QUALITY OF LIFE AND ITS ASSOCIATED FACTORS AMONG PATIENTS WITH CARDIAC IMPLANTABLE ELECTRONIC DEVICES IMPLANTED AT JAKAYA KIKWETE CARDIAC INSTITUTE

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TITLE

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By

Jovina Lawrence Nkya, (MD)

A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine in Internal Medicine at

Muhimbili University of Health and Allied Sciences

October, 2020

CERTIFICATION

The undersigned certifies that, he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: ‘‘**Quality of life of and its associated factors among patients with cardiac implantable electronic devices implanted at Jakaya Kikwete Cardiac Institute** ’’ in partial fulfillment of the requirements for the degree of Master of medicine in Internal Medicine at Muhimbili University of Health and Allied Sciences.

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Dr Reuben Mutagaywa

(Supervisor)

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Date

DECLARATION AND COPYRIGHT

I, **Jovina Lawrence Nkya** declare that this, dissertation is my own original work and has not been accepted for a similar degree in any University.

Signature: …… Date: ……

ACKNOWLEGMENT

First and foremost, I thank the Almighty God for His grace and protection throughout my studies and research work.

I sincerely, express my deepest gratitude to my research supervisor Dr Reuben Mutagaywa for his mentorship, encouragement and spending much of his time guiding me throughout every step of this research paper.

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DEDICATION

I dedicate this work to my parents, Mr and Mrs Lawrence Nkya and my brother Joshua together with his lovely wife Mwani Nkya.

ABSTRACT

Background: Cardiac implantable electronic device is a term that encompasses pacemakers, implantable cardioverter defibrillators and cardiac resynchronization therapy. These lifelong devices are established treatments and are known to improve survival in patients with cardiac arrhythmias (1,2), however, in any chronic therapy or illness entails physical, psychological and social challenges that can interfere with daily activities of a patient and influence their quality of life (3). Individual's own perception of their health and illness plays a critical role to help health professionals to gain insight on the effectiveness of therapy and challenges faced by the patients in order to improve care (4).

Objectives: To assess the QOL and its associated factors among patients with cardiac implantable electronic devices implanted at JKCI.

Methodology: A hospital based cross-sectional study, involving patients with cardiac implantable electronic devices implanted at JKCI was conducted from October 2019 to January 2020. All patients who were registered to undergone device insertion were interviewed after informed consent was obtained. A standardized generic Kiswahili version questionnaires Short form-36 (SF-36) and a disease specific AQUAREL were filled. Baseline socio-demographic and clinical characteristics were collected from patient's files. Statistical analysis was conducted on SPSS 23.0 and a p-value of <0.05 was considered significant. Ethical clearance was obtained from the MUHAS directorate of research and publications.

Results: There were 171 patients, 52% were females and 75.4% were ≥60years. The QOL was overall good as patients scored above 50 for most domains on the SF-36 and AQUAREL except on social functioning domain on SF-36 with. Age was negatively associated with general health (R^2=75.0%, p≤0.001), increasing implant years was positively associated with physical functioning (R^2=22%, P≤0.001), role physical (R^2=5.6%, P≤0.001), bodily pain (R^2=12%, P≤ 0.002), emotional health (R^2=74%, P<0.002) and vitality (R^2= 19.6% p<0.018). On mental health domains on SF-36, female sex compared to male sex (R^2= 18.4%, P<0.025) as well as widow status compared to married status (R^2= 9.2%, P<0.05) were negatively associated with mental health.

Conclusion: Patients with cardiac implantable electronic devices at JKCI had overall good QOL however, had poor social functioning. As number of years post implant increases, the QOL gets better and with old age the QOL starts to decline. Female patients and widows have poor mental health compared to male patients and married respectively. In terms of disease-specific effects with reference to chest discomfort, dyspnea and arrhythmia most patients had high scores on AQUAREL indicating to be free of symptoms.

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LIST OF ABBREVIATIONS

AQUAREL	Assessment of quality of life and related events
AV	Atrioventricular
AVB	Atrioventricular block
BMI	Body Mass Index
BP	Bodily pain
CIED	Cardiac implantable electronic devices
BBB	Bundle branch block
CRT	Cardiac re-synchronization therapy
CRT-P	Cardiac re-synchronization therapy Pacemaker
CRT-D	Cardiac re-synchronization therapy Defibrillator
CVD	Cardiovascular disease
DDDR	Dual chamber, rate adaptive pacemaker
GH	General health
JKCI	Jakaya Kikwete Cardiac Institute
MUHAS	Muhimbili University of Health and Allied Sciences
MH	Mental health
NYHA	New York heart association classification
PH	Physical health
QOL	Quality of life
RE	Role emotional
RP	Role physical
SCD	Sudden cardiac death
SD	Standard Deviation
SF	Social function
SPSS	Statistical Package of Social Sciences
USA	United States of America
SF-36	Short form health survey
VT	Vitality
VVIR	Ventricular pacing, ventricular sensing, rate modulated pacing mode
WHO	World Health Organization

DEFINITION OF TERMS

Cardiac implantable electronic devices - A term comprising of cardiac implantable electronic devices including a pacemaker, implantable cardioverter defibrillator and cardiac synchronization therapy.

Quality of life- According to World Health Organization (WHO) it defines QOL as; an individual's perception of their position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

Short Form Survey 36 (SF-36) – is a validated tool with a set of structured and easily administered QOL questions. It can be administered for any disease. It has 8 domains including;

Physical health, Role Physical, Bodily Pain, General Health, Vitality, Social Health, Role Emotional and Mental health.

- Physical health- limitation to physical activity e.g. walking and dressing.
- Role physical- difficulties with work or daily activities due to physical health problems.
- Bodily pain- Amount of pain and interference with regular daily activities.
- General health- rating of health, comparison with others and expectation for future health.
- Vitality- Energy and tiredness ratings.
- Social health- Limitations to social activities e.g. meeting friends.
- Role emotional – Difficulties with work or daily activities due to emotional problems.
- Mental health- Presences of depressive feelings or anxiety.

Assessment of Quality of life and Related Events (AQUAREL) - is a questionnaire developed as an extension of the SF-36 for patients on chronic pacing. The questions are related to cardiac complaints and rhythm disorder summarized into chest discomfort, dyspnea and arrhythmias.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Cardiovascular diseases (CVD) are a constellation of chronic diseases affecting the heart and blood vessels (5). History of cardiovascular medicine dates back to the days of William Harvey's discovery of anatomy and circulation of blood in the early 17thcentury, that created an arena of fascination and interest among scientists to progress the cardiac medical field, this has led to invention of advanced technologies such as cardiac implantable electronic devices (6–8), despite such evolution in treatment, prevention and rehabilitation, CVD are still the leading cause of mortality worldwide (9).

Cardiac implantable electronic device are simply, devices that help a slow or unsynchronized heart to beat at a normal rate and rhythm (10). It comprises of cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization therapy devices. A pacemaker is a small device implanted in the chest or abdomen and is composed of a battery powered generator that produces electrical impulses which are transferred through wires/leads to your heart to prompt it to beat in a regular rhythm (1). Implantable cardioverter defibrillator (ICD) is a device capable of treating tachyarrhythmias by performing cardioversion and defibrillation (11). Cardiac resynchronization therapy (CRT) is a special type of pacemaker used in heart failure patients; CRT device can be cardiac resynchronization therapy pacemaker (CRT-P) or cardiac resynchronization defibrillator (CRT-D). CRT-P treats slow heart rate but can also deliver electric impulses to the ventricles to help them contract in synchrony while a CRT-D works like a CRT-P with an added ability to perform defibrillation (12).

The first artificial pacemaker was implanted in October 1958, by a Swedish cardiac surgeon Professor ÅkeSenning to a patient with atrioventricular block although the device lasted for a few hours it opened a new field for device therapy (1). Pacemakers can now be placed permanently and there are evolving strategies to decrease size of the devices, prolong battery life and involvement of less invasive surgery in order to ensure ease of implantation with fewer complications, furthermore there are ongoing clinical trials for implanting leadless pacemakers that would be safer and more efficient (13,14). All of this developments aim to improve survival and QOL of patients.

In developing countries, there is a projection of increase in cardiac device implantation due to a rise of cardiovascular diseases caused by the change of disease pattern from infectious and nutritional deficiencies to non-communicable diseases (15). Incorporation of latest estimates show that by 2030,CVD in Sub-Saharan countries will be the leading cause of death contributing to 13.4% versus 13.2% from HIV/AIDS disease (16). Data as such, is alarming although not all of these cardiac diseases would require device implantation, conduction abnormalities and arrhythmias that do, are the foremost in causing sudden cardiac deaths. The anticipation of rise in implantation of cardiac implantable electronic devices imperatively makes, assessing how patients currently with devices fair in terms of their QOL very essential (17,18).

The assessment of QOL of patients is an important concept and has become a growing international concern with modern medicine; it is a subjective evaluation of a patient's own physical, mental and social health (19). Implantation of cardiac devices has shown to improve the survival of patients however, a patient's experience of a foreign device in their body may be life changing with psychological, mental, emotional and physical challenges (20). Studies (21–24), on QOL in Asia, Europe and America have demonstrated overall improvement in QOL after cardiac implantable electronic device implantation but, some studies have shown poor QOL in certain aspects of functionality. A study by Barros R et al (25), in Brazil found poor QOL in physical health, Polikandrioti M et al (26), in Greece demonstrated high levels of anxiety and depression among pacemaker patients instituting poor mental health while Chen H et al (27), found low QOL in work capability, social participation and sexual function. Data on QOL for patients with cardiac electronic implantable devices in Africa is sparse and as QOL is profoundly modified by social demographics, clinical characteristics and environmental factors (4), it is rather limiting to draw conclusions from elsewhere about the QOL of our own cardiac device patients.

In Tanzania the first cardiac electronic device, a pacemaker was implanted in 2013 and since then about 250 devices have been implanted at Jakaya Kikwete Cardiac Institute, no local data is available on the QOL of these patients or factors that influence it, availability of such data will be crucial to reflect the response to therapy and put to light

challenges faced by our own patients in order to strengthen care and mitigate these challenges.

1.2. LITERATURE REVIEW

1.2.1 Pacing for cardiac disease

A worldwide survey done from 2005 to 2009 by Mond H et al (28), on implantation of cardiac electronic implantable devices which included 61 countries found that in 2009, there were 1,002,664 pacemakers implanted with 737,840 new implants and 264,824 replacements. All countries demonstrated increase in implant numbers over the 4 years between surveys. The survey data however involved only 2 countries in Africa which were South Africa and Sudan. South Africa was found to have the largest number of device implantation in Africa of 2939 while in the USA; the leading country worldwide had 225,567 devices implanted the same year. In 2016, the estimated number of implants per year worldwide was 1.2 million devices, this number is projected to increase to 1.43 million implants by 2030 (29).

In Africa, the Pan African Society of Cardiology (PASCAR) study (30), looked at statistics and use of cardiac electronic devices and interventional electrophysiology procedures from 2011 to 2016, collected data from 31 African countries showed that (26%), a quarter of the countries in Africa had no cardiac device implantation services, these were 8 out of the 31 countries surveyed. The median pacemaker implantation rate was 2.66 per million populations per country (range: 0.14–233 per million populations). ICD and CRT were performed in 12/31 (39%) and 15/31 (48%) countries respectively, mostly performed by visiting physicians and teams outside Africa. The survey showed diversity in terms of, access to arrhythmia care across Africa and concluded that there is limited access to cardiac device implantation services in Africa (30).

In terms of prevalence data from individual countries they are few reports on prevalence of cardiac implantable electronic device implantation of a whole country available (31), among the few is from USA Medical Device Implant National Health Survey that reported a population overall prevalence estimated at 260/100 000 for aged 8-64 and 26000/200 000 for those aged ≥75 years and it was predicted that within 25 years the rates will

double (32) . Records from Brazil showed a lower prevalence of 136/1 000000 (28), no local published data on prevalence is available in our country or neighboring countries.

The rise of rhythm and conduction disorders worldwide has led to increase in the need for cardiac device implantations (30), a study done in Spain by Eduardo V et al (33), detailed that nearly 40% of the patients in the cardiac unit and 1 in every 5 of those been seen for the first time required electrophysiology studies**,** these values were similar to a study by Aurelian L et al (34), were among 180 patients, 92.78% presented with an arrhythmia out of which, 15.56% had a conduction abnormality that required device implantation.

Many patients in Africa were found to require a device implantation according to the PASCAR report however not all patients were able to get this service and there was a 200 fold time higher cardiac device implantation in Europe than in Africa attributed to factors such as, absence of centers capable of performing implantation, lack of trained personnel and high cost of performing the procedure (30)**.** The high rate of implantation and early electrophysiology studies with timely implantation of cardiac devices in developed countries, has greatly reduced mortality from sudden cardiac death (17).

In Tanzania, currently there are two centers capable for implantation of cardiac implantable electronic devices. JKCI was the first center to perform implantation in November 2013 with a total number of about 250 pacemakers inserted by June 2019. JKCI is the national's largest cardiac institute with device implantations done routinely. The procedures are done with local cardiologist doctors. In 2016 it was stated from JKCI data that 100 patients required pacemaker insertions but only 35 pacemakers were inserted mostly due to financial reasons. A study done in Cameroon from 2009 to 2011(35), found 26 patients required a pacemaker however only 15 had pacemaker implanted and later observed that there was, 45% mortality over 16 months in the patients who had not received pacemakers similarly in Nigeria, in 2001 to 2006 (36), complete heart block was diagnosed in 31 patients but only 23 patients had devices implanted while 8 patients could not afford the procedure.

There has been efforts in some countries to tackle the problem of affordability by recycling used devices taken from dead patients, several studies (37–42), from USA, Europe and

Nigeria found there was no significant clinical difference between recycled devices compared to new ones in terms of rates of infection or device function capability. These studies recommended use of recycled cardiac devices especially in developing countries where many patients are unable to afford new devices. In Tanzania this initiative has not yet begun.

1.2.2 QOL post implantation of Cardiac implantable electronic devices

QOL in chronic illness entails information on the impact of illness in the overall life of an individual rather than mere clinical outcome hence provides a reflection of the effect of therapy on day to day activities of a patient (43).The assessment of QOL of patients is an important concept due to aging populations, the rapid growing rates of chronic conditions and the increasing in cost of healthcare (44). The life expectancy in Tanzania is now nearly 10 years more than in the past decade (45), therefore monitoring and assessing the QOL status of diseased populations can inform public and healthcare policy makers.

Surveys on health related QOL and its associated factors after cardiac device implantation has been done in various areas worldwide (22,25,27,46,47), to explore the limitations related to physical health such as pain, mental, emotional problems and other health-related issues post implantation. There is limited data on QOL post cardiac device implantation in Africa (30). In Tanzania there is no local data available for the QOL in these patients.

In assessment of QOL among cardiac device patients various standardized instruments have been used; these tools have proven sufficient to determine how the devices interfere in a patient's life (48). Questionnaires are the most popular tools for assessment, with SF-36 the most worldwide used tool (34).The SF-36 can be used in any disease; it covers 8 domains (emotional, physical, mental, role emotional, general health, role physical, body pain and vitality). The Kiswahili version of SF-36 has been used in different studies (49–52), in Tanzania, for assessment in patients with other diseases. The AQUAREL questionnaire is a cardiac disease device specific tool with 3 domains of (chest discomfort, arrhythmias and dyspnea) and is used as an extension of the SF-36. The AQUAREL has

shown good validity and reliability due to its psychometric properties and the usage of the two tools provide a wide coverage in assessing patients functionality (48). Concerning other disease specific instruments like the Karolinska QOL questionnaire it did not have a desirable content validity which constitutes a serious limitation (53), while QOL index cardiac version-IV has good validity and reliability however it is not strictly cardiac device specific (54).

QOL assessment comprise of physical, mental and social functioning of an individual. Cardiac devices are designed to improve QOL (20), generally several studies (21–24), on QOL in Asia, Europe and America have demonstrated overall improvement in QOL after these device implantation with patients experiencing relief of symptoms however, some patients experience distress in their daily activities post implantation, frequent complaints being those physically related (55), in a study by Barros R et al done in Brazil (25), the lowest QOL scores post implantation assessed by SF-36 with 0 being the lowest score and 100 the highest score, found a score of 58.4 in physical functioning, followed by emotional functioning 62.6, similar findings reported by Zatta L (56), done in Portugal showed the scores in physical functioning were as poor as 00.0 and role emotional 33.3.

Regards to issues on mental health a study done by Luca D et al (57), found depression and anxiety levels were very low in post implantation patients compared to pre implantation patient while in Whang W et al in USA (58), identified severe symptoms of depression and anxiety levels in implanted patients and that depression had an association to increased mortality however, no clear relationship whether depression increased the risk of arrhythmias was established. A study by Lamyaa E et al (59), identified presence of psychiatry disorders in children with cardiac devices. The high levels of anxiety and depression in patients with cardiac devices causing poor mental health was due to fear of death, malfunctions of the device, difficulties to return to work and performing life daily activities. Assessing mental health as in this study can help reduce frequent re-admissions, long hospital stay, suicide attempts and poor adherence to medications due to poor mental health (60).

In Tanzania a case report (61), was published on a suicide attempt by a cardiac pacemaker patient who jumped off the second floor through the ward window in a hospital, 4 days

after pacemaker implantation. Such a case strongly reinforces the need for assessment of mental health as a component of QOL in our patients that will be performed by our study.

On regards to social functioning Chen H et al (27), found low QOL in work capability, social participation and sexual function and that there was no significant improvement observed before and after implantation while Zatta T et al (56), observed a perfect high score on social function 100.0 with patients reporting resolution of symptoms such as syncope and dyspnea after implantation.

1.2.3Factors affecting quality of life post CIED implantation

1.2.3.1 Socio-demographic factors

The QOL varies with race, sex, culture and value system (62). A study in Brazil by Barros R et al (25), reported men to have a higher QOL scores on both SF-36 and AQUAREL compared to women similar findings were reported by Oliveira B et al (63), that women presented with dyspnea symptoms more compared to men while Nowak B et al (64), who found similar findings suggested that there is a delay in the indication of pacemakers in women compared to men due to presentation of conduction abnormalities late in females compared to men however, in the Intrinsic RV trial (65), a study from USA on QOL post device insertion of 1530 patients found women had worse QOL prior implantation but after implantation both men and women had equal QOL scores.

In a study by Kurocova R et al (66), in Slovakia reported older patients and those unmarried experienced poor QOL compared to younger and married similar findings by Barros R et al (25), who also reported that as age increases, the QOL worsens and the longer the pacemaker implantation time span, the worse the QOL.

Intrinsic RV trial (65), also found higher QOL scores among younger patients < 50years compared to older patients. The general population in developed countries is older than in developing countries, due to high life expectancy rates indicating many older patients live with cardiac implantable electronic devices compared to developing countries, could this translate to a better QOL in our own settings, this is a question that this study will possibly give an answer to.

1.2.3.2 Type of device and pacing mode

There is a controversy on whether to use single chamber (VVIR) or double chamber (DDD) pacing modes especially, in patients who have indication for VVIR and can be managed well on it. In a study (67), comparing VVIR versus DDD pacing modes among elderly patients found improved QOL after implantation in both and no statistical significant difference between VVIR and DDD in terms of QOL or clinical outcomes such as cardiovascular events or death, similar findings were observed by Moro E et al (68), who found better QOL with DDD and even, those patients who once were on VVIR then changed to DDD, preferred DDD better than VVIR. Andersen R et al (69), reported that dual pacing (DDD) reduced embolic events, atrial fibrillation and mortality compared to ventricular pacing (VVIR).

Other studies (70,71), have found benefits with single chambered devices on (VVIR mode) compared to double chambered (DDD mode) and even further associated DDD to cumbersome surgeries during implantation, higher infection rates and cost of device compared to single chamber devices. In JKCI the pacing modes performed are either DDD or VVIR which are the commonest pacing modes; this study will further contribute on the QOL experiences of our own patients who have single or double chambered devices.

Studies to assess the QOL in patients with CRT a study by Lenarczyk R et al (72), assessed patients prior and 6 months after implantation and found, QOL improved in 81% while it worsened in 19% of the patients. A meta-analysis by Chen H at al (27), also demonstrated that CRT-D devices improved QOL in comparison to patients with defibrillators alone, especially in patients with moderate to severe heart failure.

1.2.3.3 Duration post implantation

Patients with longer time span post CIEDs had a poor QOL demonstrated in a study by Barros R et al (25), compared to patients with shorter implantation duration time this was similar to findings by Udo E et al (73).

1.2.3.4 Indication for device placement

The indications for cardiac implantable devices vary among patients, in a study by Van E et al (74), found atrial fibrillation with slow ventricular rate is the best predictor of higher

QOL compared to other indications, similar findings by Benzer W et al (75), in Austria who found patients with sick sinus syndrome and atrial fibrillation scored higher QOL scores compared to patient with heart block as well as Lamas G et al (67), who observed high scores in QOL in patients with sinus node dysfunction with DDD pacing compared to heart block patients with DDD pacing.

Atrioventricular block as an indication is much common in developing countries than European countries were indication for pacemakers are commonly sinus node dysfunction and AF because the incidence rates of sinus node dysfunction and AF diseases increase with age naturally making them more prevalent in European population (76). The above studies suggest worse QOL in patients with AV block which is the common indication in developing countries making it predictable that our own patients may have poor QOL scores therefore, it is important to further explore this concept with this study.

1.2.3.5 Co-morbidities

In a study by Udo E et al (73), it found diabetes, hypertension and heart failure patients post pacemaker implantation had the least scores in QOL similar to a study by Herce B et al (71), that showed diabetes and underlying heart disease were associated with higher risk of infections and poor QOL scores post cardiac device implantation. Obese patient were found to have a lower QOL compared to patient who had a normal BMI (77,78).

1.2.3.6 Complications

Complication post device implantation can be short term or long term complications. The time to complication and recurrence of complications influence QOL post implantation (29), however this conflicts to a study by Udo.E et al (79), that reported short term complications are not predictive of long term complications after cardiac device implantation.

A study by Tinetti M et al (80), done in UK reports poor QOL in physical functioning domain due to post implant arrhythmic complications commonly dizziness and fainting attacks, similar common complaints led to poor QOL reported in studies by Sheldon R et al done in Canada (81), and Helguera M et al in USA (82). A study done in UK by

Harcombe A et al (83), instead reported common problems to be infections and skin erosions similar to a 5 year follow up study done in Nigeria (84), that reported pacemaker infection 5.9% and pocket erosion 3.9% .Although studies report low risk of complication associated with implantation ranging from 3% to 9% but with high increasing number of new implants per year the intra-operative, early and late post procedural complications are consequently projected to rise (20,85,86), hence it requires to careful monitor and know the trends of complication post implantation in order to be prepared for future patients.

1.2.4 Mortality

Before the era of cardiac devices, 50% of patients with advanced AV block died within a year and 75% to 90% were dead within 5years after diagnosis (87,88). Introduction of cardiac implantable electronic devices have shown improvement in survival up to 20 years (88,89). The most common cause of death in these patients is heart failure and sudden cardiac death. In a study that followed 6501 patients after pacing found that young age, women, near syncope compared to syncope, sick sinus compared to AF and DDD/AAI compared to VVI were better prognostic indicators for survival (88).

1.3 Conceptual framework

Figure 1 shows relationship between socio-demographic and associated factors with QOL of patient with cardiac implantable electronic devices, constructed from literature review.

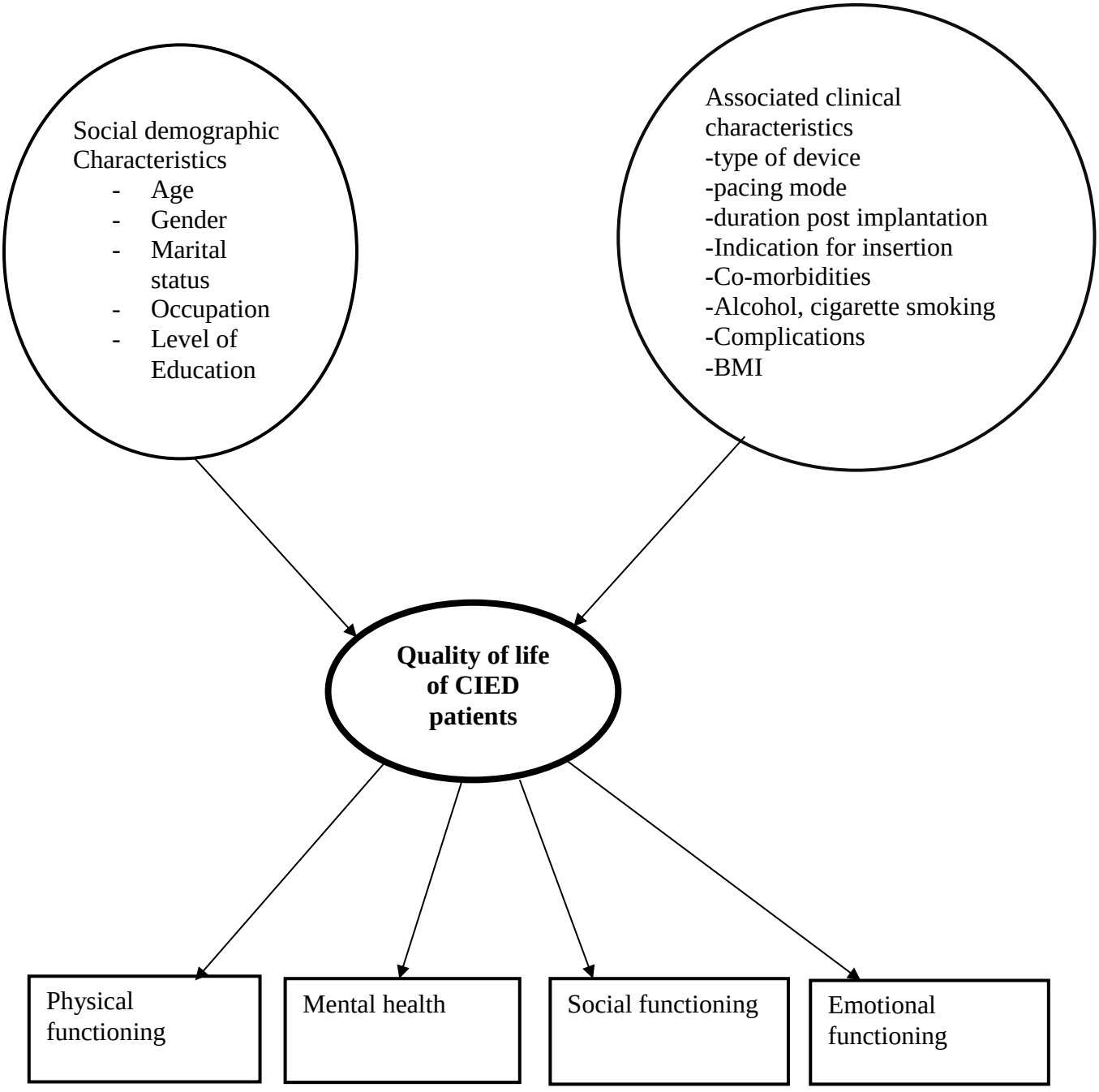

Figure 1: Conceptual framework

CHAPTER TWO

2.0 PROBLEM STATEMENT AND OBJECTIVES

2.1 Problem statement

Worldwide, there is an increasing incidence of cardiovascular diseases (16), and as the global life expectancy is increasing, consequently so do arrhythmic and conduction disorders that require cardiac pacing (31,90). Cardiovascular diseases are currently the leading cause of mortality in the world estimated at 17.2 million deaths per year (9), keeping that in perspective, it means going into the future advanced interventions such as device therapy will be a paramount treatment strategy.

Cardiovascular implantable electronic devices have clearly improved survival of patients (1,2), but still there is a concern of the impact of this lifelong therapy on the daily life activities of a patient rather than just a mere outcome of prolonged life (19). Studies elsewhere outside of Africa (21–24), have reported good QOL while other studies (25–27), have shown poor QOL among cardiac device patients due to increased levels of anxiety, depression, poor social health and physical limitations. There is even, a reported case of a suicide attempt of a patient, 4 days after pacemaker implantation in our own country of Tanzania (61). The importance of this understudied topic locally cannot be overstated and with the increase in cardiac device implantation yearly in our settings together with the fact that QOL is influenced with demographic factors (4), and the absence of data on the topic locally or from our neighboring countries it therefore, becomes very important to undertake this study on QOL and its associated factors among patients with cardiac implantable electronic device at JKCI to fill this gap.

2.2 Rationale of the study

This study is designed to evaluate the QOL and its associated factors among patients with cardiac implantable electronic devices implanted at JKCI with the anticipation that it would provide reliable and valid information concerning the challenges whether physically, mentally or socially experienced by patients. This will be helpful in evaluating the effectiveness of the therapy and direct on how to project available limited resources to mitigate the challenges faced by these patients.

The data will also help cardiologists and their patients to discuss on what realistic

expectations to have post implantation and if a satisfactory QOL is observed, then it will equip them to confidently recommend device implantations to other patients who need this therapy.

2.3 Hypothesis

Patients with cardiac implantable electronic devices implanted at JKCI have a good QOL**.**

2.4 Research question

What is the QOL of patients with cardiac implantable electronic devices implanted at JKCI and what are the factors that influence the QOL among these patients?

2.5 Broad and specific objectives

2.5.1 Broad objective

To evaluate patients quality of life and its associated factors among patients with cardiac implantable electronic devices implanted at Jakaya Kikwete Cardiac Institute between 2013 and 2019.

2.5.2 Specific objectives

1. To describe socio-demographic and clinical characteristics among patients with cardiac implantable electronic devices implanted at JKCI between 2013 and 2019.
2. To assess the quality of life among patients with cardiac implantable electronic device implanted at JKCI between 2013 and 2019.
3. To determine the associated factors influencing QOL among patients with cardiac implantable electronic devices implanted at JKCI between 2013 and 2019.
4. To establish the survival among patients with cardiac implantable electronic devices implanted at JKCI between 2013 and 2019.

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1Study design

This was a hospital based descriptive cross-sectional study among patients with cardiac implantable electronic devices implanted at Jakaya Kikwete Cardiac Institute.

3.2 Study site

Jakaya Kikwete Cardiac Institute is located in Dar es Salaam, Upanga in the same area as the Muhimbili National hospital. It is the national specialized cardiac center for care and research with a 103 bed capacity, attending on average 700 outpatients and 100 inpatients per week. The institute was the first cardiac center in the country to start insertion of cardiac implantable electronic device, a pacemaker in 21stNovember 2013.

3.3 Study time

This study was done from October 2019 to January 2020. This 4 month study period was chosen out of convenience and was intended to get a maximum number of patients who had their devices inserted at JKCI starting from the first patient in 21st November 2013 to patients inserted on 30thJune 2019, three months before the study was conducted.

3.4 Study population

The study population included patients who had a cardiac implantable electronic device implanted at JKCI from 21st November 2013 to 30thJune 2019.

3.5 Inclusion criteria

- Adults above 18 years of age.
- All patients with cardiac implantable electronic device implanted at JKCI.

3.6 Exclusion criteria

- Persons who had speech, hearing or mentally impairment due to inability to respond to questionnaire.

3.7 Determination of sample size

For calculation of sample size in health related QOL scales, an essential step is obtaining a sample size that will allow a reasonable chance (power) of detecting a predetermined difference (effect size) in the outcome variable (91). Effect size is used to quantify effect of an intervention and in calculation of sample size in health related QOL data, the choice of the sample size formulae strictly depends on the way data will be analyzed (91,92).

For this study the data from QOL scales was to be treated as a continuous outcome and as normally distributed. Mean and mean difference was to be used hence a one sample formulae was used in calculation of sample size,

$$n = \frac{2(Z_{1-\alpha/2} + Z_{1-\beta})^2}{ES^2}$$

Where by

n = Sample size

$\alpha = 0.05$ (95% confidence interval)

β = 80% power

$Z_{1-\alpha/2} = 1.645$

$Z_{1-\beta} = 0.84$

Effect size ES= 0.3

From a study by Barros R et al (27), the effect size that was used was 0.3

$$n = \frac{2 (1.645 + 0.84)^2}{0.3^2}$$

n= 137

Therefore the estimated minimal sample size was 137 patients.

The power of the study was 80% with a non-response rate (f) of 10% using the formulae:

N= (n X 100)/ (100-f)

Therefore, the sample size used was 153 patients.

3.8Variables

3.8.1 Dependent variable

In this study, the dependent variable was quality of life.

3.8.2 Independent variable

- Baseline social-demographic characteristics such as age, sex, level of education, residency and occupation
- Type of cardiac implantable device inserted
- Duration of time since the CIED was implanted
- Indication for device insertion and pacing mode
- Co-morbidities at baseline example Diabetes, hypertension
- History of alcohol use or cigarette smoking
- Baseline Body Mass Index (BMI)
- Any device related complication documented in the file of the patient

3.9 Data collection methods

Convenience sampling technique was employed whereby all available patients were requested via telephone to come to JKCI for an interview and those who were far, a telephone interview was conducted and data was filled by the principle investigator on the SF-36 and AQUAREL questionnaires and other baseline information was obtained from the patient's files at JKCI.

3.10 Data collection tool

The two tools used were the SF-36 and AQUAREL questionnaires. SF-36 questionnaire is the most widely used generic health-related QOL instrument in the world and its validity and reliability has been established in several countries (34). It is not disease specific, it is multidimensional questionnaire and as an interview administered instrument, it is applicable in all age groups (93). The SF-36 has shown consistency and construct validity with a very low missing response rate demonstrating acceptability of person to person interview as well as in telephone administration in various studies (94,95).

The AQUAREL questionnaire has been proven to provide better assessment of QOL in cardiac devices assessment when used along with the SF-36 and its reliability and validity has been tested in a number of studies in different areas and has shown consistent results with high validity and reliability (48, 53).

To evaluate the QOL, the SF-36 questionnaire was administered to 53 patients through person to person interview as well as to 118 patients via telephone interviews by the principle investigator. It is composed by 36 item questions distributed in eight domains: functional capacity, physical aspects, pain, general health status, mental health, vitality, social aspects and emotional aspects (96). The scores of each domain can vary from 0 to 100 and the higher the score, the better the QOL. The mean score of 50 has been articulated as a normative value, with a score higher than 50 indicating good health and below 50 indicating poor health (25). The scoring system used was the scoring system proposed by Ware J et al who constructed the questionnaire (96).

The AQUAREL questionnaire was administered along with the SF-36 to 53 patients via person to person interview and 118 patients via telephone interview by the principle investigator; it consists of 20 questions divided into three domains: chest discomfort, arrhythmia, and dyspnea on exertion. Every domain has specific items with five response categories, with values ranging from 1 to 5. Final scores can range from zero (all complaints) to 100 (no complaints), where a score of 100 represents perfect QOL (25). A cut-off point of 50 (mean score) is established to determine the best and worst domains. Domains with scores lower than 50 represent worse QOL and those with scores 50 or over represent better QOL. A low numeric score reflects poor health perception, loss of function, and presence of pain whereas a high numeric score reflects good health perception, preserved function, and absence of pain (25).

The three domains of the AQUAREL QOL questionnaire are (chest discomfort: questions 1 to 6, 11 and 12; dyspnea: questions 7 to 10, 18 to 20; arrhythmia: questions 13 to 17). Individual scores obtained for each of the domains were added up and computed using Oliveira's Formula, where equivalence between the letters of the answers for items of

every question in the AQUAREL questionnaire and the 5-point likert scale was: a)=5; b)=4; c)=3; d)=2 e e)=1(25,48).

Oliveira's formula: Score = 100 – {[(ΣN - n°N) / (n°N X 5) – n°N]} X 100
Where: ΣN = sum of points from questions that comprise the score
nº N = number of questions that comprise the score

3.11 Data management and analysis

The data obtained from the questionnaires was entered electronically in the computerized software program, statistical package of social sciences (SPSS) version 23.0 for windows for data analysis. Cross checking of filled questionnaires after was done for quality control of data.

For describing the study sample; frequency was calculated for categorical variables such as; age, sex, duration of time since implantation and summarized using frequency tables while means, standard deviation and confidence intervals were calculated for continuous variables. For comparison of categorical variables between two groups independent t-test was done while, for categorical variables with more than two groups the Analysis of variance (ANOVA) was used.

For identifying factors affecting the patient's quality of life, a two step regression analysis was done for the SF-36 and the AQUAREL scores. A univariate analysis was done for each significant demographic and clinical variable obtained from independent t-test and ANOVA, for each of the SF-36 and AQUAREL domain scores. Second those significant factors in the first step were included in the multiple linear regression model for each score to identify the significant factors after adjustment of possible confounding effects. The level of significance used was $p<0.05$.

3.12 Data Storage:

The questionnaires used for data collection were stored in a secure place to access whenever necessary, ensuring confidentiality.

3.13 Ethical consideration:

Ethical clearance to conduct this study was received from MUHAS Institution Review Board, through school of medicine. A separate permission to conduct the study was sought from JKCI administration. Participant who had person to person interview signed a written informed consent form voluntarily and for telephone interviews, a verbal consent was sought. This risk and benefits of participating were explained and study participants were informed about their rights of participation and told that their refusal would not affect their subsequent care. No direct patient identifiers were used in data collection and information was kept confidential.

CHAPTER FOUR

4.0 RESULTS

4.1 Recruitment of the study participants

Between the period of 21st November 2013 and 30th June 2019, a total number of 249 patients are listed to have undergone insertion of a CIED at JKCI. A total of 234 patient records were able to be retrieved, this means 12 records were unavailable, further enquiries were made at the records department but it was not established why these records were missing. Of the 234 records retrieved, 23 records had missing phone numbers and 3 had recordings of in-hospital patient deaths. Data was therefore extracted from 211 patient's records as shown in the recruitment flow chart below (Figure 1). A phone call was placed to establish patient's presence. Phone contacts that were not reachable were 22 phone contacts and the remaining 189 responded to the phone call, among these 17 patients were confirmed to have died, 1 patient declined to participate and the remaining 171 patients were enrolled in the study.

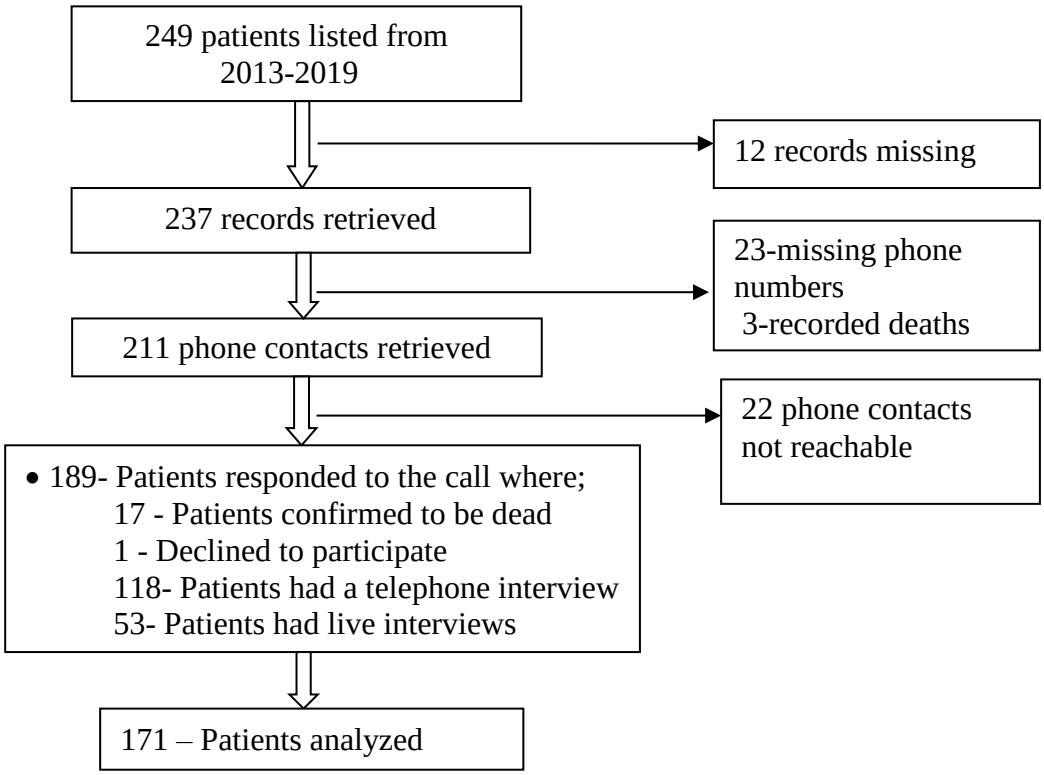

Figure 2: Recruitment flow chart

4.2 Baseline Socio-demographic characteristics

Table 1 shows baseline socio-demographic characteristics among the 171 study participants. The baseline mean age of the study participants in our study was 71yrs with an age range from 36 yrs to 91 yrs in that; 75.4% were ≥60yrs. 52% were females, 21.1% reported to have never received any formal education while 36.3% had been to a college/university. A larger percent of patients were unemployed 29.8% while 18.7% were employed. 64.9% were reported to be married and 30.4% were divorced/ widowed. About 60% of the patients were residents from an urban setting.

Table 1: Baseline socio-demographic characteristics of 171 study respondents.

VARIABLE	TOTAL	PERCENTAGE (%)
Age		
< 60yrs	42	24.6
≥60yrs	129	75.4
Sex		
Male	82	48
Female	89	52
Education level		
No formal	36	21.1
Primary	34	19.9
Secondary	39	22.8
College/University	62	36.3
Employment status		
Un-employed	51	29.8
Self-employed	43	25.1
Employed	32	18.7
Retired	45	26.3
Marital status		
Single	8	4.7
Married	111	64.9
Divorce/Widowed	52	30.4
Residence		
Rural	69	40.4
Urban	102	59.6

4.3 Baseline clinical characteristics

The baseline clinical characteristics seen among the 171 patients with a pacemaker are described in table 2; the number of CIEDs inserted has increased over the years with only 4 devices initially inserted 5 years ago. The major indication was advanced AV block 88.3%.The commonest pacing mode was DDD 60.8% and the percent of CRT was 7.0%. The commonest co-morbidity was hypertension at 62% followed by diabetes at 26% and 24% of patients were documented to have heart failure. History of alcohol use was 46.2% while, smoking was reported in 13.5% patients and 46.5% of the patients were reported to be overweight. The complications post implantation reported was 22.2% with the highest being pacemaker infection.

Table 2: Baseline clinical characteristics of 171 study respondents.

VARIABLE	TOTAL	PERCENTAGE (%)
Implant years		
<1 yr	43	25.1
1 yr	63	36.8
2 yrs	31	18.1
3 yrs	24	14.0
4 yrs	6	3.5
5 yrs	4	2.3
Indications		
AV block	151	88.3
Others	20	11.7
Pacing mode		
VVIR	55	32.2
DDD	104	60.8
CRT	12	7.0
Hypertension		
No	65	38.0
Yes	106	62.0
Diabetes mellitus		
No	127	74.0
Yes	44	26.0
Heart failure		
No	130	76.0
Yes	41	34.0
Alcohol use		
No	92	53.8
Yes	79	46.2
Cigarette smoking		
No	148	86.5
Yes	23	13.5
***BMI**		
Normal	41	31.5
Over-weight	61	46.5
Obese	28	21.5
Complication		
No	133	77.8
Yes	38	22.2

**BMI –only 130 patients were analyzed due to recorded generalized edema or ascites in the excluded patient's files.* AV, Atrioventricular.

4.4 QOL of patients among patients with cardiac implantable electronic devices.

SF-36 questionnaire

The QOL among the patients with CIEDs in this study was overall good with the highest scores being on role emotional domain 82.6 and the lowest score on social functioning of 49.8 on the SF-36 questionnaire as shown on Table 3.

AQUAREL questionnaire

The scores of the study participants on the AQUAREL questionnaire were also high indicating good QOL in all domains. The mean scores for each of the three domains were all above 80, with the highest score on the dyspnea domain 93.5 and the least score on the arrhythmia domain 82.6 as shown on Table 3.

Internal validity of SF-36 and AQUAREL questionnaire

The internal validity measured by cronbach alpha for the SF-36 ranged from an acceptable 0.622 on the general health domain to 0.974 on role physical domain, while that of the AQUAREL questionnaire ranged from 0.643 for arrhythmia domain to 0.906 for the chest discomfort domain as shown on Table 3.

Table 3: QOL mean scores for 171 study respondents on SF-36 and AQUAREL.

Questionnaire Scale	No of patients	Mean(SD)	95% CI	Cronbach alpha (α)
SF-36				
Physical functioning	171	71.4(25.2)	70.6-72.2	0.907
Role physical functioning	171	75.1(41.7)	74.8-75.5	0.974
Body pain	171	75.4 (23.1)	75.6-75.7	0.801
General health	171	65.0(15.9)	64.7-65.4	0.622
Vitality	171	66.4 (21.8)	65.7-67.2	0.803
Role emotional functioning	171	82.6 (36.4)	82.3-82.9	0.956
Social functioning	171	49.8 (12.8)	49.5-49.7	0.764
Mental health	171	79.4(15.7)	78.9-79.9	0.756
AQUAREL Scale				
Chest discomfort	171	89.4 (15.1)	89.1-89.6	0.906
Dyspnea score	171	82.6 (9.8)	82.3-83.8	0.643
Arrhythmia score	171	93.5 (18.2)	93.4-93.6	0.856

CI, confidence interval; SD, Standard deviation

4.5 Comparisons of QOL mean scores on SF-36 according to baseline socio-demographic characteristics

Table 4 shows QOL scores and comparison according to baseline clinical characteristics were; patients who are ≤ 60 yrs of age had higher mean physical functioning score of 81.4 than older patients ≥60 yrs with a mean score of 71.4 ($p<0.001$), as well as on general health younger patients had higher mean score than older patients ($p< 0.014$). In regards to vitality however, older patients ≥60 yrs had better QOL scores than younger patients ($p<0.011$). Males had higher mean score than females on mental health domain ($p<0.01$).

University graduates had overall better QOL scores than other groups and there is a statistically significant difference observed between the education groups in physical function ($p<0.05$), bodily pain ($p<0.034$) and vitality ($p<0.043$).

A statistical significant difference was observed between employment groups on physical functioning ($p<0.028$) and between marital status groups on physical functioning ($p<0.033$).

Table 4: Comparison of QOL mean scores on SF-36 according to baseline socio-demographic characteristics.

Variable	Physical function	Role-Physical	Bodily Pain	General Health	Vitality	Social function	Role-Emotional	Mental Health
Age								
≤60 yrs	81.4±19.2	74.4±42.6	79.5±23.6	70.3±17.7	64.0±22.6	50.0±12.3	74.4±42.5	79.0±16.2
>60 yrs	68.1±26.2	75.4±41.7	74.0±23.6	63.3±15.1	73.8±17.4	49.5±13.0	75.4±41.7	79.4±15.7
p-value	***0.001****	*0.895*	*0.176*	***0.014****	***0.011****	*0.832*	*0.532*	*0.632*
Gender								
Male	74.4±22.4	77.7±41.2	78.4±21.4	64.9±15.6	68.9±20.6	50.8±9.3	85.0±35.2	82.5±15.7
Female	68.7±27.4	72.4±42.2	72.6±24.4	65.1±16.4	64.1±22.9	48.6±15.4	80.5±37.5	76.4±15.2
p-value	*0.138*	*0.436*	*0.102*	*0.937*	*0.153*	*0.271*	*0.428*	***0.01****
Education								
No formal	64.6±28.8	70.8±45.3	71.3± 24.3	61.9±15.4	60.2±21.9	48.6±11.9	74.1±42.2	73.2±17.2
Primary	71.3±23.3	75.0±40.3	68.7± 21.8	64.9±14.0	63.1±23.9	51.1±12.8	92.2±23.3	81.8±13.8
Secondary	67.7±23.6	75.6±39.9	75.0±21.3	66.9±15.5	64.7±22.0	49.4±16.2	78.6±40.8	78.9±16.7
University	77.7±24.1	77.4±42.1	81.7±23.2	65.8±17.7	72.5±19.4	49.6±11.1	84.9±35.0	81.9±14.4
p-value	***0.050****	*0.904*	***0.034****	*0.552*	***0.043****	*0.877*	*0.169*	*0.046*
Employment								
Un-employed	67.9±25.5	75.0±43.3	74.9± 22.3	65.0±15.2	67.5±19.9	50.5±9.7	80.3±38.4	80.6±11.7
Self employed	79.4±21.2	74.2±43.8	80.3± 22.9	68.0±17.2	72.2±17.7	49.2±13.1	86.5±32.6	79.8±13.9
Employed	76.5±27.4	79.7±39.1	78.0±25.3	67.3±16.7	67.8±24.6	48.5±15.2	84.5±35.9	78.4±18.1
Retired	64.8±23.6	71.7±41.8	69.9±21.6	60.8±14.8	57.9±21.9	50.0±13.6	80.7±37.9	78.4±18.1
p-value	***0.028****	*0.844*	*0.210*	*0.158*	***0.015****	*0.897*	*0.856*	*0.894*
Marital status								
Single	84.4±15.7	75.0±46.3	76.5±17.2	58.8±7.0	68.1±17.3	51.6±17.0	87.5±35.3	81.0±7.9
Married	73.6±25.5	75.6±41.3	75.5±22.7	66.5±16.7	68.6±21.6	50.0±13.1	82.5±37.0	80.8±16.3
Widowed	64.6±24.5	74.0±42.5	74.8± 25.1	62.8±15.1	61.5±22.4	48.6±11.8	82.1±35.8	76.0±14.7
p-value	***0.033****	*0.973*	*0.974*	*0.209*	*0.153*	*0.729*	*0.926*	*0.179*
Residence								
Rural	67.1±26.6	71.0±44.5	72.6±24.5	64.0±14.8	64.8±22.8	49.8±13.5	81.0±37.7	79.8±16.5
Urban	74.3±24.2	77.9±39.7	77.3±22.1	65.8±16.8	68.0±21.2	49.8±12.4	83.6±35.6	79.1±15.1
p –value	*0.07*	*0.436*	*0.29*	*0.201*	*0.467*	*0.438*	*0.764*	*0.661*

***p≤0.05**

4.6 Comparison of QOL mean scores on SF-36 according to baseline clinical characteristics

Table 5 shows QOL mean scores for the study participants and comparison according to baseline clinical characteristics. Patients who had cardiac implantable electronic devices implanted for ≥3yrs had overall better QOL scores and there was a statistically significant difference observed between implantation years groups on physical functioning ($p<0.000$) and general health ($p<0.008$).

A statistical significant difference was observed between BMI groups on vitality ($p<0.471$), and patients with no complications had higher vitality score of 68.3 ($p<0.032$) and mental health score 73.8 ($p<0.013$) than patients who had experienced complications.

Table 5: Comparison of QOL mean scores on SF-36 according to baseline clinical characteristics.

Variable	Physical Function	Role-Physical	Bodily Pain	General Health	Vitality	Social Function	Role-Emotional	Mental Health
Implant yrs								
<1 yr	68.3±24.0	71.5±45.2	71.5±25.2	63.8±15.5	66.2±19.9	50.6±11.2	73.6±43.4	78.2±13.6
1 yrs	62.1±27.1	61.5±46.0	73.0±24.9	66.3±18.2	59.9±23.7	51.6±14.6	79.4±38.1	77.8±17.3
2 yrs	81.3±23.3	90.3±30.1	76.4±19.8	61.8±11.8	71.9±20.7	45.9±13.8	90.3±30.1	80.8±15.3
≥3yrs	84.4±17.8	87.5±31.3	82.4±17.9	66.3±15.5	75.6±18.6	46.9±10.6	90.3±28.6	83.3±16.5
p-value	***0.000****	***0.001****	*0.092*	*0.476*	***0.008****	*0.197*	*0.060*	*0.516*
Indications								
AV	72.3±25.5	75.2±41.5	75.1±22.0	65.6±14.9	67.3±21.5	49.9±11.2	81.7±37.1	79.6±15.3
Others	64.8±22.3	75.0±44.4	78.3±30.6	60.5±22.8	59.8±23.9	47.5±21.7	90.0±30.8	77.4±18.7
p-value	*0.211*	*0.987*	*0.652*	*0.337*	*0.146*	*0.430*	*0.338*	*0.552*
Pacing mode								
DDD	70.2±26.5	78.2±40.1	76.3±23.3	62.9±15.7	63.1±22.7	51.2±6.9	77.8±16.8	79.4±21.3
VVIR	72.5±25.2	74.3±42.0	74.9±22.1	66.5±15.0	68.7±20.7	49.3±14.2	79.8±13.7	85.1±14.6
CRT	66.9±20.5	69.2±48.0	75.5±31.4	62.1±23.5	62.3±26.2	46.2±18.7	83.1±19.4	77.5±27.5
p-value	*0.684*	*0.742*	*0.933*	*0.314*	*0.252*	*0.409*	*0.366*	*0.499*
Hypertension								
No	72.9±23.4	80.2±37.9	73.8±20.9	65.5±14.4	63.8±19.4	50.6±11.9	88.2±31.4	79.3±15.6
Yes	70.6±26.3	72.2±43.6	76.2±24.3	64.8±16.8	67.9±23.0	49.1±13.4	79.5±38.7	79.4±15.7
p-value	*0.559*	*0.212*	*0.448*	*0.778*	*0.234*	*0.457*	*0.135*	*0.916*
Diabetes Mellitus								
No	69.7±25.7	72.4±42.9	73.1±23.0	64.5±16.4	65.1±22.2	49.2±13.4	83.6±34.9	78.4±15.9
Yes	76.0±23.4	82.8±37.6	81.8±22.5	66.7±14.9	70.1± 20.6	50.8±11.1	80.0±40.5	82.0±14.9
p-value	*0.155*	*0.153*	*0.310*	*0.428*	*0.189*	*0.467*	*0.571*	*0.183*

Continue table 5;

	Physical Function	Role-Physical	Bodily Pain	General Health	Vitality	Social Function	Role-Emotional	Mental Health
Heart failure								
No	71.3±26.1	76.5±41.0	73.6±22.3	64.8±15.1	66.3±22.6	50.7±12.2	81.8±37.1	79.8±15.9
Yes	71.8±22.4	70.7±44.0	81.1±24.9	65.7±18.7	66.8±19.5	46.3±14.3	85.4±34.2	78.0±14.9
p-value	*0.902*	*0.439*	*0.070*	*0.761*	*0.894*	*0.086*	*0.585*	*0.538*
Alcohol								
No	70.8±27.1	74.7±41.5	75.4±22.4	66.9±15.7	65.8±22.6	49.9±13.6	81.5±36.4	79.0±16.1
Yes	72.1±23.0	75.6±42.2	75.3±24.1	62.9±16.2	67.2±21.0	49.4±12.0	83.9±36.5	79.8±15.3
p-value	*0.743*	*0.888*	*0.979*	*0.105*	*0.665*	*0.801*	*0.663*	*0.712*
Smoking								
No	72.0±26.1	75.3±41.4	75.0±23.2	65.4±15.9	67.0±22.2	49.8±13.4	80.6±37.9	78.8±15.9
Yes	67.8±19.2	73.9±44.8	77.7±22.7	62.3±16.6	62.6± 18.8	48.4±8.7	95.7±20.8	82.8±14.3
p-value	*0.467*	*0.879*	*0.609*	*0.379*	*0.368*	*0.612*	*0.107*	*0.236*
BMI								
Normal	68.3± 24.0	71.5±45.2	71.5± 25.2	63.8±15.5	66.2±19.9	50.6±11.2	73.6±43.4	78.2±13.6
Overweight	62.1±27.1	61.5±46.0	73.0± 24.9	66.3±18.2	59.9±23.7	51.6±14.6	79.4±38.1	77.8±17.3
Obese	81.3±23.3	90.3±30.1	76.4±19.8	61.8±11.8	71.9±20.7	45.9±13.8	90.3±30.1	80.8±15.3
p-value	*0.060*	*0.685*	*0.685*	*0.758*	***0.471****	*0.497*	*0.908*	*0.401*
Complication								
No	73.1±24.1	76.1±41.2	75.6±23.4	65.8±16.0	68.3±21.5	49.1±12.8	83.9±34.9	81.0±14.6
Yes	65.5±28.3	71.7 ±43.5	74.8±22.3	62.4±15.8	59.7±21.9	51.6±12.7	78.1±41.2	73.8±18.1
p-value	*0.104*	*0.566*	*0.862*	*0.258*	***0.032****	*0.274*	*0.381*	***0.013****

AV, Atrioventricular; CRT, cardiac resynchronization therapy; DDD, Dual chamber rate adaptive,
***p≤0.05**

4.7 Heath transition question on SF-36 questionnaire

Table 6 shows the responses of the 171 study participants on the additional question on the SF-36 questionnaire that addresses health transition by comparing, health status of the present compared to 1 year ago. Possible answers were as follows: 1) much better now than 1 year ago; 2) somewhat better now than 1 year ago; 3)about the same as 1 year ago; 4) somewhat worse than 1 year ago and 5) much worse than 1 year ago. In this study majority of patients stated that their health is somewhat better now compared to 1 year ago (53.8%) while 33.9% recalled their health to be much better compared to 1 year ago and only 1.8% stated that it was much worse compared to 1 year ago.

Table 6: Response to health transition on SF-36 for 171 study respondents

Compared to 1 year ago, how would you rate your health in general now?	Much better now than one year ago		Somewhat better now than one year ago		About the same		Somewhat worse now than one year ago		Much worse than one year ago	
	N	%	N	%	N	%	N	%	N	%
	58	33.9	92	53.8	11	6.4	7	4.1	3	1.8

4.8 Comparison of QOL mean scores on AQUAREL according to socio-demographic characteristics

Table 7 shows mean scores on AQUAREL questionnaire based on baseline socio-demographic characteristics; rural participants were found to have better QOL on arrhythmia domain with a higher score of 95.7 compared to participants residing in urban areas with a score of 92.0 ($p<0.015$). No significant difference between the other social demographic characteristics was observed between groups on AQUAREL questionnaire.

Table 7: Comparison of QOL mean scores on AQUAREL according to baseline socio-demographic characteristics.

	Chest discomfort	Dyspnea	Arrhythmia
Gender			
Male	91.0±14.3	83.3±19.1	93.4±11.1
Female	88.0±15.7	82.1±17.5	93.6±8.4
p-value	*0.194*	*0.905*	*0.686*
Age Groups			
≤60	90.3±16.5	85.2±18.0	93.7±10.2
>60	89.1±14.6	81.8±18.3	93.4±9.6
p- value	*0.649*	*0.304*	*0.891*
Education			
None	86.9±15.9	79.2±18.3	94.9±7.6
Primary	88.7±12.6	79.3±18.2	96.0±6.0
Secondary	90.8±13.2	85.1±20.7	96.8±5.9
University	90.3±17.0	86.2±14.7	93.0±11.5
p-value	*0.673*	*0.463*	*0.164*
Employment			
None	90.0±13.2	81.6±18.1	95.2±7.2
Primary	88.7±19.6	83.8±19.9	93.4±10.9
Secondary	86.5±16.7	88.5±15.0	96.3±6.3
University	85.1±10.6	78.1±18.9	94.2±10.6
p-value	*0.338*	*0.053*	*0.519*
Marital			
Single	88.2±14.6	83.9±17.5	93.6±9.3
Married	86.7±17.0	79.3±19.2	91.0±12.1
Divorce/widowed	92.7±14.4	86.8±18.0	96.6±6.1
p-value	*0.677*	*0.406*	*0.538*
Residence			
Rural	90.0±12.4	83.7±15.5	95.7±6.4
Urban	89.0±16.7	82.0±19.9	92.0±11.3
p-value	*0.676*	*0.533*	***0.015****

***p≤0.05**

4.9 Comparison of QOL mean scores on AQUAREL according to baseline clinical characteristics

Table 8 shows mean scores on AQUAREL questionnaire based on baseline clinical characteristics. No statistical significant difference on QOL scores was observed between groups when compared on the AQUAREL questionnaire based on baseline clinical characteristics.

Table 8: Comparison of QOL mean scores on AQUAREL according to baseline clinical characteristics.

	Chest discomfort	Dyspnea	Arrhythmia
Implant years			
<1 yr	88.2±14.6	83.9±17.5	93.6±9.3
1 yrs	86.7±17.0	79.3±19.2	91.0±12.1
2 yrs	92.7±14.4	86.8±18.0	96.6±6.1
≥3 yrs	95.1±10.6	86.2±14.7	96.5±6.0
p-value	*0.136*	*0.262*	*0.079*
Hypertension			
No	89.6±15.4	82.1±16.1	94.5±8.9
Yes	89.3±14.9	82.9±19.3	95.1±8.6
p-value	*0.914*	*0.770*	*0.681*
Diabetes Mellitus			
No	89.3±15.4	81.3±19.1	94.8±9.0
Yes	89.7±14.6	86.3±14.9	95.2±7.9
p-value	*0.868*	*0.117*	*0.763*
Alcohol			
No	88.4±15.9	82.6±18.4	93.5±10.4
Yes	90.5±14.1	82.8±18.1	93.5±9.2
p- value	*0.369*	*0.953*	*0.804*
Smoking			
No	89.4±15.0	83.1±17.3	93.3±9.7
Yes	89.4±16.0	80.1±23.5	94.5±10.8
p-value	*1.00*	*0.470*	*0.953*
Heart failure			
No	88.7±15.6	18.3±1.60	95.1±8.6
Yes	91.5± 13.5	18.3±2.9	94.3±9.2
p- value	*0.300*	*0.895*	*0.608*
Indications			
AV	89.4±14.8	82.9±17.5	95.1±8.7
Others	89.1±17.9	81.1±23.3	93.2±9.5
p- value	*0.916*	*0.675*	*0.377*

Continue table 8

	Chest discomfort	Dyspnea	Arrhythmia
Pacemaker mode			
DDD	89.0±16.8	79.4±21.2	95.4±8.9
VVIR	89.6±13.7	85.0±14.6	95.0±8.4
CRT	88.9±19.4	77.5±27.5	92.3±10.9
p-value	*0.969*	*0.099*	*0.526*
Complication			
No	*89.7*±16.0	18.5±18.6	95.3±8.3
Yes	88.2±13.0	16.5±16.5	93.6±10.3
p-value	*0.593*	*0.073*	*0.290*
BMI			
Normal	88.9±17.4	87.2±15.4	93.9±9.7
Overweight	88.1±14.0	79.8±19.1	94.8±9.0
Obese	89.7±16.3	81.9±19.5	97.3±5.3
p-value	*0.906*	*0.131*	*0.262*

CRT, cardiac resynchronization therapy; DDD, Dual chamber rate adaptive, ***p≤0.05**

4.10 Multiple regression analysis.

Table 9 shows results from multiple regression analysis. We found that age of a patient was negatively associated with general health (R2 =75.0%, P≤0.001) and implant years was positively associated with physical functioning (R2 =22%, P≤0.001), role physical (R2 =5.6%, P≤0.001), Bodily pain (R2 =12%, P≤ 0.002), emotional health (R2=7.4%, P<0.002) and vitality (R^2= 19.6% p<0.018). On evaluation of Mental health domain of SF-36, female sex compared to male sex (R^2= 18.4%, P<0.025) together with widow status compared to married status (R^2= 9.2%, P<0.05) were negatively associated with mental health. Domain for social functioning on SF-36 and AQUAREL domains (chest discomfort, arrhythmias and dyspnea) had no statistical significant associated factors.

Table 9: Multiple regression analysis for the SF-36 subscales

Dependent variable	**Independent Variable**	**B**	**95% CI for B**	**Standardized β**	**p-value**	**R^2**
Physical functioning	Implant years	6.901	4.595-9.729	0.330	0.001	0.221
Role physical	Implant years	7.961	3.701- 11.950	0.236	0.001	0.056
Bodily pain	Implant years	4.181	1.675-6.673	0.283	0.002	0.120
General Health	Age of patient	-0.366	-0.573- (-0.153)	0.258	0.001	0.750
Vitality	Implant years	2.581	0.663-5.253	0.164	0.018	0.196
Emotional Functioning	Implant years	6.396	2.865-10.176	0.217	0.002	0.074
Mental health	Sex of patient (ref male) Widower (ref married)	-5.592 -7.421	-10.395-(-0.760) -10.995-(0.181)	0.024 0.304	0.025 0.05	0.184 0.092

4.11 Mortality

Table 10 shows the results on mortality, at the time of the study out of the 249 patients 172 patients (69.1%) were alive. Through phone calls and recorded hospital files we were able to confirm that 20 (8.0%) were deceased. The calculated mean duration for the alive patients with cardiac implantable electronic device implantation was 1.4 years.

Table 10: Mortality outcome after cardiac implantable electronic device implantation

Variable		**Frequency**
Outcome	Alive Dead	172 (69.1%) 20 (8.0%)
Mean duration with pacemaker for alive patients (years)	Mean Min - max	1.4 (0-5)

CHAPTER FIVE

5.0 Discussion

In regards to assessment of QOL, our study findings reveal that the overall QOL in patients with cardiac implantable electronic devices is good. The patient's scores in each domain of the SF-36 and AQUAREL were all above 50, except for social functioning domain on the SF-36 with a score of 49.8. A score of 50 is a proposed cut off point for both the SF-36 and AQUAREL questionnaire were scores range from 0 to 100 and scoring above 50 indicates a good QOL and below 50 indicates a poor QOL (97). A reported overall good QOL among cardiac implantable electronic device patients has been shown by other studies (22,25,47,97,98).

In regards to social functioning score, studies (99–102), on QOL demonstrate high social function in developing countries such as our own with a speculation that close communal relations and a sense of collectivism play pivotal role in contributing to a good social health. In contrast our study reveals that the lowest scored domain was on social functioning and there were no significant factors identified to be associated with this low social function score. Our study findings could possibly be explained by that, most of our patients are of older age with a mean age of 71 years, many are currently not working or have retired, hence may have relatively more free time and still live in communities with a high fair share of social events but these same patients are usually advised to avoid strenuous activities this might be misinterpreted and extend to cause high alertness, self-imposed fear and over protectiveness from relatives causing restrictions to participation in many of the social events leading to a feeling of being left out, thus causing a perceived poor social health however with well elaborated information, knowledge and encouragement on participation of social events among patients with cardiac implantable electronic devices it can help to eliminate these fears from patients and their relatives and improve social health promoting a good QOL (103). A study by Malm D et al (104), and Ghojazadeh M et al (105), on patients experiences in daily living with a pacemaker found uncertainty and absence of clear knowledge among patients themselves, their relatives and co-workers on what tasks pacemaker patients are permissible to perform, led to restriction on social participation and poor QOL.

The highest scored domain on SF-36 in our study was on role emotional which measures difficulties with work or daily activities caused by emotional problems. There were no significant factors identified to be associated with this high score. Some studies (25,73), have also shown persistent increase in role emotional functioning years after implantation. High role emotional score in our study may be due to also high scores on AQUAREL questionnaire indicating the absence of chest discomfort, arrhythmias and dyspnea symptoms among most of our patients. A good role emotional score is correlated to a good physical health. In studies by Barros R et al (25), and Oliveira B et al (63), the domains with the lowest scores were on role emotional as well as physical function and explained that these patient's physical restrictions could possibly have influenced the role emotional domain however in our study the physical function score on SF-36 was 71.4considerably higher than that found in these two studies.

The health transition question on SF 36 compares a patient's health in general compared to one year ago; from this study 33.6 percent of the patient recalled that, their general health was much better than a year ago and most of the patients 53.8% responded that it was somewhat better compared to one year ago henceforth when added up, 86.4% reported that there was a better health transition from the previous year while only 4.1% reported somewhat worse and 1.8% reported much more worse. The patients who had a device less than a year, the question assessed their general health status before the implanted device henceforth, these results reflect that there is a positive effect of the intervention and improvement of health for most patients post implantation. The health transition question is considered to be highly sensitive to changes in QOL (106).

Health related QOL measured on the AQUAREL with the domains of dyspnea, arrhythmia and chest pain were above 80 in all three domains this shows that our patients have a good QOL, similar high scores have been found among pacemaker patients in other studies (25,107). Studies (74,108,109), that evaluated pre and post pacemaker implantation scores found lower scores on AQUAREL pre-implantation and significantly increase in scores post implantation signifying the resolution of patient's symptoms such as dyspnea and arrhythmias.

Factors affecting the quality of life

The average baseline age at time of implantation in this study was 70years of age similar to other studies(88,110,111), done in other parts of the world attributable to increase in conduction abnormalities in impulse generation and conduction flow with advancing age (112). Older patients scored lower in physical health, general health and vitality and in the multivariate regression analysis increase in age had statistical significant negative effect on PF, RP and GH on SF-36 but there was no statistical significant relation between age and QOL scores on AQUAREL possibly, this is due to the broader domains on SF-36 compared to AQUAREL bound to be affected by age, similar findings were found by Bassalobre et al (97), and Cunha et al (113).

The decline in QOL with age can be likely due to effect of non-cardiovascular co-morbid diseases commonly present more in the elderly population however a contradiction arises since, findings in our study also show that as implantation time duration increased so did QOL scores, therefore patients who had the cardiac implantable devices for a longer duration had better QOL compared to patient who had the device for a shorter duration. This contradiction is possibly explained by that the positive effect of having a device for a longer duration is eventually outweighed by age-related decline in function, other studies have shown gradual increase in QOL scores after implantation to about 4 year in the MOST-trial (67), and to a maximum of 7years in a study by Udo E et al (114), and then eventually the scores start to decline.

The responses from our study show that male gender generally had higher QOL scores in almost all domains both on SF-36 and AQUAREL and on the multiple regression model, being female had a statistical significant negative impact on mental health, similar to findings by Uchmanowicz I et al (47),that reported women had lower mental health scores compared to men, when assessment was done in both groups of patients who were awaiting pacemaker implantation and as well as those who already had a pacemaker implanted, similar findings were explained by Nowak et al(64),who also suggested that the prevalence of AV block is observed to occur earlier in life in men compared to females and thus earlier recognition and implantation is done at a younger age possibly explaining better QOL seen in males.

In this study however the baseline mean age of males and females were almost the same hence other factors such as economical, cultural and health seeking behavior could possibly be the reason for this observed difference and would require further studies to explore.

Education levels significantly influenced the domains of physical functioning, bodily pain, vitality and mental health scores where by patients with university or college level education had generally better mean scores than other levels of education except on social health this could have been attributed to the fact that in assessment of QOL, a person's perceptions on their health is linked to low levels of education ,unemployment, low income and difficulties to assess health care thus negatively perception on QOL however in the multiple regression analysis, education was not found to be statistically significant. Understanding of a disease process, ways of avoidance of complications and how to live with a cardiac device might be more influential to improve QOL despite the patient's education background therefore a study on knowledge among these patients would be crucial at this point (115,116). A study on health literacy on QOL in pacemaker patient found that when health education was given in inform of video projections and easy illustrations helped patients to be well informed and they could confidently get back to their jobs thus improving their financial, psychological health and QOL (98).

Employment status had no significant difference on the QOL on SF-36 and AQUAREL similar findings were found by Lopez F (46), while patients who were widowed/divorced when compared to the married were found to have poor mental health this might be attributed to absence of spousal support similar results were demonstrated by Kurocova R (66), and Gerlichova K (117).

There was no statistical significant difference between patients with history of alcohol use. No statistical significant difference was also observed with smoking on the QOL probably due to small numbers of smokers in our study our findings were similar to those by Cardoso N et al (118), however in a systematic review (119), smoking was characterized with low QOL and increase in number of pacemaker insertion among smokers due to established cardiovascular risk associated with smoking.

The common indication for cardiac implantable electronic devices among patients in our setting was atrioventricular block commonly complete heart block, this is the same to other studies (120). Results from our study also indicate that, there was no statistical significant difference in the QOL scores associated with different indications for pacing however, in a study by Benzer L (75), patients with sinus syndrome and atrial fibrillation scored higher QOL scores compared to patient with heart block similar findings were also observed by Lamas G et al (67), with high scores in QOL in patients with sinus node dysfunction with DDD pacing compared to heart block patients with DDD pacing.

This study found no relationship between the different modes of pacing on the QOL of patients both on the SF-36 and AQUAREL contrary to a study by Paul S et al (121), found that patients with DDD mode had better scores in the arrhythmia and dyspnea compared to VVIR mode which was attributed to pacemaker syndrome associated with ventricular pacing where a patient feels symptoms of palpitations, presyncope, pounding feelings, chest pain, and dyspnea with exertion contributing to a lower QOL however in study done by Kerr C et al (122), and CTOPP a large trial done in Canada (122), showed no significant difference in QOL between the physiological pacing of DDD and VVIR and concluded that previous studies that showed difference had smaller number of participants and that while pacemaker syndrome in patients with VVIR does exist, its incidence is rare and its effects are modest compared to previously assumptions these findings are in agreement to a meta-analysis (123), in which concluded that physiological pacing DDD had no statistical significant difference from VVIR and did not improve survival, reduce heart failure or cardiovascular death. The most common pacing mode at JKCI is DDD but the findings in our study are supportive to the CTOPP (122), and MOST trials (114), supporting VVIR is as good as DDD in our patients with a known added advantage of easier implantation in VVIR.

Presence of heart failure had no statistical significant difference on the QOL in our study however from other studies (73,124), presence of heart failure was an important associated factor to a poor QOL however our patients with heart failure possibly, have good adherence to anti-failure medications and factors that can cause acute decompensated heart failure **are addressed in most patients during clinic visits but further studies is needed.**

Our study found that BMI had no effect on the QOL scores among patient on the SF-36 and AQUAREL however two studies (77,78), found that obesity had a negative effect on the QOL scores while Kirkfeldte R (74,86), found underweight patients had poor QOL score due to increased complication however, due to edema a number of patients were not included in our analysis and due to lack of other form of nutritional status assessment data such as skin fold thickness at baseline from patients files.

The presence of complications post cardiac device insertion was associated with lower mental health scores and vitality however on the multiple regression analysis the effect of complications on quality of life scores was found to be statistically not significant.

Mortality

The mean duration was 17 months (1.4years) for the alive patients in our study. In terms of mortality, we confirmed death verbally and through files in 20 patients (8%) while 172 patients (69%) were alive after 5 years, this number is higher than the reported survival of 32% found by Brunner M et al (88), and 58.3% reported by Shlomo A et al (125), both after 5 years. However due to failure to establish the status of the other 22.9% of the patients because of missing files, phone contacts in the files or being unreachable for various reasons including wrong phone number or number being out of commission the mortality could be higher.

5.1 Strength of the study and limitations

To the best of our knowledge this is the first study to be done in Tanzania and thus can later be used as a reference for other studies. The assessment for the QOL was done in patients from the very first patients who had a device implanted at JKCI 5 years to 3 months before the study period therefore, this provides a wide comprehensive overview of the QOL over the years backed up by SF-36 questionnaire which is observed to be a stable tool for assessing QOL within short to over long periods of time.

The limitation of this study is the lack of pre-implantation assessment of QOL that could be used for comparison reasons with the QOL after pacemaker implantation. Assessment using the questionnaires introduced a recall bias as some patients had to remember their health condition over a year ago.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

Patients with cardiac implantable electronic device have overall good QOL with the highest score in role emotional followed by physical functioning. Social functioning is of the greatest challenge in these patients. As number of years increases post implant, the better the QOL however with old age the QOL starts to decline. Female patients and widows have poor mental health compared to males and married individuals respectively. In terms of diseases specific effects with reference of chest discomfort, dyspnea and arrhythmia most patients have very high scores indicating to be free of symptoms.

6.2 Recommendations

Physicians can recommend this therapy confidently to our patients who need it, however we suggest that clinical practitioner should provide encouragement on participation of social events that can help to eliminate fears from patients and their relatives and improve social function promoting a good QOL.

Special attention, counseling and involvement of other departments such as psychological counseling should be considered to patients who have had a recent cardiac device implantation, old patient ≥ 60 years, females and widowers to help them cope and improve their QOL.

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8.0 APPENDICES

8.1 ANNEX I: INFORMED CONSENT FORM- ENGLISH VERSION

Consent to participate in a study on, assessment of quality of life among patients with cardiac electronic implanted devices implanted at JKCI, between 2013 and 2019.

Dear Sir/Madam

My name is DR JOVINA L NKYA a resident doctor in the department of internal medicine at Muhimbili University of health and allied sciences (MUHAS), I am conducting a research study on the quality of life of patients with cardiac implantable devices implanted at JKCI between 2013 and 2019.

I hereby request your participation.

Purpose of the study:

The aim of this study is to assess the quality of life of patients with cardiac implantable devices implanted at JKCI from October 2019 to January2020.

How to participate:

Patients, who are willing to participate in this study, will have to sign a consent form.

Short interview will be done and other information will be obtained from files at JKCI.

Confidentiality:

Information obtained from you will be kept confidential and shall be very helpful in this study as well as in promoting better health of patients with cardiac implantable electronic devices.

Cost:

You will not be required to pay any amount for your participation in this study

Voluntary participation and the right to withdraw from the study:

Your participation is voluntary and you have the right to withdraw from participating in this study at any time. Whatever your decision may be, it will have no effect in any way to your rights to care and treatment.

Risks:

There are no risks involved.

Benefits:

Your participation in this study will help you know about the quality of life of patients with cardiac devices and enable health providers to improve treatment.

I hope that the information from this research will be useful in contributing to improve the quality of your care at JKCI

Contact person

If you have any inquiries about this study, please do not hesitate to contact:

Dr JOVINA NKYA
Principal investigator
Muhimbili University of health and Allied Sciences (MUHAS)
Department of Internal medicine
P.O.BOX 65001 Dar-es-salaam
TEL: 0714 258313
OR
DR REUBEN MUTTA
Supervisor of this research
Muhimbili University of Health and Allied Sciences (MUHAS)
Department of Internal medicine
P.O BOX 65001 Dar-es-salaam
Tel.0717 921555
OR
Dr PETER KISENGE
CO-supervisor of this research
Jakaya Mrisho Kikwete Hospital
P.O BOX 65001 Dar-es-salaam
Tel.0713 236502

OR

In case of any information about your rights as a participant in this study please contact

The chairperson of Research and Ethical Committee
Muhimbili university of Health and Allied Sciences (MUHAS)
P.O BOX 65001 Dar-es-salaam
Tel.022-2152489

I will be grateful if you willingly agree to participate in this study.

I have understood the above information and my questions have been answered by the investigator to my satisfaction. I willingly agree to take part in this research.

Name of the participant

Signature of the participant ……... Date …….

Signature of investigator …… Date …….

8.2 ANNEX II: INFORMED CONSENT: SWAHILI VERSION

FOMU YA RIDHAA

Ridhaa ya kushiriki katika utafiti wa kuchunguza ubora wa maisha ya wagonjwa wenye vifaa vya moyo vya umeme vilivyowekwa katika hospitali ya JKCI kuanzia 2013 hadi 2019

Kwa bwana/bibi……..

Tafadhali jina langu ni **DR JOVINA L NKYA**, mwananfunzi wa udaktari bingwa kutoka idara ya magonjwa ya ndani ya chuo kikuu cha afya na sayansi shirikishi cha Muhimbili.Ninafanya utafiti wa kuchunguza ubora wa maisha wa wagonjwa wenye vifaa vya moyo vya umeme vilivyowekwa katika hospitali ya JKCI kuanzia 2013 hadi 2019.

Namna ya kushiriki:

Kwa wagonjwa watakaoridhia kushiriki katika utafiti huu watajaza na kusaini fomu ya ridhaa na pia habari zingine zitatumika kutoka kwenye mafaili yao yaliyopo hospitali ya JKCI.

USIRI

Taarifa zote zitakazopatikana kutoka kwako zitatunzwa kwa usiri wa hali ya juu na zitatumika kwa ajili ya utafiti huu na pia kuboresha hali ya kutoa huduma kwa wagonjwa

GHARAMA:

Kutakua hakuna gharama yoyote katika kushiriki kwenye utafiti huu.

Hiyari ya kushiriki na kujitoa

Ushiriki katika utafiti huu ni wa hiyari na pia ni haki yako kujitoa katika utafiti huu muda wowote unapohisi kufanya hivyo. Maamuzi yako ya kuamua kutoshiriki au kujitoa katika utafiti huu hayataathiri haki yako ya kupata huduma na matibabu.

Madhara ya kushiriki utafiti:

Hakuna madhara yeyote yatakayompata mshiriki wa utafiti huu.

Manufaa ya kushiriki utafiti:

Ushiriki wako katika utafiti huu utakuwa na faida kwako kwa kuweza kujua kuhusu ubora

wa maisha kwa wagonjwa wa vifaa vya umeme wa moyo

Pia, matokeo ya utafiti huu yatasaidia kushauri katika matibabu sahihi kwa wagonjwa wenye vifaa vya moyo vya umeme. Nitashukuru sana kama kwa hiyari yako utaamua kushiriki katika utafiti huu.

Kauli ya Mtafiti:

Mimi mtafiti,nakiri nimemuelewesha mshiriki wa utafiti huu kuhusu huu utafiti.

Sahihi……..

Tarehe…….

Mawasiliano kwa wahusika:

Kwa maswali au maoni kuhusian na utafiti huu tafadhali wasiliana na wafuatao:

Dr JOVINA NKYA

Mtafiti mkuu

Chuo kikuu cha afya na tiba shirikishi Muhimbili

Idara ya magonjwa ya ndani

S.L.P 65001 Dar-es-salaam

Nambari ya simu: 0714 258313

AU

DR REUBEN MUTTA

Msimamizi wa utafiti huu

Chuo kikuu cha afya na tiba shirikishi Muhimbili

Idara ya magonjwa ya ndani

S.L.P 65001 Dar-es-salaam

Nambari ya simu: 0717 921555

AU

Dr PETER KISENGE

Msimamizi mwenza wa utafiti huu

Hospital ya JKCI

S.L.P 65001 Dar-es-salaam

Tel.0713 236502

AU

Kwa mawasiliano zaidi kuhusiana na haki zako kwenye utafiti huu kama mshiriki, tafadhali wasiliana na:

Mwenyekiti wa tume ya tafiti na uchapishaji wa tafiti

Chuo kikuu cha afya na tiba shirikishi Muhimbila

S.L.P 65001 Dar-es-salaam

Nambari ya simu.022-2152489

Kauli ya Mshiriki

Natoa idhini mwenyewe bila aina yeyote ya kushurutiwa au kulazimishwa kushiriki katika utafiti uliotajwa hapa kuhusu utafiit wa ubora wa maisha baina ya wagonjwa wenye vifaa vya moyo vya umeme katika hospitali ya JKCI. Nafanya hivi baada ya kuelewa taarifa zote nilizoelezwa na Dr Jovina Nkya na pia amenijibu na kunielewesha zaidi maswali niliyomuuliza.

Nimeelewa kikamilifu kuhusu madhumuni ya hali yake na naelewa kuwa nitaulizwa maswali. Pia naelewa kujiondoa wakati wowote iwapo nitabadilisha mawazo.

Sahihi ya mshiriki …….

Saini ya mshiriki ……

Tarehe ……

8.3 ANNEX III: HEALTH QUESTIONNAIRE ENGLISH VERSION

ON, QUALITY OF LIFE OF PATIENTS WITH CARDIAC ELECTRONIC IMPLANTED DEVICE IMPLANTATED AT JKCI.

The aim of this study is to assess the quality of life of patients with cardiac electronic implanted devices implanted at JKCI from 2013 to 2019.

I look forward to your participation to answer the questions. The information that you will provide will be kept confidential.

The database from the results may be used to improve treatment. If you are willing to participate in this study please answer the questions that follow

Instructions:

1. Please answer ALL questions that apply to you.

PATIENT PARTICULARS

STUDY NUMBER	
HOSPITAL NUMBER	
INITIALS	
AGE	
SEX	
PHONE NUMBER patient	
PHONE NUMBER next of kin	
Date of admission for procedure	

Socio-demographic characteristics	
Marital status (1.Single, 2.married 3.divorced/widowed)	
Residence	1.Rural 2.urban
Occupation (1,employed 2. self-employed 3. not formally employed 4. unemployed)	
Level of formal education (1.none, 2.primary, 3.secondary, 4.university or college	
Baseline clinical and laboratory characteristics(at admission for insertion of the device)	
Pedal edema	
Ascites	
Heart failure	1. Yes 2. no
Weight	
Height	
BMI	
Pacemaker insertion procedure	
Year of implantation other implants	
Pacemaker status	1. New

	2. Re-use	
Pacemaker mode	**VVIR**	
	AAIR	
	VVD	
	DDD	
	Biventricular	
	ICD	
	CRT	

Complications	**Yes**		**No**
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	
	JKCI	
	Other hospital(public)	
	Other hospital (private)	

SF 36 QUESTIONNAIRE

SF-36 Survey

Date: / /2014 Patient's Name

Visit: □ Pre-op ☐ 6 week □ 3 month □ 6 month □ 1 year

INSTRUCTIONS: Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by circling the number that best represents your response.

1. In general, would you say your health is?

Excellent (1)	Very Good (2)	Good (3)	Fair (4)	Poor (5)

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago (1)	Somewhat better now than one year ago (2)	About the same as one year ago (3)	Somewhat worse now than one year ago (4)	Much worse now than one year ago (5)

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much: (circle one number on each line)

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
A. **Vigorous activities**, such as running, lifting heavy objects participating in strenuous sports	1	2	3
B. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
C. Lifting or carrying groceries	1	2	3
D. Climbing **several** flights of stairs	1	2	3
E. Climbing **one** flight of stairs	1	2	3
F. Bending, kneeling, or stooping	1	2	3
G. Walking **more than a mile**	1	2	3
H. Walking **several hundred yards**	1	2	3
I. Walking **one hundred yards**	1	2	3
J. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?(Circle one number on each line)

	All the time	**Most** of the time	**Some** of the time	A **little** of the time	**None** of the time
A. Cut down on the **amount of time** you spend on work or other activities	1	2	3	4	5
B. **Accomplished less** than you would like	1	2	3	4	5
C. Were limited in the **kind** of work or other activities	1	2	3	4	5
D. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number on each line)

	All the time	**Most** of the time	**Some** of the time	**A little** of the time	**None** of the time
A. Cut down on the **amount of time** you spend on work or other activities	1	2	3	4	5
B. **Accomplished less** than you would like	1	2	3	4	5
C. Did work or activities **less carefully than usual**	1	2	3	4	5

6. During the <u>past 4 weeks</u>, to what extent has your <u>physical health or emotional problems</u> interfered with your social activities with family, friends, neighbours, or groups? (Circle one)

Not at all (1)	Slightly (2)	Moderately (3)	Quite a bit (4)	Extremely (5)

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>? (Circle one)

None (1)	Very Mild (2)	Mild (3)	Moderate (4)	Severe (5)	Very Severe (6)

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)? (Circle one)

Not at all (1)	Slightly (2)	Moderately (3)	Quite a bit (4)	Extremely (5)

9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>… (Circle one number on each line)

	All the time	**Most** of the time	**Some** of the time	**A little** of the time	**None** of the time
A. did you feel full of life?	1	2	3	4	5
B. have you been very nervous?	1	2	3	4	5
C. have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5
D. have you felt calm and peaceful?	1	2	3	4	5
E. did you have a lot of energy?	1	2	3	4	5

F. have you felt downhearted and depressed?	1	2	3	4	5
G. did you feel worn out?	1	2	3	4	5
H. have you been happy?	1	2	3	4	5
I. did you feel tired?	1	2	3	4	5

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
(1)	(2)	(3)	(4)	(5)

11. How TRUE or FALSE is each of the following statements for you? (Circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
A. I seem to get sick a little easier than other people	1	2	3	4	5
B. I am as healthy as anybody I know	1	2	3	4	5
C. I expect my health to get worse	1	2	3	4	5
D. My health is excellent	1	2	3	4	5

AQUAREL QUESTIONNAIRE
Appendix; version of Aquarel

1. Have you felt discomfort in the chest?
    1. No discomfort at all
    2. Very mild discomfort
    3. Mild discomfort
    4. Moderate discomfort
    5. Great discomfort

2. Do you get chest discomfort while walking upstairs or uphill?
    1. No discomfort
    2. Very mild discomfort
    3. Mild discomfort
    4. Moderate discomfort
    5. Severe discomfort

3. Do you get chest discomfort while walking quickly on level ground?
    1. No discomfort
    2. Very mild discomfort
    3. Mild discomfort
    4. Moderate discomfort
    5. Severe discomfort

4. Do you get chest discomfort while walking on level ground at the same pace as people usually do at your age?
    1. No discomfort
    2. Very mild discomfort
    3. Mild discomfort
    4. Moderate discomfort
    5. Severe discomfort

5. Have you been restricted by chest discomfort during physical exercise
    1. Not restricted at all
    2. Slightly restricted
    3. Moderately restricted

4. Very restricted
5. Extremely restricted

6. Have you experienced chest discomfort at rest?
    1. No discomfort
    2. Very mild discomfort
    3. Mild discomfort
    4. Moderate discomfort
    5. Severe discomfort

7. Do you get short of breath while walking upstairs or uphill
    1. No short of breath
    2. Very mild short of breath
    3. Mild short of breath
    4. Moderate short of breath
    5. Extreme short of breath

8. Do you get short of breath while walking quickly on level ground
    1. Not short of breath
    2. Very mild short of breath
    3. Mild short of breath
    4. Moderate short of breath
    5. Extreme short of breath

9. Do you get short of breath while walking on level ground at the same pace as people usually do at your age?
    1. Not short of breath
    2. Very mild short of breath
    3. Mild short of breath
    4. Moderate short of breath
    5. Extreme short of breath

10. Have you been restricted by breathlessness during physical exercise
    1. Not restricted at all
    2. Slightly restricted

3. Moderately restricted
4. Very restricted
5. Extremely restricted

11. Have you been out of breath at rest?
    1. Not out of breath
    2. Slightly out of breath
    3. Moderately out of breath
    4. Very out of breath
    5. Extremely out of breath
12. Do you awake when sleeping due to shortness of breath?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
13. Did you have swollen ankles?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
14. Have you suffered from irregular heartbeat?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
15. Have you suffered from heart pounding?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously

16. Have you suffered from pounding in the neck or abdomen?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
17. Have you felt close to fainting?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
18. Have you had trouble falling asleep?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
19. Do you feel tired and exhausted after night's sleep?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
20. Have you been restricted in your daily activities due to tiredness or lack of energy ?
    1. Never
    2. Seldom
    3. Once in awhile
    4. Often
    5. Continuously
    6.

----------END----------

Thank you for your co-operation

8.4ANNEX IV: HEALTH QUESTIONNAIRE SWAHILI VERSION

MAELEKEZO YA KUJIBU

Maswali juu ya ubora wa maisha ya wagonjwa wenye kifaa cha umeme JKCI.

Lengo la utafiti huu ni kuchunguza ubora wa maisha ya wagonjwa wenye vifaa vya moyo vya umeme vilivyowekwa katika hospital JKCI kuanzia 2013 hadi 2019

Ninatarajia ushirikiano wako katika kujibu maswali. Taarifa ambayo utatoa itahifadhiwa kwa siri.

Na matokeo, yataweza kutumika kuboresha matibabu. Ikiwa una nia ya kushiriki katika somo hili tafadhali jibu maswali yanayofuata

Maelekezo:

1. Tafadhali jibu maswali YOTE utakayoulizwa.

SWAHILI VERSION QUESTIONNAIRE

36-ITEM SHORT-FORM HEALTH SURVEY (SF-36)

Jibu kila swali.

B1	Kwa ujumla, unaweza kusema kuwa afya yako ni:	Nzuri kupita kiasi……...…… 1 Nzuri sana……...…2 Nzuri……...……3 Ya wastani…….…….4 Mbaya…….5	[ ]
B2	Afya yako ikoje <u>sasa ukilinganisha na mwaka mmoja uliopita?</u>	Nzuri zaidi kuliko mwaka mmoja uliopita.....….1 Kiasi ni nzuri kuliko mwaka mmoja uliopita……...….2 Sawa na ya mwaka mmoja uliopita……3 Kiasi ni mbaya kuliko mwaka mmoja uliopita…….……...4 Mbaya zaidi kuliko mwaka mmoja uliopita……...…….5	[ ]

B3.Shughuli zilizoorodheshwa hapa chini ni shughuli ambazo mtu anaweza kuzifanya kila siku. Je, afya <u>yako hivi sasa inakuzuia</u> kufanya shughuli hizi? Kama ndivyo, kwa kiasi gani?

SHUGHULI	Inazuia sana	Inazuia kiasi	Haizuii kabisa
a. **Kazi za nguvu** kama kulima, kubeba kuni kichwani, kucheza ngoma	1	2	3
b. **Kazi za kawaida** kama kuchota maji, kufagia, kufua nguo, kubeba mtoto	1	2	3
c. Kuinua au kubeba mfuko au kikapu chenye mahindi, unga au viazi kiasi cha debe moja	1	2	3
d. Kupanda **mlima mkali**	1	2	3
e. Kupanda **mlima mfupi**	1	2	3
f. Kuinama, kupiga magoti au kukuchuchumaa	1	2	3
g. Kutembea mwendo mrefu ambao ni **zaidi ya nusu** saa bila kupumzika	1	2	3
h. Kutembea mwendo mfupi ambao ni **chini ya nusu saa** bila ya kupunzika	1	2	3
i. Kutembea **kutoka goli hadi goli la kiwanja cha mpira** wa miguu bila kupumzika	1	2	3
j. Kuoga au kuvaa nguo mwenyewe	1	2	3

B4.Je afya yako katika kipindi cha mwezi mmoja uliopita imekufanya ushindwe kufanya kazi au shughuli zako za kawaida kiasi kwamba ilibidi: (Zungushia namba moja katika kila mstari)	**NDIYO**	**HAPANA**
a. Nipunguze **muda** wa kufanya kazi au shughuli zangu	1	2
b. **Nitekeleze mambo machache** kuliko nilivyotarajia	1	2
c. Nishindwe kufanya baadhi ya kazi au shughuli	1	2
d. Niwe na **matatizo** katika kutekeleza kazi au shughuli zangu (Kwa mfano, nilijilazimisha kufanya kazi)	1	2

B5.Je katika kipindi cha mwezi mmoja uliopita umekuwa na fikra au mawazo mengi yaliyokufannya hata ushindwe kufanya kazi au shughuli zako za kawaida kama ifuatavyo?

	NDIYO	**HAPANA**
a. Nipunguze **muda** wa kufanya kazi au shughuli zangu	1	2
b. **Nimetelekeza mambo machache** kuliko nilivyotarajia	1	2
c. Sikufanya kazi au shughuli zangu **kwa uangalifu** kama ilivyo kawaida	1	2

Jibu

B6.	Katika <u>kipindi cha mwezi mmoja</u> uliopita, ni kiasi gani matatizo ya kiafya au mawazo yameathiri shughuli zako za ki-familia, shughuli na marafiki, majirani au makundi ya watu unaoshirikiana nao?	Hayakuathiri kabisa…….1 Yameathiri kidigo……2 Yameathiri kwa wastani……..3 Yameathiri kwa kiasi kikubwa…4 Yameathiri kwa kiasi kikubwa sana……..…5	[ ]
B7	Umeshakuwa na <u>maumivu ya mwili</u> kiasi gani katika kipindi cha <u>mwezi mmoja uliopita?</u>	Hakuna maumivu…….1 Maumivu kidogo…….….2 Maumivu makali kidogo…….….3 Maumivu makali…….…….4 Maumivu makali sana…….…….5	[ ]
B8	Katika mwezi mmoja uliopita, maumivu yalikuzuia kwa kiasi gani kufanya kazi zako za kila siku (ndani na njae ya nyumbani kwako)?	Hayakunizia kabisa……..1 Yalinizuia kiasi kidoga……...…2 Yalinizuia kwa wastani……...…3 Yalinizuia kwa kiasi kikubwa…..4 Yalinizuia kwa kiasi kikubwa sana…….….5	[ ]

B9.Maswali yafuatayo yanahusu jinsi unavyojisikia kiafya, vile vile jinsi gani shughuli zako zilivyofanikiwa kwakipindi cha mwezimmoja uliopita. Kwa kila swali, tafadhali toa jibu lililo karibu na jinsi ulivyokuwa unajisikia. Je ni muda kiasi gani kwa kipindi cha mwezi mmoja uliopita umekuwa ukijisikia au kuwa na yafuatayo

	Muda wote	**Muda mwingi**	**Muda wa Kutosha kidogo**	**Baadhi ya muda**	**Muda mchache**	**Hakuna Muda Wowote**
a. Je ulijisikia una nguvu zote?	1	2	3	4	5	6
b. Je umekuwa ni mtu mwenye wasiwasi?	1	2	3	4	5	6
c. Je ulikuwa huna raha kiasi cha kutofurahishwa na kitu chochote?	1	2	3	4	5	6
d. Ulijisikia mtulivu na mwenye amani?	1	2	3	4	5	6
e. Je ulikuwa na nguvu nyingi?	1	2	3	4	5	6
f. Ulijisikia kusononeka?	1	2	3	4	5	6
g. Je ulijisikia kuwa na uchovu?	1	2	3	4	5	6
h. Je ulijisikia ni mtu mwenye furaha?	1	2	3	4	5	6
i.Je ulijisikia kuchoka?	1	2	3	4	5	6

Jibu

B10.	Katika mwezi mmoja uliopita, ni kwa muda gani matatizo ya Kiafya au kimawazo yameingilia shughuli zako za kijamii (kama kutembeleana na marafiki, ndugu na jamaa n.k)?	Muda wote……1 Muda mwingi……....2 Muda Fulani…….…….3 Mudakidogo……..……4 Haya kuwahi kuniingilia muda wowote…….5	[ ]

B11.Kati ya maelezo yafuatayo, niyapi yaliyo ya ukweli au yasiyo ya ukweli kwako?

	Ni kweli hasa	Ni kweli Kwa kiasi kikubwa	Sijui	Si kweli kwa Kiasi kikubwa	Si kweli i kabisa
a. Ninaonekana kuugua kirahisi zaidi kuliko watu wengine?	1	2	3	4	5
b. Nina afya ya kutosha kama mtu yeyote yule ninayemjua?	1	2	3	4	5
c. Ninategemea afya yangu kuwa mbaya	1	2	3	4	5
d. Afya yangu ni nzuri kupita kiasi	1	2	3	4	5

Asante kwa kujibu maswali haya.

DODOSO YA AQUAREL

1. Je, umehisi maumivu yoyote katika kifua??
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno
2. Je, huwa unapata maumivu ya kifua wakati wa kupanda ngazi au mlima?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno
3. Je, Huwa unapata maumivu ya kifua ukitembea haraka kwenye ardhi ya tambarare?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno
4. Je, Huwa unapata maumivu ya kifua ukitembea kwenye ardhi ya chini kwa mwendo wa sawa na watu wenye rika kamalako?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno
5. Je, maumivu ya kifua yamekua kikwazo kwako wakati wa mazoezi ya mwili?
    1. Siyo kikwazo
    2. Ni kikwazo kwa kiasi kidogo
    3. Ni kikwazo kwa kiasi cha wastani
    4. Ni kikwazo kwa kiasi kikubwa
    5. Ni kikwazo kwa kiasi kikubwa mno

6. Je, umewahi unapata maumivu ya kifua wakati wa mapumziko?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno

7. Je, Huwa unapata shida ya pumzi wakati unapanda ngazi au kupanda mlima?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno

8. Je, huwa unapata shida ya pumzi wakati unatembea kwa haraka kwenye ardhi ya tambarare?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno

9. Je, Huwa unapata shida ya pumzi ukitembea kwenye ardhi ya chini kwa mwendo wa sawa na watu wenye umri wako?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno

10. Je, shida ya pumzi imekua kikwazo kwako wakati wa mazoezi ya mwili?
    1. Hakuna kabisa
    2. Ni kikwazo kwa kiasi kidogo
    3. Ni kikwazo kwa kiasi cha wastani
    4. Ni kikwazo kwa kiasi kikubwa
    5. Ni kikwazo kwa kiasi kikubwa mno

11. Je, umewahi pata shida ya pumzi wakati wa mapumziko?
    1. Hakuna kabisa
    2. Kwa kiasi kidogo
    3. Kwa kiasi cha wastani
    4. Kwa kiasi kikubwa
    5. Kwa kiasi kikubwa mno
12. Je, huwa unaamka wakati umelala kwa sababu ya shida ya kupungukiwa na pumzi?
    1. Kamwe haijatokea
    2. mara nadra sana
    3. mara moja moja
    4. mara kwa mara
    5. mara mfululizo
13. Je, una tatizo la miguu kuvimba??
    1. Kamwe haijatokea
    2. mara nadra sana
    3. mara moja moja
    4. mara kwa mara
    5. mara mfululizo
14. Je, unasumbuliwa na tatizo la mapigo ya moyo kupiga bila mpangilio?
    1. Kamwe haijatokea
    2. mara nadra sana
    3. mara moja moja
    4. mara kwa mara
    5. mara mfululizo
15. Je, Unasumbuliwa na tatizo la mapigo ya moyo kupiga kwa nguvu?
    1. Kamwe haijatokea
    2. mara nadra sana
    3. mara moja moja
    4. mara kwa mara
    5. mara mfululizo

16. Je, Unasumbuliwa na tatizo la kusikia mapigo kupiga kwa nguvu kwenye shingo au tumbo?

1. Kamwe haijatokea
2. mara nadra sana
3. mara moja moja
4. mara kwa mara
5. mara mfululizo

17. Je, umejisikia hali ya kupoteza fahamu?

1. Kamwe haijatokea
2. mara nadra sana
3. mara moja moja
4. mara kwa mara
5. mara mfululizo

18. Je, umekuwa na tatizo la kupata usingizi?

1. Kamwe haijatokea
2. mara nadra sana
3. mara moja moja
4. mara kwa mara

□ mara mfululizo

19. Je, huwa unahisi mwili kuchoka baada ya kuamka asubuhi?

□ Kamwe haijatokea

□ mara nadra sana

□ mara moja moja

□ mara kwa mara

□ mara mfululizo

20. Je, umekuwa ukipata shida katika shughuli zako za kila siku kutokana na uchovu au ukosefu wa nguvu mwilini?

1. Kamwe haijatokea
2. mara nadra sana
3. mara moja moja
4. mara kwa mara
5. mara mfululizo

----------MWISHO----------