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HEALTH RELATED QUALITY OF LIFE AFTER HYSTERECTOMY PERFORMED FOR BENIGN CONDITIONS IN TERTIARY REFERRAL HOSPITALS, RWANDA

Dissertation Submitted in Partial Fulfillment of the Requirements for the Award of Degree of Master of Medicine in Obstetrics and Gynecology of the University Of Rwanda

PRINCIPAL INVESTIGATOR

TWAHIRWA Bonaventure

REG NUMBER: 10107423

SUPERVISORS

Urania MAGRIPLES

RUKUNDO Jean Damascène

CO-SUPERVISORS

RURANGWA Théogène

RUZINDANA Kenneth

BAGAMBE Patrick

Prof RULISA Stephen

December, 21st 2020

DECLARATION

I declare that this dissertation is the result of my own work and has not been submitted for any other degree at the University of Rwanda and any institution.

Name: TWAHIRWA Bonaventure Signature:..... Date:21/12/2020

Supervisor:

I, hereby declare that this dissertation has been submitted with my approval as supervisor.

Name: RUKUNDO Jean Damascène Signature:..... Date:21/12/2020

DEDICATION

To God the almighty

To my wife and my child

To my classmates and other people

who contributed to my studies

I dedicate this work

ACKNOWLEDGEMENTS

First and foremost, this research project would not have been possible without the help and guidance from Urania MAGRIPLES, RUKUNDO Jean Damascène *and co-supervisors* despite their daily responsibilities.

I thank the University of Rwanda and its staff for having contributed enormously to the knowledge I got during residency program.

I hereby thank the authorities of CHUK, CHUB, and RMH for providing access to the medical records.

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Last but not the least I thank all patients who accepted to participate in the study.

ABSTRACT

Objective: Hysterectomy is the most common major surgical procedure performed by gynecologists. Most studies reporting on surgical procedures emphasize surgical outcomes such as operation time, surgical complications and hospital stay. Most women undergo hysterectomy to relieve symptoms and improve their health related quality of life (HRQoL). It is an important outcome variable in clinical research for benign gynecological conditions. The objective of this study was to assess the HRQoL in women after hysterectomy performed for benign gynecological conditions in Rwanda.

Methods: A prospective longitudinal study was conducted in 3 national public tertiary hospitals in Rwanda over 10 months. A total of 110 women were enrolled in the study. Health Related Quality of Life was measured using the Short-Form-36 Health Survey (SF-36) questionnaire. HRQoL scores before surgery and at 3 months postoperative were compared using nonparametric tests.

Results: The mean age of patients was 51 ± 9 years. Most of the women were premenopausal (64.1%). The most common indications for hysterectomy were fibroids (52.2%) and uterine prolapse (22.8%). Most of the hysterectomies (76.1%) were performed transabdominally. The average length of hospital stay was 6 ± 4 days. All domains showed significant improvement in HRQoL scores after hysterectomy ($p < 0.001$). The Physical Health component summary improved from 28.8 to 61.3($p<0.001$) and the Mental Health component summary improved from 35.8 to 67.0 ($p < 0.001$).

Conclusions: Health related quality of life significantly improve after hysterectomy performed for benign gynecological conditions in Rwanda. These findings are vital and may be useful to patients and health care providers in counselling women before hysterectomy.

Keywords: Health related quality of life; Hysterectomy; Benign condition

TABLE OF CONTENTS

LIST OF FIGURES AND TABLES

LIST OF FIGURES

LIST OF TABLES

ACRONYMS AND ABBREVIATIONS

AUB - Abnormal uterine bleeding

BMI - Body Mass Index

CBHI -Community Based Health Insurance

CHUB - Centre Hospitalier Universitaire de Butare

CHUK - Centre Hospitalier Universitaire de Kigali

CMHS -College of Medicine and Health Sciences

GTD - Gestational trophoblastic disease

HRQoL - Health-Related Quality of Life

IQR - Interquartile range

IRB -Institutional Review Board

LH -Laparoscopic Hysterectomy

MCS -Mental Component summary

OBGYN - Obstetrics and Gynecology

PCS -Physical Component Summary

QoL -Quality of Life

RMH - Rwanda Military Hospital

SD - Standard deviation

SF-36 -Short Form-36

SPSS -Statistical Package for the Social Sciences

TAH -Total Abdominal Hysterectomy

TVH -Total Vaginal Hysterectomy

UR - University of Rwanda

WHO - World Health Organization

INTRODUCTION

Hysterectomy is one of the most common major operation performed by gynecologist worldwide, second only to cesarean section.[1-3] It can be performed using vaginal, abdominal or laparoscopic approaches and the choice of approach is influenced by many factors.[3] Over 600,000 hysterectomies are performed in the United States annually.[2] In almost 90% of women having a hysterectomy, the surgery is carried out for benign conditions, particularly uterine fibroids, which is the most common indication for the procedure.[3] Jayasundara et al. found that total abdominal hysterectomy for non-malignant conditions was 89% and in Taiwan, Ya-Ling et al. found that the most common indication was fibroids (84.2%).[4,5]

Benign gynecological conditions can cause a diversity of physical symptoms and have a negative impact on quality of life. Hence hysterectomy provides alleviation of any of these disturbing complaints and consequently can improve the quality of life.[6] According to the definition established by the World Health Organization (WHO), quality of life is an individual's perception of life in the context of value systems and the culture in which they live and relating to their expectations, concerns, goals and standards.[4,7] This outcome variable is a broad term, dealing with environment-based quality of life and health-related quality of life (HRQoL).[6]

Nowadays, it is known that the functional impact on patients' lives of medical interventions is important in predicting the need for services, and that it is inadequate to measure outcome of medical intervention considering morbidity and mortality.[8] In many studies reporting on surgical procedures, outcome variables focus on patient morbidity such as hospital stay, surgical complications, operation time, and recurrence rate. However, from the patient's perspective, outcome measures related to quality of life and health status such as symptom resolution, satisfaction and return to normal activities are also important as the traditional surgical outcomes.[8] These HRQoL variables measured concurrently and prospectively, contribute additional features to mortality and morbidity measures. HRQoL involves several areas that cover the generic dimensions necessary to any HRQoL assessment, which are social, physical, emotional functioning and perceptions of overall quality of life corresponding to a disorder or its particulars treatment modalities.[4,9] For particular investigations, however, the assessment of other aspects of HRQoL may be important. These aspects include: sexual functioning, psychological, productivity, symptoms, sleep disturbance and pain. The specific aspects of HRQoL assessed in any study will vary depending on the particular health condition and research subject under investigation.[9] Quality of life is a necessary outcome variable in medical research and in surgery for benign gynecological conditions. Although surgery can have positive and negative effects, most women reported a reduction in physical complaints and an increase in health perceptions after hysterectomy.[4,8,10,11] In

Malaysia, Mohd et al. found that hysterectomy improves QoL subscale scores up to 3 months after surgery irrespective of age at the time of operation.[12]

Due to the rate of complications after hysterectomy and the significant number of surgeries that do not relieve discomfort, nonsurgical therapy may be more appropriate initially and when nonsurgical management fails to succeed, hysterectomy can be performed to treat benign conditions, hopefully relieving such discomfort and enhancing the quality of life.[11]

In Rwanda, Murwanashyaka et al. showed that hysterectomy was the most common gynecologic surgery performed (32.1%).[13] There is lack of information regarding HRQoL after hysterectomy in Rwanda. Therefore, it is important to assess whether hysterectomy improves HRQoL in our setting. As HRQoL refers to an individual's total well-being, having a proper understanding of this concept by nursing and medical staff allows them to provide accurate information to the patient during pre- and postoperative counselling, thereby enhancing the appropriateness of treatment and care. Hence the aim of this study was to assess the health related quality of life in women after hysterectomy performed for benign conditions in our setting and to determine the associations of HRQoL with patient characteristics, indications of hysterectomy for benign conditions, the types of hysterectomy for benign conditions and the rate of hysterectomy among obstetrics and gynecological (OBGYN) surgeries performed in women.

MATERIALS AND METHODS

This was a prospective longitudinal study conducted from the 1st June 2019 to the 31st March 2020 in women participant who underwent hysterectomy for benign gynecological conditions at Rwanda Military Hospital (RMH), Kigali University Teaching Hospital (CHUK) and Butare University Teaching Hospital (CHUB). These are the national public referral hospitals providing tertiary care services in Rwanda where most surgeries are performed. All patients who consulted OBGYN department at national public referral hospitals were evaluated either by an OBGYN consultant or an OBGYN senior resident, the diagnosis and management plan were established. A convenience sample of 110 women who underwent hysterectomy for benign conditions as the treatment option were recruited to be participants in the study. All participants who had hysterectomy for benign gynecological conditions based on the final histopathology report were included and the exclusion criteria was the loss to follow up. Data was collected using a questionnaire. The questionnaire comprised of two parts: the first part was used to assess the demographic and clinical characteristics of participants and the second part was used to assess the HRQoL. Clinical characteristics of participants were collected by either principal investigator or trained nurse in perioperative period from patient's interview and medical records using pre-established questionnaire and the HRQoL data were collected by principal investigator or trained nurse using the SF-36 questionnaire (also known as the RAND

36-Item Health Survey) prior to surgery. During the follow up at 3 months postoperative, the health related quality of life data were collected by principal investigator, patients were interviewed on telephone and completed the SF-36 questionnaire.

The SF-36 is a 36-items questionnaire which measures eight health subscales: bodily pain; general health; physical functioning; role limitations due to physical health problems; social functioning; energy/fatigue; role limitations due to emotional problems and emotional wellbeing. The SF-36 was built to represent two major subscales of health: the mental component summary (MCS) and the physical component summary (PCS). The summary components comprise 35 of the 36 items in the form; 14 in the MCS and 21 in the PCS.[5,6] For each subscale, item scores are coded, summed and converted into a scale from 0 (worst health) to 100 (best health).These 36 items were adapted from the tool completed by patients participating in the medical outcomes study in different systems providing health care.[14] The SF-36 Kinyarwanda version was used.[15]

Data entry was done using Epidata 3.1 then exported to IBM SPSS statistics version 25 for analysis. Descriptive statistics such as means and percentages provided a general description of sample characteristics. Data distribution was evaluated using Shapiro-Wilk test. Because the data were skewed, Kruskal-Wallis and Mann–Whitney *U* tests were used to analyze the associations between overall QoL and patient characteristics. To assess the HRQoL quality of life, Wilcoxon signed rank test was used to analyze the associations of HRQoL score before and 3months after surgery. Associations were considered to be statistically significant at a p-value < 0.05.

All women provided written informed consent before the study. Ethical approval (N^{o}144/CMHS/IRB/2019) was obtained from the Institutional Review Board of College of Medicine and Health sciences at University of Rwanda before starting the study. Approval from research ethics committees of CHUK, CHUB and RMH were offered before data collection.

RESULTS

A total of 4211 OBGYN surgeries were performed in study period, Hysterectomy was the second most common procedure after cesarean delivery (6.7%) **Figure 1**. Of the 110 patients enrolled 92 patients were analyzed, 11 patients were excluded for malignancy confirmed by histopathology **Figure 2**. The mean age of participants was 51 ± 9 years and majority were between 40-50 years (47.8%). Most of participants were premenopausal (64.1%). CBHI was the most health insurance (89.1%). Most women were Protestant (45.7%) and married (56.5%). The majority of the patients undergoing hysterectomy were multiparous with (63.7%) of women having parity of four or more as shown in **Table 1**.

The average length of hospital stay was 6 ± 4 days. The most common indication for hysterectomy was fibroids (52.2%). Most of the hysterectomies (76.1%) were performed using abdominal approach. Uterine prolapse was an indication for hysterectomy performed at advanced age (60 ± 8).**Table 2.**

There was a significant difference of QoL before surgery between educational level and parity in overall QoL (p=0.001; p=0.039) respectively and there was statistically significance in QoL between premenopausal and postmenopausal women at 3 months postoperative (p=0.049), however the overall QoL was not significantly different at 3 months between women with and without complications [63.0(30.2-96.5) vs. 68.0 (16.2-98.3), p=0.533]. **Table 3.** The overall complication rate was 10.9% and surgical site infection was the most common complication (5.4%). The presence of complications was significantly associated with increased length of hospital stay (p=0.027).

