BASELINE PROFILE, RHYTHM ABNORMALITIES AND OUTCOMES FOR PATIENTS WITH PACEMAKERS INSERTED AT THE KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE AT THE UNIVERSITY OF NAIROBI

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ABBREVIATIONS

AAI – Atrial pacing, Atrial Sensing and Inhibited pacing mode

AV - Atrioventricular

AVB – Atrioventricular Block

AVN – Atrioventricular Node

BBB – Bundle Branch Bloc

CRT – Cardiac resynchronization therapy

CVD – Cardiovascular disease

CNS – Central nervous system

DDDR – Dual chamber pacing, dual chamber sensing, rate modulated pacing mode

DM - Diabetes mellitus

ECG - Electrocardiogram

HB – heart blocks

HV-His Ventricular

ICD – implantable cardiovertor defibrillator

KNH – Kenyatta National Hospital

MI – Myocardial infarction

MRSA – Multidrug resistant Staphylococcus aureus

RA – Rheumatoid Arthritis

RHD – Rheumatic heart disease

PICC – peripherally inserted central catheter

SSS – Sick sinus Syndrome

SLE – Systemic lupus erythematosus

SVC – Superior Vena cava

SAN – Sino atrial node

SVT – Supraventricular tachycardias

SPSS – Statistical package for social studies

UK – United Kingdom

UON – University of Nairobi

USA – United States of America

VT- ventricular tachycardia

VVIR – Ventricular pacing, ventricular sensing, inhibited, rate modulated pacing mode

WHO – World health Organisation

ABSTRACT

Keywords: pacemaker, rhythm abnormalities, indications, outcomes, Kenyatta

Background: Permanent pacemakers are the only treatment for high degree atrioventricular block or symptomatic bradycardia. Quadrennial surveys by the World Society of Arrhythmias have demonstrated a rise in the uptake of device therapy worldwide. However there is limited data on pacemaker use in Sub-Saharan Africa including Kenya.

Objectives: The aim of this study was to determine the baseline clinical characteristics, rhythm abnormalities at presentation and the outcomes for patients who underwent pacemaker insertion at the KNH between 1st January 2011 and 31st December 2015.

Methodology: This study was a retrospective chart audit based at the records department of the KNH. Patient details were retrieved from a register in the cardiac catheterization laboratory and the matching record searched for. Patients whose records were retrieved and who met the inclusion criteria constituted our study population. The vital status for each patient was then established via a phone call placed to the contacts in their record.

Results: Between 2011 and 2015, 359 patients underwent pacemaker insertion at KNH. We retrieved records for 214 patients who formed our study population. We were able to contact 165(77.1%) by phone. Most patients were elderly (median age of 71years) and female (65.4%). The most frequent presentation was dyspnoea (41.6%) and dizziness (29.9%). The commonest co-morbidity was hypertension (64%). The leading indication for pacemaker insertion was complete heartblock in 78%. The pacemaker mode most employed was DDD in 54.2%. Majority of the patients (92.1%) had presented for an index pacemaker insertion. Complications were recorded for 8.9% of patients. The median duration lived with a pacemaker in situ was 3 years and 69.2% of the 214 patients were alive at the time of the study. We confirmed that 7.9% were deceased while the vital status for 22.9% could not be established.

Conclusion: The commonest indication for pacemaker insertion at KNH is complete heart block. Most of the patients undergoing the procedure are elderly and hypertensive. Complication rates were comparable to those of developed countries with low infection rates and no mortalities during the procedure.

1.0 INTRODUCTION

Cardiovascular disease is currently the leading cause of death worldwide accounting for 31% of mortalities(1). Majority of these cardiovascular deaths are due to coronary artery disease. Three quarters of these deaths occur in low and middle income countries(1). Local data also suggests an increasing burden of non- communicable diseases including cardiovascular disease (2). The indication for 95% of pacemaker insertions according to the 11th worldwide survey on pacemakers by Mond et al is bradycardia(3). The exact incidence of bradycardia in the general population is unknown which may be attributed in part to its varied presentation. Some patients are asymptomatic while others present with sudden cardiac death as the initial manifestation. There is limited Kenyan data on the prevalence of these disorders.

1.1 Pacemakers

Pacemakers are the only effective treatment for bradycardia. Development of these devices began as early as 1889 when John Alexander Williams reported in the British Medical Journal that external application of an electrical impulse on the human heart in asystole caused it to contract at the same rate(4). This principle was later applied in 1926 when the first pacemaker was invented by Lidwill et al and later credited with the resuscitation of a stillborn infant(5). In 1932 Albert Hyman coined the term pacemaker, but it wasn't until after the Second World War that the greatest advancements in pacemaker development occurred(6). Initially devices were large and cumbersome like the Bigelow device(7). However the invention of the transistor in the 1950s enabled creation of smaller devices and larger devices were phased out. Devices have gradually become even more sophisticated in function and diminutive in size with time. Currently available pacemakers consist of traditional devices which fit in the palm and more recently invented pill-sized leadless devices inserted directly into the myocardium(8). Other important technological advances are the lithium battery which has a lifespan of 12-13years and titanium casing which prevents water vapor entry into the device and interfering with circuits(9). The pulse generator contains a battery which powers the device and has a life of 11 to 13 years. In modern pacemakers the pulse generator is multi-programmable i.e. can be set to pace different modes (10).

1.2 Pacemaker nomenclature

Standard nomenclature is employed to classify pacemakers, that is the NASPE/BPEG code (North American Society of Pacing and Electrophysiology/ British Pacing and

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Electrophysiology Group)(11). This code employs the use of five letters each of which represents a particular function of the pacemaker (Table 1). Examples of pacemaker modes based on this code include: VVIR which means the pacemaker is pacing the ventricle, sensing ventricle beats and the response to sensed beats is inhibition of impulse emission from the pacemaker and the pacemaker is also capable of rate modulation. Other commonly used modes include DDDR and AAI.

Table 1: The Revised NASPE/ BPEG Code for Anti-Bradycardia Pacing

Letter position	I	II	III	IV	V
	Chambers paced	Chamber sensed	Response to sensing	Rate modulation	Multisite pacing
	O	O	O	O	O
	A	A	T	R	A
	V	V	I		V
	D	D	D		D

O= none, A = atrium, V= ventricle, T= triggered, I= inhibited, R= rate modulation

1.3 Diagnosis of arrhythmias requiring pacemaker insertion

A resting 12 lead ECG is adequate for diagnosis when the arrhythmia is persistent(12,13). If it is non-diagnostic ambulatory ECG monitoring should be performed. This involves 24 to 48 hour continuous monitoring or use of a trans-telephonic event monitor for up to 4 weeks. If more prolonged monitoring is required an implantable loop recorder can be used. The aim is to identify symptomatic episodes and correlate with ECG findings. In young persons or those with atypical presentations additional tests that can be performed include exercise stress tests to look for chronotropic incompetence, assessment of the intrinsic heart rate with atropine or isoproterenol and beta blockers and electrophysiological studies to assess for sino-atrial node recovery time, sino-atrial conduction time and sinus node and atrial tissue refractory periods. Another useful test which can help to unmask arrhythmias is the tilt table test. In KNH the 12 lead ECG is the mainstay of diagnosis of rhythm abnormalities.

2.0 LITERATURE REVIEW

2.1 BACKGROUND

Mond et al carried out a worldwide survey on cardiac pacing and implantable cardiovertor defibrillator devices in 2009(3). They found that in 2009 alone 1,002,664 pacemakers were inserted. 75% were new devices with 25% being replacements. Developed countries had the highest pacemaker implantation rates. USA was leading with 225 567 pacemaker implants in that year(3) . Virtually all the countries which took part in the survey demonstrated an increase in the number of implants when figures were compared with a similar survey done 4 years earlier. They found that the commonest indications for pacemaker insertion were high degree atrioventricular block (complete heart block and Mobitz type 2) and sick sinus syndrome. The proportion of patients receiving pacemakers for sick sinus syndrome was higher in the Europe and North America compared to Africa(3). Although all countries demonstrated an increased uptake of DDDR pacing there still remained a high degree of VVI pacing in the less developed countries. In Africa , South Africa was found to have the largest number of insertions per annum with 2939 insertions in 2009 carried out at 49 insertion centres(3). One of the limitations of this survey is that data was collected from only 61 countries which account for 74% of the world's population. Data from most African countries including Kenya was lacking.

The incidence and prevalence of the commonest indications for pacemaker insertion in the general population is largely unknown especially in Kenya. Several studies have attempted to provide estimates of these figures. Kojic et al carried out a prospective study in Reykjavik Iceland with a study population comprising 9139 men and 9773 women(14). They found a prevalence of 0.04% for complete heart block. The block was transient in the majority 64%. These finding were corroborated by a similar study in the Tecumseh, USA(15). Here a population sample of 8641 men revealed only two with third degree AVB yielding a prevalence of 0.02%. In another study Johnson et al investigated 67375 asymptomatic airmen and none was found to have complete heart block(16). From these studies it can be concluded that the prevalence of complete heart block is low in the respective populations. Kenyan data with regards to the same is lacking.

Paul Jensen et al carried out an analysis of 20,572 participants in the Atherosclerosis risk in communities (ARIC) and the Cardiovascular Health in Communities (CHS) studies(17)in the

United States of America. During a 17 year follow-up period they found the incidence of SSS to be 0.8 per 1000 person years. Blacks were noted to have a 41% lower risk of SSS than whites. This is corroborated by figures from the 11th survey which indicate there is a larger proportion of patients undergoing pacemaker insertion for SSS in countries where the population is predominantly Caucasian(17). As populations worldwide continue to experience significant gains in life expectancy as indicated by United Nations population fact charts then the demand for pacemakers can be expected to continue to rise(18).

2.1.1 Pacemaker Insertion in Africa

In 2014 PASCAR(The Pan African Society of Cardiology) carried out at a survey on pacing and electrophysiology in Africa(19). This involved fourteen countries: South Africa, Tunisia, Morocco, Sudan, Kenya, Nigeria, Senegal, Cameroon, Libya, Ghana, Benin, Mali, Niger, Sierra Leone and Uganda. It was found that there were severe shortages of pacemakers in all countries surveyed. There was also a severe shortage of expertise required for device insertion. Most African centers were low volume implanters with pacemaker implantation rates being generally low in the African countries surveyed.

