GLOBAL VOICES

Permanent pacemaker insertion for bradyarrhythmias in a secondary health facility in sub-Saharan Africa



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BACKGROUND Permanent cardiac pacemaker (PPM) insertion has been used clinically since 1960. It is a lifesaving procedure in symptomatic bradyarrhythmia. The experience of PPM implantation in non-Western countries has not been well characterized.

OBJECTIVE This study reports our experience in pacemaker insertion in the newly remodeled District General Hospital Awa. The Akwa Ibom state government fully sponsored the procedures with state funds; otherwise, patients would have to pay out of pocket.

METHODS The general hospital is fully equipped with an ultramodern theater with C-arm fluoroscopy and audiovisual facilities, and there is an anteroom in the procedural suite where people can watch for virtual learning. This is the first of its kind.

RESULTS A single-chamber (VVIR) pacemaker was implanted in all patients. There were no acute complications postsurgery. All patients were followed for at least 3 months. There were no deaths reported at the 3-month follow-up. Device interrogations were

performed at the 3-month follow-up visit, and device parameters were all stable with excellent sensing thresholds. Routine follow-up for our center is a regular 2-monthly follow-up in the first year.

CONCLUSION We conclude that permanent pacemakers can be safely carried out in a well-equipped district general hospital. Most needy patients are likely older, with complete heart block as the commonest indication. However, government and/or nongovernmental organizations need health insurance or subsidization to make it sustainable in low-income countries to which Nigeria belongs.

KEYWORDS Pacemaker; Bradyarrhythmia; Device implantation; Challenges; Secondary health facility; Management; Nigeria

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Introduction

The implantable permanent pacemaker (PPM) has been in clinical use since 1960. The indications for PPM are high-grade atrioventricular (AV) block (complete heart block and Mobitz type 2 second-degree AV block), symptomatic sinus node dysfunction, symptomatic bradycardia with atrial fibrillation, and recurrent syncope due to carotid sinus syndrome or other disorders of the autonomic nervous system. These are highly fatal but treatable conditions. Ekpe and colleagues reported 50% mortality among 8 patients with

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complete AV block that did not receive pacing within 1 year of diagnosis.

Cardiac pacemaker implantation in Nigeria has commonly been carried out in highly specialized health institutions (tertiary and quaternary hospitals and specialist hospitals) with the appropriate cardiac catheterization laboratories and specialists, including cardiothoracic surgeons, interventional cardiologists, radiographers, cardiac nurses, and cardiac technicians. However, it was recognized that there was a need to bring PPM implantation closer to where people live and develop programs for PPM implants in the smaller secondary hospitals. This approach was modeled after the British Cardiac Society, which in 1987 created a system to bring specialized cardiac care to UK secondary hospitals.

KEY FINDINGS

- Permanent cardiac pacemaker (PPM) implantation can be safely carried out in a well-equipped district general hospital in Nigeria with minimal complications and satisfactory outcomes.
- Most needy patients are likely older with comorbidities such as hypertension, and complete heart block was the commonest indication.
- This expensive procedure is not affordable to the majority of patients who need it in low- and middle-income countries like Nigeria.
- The procedures can be done with little or no complications and no mortality.
- The procedures can only be made possible through increased private and industry support, and a strong commitment to establishing a strong national healthcare system in Nigeria.

Nonetheless, the high cost of this treatment, its noncoverage by Nigeria's national health insurance scheme, and patients' inability to pay out of pocket have greatly limited the number of patients utilizing this service at specialty hospitals. ^{5,9,10} Furthermore, through the Nigerian Cardiac Society we confirmed that no district general hospitals have performed PPM implantation before.

Therefore, this study aimed to present our experience in elective PPM implantation in a district general hospital in Akwa Ibom State, Nigeria, sub-Sahara Africa. We evaluated patient characteristics, indications for PPM, procedural techniques, treatment outcomes, and complications.

Methods

Study design and setting

This is a prospective analysis of all cases of PPM implantation over 4 months in Awa General Hospital. The hospital was recently renovated and equipped with state-of-the-art radiodiagnostic and medicosurgical equipment, including Carm fluoroscopy, as shown in Figure 1. Awa is in Akwa Ibom state, in southern Nigeria. The procedures were performed by a team of specialists: cardiologists and anesthetists headed by a cardiothoracic surgeon.

Patient selection

Patients were recruited by the cardiothoracic and cardiology units of the University of Uyo Teaching Hospital. Patients diagnosed with heart block were referred to either of the 2 units for full evaluation and confirmation of diagnosis. Patients with heart block who met inclusion criteria and exclusion criteria were included in the list of recipients appropriate for PPM implantation.

The inclusion criteria were patients with any of the following diagnoses: (1) sinus node dysfunction including



Figure 1 Picture of the Digiscan Allengers C-arm at General Hospital Awa.

symptomatic sinus bradycardia and symptomatic chronotropic incompetence (failure to achieve 85% of agepredicted maximal heart rate during formal or informal stress test or inability to mount age-appropriate heart rate during activities of daily living; (2) acquired AV block such as complete third-degree AV block with or without symptoms, symptomatic second-degree AV block (Mobitz type I and II), exercise-induced second- or third degree AV block in the absence of myocardial infarction, or alternating bundle branch block; or (3) neurocardiogenic syncope and hypersensitive carotid sinus syndrome exhibiting recurrent syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of more than 3 seconds. The exclusion criteria were patients with any of the following diagnoses: (1) terminal disease, active infection, severe bleeding risk, asymptomatic sinus bradycardia, or asymptomatic Mobitz type 1 second-degree AV block; or (2) reversible causes of bradycardia that can be temporized with conservative watching or a temporary transvenous pacemaker.

Preprocedural preparation

All team members employed sterile precautions, thorough procedure field prep, and large sterile drapes. The patient did not have a skin prep at home the night before the procedure; generally, in the United States and Europe, patients

typically do a chlorhexidine scrub. None of the patients were on an anticoagulant before the procedure; otherwise, such patients would have been instructed to withhold it for a minimum of 48 hours or would be excluded if they could not stop anticoagulation. Infection was further prevented by a broad-spectrum prophylactic antibiotic that was intravenously given within 30 minutes before starting the procedure.

Procedural technics

PPM implantation was accomplished through transvenous placement of a lead to the endocardium of the right ventricle that was subsequently connected to a pacing generator placed subcutaneously in the infraclavicular region.

Venous access and creation of pulse generator pocket

All operators used a subclavian venous access, which was performed first, leaving the guidewire positioned in the right atrium. A subcutaneous pocket was then formed in the infraclavicular upper chest. After confirmation of lead position and thresholds, the proximal end of the lead was secured to the underlying tissue and pectoralis muscle with a nonabsorbable suture sewn to a sleeve on the lead.

Positioning of pulse generator and closure

When the lead had been properly positioned tested and sutured to the underlying tissue, the pacemaker pocket was irrigated with an antimicrobial solution, and the pulse generator was connected securely to the lead. It was necessary to secure the pulse generator to underlying tissue with a suture to prevent migration or twiddler syndrome. After hemostasis was confirmed, a final look under fluoroscopy was done to determine the appropriate lead positioning before closure of the incision. The incision was closed in layers with absorbable sutures. Sterile dressing was applied to the incision surface. An arm restraint or immobilizer was applied to the unilateral arm for 12 to 24 hours to limit movement.

Programming and immediate postoperative management

A postoperative chest radiograph was obtained to confirm lead position and rule out pneumothorax. Before discharge on the following day, posteroanterior and lateral chest radiographs were ordered again to confirm lead position and exclude delayed pneumothorax. Pain levels were typically low after the procedure, and the patients were given pain medication to manage breakthrough pain associated with the incision site. They are routinely followed every 2 months for the first year.

Results

Five (62.5%) females and 3 (37.5%) males had PPM procedures. Their age ranged between 51 and 70 years, with a mean of 61.0 ± 8.9 years.

The commonest symptom was dizziness in 6 (75%) patients, followed by dyspnea and leg swelling seen in 3



Figure 2 Picture of the Medtronic programming device used on the patients, all pacemakers implanted were either Medtronic or Vitatron.

patients each. Less common symptoms were palpitation, fainting, cough, and easy fatigability. The main indication for PPM implantation was complete heart block in 6 (75%) patients, followed by symptomatic bradycardia and idioventricular rhythm (profound sinus node dysfunction), seen in 1 patient each. The most common comorbidity was hypertension in 5 (62.5%) patients, followed by osteoarthritis in 3 (37.5%), and 1 (12.5%) patient had both hypertension and diabetes mellitus at diagnosis. The procedures were performed by a team of specialists: cardiologists, anesthetists, and cardiothoracic surgeons headed by a cardiothoracic surgeon. A single-chamber (VVIR) pacemaker was implanted in all patients. One further patient recruited could not have the PPM inserted due to the atypical anatomy of her venous system despite repeated attempts at catheterization. There were no acute complications postsurgery. All patients were followed for at least 3 months. There were no deaths reported at the 3 months follow-up. Device interrogations were performed at the 3-month follow-up visit, and device parameters were all stable with excellent sensing thresholds. Routine follow-up for our center is a regular 2-month follow-up in the first year. Figure 2 shows the device used.

The research reported in this article adhered to the Declaration of Helsinki. The University of Uyo Teaching Hospital institutional review board approved the guidelines and the study; all patients provided written informed consent.

Discussion

This study described the initial experience of our team in carrying out elective PPM implantation in a newly refurbished district general hospital in Akwa Ibom State. While earlier studies in Africa have reported their experiences in carrying out this procedure in a specialist hospital, we report our experience of PPM implantation in a district general hospital appropriately equipped to perform this procedure. In this first experience with these physicians and this hospital, 8

middle-aged patients, the majority of whom were female with at least 1 comorbid condition, had successful PPM implantation. The most common comorbidity reported in this study was hypertension. These procedures were done safely with no complications. While earlier studies in Africa have reported their experiences in carrying out this procedure in a specialist hospital, we recorded successful outcomes carrying out PPM implantation in a secondary hospital equipped with human and material resources. The procedures were made possible through the commitment and political willingness of the state government. The state government fully sponsored the procedures and patients did not have to pay out of pocket. This initiative from the government helped address important healthcare gaps in Nigeria among the populace, eventually making this expensive procedure accessible to indigenous Nigerians. The procedures were covered by state healthcare insurance in this study and this hospital, but this is not the situation in most other general hospitals. Thus, there is a need to ensure the continuity of this great initiative for health equity among the Nigerian populace.

Other studies from Africa

A growing body of literature summarizes the experience with PPM in Nigeria. ^{3–7,10–13} Most of these are small series of patients receiving PPM implants in tertiary hospitals that range from 3 to 100 patients, with patients in an older range of 15 to 98 years of age, and a mean age of 66.7 years. The studies vary according to sex differences, with some showing a male preponderance ^{3–7,11–13} and others with more females. ¹⁰ The primary indication for pacemaker implantation was AV block; most patients had dyspnea, syncope, or fatigue. Single chambers were primarily used, though in the study by Edafe and colleagues, ¹³ 90% received a dual-chamber pacemaker. However, in the study by Aktoz and colleagues, ¹⁴ and over 10 years, pacemaker selection shifted from VVI to DDD.

It is important to consider complications in new and/or small pacemaker implantation programs. Our study of 8 patients implanted in a district general hospital showed no serious acute complications or deaths at 3 months. Pacing parameters were also stable at 3 months.

In the studies noted previously in which patients had their implantations in tertiary hospitals, complication rates have been reported as high as 7.5% (most common is lead dislodgement but includes pneumothorax and hematoma). In comparison, in a large Australian cohort study of 10,883 patients, Gillam and colleagues ¹⁵ reported rehospitalizations for infection, acute procedure complications, or thromboembolism in 1% to 2% of patients at 90 days of follow-up. They also noted that 10% of patients with a single-chamber pacemaker and 7% of dual-chamber pacemaker were hospitalized for a cardiovascular event.

Economics of PPM implantation in Nigeria

Even though the average cost of pacing has been reported to reduced significantly over the years, procurement of this all-important treatment modality remains a major financial drain, especially in a poor country like Nigeria. Thomas reported that out of the 62 patients who qualified for pacemaker insertion, only 41 could meet their financial needs. Even though 51 (82.3%) belonged to higher social classes, only 8 patients could self-sponsor themselves.

Affordable healthcare in Nigeria remains a major challenge. This could be achieved with greater government support to cut down the cost of various devices used in managing symptomatic bradycardia. Collaboration with device manufacturing companies could work out methods to reduce costs for the sub-Sahara Africa region. The government could create a "soft landing" for the device companies to expedite the donation process, and decrease costs while increasing accessibility. Training human resources locally, supporting more research, and reducing the costs of these devices realistically require support from the government, private sector, and pacemaker manufacturers abroad. These efforts are needed to ensure the continuity of this program. These efforts may be adversely affected due to changes in government leadership and political priorities. Finally, an operational national health insurance system is needed to ensure that more patients can receive these lifesaving procedures.

Conclusion

In our case series, we demonstrate that PPMs can be safely carried out in a well-equipped district general hospital in Nigeria. Most needy patients are older and most often have complete heart block as the commonest indication. However, there remains a great need for increased government support through better health insurance, and increased support from governmental and nongovernmental organizations to sustain the pacemaker implantation programs in Nigeria.

Funding Sources: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Disclosures: The authors have no conflicts to disclose.

Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: All patients provided written informed consent.

Ethics Statement: The research reported in this article adhered to the Declaration of Helsinki guidelines and the study was approved by the University of Uyo Teaching Hospital institutional review board.

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