All domains showed significant improvement in HRQoL scores after hysterectomy (p <0.001). The PCS improved from 28.8 to 61.3 (p<0.001) and the MCS improved from 35.8 to 67.0 (p <0.001). **Table 4.**

DISCUSSION

Hysterectomy performed for benign conditions is usually aimed at improving the quality of life for the woman by alleviating the symptoms, resuming function and alleviating the woman's fear of progress to a malignant state. The results of this study have shown a significant improvement in all eight subscales of HRQoL measured before and at three months post hysterectomy for benign conditions. These results are similar to the findings from Taiwan and Malaysia that used a different tool and demonstrated post-surgery improvement of QoL after 8 and 12 weeks respectively[12,16] with other studies that measured the HRQoL at 6 months and beyond post-surgery have also shown significantly improved and maintained HRQoL afterwards.[8,17- 20]

Whether a woman with a gynecologic issue still desires for fertility is one of the drivers in decision making for surgical management and hence it is common for gynecologist to be reluctant in deciding hysterectomy for a woman in reproductive age or who has not completed their childbearing. Even though there was no statistically significance in pre-surgery scores between premenopausal and post-menopausal women, the former were significantly more likely to have better perception of their HRQoL after hysterectomy even though their natural ability to conceive was lost (70.2 vs 59.7, p=0.049). This is contrary to the results from Iran which showed a low quality of life after hysterectomy particularly for social and psychological aspects in premenopausal women but this study also used a different tool to evaluate the HRQoL.[21]

The pre-surgery median difference between women who attended at least secondary education and women who had primary or no education was lost when hysterectomy was performed. This implies possible delay in health care seeking behavior among less educated women until they have develop more severe symptoms compared to the more educated women who have more access to health education and are more knowledgeable about symptoms that prompt for early consultation. Similar findings were observed in India that have shown higher mean scores on MCS as a result of higher education but different from Korea where women with lower education had otherwise higher level of sexual satisfaction after surgery.[18,22]

During surgical practice, surgeons attempt to minimize all preventable complications of surgery. Among our study participants, complications were associated with longer hospital stay but none of the surgical complications has shown significant association with HRQoL.

This could demonstrate adequate patients' counseling and education on complications of surgery in addition to its proper management while keeping the patients' satisfaction. This was also highlighted by Radosa et al showing a better perception of quality of life as a result of good counseling.[23]

The type of surgical approach chosen to perform hysterectomy has been documented to have a remarkable impact on long-term HRQoL, length of hospital stay and complications.[24,25] While systematic reviews have shown fewer blood loss, shorter hospital stay and better scores of HRQoL compared to TAH [25,26], laparoscopic and vaginal hysterectomies are not yet routinely integrated into practice by local medical staff in Rwanda and hence, it was difficult to compare the effect of different modalities given their small numbers in our cohort.

As the country has engaged the community in improving maternal health through the help of community health workers, there is a need to address other women's issues by education and utilization of health services before the quality of life is compromised. Hysterectomy should be offered when the medical management has failed to alleviate the patient's complaint regardless of the age and menopausal status but patient autonomy and fertility desire should be fully discussed.

The strengths of our study is the use of the SF-36, the most common used and validated tool of HRQoL worldwide. It was also available in Kinyarwanda that improved communication with participants. In addition, this questionnaire has been used in other studies, permitting our findings of being compared with those of other studies. It is important to have culturally appropriate and validated methods of assessment as results from other settings may not be able to be extrapolated to Rwanda. Another strength of this study is its prospective follow up design, which decreases the probability of recall bias. Patients were requested to

remember only the previous four weeks when they filled the SF-36.[19] Missing data and loss to follow up were also minimised.

The limitations of our study is that SF-36 instrument does not make examination on disease-specific gynecologic quality of life such as defecation complaints, urogenital distress, menstrual symptoms, depression, sexual problems or speed of recovery. In addition, there were difficulties in patient enrolment and retention in order to get adequate sample size and to minimise the loss to follow up. There were limited alternative modalities to the transabdominal approach to make valid comparisons.

The results of this study measured the fundamental HRQoL after hysterectomy performed for benign conditions in Rwanda. Considering these results, disease specific quality of life studies could be considered to evaluate the effect of hysterectomy in our settings. Furthermore long term follow up could be studied as complications evolve over time. Quality of life monitoring for a health system is important to insure that elective surgical interventions have a sustained positive impact on patients. This study represents the first to examine quality of life after hysterectomy and further study is necessary to insure appropriate care for our patients.

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FIGURES AND TABLES

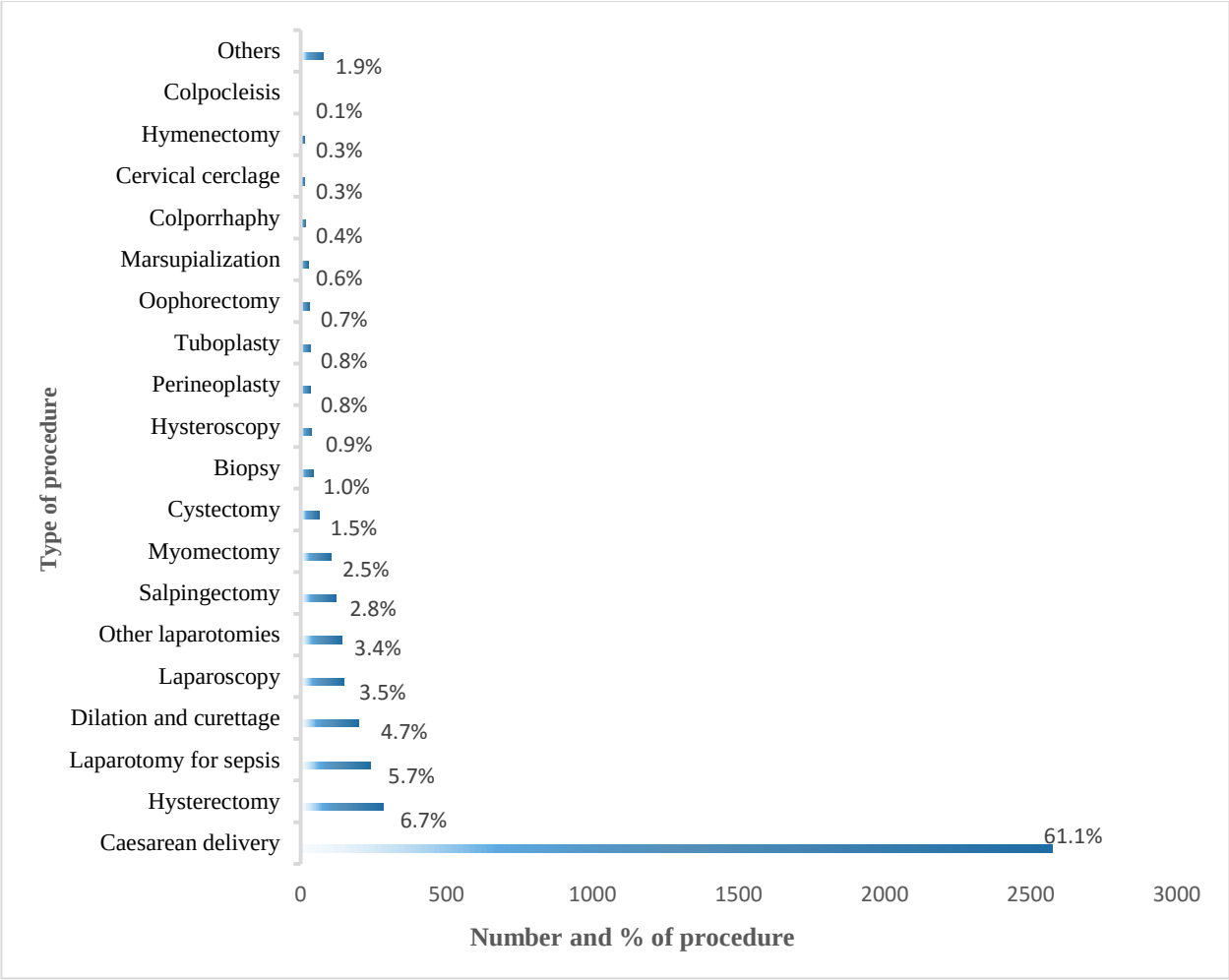

Figure 1: Obstetrics and gynecologic surgeries in tertiary hospitals

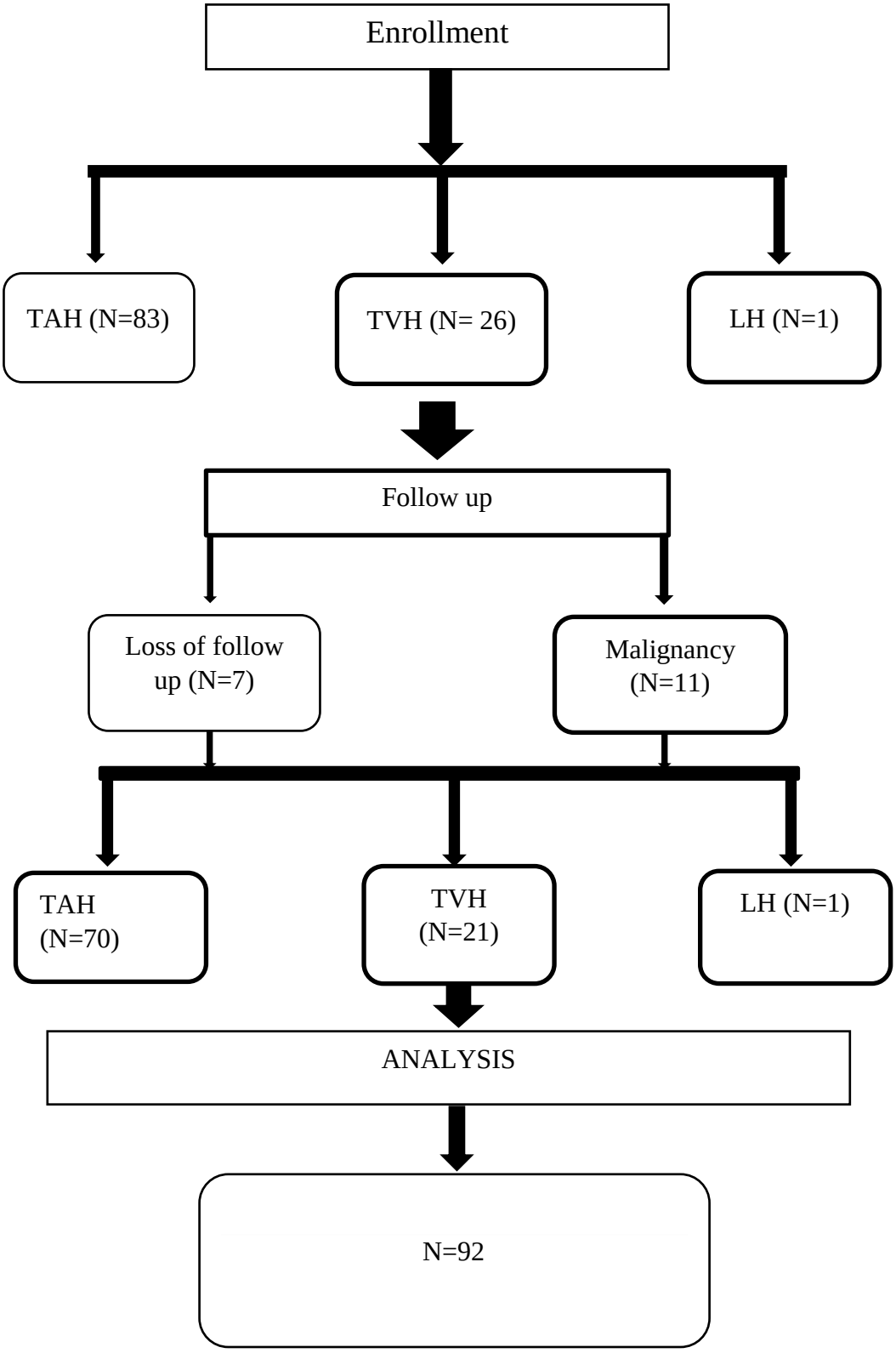

Figure 2: Number of patients recruited, followed up and analyzed

Table 1*: Demographics and characteristics of participants*

Variable	N	%
Age		
<40 years	5	5.4
40-50 years	44	47.8
>50 years	43	46.7
Health insurance		
CBHI	82	89.1
Private	3	3.3
Others	7	7.6
Religion		
Protestant	42	45.7
Catholic	38	41.3
Muslim	3	3.3
Other	9	9.8
Marital status		
Married/cohabitant	52	56.5
Widow	25	27.2
Single	10	10.9
Divorced	5	5.4
BMI		
<18.5	14	15.6
18.5-24.9	46	51.1
25.0-29.9	20	22.2
30.0-34.9	9	10.0
>35.0	1	1.1
Parity		
0	13	14.3
1-3	20	22.0
≥4	58	63.7
Educational level		
No formal education	29	31.5
Primary	43	46.7
Secondary	14	15.2
University	6	6.5
Type of anesthesia		
Spinal anesthesia	30	32.6
General anesthesia	62	67.4
Menopausal status		
Premenopausal	59	64.1
Postmenopausal	33	35.9

Table 2. Number, age, length of stay, hysterectomy indication according to the type of procedure

	Surgical approach			**Total**
	TAH	**TVH**	**LH**	
N (%)	70 (76.1%)	21 (22.8%)	1 (1.1%)	92 (100%)
Age (M ± SD)	48 ± 8.0	60 ± 8.0	-	51 ± 9
Hospital stay (M ± SD)	5 ± 4	6 ± 3	-	6 ± 4
Indications [N (%)]				
Uterine fibroids	48 (100.0%)	0 (0.0%)	0 (0.0%)	48(52.2%)
AUB	10 (90.9%)	0 (0.0%)	1 (9.1%)	11(12.0%)
Uterine prolapse	0 (0.0%)	21 (100.0%)	0 (0.0%)	21(22.8%)
Benign ovarian tumor	4 (100.0%)	0 (0.0%)	0 (0.0%)	4 (4.3%)
GTD	7 (100.0%)	0 (0.0%)	0 (0.0%)	7 (7.6%)
Pelvic pain	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (1.1%)

Table 2: Associations between overall QoL and patient characteristics. Data are median

Variables	Baseline QoL Med (Min-Max)	p value	QoL at 3 months Med (Min-Max)	p value
Age				
≤45 years	33.2 (11.7-84.4)	0.369	71.3 (16.2-96.5)	0.360
>45 years	30.3 (15.9-78.1)		64.8 (30.1-98.3)	
Body mass index				
Underweight	25.6 (15.9-52.4)		61.2 (30.6-94.7)	
Normal weight	30.5 (11.7-84.4)	0.080	68.0 (16.2-98.2)	0.93
Overweight/Obese	35.0 (19.2-60.0)		68.9 (25.8-98.3)	
Menopausal status				