Tantchou Tchoumi et al carried out a follow–up study at a Catholic mission hospital in Cameroon between 2009 and 2011(20). Over this period 26 cases of complete heart block were diagnosed at this centre. Only 15 patients managed to get a pacemaker inserted. They found that mortality in the non-implanted cases was 45% over 16months. The main factor contributing indirectly to death was a lack of funds for pacemaker insertion. None of the patients who received an implant died during the 16 month follow-up period.

Ekpe et al carried out a retrospective 5 year review of cardiac pacemaker treatment at a University teaching hospital in Nigeria between April 2001 and March 2006(21). During this period 31 cases of complete heart block were diagnosed but only 23 underwent pacemaker insertion. 8 patients could not afford the device.

To meet the demand for pacemakers which are expensive some countries are exploring the option of recycling of pacemakers e.g. Nigeria(22). Here pacemakers with sufficient battery reserve are harvested from patients who died with a PM in situ e.g. in the USA which has the largest population of patients living with pacemakers. Devices are then sterilized before

reuse. A meta-analysis by Baman et al demonstrated that pacemaker reuse may be a safe and efficacious means of treating patients with no other means of accessing a device(23).

2.1.2 Pacemaker insertion in Kenya and Kenyatta National Hospital

There is limited data on pacemaker insertion in Kenya. According to a 2014 survey Kenya had 6 pacemaker insertion centers and between 20-30 doctors trained in pacemaker insertion(19). Kenyatta National Hospital, the largest referral hospital in Kenya is one of these centers. KNH has a functional cardiac catheterization laboratory where pacemaker insertion is carried out routinely. Due to closure of the cardiac catheterization lab for a period prior to 2010 the current patient register for all procedures dates back to just 2011.

Pacemaker insertion at this institution is carried out mainly by local cardiologists. However since 2011 a local non-governmental organization has sponsored annual pacemaker insertion projects boosting the numbers of patients able to receive this therapy(24). During projects foreign cardiologists are also involved in device insertion. At KNH the type of devices in use are the traditional permanent pacemakers. These consist of a pulse generator and insulated conducting wires referred to as leads. The device is usually inserted through a minimally invasive procedure under local anesthesia and light sedation. The pulse generator is located under the skin usually of the anterior chest wall or the abdomen and connected to the heart via leads. The leads are passed to the heart via a subclavian vein or cephalic vein through superior vena cava route

2.2 Indications for Pacemaker Insertion Including Rhythm Abnormalities

Cardiac pacing can be temporary or permanent. Temporary pacing is indicated for short term or reversible indications such as drug overdose or myocardial infarction or bradycardia post-cardiac transplant. Permanent cardiac pacing is necessary when the aetiology is persistent or irreversible. This study will focus on the permanent pacemaker.

2.2.1 Bradycardia

According to the last published survey on pacemaker therapy by Mond et al the indication for 95% of pacemaker insertions was bradycardia(3). High degree atrioventricular block (complete heart block and Mobitz type II) was the most common cause of bradycardia leading to pacemaker insertion in 77% followed by sick sinus syndrome (3,12,13).

Bradycardia can result either from abnormal impulse generation or failure of conduction of impulses from the atria to the ventricles. A postmortem study by Zoob et al done to establish the aetiology of heart block showed that majority of the cases were due to idiopathic fibrosis and sclerosis of the conducting system(25). Ischemic disease accounted for 40% of the cases(25). However any disease process affecting the sino atrial node or the conducting system of the heart can lead to bradycardia for example infiltrative diseases such as amyloidosis, collagen vascular diseases, congenital heart diseases, infections, genetic diseases associated with cardiomyopathy, inflammation, trauma, neoplasia, medication, electrolyte imbalances, sports, hypothermia, metabolic disorders such as hypothyroidism. It is important to note that the commonest causes of bradycardias are reversible for example in the emergency room setting 21% of bradycardias are due to drug effects, 14% are due to myocardial infarction, 6% due to intoxication and 4% due to electrolyte imbalances(12).

Bradycardia produces symptoms by causing a reduction in cardiac output. Reduction of blood flow to the brain can manifest as syncopal attacks which is the most dramatic presentation. But patients can also present with presyncope, fatigue, irritability, lassitude, cognitive impairment, dizziness and vertigo. They can also present with symptoms of congestion such as shortness of breath, heart failure, reduced exercise tolerance, vertigo, sudden dyspnoea and palpitations(12).

2.2.1.1 Sick Sinus Syndrome:

This term encompasses a number of disorders including persistent sinus bradycardia, chronotropic incompetence, paroxysmal or persistent sinus arrest(13). It is primarily a disease of the elderly with most patients being diagnosed in the 7th and 8th decades of life. Sick sinus syndrome has a variable natural history but in general symptoms such as syncope tend to recur. However the incidence of sudden cardiac death and mortality is similar to that of the general population. Systemic thrombo-embolism is more common in the untreated. In one series 15.2% of the unpaced had thrombo-embolism compared to 1.3% in age-matched controls(26). The indication for pacemaker insertion in this group is to prevent recurrence of symptoms(12,13).

2.2.1.2 Atrioventricular Block

Atrioventricular block can be classified depending on the degree of conduction block as first degree, second degree or third degree. Type two second degree heart block and third degree

heart block are sometimes referred to as high degree atrioventricular block. Anatomically atrioventricular block can be classified as supra-, intra- or infra His(13).

According to a study by Chow et al, first degree atrioventricular block is estimated to have a prevalence of 3-4% in healthy older men(27). Earlier studies such as the Manitoba study carried out on 3983 healthy male aviators who were followed up for 30years showed no significant difference in mortality between these patients and age matched controls(28). But more recently the Framingham study has shown that these patients actually have an increased risk of atrial fibrillation , future pacemaker insertion and all-cause mortality than their peers(29).

High degree atrioventricular block which encompasses both Mobitz type 2 and third degree atrioventricular block accounts for 40% of pacemaker insertions. In the Reykjavic study the prevalence of this HAVB in the general population was estimated to be low at about 0.04%(27).

Patients with high degree atrioventricular block have increased mortality and morbidity compared to the normal population. This results from heart failure or sudden cardiac death due to prolonged asystole or bradycardia-triggered ventricular tachyarrhythmias(12). The mortality rate for these patients prior to the pacemaker era was 50% within the first year of diagnosis for complete atrioventricular block(30). Pacemaker insertion results in improvement in symptoms and has mortality benefit for both adults and children. Evidence for this comes from several non-randomized trials(30).

2.2.1.3 Chronic Bifascicular Block:
In this condition there is impaired conduction of cardiac impulses at a level below the atrioventricular node, within the bundle of His. The defect involves the right bundle branch and one of the fascicles of the left bundle branch. For patients with a BBB pacemaker insertion is indicated if they have syncope and a positive electrophysiological score including AV block at the intra or infra-His level, markedly prolonged conduction between the His bundle and the ventricle (HV interval > 100ms) or pacing-induced AV block within or below the His bundle(13).

2.2.1.4 Post Myocardial Infarction:

Post MI patients can develop atrioventricular block. The prognosis for this cadre of patients is unfavorable and they have increased risk of sudden cardiac death. Development of a conduction defect is indicative of extensive myocardial damage. Most conduction blocks resolve within 2 to 7 days. If bradycardia persists, permanent pacemaker insertion is indicated(12,13).

2.2.1.5 Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

In these patients stimulation of the carotid sinus leads to syncope or presyncope. There are two components to this response i.e. cardio-inhibitory and vasodepressor. These are due to increased parasympathetic and sympathetic tone respectively. Data from studies done so far is conflicting on the benefit of pacemakers in these patients e.g. the Vasovagal Pacemaker Study demonstrated benefit which was not demonstrated in Vaso-Vagal Pacemaker II Study, therefore pacemakers are not considered first line therapy(31,32). However pacing is considered in persons over the age of forty with recurrent unpredictable syncopal attacks and documented sinus arrest or atrioventricular block(13).

2.2.1.6 Post-Cardiac Transplantation:

The incidence of bradyarrhythmias after heart transplant ranges from 8 to 23%. This is an ominous sign and is associated with sudden cardiac death. Temporary treatment with theophylline may obviate the need for pacing. 50% of bradycardias resolve within 6 to 12 months. Pacemaker insertion is recommended for irreversible arrhythmias(12,13).

2.2.1.7 Neuromuscular Disease:

Disease of the conduction system with eventual progression to complete AV block is a well-recognized complication of some neuromuscular diseases such as myotonic dystrophy and Emery Dreyfuss muscular dystrophy(12,13).

2.2.2 Heart Failure:

Heart failure with left ventricular dysfunction and a low ejection fraction is sometimes accompanied by electromechanical uncoupling or dysynchrony which can lead to a functional mitral regurgitation and adverse remodeling of the ventricle and increased ventricular dilation. Presence of dysnychrony and a wide QRS complex are predictors of worsening heart failure, sudden cardiac death and total mortality. Studies such as the COMPANION study

(Comparison of Medical Therapy, pacing and defibrillation in Heart Failure Trial) and the CARE HF (Cardiac resynchronization in heart failure trial) demonstrated that pacemaker therapy (biventricular pacing) significantly reduced mortality(33,34). Cardiac resynchronization therapy is of benefit to NYHA class III patients with an EF of 35% or less(34,35).

2.2.3 Prevention and Termination of Arrhythmias by Pacing:

Permanent pacemakers can be of utility in the treatment or prevention of certain ventricular and supraventricular tachycardias. For example pacing techniques such as programmed stimulation and rapid pacing in short bursts can be used to terminate reentrant rhythms such as atrial flutter , paroxysmal reentrant ventricular tachycardia or supraventricular tachycardia(13). Continuous pacing is utilized in long QT syndrome patients to prevent ventricular tachycardia. Pacing is also indicated in patients with symptomatic recurrent SVT which is refractory to treatment with medication or radiofrequency catheter ablation but which has been demonstrated to be terminated by pacing (13).

3.0 OUTCOMES POST PACEMAKER INSERTION:

3.1 Mortality

Prior to the introduction of pacemakers 50% of patients with advanced atrioventricular conduction defects died within a year of diagnosis(12,30). Furthermore 75 to 90 % were dead within 5 years of diagnosis. After pacemakers were introduced, several studies have demonstrated the improved quality of life, functional status and increased survival after pacemaker insertion. An example is the Devon heart block study a 14year prospective study done in the UK done to assess survival of patients with second degree heart block with and without pacing(36). The five year survival for all paced patients was 78% while the survival of the non-paced was only 41%. In a longitudinal study conducted at a teaching hospital in Germany, 44.8% of patients were alive after 10 years and 21.4% were still alive 20years after pacemaker insertion(37).

Post pacemaker insertion, in-hospital mortality rates are low occurring in <1% of the patients. Death can be procedure related when it is usually due to perforation of the subclavian artery, the right ventricle or the left ventricle. Death can also be due to causes unrelated to

procedures for example myocardial infarction, pulmonary embolism, stroke, heart failure or overwhelming sepsis(38).

3.2 Complications

Generally pacemakers are considered to be safe therapy. Majority of complications occur during the first 6 months. In the short term i.e. 2 months 12.4% of patients have complications while 9.2% have complications in the long-term according to data from a prospective study carried out in Europe(12,39). Rates of complications are inversely proportional to the experience of the PM insertion center. Higher rates are seen at centers handling few patients(40).

The most frequent complications are procedure related/traumatic e.g. pneumothorax occurs in 2.1%(38). Use of the cephalic vein approach is associated with a lower incidence of pneumothorax and hemothorax than the subclavian vein approach. Other traumatic events such as cardiac perforation and tamponade have been reported in 1%. Cardiac surgery is not required for most patients with tamponade, pericardiocentesis and lead repositioning usually suffice. Pocket haematomas occur in 4.9% and it has been found that the greatest predisposing factor for this is prior anticoagulation or antiplatelet agent use. Warfarin use is associated with fewer complications than heparin(38).

Infection is one of the most feared complications as it can lead to device removal/ loss. Patients with a focus of infection elsewhere on their body carry the highest risk of infection. The estimated risk of infection is 1 to 2 %(38). Risk factors for infection requiring device removal include early onset fever i.e. fever developing within 24hours of device implantation, early re-intervention, lead revision, or hematoma evacuation. The presence of any indwelling lines or catheters such as central line or temporary pacing also increases the risk of infection. De novo implantation and antibiotic prophylaxis are associated with reduced risk of infection. 60% of infections are pocket infections while 40% are endovascular. Vegetations are seen on echocardiography in up to 10% of patients. The commonest organism isolated is Staphylococcus aureus with 50% being MRSA. Majority of the infections (60%)manifest within 90days of the procedure and usually require removal of the pacemaker(38).

Pacemaker syndrome occurs in 25% of patients with sick sinus syndrome or atrioventricular block who are paced with a single chamber pacing(38). It is due to loss of atrial and ventricular synchrony. The atria contract against closed AV valves. This results in decreased stroke volume. Symptoms include; syncope, presyncope, fatigue, cough, dizziness, dyspnoea, orthopnea, paroxysmal nocturnal dyspnoea or a sensation of fullness of throat. Signs include tachycardia, hypotension, rales, jugular venous pressure with cannon waves, peripheral edema and murmurs of tricuspid regurgitation and mitral regurgitation. The patient has a normal functioning pacemaker but abnormal hemodynamics(12).

Table 2: Summary of Common Pacemaker Related Complications

Related to venous access	Pneumothorax
	Haemothorax
Lead related	Brady/Tachyarrhythmias
	Cardiac Perforation
	Cardiac Tamponade
	Coronary Sinus Dissection Or Perforation
	Dislodgement
	Diaphragmatic Stimulation
	Lead Malposition
	Venous Thromboembolism
Pocket related	Haematoma
	Wound Pain
Infections	Pocket Infection Without Bloodstream Infection
	Device Related Endocarditis
	Pocket Infection With Bloodstream Infection

Venous stenosis/thrombosis has been seen in up to 33-64% of patients(41,42). Risk factors for VTE include a left ventricular ejection fraction less than 40%, no prior anticoagulation, previous hormonal therapy, prior history of VTE and placement of multiple leads. During manipulation of leads into place some patients can develop sustained arrhythmias although the incidence is low e.g. ventricular fibrillation is seen in 0.1% (38).

3.3 Quality of life

Health is a multidimensional construct with physical, mental and social aspects. To measure health in all its dimensions quality of life measurement tools are used. It has been found from several studies that the quality of life of patients is significantly improved post pacemaker

insertion. For example Chen et al carried out a 6 month follow-up study in Taipei and found that there was significant improvement in physical symptoms, general wellbeing and physical activity(43). A similar study in done in Romania demonstrated the same results(44).

3.4 Prognostic factors for outcomes post pace-maker insertion

In a large longitudinal study carried out at a German university several baseline characteristics were noted to be of prognostic significance(37). The baseline ECG rhythm was one of these. Patients with sick sinus syndrome had the best survival on average 132.9months compared to those with atrioventricular block 94mths and atrial fibrillation 85mths, post pacemaker insertion. However patients with sick sinus syndrome were significantly younger than their counterparts in this study. A wide QRS complex e.g. due to BBB was also associated with a trend towards lower survival.

Female sex was also found to be important(37). The mean age of women at pacemaker implantation was significantly greater than that of men (73 vs. 71 years). However mean survival was greater for women than men. Women lived on average 118 months after pacemaker insertion compared to men who lived 91.7 months on average. Age at implantation also significantly influenced duration lived with device after insertion(37). Those under 70yrs lived 170.9mths after PM insertion while those over 70years lived on average 80mths. Pacemaker type inserted also influenced survival. Those with VVI mode pacemakers survived for a mean of 84mths while those with AAI or DDD pacing survived longer with a mean of 175mths or 199mths lived after device insertion.

For short term complications risk factors which have been identified include male gender, older age at implantation, body mass index of less than 20 or above 30, prior history of a cerebrovascular accident, presence of congestive cardiac failure, use of anticoagulants and passive atrial lead fixation(39). For long term complications risk factors that have been identified include age, low body mass index, hypertension and dual chamber device insertion(39). Identification of risk factors is important as it may serve as a guide to risk stratification of patients so that those more likely to experience complications are identified early for closer follow-up.

4.0 JUSTIFICATION

Symptomatic bradycardia is a treatable cause of morbidity and mortality. Permanent pacemakers are the only effective treatment for this condition. The uptake of device therapy has been on the rise in Africa. However there is limited Kenyan data on the clinical presentation as well as the rhythm abnormalities that require permanent pacemaker insertion. We also do not know the treatment outcomes with regards to complications, mortality and morbidity after pacemaker insertion. This is especially important as the patients who undergo this procedure are inherently a high risk cohort due to advanced age and the presence of co-morbidities.

We chose to limit the study period to between 1st January 2011 and 31st December 2015 as the cardiac catheterization laboratory register had only listed patients who had pacemakers inserted during this period.

5.0 RESEARCH QUESTION:

What are the baseline characteristics and outcomes for patients who have had a pacemaker inserted at the Kenyatta National Hospital between 1st January 2011 and 31st December 2015?

6.0 STUDY OBJECTIVES

6.1 Broad Objective:

To describe the baseline characteristics and outcomes for the patients who have had pacemakers inserted at the Kenyatta National Hospital between 1st January 2011 and 31st December 2015.

6.2 Specific Objectives:

Primary objectives:

- To document the rhythm abnormalities present at the time of insertion.
- To describe the clinical features and concurrent diagnoses present at the time of insertion.
- To document the frequency of complications occurring after pacemaker insertion for patients with pacemakers inserted between 1st January 2011 and 31st December 2015.

Secondary objective:

- To establish the survival and loss to follow up of patients with pacemakers inserted between 1st January 2011 and 31st December 2015.

7.0 METHODOLOGY

7.1 Study Site
This study was carried out at the Cardiology unit and the Health Records department of the Kenyatta National Hospital. Pacemaker insertion is routinely performed in the Cardiology unit.

7.2 Study Design
This was a retrospective records review. Study subjects were identified from the pacemaker registry; thereafter files were retrieved from the records department at KNH. Overall 359 patients had a pacemaker inserted during the study period 1st January 2011 and 31st December 2015. Records for 135 (37.6%) were not retrieved and hence not analysed.

7.3 Study Population
 Data was extracted from available health records of all adults who had a pacemaker inserted at the Kenyatta National Hospital during the period between 2011 and 2015. An adult was defined as any person over the age of 18 years.

7.4 Sample Size
We included all available patient records for patients who had undergone pacemaker insertion during the above period in the study.

7.5 Sampling Method
We used an exhaustive sampling frame. We retrieved names and file numbers for all patients who had undergone pacemaker insertion at KNH from a register kept in the Cardiology Unit. We then made a search for the matching health records at the Records Department. We extracted data from all the records which met the inclusion criteria.

7.6 Case Definition:

Cases were defined adults listed in the cardiac catheterization laboratory register as having undergone permanent pacemaker insertion at KNH between 1st January 2011 and 31st December 2015.

7.7 Inclusion Criteria:

- Any record for an adult listed in the cardiac catheterization laboratory register as having undergone pacemaker insertion between 2011 and 2015.

7.8 Exclusion Criteria

- Any record for a patient under the age of eighteen years.
- Records without pacemaker insertion procedure notes were considered incomplete and excluded.

7.9 Data Collection

Available health records for patients who had a pacemaker inserted at KNH were retrieved from the KNH records department. For patients who met the inclusion criteria, data was extracted from their record with the aid of a pre-designed study questionnaire (Appendix 3). The patient's vital status was then established by verbal confirmation. A phone call was placed directly to each patient and their next of kin through contacts present in the file. The format of the phone call is outlined in Appendices 2 and 3.

7.10 Study Variables:

These included the following:

- Socio-demographic characteristics such as age at pacemaker implantation, sex, level of education and occupation.
- Concurrent diagnoses at baseline such as hypertension, diabetes and stroke
- Indications for pacemaker insertion including the baseline ECG rhythm for example complete heart block, sick sinus syndrome or Mobitz type 1.
- Presenting symptoms recorded in initial assessment notes including syncope, pre-syncope, lower limb swelling and dyspnoea. Symptoms were recorded with the exact terminology used by the doctor who wrote in the patient record.
- Complications experienced including infections and lead dislodgement.

- Prior medication use for example antihypertensives, diuretics and anticoagulants.

- Route of pacemaker insertion for example left subclavian vein, left cephalic vein or right subclavian vein.

- Pacemaker type inserted for example dual chamber device (DDDR) or single chamber devices.

- Time to first complication from time of pacemaker insertion.

- Mean duration lived with pacemaker from the time of insertion.

7.11 Quality Assurance:

A pre-designed questionnaire was used to collect data from each participant to ensure uniformity. The principal investigator undertook the extraction of data using the questionnaire. The principal investigator trained an assistant who placed a call to each patient or next of kin through contacts available in the patient record. Each phone call was carried out according to the same format as outlined in Appendices 2 and 3. Data was then entered into a secure database by a qualified data clerk and verified by the principal investigator.

7.12 Data Management and Analysis

Data was coded from data collection tools and then entered into an SPSS Database. Data was then cleaned and verified. The cleaned data was analysed with SPSS version 21.0 software. The study population was described by their clinical and socio-demographic characteristics. Categorical data such as sex, blood pressure and co-morbidities were summarized into frequencies and continuous data such as age and duration lived with pacemaker were summarized as means and medians. Data was then presented in tables, pie charts and bar charts as appropriate.

8.0 RESULTS

Between the period 1st January 2011 and 31st December 2015, 359 patients are listed as having undergone pacemaker insertion at the Kenyatta National hospital. The number of pacemakers inserted each year is summarized in figure 2. We managed to retrieve 224 patient records. This means 135 records were unavailable. Further enquiries were made at the records department but we could not establish why these records were missing. Of the 224 records retrieved 3 records belonged to patients who were under 18 years of age while 7 records were incomplete. Data was therefore extracted from 214 patient records as shown in the recruitment flow chart below (Figure 1). We then placed a phone call to each patient by the number available in the patient record to establish their vital status. Phone contacts were present in 190 records and out of this number 165 responded to the phone call.

Figure 1: Recruitment flow chart
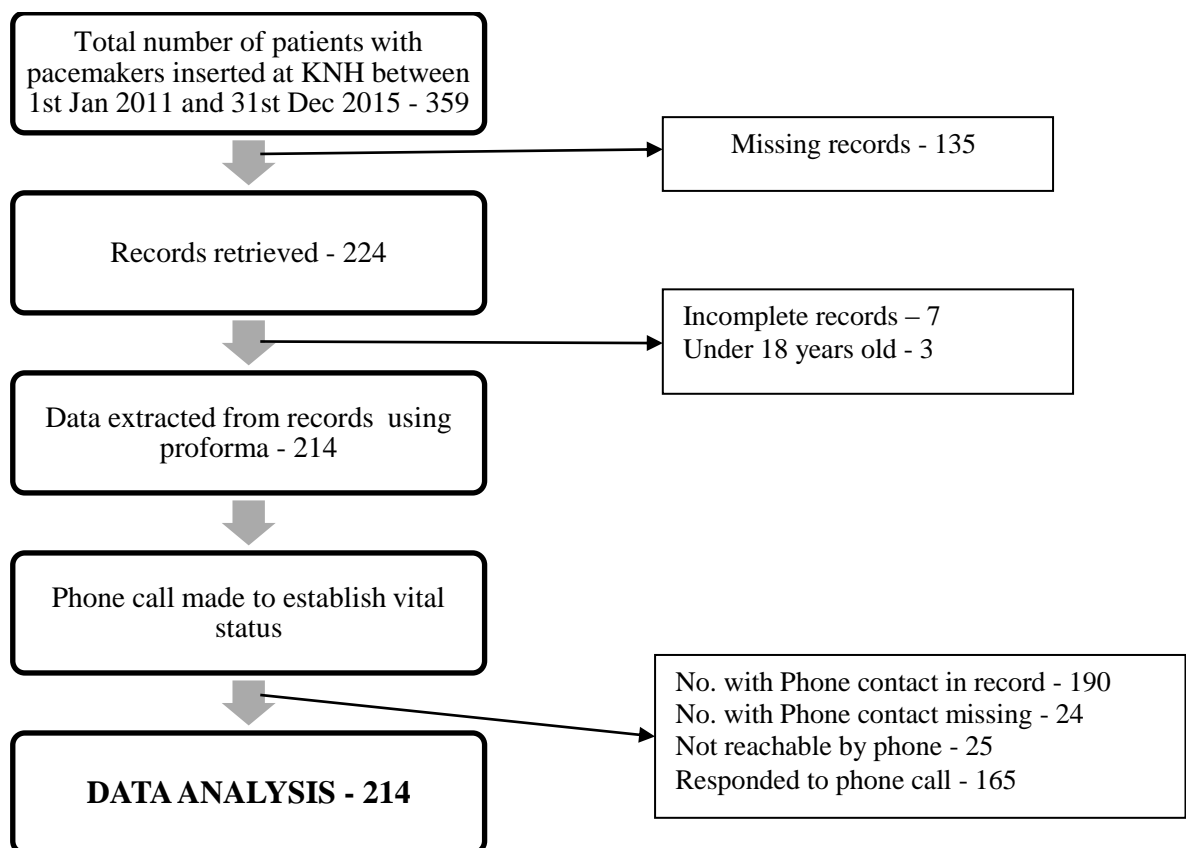
Figure 2: Number of Pacemaker insertions per year from 2011-2015
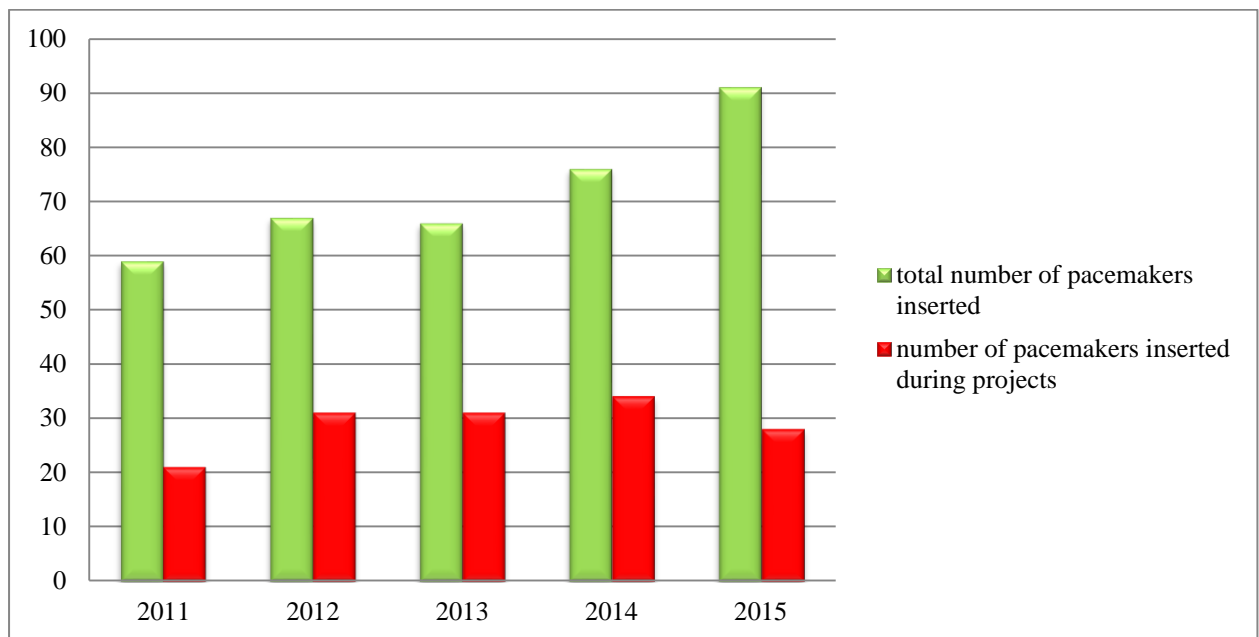
8.1 Socio-demographic characteristics

The median age of our study participants was 71 years with an age range of 26 to 98 years. Females accounted for 65% of the patients. The average age for females was 71.5 years and males 70.2 years. 43.5% of patients were resident in a rural setting. 37.9% were unemployed or retired. With regards to level of education 55.6% of patients had achieved at least a minimum of primary school education while 15.9% of patients had not received formal education. (Table 3).

8.2 Indications for Pacemaker insertion

The main indications for pacemaker insertion as derived from procedure notes included complete heart block in 73.3% and second degree atrioventricular block in 9.8%. Other indications were sick sinus syndrome in 4.7% and cardiac resynchronisation therapy in 1.9%. Of the patients with complete heartblock 4.7% had co-existing atrial fibrillation (Figure 3).

Table 3: Socio-demographic characteristics

Variable (study population N= 214)	n (%)
Age	
Mean age (SD)	70.6yrs(11.8)
Median Age	71yrs
Range (min -max)	29-98yrs
Mean age by sex	
Females	71.5yrs (12.2)
Males	70.2yrs (11.8)
Sex	
Male	74 (34.6)
Female	140 (65.4)
Usual residence	
Urban	56 (26.6)
Rural	94 (43.5)
Unknown	64 (29.9)
Education level	
None	33 (15.9)
Primary	57 (26.6)
Secondary	33 (15.4)
College	29 (13.6)
Missing	62 (28.6)
Occupation	
Employed	73 (35.0)
Unemployed/retired	84 (37.9)
Missing	57 (27.1)

SD= standard deviation

8.3 Baseline Clinical Characteristics and Co-morbidities

The symptoms at presentation included dyspnoea in 41.6%, dizziness in 29.9%, syncope in 17.3%, palpitations in 12.1%, presyncope in 6.1%, convulsions in 4.2%, 6.1% of the patients were asymptomatic. Note that symptoms are not mutually exclusive. The co-morbidities recorded at presentation included hypertension in 64%, congestive cardiac failure in 22.9%, diabetes in 15.9 %, chronic kidney disease in 4.2%, dilated cardiomyopathy in 3.7%, valvular heart disease in 1.4%, hyperthyroidism in 1.4% and chronic lung disease in 2.8%. More than half the patients were (54%) were on medication. The patient medications recorded included furosemide 24.8%, angiotensin receptor blockers (15.9%), aldactone (12.6%) angiotensin converting enzyme inhibitors (6.5%), anticoagulants (6.1%), beta blockers in 2.8% and oral corticosteroids in 1.4%. (Figure 6).

