College of Medicine and Health Sciences
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FACTORS INFLUENCING HEALTH-RELATED QUALITY OF LIFE AFTER GASTRECTOMY FOR CANCER: CASE STUDY OF THE UNIVERSITY TEACHING HOSPITAL OF KIGALI (CHUK)

Dissertation submitted in partial fulfilment of requirements for the award of the Degree of Master of Medicine in General Surgery of the University of Rwanda

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KIGALI, 4th April , 2023

DECLARATION

The researcher:

I, Dr NSABIMANA Venuste,declare that this dissertation, ""Factors influencing health-related quality of life after gastrectomy for cancer in CHUK"", is my work, and no one has submitted it to any other University for the award of a degree.

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I hereby declare that this dissertation, **""Factors influencing health-related quality of life after gastrectomy for cancer in CHUK"",** was submitted by Dr Venuste NSABIMANA with my approval.

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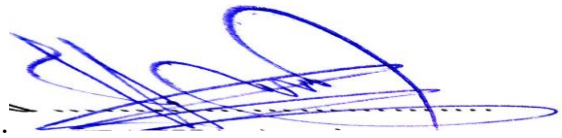

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ABSTRACT

Background: Gastric Cancer is the fourth most common cancer type and the second leading cause of cancer death worldwide. A good assessment of the health-related quality of life (QoL) in patients with gastric Cancer is vital to clinical practice to inform decision-makers on appropriate care. This knowledge aids patients, their families and treating doctors to address those factors that can be modifiable.

Objectives: This study aims to assess factors influencing health-related Quality of life post gastrectomy for cancer patients in Kigali University Teaching Hospital (KUTH).

Methods: A prospective cross-sectional study of 71 patients operated for gastric adenocarcinoma from January 2017 to October 2022. Data Collection was done from February 2022 to October 2022, and the data was collected using a questionnaire including an instrument for assessing the quality of life, demographics and clinical information. Quality of life was assessed using the European Organisation for Research and Treatment of Cancer Quality of life (EORTC QLQ-C30 STO22) site specific for gastric Cancer comprising 52 questions. Collected data have been entered in Epidata version 3.1 and then exported to STATA MP 13 for analysis.

Results: In this study, the majority of respondents are male, at 57.75%. The median age of the study participants was 63 years ranging from 22 to 82 years of age. The mean body mass index (BMI) is 20.7 ± 2.9. 70.42% are married. Only four participants(5.63%) attended university, 31% attended secondary school , and 49% attended primary school. Of the participants, 33.8% are classified in the third category of UBUDEHE, 49.3% in the second category and 16.9 % in the first category.

All the tumours are gastric adenocarcinoma. Of the total participants (5.63%), 61.9% were in stage III, 22.5% in stage II and 15.5% in stage I. Forty-three per cent of the tumours were well differentiated, 38% with moderate differentiation and 18.3% with poor differentiation. Sixty-two per cent of the tumours were classified as Intestinal type by Lauren classification, 18.3% classified as diffuse type, and 19.7% as mixed. Fifty per cent of the participants underwent open

partial gastrectomy, 36.6% underwent open near total gastrectomy and 12.68% underwent open total gastrectomy. Compared to the Dutch reference population most gastrectomy patients at CHUK have a slightly good score in Global HRQOL 70.4 vs 74, a good cognitive functioning at 90.14 (SD=14.52) and the lowest mean functioning score is in emotional functioning at 72.88 (SD=15.66).In general symptoms scales, the highest scores were found in financial difficulties scales. Factors associated with Poor global health status. Tumour differentiation and Lauren class of the tumour were found to be the accurate predictors of the global Quality of life (p=0.048)

Conclusion: Patients who have undergone gastrectomy have a slight reduction in their global health-related quality of life. Most patients regain a good functional score. Most gastric cancer patients present at a late stage. Tumour differentiation and Lauren class are predictors of global Quality of life.

Keywords:Gastric cancers, Gastrectomy, *Quality of life, EORTC QLQ-C30 STO22*

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LIST OF ABBREVIATIONS

AJCC: American Joint Committee on Cancer

BMI: Body mass Index

COX2: Cyclooxygenase-2

CHUK: Centre Hôspitalier Universitaire De Kigali

CMHS: College of Medicine and health Science

EQ-5D-5L: EuroQol- 5 Dimensions-5 Levels

EQ-VAS: EuroQol-Visual Analogue Scale

EORTC: European Organisation for Research and Treatment of Cancer

FACT-G: Functional Assessment of Cancer Therapy General

FLIC: Functional Living Index-Cancer

GI: Gastrointestinal

GIST: Gastrointestinal Stromal tumours)

HNPCC: hereditary nonpolyposis colorectal cancer

HRQoL: Health-Related Quality of life

H pylori: Helicobacter Pylori

i.e.: id est

IRB: Institutional Review Board

KUTH: Kigali University Teaching Hospital

LMICs: Low and Middle-Income Countries

MALT: Mucosa-Associated Lymphoid Tissue

P53: Tumour Protein p53

SPSS: Statistical Package for the Social Sciences

TNM: Tumour, Nodes, Metastasis

UGIS: Upper Gastrointestinal Series

UR: University of Rwanda

QoL: Quality of life

QLQ: Quality of Life Questionnaire

QLQ-STO22: Quality of Life Questionnaire Core with Gastric cancer-specific module

DEFINITIONS

Body Mass Index (BMI): It is a measure of body density based on how body weight and height relate to one another following the formula: Weight (kg)/Height Squared (BMI) (m2). BMI and body fat are correlated (ADIPOSE TISSUE). Their interaction differs according to age and gender. Adult BMI falls into the following categories: underweight if under 18.5; normal if between 18 and 24; overweight if between 25 and 29; and obese if over 30(1).

Gastric cancer: is stomach neoplasms or tumours (2).

Gastrectomy is the excision of the stomach in its entirety (total gastrectomy) or in part (subtotal gastrectomy, partial gastrectomy, gastric resection).

Modifiable risk factors: are factors that affect the likelihood of being unwell, disabled, ill, or dying that can be eliminated or minimised by altering our behaviour or the environment. For instance, someone overweight might alter their food and exercise routines to lose weight, or someone who smokes might decide to cut back or quit due to rising cigarette prices.(3)

quality of life: is a concept that extends beyond physical symptoms and includes social health, psychological well-being, and disease perception; it is frequently referred to as health-related quality of life(HRQoL)(4)

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DEDICATION

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FACTORS INFLUENCING HEALTH-RELATED QUALITY OF LIFE AFTER GASTRECTOMY FOR CANCER: CASE STUDY OF THE UNIVERSITY TEACHING HOSPITAL OF KIGALI (CHUK)

CHAPTER 1. INTRODUCTION

1.1. Background

Gastric cancer is the fourth most common cancer type and the second leading cause of cancer death worldwide (5,6). It is Africa's ninth most common cause of cancer mortality(7). In Africa, gastric cancer is ranked the twelfth most common cancer (6). Gastric neoplasm ranked in the top five for both sexes in all sub-Saharan African regions (8). Sub-Saharan Africa carries higher mortality with 5-year survival ranging between 2.38 to 30%(9,10).

East Africa has the highest incidence and mortality among other African countries, with 4.7/100,000 and 4.6/100,000, respectively(6).Uganda has an incidence of 4.2% per 100,000, and Kenya has 6.6% of patients with dyspepsia. In Tanzania incidence of gastric cancer is 16.3% ,15.1% of malignancies in men and women respectively (11).The incidence of gastric cancer in Rwanda is as high as 6.6%(12).

Worldwide the incidence of cancer has decreased dramatically in the last fifty years thanks to the treatment of Helicobacter pylori. Surgical resection is the main potentially curative treatment for stomach neoplasm,(4,13,14). Most patients with clinically resectable locoregional disease is a must to sustain gastrectomy(15). The curative surgical treatment goals are resectioning all tumours (16–18).Helicobacter pylori, genetic, nutritional, and environmental variables are among the multifactorial risk factors for gastric cancer, others being alcohol, and smoking(19,20).

Quality of life is the state of well-being that people can encounter and stands for both objective and subjective personal feelings. Regardless of the persistent existence of GI symptoms such as reflux, early satiety, and episodic nausea, overall quality of life (QoL) after gastrectomy does not seem to be permanently harmed(21).

QoL is a concept that extends beyond physical symptoms and includes social health, psychological well-being, and disease perception; it is frequently referred to as health-related quality of life(HRQoL)(22).

In 1993, the Quality of Life Questionnaire (QLQ-C30) of the European Organization for Research and Treatment of Cancer has been established. It is one of the most extensively utilised tests for evaluating cancer patients' symptoms and functional abilities. It is validated and offered in a wide range of languages. Its 30 questions include general, social, emotional, cognitive, physical, and role functioning in addition to common cancer-related symptoms(22–25).

The QLQ-C30 is used for cancer-related English language questionnaires with a section on financial difficulty (23). A disease-focused module, QLQ-STO22, was created to measure and compare HRQoL in stomach neoplasm patients in 2001. It focused mainly on upper GI symptoms(26,27).

The QLQ-C30 with QLQ-STO22 is arguably the most comprehensive HRQoL package for gastric cancer. The majority of surgeries, including radical gastrectomy, temporarily lower HRQoL .This temporary decrease exists regardless of the degree of resection (28). Post gastrectomy syndrome, early satiety, abdominal cramping, diarrhoea, and dumping may persist for greater than 1 year, But the recovery of global HRQoL frequently happens before symptom resolution (22).

A significant study utilising the QLQ-C30 STO22 found that a considerable number of complaints and symptoms are less in comparison to pre-surgery just 13 months post gastrectomy(13,23,29). Nevertheless, overall Quality of life and emotional function were than initial pre-surgery after only 3 monthspost-stomach resection (22).

1.2. PROBLEM STATEMENT

Gastric cancer ranks third as the leading cause of cancer-related death in LMICs (14). Gastric cancer is the fifth most common cancer in Eastern Africa (30).In a study conducted by Martin et al.in three hospitals across Rwanda in 2018, they identified 229 patients with gastric cancer. Among them a third of them underwent a curative surgery (30). The first study done by

Niyongomba et al.2021 on short term outcomes identified that 241 gastric cancer patients were operated on at Kigali University Teaching hospital(31).

In 2019 at CHUK, more than 25 gastrectomies for cancer were done (*CHUK statistics book*). Gastric cancer is a significant concern. A study done at CHUK revealed that 199 patients were diagnosed with gastric cancer, which was associated with high perioperative mortality. Surgery remains the cornerstone in treating and curing gastric cancer(15,23).

Incorporation of quality of life before gastrectomy in preparation for the patient is not routinely done in clinical practice, and it is done in some High-income countries. Given the support this can make on patients, it is a needed value to our patients to improve the quality of care (32,33). This study aims to assess the health-related quality of life post gastrectomy for gastric cancer patients in Kigali University Teaching Hospital of Kigali.

1.3. RESEARCH GAP

It has been proven that quality of life is impaired post gastrectomy for gastric cancer(28).

Knowledge of the elements impacting quality of life after gastrectomy is vital to clinical practice to inform decision makers on appropriate care, patients, their families and treating doctors to address those factors that can be modifiable. Quality of life post gastrectomy is not integrated in patient education before surgery. We feel that it is an added tool before undergoing a heavy, detrimental surgery like gastrectomy associated with a profound change in the quality of life (29,33,34). There is a gap in the knowledge of the quality of life for gastriccancer patients.

1.4. STUDY JUSTIFICATION

Knowledge of factors influencing health-related Quality of life after gastrectomy for cancer is important:

- To generate local epidemiological data for the QoL of the patients after gastrectomy for gastric cancer at CHUK
- To help hospital managers and the national level address the problem
- To inform decision-makers on appropriate care and meeting patients' expectations
- It will serve as the baseline for further studies

1.4.1. Geographical coverage

The University teaching hospital of Kigali/CHUK is the largest hospital located in District of Nyarugenge at KN 4 Ave, Kigali City. It is also the biggest referral hospital of the country with a capacity of 519 beds. CHUK provides quality healthcare to the population, training, clinical research and technical support to district hospitals. There are more than 15,000 patients admitted each year. (Rwanda Ministry of Health, 2020).

1.4.2. Theoretical coverage

This study will look at health quality Quality of life post gastrectomy for gastric cancer patients operated on at University Teaching Hospital of Kigali

1.5. RESEARCH QUESTION

What are the modifiable factors which influence health-related Quality of life post gastrectomy for gastric cancer patients in CHUK

1.6. OBJECTIVE

1.6.1. Main objective

To assess factors influencing health-related Quality of life post gastrectomy for gastric cancer patients at the University Teaching Hospital of Kigali.

1.6.2. Specific objectives

1. To describe the socio-demographics of gastric cancer patients in CHUK
2. To describe the clinico-pathological characteristics of gastric Cancer in CHUK.
3. To determine gastric cancer patients' health-related Quality of life

1.7. Variables

In this study, variables were used according to the objectives targeted in this clinical trial of assessing factors influencing health-related Quality of life post gastrectomy for cancer. The study variables included the baseline data and the components of the EORTC QLQ-C 30 version 3.0 and QLQ-C30 STO22

Table 1. 1 Variables

Specific objectives	Variables	Data collection methods	data Source
1. To describe the socio-demographic of gastric cancer patients in CHUK	Demographic(Age,gender,education level, Socioeconomic category (Ubudehe),address, occupation,	Questionnaire	Primary data
2. To describe clinico-pathological characteristics of gastric cancer patients in KUTH.	diagnosis, the time elapsed since surgery, type of surgery, interval time diagnosis to surgery cancer stage, pathology type adjuvant and neoadjuvant chemotherapy, tumour stage , comorbidities, BMI, Pre-operative and post-operative total parenteral nutrition	Questionnaire	Primary Data
3.To describe gastric cancer patients health-related Quality of life	Global health scale Physical functioning Role functioning Emotional functioning Cognitive functioning Social functioning Symptoms scales	Questionnaire/ QLQ-C30 STO22 scale	Secondary data

1.8. Theoretical framework

Our conceptual framework was based on the conceptual mapping 3-Dimension theoretical framework of the EORTC-QOL cancer survivorship questionnaire. Due to its comprehensive approach to evaluating Quality of life and its definitions when seeking solutions to the research topic.

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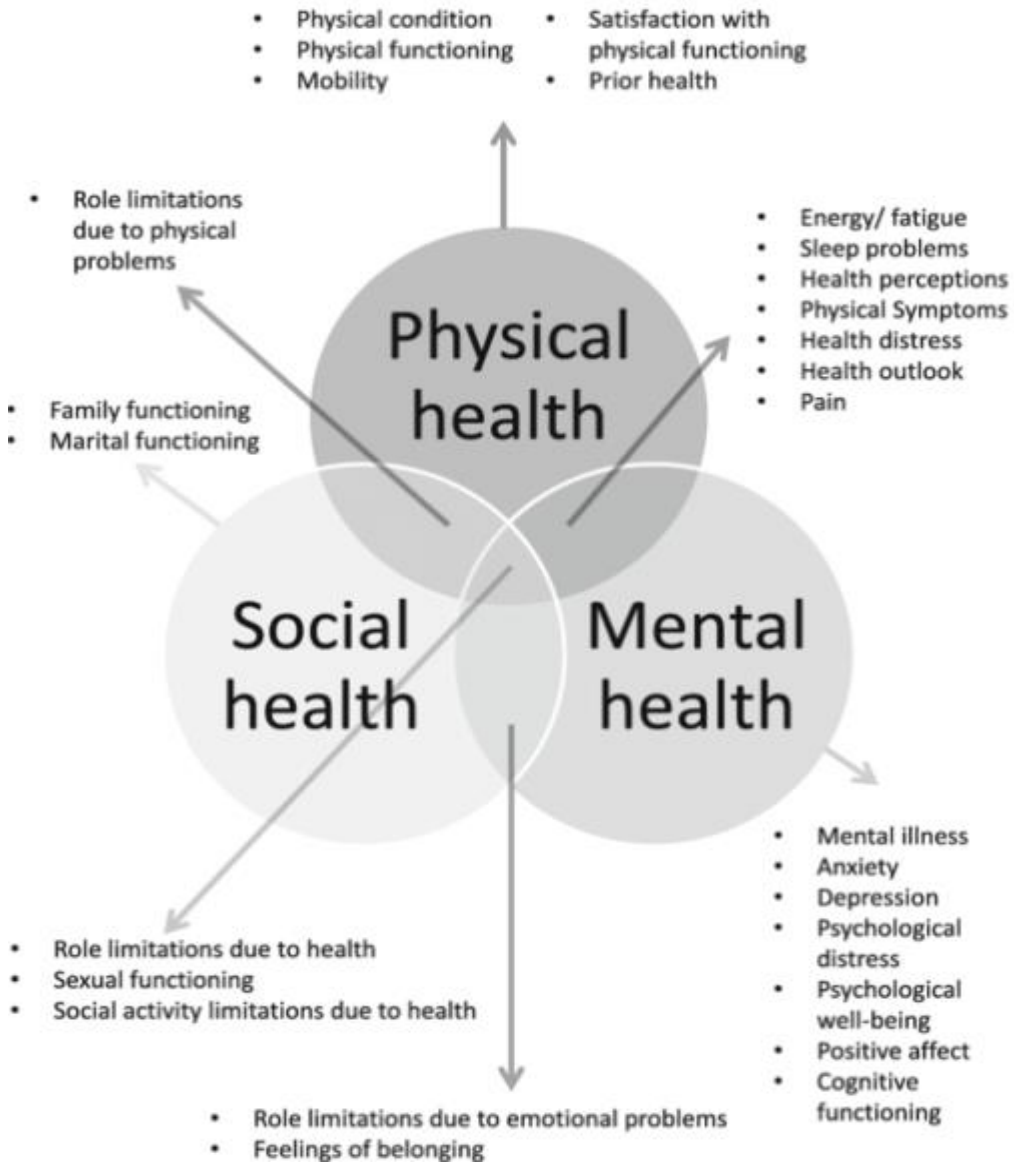

Figure 1. 1Theoretical framework

1.9. Conceptual framework

Post Gastrectomy patient's health-related quality of life can be influenced by different featuresincluding Quality of life, Functional aspects and symptoms, type of surgery, cancer stage, physical perception, and body image.

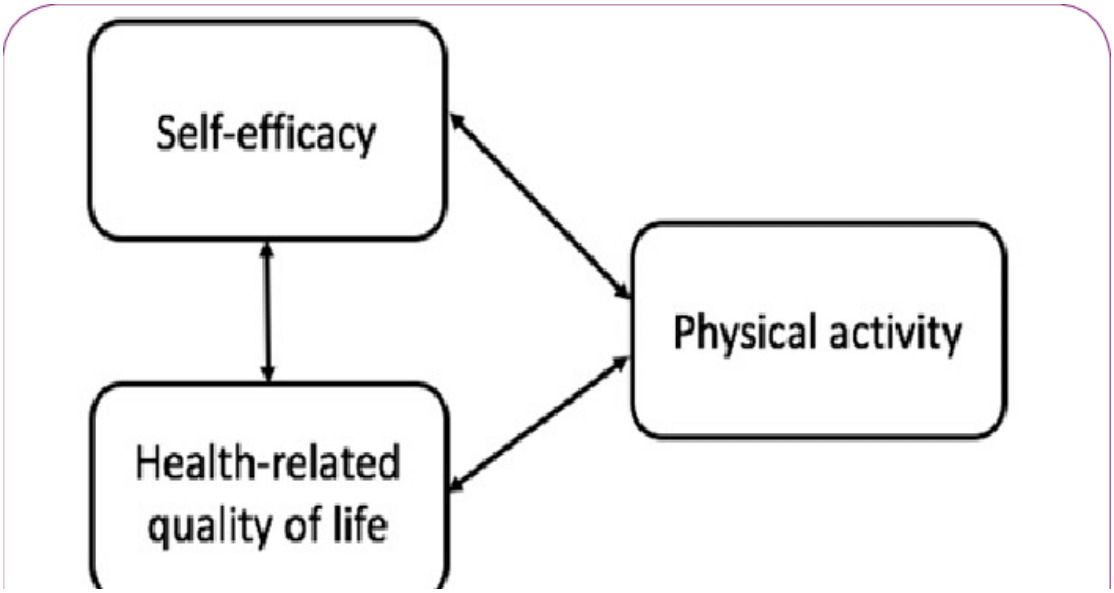

Figure 1. 2 Conceptual framework of the patients with gastric cancer after surgery

CHAPTER 2. LITERATURE REVIEW

2.1. Introduction to the literature review

Different studies have proven a change in Quality of life of gastric cancer patients, especially after gastrectomy (35). Quality of life has multiple dimensions that can be evaluated using validated questionnaires like the QLQ-C30 comprising separate priorities. Unique tools have been created and verified to evaluate Quality of life especially in gastric cancer patients QLQ-STO22(22).

This literature search navigated through all known factors influencing the Quality of life of gastric cancer patients. It will fill the gap in knowledge of the epidemiology of gastric cancer globally, in Africa, regionally and in particular Rwanda. Additionally, this literature survey discussed the multimodal ways of treatment of gastric cancer, surgical and medical screening modalities, and staging of gastric cancer. Lastly, the level of function of gastric cancer patients is discussed here, as the importance of measuring Quality of life.

The area of the literature search was factors influencing health-related Quality of life following gastrectomy for gastric cancer. Searches were conducted using Google Scholar, PUBMED, MEDLINE, EMBASE, COCHRANE library databases, and HINARI. To organise all the reviewed literature, a matrix was employed. Gastric Cancer, gastrectomy, and Quality of life were the search terms employed in this investigation. The literature search was conducted in English-language papers.

2.2. Gastric cancer

Gastric cancer is stomach neoplasms or tumours. The commonest primary gastric neoplasm is adenocarcinoma (95%); followed by lymphoma then GIST (Gastrointestinal Stromal tumours) take most of the remaining percentage(2).

2.3. Epidemiology of Gastric Cancer

Gastric cancer is one of the most diagnosed cancers worldwide and the leading in cancer death (36). Gastric neoplasm is ranking by 5th most common cancer and the 3rd most frequent cause of cancer death worldwide (20,37–39).Gastric cancer has a higher incidence in East Asia, with China-Japan leading the list (5) .It is Africa's ninth most common cause of cancer mortality(7).Gastric neoplasm ranked in the top five for both sexes in all sub-Saharan African regions (8).

In sub-Saharan Africa, it carries higher mortality with 5-year survival ranging between 2.38 to 30%(9,10).East Africa has the highest incidence and mortality among other African countries, with 4.7/100,000and 4.6/100,000, respectively(6).Uganda has an incidence of 4.2% per 100,000, and Kenya has 6.6% of patients with dyspepsia. In Tanzania incidence of gastric cancer is 16.3% ,15.1% of malignancies in men and women respectively (11).

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In Rwanda, individuals with stomach cancer frequently present with advanced disease and delayed consultations(30,31,40). That malignancy has a big association with poor outcomes, like it was shown as evidence by increased inpatients mortality and short post discharge survival (31).

2.4. Risk Factors of developing Gastric cancer.

Worldwide, 50% of the population is infected with Helicobacter pylori(41).This infection is potentially a chronic disease that does not go away unless treated effectively. Gastritis induced by Helicobacter pylori is attributed to 80% to 90% of total gastritis(42,43). Chronic gastritis is a well-known and primary risk factor for developing gastric adenocarcinoma. The Intestinal metaplasia degree and extent is a risk factor for gastric carcinoma(43).There is a threefold increased risk of development of gastric cancer in people with chronic H pylori infection(44).

Elimination of H pylori by a specific treatment, most gastric adenocarcinoma would be prevented as well (45). H pylori is responsible for developing many other gastric neoplasm like MALT lymphoma and hyperplastic gastric polyps(46).Gastric cancer is much more prevalent in people with low social, and economic status. It is well known that gastric cancer is more common in whites than blacks, and males have a threefold increased risk of developing Gastric cancer than women(42,47).

It is known that Gastric cancer is the disease of older people, however, it is also in young people, and when it is the case, it is poorly differentiated, too aggressive and can affect the whole stomach (linitis plastica)(45). Some of the aetiology for gastric malignancy are familial as origin , blood group A, and pernicious anaemia, environmental factors play a part in the growth of stomach cancer (48).

Some diets like over salted food or smoked food, is also risk factors in the development of gastric cancer(49).Upper gastrointestinal malignancies are influenced by environmental factors in Africa, including biomass smoke exposure(50).Some factors were shown to be protective against gastric cancer like minimal consummation of food conserved with nitrates products reduces the risk of developing gastric cancer (38).

Tobacco use is associated with the risk of gastric cancer, whereas alcohol does not affect the developing of gastric cancer. Epstein-Barr Virus is present in 10% of gastric adenocarcinoma

(51,52).Some genetic factors associated with gastric cancer include suppression of P_{53} and amplification of COX2 genes(53).

2.5. Screening of Gastric Cancer

Gastric cancer can remain asymptomatic until advanced stages, when treatments are less effective, hence leading to a poor prognosis(54). Cancer screening programs can help improve prognosis and patient quality of life through early detection. Gastric cancer rarely can occur in people under the age of 50. Its occurrence is increased by sixth and seventh decade of life(5).

Gastric cancer is frequently diagnosed at an advanced stage in any part of the world (47). It is essential to make a screening in high-risk populations(47). The first method of diagnosis for gastric cancer is endoscopy and biopsy(55).Two nations with an increased incidence of Gastric cancer have initiated mass screening, Korea and Japan(56,57).The latter recommend endoscopy and radiographic screening(56).

Endoscopy had a higher sensitivity in detecting gastric cancer than upper gastrointestinal series(UGIS), and Endoscopy remains the gold standard mode of screening for gastric cancer.(47,57,58).The most thoroughly researched biomarkers (pepsinogens, the ABC technique) are only moderately sensitive to cancer and are intended to detect precancerous lesions(59,60).

In people who have a high risk of getting gastric cancer (such as those with HNPCC, familial adenomatous polyposis, gastric adenomas, Ménétrier's illness, intestinal metaplasia or dysplasia, and distant gastrectomy or gastrojejunostomy), screening is beneficial(61,62).These patients should have periodic endoscopy and biopsy and screening improved the 5-years survival rate(63). The test-and-treat approach for H. pylori is a potentially efficient way to lower gastric cancer mortality in Western nations. The general population in Western nations, however, does not find upper endoscopy to be cost-effective for screening for stomach cancer(60)

2.6. Staging of Gastric Cancer

2.6.1. Histology

Histology, or the extent of the tumour penetration as well as lymph node involvement, make the

two most crucial prognostic factors in gastric cancer. In determining the prognosis, tumour grading (differentiation degree: well, moderately, or badly) is also crucial (68).

The histology of stomach cancer is categorised by World Health Organization as: Adenocarcinoma (Papillary, Tubular, Mucinous adenocarcinoma, Signet-ring cell carcinoma), Small cell carcinoma, undifferentiated carcinoma, adenosquamous carcinoma, and others (GIST, lymphoma, etc.) (64,65).

2.6.2. Pathologic staging

Fundamentally, the pathologic stage is more linked to the prognosis. Gastric cancer grading used TNM classification system where it is presented as early for TNM stages 1 and 2 or late for TNM 3 and 4.Staging is important to group patients into risk categories that determine prognosis

and indicate the recommendations for patients with the same prognosis and was used by American Joint Committee on Cancer. The group is based on primary tumour size (T), regional lymph node status (N), and metastasis (M).American Joint Committee on Cancer (AJCC) is the most used system (66)

*T*1: invading tumour reaches lamina propria, muscularis mucosa, or submucosa

*T*2: Penetration of the tumour in the muscularis propria

*T*3: Tumour penetrates subserosal connective tissue without reaching visceral peritoneum or neighbor structures

*T*4*a*: invading tumour reaches serosa (visceral peritoneum)

*T*4*b*: invading mass neighbor organs

*N*0: absence of regional lymph node spreads

*N*1: 1-2 regional lymph nodes are involved

*N*2: 3-6 regional lymph nodes are invaded

*N*3: ≥7 regional lymph nodes are positively affected

*N*3a: 7-15 regional lymph nodes positively invaded

*N*3b: ≥ 16 regional lymph nodes are affected,

*M*0 absence of distant metastasis, *M*1 Distant metastasis

	cM0					pM1
	pN0	pN1 (1,2)	pN2 (3-6)	pN3a (7-15)	pN3b (16-)	Any N
pT1a/pT1b	IA	IB	IIA	IIB	IIIB	IV
pT2	IB	IIA	IIB	IIIA	IIIB	
pT3	IIA	IIB	IIB	IIIB	IIIC	
pT4	IIB	IIIA	IIIA	IIIB	IIIC	
pT4b	IIIA	IIIB	IIIB	IIIC	IIIC	

Figure 2. 1 pTNM stages

Newly proposed classification of pTNM stage in the eighth edition.AJCC(68).

2.6.3. Staging Laparoscopy and Peritoneal Cytology

Explorative Laparoscopy has gained a considerable adjunct role in the staging of gastric cancer staging, particularly in patients with more substantial tumours. This tool helps in the rapid identification of macroscopic peritoneal metastases (67). Moreover, if the cytology results shift to negative after pre-surgery chemotherapy, patients with initial positive cytology may come out an excellent prognosis (68).

2.7. Treatment of Gastric Cancer

2.7.1. Chemotherapy

Studies showed that patients who presented with removable stomach as well as distal oesophageal adenocarcinomas, pre-surgery regimen chemotherapy downstage tumour size as

well stage. In the same line chemotherapy significantly make a move to disease free progression and global survival in treating patients with locally advanced tumours (69,70).Post-operative adjuvant therapy has been shown to increase overall survival and relapse-free survival in stage II or stage III patients with stomach cancer who underwent D2 gastrectomy in a randomised control trial study (71).

Some drugs like regorafenib improved progression-free survival in patients with refractory advanced gastric adenocarcinoma without an excessively negative effect on QoL (72). Moreover, Patients with resectable gastric cancer who received

adequate preoperative neoadjuvant regimen and surgery did not have improvement an overall survival with postoperative chemo-radiotherapy compared to postoperative chemotherapy(73).Given the limited role of surgery in Stage IV gastric cancer, chemotherapy is the main treatment modality in his group of patients (74). Molecular targeted chemotherapy is evolving intreating advanced gastric disease(75).

2.7.2. Surgical Treatment of Gastric cancer

The cornerstone of gastric cancer is surgery(68,76).Surgery being the mainstay of treatment when associated with other multimodal modalities in the treatment of gastric cancer, the prognosis is much better, and the 5-year survival rate is significantly increased(69,73).D2-lymphadenectomy has opted in the European Society for Medical Oncology guidelines since the early 2010s as the gold standard surgical procedure for resectable stomach malignancy(15).

D1 lymphadenectomy in distal gastrectomy implies removal of 1 to 7 station group of lymph node. Moreover, stations 8^{th} to station 12 clearing constitutes D2 lymphadenectomy(77). Radically, Dissection of level 2 lymph node is the standard of surgery of stomach neoplasm treatment in Eastern countries, particularly in Japan(77,78).It is well known that proximal stomach resection is successfully carried out in stage Ia,Ib stomach neoplasm cancer, and present a superb cure percentage thanks to the survival interest and retained function(27).

It has been hypothesised that for stomach tumours in the middle third of the stomach, distal subtotal gastrectomy decreases postoperative complications, shortens hospital stays after surgery and speeds up recovery. Extended-term survival of patients undergoing subtotal gastrectomy equals the ones that of the whole removal of the stomach with oncology-staged neoplasm (79). Surgical treatment is advancing with new technologies and a good understanding of anatomy . Regarding surgical treatment, options are open gastrectomy or laparoscopically assisted gastrectomy; all are safe(80).

It has been suggested total laparoscopic gastrectomy is significantly valid as a modality of treatment as open total gastrectomy with the advantage of the better perioperative outcome of the former(81,82).For instance, in some studies, it has been shown that distal laparoscopic stomach removal with the whole nasogastric clearing decrease a significant amount of malignant loads

cells in peritoneal cavity survival free of disease compared to dissection of level 2 stomach removal (83)**. S**pleen-preserving laparoscopic L2 total gastrectomy for advanced top-third gastric cancer is safe and effective (84,85).

In summary, treatment of stomach neoplasms can be done with surgery, neoadjuvant or a combination of the surgery and chemotherapy, depending on the stage.

2.8. QUALITY OF LIFE

2.8.1. Measurement tools for the quality of life

Multiple tools were carried out to assess the patient's quality of life. Some are general, others specific. (86). Questionnaires created sorely to measure the quality of life of neoplasia patients include the Quality of Life Questionnaire of the European Organisation for Research and Treatment in Cancer(EORTC QLQ-C30 version 3), (FACT-G) (87).

The tools that are utilised the most frequently are FACT-G and EORTC QLQ-C30. Version 3 EORTC QLQ-C30 is a validated questionnaire to measure overall health-related quality of life in neoplasia patients. First used in 1993, and it has been employed in multiple clinical trials and non-trial worldwide research. It calculates scales in functional ability (role, physical, cognitive, social-emotional), complaints items (pain, fatigue, anorexia, vomiting) and global health status (overall assessment)(24,88).QLQ-C30 STO22 specific module for gastric cancer patients has 9 Items (Dysphagia, chest and abdominal pain, acid regurgitation, eating limitations, anxieties, dryness of oral cavity, taste problem, the outlook of the body, hair loss) (24).

2.8.2. Level of the function of Gastric cancer patient

The undertreated patients' complaints can negatively influence patients' health outcomes, like functional performance, psychological status, quality of life, and survival rate (89). Early satiety, abdominal cramps in the abdomen, diarrhoea, and dumping are some of the most common symptoms post gastrectomies. Given that some of the symptoms can last over 12 months, a gain in overall HRQoL often precedes symptom recovery. Whole QoL as well as emotional function in terms of emotional ability were great by three months after stomach resection(4).

A famous US cancer centre, In their longitudinal cohort study, entire QoL recover edging theinitial in less than half of a year for more than a half of patients (13).But, issues like anorexia, easy fatigability, and lower eating desire kept down over one year to one year and half (4).Another study showed that potentially curative gastrectomy for cancer has a negative resulton HRQL that

mainly recovers in patients surviving some two years. Patients who succumb within two years may experience low post-operative recovery (29).

Studies suggest that after a whole stomach removal in a long-interval period patients may resume their normal health but it all depend on used assessment tools (90).

2.8.3. Importance of measuring the Quality of life

Different research was carried out to elicit the importance of determining the Quality of life (QoL) in stomach neoplasia population. Their results were that quality of life can help predict survival in cancer patients(91).It is helpful for gastric cancer patients with gastrectomy to adapt well to changes after surgery to improve the quality of life(92).Even if long-term survivors of a distal subtotal gastrectomy are thought to be disease-free, the procedure nevertheless impacts their Quality of life. The QLQSTO22 gastric module, which focuses primarily on upper GI symptoms, can be utilised for all facets of multimodal gastric cancer therapy(91).

2.8.4. Factors influencing Quality of lives

Though, global QoL post gastrectomy does not seem to be compromised despite gastrointestinal (GI) complaints such as dumping, quick abdominal fullness, and periodic anorexia(93). Health-related Quality of life (HRQoL) is more comprehensive than only physical symptoms and includes social health, psychological well-being, and perception of sickness (4).

Surgical procedure affects the Quality of life in its entirety, as found detected in EORTC QLQ-C30 and STO22 among patients treated by the three gastric surgery: partial, near, and total gastrectomy, whether open or laparoscopy. The laparoscopic method yields better short-term outcomes, while TG persisted to detrimental impact the HRQOL in multiple areas a year post-surgery (26).

Given the fact that it produces a much higher quality of life for patients than total gastrectomy, subtotal gastrectomy is recommended for a tumour found in the distal stomach (94) because it produces a much higher quality of life for patients than total gastrectomy(34).

One study showed that income and gender were independent factors affecting QOL levels(95).It was found that nearly all items imparting QoL are modifiable, mainly patients' complaints (easy tiredness, nausea, shortness of breath) and depression. A decrease in education, singles, and numerous conditions showed a decrease of HRQoL. Interestingly as you correct the number of

factors, will HRQoL globally rise and in two levels of educational-level groups(96). Studies demonstrated that the type of surgery, and age significantly affect the outcome of QoL(93–95,97)

Subtotal gastrectomy for distal cancer was found to have a better first-year QoL than total gastrectomy, and pouch reconstruction is linked to fewer symptoms (98)**.** In one study, health education improved the overall health score of patients with gastric cancer after surgery. It can also improve physical, role, emotional, cognitive, and social scores. It can significantly improve patient's quality of life(99).

CHAPTER 3. RESEARCH METHODOLOGY

3.1. Study design

This is a cross-sectional study from February 2022 to October 2022 of patients operated on for gastric cancers over five years (2017-2022).

3.2. Study site

This study was carried out at the University teaching hospital of Kigali/CHUK, Department of Surgery

3.3. Study population

All elective patients operated for gastrectomy on confirmed gastric adenocarcinoma after at least three months post-surgery

3.4. Selection Criteria

3.4.1. Inclusion criteria

- ≥18 years and above
- Post-gastrectomy patients for a confirmed gastric adenocarcinoma on anatomopathology
- Patients with ≥ 3 months post gastrectomy
- Elective cases
- Patients with complete clinical information

3.4.2. Exclusion Criteria

- Patients with gastric adenocarcinoma and another malignancy
- Patients with incomplete clinical information

3.5. Sample size justification

Sample size calculation in cross-sectional studies formula as below:

$n=Z^2P\ (1-P)/\ [d^2]$

n: is the sample size,

Z: is the statistic corresponding to the level of confidence
P: is the anticipated prevalence
d: is precision

$n=1.64^2x0.07\ (1-0.07)/[0.05^2]=71$ patients

3.6. Study Procedure

We used theatre registries for all elective surgeries from 1st January 2017 to 30th September 2022. We identified 238 patients operated on for gastric cancer; 173 patients had adenocarcinoma, and the remaining shared Gastrointestinal stromal, Lymphoma, and chronic atrophic gastritis. After identifying patients from the registry, we used CHUK electronic database to identify the clinicopathologic of patients, surgical stage and their phone contact.106 had a well-filled electronic database, and 92 patients had active phone contact. We recruited 71 patients matching our sample size.

Twenty-nine patients attended OPD, and a signed consent form was obtained. A Translated questionnaire in Kinyarwanda was filled. We administered a Data collection questionnaire of 16 questions of socio-demographics, clinicopathologic characteristics and 52 questions of QLQ-C30 STO22 with the help of a trained research assistant.Forty-two patients gave verbal informed consent, and the same questionnaire was filled by help of principal researcher and the phone talk ranged between 23min-35min was carried out by principle researcher.

3.7. Psychometric measures of the instrument

EORTC QLQ-C 30 3rd version has (Global healthy Scale, Functional Scale: Physical, Role, Emotional, cognitive, social functioning), and QLQ-C30 STO22 has 9 Items (Dysphagia, chestand cramps in abdomen, acid regurgitation, eating auto restriction, anxieties, dryness of oral cavity mouth, taste problem, outlook of the body, hair fall). We did a multivariate logistic regression of EORTC QLQ C-30 STO22 functional and symptom scales with global health status (QoL) of gastric cancer patients. All of the scales and single-item measures range in scores from 0 to 100. A high scale score represents a higher response level. Thus a high score for a functional scale represents a high / healthy level of functioning; a high score for the global health status / QoL represents a high QoL, but a high score for a symptom scale / item represents a high level of symptomatology / problems.

The manner of scoring these scales was the same in all cases to make the estimation of the average of the items that contribute to the scale; this is the raw score and to use a linear transformation to standardise the raw score, so that scores range from 0 to 100; the level of functioning was better with higher score while high level of symptoms represents a worse score.
If items I1, I2 ... In are included in a scale, the procedure is as follows:
Raw Score = RS = (I1 + I2 +...+ In)/n
Apply the linear transformation to 0-100 to obtain the score
Functional scales: S= {1-(RS-1)/range} x100
Symptoms scales/items: S= {(RS-1)/range} x100
Global health status/QoL: S= {(RS-1)/range} x100

Range is the difference between the maximum possible value of RS and the minimum possible value. The QLQ-C30 has been designed so that all items in any scale take the same range of values. Therefore, the range of RS equals the range of the item values. Most items are scored 1 to 4, giving range = 3. The exceptions are the items contributing to the global health status / QoL, which are scored 1 to 7 with range = 6, and the initial yes/no items on the earlier versions of the QLQ-C30, which have a range = 1.

3.8. Data analysis plan

The data collection questionnaire was used following QLQ-C30 STO22 of 52 items, then data was computed and hence analysed using SPSS 23rd version. Data is expressed in proportions and frequency tables for categorical variables. Means and standard deviation are used to summarise continuous variables. We did Binary logistic regression analysis to study the relationship between predictors and Global health status (EORTC QLQ C-30 STO22 functional and symptom scales with global health status). Then later, the factors that showed to be associated with the outcome (global health status) in the binary logistic regression analysis were further analysed in the multivariable logistic regression analysis to identify the real predictors of the outcome.

Statistical significance for the associations was considered at ap-value of less than 0.05. Patients were contacted on the phone, and the scheduled meeting was done at the outpatient department. A hard copy questionnaire was administered to each for filling after signing a consent form.

3.9. Validity and Reliability of the instruments

3.9.1. Validity

The degree to which an instrument measures what it intends to measure is called validity

3.9.2. Reliability

An evaluation tool uses reliability to produce consistent outcomes. The EORTC QLQ-C 30version 3.0 and QLQ-C30 STO22 methods for assessing life quality are well-established, trustworthy, and widely accepted as validated tools for gastric cancer patients.

3.10. Ethical consideration

The department of surgery/University of Rwanda approved the research proposal. We got ethical approval from IRB (Institutional Review Board) CMHS/UR. Ethical clearance from the research site was obtained from the University Teaching Hospital of Kigali/CHUK. Study participants signed informed consent before enrollment into the study. Patients' information remained confidential, with patients' right to withdraw from the study upon their will. All documents were kept confidential and private.

3.11. Dissemination

Health research's primary purpose is to support evidence-based practice and patient treatment. Following the completion of this study, we will deliver our findings to Kigali University Teaching Hospital stakeholders. A Poster presentation was made at the 1st Rwanda Surgical Research Open Day conference.

Following the completion of the thesis, the papers produced will be submitted to high-index journalsfor publication.

3.12. Study Limitations

1. Patients selection from the retrospective data
2. Single centre study for results generalisability
3. Heterogeneity of timeline operated patients
4. This study's cross-sectional design precluded the examination of repeated measures of HRQOL over time.

CHAPTER 4. RESULTS AND ANALYSIS

4.1. Introduction to the Findings

In the present section, the results are a way of responding to the study objectives. We analysed 71 patients as per our sample.

4.2. Socio-demographic of gastric cancer patients in CHUK

The median age of the study participants was 63 years ranging from 22 to 82 years of age, and the mean body mass index (BMI) was 20.7(± 2.9) with a standard deviation of 2.9. Male gender was predominant at 57.75%, and of the total participants, 70% were married. 5.63% of participants attended university, 31% attended secondary school and 49% attended primary school. Of the total participants, 56.3% were from urban areas. Regarding the Socioeconomic category (Ubudehe) 33.8% were classified in the third category of Ubudehe, 49.3% in the second category and 16.9 % in the first category (Table 1).

Table 4. 1 Sociodemographics characteristic of study participants

Characteristics	**n**	**%**
Age (years) [Median (Q1-Q3)]	63 (50-68)	
BMI (kg/m2)[Mean ± SD]	20.7 ± 2.9	
Sex		
Male	41	57.75
Female	30	42.25
Marital status		
Single	6	8.45
Married	50	70.42
Widowed	12	16.9
Separated	3	4.23
Education		
Illiterate	10	14.08
Primary	35	49.3
Secondary	22	30.99
University	4	5.63

Occupation		
Agriculture	28	39.44
Business	16	22.54
Public sector	3	4.23
Private sector	6	8.45
Student	2	2.82
Unemployed	16	22.54
Residence		
Rural	31	43.66
Urban	40	56.34
Economic category		
Ubudehe 1	12	16.9
Ubudehe 2	35	49.30
Ubudehe 3	24	33.8

4.3. Clinicopathological characteristics of the patients with gastric adenocarcinoma

Fifty per cent of the participants underwent open partial gastrectomy, 36.6% underwent open near total gastrectomy and 12.68% underwent open total gastrectomy. Of the total participants, 61.9% were in stage III, 22.5% in stage II and 15.5% in stage I. Forty-three per cent of the tumours were well differentiated, 38% with moderate differentiation and 18.3% with poor differentiation. Sixty-two per cent of the tumours were classified as Intestinal type by Lauren classification, 18.3% were classified as diffuse type, and 19.7% as mixed (Table 2).

Table 4. 2 Clinicopathological characteristics of the patients with gastric adenocarcinoma

Characteristics	Frequency	Percentage
Type of surgery		
Open partial gastrectomy	36	50.7
Open near total gastrectomy	26	36.62
Open total gastrectomy	8	12.68
Tumour stage		
I	11	15.49
II	16	22.54
III	44	61.97
Tumour differentiation		
Well	31	43.66
Moderate	27	38.03
Poor	13	18.31
Lauren classification		
Intestinal type	44	61.97
Diffuse	13	18.31
Mixed	14	19.72
Presence of comorbidities		
Hypertension	13	18.31
Hepatitis	8	11.27
Diabetes	4	5.63
Atherosclerosis	2	2.82
HIV	1	1.41
None	43	60.56
Time elapsed since surgery		
3-6 months	17	23.94
6-12 months	20	28.17
1-2 years	22	30.99
>2 years	12	16.9

4.4. Health-related Quality of life scores of 71 patients who underwent gastrectomy for gastric adenocarcinoma

The mean Global health status scores from the study participants were generally good at 70.4 (SD=22.83), and considering the QLQ-C30 functional scales scores, the highest mean functioning score was in cognitive functioning at 90.14 (SD=14.52) , the lowest mean functioning score was in emotional functioning at 72.88 (SD=15.66). Considering the general symptoms scales, the

highest scores were found in financial difficulties scales (73.71 ± 29.76), followed by the fatigue scale, nausea and vomiting scale, appetite loss scale, pain scale, and the symptom with the lowest Quality of life score were diarrhoea with 1.88 (SD=9.57).

Considering the quality of life questionnaire (QLQ)-STO22, the mean body image scale score was found to be 16.43 (SD=23.82). We observed that the highest scores on the hair loss scale were were followed by eating restrictions, anxiety, reflux, dry mouth, and pain and the lowest scores were found on taste scales (Table 3).

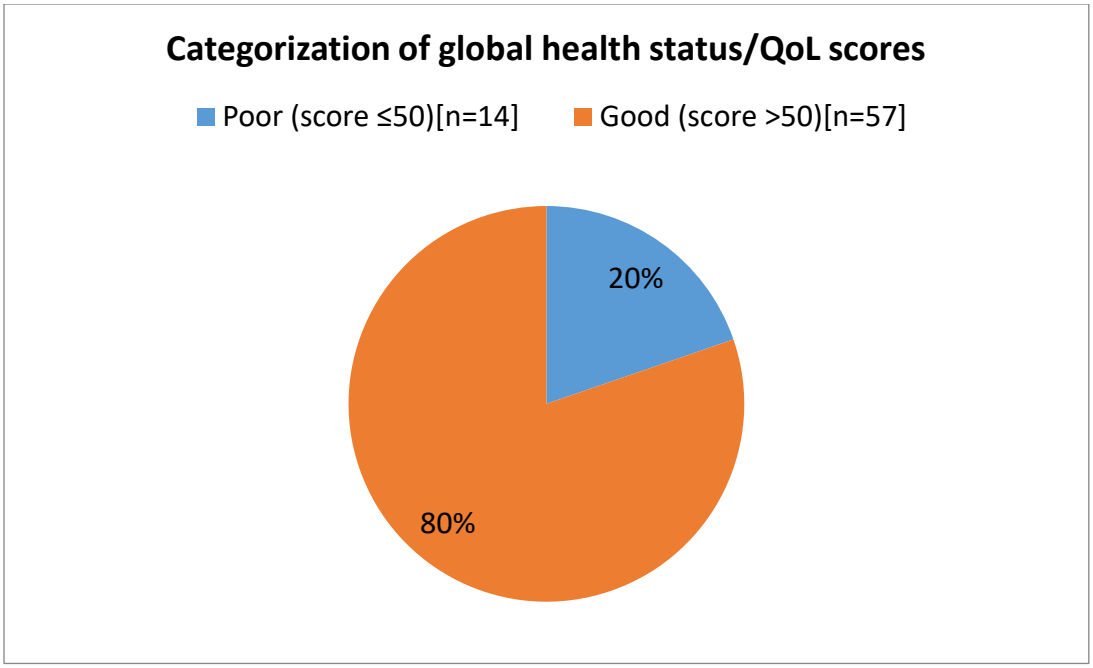
Table 4. 3 Health-related Quality of life scores of 71 patients who underwent gastrectomy for gastric adenocarcinoma

Scales	Mean ± SD	Median (Q1-Q3)
Quality of life questionnaire (QLQ)-C30		
Global quality of life	70.42 ± 22.83	75.0 (66.6-83.33)
Functional scales		
Physical functioning	86.94 ± 12.67	86.66 (80-100)
Role functioning	85.91 ± 21.57	100 (83.33-100)
Emotional functioning	72.88 ± 15.66	75 (66.66-83.33)
Cognitive functioning	90.14± 14.52	100 (83.33-100)
Social functioning	76.76 ± 23.14	83.33 (66.66-100)
General symptoms scales		
Fatigue	16.27 ± 16.88	11.11 (0-22.22)
Nausea and vomiting	15.96 ± 23.81	0.00 (0-16.66)
Pain	14.32 ± 19.17	16.66 (0-16.66)
Dyspnea	5.63 ± 13.78	0.00 (0-0)
Insomnia	6.10 ± 17.19	0.00 (0-0)
Appetite loss	15.02 ± 20.92	0.00 (0-33.33)
Constipation	4.22 ± 14.83	0.00 (0-0)
Diarrhea	1.88 ± 9.57	0.00 (0-0)
Financial difficulties	73.71 ± 29.76	66.66 (66.66-100)

Quality of life questionnaire (QLQ)-STO22		
Functional scales		
Body image	16.43 ± 23.82	0.00 (0-33.33)
General symptoms scales		
Dysphagia	14.08 ± 16.68	11.11 (0-22.22)
Pain	8.13 ± 13.40	0.00 (0-11.11)
Reflux	12.20 ± 15.77	6.66 (0-13.33)
Eating restrictions	29.57 ± 25.07	16.66 (16.66-33.33)
Anxiety	23.00 ± 17.04	20.0 (13.33-33.33)
Dry mouth	9.86 ± 21.37	0.00 (0-0)
Taste	7.98 ± 19.07	0.00 (0-0)
Hair loss	69.01 ± 46.57	100 (0-100)

Figure 4 highlights that of all the participants, 80% scored more than 50 over 100 in the global health status scale, which is considered a good score, and the remaining 20% scored less than 50 over 100, considered a poor score.

Figure 4. 1 Categorisation of Global Health Status scores among the patients who underwent gastrectomy for gastric adenocarcinoma



4.5. Association global health status scores from QLQ-C30 with clinicopathological characteristics among study participants(binary logistic regression analysis)

Table 4 shows that patients who were interviewed one year post-operative were 8.86 times more likely to have poor global health status scores than those interviewed after one year post-operative, with a statistically significant difference (OR=8.86; 95% CI: 1.81-43.39; p=0.007). There was no statistically significant difference in the global health status scores across age, gender, body mass index, marital status, economic category, education, and time between symptoms onset and surgery categories.

Table 4. 4 Association global health status scores from QLQ-C30 with social and demographic characteristics among study participants (binary logistic regression analysis)

Characteristics	QLQ-C30 Global health status score		OR (95% CI)	P
	Good (n=58)	Poor (n=14)		
Age				

≤65 years	32 (76.19%)	10 (23.81%)	ref	
>65 years	25 (86.21%)	4 (13.79%)	0.51 (0.14-1.82)	0.302
Gender				
Male	32 (78.05%)	9 (21.95%)	1.41 (0.41-4.72)	0.581
Female	25 (83.33%)	5 (16.67%)	ref	
Marital status				
Single	3 (50.00%)	3 (50.00%)	5.25 (0.89-30.81)	0.066
Married	42 (84.00%	8 (16.00%)	ref	
Divorced/widow	12 (80.00%)	3 (20.00%)	1.31 (0.30-5.73)	0.718
Residence				
Rural	24 (77.42%)	7 (22.58%)	1.37 (0.42-4.43)	0.594
Urban	33 (82.50%)	7 (17.50%)	ref	
Economic category				
Cat 1	10 (83.33%)	2 (16.67%)	0.76 (0.12-4.64)	0.766
Cat 2	28 (80.00%)	7 (20.00%)	0.95 (0.26-3.44)	0.938
Cat 3	19 (79.17%)	5 (20.83%)	ref	
Education				
Illiterate	7 (70.00%)	3 (30.00%)	0.43 (0.04-4.63)	0.486
Primary	30 (85.71%)	5 (14.29%)	0.16 (0.02-1.46)	0.107
Secondary	18 (81.82%)	4 (18.18%)	0.22 (02-2.08)	0.188
University	2 (50.00%)	2 (50.00%)	ref	
Time elapsed since surgery				
≤1 year	23 (65.71%)	12 (34.29%)	8.86 (1.81-43.39)	0.007
>1 year	34 (94.44%)	2 (5.56%)	ref	
Time between diagnosis and surgery				
≤3 months	46 (83.64%)	9 (16.36%)	0.43 (0.12-1.54)	0.195
>3 months	11 (68.75%)	5 (31.25%)	ref	
BMI Category				
<18.5	13 (68.42%)	6 (31.58%)	2.63 (0.75-9.27)	0.131

18.5-24.9	40 (85.11%)	7 (14.89%)	ref	
25.0-29.9	4 (80.00%)	1 (20%)	1.42 (0.14-14.74)	0.765

Patients with poor tumour differentiation were 12 times more likely to have poor global health status score than those with well-differentiated tumours (OR=12.43, 95% CI: 2.05-75.23; p=0.006). Patients with moderately differentiated tumours were 4.1 times more likely to have poor global health status scores than those with well-differentiated tumours, but the difference was not statistically significant (OR=4.14; 95% CI: 0.76-22.58; p=0.1). Patients with tumours classified as mixed by Lauren classification were ten times more likely to have poor global health status scores than those with intestinal type classified tumours (OR= 10.00 95% CI: 2.30-43.39; p=0.002). Patients with tumours classified as diffuse were three times more likely to have poor global health scores than those with intestinal-type classified tumours, but the difference was not statistically significant,but with clinical implication. (OR= 3.00; 95% CI: 0.57-15.61; p= 0.192).

There was no statistically significant difference in the global health status score groups across the type of surgery and tumour stage (Table 5).

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Table 4. 5 Association global health status scores from QLQ-C30 with clinicopathological characteristics among study participants (binary logistic regression analysis)

Characteristics	QLQ-C30 Global health status score		OR (95% CI)	p-value
	Good (n=58)	Poor (n=14)		
Type of surgery				
Open partial gastrectomy	32 (88.89%)	4 (11.11%)	ref	
Open near total gastrectomy	18 (69.23%)	8 (30.77%)	3.55 (0.94-13.46)	0.062
Open total gastrectomy	7 (77.78%)	2 (22.22%)	2.28 (0.34-15.04)	0.39
Tumour stage				
I	11 (100%)	0 (0.00%)	_	
II	15 (93.75%)	1 (6.25%)	ref	
III	31 (70.45%)	13 (29.55%)	6.29 (0.75-52.68)	0.09
Tumour differentiation				

Well	29 (93.55%)	2 (6.45%)	ref	
Moderate	21 (77.78%)	6 (22.22%)	4.14 (0.76-22.58)	0.1
Poor	7 (53.85%)	6 (46.15%)	12.43 (2.05-75.2)	0.006
Lauren classification				
Intestinal type	40 (90.91%)	4 (9.09%)	Ref	
Diffuse	10 (76.92%)	3 (23.08%)	3.00 (0.57-15.6)	0.192
Mixed	7 (50.00%)	7 (50.00%)	10.00 (2.3-43.4)	0.002

4.6. Multivariable analysis of factors associated with global health status scores from QLQ-C30 among study participants

We found that the umor differentiation and Lauren class were the real predictors of the global status scores among our patients. Patients with moderate and poor tumor differentiation were more likely to have poor general health status scores as those with well differentiated tumor (p=0.048).Patients with tumours classified as mixed are more likely to have poor global status scores after surgery than those with diffuse and intestinal types(Table 6).

Table 4. 6 Multivariable analysis of factors associated with global health status scores from QLQ-C30 among study participants

Predictors	AOR	95% CI	SE	Z	p-value
Lauren classification					
Intestinal	1				
Diffuse	2.06	0.37-11.50	1.807	0.82	0.41
Mixed	10.53	1.57-70.54	10.218	2.43	0.015
Differentiation					
Well	1				
Moderate	6.63	0.89-49.44	6.798	1.85	0.065
Poor	5.87	0.81-42.56	5.937	1.75	0.079
Constant	0.03	0.004-0.18	0.0270	-3.76	<0.001

CHAPTER 5. DISCUSSION

5.1. Introduction

Our research aimsto assess factors influencing health-related quality of life post gastrectomy in stomach cancer patients in the University teaching hospital of Kigali/CHUK to produce evidence to enhance patient care. The primary conclusions of this study are covered in this part, along with the multivariate analyses that produced them. The components of these sections are in the line with the main objectives of this study.

5.2. Discussion of the results

5.2.1. Socio-demographic of gastric cancer patients in CHUK

In this study, the majority of respondents were male at 57.75%. This highlights the higher male like the hood of developing in gastric cancer, and it is similar to what was found in review studies done by *Lyon et al,2019,S.Li et al,2019* in their review studies, found similar results (42,47).The median age [Median (Q1-Q3)] 63 (50-68) was 63 years ranging from 22 to 82 years of age. It is well known that males are at high risk of getting gastric cancer due to the lack of estrogen protection to chronic H.Pylori infection.

The mean body mass index (BMI) was 20.7(± 2.9). 70% were married. Only five per cent of participants attended university, one-third attended secondary school, while half attended primary school(100). Of the total participants, more than half are from urban areas and, third are classified in the third socioeconomic category(ubudehe,), half in the first category and 16.9 % in the first category. These results are similar to those found by other studies highlighting the association of low socioeconomic status and education level with the incidence of gastric cancer

(100–103).

In our study, the patients in Socioeconomic category categories 1 and 2 have an increased odd ratio of poor quality of life compared to Socioeconomic category 3. The pathway through which socioeconomic status influences stomach cancer risk is not established but is likely to reflect differences in risk factors for stomach cancer: tobacco smoking, diet and a higher likelihood of infection with Helicobacter pylori(48).

5.2.2. Clinicopathological characteristics of the patients with gastric cancer

Forty-three per cent(43%) of the tumours are well differentiated, 38% with moderate differentiation and 18.3% with poor differentiation. Sixty-two per cent of the tumours are classified as Intestinal type by Lauren classification, 18.3% are classified as diffuse type, and 19.7% as mixed.*Lyons et al,Annamaria et al in 2019 and 2020 respectively.*They found the similar results in their study revealing the predominance of intestinal type over diffuse and mixed type (42,67). These findings demonstrate the close relationship between environmental elements like Helicobacter pylori, food, and lifestyle, and gastric adenocarcinoma.

Half of the participants underwent open partial gastrectomy, thirty-six per cent open near total gastrectomy and ten per cent open total gastrectomy. This result can be explained by the fact that most gastric cancer are non-cardia, requiring partial or nearly total gastrectomy. Two third are in stage were in stage III, one-fifth in stage II and fifteen in stage I. This is because gastric cancer lacks specific symptoms, and when they show up they are painless. Patients present most of the time with advanced disease at the initial diagnosis, that's why few patients present with lower stages. In a study done in Rwanda by *Martin et al. in 2018* and *Niyongombwa et a.l in 2021* they found similar results of advanced stage at the time of patient presentation(30,31).

The mean Global health status scores from the study participants were generally good at 70.4 (SD=22.83), which is slightly low compared to the EORT reference of 74 in a study done by *Scott et all,2008* in the Dutch population(24).This is the highlight similarity with other studies that found minimal change in global health status after three months post gastrectomy by

Hu&Zayfudim in 2020(4). And another study done by *Karanicolas et al.,2013* found a return to a good Global health status within one year post gastrectomy(13).

Patients with poor tumour differentiation were 12 times more likely to have poor global health status scores as those with well-tumour differentiation.Patients with poor tumour differentiation were 12 times more likely to have poor global health status scores as those with well tumour differentiation (p=0.006). Patients with moderately differentiated tumors were 4.1 times more likely to have poor global health status scores than those with well-differentiated tumors but the difference was not statistically significant (p=0.1).These findings are similar to the result of *Kobayashi* et al.*2011*(26).

Patients with tumours classified as mixed by Lauren classification were 10 times more likely to have poor global health status scores as those with intestinal type classified tumors (p=0.002) while patients with tumors classified as diffuse were 3 times more likely to have poor global health scores as those with intestinal type classified tumors.Still the difference was not statistically significant (p= 0.192).In other studies, it was found that Lauren's class is associated with Quality of life (2,104,105).

This is the first study that generated local epidemiological data for the QoL of the patients after gastrectomy for stomach cancer at CHUK. This study demonstrates that after gastrectomy, patients experience change in Global HRQoL but most (80%) maintain a high and reasonable life satisfaction. This study discovered a high predominance of gastric cancer in men. Factors associated with poor global Quality of life are low socioeconomic status and level of education. Our study also found an association of time elapsed since surgery and global quality of life, where less than a year global Quality of life is likely to be poor((106).

They are some limitations of this study. The first is Patients selection from the retrospective data. The second is the fact that it is a single-center study for results generalisability. Hence a national-level study is recommended. Another source of bias might be the heterogeneity of timeline-operated patients. The analysis of repeated HRQOL measurement over time was not possible due to the cross-sectional design of this study.

CHAPTER 6. CONCLUSION AND RECOMMENDATION

6.1. Conclusion

Most gastric cancer patients present at a late stage.Patients who have undergone a gastrectomy endure functional limitations and symptoms but only a little reduced level of global health-related Quality of life. Tumour differentiation and Lauren's class were found to be the actual predictors of global status.The most affected item in our participants was financial difficulties scales followed by fatigue, nausea and vomiting scale, appetite loss scale, and pain.

6.2. Recommendation

- ✓ Encourage patients to early consultation
- ✓ To start and implement the screening of gastric cancer for early detection of the malignancy
- ✓ To CHUK, patient education should be provided, and patients informed of changes in Quality of life after gastrectomy and the potential good return to baseline progressively over time
- ✓ Further research with interventions and multicentre at the national level is needed to investigate the modifiable factors associated with QoL.
- ✓ We recommend the ministry of health to government support gastric cancer patients through an association, where they would receive both financial and psychological support to lower the burden of gastric cancer’s economic hardship

CHAPTER 7. REFERENCES

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CHAPTER 8. APPENDICES

8.1. Appendix 1 : budget of research" factors influencing health related quality of life after gastrectomy for cancer in CHUK

ITEMS	NUMBER	PRICE/UNIT	TOTAL PRICE(FRW)
1. Communication and transport(researcher,and /or Patients)		20000	1000,000
2. Assistant researcher +Data collection	2	200000	400000
3. Data collection tools	71	2000	142000
4.Others(Divers) or Miscellanous			400,000
5. Statistician	1		500,000
6. Report writing and print+thesis copy for dissertation	5 BOOKS	30000	150,000
Total			2,592,000

8.2. Appendix:1 Consent form english version

This agreement consists of two parties: The investigator, and the patients or the patient's guardian requested to be recruited in the research study. It contains information regarding the research study and the agreement (informed consent act) between two parties.

This research study entitled "Factors influencing health related quality of life after gastrectomy for cancer in CHUK" aims to investigate the c factors influencing health related quality of life in patients operated for gastric cancer in CHUK. The outcome of this study will clarify the weight and burden of the diseases, this will push the program and policy makers to invest more or to attract the partners in this important specialized surgical area to increase its surgical capacity and to increase the perioperative optimization mechanisms and the modifiable factors will be recognized and fixed to anticipate the postoperative complications. There will be no payment or per diem that will be given to participants and participation in this research study will not influence the flow of their management.

The participant has full right to retract his informed consent at each step of the research study before its completion. There is no health hazards (physiological or psychological) related to the participation in this research study.

Participant information collected in this research study will be confidential and will only be used for the presented research study.

The participant has full right to get the information on the outcome of the research study after its completion if needed.

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Names and signature of Participant/ Guardian

……..

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8.3. Appendix: 2 Consent form in kinyarwanda

Aya masezerano arimo impande ebyiri: umushakashatsi n' umurwayi cg umwishingizi we usabwa kwinjizwa mu bushakashatsi. Akubiyemo amakuru kubushakashatsi ndetse n'ibyo impande zombi ziyemeje.

Ubu bushakashatsi bwiswe "**Factors influencing health related quality of life after gastrectomy for cancer in CHUK"**tugenekereje mu Kinyarwanda bisobanura ngo **" Impamvu zituma ababazwe indwara ya kanseri yo mu gifu babaho muburyo butandukanye mu bitaro bikuru bya kaminuza bya Kigali (CHUK)".** Niwinjira muri ubu bushakashatsi, uzasubiza ibibabazo byanditse uzabazwa n'umushakashatsi. hazasuzumwe ubuzima bw'abarwayi nyuma yo kubagwa uburwayi bwa kanseri yo mu gifu n'impamvu zitandukanye zishobora guhindura ubwo buzima bityo hazafatwe ingamba zitandukanye zo guteza imbere ubuvuzi bwo kubaga indwara za kanseri no gutegura neza abagiye kubagwa kugirango hirindwe

igaruka mbi nyuma yo kubagwa no gutegurira abarwayi kumenya ubuzima bwanyuma yo kubagwa.

Nta ndonke cyangwa ingurane zizatangwa muri ubu bushakashatsi. Nta ngaruka bizagira mu buryo bari basanzwe bakurikirana.

Uwinjijwe mubushakashatsi afite uburenganzira busesuye bwo kwisubiraho akabuvamo igihe cyose abishakiye .Nta ngaruka nimwe y'ubuzima izwi yaturuka ku mikorerwe y'ubu bushakashatsi.

Umushakashatsi yiyemeje ko amakuru y'uwinjijwe mu bushakashatsi azagirwa ibanga kandi ko atazakoreshwa mu yindi mpamvu itari ubu bushakashatsi.

Uwinjijwe mubushakashatsi yemerewe kubaza ibyavuye mu bushakashatsi niburangira igihe yaba abikeneye.

Amazina n'umukono by'Umushakashatsi.

Dr. NSABIMANA Venuste (UR-CMHS)

Tel: 0785828490

E-mail: diaro76@gmail.com

Umukono, umurwayi /Umwishingizi

……..

Kubindi bisobanuro wahamagara aba bakirikira:

Umugenzuzi mukuru w'ubushakashatsi

Dr.INGABIRE ALLEN JC,MD,MMed,MPH,FCS(ECSA),PhD©,Consultant Orthopaedic Surgeon,Senior Lecturer of Surgery,Deputy Director,NIHR Research Hub on Global Surgery/Rwanda, University Teaching Hospital of Kigali, University of Rwanda.

Tel:+250788549975

Email:ijea2000@gmail.com

Uwungirije Umugenzuzi mukuru

Dr.NIFASHA Antoine, MD,Mmed

Senior Consultant General Surgeon

Tel: 0782018377

Email: antoine.nif@gmail.com

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 9th /March /2022

Dr NSABIMANA Venuste
School of Medicine and Pharmacy CMHS, UR

Approval Notice: No 192/CMHS IRB/2022

Your Project Title ***"Factors Influencing Health Related Quality Of Life after Gastrectomy for Cancer in CHUK"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
			No (Reason)	
Name of Members	**Institute**	Yes	**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Stefan Jansen	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	
Prof Gishoma Darius	UR-CMHS	X		
Prof 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 7th March 2022, **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 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 9th March 2022

Expiration date: The 9th March 2023

Assoc. Prof Stefan Jansen
Ag. Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

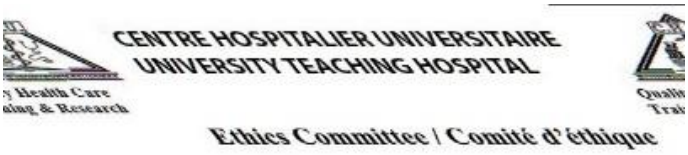
Cc:

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

Email: researchcenter@ur.ac.rw P.O Box 3286 Kigali, Rwanda www.ur.ac.rw

8.4. Appendix:4 CMHS/UR review board

8.5. Appendix :5 CHUK Ethical Approval



6th Apr,2022

Ref.:EC/CHUK/054/2022

Review Approval Notice

Dear NSABIMANA Venuste,

Your research project: ***"Factors influencing health related quality of life after gastrectomy for cancer in CHUK"***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 6th Apr,2022 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:www.chuk.rw/research/fullreport/?appid=553&&chuk.

PS: Please note that the present approval is valid for 12 months. Yours sincerely,

Dr Emmanuel Rusingiza Kamanzi The Chairperson, Ethics Committee, University Teaching Hospital of Kigali

Scan code to verify.

"University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops)

Which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations "

Web Site : www.chuk.rw *; B.P. 655 Kigali- RWANDA Tél.: 00 (250) 252575462. E-Mail:* chuk.hospital@chuk.rw

8.6. Appendix: 3 DATA COLLECTION FORM" Factors influencing health related quality of life after gastrectomy for cancer in CHUK"

Social demography Details	1.Age		Patient's Initials	
	2.Sex	Male ☐ Female ☐	ID	
3. Marital status	Single ☐	Married ☐	Widowed ☐	Separated ☐
4. Level of education	Illiteracy ☐	Primary ☐	secondary ☐	University ☐
5. Activity	Agriculture ☐	Business ☐	Public sector ☐ Private sector ☐	Unemployment ☐ Student ☐
6.Residence area	Rural ☐	Urban ☐	ubudehe category ☐	
Clinical characteristics of participants				
7.Interval Time since diagnosis to surgery Days months			Days ☐	Months ☐ Years ☐
Time elapsed since surgery	3-6 Months ☐		6-12 Months ☐	1-2 Years ☐ >2 years ☐
8.**Type of surgery**	Open Partial Gastrectomy ☐	Open Near Total Gastrectomy ☐	Open Total Gastrectomy ☐	Laparoscopic Assisted Gastrectomy ☐
9.Tumor stage	I ☐	II ☐	III ☐	pTNM ☐

10.a.Pathology type	Adenocarcinoma		
10.b Tumor grade (degree of differentiation		Well	Poor
		Moderate	
11. Neoadjuvant Chemotherapy		Yes	No
12. Chemotherapy Post Surgery		Yes	No
13. Commobidities	Diabetes mellitus	Hypertension Atherosclosis	V
	Hepatitis	Others	None……
14.BMI	<18, 5	25-29.9	35-39.9
	18.5-24.9	30-34.9	>40
15.Total parenteral Nutrition Pre ope	Yes No	16.Total parenteral Nutrition Post surgery	Yes No

3. EORTC Quality of life Questionnaire 30 Version 3

Questions	**Not at all**	**A little**	**Quite a bit**	**Very much**
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or	1	2	3	4

suitcase?				
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
6. Were you limited in doing either your work or other daily activities?	1	2	3	4

7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4
During the past week:				
17. Have you had diarrhea?	1	2	3	4
18. Were you	1	2	3	4

tired?				
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment	1	2	3	4

interfered with your family life?				
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you "GLOBAL HEALTH STATUS"

	Very poor	**Poor**	**Fair**	**Very fair**	**Good**	**Very Good**	**Excellent**

29. How would you rate your overall health during the past week?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
30. How would you rate your overall quality of life during the past week?	**1**	**2**	**3**	**4**	**5**	**6**	**7**

EORTC QLQ-STO 22

IN THE PAST WEEK	**Not at All**	**A Little**	**Quite A bit**	**Very much**
31. Have you had problems eating solids foods?	**1**	**2**	**3**	**4**
32. Have you had problems eating liquidized or soft food?	**1**	**2**	**3**	**4**
33. Have you had problems drinking liquids?	**1**	**2**	**3**	**4**
34. Have you had discomfort when eating?	**1**	**2**	**3**	**4**
35. Have you had pain in your stomach area?	**1**	**2**	**3**	**4**
36. Have you had discomfort in your stomach area?	**1**	**2**	**3**	**4**
37. Have you had bloated feeling in your abdomen?	**1**	**2**	**3**	**4**
38. Have you had trouble with acid or bile coming into your mouth?	**1**	**2**	**3**	**4**
39. Have you had acid indigestion or heartburn?	**1**	**2**	**3**	**4**

40. Have you had trouble with belching?	**1**	**2**	**3**	**4**
41. Have you felt full up too quickly after beginning to eat?	**1**	**2**	**3**	**4**
42. Have you had trouble enjoying your meals?	**1**	**2**	**3**	**4**
43. Has it taken you a long time to complete your meal?	**1**	**2**	**3**	**4**
44. Have you had a dry mouth?	**1**	**2**	**3**	**4**
45. Did Food and Drink taste different from usual?	**1**	**2**	**3**	**4**
46. Have you had trouble with eating in front of other people?	**1**	**2**	**3**	**4**
47. Have you been thinking about your illness?	**1**	**2**	**3**	**4**
48. Have you worried about your weight being too low?	**1**	**2**	**3**	**4**
49. Have you felt physically less attractive as a result of your disease or treatment?	**1**	**2**	**3**	**4**
50. Have you worried about your health in the future?	**1**	**2**	**3**	**4**
51. Have you lost any hair?	**yes**	**No**		
52.Answer this question only if you lost any hair: If so, were you upset by the loss of your hair?	**1**	**2**	**3**	**4**