Premenopausal	32.9 (11.7-84.4)	0.145	70.2 (16.2-98.3)	0.049
Postmenopausal	27.4 (15.9-54.3)		59.7 (30.1-97.5)	
Type of anesthesia				
Spinal anesthesia	28.6 (11.7-78.1)	0.185	68.2 (30.1-98.3)	0.816
General anesthesia	32.8 (16.2-84.4)		67.3 (16.2-98.2)	
Comorbidities				
Yes	27.2 (19.2-66.3)	0.351	71.8 (30.2-98.3)	0.428
No	32.9 (11.7-84.4)		64.8 (16.2-98.2)	
Education				
None/Primary	28.6 (11.7-78.1)	0.001	67.3 (16.2-98.3)	0.586
Secondary/University	42.0 (23.2-84.4)		68.0 (38.8-96.5)	
Parity				
≤3	33.9 (16.2-84.4)	0.039	70.2 (16.2-98.2)	0.253
≥4	28.6 (11.7-73.1)		63.8 (25.8-98.3)	
Complications				
Yes	35.3 (20.1-84.4)	0.410	63.0 (30.2-96.5)	0.533
No	31.5 (11.7-78.1)		68.0 (16.2-98.3)	
Type of hysterectomy				
TAH	32.9 (16.2-84.4)	0.218	69.6 (16.2-98.3)	0.302
TVH	27.4 (11.7-78.1)		60.2 (30.1-92.8)	
Hospital stay				
≤6 days	32.9 (11.7-84.4)	0.115	69.2 (16.2-98.3)	0.625
>6 days	26.0 (19.3-44.4)		67.3 (30.1-92.2)	

Table 3: Quality of life before and after hysterectomy. Data are median (IQR). Higher scores indicate better functioning for the quality of life subscales (SF-36)

SF-36 Component	Baseline	3 months	P value
Physical functioning	47.5 (30.0)	82.5 (25.0)	<0.001
Role limitation due to physical health	0.0 (0.0)	12.5 (50.0)	<0.001
Bodily pain	35.0 (42.0)	88.0 (25.0)	<0.001
General Health perception	25.0 (22.0)	62.5 (40.0)	<0.001
Physical component summary	28.8 (25.2)	61.3 (26.4)	<0.001
Energy/Fatigue	32.5 (29.0)	55.0 (25.0)	<0.001
Social functioning	75.0 (47.0)	100.0 (0.0)	<0.001
Role limitation due to emotional health	0.0 (0.0)	33.0 (100)	<0.001
Emotional wellbeing	36.0 (32.0)	80.0 (32.0)	<0.001
Mental component summary	35.8 (14.9)	67.0 (37.4)	<0.001

ANNEXES

Annex 1. INFORMED CONSENT (ENGLISH VERSION)

Title of Study: HEALTH RELATED QUALITY OF LIFE AFTER HYSTERECTOMY PERFORMED FOR BENIGN CONDITIONS IN TERTIARY REFERRAL HOSPITALS, RWANDA

Researcher's Name: TWAHIRWA Bonaventure

Phone number (+ 250)788918750

INTRODUCTION

My name is TWAHIRWA Bonaventure; I am a student at the University of Rwanda, Undertaking a masters in obstetrics and Gynecology. One of the requirements for the Degree is to conduct a research project.

PURPOSE OF STUDY

The purpose of the study is to assess the health related quality of life in women after hysterectomy performed for benign gynecological conditions in tertiary referral hospital.

DESCRIPTION OF THE STUDY PROCEDURES

When you agree to participate in this study, Firstly, you will be asked to sign this consent form, then you will be explained about question, and you are thereby requested to answer a questionnaire, you will be required to submit it back to the researcher after fill it. Also you will be given a signed and dated copy of the consent form to keep, along with any other printed materials deemed necessary by the researcher.

RISKS/DISCOMFORTS OF BEING IN THIS STUDY

There no known risks. And there are no reasonable foreseeable (or expected) risks.

BENEFITS OF BEING IN THE STUDY

During this study you will benefit the follow up for 3 months

CONFIDENTIALITY

The questionnaire used in this study will not be collecting or retaining any information about your identity like your name. Also the researcher will not include any information in any report he may publish that would make it possible to identify you. The questionnaires will be destroyed after the study is complete.

The records of this study will be kept strictly confidential. Research records will be kept in a Locked keyboard and all electronic information will be coded and secured using a password Protected file.

PAYMENTS

This study has academic purpose no any funds so there will be no payment to participate in this study

RIGHT TO REFUSE OR WITHDRAW

The decision to participate in this study is voluntary. If you refuse to take part in the study at any time, there will be no negative consequences for you. You have the right not to answer any single question or question you think concerns your dignity, as well as to withdraw completely from the study at any point during the process.

RIGHT TO ASK QUESTIONS AND REPORT CONCERNS

You have the right to ask questions about this research study and to have those questions answered by the research before, during or after the research. If you have any further questions About the study, at any time feel free to contact:

Contact details of researcher (for further information / reporting of study related adverse events).

Bonaventure TWAHIRWA

Tel :(+250) 0788918750 Email: twahirwab@gmail.com

If you have any other concerns about your rights as a research participant that has not been answered by the researcher, you may contact

1. Contact details of the research ethic committee of IRB (for reporting of complaints / problems).

Chairperson of IRB College of medicine and health science

0788490522

2. Contact details of the research ethic committee of IRB (for reporting of complaints / problems).

Deputy Chairperson of IRB College of medicine and health science

0783340040

3. Contact details of the research supervisor number 1 (for further information on the Research and reporting of study related adverse events).

Urania Magliples

203-785-3091 or (+250)0782332160 email:Urania.magliples@yale.edu

4 . Contact details of the research supervisor number 2 (for further information on the Research and reporting of study related adverse events).

Jean Damascene RUKUNDO

(+250)0783617334 email: rukhjeda@gmail.com

DECLARATION OF CONSENT TO PARTICIPATE IN THE RESEARCH

I hereby confirm that I understand the contents of this document and the nature of the research project, and I consent to participating voluntarily in the research project.
I understand that I am at liberty to withdraw from the project at any time, should I so desire.

Participant's Signature: …….. Date:……

Annex 2.INFORMED CONSENT (KINYARWANDA VERSION)

Kwemera kugira uruhare mu bushakashatsi

Izina ry'ubushakashatsi: IMINOGERE Y'IMIBEREHO Y'ABABYEYI NYUMA YO GUKURWAMO NYABABYEYI BITEWE N' UBURWAYI BUTARI KANSERI BIVURIZA MU BITARO BIKURU.

Izina ry'umushakashatsi: Muganga TWAHIRWA Bonaventure

Nomero za telefone:(+250) 0788918750

IRI BURIRO

Nitwa TWAHIRWA Bonaventure nkaba ndi umunyeshuri muri koreji y'ubuvuzi n'ubumenyi bw'ubuzima rya kaminuza y'u Rwanda.

Nkaba ndi gukora ubushakashatsi ku kureba "Iminogere y'imibereho y'ababyeyi nyuma yo gukurwamo nyababyeyi bitewe n' uburwayi butari kanseri bivuriza mu bitaro bikuru ". Kimwe mubisabwa kugira ngo mbone impamyabumenyi ni ugukora ubushakashatsi.

INTEGO Y'UBUSHAKASHATSI

Ubu bushakashatsi bugamije kureba iminogere y'imibereho y'ababyeyi nyuma yo gukurwamo nyababyeyi bitewe n' uburwayi butari kanseri.

IBIZAKORWA MURI UBU BUSHAKASHATSI

Mu gihe wemeye kugira uruhare muri ubu bushakatsi, bwambere usabwa kuzuza amasezerano yemera kugira uruhare mu bushakashatsi ndetse ugasobanurirwa ibibazo binyuranye bibazwa kuri ubwo bushakashatsi, unahabwe urupapuro rw'ibibazo bibazwa ku bushakashatsi ufite gusoma ukarwuzuza nyuma yo kurwuzuza ukarugarurira umushakashatsi. Kopi y'urupapuro rw'amasezerano urayihabwa n'izindi kopi zakenerwa mu bushakashatsi

INGARUKA/ KUTAGUBWANEZA ZO KUBA MURI UBU BUSHAKASHATSI

Nta ngaruka zizwi, nta niziteganywa muri ubu bushakashatsi.

INYUNGU ZO KUBA MURI UBU BUSHAKASHATSI

Ubu bushakashatsi bufite inyungu yo gukurikiranwa mu gihe cy'amezi atatu

KUGIRA IBANGA

Amakuru yose tuzakura muri ubu bushakashatsi azaguma ari ibanga kandi nta zina rizagara ku rupapuro ruriho ibibazo n'ibisubizo.Nta makuru namwe akwerekeyeho tuzakubaza muri ubu bushakashatsi,amakuru yose azabikwa ahantu zihezewe kandi ntawundi muntu usibye abari muri ubu bushakashatsi wemerewe kuyabona.

AGAHIMBAZAMUSYI

Ubu bushakashatsi bufite intego kubijyanye n'amashuri nta nkunga y'amafaranga cyangwa indi ntego ifite inyungu bityo rero nta mafaranga cyangwa impano duteganya gutanga ku kwemera kugira uruhare muri ubu busahakashatsi.

UBURENGANZIRA BWO KWANGA CYANGWA KUVA MU BUSHAKASHATSI

Umugambi wo kugira uruhare muri ubu bushakashatsi bushingiye kubushake bwawe bwose, Ufite uburenganzira ubwo aribwo bwose bwo kutagira uruhare muri ubu bushakashatsi kandi ntibigire icyo biguhungabanyaho. Ufite uburenganzira bwo kutagira ikibazo na kimwe usubiza cyangwa ikibazo waba wumva kirebena n'ubusugire cyawe. Kimwe nuko ufite uburenganzira bwo kuba wava cyangwa wahagarika ubushakashatsi igihe icyo aricyo cyose nubwo bwaba bwatangiye.

UBURENGANZIRA BW'UWO WABAZA IKIBAZO NO GUTANGA RAPORO Y'IBYO WUMVA BITAMEZE NEZA

Ufite uburenganzira bwo kubaza ibibazo bijyanye n'ubu bushakashatsi no kuba cya subizwa n'umushakashatsi mbere. haramutse hari ikibazo ushobora kwifuza kuzabaza nyuma ushobora kukibaza wisanzuye igihe icyo aricyo cyose ukampamagara

TWAHIRWA Bonaventure

kuri telephone (+250) 0788918750 cyangwa ukaba wanyandikira kuri twahirwab@gmail.com.

Uramutse wifuza kumenya incamake y'amakuru y' ubu bushakashatsi. Kandi niba waba ufite ikintu cy'umwihariko cyo kubaza cyangwa uburenganzira bwawe butubahirijwe nkuwagize uruhare mu bushakashatsi kitabashije gusubizwa n'umushakashatsi wakigeza kuri aba bakurikira:

1.Uhagarariye Kaminuza mu bushakashatsi wa mbere

(+250)0788490522

2.Uhagarariye Kaminuza mu bushakashatsi wa kabiri

(+250)0783340040

3. Urania Magliples

Uhagarariye ubushakashatsi wa mbere

Urania Magliples

203-785-3091 or (+250)0782332160 email:Urania.magliples@yale.edu

4. RUKUNDO Jean Damascene

Uhagarariye ubushakashtsi wa kabiri

Jean Damascene RUKUNDO

(+250)0783617334 email: rukhjeda@gmail.com

AMASEZERANO

Njye numvise kandi nasobanuriwe neza ibigize ubu bushakashatsi n'urwego rw'ubushakashatsi Nyuma yo kubyisomera, gusobanurirwa no kumva amakuru yose nahawe yavuzwe haruguru, Nemeye kugira uruhare muri ubu bushakashatsi kugiti cyanjye bikemezwa n'umukono wanjye.

Umukono wuwemeye kugira uruhare mubushakashatsi Italiki

…….. ……

Annex 3.DATA COLLECTION TOOL

QUESTIONNAIRE

PARTICIPANT IDENTIFICATION

Study ID:

A. Patient demographic and Clinical information questionnaire

1. Hospital site:

CHUK □

CHUB □

RMH □

2. Age:

3. Health insurance

Public □

Private □

Other insurance □

4.Religion

Catholic □

Muslim □

Christian □

Other □

5. Marital Status:

Single □

Married /Cohabitant □

Divorced □

Widow □

6. Patient Occupation:

House wife □

Farmer □

Civil Servant □

Business □

Others (Specify) ……

7. Ubudehe Category:

8. BMI: Weight: Height:

9. Education level

No formal education □

Primary □

Secondary □

University □

10. Parity:

11. Menopause at the time of hysterectomy

Yes □

No □

12. Type of anesthesia given

SA □

GA □

13. Indication of hysterectomy

Uterine fibroids □

Abnormal uterine bleeding □

Uterine prolapse □

Pelvic pain □

Others- specify: …….

14. Type of hysterectomy

Total abdominal hysterectomy □

Subtotal hysterectomy □

Total vaginal hysterectomy □

Laparoscopic hysterectomy □

15. Concomitant operation

Bilateral salpingophorectomy □

Bilateral salpingectomy □

Vagina wall repair □

Others-Specify:……

16. Past medical history: **Tick all that apply**

Anemia □

Hypertension □

Diabetes

Known psychological disorders □

Others-Specify……..

17. Past surgery:

None □

Cesarean section □

Others: Specify……..

18. Postoperative complications: **Tick all that apply**

None □

Fever □

Anemia □

Urinary tract infection □

Wound infection □

Bleeding requiring transfusion □

Pelvic abscess/infection □

Bladder/Bowel injury □

Reoperation □ Reason of reoperation: Specify……

Readmission □ Reason of readmission: Specify……

Others-Specify……..

19. Length of stay in hospital (In days):

B. UKO UBUZIMA BUHAGAZE, SF36 mu Kinyarwanda

Ibibazo bikurikira biratuma tumenya uko ubuzima bwanyu buhagaze dukurikije uko mubyumva. Musubize neza niba mutabyumva neza mutange igisubizo cyegereye icyo mushaka kuvuga.

(Hitamo igisubizo kimwe kuri buri kibazo)

1. Muri rusange mwumva ubuzima bwanyu bumeze : Hitamo igisubizo cyawe	
Neza buhebuje	1
Neza cyane	2
Neza	3
Nabi	4
Nabi cyane	5
2. Ugereranyije n'umwaka ushize muri iki gihe, Ubu mubona ubuzima bwanyu bumeze bute ? Hitamo igisubizo Cyawe	
Bwiza cyane kurusha umwaka ushize	1
Bwiza	2
Bujya kumera kimwe	3
Bujya kuba munsi yuko bwari buri	4
Bubi munsi yaho cyane	5

Dore ibyo mushobora gukora mu buzima bwanyu bwa buri munsi.Kuri buri byose nimwerekane niba hari ibyo

ubuzima bwanyu mufite ubu bubabuza gukora. **(hitamo igisubizo kimwe kuri buri murongo)**

	Bumbuza cyane	Bumbuza gahoro	Ntibumbuza na gato
3. Gukoresha	1	2	3

imbaraga cyane nko kwiruka, guterura ibintu biremereye,gukora imikino ngorora ngingo			
4 .Gukoresha imbaraga buhoro nko guterura ameza ,gukubura, gukina igisoro	1	2	3
5. Guterura no kugenda genda	1	2	3
6. Kuzamuka ingazi zirenze imwe	1	2	3
7. Kuzamuka ingazi imwe	1	2	3
8. Kunamira imbere, gupfukama, gusutama	1	2	3
9. Kugenda birenze kilometero kimwe	1	2	3
10. Kugenda metero zirenze ijana	1	2	3
11. Kugenda metero ijana	1	2	3
12. Gukaraba cyangwa kwambara	1	2	3

Muri ibi byumweru bine bishize kandi tugendeye uko ubuzima bwanyu buhagaze mu mbaraga.

(hitamo igisubizo kimwe kuri buri murongo)

	Yego	Oya
13. Mwagabanyije igihe mumara ku kazi kanyu cyangwa mu mirimo yanyu ya buri munsi?	1	2
14. Mukora ibintu bike kubyo mwifuzaga gukora?	1	2
15. Hari ibyo mwahagaritse gukora ?	1	2
16. Mwigeze munanirwa gukora ibyo mwari musanzwe mukora(urugero nko kubasaba imbaraga zisumbyeho)	1	2

Muri ibi byumweru bine bishize kandi tugendeye uko mwumvise mubabaye cyangwa muhangayitse ku buryo:

(hitamo igisubizo kimwe kuri buri murongo)

	Yego	Oya
17. Mwagabanyije igihe mumara ku kazi kanyu cyangwa mu mirimo yanyu ya buri munsi?	1	2
18. Mukora ibintu bike kubyo mwifuzaga gukora?	1	2
19. Mwigeze munanirwa gukora ibyo mwari musanzwe mukora neza kandi mu menyereye?	1	2

20. Muri ibi byumweru bine bishizeho ni mu buhe buryo mwumvise bitagenda neza mu mibanire yanyu n'abandi,mu muryango,mu nshuti zanyu,no mubo muziranye ? Igisubizo cyanyu mugishyirrrre mu kaziga

(Hitamo igisubizo kimwe)

Nta na rimwe 1

Gahoro 2

Biringaniye 3

Cyane 4

Cyane birenze 5

21. Mu byumweru bine bishize mwumvaga ububabare bwanyu bwiyongera ?

Igisubizo mwahisemo mugishyire mu kaziga**(Hitamo igisubizo kimwe)**

Ntabwo 1

buhoro cyane 2

buhoro 3

buringaniye 4

bwinshi 5

Bwinshi bikabije 6

22. Muri ibi byumweru bine ni mu buhe buryo mwumvise ububabare bwanyu bubabuza gukora akazi mukora cyangwa akazi kanyu ko mu rugo ?**Hitamo igisubizo kimwe)**

Nta na mba 1

Buhoro cyane 2

Biringaniye 3

Cyane 4

Cyane bikabije 5

Ibibazo bikurikira birerekana ukuntu muri ibi byumweru bine bishize mwiyumvise. Kuri buri kibazo murerekana igisubizo kibabereye cyiza.Muri ibi
byumweru bine bishize hari igihe : **(hitamo igisubizo kimwe kuri buri murongo)**

	Buri gihe	Kenshi cyane	kenshi	Rimwe na rimwe	gake	Nta na rimwe
23. Mwumvise mushobora gukora ?	1	2	3	4	5	6
24. Mwumvise mubabaye cyane ?	1	2	3	4	5	6
25.Mwumvise mucitse intege nta kintu na kimwe gishobora kubihindura ?	1	2	3	4	5	6
26.Mwumvise mutuje kandi nta kibavuna ?	1	2	3	4	5	6
27. Mwigeze mwumva mufite imbaraga nyinshi ?	1	2	3	4	5	6
28. Mwigeze mwumva mubabaye	1	2	3	4	5	6

kandi mucitse intege ?						
29.Mwumvise imbaraga za shize ?	1	2	3	4	5	6
30.Mwumvise mwishimye ?	1	2	3	4	5	6
31. Mwigeze mwumva munaniwe ?	1	2	3	4	5	6

32. Muri ibi byumweru bine bishize ni hari igihe kubera ubuzima bwanyu mwumvise bitagenda neza mu mibanire
yanyu n'abandi,mu muryango,mu nshuti zanyu,no mubo muziranye ? Hitamo igisubizo cyawe igihe

(Hitamo igisubizo kimwe)

Buri gihe 1

Kenshi cyane 2

kenshi 3

Rimwe na rimwe 4

Ntanarimwe 5

Erekana kuri buri nteruro ikurikira ni mu buhe buryo aribyo cyangwa ataribyo ku berekeranye namwe :
Hitamo igisubizo cyawe **(hitamo igisubizo kimwe kuri buri murongo)**

	Nibyo	Ibi nibyo biri	Ntabwo	Ntabwo	Ntabwo

		byo	mbizi	aribyo	aribyo na gato
33. Ndarwaraguri ka kurusha abandi	1	2	3	4	5
34. Mfite ubuzima bwiza nk'abandi bose	1	2	3	4	5
35. Mporana impungenge ko mu buzima bwanjye bigenda nabi?	1	2	3	4	5
36. Mfite ubuzima bwiza bushoboka	1	2	3	4	5

Annex 4. IRB APPROVAL

UNIVERSITY OF RWANDA — COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 3rd /04/2019

Dr TWAHIRWA Bonaventure,
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 144/CMHS IRB/2019

Your Project Title ***"Assessment Of The Change Of Quality Of Life In Women After Hysterectomy Performed For Benign Gynecological Conditions In Tertiary Referral Hospitals, Rwanda"*** Has Been Evaluated By CMHS Institutional Review Board.

		Involved in the decision		
		Yes	No (Reason)	
Name of Members	**Institute**		**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 31st March 2019, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

EMAIL: *researchcenter@ur.ac.rw* P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/ www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 3rd April 2019

Expiration date: The 3rd April 2020

Professor GAHUTU Jean Bosco
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR