
Class IIb (weak supportive evidence)	0
Class III (not indicated)	0

Table 6: Indications of temporary pacemaker implantation:

Indications	NO.
Bradycardia post-acute MI.	8
Hemodynamically unstable patient.	7
Post-cardiac surgery.	3
Unavailability of permanent Pacemaker .	2

Among the procedures of permanent pacemaker implantation, the mode of pacing was as follow:

- **VVI** mode was used in 49 patients (43.3%)
- **DDD** mode was used in 22 patients (24.4%)
- **VDD** mode was used in 10 patients (11.1%)
- **VVIR** mode was used in 10 patients (11.1%)
- **DDDR** mode was used in 6 patients (6.6%)
- **VDDR** mode was used in 3 patients (3.3%)

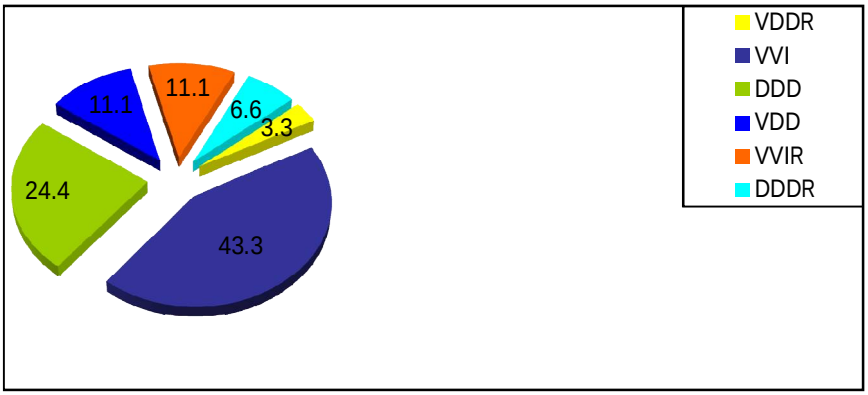

Fig. I: Pacing modes in patients underwent permanent pacemaker

Table 7: Early complications of permanent pacemaker implantation

Complications	NO.(%)
Total No. of procedures	94
Pacemaker infection Treated conservatively Change position of generator	3 (3.1) 2 (2.1) 1 (1.06)
Local hematomas	2 (2.1)
Re-operation(for lead re-positioning)	1 (1.06)
Failed attempt to get IV access (required venous cut down).	1 (1.06)
Skin erosion (change position of generator)	2 (2.1)

DISCUSSION:

This study is intended to evaluate the practice of permanent pacemaker implantation in a single cardiac center.

All patients who underwent first pacemaker implantation were symptomatic, syncope and dizziness were the most commonly reported symptoms. In addition, all patients who underwent second pacemaker implantation were symptomatic and no a symptomatic second implant was reported. This may be due to lack of proper follow-up of patients with pacemaker and this may be due to the special property of our patients who seeks medical advice only when became symptomatic and also due to difficult hospital .transportation. also It is worthy to report that lacks of separate electrophysiological unit.

The most common indication for permanent pacemaker implantation was the AV block (90%), while sinus node dysfunction was (4.4%) of the permanent pacemaker implantation.

In the **Danish pacemaker Registry** [14] for the year 2003, AV block was the indication in 40%, sick sinus syndrome in 35.5% and atrial flutter and fibrillation in 17.9% of the patients. The low diagnostic threshold for sinus node dysfunction among the referring physicians may be was behind the low incidence of permanent pacing for sinus node dysfunction and also may be due to lack of invasive electrophysiological facilities that may diagnose sinus node dysfunction in our center.

Am Greenspan, et al have reported that 20% of permanent pacemaker implantation at thirty hospitals in Philadelphia are not indicated.[15]

While in our study there is no incidence of unwarranted permanent pacemaker implantation and this may be due to the fact that our study was conducted in a specialized cardiac hospital which receives the referred cases and has a postgraduate teaching program.

Regarding the mode of pacing, in our center VVI mode represents more than one third of the modes used and it is the most common mode of pacing.

In the **Danish pacemaker Registry**,[14] physiological pacing defined as atrial based pacing, was chosen in 74% of all implants. VVI mode was used in 25.8% of patients.

Our high incidence of VVI pacing may be due to time shortage where VVI pacemaker implants need less time than other mode and because of lack of a separate catheterization laboratory in the hospital for E.P studies. Sometimes due to unavailability of other pacing modes.

Complications were reported in 11% of the procedures and no mortality was encountered. In consistence with our results; **Karachalios, et al** [16] reported that non-infectious complications occurred in almost 90% of the patients with implantable cardioverter defibrillator and pacemaker devices.

The study showed that the most common complications in patients undergoing device implantation were hematoma and lead dislodgment.

Pacemaker infection occurred in 3.1% of the procedures, two of them responded to medical treatment and one of them necessitated change of position of generator.

Skin erosion occurred in 2.1% of the procedures that necessitated change of position of the generator.

In a study by **Beeler BA, et al** [17] reported that early infections of pacemaker implants (within 2-4 weeks of insertion) were 1-2%.

Among the three risk factors for pacemaker infection studied (age, DM, non-expert operator), DM seems to be associated with significant increase in risk of pacemaker infection. It is well known that DM represents a risk factor for infection anywhere in the body [16,17].

Bleer BA, et al[17] reported factors that predispose the patients to develop pacemaker infections, these include; Chronic underlying conditions such as DM, malignancy, skin disorders, malnutrition and the use of anticoagulants, steroids or other immunosuppressive agents. He reported also that the incidence of erosions, infections, hematomas and lead displacements early after pacemaker is increases by operator inexperience.

CONCLUSIONS:

This study concludes that syncope and dizziness are the most presenting symptoms. And the complete heart block was the most common indication for pacemaker implantation in our center. The low incidence of permanent pacing for sinus node dysfunction in the center indicating low diagnostic threshold for sinus node dysfunction among the referring physicians, also may be due to lack of invasive electrophysiological facilities that may diagnose sinus node dysfunction in this center.

This study found the ischemic heart disease represented in about one third of the cases which is more than the international standards. The most common early complications is surgical site infection approaching the international standards.

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