An Audit of Permanent Pacemaker Implantations at the Charlotte Maxeke Johannesburg Academic Hospital from 2009 – 2018

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A research report submitted to the Faculty of Health Sciences, University of Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the Degree of Master in Medicine.

Johannesburg, 2019

Table of Contents

List of figures and tables

DECLARATION:

I, Mazwi Mabika, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine (MMed) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other university.

[Signature of candidate]

_____ day of_____2019

RE: Dr Mazwi Mabika

Student number: 0403815G

MMed Internal Medicine

This letter serves to certify that Dr Mazwi Mabika has done his research in Internal Medicine. His research report is titled: An Audit of Permanent Pacemaker Implantations at the Charlotte Maxeke Johannesburg Academic Hospital from 2009 – 2018.

He compiled the research report himself and followed the protocol of his study accordingly.

Kind Regards

Dr Nqoba Tsabedze

Dr Dineo Mpanya

ACKNOWLEDGEMENTS

I would like to show gratitude and appreciation to Mr Mthunzi Mbatha (Division of Cardiology, University of the Witwatersrand) for his assistance with patient records.

I would also like to show my appreciation to all my colleagues in the Division of Cardiology, at Charlotte Maxeke Johannesburg Academic Hospital for their assistance.

NOMENCLATURE

PPI: Permanent pacemaker implantation

CRT: Cardiac resynchronization therapy

AF: Atrial fibrillation

NYHA: New York Heart Association

LV: Left ventricle

RV: Right ventricle

ESC: European Society of Cardiology

ECG: Electrocardiogram

ECHO: Echocardiogram

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

WCC: White cell count

INR: International normalized ratio

CRP: C-reactive protein

eGFR: Estimated glomerular filtration rate

SSS: Sick sinus syndrome

AV: Atrioventricular

ABSTRACT

Background: Transvenous permanent pacemakers are electronic impulse generators indicated for implantation in patients with symptomatic bradycardia, commonly due to atrioventricular (AV) heart block or sick sinus syndrome. Biventricular cardiac resynchronisation therapy (CRT) pacemakers are indicated for implantation in patients with refractory, symptomatic heart failure with a broad QRS complex of more than 130 milliseconds. A large body of epidemiological data on permanent pacemaker implantation indications and complication rates originates from the developed world with minimal data from developing regions, especially sub-Saharan Africa. This study aims to describe and analyse the patient demographics, clinical indications, peri-operative and long-term complications as well as to find independent predictors of complications in patients undergoing permanent pacemaker implantation (PPI) at a high volume, teaching hospital in Johannesburg, South Africa.

Methods: We retrospectively reviewed inpatient and outpatient medical records for all patients who underwent PPI at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) between January 2009 and November 2018. Patients' demographic data, medical co-morbidities, clinical indications, peri-implant laboratory biochemical markers, details of pacemaker mode and peri or post-procedure related complications were noted. Patients 18 years of age and above undergoing their first impulse generator implantation were eligible for analysis.

Results: One thousand and sixty patients underwent permanent pacemaker implantation during the ten years. Only 578 (55%) patients met the study inclusion criteria. The median age at first permanent pacemaker implantation was 71.8 years [IQR: 61.5 – 78.8], and the study cohort consisted of 327 (56.6%) females. A total of 43 (7.45%) patients who experienced PPI related complications were identified. Lead

dislodgement was the most common complication occurring in 16 (2.77%) patients. Females were three times more likely to experience a complication [OR: 3.21 CI: 1.37 – 7.56].

Conclusion: This study demonstrates that, in our cohort, symptomatic bradycardia requiring pacing is mostly a disease of the elderly with AV block being the most common indication for PPI. Our study complication rates are similar to those reported in data published from the developed world. Large, multicenter, prospective studies are required from our region to define better clinically relevant risk factors associated with PPI complications.

KEYWORDS:

Pacemaker implantation

Symptomatic bradycardia

Biventricular pacing

Complications

Risk factors

1. INTRODUCTION

Cardiac pacemakers have become the standard of optimal care for treating persistent, symptomatic bradyarrhythmias such as atrioventricular block, sick sinus syndrome and atrial fibrillation with bradycardia.[1] There is an abundance of epidemiological data on pacemaker implantation indications and complications, originating from the developed world, with a paucity of data from the developing world, especially sub-Saharan Africa.[2-4]

The Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) is a relatively high-volume hospital implanting more than 150 pacemakers annually. Despite this, there are no institutional data on the indications, procedural successes and complications reported during permanent pacemaker implantation (PPI). The aim of this study was, therefore, to describe and analyse the patient demographics, clinical indications and peri-operative (during admission) and long term (after discharge from hospital) complications, as well as to find independent predictors of complications in patients undergoing PPI at a high volume, teaching hospital in Johannesburg, South Africa. To the best of our knowledge, this is one of the few, current studies from sub-Saharan Africa (SSA) reporting on the demographics and complications of PPI.[5,6]

2. METHODS AND MATERIALS

2.1 Study design and population

This was a retrospective review of inpatient and outpatient medical records for all patients 18 years of age and above who underwent PPI at CMJAH, between January 2009 and November 2018. We excluded patients with temporary pacemaker implantation, implantable loop recorder implants and impulse generator box change.

The primary investigator collected data from the permanent pacemaker implantation operative reports, the (electronic) inpatient admissions cardiology database notes and the outpatient pacemaker clinic files from the department of cardiology at CMJAH. All implantations were performed by qualified cardiologists or cardiology fellows in training, under the supervision of a qualified cardiologist.

The extracted demographic data included gender, date of birth, ethnic group, medical co-morbidities and chronic medication. All patients' race data was verified against the hospital Medicom system to confirm ethnicity.

The laboratory biochemistry parameters that were extracted included the white cell count, platelet count, INR (International normalised ratio), C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), urea and electrolytes, creatinine and the estimated glomerular filtration rate (eGFR). These laboratory blood biochemistry results were retrieved from the National Health Laboratory Service (NHLS) electronic databases.

Data from the permanent pacemaker implantation procedure was collected. The data included the date of the first implantation, indications for pacemaker implantation, the age of current impulse generator, the permanent pacemaker model, the mode of pacing, whether rate responsiveness was available and switched on or off, the electrocardiography diagnosis and the cardiac rhythm. A subgroup of patients outlives the impulse generator battery life span. This group of patients then require an impulse generator change. These patients were identified when reviewing the outpatient pacemaker clinic files and were excluded from the final analysis.

All documented peri-operative and long-term complications were recorded. Complications for PPI were classified as peri-operative (occurring during the implantation admission) and long-term (after discharge from hospital).[2] Complications included pacemaker sepsis, haemorrhage, haemothorax, haematoma, pneumothorax, diaphragm stimulation, lead dislodgement, lead fracture, ventricular perforation and death.

2.2 Ethics and consent

Ethics for the study was sought from the University of Witwatersrand Human Research Ethics Committee and the relevant hospital authorities. The study observed all protocols and principles outlined in the declaration of Helsinki 2017 [7]

2.3 Data analysis

The statistics data was generated with STATA MP software, version 15.0 (StataCorp, Texas, USA). Normally distributed continuous variables were summarised as the mean and standard deviation. The median and interquartile ranges were used for continuous variables with a skewed distribution. The chi-square test was used to compare categorical variables. Both univariable and multivariable regression analyses were done. Confidence intervals were calculated at 95% interval levels, and differences were considered statistically significant at a p-value of < 0.05.

3. RESULTS

The study population comprised of 578 patients consisting of 327 (56.6%) females. The median age at first pacemaker implantation was 71.8 years (IQR: 61.5-78.8). The majority of the study population were black (45.67%), followed by whites (40.31%), Indians (9.52%) and coloureds (4.5%).

One thousand and sixty patients underwent PPI between 2009 and 2018. Only 963 (90.8%) patients had their implantation operative reports available. We excluded 382 patients as the indication for permanent pacemaker implantation was an impulse generator change. Furthermore, three patients were younger than 18 years of age at the time of the first pacemaker implantation and were therefore excluded from the final analysis (Figure 1).

Hypertension was the most prevalent comorbidity and was reported in 241(41.70%) patients who underwent PPI. At the time of pacemaker implantation, the median platelet count was 288 X 10^9/L (211- 366) and the white blood cell count as well as the c-reactive protein levels were within normal limits. The rest of the baseline clinical parameters are shown in Table 1.

In this study population, atrioventricular heart block was the most common indication for PPI and was reported in 428 (74.05%) patients. During the study period, 12 cardiac resynchronisation pacemaker devices and three automated intracardiac defibrillators were newly implanted. The rest of the indications for pacing are shown in Figure 2. Dual sensing, dual pacing and dual inhibition (DDD) was the most common mode of pacing (72.7%) followed by ventricular sensing, ventricular pacing and inhibition (VVI) (24.17%) and atrial sensing, atrial pacing and atrial inhibition

(AAI) and ventricular pacing, dual sensing and dual inhibition (VDD) both with 1.39%. Only two patients had ventricular pacing, no sensing and no inhibition (VOO) pacemakers.

Overall, complications occurred in 43 patients (7.45%) with lead dislodgement documented in 16 patients (2.68%). These patients were taken back to theatre for lead repositioning. Pacemaker sepsis occurred in 12 patients (2.07%) and six patients (1.04%) complicated with a pneumothorax post PPI. Our data analysis revealed an association between the female gender and the occurrence of a complication (p=0.017) (Table 3). Females were three times more likely to experience a complication [OR: 3.21 CI: 1.37 – 7.56] (Table 4).

One of the patients who complicated with a pneumothorax was a 78 years old female with a background medical history of haematological malignancy. Her pneumothorax required an intercostal drain, which subsequently complicated with an empyema on day three post PPI. The patient was optimally treated in the intensive care unit after surgical drainage of the empyema. She later complicated with sepsis-related multiple organ failure and subsequently demised. The rest of the complications are presented in Table 2.

4. Discussion

This study demonstrates that, in our study population, symptomatic bradycardia requiring pacing is mostly a disease of the elderly with AV block being the most common indication for PPI. Our median age at first implantation was 71.8 years, and this is similar to data from Israel published by Antonelli et al.[8] who reported a mean age of 74.6 years.[8]

Interestingly the male to female ratio was equally split with a slight predominance of females at 56.6%. This is most likely related to the higher life expectancy for females; hence more females will ultimately complicate with symptomatic bradycardia and require PPI. Similarly, in a Turkish study by Bayata et al.[9] , it was reported that nearly 50% of their patients that underwent PPI were females, this is in keeping with our current findings.

The current study also found that in our cohort the common indications for permanent pacemaker implantation were AV block (74%), sick sinus syndrome (9.9%), atrial fibrillation with bradycardia (5.36%) and idiopathic symptomatic bradycardia (7.09%). Bayata et al.[9] also reported that AV block accounted for 71% of all PPI, sick sinus syndrome (21.5%) and atrial fibrillation with bradycardia at 3.95% in a study population of 1187 patients.[9]

Several studies have demonstrated an association between specific patient and procedural factors with complications for pacemaker implantation.[2,3,10,15] In a large population-based cohort study of 28 860 Danish patients who underwent PPI between 1997 and 2008, lead complications occurred in 3.6%. LV leads had the most complications (4.3%) followed by right atrial leads (2.3%) and right ventricular leads (2.2%). The study found that chronic heart failure, implantation in a non-university hospital, an inexperienced operator (< 25 implantations), dual chamber pacemaker device and passive fixation of the right atrial lead, all increased the risk of complications.[3]

A separate study of 1517 patients receiving new pacemakers between 2003 and 2007, reported a short term (during the admission) and long-term (after discharge from hospital) complications of 12.4% and 9.2% respectively. Male gender, age at implantation, body mass index, use of anticoagulation drugs and passive atrial lead fixation were predictors of short-term complications. Predictors of long-term complications were increased body mass index, hypertension and a dual chamber device implantation.[2] These complication rates were higher than the complication rate of 7.45% found in our study cohort. These differences are likely due to different study populations and different definitions used to describe a clinically significant complication.

Routine blood tests were done in all our study patients before PPI. The white cell count (WCC) and C-reactive protein (CRP) were done to exclude any pre-existing infective process that may predispose the patient to pacemaker sepsis.[11] Most of our study patients had a WCC and a CRP within the normal range. Patients with marginally elevated WCC and CRP did not demonstrate higher rates of sepsis compared to patients with normal CRP and WCC. Other laboratory parameters assessed were platelet count, renal function tests and the international normalised ratio (INR) as they have been shown to be associated with an increased risk of bleeding.[12] Our study showed that there was no statistically significant difference in the mean INR, platelet count and eGFR in patients who had complications and those who did not.

On multivariable logistic regression analysis of our study cohort, females were found to be three times more likely to experience a complication [OR: 3.21 CI: 1.37 – 7.56]. We were unable to hypothesise a physiologically plausible explanation for this

observation, and none of the previously published data has claimed similar findings. Contrary to our findings, In the FOLLOWPACE study, Udo et al. reported male gender as an independent predictor for complications within two months of PPI.[2]

Pacemaker sepsis is a devastating complication for pacemaker implantation that requires complete removal of the device and implantation at a different site after a course of antibiotics.[13] Current data shows that the incidence of device infection after permanent pacemaker implantation is 0.1 - 0.7% and 0.7 – 1.2% for implantable cardiac defibrillators.[14] We found that both short term and long term pacemaker sepsis occurred in 2.07% of our patients with long term sepsis being the most common (1.38%). In another study, Aggarwal et al.[15] found the incident of pacemaker sepsis to be 1%. We hypothesize that the major cause of sepsis in our patients is likely non-compliance to sterile techniques while performing pacemaker implantation. Measures such as enforcing compulsory attendance of infection control practical seminars may assist in reducing complication related to sepsis.

5. Study limitations

This is a single centre, retrospective observational study. Some of the main limitations of the study include missing relevant clinical data, room for selection bias as only a small sample of patients were studied. The level of experience of the implanting operators was not documented. This could have assisted in accounting for complications that occurred during the procedure. The presence of structural heart disease was also not documented, however, most of these patients would have had a screening echocardiogram before PPI. Outcomes data was also not

available, as the collection of this data is not routinely done in our institution. The potential impact of the above limitations includes inferior level of evidence and an inability to determine causation.

6. Conclusion and recommendations

This study demonstrates that, in our cohort, symptomatic bradycardia requiring pacing is mostly a disease of the elderly with AV block being the most common indication for PPI. Our study complication rates are similar to those reported in data published from the developed world. Large, multicentre, prospective studies are required from our region to define better, hard outcomes and clinically relevant risk factors associated with PPI complications.

7. Funding

None

8. Conflict of interest

None to declare

9. References

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10. Tables and Figures

Figure 1. Study Flow chart

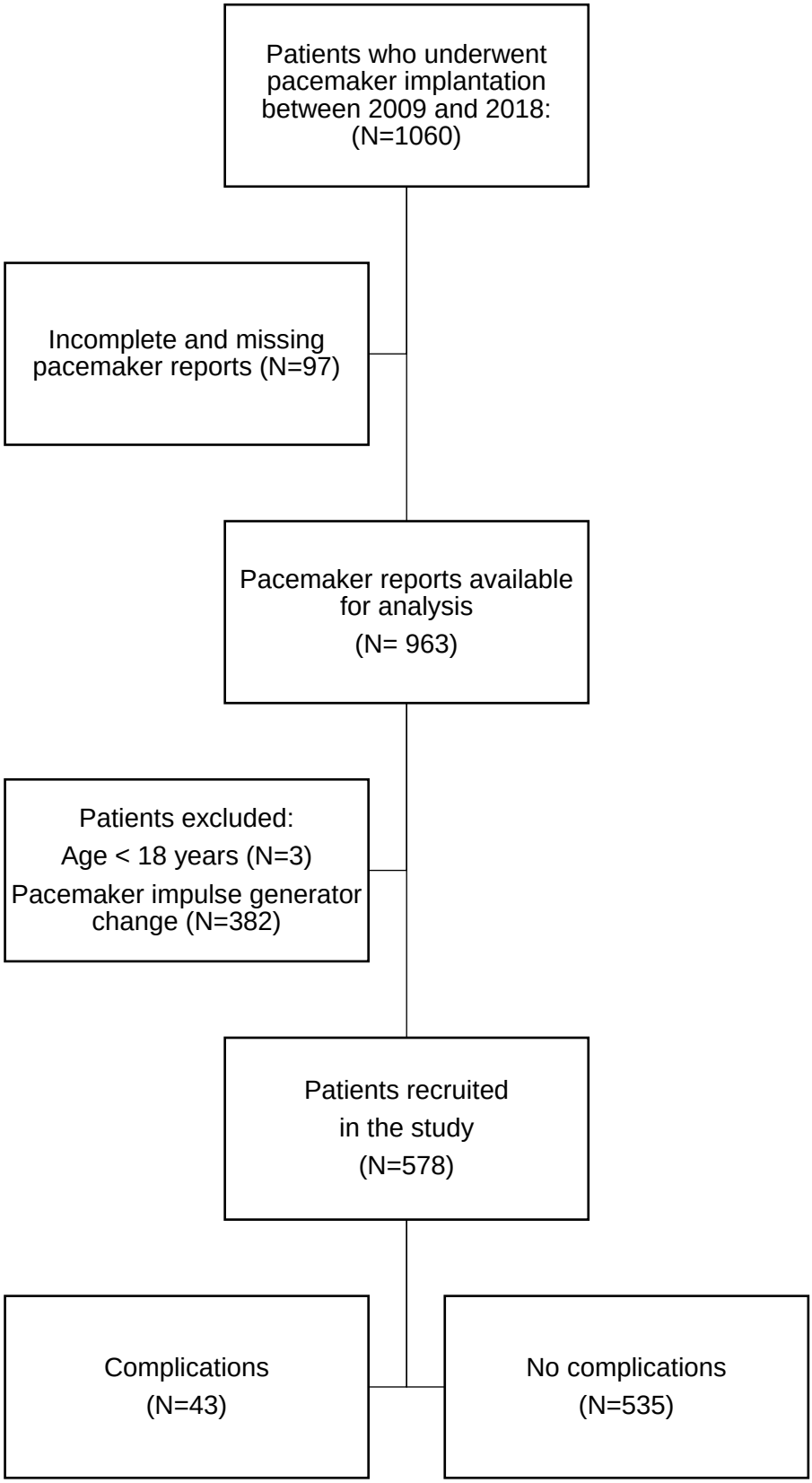
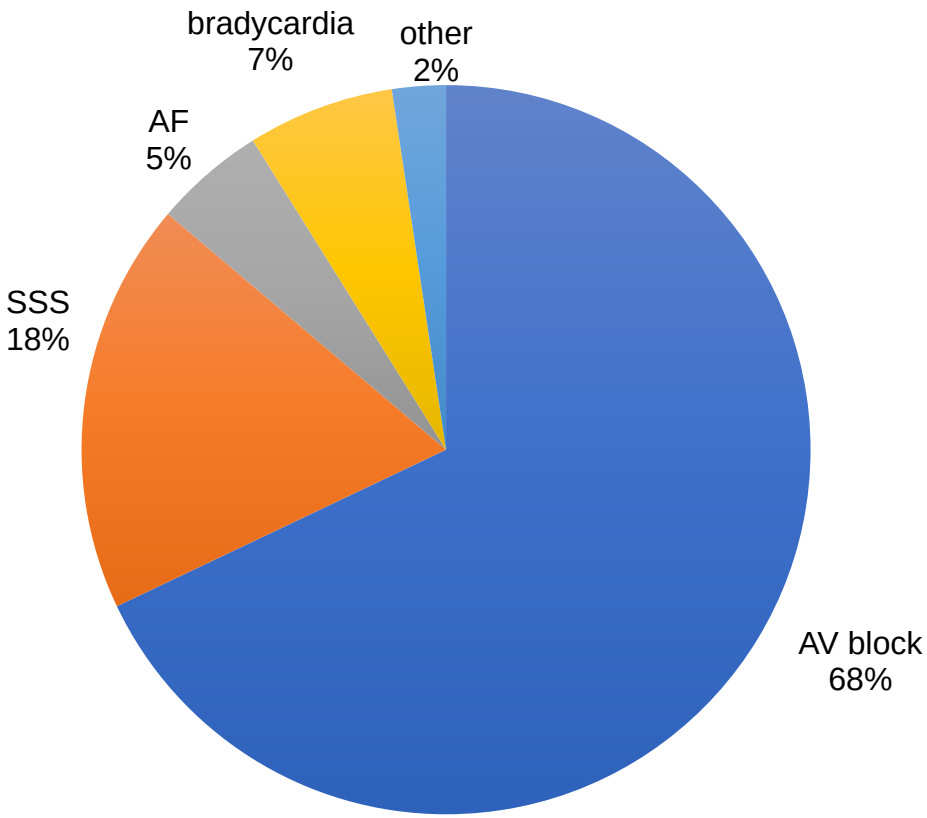


Table 1. Baseline demographic and clinical characteristics of patients referred for permanent pacemaker implantation according to occurrence of complications

Variable	Overall Population (N=578)	Complications (N=43)	No complications (N=531)	p-value
Age (years)	71.8 (IQR: 61.5-78.8)	67.77	69.54	0.4724
Females	327 (56.6)	32 (74.42)	295 (55.14)	0.014
Ethnicity				0.561
African	264 (45.67)	24 (55.81)	240 (44.86)	
White	233 (40.31)	14 (32.56)	219 (40.93)	
Indian	55 (9.52)	3 (6.98)	52 (9.72)	
Coloured	26 (4.50)	2 (4.65)	24 (4.49)	
Comorbidities				
Hypertension	241 (41.70)	21 (48.84)	220 (41.12)	0.324
Diabetes Mellitus	60 (10.38)	5 (11.63)	55 (10.28)	0.780
IHD	40 (6.92)	0 (0)	40 (7.48)	0.063
Cardiomyopathy	35 (6.06)	5 (11.63)	30 (5.61)	0.111
CKD	25 (4.33)	1 (2.33)	24 (4.49)	0.503
Biochemistry				
WCC (10^9/L)	7.02 (IQR: 5.73-8.64)	7.79	7.33	0.2395
Platelets (10^9/L)	288 (IQR: 211-366)	267	298	0.0232
CRP (mg/L)	10 (IQR: 10-13)	16	15.5	0.8714
INR	1.07 (IQR: 1.01-1.14)	1.15	1.11	0.3229
GFR (ml/min)	76.16(IQR: 55.3-92.5)	75.7	76.8	0.8712

Data shown as mean and standard deviation for normally distributed data. The median and interquartile ranges (IQR) were used for continuous variables with a skewed distribution. CKD: chronic kidney disease; CRP: C-reactive protein; eGFR: estimated glomerular filtration rate; WCC: white cell count; IHD: ischaemic heart disease; INR: international normalized ratio

Figure 2. Graph showing indications for permanent pacemaker implantation



SSS: Sick sinus syndrome; AV: atrioventricular; AF: atrial fibrillation with bradycardia

Table 2: Number of patients with peri-operative and post-operative complications

Complication	Peri-operative N (%)	Post-operative N (%)
Sepsis/infection	4 (0.69)	8 (1.38)
Haemorrhage	3 (0.52)	
Haemothorax	1 (0.17)	
Haematoma		3 (0.52)
Pneumothorax	6 (1.04)	
Diaphragm stimulation		1 (0.17)
Lead dislodgement	9 (1.56)	7 (1.21)
Lead fracture		1 (0.17)
Ventricular perforation	1 (0.17)	
Other	6 (1.04)	
Death	1 (0.17)	
Total	**31 (5.36)**	**20 (3.45)**

Table 3. Univariable logistic regression

	Odds ratio	Std. error	z	p- value	Confidence interval
Age* (years)	0.99	0.01	0.83	0.404	0.97 – 1.01
Female	2.37	0.85	2.39	0.017	1.16 – 4.79
Indian	0.58	0.36	- 0.87	0.384	0.17 – 1.99
White	0.64	0.22	- 1.28	0.200	0.32 – 1.27
Coloured	0.83	0.64	- 0.24	0.812	0.18 – 3.74
Diabetes	1.14	0.57	0.28	0.781	0.43 – 3.04
Hypertension	1.37	0.43	0.98	0.325	0.73 – 2.55
Atrial fibrillation	0.62	0.38	- 0.79	0.432	0.18 – 2.06
White cell count	1.09	0.08	1.15	0.249	0.94 – 1.25
Platelet count	0.99	0.00	- 1.66	0.096	0.99 – 1.00
CRP	1.00	0.01	0.15	0.882	0.98 – 1.02
eGFR	0.99	0.00	- 0.21	0.834	0.99 – 1.01

* Age: Age at first pacemaker implantation; CKD: chronic kidney disease; CRP: C-reactive protein; Diabetes: diabetes mellitus; eGFR: estimated glomerular filtration rate; std error: standard error.

Table 4. Multivariable logistic regression

	Odds ratio	Std. error	z	p- value	Confidence interval
Female	3.21	1.40	2.67	0.007	1.37 – 7.56
Platelet count	0.99	0.00	- 1.87	0.061	0.99 – 1.00

APPENDIX A – DATA COLLECTION SHEET

Pacemaker Implantation at CMJAH: 2009-2018

Record ID	_____
Pseudo Number	_____
Date of Data Collection	_____
Gender	◯ Male ◯ Female
Date of Birth	_____
Ethnic Group	◯ African ◯ Indian ◯ White ◯ Coloured
Co-morbidities	☐ Mitral valve regurgitation ☐ Mitral valve stenosis ☐ Aortic regurgitation ☐ Aortic stenosis ☐ Hypertension ☐ COPD ☐ Systemic Lupus Erythematosus ☐ Cardiomyopathy ☐ Chronic kidney disease ☐ Ischaemic heart disease ☐ Gout ☐ Dementia ☐ Arthritis ☐ Diabetes Mellitus ☐ Congenital heart disease
Chronic Medication	☐ Beta blocker ☐ Calcium channel blocker ☐ Digoxin ☐ ACE inhibitor ☐ Loop diuretics ☐ Thiazide diuretics ☐ Aspirin ☐ Statins ☐ Amiodarone ☐ Other
If other, please specify	_____
White cell count (10^9/L)	_____
Platelet count (10^9/L)	_____

INR	
CRP (mg/L)	
ESR (mm/hr)	
Urea (umol/l)	
Creatinine (mg/dl)	
eGFR (ml/min)	
Date of First Implant	
Age at first implant	
Indication For Pacing	☐ Symptomatic bradycardia ☐ CRT- HF with wide QRS and prolonged> 130 ms ☐ ICD - Primary or secondary prevention ☐ Sick sinus syndrome ☐ Syncope ☐ Atrioventricular block ☐ Atrial fibrillation
Pacemaker Model	◯ Medtronic ◯ St Jude ◯ Boston ◯ Biotronik ◯ Other
Mode of Pacing	◯ VVI ◯ AAI ◯ DDD ◯ VOO ◯ VDD
Rate Response	◯ On ◯ Off
ECG Diagnosis	☐ Third degree AV block ☐ Second degree AV block ☐ Sinus Node Dysfunction ☐ Brugada syndrome ☐ LBBB ☐ RBBB ☐ Other

Rhythm	☐ Sinus rhythm ☐ Atrial fibrillation ☐ Other
Peri-operative Complication	☐ Excessive bleeding ☐ Pneumothorax ☐ Lead dislodgement ☐ Sepsis or infection ☐ Stroke ☐ Right ventricle or right atrial perforation ☐ Death ☐ Ventricular tachycardia ☐ Cardiac arrest requiring CPR ☐ None ☐ Other ☐ Haemothorax ☐ Cardiac perforation ☐ Cardiac tamponade
Long term Complications	☐ Diaphragm stimulation ☐ Pocket sepsis ☐ Lead dislodgement with loss of capture ☐ Lead fracture with increase impedance ☐ Haematoma ☐ None ☐ Other ☐ Lead malposition
Date of Impulse Generator Change	_____
Longevity of First Pacemaker	_____
Date of Second Implant	_____
Date of Second Impulse Generator Change	_____
Longevity of Second Pacemaker	_____
Additional notes	_____

APPENDIX B – Ethics approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Mazwi Mabika

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180938

NAME: (Principal Investigator)	Dr Mazwi Mabika
DEPARTMENT:	Internal Medicine Cardiology Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	An Audit of Permanent Pacemaker Implementations at the Charlote Maxeke Joahnnesburg Academic Hospial from 2009-2018
DATE CONSIDERED:	28/09/2018
DECISION:	Approved Unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Nqoba Tsabedze
APPROVED BY:	Doctor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	26/10/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **September** and will therefore be due in the month of **September** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES