UNIVERSITY OF RWANDA

College of Medicine and Health Sciences

CLINICAL OUTCOMES OF RWANDAN CHILDREN OPERATED FOR RHEUMATIC HEART DISEASE FOLLOWED UP AT TERTIARY LEVEL

A Dissertation submitted in partial fulfillment of the requirements for the Degree of Master of Medicine in General Pediatrics and Child health: University of Rwanda

Principal Investigator: Dr**.** Naphtal Nyirimanzi

Supervisor: Dr. Emmanuel Rusingiza

Co-supervisors: Dr. JaBaris Swain

Professor Dr. Joseph Mucumbitsi

Kigali-Rwanda

June 2015

DECLARATION AND COPYRIGHT

This declaration is made onJune 1st, 2015.

I, **Naphtal Nyirimanzi**, Resident in Pediatrics at University of Rwanda, declare that this dissertation entitled "Clinical outcomes of Rwandan children operated for rheumatic heart disease followed-up at tertiary level" is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

_____ _____

01/6/2015 Dr. NYIRIMANZI Naphtal RMC: 1469

DEDICATION

To Almighty my God

To my dear parents

To all my family

To all my teachers

To all my friends and colleagues,

This work is dedicated.

ACKNOWLEDGEMENT

I would like to cordially address my thanks to God for His love.

I sincerely thank the Government of Republic of Rwanda which through University of Rwanda emphasizes on training of health professionals competent in both clinical and research practice.

Our respectful acknowledgement is addressed to all academic and administrative authorities of University of Rwanda (UR), College of Medicine and Health Sciences, Faculty of Medicine for high quality of education and training.

I wish to express my sincere gratitude to my supervisors, Dr. Emmanuel K.Rusingiza, Prof. Joseph Mucumbitsi and Dr. Swain JaBaris for their patience, guidance, encouragement and support in shaping the outlook of this dissertation. They provided invaluable insights that have guided my thinking and understanding.

My special appreciation goes to my parents Etienne Boyi and Rahab Nyiratebuka, who, all the lifelong, are devoted to prepare for us a victorious future. My appreciation also goes to my brothers, sisters and in-laws for their support.

I would like to acknowledge the efforts, support, guidance; cooperation and encouragement of all the members of staff of the Department of Pediatrics at University of Rwanda, College of Medicine and Health Sciences. Likewise I acknowledge the support and guidance of the staff of Department of Pediatrics of University Teaching Hospital of Kigali and Butare, King Faisal Hospital and Rwanda Military Hospital, clinical services.

"May each one of you find through this work, the fruit of the unforgettable rendered service".

ABBREVIATIONS

%: percent

ARF: Acute Rheumatic Fever

ASD: Atrial Septal Defect

BUTH: Butare University Teaching Hospital

CBHI: Community Based Health Insurance

CDC: Center for Disease Control and Prevention

CHD: Congenital Heart Disease

CHUB: Centre Hospitalier Universitaire de Butare

CHUK: Centre Hospitalier Universitaire de Kigali

EF: Ejection Fraction

FRW: Rwandan Francs

IM: Intramuscular

INR: International Normalized Ratio

IRB: Institutional Review Board

KFH: King Faisal Hospital

LVDd: Left Ventricular Dimension in diastole

LVDs: Left Ventricular Dimension in systole

MMI: Military Medical Insurance

MoH: Ministry of Health

PDA: Patent Ductus Arteriosus

PIH: Partners in Health

RHD: Rheumatic Heart Disease

RSSB: Rwanda Social Security Board,

SD: standard deviation

SPSS: Statistical Package for Social Science

ToF: Tetralogy of Fallot

UR: University of Rwanda

USA: United States of America

USD: American United States Dollars

UTH: University Teaching Hospital

UTHK: University teaching Hospital of Kigali

VSD: Ventricular Septal Defect

ABSTRACT

Subject of the study: Clinical outcomes of Rwandan children who have undergone open heart surgery for rheumatic heart disease at the tertiary level of care.

Background: The exact outcomes and follow-up aspects of children who have undergone open heart surgery for rheumatic heart disease living in developing countries are generally not known.

Objective: To determine the outcomes and follow-up aspects of Rwandan children who have undergone open heart surgery for rheumatic heart disease and highlight challenges to care in order to improve the overall domestic management of pediatric rheumatic heart valve disease surgery pediatric patients in Rwanda.

Study type:cross-sectionalanalytical study.

Methods: A cross-sectional analytical study was conducted in the department of Pediatrics of University Teaching Hospitals: Kigali and Butare, Rwanda Military Hospital as well as King Faisal Hospital, Kigali. This study included all children, 18 years old or less at the time of surgery for rheumatic heart diseases during the study period,from January 2006 to March 2015. Data was collected from files and records of patients, from clinical and para-clinical examinations as well as interview. The information was filled in spreadsheet format. The data entry and analysis wasperformed using EpiData 3.1 and SPSS 20.0 for windows; recording and presentation of results was done using Microsoft Excel and Microsoft Word.

Results: Sixty-nine patients were included in our study, now aged between 8 and 24 years, the mean was 15.5 years ±3.4 SD. Female patients were 56.5%. Majority of them were symptomatic before surgery (NYHA IV: 88.4%, NYHA III: 7.2%), Mitral valve regurgitation was predominant: 92.6%, aortic valve regurgitation: 20.5%. Tricuspid valve regurgitation was 29.4%. Mitral stenosis was present in 14.7%. The main surgical procedure done was mechanical valve replacement: mitral in 46 patients (66.7%), aortic in 8 patients (11.6%) tricuspid in 4 patients (5.8%). After surgery, most of children presented clinical improvement (NYHA I: 59.4% and NYHA II: 27.5%). Regularity of follow-up was 76.8%. The mean INR was2.53±1.25 SD. Secondary prophylaxis of ARF is mainly withBenzathin Penicillin G monthly injections (69.6%). Sixchildren (8.69%) died of different conditions, mainly due to heart failure for 3

patients (4.35%) and infective endocarditis in 2 patients (2.89%). Quality of life was reported to be generally good after surgery.

Conclusion: Even though cardiac surgery in children suffering from severe heart valve rheumatic lesions is still challenging in third world, rheumatic heart disease surgery in children is associated with good outcomes. The causes of death are preventable in most of the cases.

Key words: Heart surgery, rheumatic heart diseases, outcomes, complications, children

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

TABLE OF CONTENTS

CHAPTER I. INTRODUCTION

1.1 BACKGROUND

Children in low and middle income countries continue to experience higher rates of non-communicable diseases, including cardiovascular diseases. Lower levels of access to health care, higher hospital admission rates and poor quality of health conditions and settings contribute to the increased morbidity and mortality at younger age.(Lawrence J, 2012)

Among the cardiovascular diseases, there are congenital anomalies (cyanotic and non-cyanotic) and acquired heart diseases. Nowadays, there is an increasing number of acquired heart diseases in children from developing countries, rheumatic heart disease being the predominant.(Yusuf, 2001)

The global incidence of acute rheumatic fever in children aged 5–14 years is roughly 300 000–350 000 per year, although incidence varies substantially by region. In areas of poor or no medical attention, the natural course of the disease prevails because patients have no access to treatment.(Eloi Marijon et al., 2012)

Epidemiologically, the patterns of heart diseases differ greatly between developed countries and the rest of the world. In the sub-Saharan Africa, rheumatic heart disease remains a threatening public health condition while congenital heart diseases remain with poor prognosis. As there is limited high setting health access, the African children are still presenting with increased morbidity and mortality due to cardiovascular diseases. However, early diagnoses of non-complicated lesions can help in early treatment by timely referral before onset of permanent sequelae; unfortunately, it remains hindered by limited resources. (S.L. Rohde et al., 2010)

The limited access to surgical programs with long waiting lists requires referral of children abroad for adequate management.(Liesl Zühlke et al., 2013;0:1–8)

Sub-Saharan Africa represents over 24 % of the overall disease burden, but it has only 3% of the global health workforce; while America with only 10% of the world disease burden, has 37% of the global workforce. (ChodchanokVijarnsorn et al., 2011)

Cardiac surgery requires sophisticated and modern diagnostic and surgical techniques and infrastructures. It needs personnel with advanced training and skills.(Frank Edwin et al., 2011)

Very few African countries have necessary domestic resources to provide adequate cardiac care to their community.

Medical and surgical management with severe rheumatic heart diseases remains the least cost-effective intervention and consumes the vast majority of health funds in poor countries. The valvuloplastyis the most attempted procedure and has the advantages of non-use of anticoagulants, thus allowance for pregnancies. Mechanical valve replacement remains a dilemma for low or limited resource settings due to the lack of adequate supply in anticoagulants.(ChodchanokVijarnsorn et al., 2011)

All these techniques present advantages and disadvantages: mechanical valve replacement offers a higher longevity and lesser need for reoperation. However, it also requires life-long anticoagulation, which confera high risk of bleeding, making this a less attractive option. On the other hand, biological valves do not require long-life anticoagulation and do not present the risk of thromboembolism. The problem, however, lies in the known fact that biological valves are short-lived and their need in reoperation is high.(Tefera E et al, 2014)

Catheterization, which has to be done by specialized cardiologist, can present with some complications as well: balloon rupture and embolization of its fragments, failure of balloon deflation, cardiac perforation and/or damage, vascular injury, embolic complications such as stroke. Those complications are difficult to manage in setting with low health facility.(Timothy F. Feltes et al, 2011)

After surgery, most children who have undergone open heart surgery require close follow-up. However, due to the limited number of trained personnel and infrastructures, the life of these patients remains at high risk. These patients are less likely to appear for frequent follow-up because they stay not only too far from specialized centers, but also in settings of underdeveloped transport infrastructures.(Tefera E et al, 2014)

Patients with mechanical valvesrequire long-life, regular and consistent Warfarin anticoagulation with risk of thrombosis and bleeding. INR checking and Warfarin dosing need to be done regularly. However, most sub-Saharan African countries present the laboratory problem of regular INR measurement as well as the problem of Warfarin delivery.(Tefera E et al, 2014)

Humanitarian partnerships have been identified as one way to overcome these barriers and to address the challenges of providing cardiac surgery in resource limited settings. Some effective strategies include:

- Referring children abroad in order to receive cardiac surgical care either pro bono or at reduced billing,
- Visiting surgical teams coming to help those children in their countries, thus also improving the knowledge and clinical skills of host medical staff.

Thus far, in Rwanda, 2 visiting pediatric teams regularly perform cardiac catheterization and/or open heart surgery for correctable congenital heart diseases: the Chain of Hope, Belgium and Open Heart International, Australia, since 2006 and 2008 respectively. However, these visiting teams operated mostly on congenital cases while few children presenting with rheumatic heart diseases can be eligible for cardiac surgery by the Australian team. Two other adult teams: Team Heart, Boston-USA and Healing Hearts Northwest, Washington-USA operate occasionally on older children with RHD.

Despite these efforts, rheumatic heart diseases remain one of the major medical causes of death for children under age 18 years.

The procedures and interventions done represent a small proportion compared to the cases needing surgical treatment.

Additionally, the outcome of rheumatic heart disease surgery in children is not well documented in poor countries, highlighting the necessity of a thorough analytical study in order to sort out all major outcomes and possible problems related to the follow-up.

The majority of cardiac surgical procedures are done by visiting teams, or the children are sent abroad to have access to high-quality cardiac surgery. For this reason, there exist few data about the real outcomes of cardiac surgical interventions for rheumatic heart disease in African children. Apart Republic of South Africa, there are few cardiothoracic centers in sub-Saharan Africa like Kenya, Tanzania, Ghana, Senegal, etc. Those centers are facing problems of low number of qualified personnel and unsatisfactory infrastructures.(Mohammed Rafique Essop, Vuyisile T. Nkomo,, 2005)

Rwandahas only 4 cardiologists working in the public health institutions based in Kigali city, the capital of Rwanda. This may bring to obviously sub-optimal service delivery to cardiology patients and appropriate follow-up to rheumatic heart disease post-operative children across the country of more than 11 million people. Moreover, patients with mechanical valves have been benefiting from anticoagulation treatment and INR monitoring has been provided mostly by Team Heart Inc.

In a study done in Samoa by Satupaitea V. revealed that the rheumatic heart disease requires 77% of cardiac surgery and was taking up to 30% of overseas treatment budget. (V, 2006)

Another study done in Guatemala by Juan R. Leon-Wyss in 2008 about outcomes of pediatric cardiac surgery found that post-operative complications occurred in 523 of 2630 (20%). The most predominant complications were pleural effusion, pneumothorax, low cardiac output, bleeding, capillary leak syndrome, arrhythmia and nosocomial infections; mean stay in intensive care unit was 3 days (1 to 78 days), the mean of hospital stay was 6 days (1to 97 days). The mortality was 8.3 %.(Juan R. Leon-Wyss et al. , 2009)

In a study done in Tanzania by Nyawawa ETM et al., it was demonstrated that valvular disease resulting from rheumatic heart disease represented the majority of open heart surgical cases, with overall mortality of 13.3%.(Evarist T.M Nyawawa et al., 2010)

In the PIH Guide to Chronic Integration for Endemic Non-communicable Diseases, Gene Bukhman and colleagues found that between 2006 and 2011, about 200 cardiac surgeries have been done in Rwanda with 6 cases of death. Between 2007 and 2010, 54% of cardiac surgeries were indicated for congenital anomalies, 43% were for rheumatic heart diseases and 3% for other conditions. Among operated patients, 132 cases were operated by visiting cardiac surgical teams, 29 were operated abroad and 9 had closed cardiac surgery by local thoracic surgeon(Gene Bukhman et al., 2011).

The recent data about rheumatic heart disease surgery for adolescents and young adults in Rwanda at King Faisal Hospital, Kigali; in partnership with Team Heart from Boston, annually since 2008 till 2013 showed that 86 procedures have been done with 128 mechanical valve replacement, valve repair in 15 cases: 13 mitral valve repair versus 10 cases of tricuspid valve repair. The 30-day mortality was less than 5%. The other complications included: bleeding,

pneumothorax, heart block third degree, endocarditis and 2 cases of hemorrhage requiring reoperation.(JaBaris D,S. et al. , 2014)

All these studies raised my curiosity to assess the outcomes of cardiac surgery for rheumatic heart diseases in Rwandan children and hence identify measures of quality service delivery in future.

1.2 RESEARCH QUESTIONS

1. What is the proportion of different presentations of rheumatic heart diseases among operated children?

2. What are the major outcomes of rheumatic heart disease surgery in children?

3. What is the quality of life after surgery of rheumatic heart disease in children?

1.3 OBJECTIVES OF THE STUDY

1.3.1 GENERAL OBJECTIVE

To assess the outcomes aspects of rheumatic heart disease surgery performed in children.

1.3.2 SPECIFIC OBJECTIVES

1. To determine the proportion of operated rheumatic heart disease conditions in Rwandan children.

2. To determine the major clinical outcomes and follow-up aspects of Rwandan children operated for rheumatic heart disease.

CHAPTER II. MATERIALS AND METHODS

2.1 STUDY AREA

The study was conducted at University Teaching Hospitals of Kigali and Butare, Rwanda Military Hospital as well as King Faisal Hospital, Kigali, which receive referred pediatric cardiology patients from all over the country. The mainstay of the study was the Pediatric Unit as well as the Department of Medical Records of those hospitals. Among those hospitals; three are located in Kigali (University Teaching Hospital of Kigali, King Faisal Hospital, Rwanda Military Hospital), another one (University Teaching Hospital of Butare) is located in southern Province, Huye District. All those hospitals receive patients from different corners of Rwanda. Each hospital has a cardiology outpatient department. Only two hospitals (CHUK and KFH) had pediatric cardiologists who were based there, others have cardiology visits on regular basis by both pediatric cardiologists. Among the children reviewed in cardiology outpatient department, there are children operated for rheumatic heart disease who need thorough and regular follow-up. The rheumatic heart disease children who have been operated were contacted, reviewed in outpatient department by cardiologist and heart ultrasound was done for each of them. The 2D and Doppler modes were used to assess the size of the heart structures and the velocities across the valves. The M mode was used to determine the systolic function of the heart. INR was checked for every patient with mechanical valve and 2 previous values were recorded in addition to the value of the day of consultation.

2.2 STUDY POPULATION AND PERIOD

Study population included all children aged 18years or less at time of surgery, operated for rheumatic heart disease from January1st 2006 to March 31st 2015. At total, eighty-four children were operated. The recruitment of the cases was prospectivein nature, collecting all useful information about the patients. The subjects whose numbers recorded in their medical files were contacted by telephone. Though those children had regular visit for cardiologist review, it was not easy to know those who have been lost for follow-up, those who died or those who emigrated. I was able to collect data on 69 operated children. I consulted the file of the patients who died in order to know the modality of death if this was applicable. Only those who were contacted and agreed to consent for the study were enrolled and had an interview to assess their quality of life. To assess the quality of life, I used Ferrans and Powers Index, Cardiac IV version.

It is a validated tool to assess quality of life for adults but as there was no validated tool for children, we used questions that we adapted for children; some items were omitted because they were not applicable to the children. Patient's identification, demography and subsequent clinical and para-clinical data were entered in data collection sheets.

2.3 STUDY DESIGN

This was a cross-sectional analytical study.

2.4 STUDY CRITERIA

Inclusion criteria:

1.All Rwandan children who underwent cardiac surgery for rheumatic heart disease in the period of this study (January 2006 to March 2015), irrespective of their places of surgery and followed-up at tertiary level in Rwanda.

2.Aged ≤18 years at the time of surgical intervention.

Exclusion criteria**:**

Patients who opted out of the study or declined consent.

2.5 DATA COLLECTION, STATISTICAL METHODOLOGY AND ANALYSIS

2.5.1 DATA COLLECTION AND ANALYSIS

The total study population included all children who had been operated for rheumatic heart disease. A pre-coded questionnaire was administered by the Principal Investigator to capture the demographic characteristics and clinical parameters of participants. The additional clinical data and results of investigations were obtained from patients' files/ records and during OPD visit. There was part of interview to evaluate the quality of life after surgery. We got answers from children, sometimes assisted by their caretakers/parents. The data collection sheets were coded for easy computer use.

Clinical parameters included: plotted weight and height, signs and stage of heart failure or infective endocarditis and any complication related to cardiac surgery for rheumatic heart disease.Specific tests included: INR value and heart ultrasound results.

The data entry was done using Epidata 3.1 computer software, analyzed using SPSS 20.0 for windows. Qualitative variables were summarized as proportions, continuous variables as means and standard deviation. Bivariate regression analysis was done using Odds Ratios, 95% confidence intervals and chi-square test was used to test for association of risk factors and variables. Statistical tests to assess the validity of association were Chi-square test ($\chi 2$) for subgroups. The significance of association was determined by calculations of P value and confidence interval. The two-sided p value <0.05 was considered confirming statistically significant association.

2.5.2 VARIABLES

For our study, there were two types of variables:

2.5.2.1 Dependent variables

a. Death.
b. Survival at discharge till review after cardiac surgery.

2.5.2.2 Independent variables

a.***Socio-demographic variables:***

This concerned: age, sex, and weight, nutritional status, socio-economic status of the patients/family, health insurance, residency, etc**.**

b.Clinical variables, surgical aspects and post-operative follow-up:
This included NYHA (New York Heart Association) classes before and after surgery, rheumatic heart valve lesions, type of heart surgery, hospital and country of operation, major problems after surgery, relevant heart ultrasound findings after surgery, follow-up aspects including compliance to Warfarin and secondary prophylaxis, INR, medications after surgery. It included also quality of life after surgery.

2.5.3 QUALITY CONTROL

1.A pretested, pre-coded and general questionnaire was used.

2.Questionnaires were cross-checked by the Principal Investigator to ensure completeness before leaving the study site.

2.5.4 ETHICAL CONSIDERATIONS

Ethical and Scientific approval was sought from the Institutional Review Board (IRB) at Kigali University Teaching Hospital (KUTH)and College of Medicine IRB. Informed written consent was sought from the caretakers of the study participants. The written assent was sought from the children aged 10 years and more.

2.6 UTILITY OF THE STUDY

Currently, all countries in the Africa are having emerging cardiovascular pathologies especially in children. They present an important public health concern. With limited means in terms of equipment and qualified personnel especially in aspects of surgery and appropriate follow-up, there is a big challenge in late outcomes. This study aimed to assess the outcomes of pediatric cardiac surgery for rheumatic heart disease and thus will help to establish the possible and sustainable solutions for identified challengesin pediatric rheumatic heart disease surgery in Rwanda.

2.7 LIMITATIONS OF STUDY

This study was conducted at KFH, KUTH, BUTH and RMH. It concerned all children operated for rheumatic heart disease. However, there were some limitations especially for those who were operated abroad, who may be lost in follow-up or migrate or with wrong contacts, not having recorded important information data, etc. Additionally, post-operative patients at school far from their respective sites of follow-up were not attending the clinics during our research period were not taken into consideration and this may be subject to bias of our results.

CHAPTER III. RESULTS

The results of our study were presented in different tables and figures. They concern demographic aspects, clinical presentations before surgery, types of surgery and the major outcomes of RHD surgery, follow-up aspects and quality of life after surgery. The total number of operated children was 84 children, but it was difficult to find data for some of them (missing them or their data). Total study population included 69 children.

3.1 DEMOGRAPHIC CHARACTERISTICS OF THE PATIENTS

At the time of follow-up, the age of population was ranging between 8 and 24 years, the mean was 15.5 years ±3.4 SD. More than half (52.2%) were 15 years old or less, the majority were female (56.5%). They were coming from different Provinces: Eastern Province 29.0%, Southern Province: 27.5%, Kigali City: 15.9%, Northern Province 14.5% and Western Province: 13.0%. Nearly all children (94.2%) were living in low socio-economic conditions. All patients had a health insurance and the majority (94.2%) was covered by the community-based health insurance (CBHI).

Table 1. Demographic aspects of study population

	Items	Frequency	Percent
Age	≤ 15 years	36	52.2
	> 15 years	33	47.8
Sex	Male	30	43.5
	Female	39	56.5
Residence	Kigali city	11	15.9
	East	20	29.0
	South	19	27.5
	North	10	14.5
	West	9	13.0
Socio-economic status	Low	65	94.2
	moderate	4	5.8
Health insurance	CBHI	65	94.2
	RSSB	3	4.3
	MMI	1	1.4

3.2 HISTORY AND CLINICAL PRESENTATION

3.2.1 Nutritional status of patients before and after surgery

Nearlyall children (98.6%) presented poor nutritional status before surgery. Sixty-two patients (89.85%) of reviewed children had anthropometry plotted, using CDC charts. After surgery there was remarkable improvement of nutrition status, twenty-two patients (35.5%) presented stunting (height for age <3rd percentile), 24 patients (38.7%) were underweight (weight for age < 3rd percentile) and 15 patients (24.2%) were chronically malnourished (both weight for age and height for age <3rd percentile). Nutritional status improved after RHD surgery.

Table 2.Presentation of weight and height for age plotting at last post-operative follow-up

Percentile		Frequency	Percent
Weight for age	<3rd	24	38.7
	3-10th	17	27.4
	10-25th	6	9.7
	25-50th	11	17.7
	50-75th	3	4.8
	> 97th	1	1.6
Height for age	<3rd	22	35.5
	3-10th	10	16.1
	10-25th	11	17.7
	25-50th	11	17.7
	50-75th	4	6.5
	75-90th	1	1.6
	90-97th	2	3.2
	>97th	1	1.6

3.2.2 Clinical presentation before surgery

The children who were operated had different clinical presentation depending on heart valve lesions and their severity.

Atrial fibrillation was present in 10.1% of the patients. Sixty-eight patients had their heart ultrasound findings documented. Statistical analysis concerned the documented heart findings beforesurgery. Mitral valve regurgitation was predominant: 63 patients (92.6%); aortic valve regurgitation was present in 14 patients (20.5%). Tricuspid valve regurgitation was present in 20 patients (29.4%). Mitral stenosis was present in 10 patients (14.7%). Aortic stenosis was present in one patient and it was moderate (1.4%). Pulmonary valve was not affected in any

patient.Somepatients were having combined valve diseases. The heart ultrasound results and different valve lesions association are detailed in Table. 3.

Most children were having difficulty in performing physical activities or even uncomfortable at rest. Most patients were in NYHA IV (New York Heart Association) classification for heart failure (88.4%);five patients were in NYHA III (7.2%) and only 3 patients (4.3%) were in NYHA II.No patient was asymptomatic before surgery. This explains the severity of conditions and the need of emergent heart surgery for survival.

The left ventricle (LV)echo dimensions and ejection fraction data were available only in 46 and 45 patients respectively; LV dimensions ranged between 3.5 to 7.8 cm with a mean of 5.5 cm ± 0.9 SD. The LV ejection fraction ranged between 50.0 and 79.0% with mean of 67.7% ±7.0 SD.

Table 3.Clinical conditions before surgery

Clinical conditions	Items	Frequency(n)	Percentage
Atrial fibrillation	Atrial fibrillation	7	10.1%
Valve lesions (moderate to severe)	Mitral valve regurgitation	63	92.6%
	Aortic valve regurgitation	14	20.6%
	Tricuspid valve regurgitation	20	29.4%
	Mitral stenosis	10	14.7
	Mitral valve regurgitation and stenosis	9	13.2%
	Mitral regurgitation and aortic regurgitation	9	13.2%
	Mitral regurgitation and aortic stenosis	1	0.01%
	Tricuspid regurgitation and mitral stenosis	4	0.05%
	Mitral regurgitation and tricuspid regurgitation	20	28.4%,
	Aortic regurgitation and tricuspid regurgitation	1	0.01%
NYHA classification	NYHA IV	61	88.4%
	NYHA III	5	7.2%
	NYHA II	3	4.3%

3.3 SURGERY ASPECTS

3.3.1 Place of surgery (Country)

Open heart surgery for rheumatic heart disease in children was done in different countries. Either they benefited the surgery from visiting teams in Rwanda, where surgery was performed at King Faisal Hospital, Kigali, or the patients were referred outside the country for rheumatic heart disease surgery. Among operated children, 40.6% patients underwent surgery in Rwanda (KFH), 43.5% were operated in India either at Fortis (20patients) or MIOT Hospital (10 patients), 14.5% patients were operated in Khartoum, Soudan (Salam Center) and only one patient was operated in Egypt.

Children who were operated in Rwanda (KFH) had surgery from different visiting teams. Team Heart (USA) has operated 16 patients, Healing Heart NorthWest (USA)has done heart surgery in 3 patients of the study population and Open Heart International (OHI) from Australia did surgery in 8 children of this study.

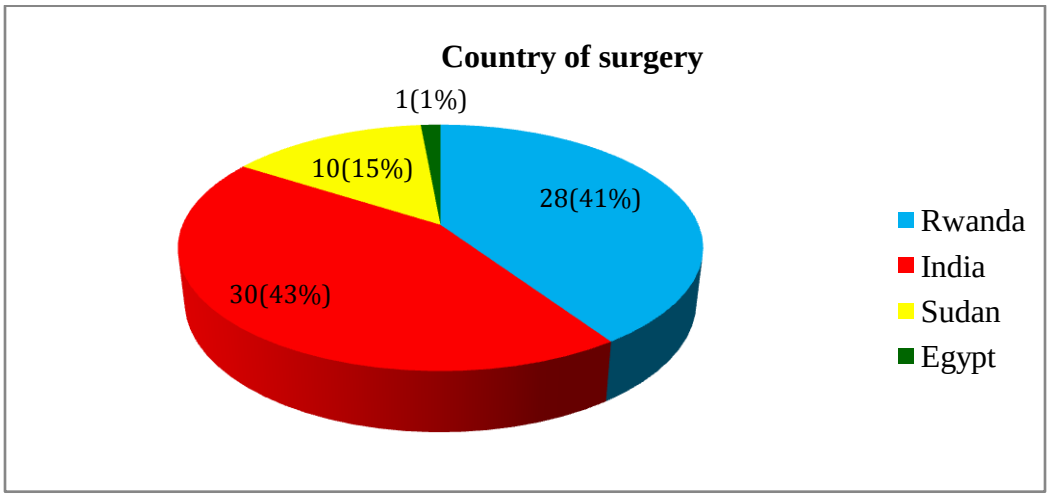

Figure 1. Country of surgery

3.3.2 Age of patients at time of surgery

The age of children at time of surgery is different from one case to another. The younger was 6 years old and the elder was 18 years old (upper limit of study inclusion criteria), the mean was 13.0 years ±2.9 SD. Around 17.4% children were 10 years old or less, 60.9% were ranging between 11 and 15 years, the rest (21.7%) were 16 years or more at the time of surgery.

3.3.3 Types of rheumatic heart disease surgery

Different surgical procedures wereperformed in order to manage rheumatic RHD valvular lesionsand are shown in Table 5. Mechanical valve replacements were as follow: mitral in 46 patients (66.7%), aortic in 8 patients (11.6%), tricuspid in 4 patients (5.8%). Biological valve replacement was done in different interventions too: mitral: 6 patients (8.7%), aortic: 2 patients (2.9%) and tricuspid biological valve replacement in 4 patients (5.8%). Valve repairs: mitral in 13 patients (18.8%), tricuspid in 8 patients (11.6%) and aortic valve repair was done in 3 patients (4.3%). In some circumstances, there had been different surgical interventions from one patient.

Table 4. Heart valve surgery interventions

Heart valve surgery	Valve(s)	Number	Percent
Mechanical valve replacement	Mitral valve	46	66.7
	Aortic	8	11.6
	Tricuspid	4	5.8
Biological valve replacement	Mitral	6	8.7
	Aortic	2	2.9
	Tricuspid	4	5.8
Valve repair	Mitral	13	18.8
	Aortic	3	4.3
	Tricuspid	8	11.6
Combinations of surgical procedures	Aortic and mitral mechanical valves	5	7.2
	Mitral and tricuspid repair	3	4.3
	Mitral biological valve and tricuspid repair	2	2.9
	Mitral mechanical valve and tricuspid repair	3	4.3
	Tricuspid and mitral mechanical valve	4	5.8
	Mitral and aortic repair	2	2.9

	Mitral mechanical valve and aortic repair	1	1.4
	Mitral repair and biological aortic valve	1	1.4

3.4 MAJOR EVENTS AFTER SURGERY

Twenty-seven(39.1%) patients were readmitted after surgery. Readmission ranged from one to four times. The major problems after surgery were: heart failure (in 8 patients) and bleeding disorder on Warfarin (in 9 patients). Other causes of readmission after surgery were thrombo-embolism and/or embolic stroke in 6 patients, infective endocarditis (in 3 patients). That was due to complications of surgery like dehiscence or leaks of replaced valve scarring or calcification of biological valve or even poor INR checking and Warfarin dosing.

Table 5. Major events after surgery

Items	Number	Percent
Readmission	27	39.13
Heart failure	8	11.59
Bleeding on Warfarin	9	13.04
Post-operative thrombo-embolism and /or ischemic stroke	6	8.69
Infective endocarditis	3	4.34
Death	6	8.69

3.5 POST-OPERATIVE FOLLOW-UP

3.5.1 Center of follow-up

Rwanda had one pediatric cardiologist since 2006 and got a second one in 2010. Operated children have to be reviewed regularly by those 2 cardiologists in four different referral hospitals.

Sixty five children (94.2%) are followed-up at Kigali University Teaching Hospital. KFH, RMH and BUTH are having few patients in post-operative follow-up.

3.5.2 Follow-up aspects

The rate of follow-up depends upon the clinical condition, socio-economic condition of the family or patient, geographic accessibility and availability of cardiologist. The majority (56.5%) had monthly appointment in different site of follow-up. Around a quarter (23.2%) of patients had poor follow-up and the main factors of poor follow-up were: poverty (46.7%) and distance (13.3%).

Table 6. Follow-up aspect

		Frequency	Percent
Rate of follow-up	Monthly	39	56.5
	once 2 months	9	13
	once 3 months	6	8.7
	once 6 months	11	15.9
	once a year	4	5.8
Regularity of follow-up	No	16	23.2
	Yes	53	76.8
Causes of poor follow-Table	Distance	2	13.3
	Unclear information	1	6.7
	Tutor problem	3	20
	Poverty	7	46.7
	Ignorance	2	13.3
NYHA after surgery	NYHA I	41	59.4
	NYHA II	19	27.5
	NYHA III	4	5.8
	NYHA IV	5	7.2

The majority of our patients presented in NYHA I (59.4%) atthe last post-operative follow-up. Fewer patients were in class NYHA II (27.5%), III (5.8%) and IV (7.2%).

3.5.3 Heart ultrasound findings in post-operative follow-up

a. Heart valves conditions after surgery

The major ultrasound findings after RHD surgery are summarized below in Table 8. Mitral valve regurgitation has been found in 18 patients (mild: 7 patients, moderate: 10 patients and severe in 1 patient), mitral stenosis was found in 10 patients (mild: 2 patients, moderate: 8 patients), aortic regurgitation was found in 23 patients (mild: 16 patients, moderate: 5 patients and severe in 2

patients), aortic stenosis was found in 11 patients (mild: 8 patients, moderate: 2 patients and severe in one patient). Tricuspid regurgitation was found in 44 patients (mild: 35 patients, moderate: 9 patients), mild tricuspid regurgitation in 2 patients. There were 2 patients with mild pulmonary regurgitation. Mitral mean gradient ranged between 1.2 to 16.8 mmHg with mean of 4.8 mmHg ±3.4. Aortic mean gradient has varied between 4 and 26.8 mmHg with mean of 12.9 mmHg ±6.0. Right ventricle systolic pressure (RVSP) ranged between 12 and 60 mmHg with mean of 34.4 mmHg±10.7.

Table 7. Heart valve conditions after surgery

		Frequency	Percent
Mitral regurgitation	Mild	7	10.1
	Moderate	10	14.5
	Severe	1	1.4
Mitral stenosis	Mild	2	2.9
	Moderate	8	11.6
Aortic regurgitation	Mild	16	23.2
	Moderate	5	7.2
	Severe	2	2.9
Aortic stenosis	Mild	8	11.6
	Moderate	2	2.9
	Severe	1	1.4
Tricuspid regurgitation	Mild	35	50.7
	Moderate	9	13
Tricuspid stenosis	Mild TS	2	2.9
Pulmonary regurgitation	Mild	2	2.9

b. Left ventricle dimensions and ejection fraction

The dimensional measurement of left ventricle is of great importance as it depicts the heart function after surgery. In our study, the left ventricle dimension in systole (LVDs) was varying between 1.7 and 8.0cm with mean of 3.3cm±1.3 SD and left ventricle dimension in diastole (LVDd)varied between3.2 and 8.6cm. The mean was 4.8cm±1.0 SD. The ejection fraction ranged between 15.0 and 83.0%. The mean was 61.6%±15.2 SD. Note that thrombus was seen in 1 patient.

3.5.4Anticoagulation (Warfarin)

Anticoagulation management is necessary in post-operative period. People with mechanical valve have to take it regularly. Warfarin dose ranged between 1to 12.5 mg with mean of 6 mg±2.5 SD. Warfarin was in most case taken regularly (75.5%), the main reasons to poor compliance were ignorance (50%), procurement problem (25%) and poverty (16.7%).

Table 8. Warfarin

		Frequency	Percent
Warfarin compliance	Irregular	12	24.5
	Regular	37	75.5
Factors of poor compliance to Warfarin	Procurement problem	3	25
	Poverty	2	16.7
	Geographic barrier	1	8.3
	Ignorance	6	50

3.5.5INR

The INR is a standardized way of monitoring anticoagulation therapy especially in people with mechanical valve replacement. It was regularly checked in 77.6% of children. The reason of poor irregular INRchecking included: ignorance: 45.5%, distance and machine problem contribute at the same level (18.2 %).

Table9. INR checking

		Frequency	Percent
Regularity of doing INR	Irregular	11	22.4
	Regular	38	77.6
Factors of not doing INR	Poverty	1	9.1
	Geographic barrier	2	18.2
	Machine problem	2	18.2
	Pain	1	9.1
	Ignorance	5	45.5

The INR values differ from condition to another one. In our study, it ranged from 1 to7.5 with mean of 2.53±1.25 SD. In our settings it has been widely changing, mostly due to poor Warfarin dosing, poor compliance to prescribed regimen and mainly due to poor medical follow-up.

3.5.6 Secondary prophylaxis

The most used antibiotic for secondary prophylaxis is Benzathin Penicillin (69.6%). It is monthly intramuscularly injected drug, which is usually more effective than daily oral Penicillin V which was used in 30.4%. The compliance was as good as 56.5%. The major reasons of poor compliance were generally ignorance: 74.2%, poverty and procurement problem at 9.7% each. Compliance to monthly IM Benzathin Penicillin was 50%; for daily oral Penicillin was 60%.

Table 10. Secondary prophylaxis

		Frequency	Percent
Antibioprophylaxis	Monhtly IM Benzathin Penicillin	48	69.6
	Daily OralPenicillin V	21	30.4
Compliance to antibioprophylaxis	Regular	39	56.5
	Irregular	30	43.5
Causes of poor compliance to antibioprophylaxis	Distance	1	3.2
	Poverty	3	9.7
	Pain	1	3.2
	Ignorance	23	74.2
	Procurement problem	3	9.7

3.5.7 Others medications

The operated patients may need other medications used in cardiology. In post-operative follow-up, the diuretics were still used in 26 patients, ACE inhibitors in 22 patients, beta blockers in 16 patients, Aspirin in 9 patients and Digoxin in 4 patients with percentages of 37.7, 31.9, 23.2, 13 and 7.8% respectively.

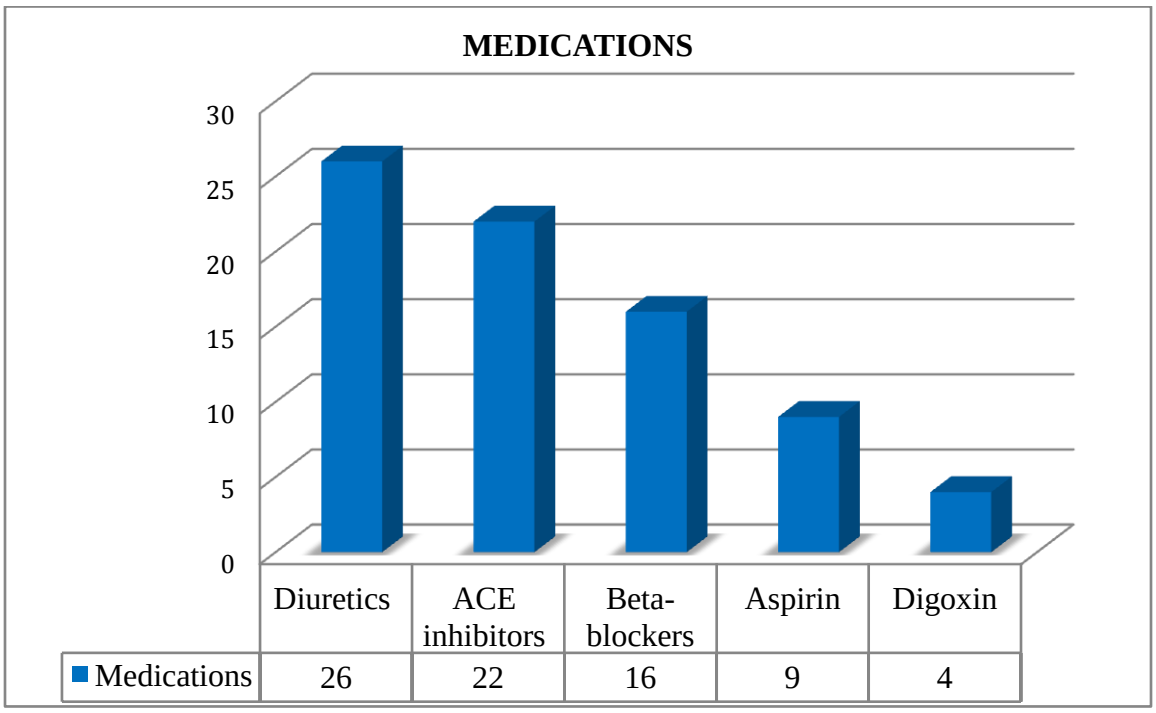

Figure 2. Medications in post-operative follow-up

3.5.8 Current situations

There has been adverse outcome after heart surgery. Of enrolled population, 63 are alive and 6 died: 4 female and 2 male patients. The most causes of death were heart failure (3 patients),dilated cardiomyopathy and infective endocarditis in 2 patients each. One patient came in cardiogenic shock and another presented bleeding with heart failure. Those children were previously on different drugs. Digoxin was prescribed in 2 patients, ACE inhibitors and diuretics in 3 patients each, beta-blockers in 2 patients. Only one patient was taking Aspirin. The heart valve surgery was mitral mechanical valve replacement in 4 patients, 2 aortic repairs. Tricuspid repair, mitral valve repair or biological mitral valve replacement was done in one patient each.

Those patients were presenting different post-operative valve lesions. There was mitral regurgitation in 3 patients (mild, moderate and severe), mild mitral stenosis in one patient, aortic regurgitation in 3(mild, moderate and severe) and 2 stenosis (mild and moderate). Tricuspid regurgitation was present in 4 patients (mild in 1 patient and moderate in 3 patients). Among those who died, one was operated at KFH by Team Heart, 5 were operated in India (three at Fortis and two at MIOT Hospital). All were having poor nutritional statuses before surgery.

3.5.9 Quality of life after rheumatic heart disease surgery

This is important component of follow-up. It shows the psychological aspect of the operated patients. The main findings are listed below, the minimum for each item is 1 and the maximum is 6.

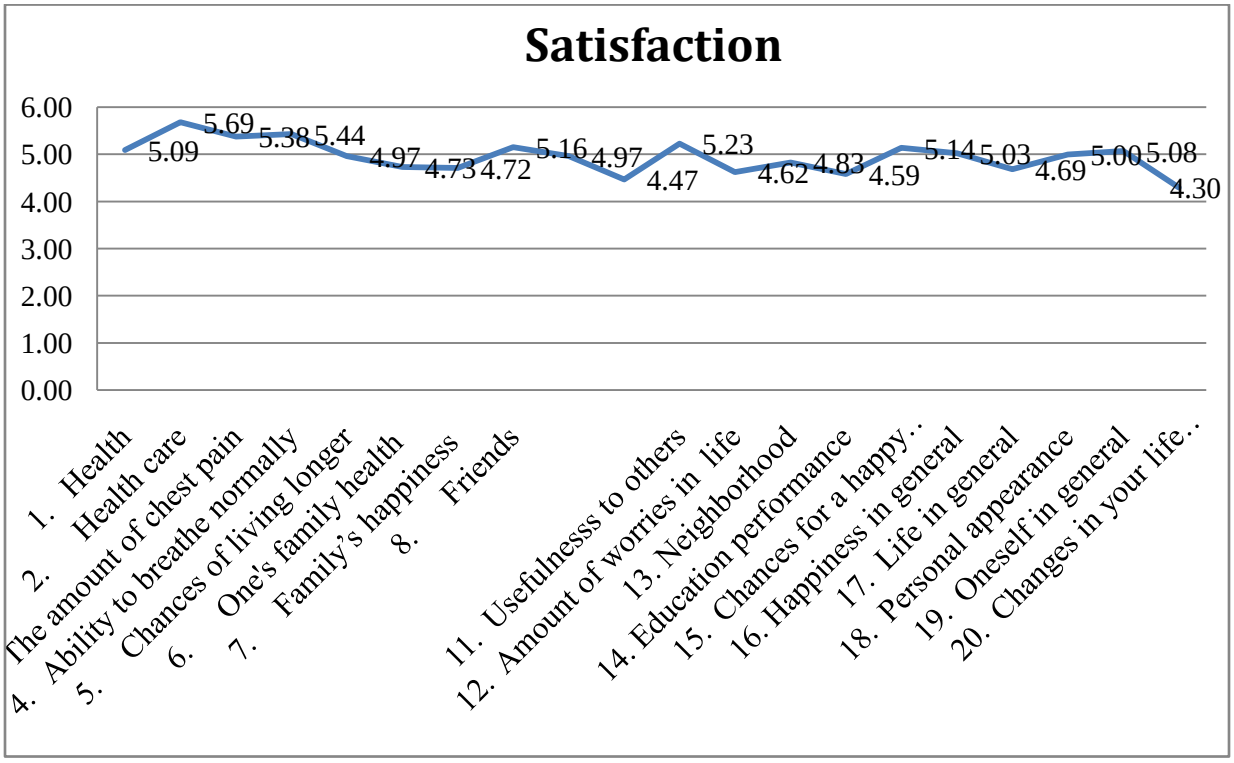

Figure 3.Satisfaction of patients after surgery

In general they are satisfied about health care, their usefulness to them and to others. They had worries and usually not happy for the changes in life they had after surgery (diet, some physical activities ...), their happiness is not optimum. They generally need psychosocial follow-up and support in order to optimize their management.

3.6 ASSOCIATION BETWEEN VARIABLES

3.6.1 Factors associated with poor outcomes

Patient clinical improvement was considered if the patient is in NYHA I or II class after surgery, he/she is alive. Those who died or are in NYHA class III or IV were considered not improved.

3.6.1.1 Heart valve surgery and outcomes

Some surgery related factors have been identified to influence or lead to poor outcomes. The ones are statistically significant are two or more heart valve surgery (p value: 0.002), and biological valve (p value: 0.000).

Table 11. Surgical factors associated with poor improvement

	No improvement after cardiac surgery		OR	95% CI	p-value
	Frequency	%			
Mitral valve surgery, grouped					
No (n=4)	0	0.0			
Yes (n=65)	9	13.8			
Aortic valve surgery, grouped					
No (n=56)	6	10.7	1.00		
Yes (n=13)	3	23.1	2.50	[0.53-11.70]	0.245
Tricuspid valve surgery, grouped					
No (n=57)	7	12.3	1.00		
Yes (n=12)	2	16.7	1.43	[0.26-7.91]	0.683
Number of valve surgery					
One valve surgery (n=48)	4	8.3	1.00		
Two valve surgery (n=21)	5	23.8	3.44	[0.82-14.42]	0.091
Valve repair					
No (n=50)	4	8.0	1.00		
Yes (n=19)	5	26.3	4.11	[0.97-17.41]	0.055
Biological valve					
No (n=61)	4	6.6	1.00		
Yes (n=8)	5	62.5	23.75	[4.11-137.22]	0.000
Mechanical valve					
No (n=20)	6	30.0	1.00		
Yes (n=49)	3	6.1	0.15	[0.03-0 .69]	0.015
Number of type of surgery					
One type (n=62)	5	8.1	1.00		
Two types (n=7)	4	57.1	15.20	[2.63-87.82]	0.002
Total (n=69)	9	13.0			

3.6.1.2 Pharmacological factors associated with poor outcomes

There were many factors associated with poor outcomes (non-improvement). Clinical conditions requiring use some medications like Digoxin, Aspirin and beta blockers were associated with

poor improvement with respective p value of 0.05, 0.008 and 0.022. Patients with poor evolution after surgery were taking those medications due to different indications like poor ventricle contractility, biological valve, etc.

Table 12. Pharmacological factors associated with poor outcomes

	No improvement after cardiac surgery		OR	95% CI	p-value
	Frequency	%			
Need to be on ACE inhibitors					
no (n=47)	5	10.6	1.00		
yes (n=22)	4	18.2	1.87	[0.45-7.77]	0.391
Need to be on Beta blockers					
no (n=53)	4	7.5	1.00		
yes (n=16)	5	31.3	5.57	[1.28-24.18]	0.022
Need to be on Aspirin					
no (n=60)	5	8.3	1.00		
yes (n=9)	4	44.4	8.80	[1.77-43.68]	0.008
Need to be on Digoxin					
no (n=65)	7	10.8	1.00		
yes (n=4)	2	50.0	8.29	[1.00-68.41]	0.05
On warfarin					
No (n=20)	6	30.0	1.00		
Yes (n=49)	3	6.1	0.15	[0.03-0.69]	0.015
Need to be on diuretics					
No (n=43)	3	7.0	1.00		
Yes (n=26)	6	23.1	4.00	[0.90-17.68]	0.068
Total (n=69)					

3.6.2 Risk factors associated with mortality

The mortality was associated with different risk factors, there pharmacological and surgery related factors.

3.6.2.1 Surgical factors associated with mortality

Heart surgery contributed to obvious improvement. However, there are some surgery related factors associated with mortality. For all studied factors, there has not been any statistical significant association.

Table 13. Surgical factors associated with mortality

	Death after cardiac surgery		OR	95% CI	p-value
	Frequency	%			
Mitral valve surgery, grouped					
No (n=4)	0	0.0	.		
Yes (n=65)	6	9.2			
Aortic valve surgery, grouped					
No (n=56)	4	7.1	1.00		
Yes (n=13)	2	15.4	2.36	[0.38-14.56]	0.354
Tricuspid valve surgery, grouped					
No (n=57)	5	8.8	1.00		
Yes (n=12)	1	8.3	0.95	[0.10-8.91]	0.961
Number of valve surgery					
One valve surgery (n=48)	3	6.3	1.00		
Two valve surgery (n=21)	3	14.3	2.50	[0.46-13.56]	0.288
Valve repair					
No (n=50)	3	6.0	1.00		
Yes (n=19)	3	15.8	2.94	[0.54-16.05]	0.214
Bioprosthesis					
No (n=61)	5	8.2	1.00		
Yes (n=8)	1	12.5	1.60	[0.16-15.74]	0.687
Mechanical valve					
No (n=20)	2	10.0	1.00		
Yes (n=49)	4	8.2	0.80	[0.13-4.76]	0.806
Number of type of surgery					
One type (n=62)	4	6.5	1.00		

Two types (n=7)	2	28.6	5.80	[0.84-39.86]	0.074
Total (n=69)					

3.6.2.2 Pharmacological factors associated with mortality

Patients who died were taking different medications. Their conditions required to be treated with diverse drugs. Their need of those medications could be associated with mortality or not. The risk of mortality was significantly associated with the need of Digoxin (p value: 0.015), conditions requiring other medications were not statistically associated with mortality (p value >0.05).

Table 14. Pharmacological factors associated with mortality

	Death after cardiac surgery		OR	95% CI	p-value
	Frequency	%			
Need to be on ACE inhibitors					
no (n=47)	3	6.4	1.00		
yes (n=22)	3	13.6	2.32	[0.43-12.53]	0.330
Need to be on Beta Blockers					
no (n=53)	4	7.5	1.00		
yes (n=16)	2	12.5	1.75	[0.29-10.57]	0.542
Need to be on Aspirin					
no (n=60)	5	8.3	1.00		
yes (n=9)	1	11.1	1.38	[0.14-13.33]	0.783
Need to be on Digoxin					
no (n=65)	4	6.2	1.00		
yes (n=4)	2	50.0	15.25	[1.68-138.41]	0.015
Total (n=69)	6	8.7			

3.6.3 Factors associated with poor improvement (multivariate logistic regression)

Multivariate logistic regression was done to look for association between different factors and lack of improvement after surgery. It revealed that patients who had two or more heart valve surgery, biological valve and those who needed Digoxin during their post-operative follow-up had significant risk of poor outcome. Practically those who needed Digoxin were having poor

heart function and associated poor clinical evolution. Biological valve is short lived and is associated with calcification thus poor heart valve function.

Table 15.Multivariate logistic regression

	No improvement after cardiac surgery		OR	95% CI	p-value
	Frequency	%			
Number of type of surgery					
One type (n=62)	5	8.1	1		
Two types (n=7)	4	57.1	24.86	[1.74-355.69]	0.018
Bioprosthesis					
No (n=61)	4	6.6	1		
Yes (n=8)	5	62.5	46.44	[3.85-560.71]	0.003
Need to be on Digoxin					
no (n=65)	7	10.8	1		
yes (n=4)	2	50	61.48	[3.70-1022.15]	0.004
Total (n=69)	9	13			

CHAPTER V. DISCUSSION

4.1 INTRODUCTION

Rheumatic heart disease continues to be the prominent acquired heart disease in developing countries.(Lawrence J, 2012; Yusuf, 2001) Management of rheumatic heart disease requires medical treatment; however it may worsen, necessitating heart surgery. Moreover due to limited infrastructures and low number of specialized personnel in heart surgery, most children are being referred abroad where the optimal management is possible. (S.L. Rohde et al., 2010; Liesl Zühlke et al., 2013;0:1–8) There are different options of rheumatic heart disease surgery: valve repair, valve replacement (biological or mechanical valve replacement). However the challenges remain post-operative follow-up and management with risk of complications.(Tefera E et al, 2014)

The study aims to evaluate the proportion of operated rheumatic heart conditions, major outcomes and post-operative follow-up challenges as well as quality of life after surgery.

4.2 DEMOGRAPHIC ASPECTS OF THE PATIENTS

The age of children at time of surgery is different from one case to another. The younger was 6 years old and the elder was 18 years old, the mean was 13.0 years ±2.9 SD. Around 17.4% children were 10 years old or less, 60.9% were ranging between 11 and 15 years, the rest (21.7%) were 16 years or more, sex ratio F: M 1.3:1. At the last post-operative follow-up, their weight was ranging between 19 and 62kg, the mean of 40.8 kg ±11.4 SD. The height varied between 109 and 183 cm, mean was 151.2cm ±14.4 SD.

In study done in Kenya by Audrey Chepkemoi Kironget et al. about echography findings in rheumatic heart disease children: age of children was varying between three and fifteen years, median age was 11 years, about 58.3% were more 10 years old. Male children were representing 33.3%, female 66.6% of enrolled population, sex ratio F: M 2:1.(Audrey Chepkemoi Kironget, Paul Kiptoon, Myra Koech, 2014)

Another study done in Nigeria by S. S. Danbauchi et al. has found that female:male ratio was 2:1. (S. S. Danbauchi, M. A. Alhassan, S. O. David, R. Wammanda and I. A.Oyati, 2004) The study done by Raja Parvez et al. concerning anticoagulation has found that male patients were

presenting 57.6%.(Raja Parvez akhtar et al., 2009)The study from Kenya was concerning rheumatic heart disease but not rheumatic heart surgery, the patients were reviewed at different stages of RHD, either at low stage or advanced needing heart surgery, however for our study, it concerned children who underwent open heart surgery who were having advanced stage of rheumatic heart disease. The two other studies were concerning all range. Another one was concerning anticoagulation after heart surgery.

This shows that female people generally are more affected by rheumatic heart disease; however, no scientific explanation has been found to justify this difference.

The majority of children (94.2%) were living in low socio-economic conditions, few of them having moderate socio-economic status (5.8%). This emphasizes that rheumatic heart disease is associated with poor life conditions and poor hygiene. The poor socio-economic conditions, lack of hygiene, poor nutrition and limited accessibility to health care remain the major factors of high prevalence of rheumatic heart disease. (Eloi Marijon et al., 2012; S.L. Rohde et al., 2010; Liesl Zühlke et al., 2013;0:1–8; ChodchanokVijarnsorn et al., 2011; Sorour, 2014)

4.3 CLINICAL PRESENTATION

In our population, atrial fibrillation was present in in 10.1% of the patients. In study of Raja et al., atrial fibrillation was present in 51.1%. (Raja Parvez akhtar et al., 2009) There is a big difference between our populations, what does justify the low prevalence of atrial fibrillation in our study. However, when present, atrial fibrillation is usually associated with increased morbidity and mortality.(Raja Parvez akhtar et al., 2009)

Heart valves were affected in different proportions, the statistical analysis concerned the documented heart findings before surgery.Mitral valve regurgitation was predominant: 63 patients (92.6%), aortic valve regurgitation was present in 14 patients (20.5%). Tricuspid valve regurgitation was present in 20 patients (29.4%). Mitral stenosis was present in 10 patients (14.7%). Aortic stenosis was present in one patient and it was moderate (1.4%). Pulmonary valve was not affected in any patient. Some patients were having combined valve diseases. Pulmonary valve was not affected in any patient. The most involved heart valve is mitral valve, followed by tricuspid then aortic valve.

Different combinations of valve lesions are the second finding after mitral valve.(Audrey Chepkemoi Kironget, Paul Kiptoon, Myra Koech, 2014; S. S. Danbauchi, M. A. Alhassan, S. O. David, R. Wammanda and I. A.Oyati, 2004; Neal D. Hillman, Lloyd Y. Tani, L. George Veasy,et al., 2004).In study of Audrey Chepkemoi Kironget, mitral valve regurgitation was 46.43%, combination of mitral and aortic valve regurgitation 35.71%, mitral valve and stenosis 5.95% and mitral and aortic valve regurgitation and stenosis represented 2.38%.(Audrey Chepkemoi Kironget, Paul Kiptoon, Myra Koech, 2014)

The study of Neal D. Hillman has shown that the most surgical indications of surgery were mitral regurgitation (31%), mitral and aortic regurgitation (27%), mitral regurgitation and stenosis (15%,) aortic regurgitation (15%), mitral valve regurgitation and stenosis with aortic regurgitation (8%) mitral regurgitation and tricuspid regurgitation (4%).(Neal D. Hillman, Lloyd Y. Tani, L. George Veasy,et al., 2004)Pulmonary valve was not affected in any case. The mitral valve is mainly affected due to high blood flow inversely to pulmonary valve.

NYHA (New York Heart Association) classification for heart failure was mainly NYHA IV (88.4%), five patients were in NYHA III (7.2%) and only 3 patients (4.3%) were in NYHA II, no patient was asymptomatic before surgery. The same findings in study done by Jabaris et al at KFH, Kigali with NYHA III-IV in all adult patients operated for rheumatic heart disease.(JaBaris D,S. et al. , 2014) Raja et al. found that most patients were presenting NYHA IV (82.6%), few with NYHA III (1.8%) and NYHA II (15.6%) before heart surgery.(Raja Parvez akhtar et al., 2009) This is due to the delay for heart surgery due to poor qualified personnel, limited infrastructures and low accessibility to high standard care of heart surgery.(Eloi Marijon et al., 2012; S.L. Rohde et al., 2010; Liesl Zühlke et al., 2013;0:1–8; ChodchanokVijarnsorn et al., 2011; Tefera E et al, 2014; Sorour, 2014)The operated patients were presenting severe conditions and the need of emergent heart surgery for survival.

4.4 SURGERY ASPECTS

Rwanda started to have visiting teams operating heart diseases since 2006. First, there was one visiting team, later on there were other teams which came in different years. On average, the number of operated patients has been increasing over time. With support of PIH in health system of Rwanda, the number of patients operated for rheumatic heart diseases has increased too.(Gene Bukhman et al., 2011)

The age of children at time of surgery is different from one case to another. The younger was 6 years and the elder was 18 years (upper limit of study inclusion criteria), the mean was13.0 ±2.9. Around 17.4% children were 10 years old or less, 60.9% were ranging between 11 and 15 years, the rest (21.7%) were 16 years or more at the time of surgery.

The study done byNeal D. Hillman has shown that the mean age at time of operation was 13.5 ±4 years.(Sorour, 2014)The patients had to wait for the opportunities of surgery, meanwhile they were managed medically. (ChodchanokVijarnsorn et al., 2011; Tefera E et al, 2014) However, the interval between onset of disease and surgery is not the same for all. The surgery based on opportunities and accessibility to health care.

The different surgical procedures have been done in order to manage rheumatic heart diseases conditions. Mechanical valve replacement: mitral in 46 patients (66.7%), aortic in 8 patients (11.6%) tricuspid in 4 patients (5.8%). Biological valve replacement was done in different interventions too: mitral: 6 patients (8.7%), aortic: 2 patients (2.9%) and tricuspid biological valve replacement in 4 patients (5.8%). Valve repair: mitral in 13 patients (18.8%), tricuspid in 8 patients (11.6%) and aortic valve repair was done in 3 patients (4.3%). There have been different surgical interventions from one patient. There were 3 patients with mitral and tricuspid valve repair, 2 patients with tricuspid repair and mitral biological valves, 3 tricuspid repair with mitral mechanical valve and 4 patients with mechanical tricuspid and mitral mechanical valve replacement. Also 2 patients had mitral and aortic valve repair, one had aortic valve repair and mitral mechanical valve replacement and 5 patients had both aortic and mitral mechanical valve replacement.

In study of Raja Parvez Akhtar et al., mitral valve replacement was done in 52.9% of patients; mitral and aortic valve replacement was done in 18.9% of patients and aortic valve replacement was done in 15% of the patients. Implanted valves were ball and cage (68%), bileaflets (24.9%) and single disc (7.1%).(Raja Parvez akhtar et al., 2009) The study concerned both children and adults who have undergone open heart surgery for rheumatic heart disease.

The study done byNeal D. Hillman has shown that the most surgical indications of surgery were mitral regurgitation 31%, mitral and aortic regurgitation in 27%, mitral regurgitation and stenosis in 15%, aortic regurgitation in 15%, mitral valve regurgitation and stenosis with aortic regurgitation in 8% mitral regurgitation and tricuspid regurgitation in 4%.(Neal D. Hillman,

Lloyd Y. Tani, L. George Veasy,et al., 2004)Eighty-four percent of patients underwent mitral valve surgery. Among these patients, 86.36% underwent mitral valve repair and 13.63% had mitral valve replacement. The aortic valve repair was done in 15.3% and aortic valve replacement was done in 34.6%.(Neal D. Hillman, Lloyd Y. Tani, L. George Veasy,et al., 2004)This is different from what has been found in Rwanda for adult patients with RHD surgery where valve repair was 17.4% of procedures (mitral repair: 15.1 % and tricuspid repair: 11.6% of interventions). Twenty three biological valve implantations have been done mostly in women (18 patients). The rest of procedures were mechanical valve replacement.(JaBaris D,S. et al. , 2014)

The latter study was done in adults with RHD surgery; the farmer was retrospective concerning the children with RHD surgery. Though there is this difference, the mitral valve is the most one affected in rheumatic heart disease and most of time is found at advanced stage of damage and hence necessitating surgery. The mechanical valve replacement is more preferred, though it does require regular anticoagulation therapy, it is more lasting than biological valve. The biological valve does not require anticoagulation; however, it is short lived and requires another surgery in shorter time.(JaBaris D,S. et al. , 2014; Audrey Chepkemoi Kironget, Paul Kiptoon, Myra Koech, 2014; S. S. Danbauchi, M. A. Alhassan, S. O. David, R. Wammanda and I. A.Oyati, 2004; Neal D. Hillman, Lloyd Y. Tani, L. George Veasy,et al., 2004)

The interval between diagnosis and surgery is long and due to lack of limited settings and personnel, few visiting teams and mere means to refer the patients abroad to benefits the high standard care. (Eloi Marijon et al., 2012; Liesl Zühlke et al., 2013;0:1–8; Frank Edwin et al., 2011; ChodchanokVijarnsorn et al., 2011)

4.5 MAJOR EVENTS AFTER SURGERY

Few patients (39.1%) were readmitted after surgery. The major problems after surgery were: heart failure (in 8 patients) and bleeding disorder on Warfarin (in 9 patients). Other causes of readmission after surgery were thrombo-embolism and/or embolic stroke in 6 patients, infective endocarditis (in 3 patients). This nearly correlates with the study done by JaBaris in Rwanda where the major causes of readmission were stroke in one patients and bleeding in 2 patients.(JaBaris D,S. et al. , 2014)Six patients died after due to different causes.

These complications may be related to surgery like dehiscence or regurgitation of valve replacement, scarring or calcification of biological valve or even poor INR checking and Warfarin dosing and compliance.(JaBaris D,S. et al. , 2014; Raja Parvez akhtar et al., 2009)Health care professionals should emphasize on compliance of anticoagulation therapy, diet restrictions for all patients taking anticoagulation. General hygiene, oral other preventive measures against infective endocarditis are of great value in this category of people.

4.6 POST-OPERATIVE FOLLOW-UP

After surgery most children had notably good clinical evolution. They become asymptomatic. Majority of people present improved heart function with NYHA I mainly and few cases with NYHA II. (JaBaris D,S. et al. , 2014; Neal D. Hillman, Lloyd Y. Tani, L. George Veasy,et al., 2004) This indicates the great benefit of surgery and the improved nutritional status of patients after surgery.

INR was ranging from 1 to7.5 with mean of 2.53±1.25 for the study population.

Raja et al. found that INR mean was 2.6± 0.59.(Raja Parvez akhtar et al., 2009) In their study of Ragab S. Shehata et al. found that INR value was changing depending on compliance: in compliant people, the mean INR was 2.28 ± 0.61, however in non-compliant people, the mean INR was 2.18 ± 0.65.(Ragab S. Shehata et al, 2014)

People with mechanical valve have to take anticoagulation. Warfarin dose has been ranging between 1to 12.5 mg with mean of 6 mg±2.5. Warfarin was regularly taken in three quarters of patients (75.5%), the main reasons of poor compliance were ignorance: 50%, procurement problem (25%) and poverty (16.7%).

Ragab S. Shehata et al. found that 61.1% of patients were compliant to Warfarin, and 31.9% were found non-compliant, male patients were less compliant than female patients. The rest was missing.(Ragab S. Shehata et al, 2014) The associated factors were age (younger less compliant), sex (male less compliant), social conditions (living alone less compliant, poorly educated) as well as single drug intake (those taking Warfarin only without other medications). Female people tend to be more careful than the male people.(Ragab S. Shehata et al, 2014)

For the study done by Raja et al., the mean of Warfarin dose was 5.16 mg ± 1.6 mg.(Raja Parvez akhtar et al., 2009) Ragab S. Shehata found that the dose of Warfarin changed with compliance: in compliant patients, the mean Warfarin dose was 3.29 mg, however in non-complaint patients; the mean dose of Warfarin was 4.05mg.(Ragab S. Shehata et al, 2014) Increased doses were found in children with poor compliance to Warfarin and to diet regimen, hence needing high doses of Warfarin to counteract the effect of vitamin K. It requires regular follow-up and education of patients about the importance of anticoagulation after mechanical valve replacement.(JaBaris D,S. et al. , 2014; Ragab S. Shehata et al, 2014)This should raise awareness of the health system about the need of anticoagulation management and sensitize patients (and their families) about post-operative management.

The causes of poor compliance were nearly similar to those of poor INR check –up where ignorance and poverty remain challenging aspects in follow-up of these patients. This finding would help us to predict the need extent of Warfarin in mechanical valve replacement hence facilitating the procurement and preventing stock out incidents in different health facilities.

In the secondary prophylaxis, the most used antibiotic is Benzathine Penicillin G (Extencilline) (69.6%), few patients were taking daily oral Penicillin V (30.4%). The compliance was as good as 56.5%. The major reasons of poor compliance were generally ignorance: 74.2%, poverty and procurement problem at 9.7% each. In study done by Brunelle Gasse et al., they found that compliance to secondary prophylaxis was 46%. The factors of good adherence were household of 5 people or more, adequate health care coverage and previous symptomatic ARF.(Brunelle Gasse, Noémie Baroux, Bernard Rouchon, Jean-Michel Meunier, Isabelle De Frémicourt, 2013)

As Extencillin is given once a month, the compliance would be high and it is far more effective than oral Penicillin. (Manyemba, J, Mayosi, B M, 2002) However the policy should be changed to once two weeks IM injection of Extencillin because it is proved to be more effective to monthly administration. Extencillin is more effective than daily oral Penicillin V.(Brunelle Gasse, Noémie Baroux, Bernard Rouchon, Jean-Michel Meunier, Isabelle De Frémicourt, 2013; Manyemba, J, Mayosi, B M, 2002) The population should be sensitized about the importance of secondary prophylaxis in order to increase their compliance and prevent other possible rheumatic attacks.

There has been adverse outcome after heart surgery. Of enrolled population, 63 are alive and 6 (8.69) died: 4 female and 2 male patients. The most frequent causes of death were heart failure (3 patients), dilated cardiomyopathy and infective endocarditis in 2 patients each.

In study of Neal Hillman, there were 2 deaths (7.7%): one was due to traffic accident, another one was due to ischemic stroke secondary to thrombo-embolism ten year after mechanical mitral valve replacement.(Neal D. Hillman, Lloyd Y. Tani, L. George Veasy,et al., 2004)

All patients who died were in NYHA IV before surgery. Advanced NYHA classes are associated with higher mortality. The same finding has been observed in study done by André Maurício Souza Fernandes et al. where NYHA classes III and IV were statistically associated with mortality.(André Maurício Souza Fernandes,Gustavo Maltez de Andrade, Rafael Marcelino Oliveira et al., 2014)

The advanced NYHA classes usually are associated with poor clinical condition; hence, the surgery does not need to be delayed. Measures have to be taken to resolve the issues of limited infrastructures and qualified personnel, which will allow early diagnosis and management of patients with rheumatic heart diseases.

CONCLUSION AND RECOMMENDATIONS

CONCLUSION

This study assessed the outcomes of rheumatic heart disease surgery in Rwandan children and found that the surgery is associated with good clinical outcomes. There is much improvement of heart function and clinical presentation of patients. However, children who undergo open heart surgery need thorough clinical and psychosocial follow-up. Preventive measures of acute rheumatic fever and rheumatic heart disease should be among health prevention program priorities.

RECOMMENDATIONS

The Government and stakeholders in health system should focus on addressing scientifically the problems related to prevalence, incidence and distribution of rheumatic heart disease. There is need of clear plan for follow-up of children who have been operated for rheumatic heart disease.

To referral hospitals:

1. Devise a clear program of follow-up of rheumatic heart disease children, especially those who have been operated,
2. Increase number of qualified personnel and infrastructures for management and follow-up of operated children operated for rheumatic heart disease.

To Ministry of Health:

1. Train qualified personnel and set appropriate infrastructures for management of rheumatic heart disease in children (medical and surgical),
2. Assist people needing emergency surgery for rheumatic heart disease to get access to surgical services,
3. Set a psychosocial management and follow-up in package of management for all patients operated for rheumatic heart disease and have adapted chart of quality of life for children.
4. Set a national rheumatic heart disease and rheumatic heart disease surgery registry.

To next researchers:

1. Do a cohort study of children who have been operated for rheumatic heart disease.

REFERENCES

Frank Edwin et al. (2011). The development of cardiac surgery in West Africa - the case of Ghana. *Pan African Medical Journal., 9* (15).

André Maurício Souza Fernandes,Gustavo Maltez de Andrade, Rafael Marcelino Oliveira et al. (2014). Evaluation of variables responsible for hospital mortality in patients with rheumatic heart disease undergoing double valve replacement. *Rev Bras Cir Cardiovasc, 29* (4), pp. 537-542.

Audrey Chepkemoi Kironget, Paul Kiptoon, Myra Koech. (2014, December). Echocardiographic characteristics of children with rheumatic heart disease at Moi Teaching and referral hospital (MTRH), Eldoret, Kenya. *European Journal of Biology and Medical Science Research, 2* (4), pp. 17-29.

Brunelle Gasse, Noémie Baroux, Bernard Rouchon, Jean-Michel Meunier, Isabelle De Frémicourt. (2013). Determinants of poor adherence to secondary antibiotic prophylaxis for rheumatic fever. *BMC Public Health, 13* (131).

ChodchanokVijarnsorn et al. (2011). Surveillance of Pediatric Cardiac Surgical Outcome Using Risk Stratifications at a Tertiary Care Center in Thailand. *Cardiology Research and Practice* , p. 9 pages.

Eloi Marijon et al. (2012, March 10). Rheumatic heart disease. *Lancet, 379*.

Evarist T.M Nyawawa et al. (2010, March-April). Cardiac surgery: one year experience of cardiac surgery at Muhimbili National Hospital, Dar Es Salaam, Tanzania. *East and Central African Journal of Surgery, 15* (1), pp. 111-118.

Gene Bukhman et al. (2011). *The PIH guide to Chronic Care Integration for endemic non communicable diseases* (Rwanda Edition ed.).

JaBaris D,S. et al. . (2014, April). Partnership for sustainability in cardiac surgery to address critical Rheumatic Heart Disease in Sub-Saharan Africa: the experience from Rwanda. *World Journal of Surgery* .

Juan R. Leon-Wyss et al. . (2009). Pediatric Cardiac Surgery: A Challenge and Outcome Analysis of the Guatemala Effort. *Pediatric Cardiac Surgery Annals* , pp. 8-11.

Lawrence J. (2012). The Worldwide Environment of Cardiovascular Disease:Prevalence, Diagnosis, Therapy, and Policy Issues: A Report From the American College of Cardiology. *Journal of the American College of Cardiology, 60 suppl S* (25).

Liesl Zühlke et al. (2013;0:1–8). Congenital heart disease and rheumatic heart disease in Africa: recent advances and current priorities. *Heart, 0*, pp. 1–8.

Manyemba, J, Mayosi, B M. (2002). Penicillin for secondary prevention of rheumatic fever. *Cochrane database of systematic reviews (Online)* (3).

Mohammed Rafique Essop, Vuyisile T. Nkomo,. (2005). Rheumatic and Nonrheumatic Valvular Heart Disease: Epidemiology, Management, and prevention in Africa. *Circulation, 112*, pp. 3584-3591.

Neal D. Hillman, Lloyd Y. Tani, L. George Veasy,et al. (2004). Current status of surgery for rheumatic carditis in children. *Annals of Thoracic Surgery, 78*, pp. 1403-1408.

Ragab S. Shehata et al. (2014). Compliant to Warfarin Therapy after Mechanical Heart Valve Replacement. *Open Journal of Thoracic Surgery, 4*, pp. 39-43.

Raja Parvez akhtar et al. (2009). Anticoagulation in patients following prosthetic heart valve replacement. *Annals of thoracic and cardiovascular surgery, 15* (1).

S. S. Danbauchi, M. A. Alhassan, S. O. David, R. Wammanda and I. A.Oyati. (2004). Spectrum of rheumatic heart disease in Zaria, Northern Nigeria. *Annals of African Medicine, 3* (1), pp. 17 – 21.

S.L. Rohde et al. (2010, September). Excellent Cardiac Surgical Outcomes in Paediatric Indigenous Patients, but Follow-up Difficulties. *Heart, Lung and Circulation, 19* (9), pp. 517–522.

Sorour, K. A. (2014). Rheumatic heart disease in Egypt: Gloomy past and promising future. *The Egyptian Heart Journal, 66*, pp. 139-142.

Tefera E et al. (2014). Treatment of Children with Rheumatic Heart Disease in Sub-Saharan Africa by Overseas' Medical Missions: Challenges Left Behind. *Journal of Cardiology and Clinical Research, 2(1)* (1016).

Timothy F. Feltes et al. (2011). Scientific Statement From the American Heart Association: Indications for Cardiac Catheterization and Intervention in Pediatric Cardiac Disease:. *Circulation, 123*, pp. 2607-2652.

V, S. (2006). Rheumatic fever and rheumatic heart disease in Samoa. *Pacific Public Health , 13* (2).

Yusuf, S. (2001). Epidemiologic Transition, Risk Factors, and Impact of Urbanization Global Burden of Cardiovascular Diseases. *Circulation, 104*, pp. 2746-2753.

APPENDICES

Appendix 1. Appendix A. Information form for the study participants care takers – English Version

TOPIC: "clinical outcomes of Rwandan children operated for rheumatic heart disease followed up at tertiary level".

Dear Participants,

You have been invited to take part in a research project concerning outcomes of Pediatric Cardiac Surgery for rheumatic heart disease in Rwandan children attending general Pediatrics aged 16 years and less at King Faisal Hospital, Kigali University Teaching Hospital and Butare University Teaching Hospital as well Rwanda Military Hospital. The objective of the study is to determine the outcomes of cardiac surgery for rheumatic heart disease in Rwandan children.

Before joining the project in question, you need to read this information form, since it contains important information to assist you in deciding whether or not signing up to participate is in your best interest. We request that you ask as many questions as you wish in order to make sure that you understand the procedures for the study, the risks and benefits. If you have a question about this document that has not been sufficiently answered or explained, do not hesitate to ask one of the research team members for more information. The physician is conducting this study for obtaining his MMED in Pediatrics he will not be paid. Your participation in this trial is voluntary. You may choose not to participate in this study. Choosing to participate or not will not affect your treatment in any way in-case of being unwell. You will still have all the benefits that would otherwise be available for you.

We are attempting to explore the burden of Rheumatic Heart Disease in Rwanda, especially surgical outcomes in Rwandan children. It will base on your clinical files and records and present clinical and paraclinical findings. You will have to acknowledge if you want to be informed of the results of the analysis or not by the physician, and leave a way for him to contact you. In case you change your mind in either way during or after the study, you may inform the study physician, and he will comply with your wishes.

After this important study is done we will be able to give relevant information to policy makers so that they can update their policies in the long run improve patient care and management of rheumatic heart disease in children.

All documents that identify you will be held in the strictest confidence and will not be released to the public. The physician principal investigator will use the child informationto perform the study. The form will only have a number, not the child's name and it will be stored in a secure place. Confidential information will only be used for research purpose and that obtained in the course of the study will only be communicated to the medical team managing your child and no one else without your permission.

The child will be identified by a code number in each report for publication produced based on this study. In order to ensure that the study data collected about the child are correct and truly relate to him / her, a group of hand-picked individuals, as well as representatives of governmental regulatory agencies, and members of the Ethics Committee will have access to your personal information at the research center. These persons will be required to keep this information confidential. By signing this document, you are allowing this access. The data may be used in the following purposes:

-To give appropriate orientation,

-To give access to other management to the child where necessary and applicable.

-To compare the results with previously published data

-To create new policies management of children with rheumatic heart disease before and after surgery.

You have the right to demand that the study physician allow you to view the personal data collected on your child and make any corrections to it, which may be necessary.

You will not receive any salary for participating in this study. We hope to better understand that these diseases under study, and perhaps through this research, develop new approaches to management of these illnesses. A written report will also be given to the parents of the child participants upon request, whom they can share with their families. We will also publish the results in order that other interested people may learn from our research.

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Dr Naphtal NYIRIMANZI , MD,MMED YEAR IV

Principal Investigator

University of Rwanda, College of Medicine and Health Sciences, Department of Pediatrics, PG year IV. Email:naphtal7@gmail.com
Cell:+250 783156255

Dr. Emmanuel K. Rusingiza,
Supervisor ,
Department of Pediatrics and Child Health, University Teaching Hospital of Kigali.
E- mail: erkamanzi@gmail.com
Cell:+ 250785466254

This study proposal will have to be approved by the CHUK and University review board. These are committees whose task it is to make sure that research participants are protected from harm. Additionally, the trial will be conducted in accordance with the Helsinki Declaration and the Guide on Best Clinical Practices.

Appendix 2.Amakuru ajyanye n'ubushakashatsi mu Kinyarwanda

Ifishi y'ikinyarwanda

Ubushakashatsi bujyanye no kureba ibiva mu mu kubaga abana barwaye indwara zijyanye n'umutima kubera gapfura, batarengeje imyaka icumi n'itandatu (igihe cyo kubagwa). Intego rusange y'ubu bushakashatsi ni ukumenya ikigereranyo cy'abana babazwe indwara z'umutima kubera gapfura, ingaruka n'ibyiza nyuma yo kubagwa.

Nshuti bakundwa bitabiriye iki gikorwa,

Mutumiwe kugira uruhare muri uyu mushinga w'ubushakashatsi urebana n'ikusanyamakuru ndetse n'ikigereranyo cy'ibiva mu kubaga indwara z'umutima kubera gapfura zabazwe mu bana byibura bafite imyaka icumi n'itandatu mu Rwanda cyangwa hanze y'igihugu. Mbere y'uko umwana wawe yinjira muri uyu mushinga, ugomba gusoma neza amakuru akubiyemo kuko ari ingira-kamaro yagufasha mu gufata icyemezo cyo kubigiramo uruhare cyangwa se kubisinyira ku bw'inyungu zawe bwite.Tugusabye kubaza ibibazo byinshi bishoboka uko ubyifuza kugira ngo usobanukirwe neza uburyo buzakoreshwa muri iyi nyigo, ingorane n'inyungu birimo. Uramutse ugize ikibazo kuri iyi nyandiko kitashubijwe neza cyangwa kitasobanuwe neza, ntushidikanye kubaza umwe mu bagize itsinda ry'ubu bushakashatsi kugira ngo bagusobanurire. Umuganga uzayobora ubu bushakashatsi ni umunyeshuri mu kiciro cy'inzobere mu kuvura abana nta gihembo ahabwa n'umutera-nkunga kugira ngo akore iri suzuma. Kureka umwana wawe akagiramo uruhare ni ubwende bwawe. Ushobora guhitamo ko atagira uruhare muri iyi nyigo. Kutabigiramo uruhare kwe ntacyo bizamutwara mu kwivuza kwe gusanzwe .

Turimo gushakisha kumenya no gusesengura ibijyanye n'ibiva mu kubaga indwara zijyanye n'umutima kubera gapfura mu bana batarengeje imyaka 16 bivuriza mu Bitaro bya Kaminuza bya Kigali n'ibya Butare, Ibitaro byitiriwe Umwami Fayisali ndetse n'Ibitaro Bikuru bya Gisirikari, baba barabagiwe mu Rwanda cyangwa hanze y'igihugu. Ibizava muri ubu bushakashatsi bizafasha leta gushyiraho ingamba nshyashya. Tuzifashisha amakuru tuzajya tubona mu gusuzuma umwana ndetse n'ifishi ye yo kwa muganga. Ni biba ngombwa tuzakoresha n'ibindi bizamini kugirango tugire amakuru ahagije ku buzima bw'umwana ku bijyanye n'indwara z'umutima ziterwa na gapfura. Ugomba kumenyesha niba wifuza kumenya ibisubizo by' ibyavuye muri iri suzuma cyangwa se ko wabihabwa n'undi muntu. Icyo gihe

uzasiga uburyo bakumenyesha. Uramutse wisubiyeho mu buryo ubwo ari bwo bwose mu gihe cy'iyi nyigo cyangwa se nyuma wamenyesha umuganga ukora kuri iyi nyigo, nawe azagendera ku byifuzo byawe.

Nyuma y' iyi nyigo y'ingira- kamaro, tuzaba dushobora gutanga amakuru ya ngombwa ku bafata ibyemezo babishinzwe kugira ngo babe babasha guhindura ibyemezo byafatwa by'igihe kirekire, mu guhindura no kwita ku barwayi ndetse no mu miyoborere ku bijyanye n'abana babagwa indwara zijyanye n'umutima kubera gapfura.

Ibyangombwa byose biranga umwana, bizashyirwa mu ibanga rikomeye kandi ntabwo bizashyirwa ku ka Rubanda. Umuganga n'itsinda rigize ubu bushakashatsi bazakoresha amakuru y'umwana wawe bwite mu gukora iyi nyigo. Ariko rero, aya makuru yerekeye umwana ntabwo azinjizwa mu mpapuro (data) zizohererezwa umwishingizi wawe cyangwa abamuhagarariye. Uzamenyekanira ku mubare w'ibanga uzagaragara kuri buri raporo izakorwa ishingiye kuri iyi nyigo. Kugira ngo bigaragare neza koko ko amakuru (data) ari ukuri, kandi ko yerekeye ku mwana, hari itsinda ry'abantu bigenga bazakoreshwa muri iyi nyigo kugira ngo bakorere umwishingizi, hamwe n'abagenzuzi ba Leta n' abagize komite yiga ku miterere y'abantu Ethics committee). Aba bazaba bafite uburenganzira kuri aya makuru aho ubushakashatsi buzakorerwa. Aba bantu basabwa kugira aya makuru ibanga rikomeye. Nusinya iyi nyandiko, uzaba utanze uburenganzira bw'uko aya makuru agerwaho. Umwishingizi cyangwa abamuhagarariye bashobora gukoresha amakuru avuye muri iyi nyigo bazaba bohererejwe, ku mpamvu zikurikira:

-Kumenya aho umwana yoherezwa
-Kugereranya ibivuye mu bushakashatsi n'ibindi byatangajwe mbere
-Gushyiraho ingamba nshya mu byerekeye gufasha no kwita ku bana babazwe indwara zijyanye n'umutima kubera gapfura.

Nta mushahara uzahembwa kubera ko wagize uruhare muri iyi nyigo. Twizeye ko tuzasobanukirwa neza iby'izi ndwara zizigwaho, kandi wenda muri ubu bushakashatsi hazavamo uburyo bushya bwo kwita ku bana babazwe indwara zijyanye n'umutima. Hazabaho gutanga inyandikomvugo ku babyeyi b'abana babigizemo uruhare ariko ari uko babisabye, kugira ngo babiganireho n'imiryango yabo. Tuzanatangaza ibyavuyemo kugira ngo ababyifuza babe bashobora kwigira kuri ubu bushakashatsi bwacu.

Uramutse ugize ikibazo icyo ari cyo cyose wakibaza ubu nonaha cyangwa se nyuma, yewe na nyuma y'uko iyi nyigo izaba yaratangiye gukorwa. Ushatse kubaza nyuma wabaza aba bakurikira:

Dr Naphtal Nyirimanzi , MD,MMED YEAR IV

Principal Investigator
University of Rwanda, College of Medicine And Health Sciences, Department of Pediatrics, PG Year IV

Email:naphtal7@gmail.com Cell :+250 783156255

Dr. Emmanuel Rusingiza
Supervisor,
Department of Pediatrics and Child Health,
Kigali University Teaching Hospital
E-mail: erkamanzi@gmail.com, Tel: +250 785466254

Appendix 3. Consent form for care taker of child-English Version

Clinical outcomes of Rwandan children operated for rheumatic heart disease followed up at tertiary level
Study no……
I, hereby, fully consent on behalf of my child to participate in this study on the **"Clinical outcomes of Rwandan children operated for rheumatic heart disease followed up at tertiary level".**
I agree my child to participate in this study. I understand that I will incur no additional medical costs as a result of participation in this study. I have been fully informed about the purposes of the evaluations that will be done. I also understand that I may withdraw my child at any time with no adverse consequences whatsoever. I agree that on condition of anonymity, the information obtained from these assessments shall be used for educational and research purposes only. This research will lead to create new policies in pediatrics population. The results of this study will assist in availing information to be used and impetus for increased research in this area, which could ultimately lead to successful interventions to prevent or attenuate these effects. Upon request, I shall have access to the assessment findings as well as a summary of the research finding at the completion of this study. I am also aware that I can contact Dr. Naphtal NYIRIMANZI on Telephone +250783156255 , Dr Emmanuel RUSINGIZA, on Telephone: +250 78546254 in case of any further clarification or queries.

Address Telephone	

My signature below, is my acknowledgement that:

- I have read the information sheet and consent form for this study,
- I had the opportunity to ask questions and the answers were satisfactory for me,
- I took time to discuss this information with others and to decide to take part or not,
- I will receive a dated and signed copy of the consent form,
- I agree to take part in this study.
- I have decided upon if I want to be informed about the results

Subject	**Person giving consent**	**Researcher**

Name (BLOCK LETTERS),		
Signature/ thumbprint		
Date:		

Appendix 4.Consent form for care taker of child -Kinyarwanda version

Ubushakashatsi mu kumenya icyegeranyo cy'ibiva mu kubaga abana b'abanyarwanda barwaye indwara zijyanye n'umutima ziterwa na gapfura bakurikiranwa mu bitaro bikuru.
Inumero y'ubushakashatsi……
Jyewe nemeye rwose ko umwana wange azagira uruhare kuri iyi nyigo irebana n'ubushakashatsi mukumenya icyegeranyo cy'ibiva mu kubaga abana b'abanyarwanda barwaye indwara z'umutima n'imiheha y'amaraso bitewe na gapfura.
Nsobanukiwe neza ko nta kindi kiguzi cy'ubuvuzi nzasabwa kubera ko nagize uruhare muri iyi nyigo. Kandi nsobanukiwe neza ko kubivamo igihe icyo ari cyo cyose nta ngaruka iyo ariyo yose byagira. Nemeye ko byaba ibanga gukoresha amakuru yavuye muri iri suzuma rizaba ryakozwe, yakoreshwa gusa mu kwiga no mu bushakashatsi. Ibizava muri iyi nyigo bizafasha mu gutanga amakuru yakoreshwa mu igena-migambi . Ndamutse mbisabye nshobora kubona ibyavuye muri iyi nyigo ndetse n'incamake y'ibyo ubushakashatsi buzaba bwaragezeho iyi nyigo irangiye. Ikindi kandi, nzi neza ko nshobora kuba nahamagara Dr. Naphtal NYIRIMANZI: +250783156255, Dr. Emmanuel RUSINGIZA, kuri Telephone: +250 78546254 ndamutse ngize ikibazo.

Address	
Telefone	

Umukono wanjye hasi uremeza ko:

-Nasomye amabwiriza ari kuri uru rupapuro yerekeye iyi nyigo.

-Nabonye umwanya wo kubaza kandi ko nahawe ibisubizobinyuze

- Nemeye kugira uruhare muri iyi nyigo.

- Nahisemo niba nifuza kumenyeshwa ibavuyemo cg niba ntabishaka.

	Uhagarariye umwana	**Umushakashatsi**
Amazina		
Umukono cyangwa igikumwe		
Italiki		

Appendix 5.Assent form for a child aged 10 years and above-English Version

Clinical outcomes of Rwandan children operated for rheumatic heart disease followed up at tertiary level		
Study no……		
I, hereby, fully assent to participate in this study on the **"Clinical outcomes of Rwandan children operated for rheumatic heart disease followed up at tertiary level**"		
I have been fully informed about the purposes of the evaluations that will be done. I also understand that I may withdraw at any time with no adverse consequences whatsoever. I agree that the information obtained from these assessments shall be used for educational and research purposes only. The results of this study will assist in availing information to be used and impetus for increased research in this area, which could ultimately lead to successful interventions to prevent or attenuate these effects in children. I am also aware that I can contact Dr. Naphtal NYIRIMANZI on Telephone +0783156255, Dr. Emmanuel RUSINGIZA, on Telephone: +250 785466254 in case of any further clarification or queries.		
My signature below, is my acknowledgement that I agree to take part in this study.		
Subject	**Person obtaining assent**	**Researcher**
Name (BLOCK LETTERS), signature/ thumbprint	**Name (BLOCK LETTERS), signature/ thumb print**	**Name (BLOCK LETTERS), signature**
Date:	**Date:**	**Date:**

Appendix 6.Informed assent form for child aged above 10 years -Kinyarwanda version

Ubushakashatsi mu kumenya icyegeranyo cy'ibiva mu kubaga abana b'abanyarwanda barwaye indwara zijyanye n'umutima ziterwa na gapfura bakurikiranwa mu bitaro bikuru.
Ubushakashatsi numero……
Kugira uruhare kuri iyi nyigo irebana n'ubushakashatsi mu kumenya icyegeranyo cy'ibiva mu kubaga abana b'abanyarwanda barwaye indwara zijyanye n'umutima ziterwa na gapfura bakurikiranwa mu bitaro bikuru.
Nsobanukiwe neza ko nta kindi kiguzi cy'ubuvuzi nzasabwa kubera ko nagize uruhare muri iyi nyigo.Kandi nsobanukiwe neza ko kubivamo igihe icyo ari cyo cyose nta ngaruka iyo ariyo yose nagira. Nemeye ko byaba ibanga gukoresha amakuru yavuye muri iri suzuma rizaba ryakozwe, yakoreshwa gusa mu kwiga no mu bushakashatsi . Ibizava muri iyi nyigo bizafasha mu gutanga amakuru yakoreshwa mu igena-migambi. Ndamutse mbisabye nshobora kubona ibyavuye muri iyi nyigo ndetse n'incamake y'ibyo ubushakashatsibuzaba bwaragezeho iyi nyigo irangiye. Ikindi kandi, nzi neza ko nshobora kuba nahamagara Dr. Naphtal NYIRIMANZI: +25073156255, Dr Emmanuel RUSINGIZA: +25078 5466254 ndamutse ngize ikibazo.
Umukono wanjye hasi uremeza ko; -Nasomye amabwiriza ari kuri uru rupapuro yerekeye iyi nyigo. -Nabonye umwanya wo kubaza kandi ko nahawe ibisubizobinyuze -Nabonye umwanya wo kubijyaho impaka n'abandi nkaba nafata icymezo cyo kubyemera cg kubireka. - Nemeye kugira uruhare muri iyi nyigo.

Subject	**Person obtaining assent**	**Researcher**
Name (BLOCK LETTERS), signature	**Name(BLOCK LETTERS),signature**	**Name (BLOCK LETTERS), signature**
Date:	**Date:**	**Date:**

Appendix 7.Data collection form for study

"Clinical outcomes of Rwandan children operated for rheumatic heart disease followed up at tertiary level".

N^{o}……

Patient ID number and initials……...

Date and time……...

Data collector…….....

Items	Variables	Labels	Sub-labels
Identification and demographic data	Age (in years/months)	……..	
	Sex	Male=1	
		Female=2	
	Weight (kg)…../Z score	……/…….	
	Height (cm)…../Zscore	……/…….	
	District/province	……/……..	
	Socio-economic conditions (ubudehe)=mutuellle	Low =1	
		Middle =2	
		Fair =3	
	Health insurance	None =1	
		Community health =2	
		RSSB =3	
		MMI=4	
		Other (national)=5	
		International=6	
		Private=7	
History and clinical presentation of disease	Nutritional status before surgery	Poor=1, Good=2	
	NYHA classification	I=1, II=2, III=3, IV=4	
	Atrial fibrillation	Yes=1, no=2	

Regurgitation	No	Mild	Moderate	Severe
Mitral				
Aortic				

	Tricuspid				
	Pulmonary				
	Stenosis	No	Mild	Moderate	Severe
	Mitral				
	Aortic				
	Tricuspid				
	Pulmonary				
	Left ventricle dimension	……..			
	EF LV	…….....			
	Nutrition status	Poor=1, Good=2			
	Other comorbidities	…….			
Operation	Country	Team		Hospital	
	Year	Age ……..			
	Type	……..			
		No	Valve repair (type)	Biological prosthesis (type)	Mechanical prosthesis (type)
	Mitral				
	Aortic				
	Tricuspid				
	Pulmonary				
	Previous infective endocarditis surgery	Yes=1 No=2			
	Stay in ICU	In days=……			
	Stay on Bypass(in minutes)	…….			
	Aortic clamp (in minutes)	…….			
	Time between diagnosis and operation (in months)	…….			
	Time since operation and study (in months)	…….			

	Total stay in Hospital (days)	…….				
Major Events after surgery	Readmission after surgery	Yes =1 No=2		Episodes:…		
	Problems:	1. 2. 3.				
Follow-up	Center of follow-up	CHUK=1, KFH=2, CHUB=3, RMH=4				
	Rate of follow-up After 3 months post-operative	Monthly=1				
		Once 2 months =2				
		Once 3 months =3				
		6 months=4				
		Yearly =5				
		Never =6				
	Regularity	No=1, yes=2				
	If irregularity, why?	Distance=1, Cost=2, Unclear information =3, Tutor problem=4 Poverty=5 Other to specify……..				
	Symptomatic	NYHA				
	Mitral valve	Regurgitation	No	Mild	Moderate	Severe
		Dehiscence	No	Mild	Moderate	Severe
		Mean gradient (in mmHg)……				
	Aortic valve	Regurgitation	No	Mild	Moderate	Severe
		Dehiscence	No	Mild	Moderate	Severe
		Mean gradient (in mmHg)……				
	Tricuspid	Regurgitation	No	Mild	Moderate	Severe
		Stenosis	No	Mild	Moderate	Severe

		Doppler gradient	……		
	Pulmonary hypertension	no	Mild	Moderate	Severe
		TR gradient/Estimated Pulmonary arterial pressure	……..		
	RVSP(Right Ventricle Systolic Pressure: mmHg				
	Left ventricular dimension	LVIDs	……..Z score		
		LVIDd	……..Z score		
	LV ejection fraction	…….			
	Thrombus	Yes=1, No=2			
	Other findings	……..			
	Evolution of EF	Statuquo =1, Improving=2, Worsening=3			
	INR	Not done: 1			
		Irregularly done: 2			
		Regularly done: 3			
	Reason of irregularity of INR	Poverty: 1			
		Geographic barrier: 2			
		Machine problem: 3			
		Pain=4			
		Other reason: ……			
	INR range for 3 previous visit	Normal:1			
		High=2			
		Low			
	Last 3 INR	1	Date		
		2	Date		
		3	Date		
	Warfarin compliance	Irregular:1			
		Regular:2			

	Reason of irregularity/non-compliance	Procurement problem:1	
		Poverty :2	
		Geographic barrier	
		Other reason:	
	Warfarin dose(mg)		
	Antibioprophylaxis	Monthly IM Extencillin	
		Daily oral Penicillin	
	Compliance	Regular=1, irregular=2	
	Reason of irregularity	Distance =1	
		Poverty =2	
		Pain =3	
		Ignorance =4	
		other =5	
	Others Medications	Beta blockers	
		Calcium channel blockers	
		Diuretics	
		ACE inhibitors	
		Digoxin	
		Aspirin	
		Antiarrhythmic drugs	
		Others	
Current situation	Alive	……..	
	Loss of follow-up	……	
	Died	In-hospital post-operative period:1	
		Within 1 month:2	
		1-3 months:3	
		4 -6 months:4	

		7-12 months:5	
		After 1 year:6	
	Place of death		
Causes of death	1. 2. 3. 4. 5.		

Other possible comments

……..……..

……..……..

……

……

Appendix 8.Assessment quality of life after rheumatic heart disease surgery (adapted chart)

HOW SATISFIED ARE YOU WITH	**Very Dissatisfied**	**Moderately Dissatisfied**	**Slightly Dissatisfied**	**Slightly Satisfied**	**Moderately Satisfied**	**Very Satisfied**
	1	2	3	4	5	6
1. Your health						
2. Your health care						
3. The amount of chest pain (angina) that you have						
4. Your ability to breathe without shortness of breath						
5. Your chances of living as long as you would like						
6. Your family's health						
7. Your family's happiness						
8. Your friends						
9. The emotional support you get from your family						
10. The emotional support you get from people other than your family						
11. How useful you are to others						
12. The amount of worries in your life						
13. Your neighborhood						
14. Your education performance						
15. Your chances for a happy future						
16. Your happiness in general						
17. Your life in general						
18. Your personal appearance						
19. Yourself in general						
20. The changes in your life that you have had to make because of your heart problem (for example, changes diet, physical activity, etc.)						

Appendix 9.Ferrans and Powers: Quality of life Cardiac Version IV

Ferrans and Powers
QUALITY OF LIFE INDEX©
CARDIAC VERSION - IV

PART 1. For each of the following, please choose the answer that best describes how ***satisfied*** you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

HOW SATISFIED ARE YOU WITH	**Very Dissatisfied**	**Moderately Dissatisfied**	**Slightly Dissatisfied**	**Slightly Satisfied**	**Moderately Satisfied**	**Very Satisfied**
	1	2	3	4	5	6
1. Your health?						
2. Your health care?						
3. The amount of chest pain (angina) that you have?						
4. Your ability to breathe without shortness of breath?						
5. The amount of energy you have for everyday activities?						
6. Your ability to take care of yourself without help?						
7. The amount of control you have over your life						
8. Your chances of living as long as your would like?						
9. Your family's health?						
10. Your children?						
11. Your family's happiness?						
12. Your sex life?						
13. Your spouse, lover, or partner?						
14. Your friends?						
15. The emotional support you get from your family?						
16. The emotional support you get from people other than your family?						
17. Your ability to take care of family						

responsibilities?						
18. How useful you are to others?						
19. The amount of worries in your life?						
20. Your neighborhood?						
21. Your home, apartment, or place where you live?						
22. Your job (if employed)?						
23. Not having a job (if unemployed, retired, or disabled)?						
24. Your education?						
25. How well you can take care of your financial needs?						
26. The things you do for fun?						
27. Your chances for a happy future?						
28. Your peace of mind?						
29. Your faith in God?						
30. Your achievement of personal goals?						
31. Your happiness in general?						
32. Your life in general?						
33. Your personal appearance?						
34. Yourself in general?						
35. The changes in your life that you have had to makebecause of your heart problem (for example, changes diet, physical activity, and/or smoking?)						

PART 2. For each of the following, please choose the answer that best describes how ***important*** that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers**.**

HOW IMPORTANT TO YOU IS	**Very unimportant**	**Moderately unimportant**	**Slightly unimportant**	**Slightly important**	**Moderately important**	**Very important**
	1	2	3	4	5	6
1. Your health?						
2. Your health care?						
3. Having no chest pain (angina)?						
4. Having no shortness of breath?						
5. Having enough energy for everyday activities?						
6. Taking care of yourself without help?						
7. Having control over your life?						
8. Living as long as you would like?						
9. Your family's health?						
10. Your children?						
11. Your family's happiness?						
12. Your sex life?						
13. Your spouse, lover, or partner?						
14. Your friends?						
15. The emotional support you get from your family?						
16. The emotional support you get from people other than your family?						
17. Taking care of family responsibilities?						
18. Being useful to others?						
19. Having no worries?						
20. Your neighborhood?						
21. Your home, apartment, or place where you live?						
22. Your job (if employed)?						

23. Having a job (if unemployed, retired, or disabled)?						
24. Your education?						
25. Being able to take care of your financial needs?						
26. Doing things for fun?						
27. Having a happy future?						
28. Peace of mind?						
29. Your faith in God?						
30. Achieving your personal goals?						
31. Your happiness in general?						
32. Being satisfied with life?						
33. Your personal appearance?						
34. Are you to yourself?						
35. The changes in your life that you have had to make because of your heart problem (for example, changes diet physical activity, and/or smoking?)						