Figure 3: Indications for Pacemaker Implantation

Legend:
- complete heart block
- second degree atrioventricular block
- sick sinus syndrome
- cardiac resynchronisation therapy
- not indicated

(78%, 11%, 3%, 3%, 5%)
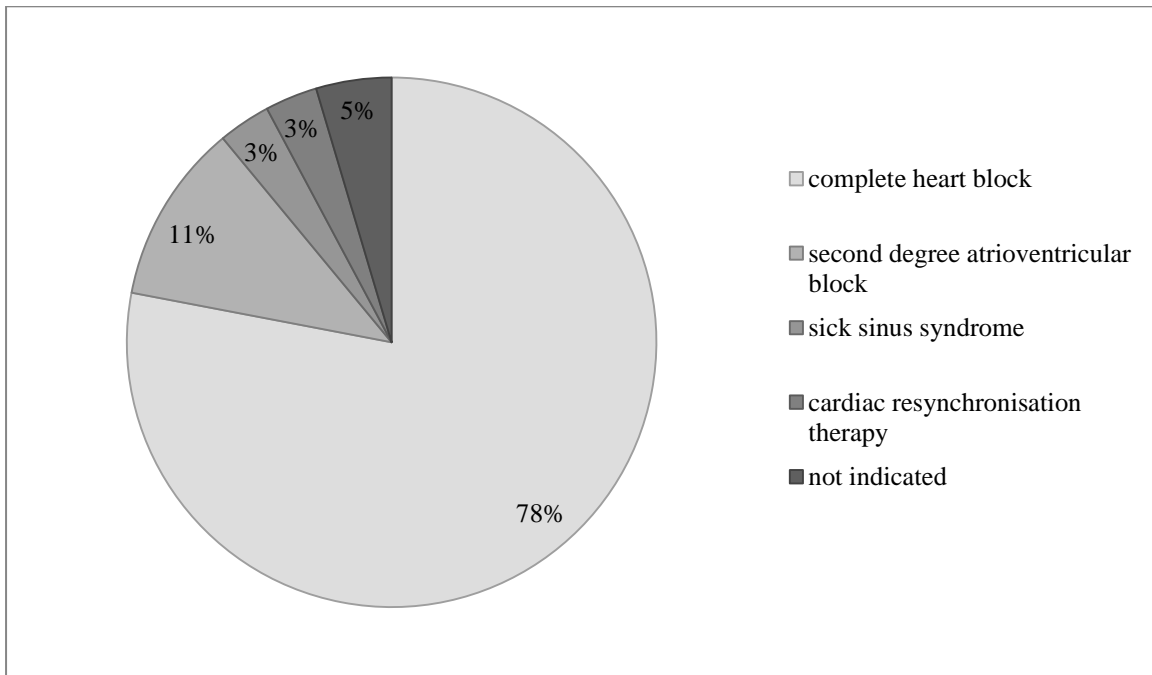
Figure 4: Commonest Symptoms recorded at Presentation (%) n=214
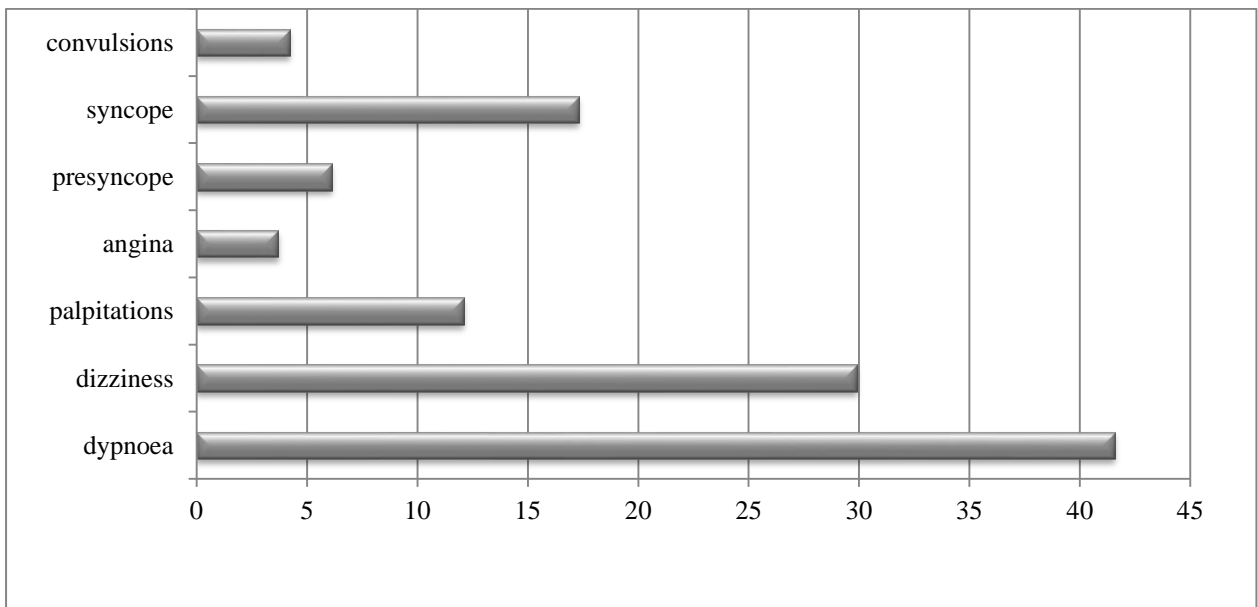
Figure 5: Concurrent Diagnoses Present at Baseline (%) n=214
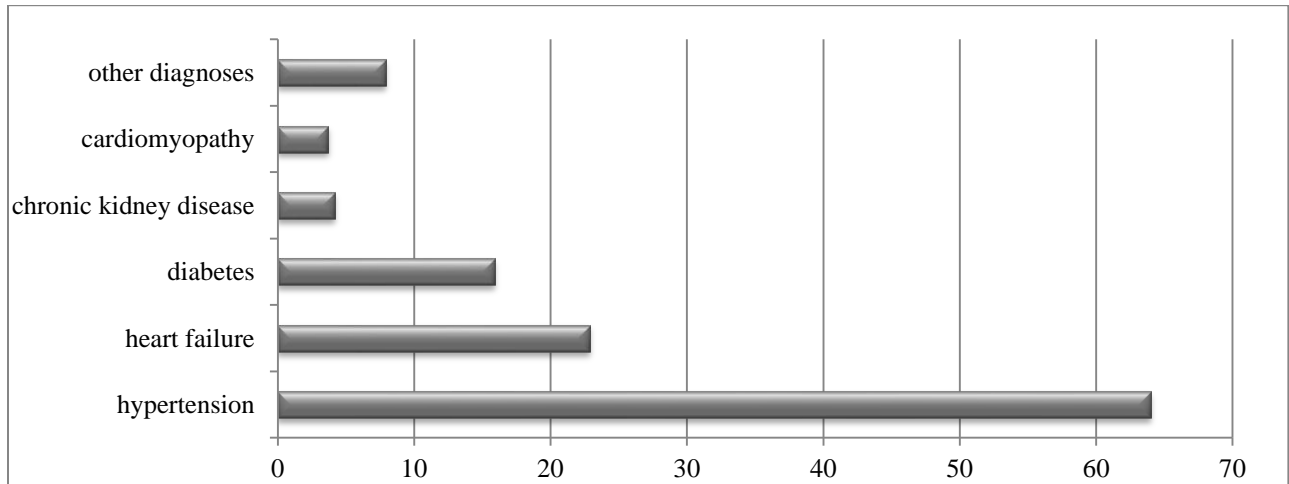
Other diagnoses includes valvular heart disease 1.4%, hyperthyroidism 1.4%, chronic lung disease 2.8%

Figure 6: Medication use at baseline (%) n=214
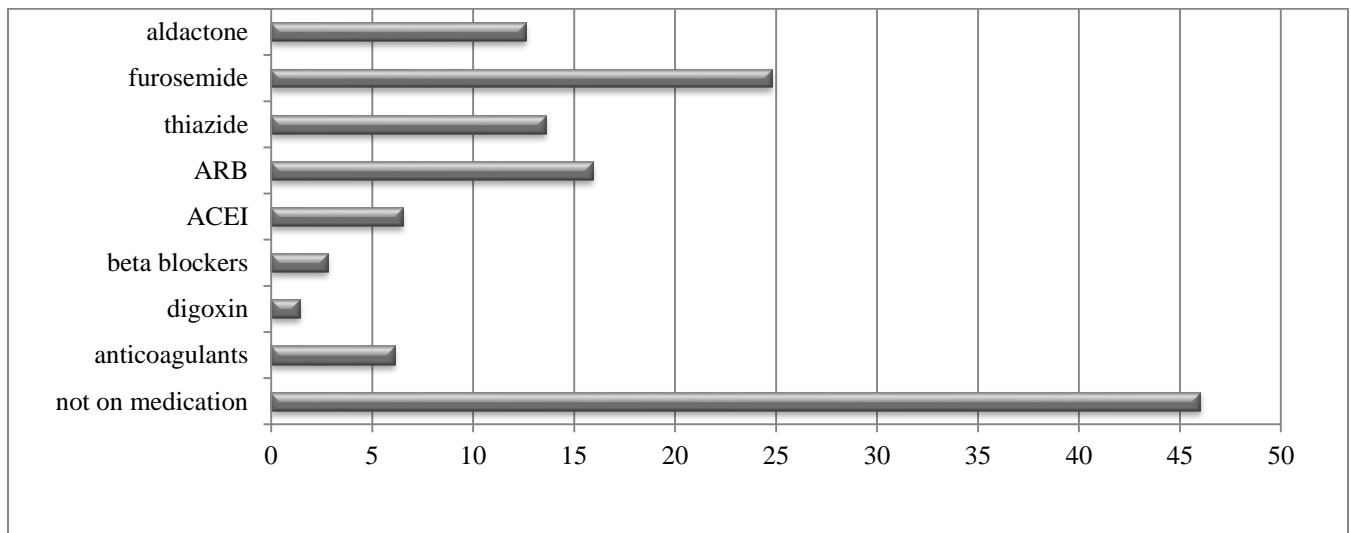
ACEI- Angiotensin converting enzyme inhibitors, ARB- angiotensin receptor blockers

Physical examination findings

The mean pulse rate was 43.6 beats per minute with a range of 21 to 117 beats per minute. The average systolic blood pressure at insertion was 158mmHg (SD 31.8) and the mean diastolic

blood pressure 74.3mmHg (SD 15.6%). Oxygen saturations were recorded for 81% of patients prior to the procedure. The mean saturation was 94.5% with a range of 82-100. Only 13 and 9 patients had their height and weight recorded respectively prior to the procedure.

Table 4: Physical Examination Findings at Presentation

Clinical Feature	n (%)
Blood Pressure n= 208 Number with elevated blood pressure at time of insertion systolic BP(Mean,SD) diastolic BP (Mean,SD)	 145 (67.8) 158.1 (31.8)(SD) 74.3 (15.6) (SD)
Pulse rate (n=209) Mean (SD) Range	 43.6 (16.4) 21-117
Mean S_aO_2 % n=173 Mean (SD) Range	 94.5 (8.4) 82-100

SD = standard deviation, BP = Blood pressure, SaO2 = oxygen saturation,

ECG findings

ECG recordings were present in the files of 190 of the patients (88.9%). The commonest rhythm abnormality was complete heart block in 78%. Most of the patients with complete heart block (61.6%) had a narrow QRS complex on ECG. Sinus node activity (denoted by p waves) was present in 91.6%. 10 patients were in atrial fibrillation and 6 had atrial flutter. The mean sinus node rate was 84 beats per minute. The electrical axis was normal in 56.3%, 30.5% had left axis deviation and 23% had right axis deviation. 16.3% had ST segment changes. Of these 67.7% had ST elevation. Left ventricular hypertrophy was present in 21.6% and right ventricular hypertrophy in 5.3 %.(See table 5)

Table 5: Summary of ECG findings

Parameter	n (%)
ECG characteristics (n=190)	
QRS width	
Narrow	122 (64.2)
Wide	68 (35.7)
Rhythm Abnormalities	
i) Complete heart block: n = 159	
Narrow QRS	98(61.6)
Wide QRS	61(38.4)
ii) Sick sinus syndrome: n = 7	
Narrow QRS	7(100)
Wide QRS	None
iii) Second degree AVB: n = 23	
Wide QRS	16(69.6)
Narrow QRS	7(30.4)
iv) First degree AVB: n=1	
Narrow QRS	1(0.5)
Sinus node activity n=190	
Present	174(91.6)
Mean sinus node rate	84bpm
Atrial fibrillation	10(5.3)
Atrial flutter	6(3.2)
P wave abnormalities	
P pulmonale	6
P mitrale	7
Inverted p waves	1
Electrical Axis n = 190	
Normal	107(56.3)
Left axis deviation	58(30.5)
Right axis deviation	23(12.1)
Extreme right axis	2(1.1)
Other findings	
ST depression	10
ST elevation	21
Left Ventricular Hypertrophy	41(21.6)
Left bundle branch block	10
Left posterior fascicle block	5
Left anterior fascicle block	9
Right Ventricular Hypertrophy	10
Tall T waves	31
T wave inversion	31
Premature ventricular complexes	14

8.5 Outcomes after pacemaker implantation

Most of the pacemakers inserted (92.1%) were index devices. The commonest pacemaker type inserted was the dual chamber device in 54.1% while 41.2% received a single chamber device. The commonest access route used during insertion was the left subclavian vein in 70.6%.The right subclavian route was used in 3.3% and the left cephalic vein in 13.1%. Route of insertion was not indicated for 13.1%. Majority of the patients undergoing insertion 93.9% received prophylactic antibiotics. Most patients (93.9%) had the procedure done under local anaesthesia. Most patients (68%) were discharged on the day of the procedure while 28% were admitted. The mean duration of admission was 5 days with a range of 1-60days.

8.6 Complications

Complications were documented in 19 patient records (8.9%). These included lead dehiscence in 7 patients, pocket infections in 3patients, pacemaker syndrome in 2 patients, one pneumothorax, 3 hematomas at the incision site, angina in one patient , asystole in 2 patients and sustained ventricular tachycardia in one patient. 9 patients had complications arising during the pacemaker insertion procedure itself. However there were no mortalities during the procedure. Most complications, 68.4%, occurred within 6 months of device insertion with 31.6% occurring more than 6 months later. Of the patients with complications 52% had a single chamber pacemaker while 48% had a dual chamber device. All patients with infections had a single chamber device inserted. All the patients with complications including those with infections had received prophylactic antibiotics.

Mortality

At the time of the study out of the 214 patients 148 patients (69.2%) were alive. Through phone calls we were able to confirm that 7.9% were deceased. For 22.9% vital status could not be established either because there a no phone number in the file (11.2%) or the patient not being reachable (11.7%) because of a wrong phone number, a number being out of commission or not picking up the phone. For those who were alive 62.1% were on follow up at KNH, 19.6% were on follow-up at private clinics and 18.2% were on follow-up at other public hospitals. The average duration lived from time of pacemaker insertion was 3 years with a range of 1 to 16 years (Table 8).

Table 6: Pacemaker insertion procedure details

Variable		n (%)
Pacing mode n = 212	VVI	88 (41.2)
	AAI	0
	VVD	0
	DDD	116 (54.2)
	Biventricular	8 (3.7)
Pacemaker status n = 214	New	197 (92.1)
	Replacement	5 (2.3)
	Missing	12 (5.6)
Active fixation n=23	Atrial	5 (21.7)
	Ventricular	18 (78.3)
Access n = 186	RSCV	7 (3.3)
	LSCV	151 (70.6)
	LCV	28 (13.1)
Antibiotic prophylaxis n = 214	Yes	201 (93.9)
	No	1 (0.5)
	Missing	12 (5.6)
Type of anesthesia used n = 214	Local	201 (93.9)
	Missing	13 (6.1)
Device manufacturer: n = 198	Biotronik	26 (12.1)
	Boston scientific	9 (4.2)
	Guidant	2 (0.9)
	Medtronic	95 (44.4)
	Pacetronix	6 (2.8)
	St Jude Medical	58 (27.1)
	Verity	2 (0.9)
Duration of admission n=209	Discharged same day	147(68)
	Number admitted	62(28)
	Mean duration of admission(days)	5days
	range	1-60

RSCV = Right subclavian vein, RFV = right femoral vein, LSCV = left subclavian vein, LCV = left cephalic vein, LFV= left femoral vein

Table 7: Complications

Variable N=214	n (%)
Complications Number with recorded complications	19(8.9)
Complications during procedure Pneumothorax Hematoma Haemothorax Asystole Angina Ventricular tachycardia	**9(4.2)** 1(0.5) 3(1.4) 1(0.5) 2(0.9) 1(0.5) 1(0.5)
***Other*:** Pocket infection Pacemaker syndrome Lead dehiscence Failure of capture	**10(4.7)** 3(1.4) 2(0.9) 7(3.3) 4(1.9)
Timing of complication During pacemaker insertion procedure within 6 months of insertion) occurring more than 6 months after insertion)	9(4.2) 13 (68.4) 6 (31.6)
Mortalities during insertion	0

Table 8: Outcomes after pacemaker implantation

Variable		Frequency (%)
Outcome	Alive Dead Missing	148 (69.2) 17 (7.9) 49 (22.9)
Current follow up	KNH Other private hospitals Other public hospitals Missing information/ deceased	92 (43.0) 29 (13.6) 27 (11.7) 66 (31.8)
Mean duration with pacemaker for alive patients (years)	Median (IQR) Min-Max	3.0 (2.0-4.0) 1.0-16.0

9.0 DISCUSSION

This study was a retrospective chart audit carried out between 1st of June 2015 and 31st of July 2015. From the KNH cardiac catheterization laboratory register 357 patients had undergone permanent pacemaker insertion during this period. We were able to retrieve patient records for 214 patients who then constituted our study population. It was not possible to establish the reason for the inability to access the remaining 143 records. From our analysis of the available records we found that majority of the patients undergoing pacemaker insertion were elderly females (65.4%) with a median age of 70.6years and a range of 29-98years. The commonest symptoms at presentation were dyspnoea and dizziness. The most frequent rhythm abnormality/ indication for pacemaker insertion was complete heart block in 78%. Most patients were known to be hypertensive. Complication rates were low (8.9%) with most occurring within 6 months of the procedure. No mortalities were recorded during the procedure and majority of the patients 69.2% were alive at the time of the study.

9.1 Rhythm abnormalities present at baseline/ indications for pacemaker insertion

The commonest indication for pacemaker insertion was complete heartblock in the majority of our patients i.e. 78%. Sick sinus syndrome accounted for 3% of pacemaker insertions, second degree atrioventricular block for 11% and cardiac resynchronization therapy for 3%. This is congruent with figures from the 2009 worldwide survey where bradycardia was the commonest indication for pacemaker insertion. However in Europe and North America the proportion of PM insertions for sick sinus syndrome is greater than in African or Asian countries. For example in Belgium SSS accounted for 42% of PM insertions (3). According to data from other African studies carried out in Nigeria, South Africa and Cameroon complete heart block is the commonest indication for pacemaker insertion. Falase et al in a retrospective study at a Nigerian teaching hospital found complete heart block in 53% and second degree atrioventricular block in 37.2% sick sinus syndrome was present in 9.8%. Dos Santos et al carried out a study on permanent cardiac pacing in South African Blacks. 77% of their patients had complete heart block which compares with the figure in our study.

Jensen et al. carried out a prospective study to describe the epidemiology of SSS in the participants of the Atherosclerosis Risk in communities (ARIC) study and the Cardiovascular

Health Study (CHS) in the USA. They found that blacks had a 41% lower risk of developing SSS than whites. This may explain the lower numbers of patients undergoing PM insertion for SSS in our setup. The reason for lower risk is unknown.

Baseline ECG characteristics

Left ventricular hypertrophy was present in 21.6%. Majority of the patients were hypertensive and this may explain the presence of LVH. 10 patients were in atrial fibrillation while 6 had atrial flutter. Q waves were present in ECGs of 12patients while 20 patients had a left bundle branch block (LBBB.) This could be indicative of presence of ischaemic heart disease as an aetiology of the heart block.

The mean heart rate i.e. ventricular rate was 43.6 beats per minute. The mean sinus rate was 84 beats per minute for our patients. This implies normal sympathetic nervous system tone. Increased sympathetic tone puts the patient at increased risk of sudden cardiac death.

The QRS complex was narrow in the majority of our patients 55.6%. In those with complete heart block 63.4% had a narrow QRS. In a study done at a Cameroonian hospital to assess the incidence and survival of patients with complete heart block it was found that 35.2% had a narrow QRS while 64.8% had a wide QRS(20). In another study by Rosen et al, they had similar findings with 67% of patients having a wide QRS and 33% narrow complexes. In our study the figures were reversed with 63.4% of patients having a narrow QRS complex and 36.6% having a wide QRS. A wide QRS has been shown to be an independent predictor of increased morbidity and mortality in other cardiac arrhythmias such as atrial fibrillation. The significance of this finding in the setting of heartblock is unknown. Hypothetically patients with a narrow QRS complex are deemed more stable than those with wide complexes. This is because electrical activity is generated higher up in the cardiac conduction pathway and therefore they have a more dependable escape rhythm and therefore are more hemodynamically stable.

9.2 Clinical features and concurrent diagnoses present at baseline
i) Socio-demographic characteristics

The median age of our study population was 71years. This is well within the range of 65 to 75 years reported in the 11th worldwide survey of cardiac pacing (3). Although cardiovascular

disease is considered to be more prevalent in the male sex, majority of the patients who underwent PM insertion were females at 65% with males being just 34.6% of the population. Female predominance is mainly seen in auto-immune disease where 78% are females as well as in other diseases like osteoporosis and breast cancer. Our figure differed from findings in other African studies where most of the PM insertions are carried out on male patients for example the study by Falase et al in Nigeria where 56.9% of patients were male and 43.1% were females. The same is reflected in the Canadian CTOPP trial where 40% of PM insertions were carried out in females(45). The reason for female predominance in our setup is unclear. One factor may be the increased health seeking behavior of females and longevity of females compared to their male counterparts(46). The missing records may also have led to skewed results.

ii) Concurrent diagnosis and other baseline features

The commonest co-morbidity was hypertension in 64%. Ekpe et al had similar findings in their study whereby 67% of the patients were hypertensive(21). Bradycardia is thought to cause elevated blood pressure by increasing ventricular filling time in diastole. This leads to greater stretch of the ventricle and in keeping with Starlings Law there is a greater force of contraction in systole. It is not surprising then that most of our patients had an elevated BP at presentation. 64% were known hypertensives while 67.8 percent had a high blood pressure reading at the time of the procedure.

The commonest symptoms recorded at presentation were dizziness in 29.9% and dyspnoea in 41.6%. Most patients were NYHA class 2 at presentation. In other studies the commonest symptom for which pacemakers were inserted was syncope in 45%(47). In our study population 17.3% had syncope. A prospective study design would have been better to ascertain the symptoms present at baseline. Our figures with regards to syncope may be lower due to underreporting or poor record keeping.

9.4 Pacemaker insertion

Relative to other African studies more pacemaker insertions are carried out at our center annually. For example Tantchou et al carried out a prospective study involving patients with

complete heartblock in Cameroon(20). Over a 2 year period 15 patients underwent pacemaker insertion at this center. Ekpe et al in a retrospective study at a Nigerian teaching hospital recorded a figure of 23 patients undergoing pacemaker insertion over a 5year period(21). Thiam et al in Dakar found that 92 implants were carried out over 3years(48). But compared to centers in the Europe our numbers are considerably small. For example Bond et al carried out a study on pacemaker complications at a District hospital in the UK. Here the number of procedures at a single center over a 3 year period was 1286(49). KNH recorded 357 insertions over 5years.

The pacing mode most commonly employed was DDD as opposed to VVI. In other developing countries the commonest mode used was VVI. This is because single chamber pacemakers are more affordable. In a study by Falase et al in Nigeria 56% of their cases had a VVI device inserted(47). In a study by Thomas et al in Nigeria 89% of pacemakers inserted were single chamber devices(50). Thiam et al in Dakar in 2003found that 87% of pacemakers inserted were single chamber devices(48). At KNH the increased number of DDD pacemakers may be attributed to donations made during the project.

Worldwide there is a trend towards use of DDD pacemakers. This was informed by data from earlier studies such as a prospective randomised trial by Andersen et al where comparison of AAI and VVI modes was done in a cohort of 225 patients with a mean follow- up of 3.3years(51). The frequency of atrial fibrillation and thromboembolic events was higher in the ventricular pacing group. An extension of the same study for a more prolonged follow-up found that the benefit of atrial pacing became enhanced with time(52). However three subsequent large prospective Randomised control trials have failed to show the same effect. These include the CTOPP-Canadian Trial of Physiological Pacing trial (DDDR vs. AAI(R) or VVI (R)) which enrolled 2568 patients, the MOST Mode selection Trial (DDDR versus VVIR) which enrolled 2010 patients and the UKPACE United Kingdom Pacing and Cardiovascular event trial (DDDR vs. VVI(R) which enrolled 2021 patients(45,53,54). These trials showed that the outcome with regards to mortality, cardiovascular events, stroke, hospital admissions and rates of development of pacemaker syndrome were similar in all pacing modes i.e. AAI, VVI or DDD. The only area where benefit was demonstrated with physiological pacing was in the reduction in the incidence of chronic atrial fibrillation. Current guidelines however still recommend DDD over VVI

despite there being no survival benefit(12,13). Studies done in the Africa have not reported increased adverse events in patients with single chamber devices. In the series by Falase et al majority of the patients received a single chamber implant (56%) and none developed pacemaker syndrome. In the study by Thomas et al where 89% received a single chamber device none had complications while in the study by Thiam et al in Dakar where 87% received single chamber implants only 1 had pacemaker syndrome(48,50). In Kenya, where most patients have limited resources it may not be practical to insist on patients acquiring a more costly device which offers no added survival benefit.

Majority of our patients came for an index pacemaker insertion i.e. 92.7% while 2.1% had a replacement. In the 2009 worldwide survey 75% of pacemakers inserted were index insertions with 25% being replacements. The reason for the low rate of replacements may be explained by the fact that device therapy has become more accessible during the last five years due to presence of donated pacemakers. Donations form a significant proportion of devices inserted, for example in 2015 alone, 31% of pacemakers inserted were donations (See figure 2). This indicates an unmet demand i.e. pacemakers are inaccessible due to high cost. It may be worthwhile therefore to explore strategies such as recycling of devices to increase availability and affordability. Reuse has been practiced since the 1970s. Timir et al carried out a meta-analysis on the safety of pacemaker re-use. They analysed 18 studies and pooled individual data (n= 2270). The rates of infection and device malfunction were low in the recycled pacemakers group. However when compared to patients who received new devices the rate of device malfunction was higher(23). There were no African studies in this analysis. Zimasa et al carried out a retrospective case comparison study at a South African hospital to assess the performance of recycled pacemakers and implantable cardiovertor defibrillators(55). There were no significant differences in performance with regards to infection rates, device malfunction, and battery loss.
 The commonest access route used was the left subclavian vein (70.6%) with the left cephalic vein used in 13.1% of cases. The left cephalic vein is associated with fewer complications such as pneumothorax and hemothorax.

9.6 Complications

In our study population complications were recorded for 19 patients (8.9%). Most complications (68.4%) occurred within 6 months of device insertion. According to a European registry most complications occur within 6 months(12). Falase et al reported complications in 19.6% of their patients. 5.9% had lead displacements, 5.9% had pacemaker infections, 3.9% had pocket erosions and there was one pacemaker related death. Thiam et al in Dakar reported complications in 9 patients out of 92 who had undergone pacemaker insertion (9.9%). infection was encountered in 5, 3 had lead displacements, one had pacemaker syndrome. Our figures are lower which could be explained by the fact that this was a retrospective study and as we were not able to retrieve the full complement of records there may have been selection bias. In addition not all the patients who received pacemakers at KNH continued their follow-up here and therefore complications may have been recorded at another facility.

The most common complication was lead dehiscence. Lead related complications are the commonest complications encountered in the USA(38). The estimated risk of infection from studies done in the USA is 1-2%(38). Our infection rate was comparable at 1.4%. Antibiotic prophylaxis was used routinely in 93.9% in our setup.This may explain the low infection rates. Most patients had the procedure done under local anesthesia which may explain the low rates of hospitalisation. Most patients were admitted and discharged home the same day (68%). Use of local anaesthesia may also increased ability to tolerate the procedure by even the extremely elderly patients. The oldest patient to undergo the procedure was 98 years old. 3 patients developed hematomas at the site of incision. 2 of them had a history of prior anticoagulant use. All bleeds resolved with conservative management. 2 patients had asystole during insertion, one had ventricular tachycardia and one experienced angina. Resuscitation was successful for all. There were no mortalities during the insertion procedure.

Mortality

Verbal confirmation was used to establish vital status in this study. This method has been utilized in other studies done locally in this institution. An example is the study by Mutuga et al on the outcomes for patients with ambulatory heart failure(56). Using the same methodology we were

able to confirm that at the time of the study 69.2% of the patients whose records were retrieved were alive. The mean duration lived with a pacemaker after insertion was 3years with a range of 1year to 16years. Prior to the introduction of pacemakers 50% of patients with advanced atrioventricular conduction defects died within a year of diagnosis. 75 to 90 percent were dead within 5 years(57). We confirmed that 7.9% of the patients were deceased at the time of the study. We could not establish the vital status for 22.9% of the patients because of missing phone contacts in the record (11.2%) and 11.7% were unreachable for various reasons including wrong phone number, number being out of commission or no response to the phone call.

10.0 LIMITATIONS AND STRENGTHS

1. Limitations:

The patient records for 143 patients were missing and we do not know the characteristics of these patients.

There was poor documentation and a lack of uniformity of the data in patient records which led to gaps in data collected for certain variables. For example important data which we meant to collect using our questionnaire such as patient weight, height and physical examination findings with regards to cardiovascular system exam were missing in most files.

This study was carried out at a single centre which is a large referral hospital and results may not therefore be generalisable to other centres. Patient selection was not randomised in our study, therefore there may have been a selection bias.

This was a retrospective study. The best study design to establish all our objectives would have been a prospective study where the principle investigator would have followed patients up closely and would have been able to ascertain the presenting symptoms, burden of disease, complications, mortality, and quality of life in a uniform manner for each patient. However this was not feasible due to time and resource constraints.

2. Strengths:

Despite missing records the study still generated useful information which can impact the management of patients undergoing device therapy at KNH.

11.0 CONCLUSION

The uptake of pacemaker therapy has been increasing from year to year over the period from 2010 to 2015 at KNH. Majority of the patients who underwent the procedure were elderly with co-morbidities. Our complication rates are low compare to other developing countries with low infection rates and no mortalities during the procedure. The commonest indication for pacemaker insertion is complete heart block and most patients received dual chamber devices.

12.0 RECOMMENDATIONS

- Kenyatta National Hospital should establish a registry to help with uniform data collection for all patients undergoing the procedure. This would improve the quality of results in future studies.
- A prospective study should be done to confirm the true rate of long-term complications and mortalities after pacemaker insertion.
- KNH should establish a special clinic for follow-up of patients with pacemakers to help to minimize losses to follow-up.
- Majority (43%) of patients are from rural settings. Pacemaker insertion should be rolled out to other public health facilities to increase availability.
- We should screen all patients with bradycardia for hypertension and diabetes.

13.0 REFERENCES

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APPENDIX 1: STUDY PROFORMA

STUDY NUMBER	
HOSPITAL NUMBER	
NAME	
AGE	
SEX	
PHONE NUMBER patient	
PHONE NUMBER next of kin	
Date of admission for procedure	
Date of procedure	
Date of discharge	
Mean hospital stay(DOA-DOD)	
Referred from	

Demographic characteristics		
Marital status (Single, married divorced, separated, widowed)		
Usual residence(county code) 1-47	Code	
	Rural or urban	
Occupation (employed, self employed, not formally employed, unemployed)		
Level of formal education (none, primary, secondary, vocational, university or college		
Nationality		

Presenting symptoms			
	yes	No	not indicated
Syncope			
Dizziness			

Dyspnoea			
Palpitations			
Angina			
Presyncope			
Convulsions			
Heart failure			
Pedal edema			
Other symptoms: specify			
Co-morbidities present at baseline:		Yes	no
	hypertension		
	Myocardial infarction		
	Valvular heart disease		
	diabetes		
	CKD		
	hyperthyroidism		
	cardiomyopathy		
	Chronic lung disease		
	other		
Alcohol use	yes	No	
Smoking	**yes**	**No**	
Prior medication use:	anticoagulants	Yes	no
	Oral corticosteroids	Yes	no
	antihypertensives	Yes	no
	digoxin	Yes	no
	Antiarrhythmic (specify)		

Indication for pacemaker insertion	
High degree atrioventricular block	
Bundle branch block	
Sick sinus syndrome	
atrial fibrillation	
Carotid sinus syncope/ neurogenic syncope	
Congestive cardiomyopathy	
Hypertrophic cardiomyopathy	
other specify	
Not indicated	

Hospitalisation				
History of previous admissions	Yes		No	
Number of previous hospitalisations				
Regular follow-up prior to procedure	Yes		No	
Duration of follow-up	<1yr	1-2yrs		>2yrs
Place of follow-up	KNH			
	other (public)			
	other (private)			

Baseline clinical and laboratory characteristics(at admission for insertion of the device)					
BP	Systolic		diastolic		
Pulse rate					
NYHA	I	II	III	IV	NI
Oxygen saturation					
pedal edema					
Ascites					
Heart murmur					

Cardiomegally displaced apex	
Weight	
Height	
BMI	
Na+	
K+	
Ca2+	
Mg2+	
Urea	
Creatinine	
HbA1C	
RBS	

ECG characteristics	
ECG Diagnosis	
Heart rate	
Sino atrial node rate	
width of the QRS complex	
Axis	
Other ECG abnormalities (specify)	
Echo findings:	

Pacemaker insertion procedure	
Year of implantation 1st implant	
Year of implantation other implants	
Pacemaker status	1. New

	2. Re-use		
Pacemaker mode	**VVIR**		
	AAIR		
	VVD		
	DDDR		
	Biventricular		
	ICD		
Manufacturer			
Approach (left subclavian)			
Type of anaesthesia used			
Antibiotic prophylaxis	1.yes(specify) 2. no		
Lead polarity	**Atrial**	BP	UP
	Ventricular	BP	UP
	Passive fixation	Atrial	Ventricular
	Active fixation	Atrial	ventricular
Complications	**Yes**	**No**	**date**
Pocket infection			
Sepsis/ systemic infection			
Infective endocarditis			
Lead dehiscence			
Failure to capture			
Pneumothorax			
Haemothorax			
Pacemaker syndrome			
Other: (specify)			
Mortality:			
Outcome	Dead	alive	
Last follow-up date			

Current place of follow-up		
Date of Death		
Place of death	Home	
	KNH	
	Other hospital(public)	
	Other hospital (private)	
Nature of death	Sudden	
	Illness	

APPENDIX 2: CONSENT EXPLANATION FOR TELEPHONE INTERVIEW

My name is Dr Juma Phoebe. I am a postgraduate student at the University of Nairobi studying Internal medicine at the department of clinical medicine and therapeutics. As part of my studies I am currently working in the cardiology clinic at the Kenyatta National Hospital. I am carrying out research on the baseline patient profile, rhythm abnormalities and outcomes for patients who have had a pacemaker inserted at the Kenyatta national hospital. This is a follow-up study and we would like to establish the current status of all our patients including ----------------------------------(patients name). This study has been reviewed and approved by the Kenyatta National Hospital- University of Nairobi Ethics Review Committee. There are no risks to you participating in this study and all information will be kept confidential and will only be available to researchers. All you are required to do is to answer a few questions. It is your choice whether or not to give this information. There will be no repercussions if you choose not to divulge information. There may be no direct benefit to you from this study, but the information retrieved will help clinicians to better manage patients with the same condition.

You can ask me any questions about any part of the research study if you wish. Do you have any questions?

(For patients)

Where are you currently being followed up?

Are you experiencing any problems with the device?

It is important that you continue to attend your clinics regularly as advised by your physician. Thank you for responding to this phone call.

(For Next of kin)

The purpose of this phone call is to reach --------------------------(patients name). Do you have any information on how I can contact him/ her?

In the event that the patient has passed on, the principal investigator shall pass her condolences to the relatives, thank them for answering the phone call and end the call at that juncture.

Should you have any concerns address them to :

Researcher: Dr Juma Phoebe 0726131605

Or

KNH/ ERC committee secretary 02-726300 Ext 44102

P.O. Box 20732, Nairobi, Kenya.

APPENDIX 3: FOMU YA MAELEZO YA IDHINI WAKATI WA KUPIGA SIMU

Jina langu ni Daktari Juma Phoebe. Mimi ni mwanafunzi wa shahada ya uzamili katika idara ya magonjwa kwenye chuo kikuu cha Nairobi. Ninafanya kazi katika kliniki ya magonjwa ya moyo kwenye hospitali kuu ya Kenyatta. Ninaongoza utafiti juu ya wagonjwa waliowekewa kidude cha kusaidia moyo kutembea vizuri kinachoitwa "pacemaker". Tunatake kujua hali ya leo ya wagonjwa wote waliowekewa kidude hiki hapa Kenyatta, mojawapo akiwa _____(jina la mgonjwa). Utafiti huu umeidhinishwa na Kamati ya Maadili ya Utafiti ya Hospitali Kuu ya Kenyatta. Hakuna madhara kwako ukikubali kushiriki kwa utafiti huu. Utahitajiwa kujibu maswali chache tu bila kushurutishwa. Majibu yako pamoja na matokeo ya utafiti yatashughulikiwa kwa njia ya siri. Huenda ikawa utafiti huu haitakuwa na manufaa kwako kwa sasa lakini matokeo ni ya manufaa kwa madaktari wanaotibu wagonjwa wenye shida ya moyo.

Je, una swali lolote kuhusu utafiti huu?

(Kwa Mgonjwa)

Unafuatiliwa katika kliniki ya hospitali gani?

Lile kidude linakuletea shida lolote?

Ni muhimu kwako kuendelea kutembelea kliniki ya moyo ulivyoagizwa na daktari wako.

Asante kwa kushiriki kwa utafiti huu.

(Kwa ndugu au dada ya mgonjwa)

Lengo la kukupigia simu ni kutaka kuwasiliana na _____(Jina la mgonjwa). Una habari yoyote kumhusu.

Endapo mgonjwa amefariki, nitawapa pole kama familia. Halafu nitashukuru ndugu/dada yake kwa kujibu simu na kumtakia kila la heri.

Ukiwa na maswali yoyote wasiliana na:

Mtafiti: Daktari Juma Phoebe 0726131601 ama

Kamati Ya Maadili Ya Hospitali Kuu Ya Kenyatta

Nambari ya simu: 02-726300-44102

S.L.P. 20732

Nairobi, Kenya.

APPENDIX IV: KNH ETHICAL APPROVAL LETTER

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Ref: KNH-ERC/A/82

2nd March, 2016

Dr. Juma V. Phoebe
Reg. No.H58/68111/2011
Dept.of Clinical Med. & Therapeutics
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Juma

Revised research proposal: Baseline patient profile, Rhythm Abnormalities and Outcomes for Patients with Pacemakers inserted at the Kenyatta National Hospital (P695/10/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 2nd March 2016 – 28th 1st March 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study.
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

"Protect to discover"