METABOLIC SURGERY FOR TREATMENT OF TYPE 2 DIABETES MELLITUS: ELIGIBILITY, DIABETES REMISSION SCORE AND AWARENESS IN A KENYAN TERTIARY HOSPITAL

DR. FRANCIS KIMERE KAARA

H58/7102/2017

A DISSERTATION SUBMITTED IN PART FULFILLMENT FOR THE AWARD OF MASTER OF MEDICINE IN GENERAL SURGERY OF THE UNIVERSITY OF NAIROBI

DECLARATION

I declare that this dissertation is my original work and has not been presented for an academic award in any other University.

Dr. Francis Kimere Kaara

H58/7102/2017

Sign: _____ Date: 19/04/2022

SUPERVISORS

This dissertation has been submitted for examination with my approval as a university supervisor.

Dr. Peter Wambugu Mwangi

MBChB, M.MED General Surgery (U.O.N)

Senior lecturer, Department of surgery,

University of Nairobi.

Sign _____ Date 19/04/2022

This dissertation has been submitted for examination with my approval as a university supervisor.

Dr Wyckliffe Kaisha Otsiany

MBChB, M.MED General Surgery (U.O.N)

Senior lecturer, Department of Anatomy

University of Nairobi.

Sign _____ Date 19/04/2022

DEPARTMENTAL APPROVAL

This research proposal was submitted at the Department of Surgery meeting held on 18/02/2021 at the University of Nairobi. It was subsequently approved by Kenyatta National Hospital- University of Nairobi Ethics and Research Committee (KNH-UON ERC) on 02/08/2021. The dissertation is hereby submitted for examination with my approval as the Chairman, Department of Surgery.

Dr. Julius Kiboi,

MBChB, MMed (Surgery),

Chairman,

Senior Lecturer and Consultant Neurosurgeon,

Department of Surgery,

University of Nairobi.

Sign _____ Date 29/4/2022

DEPARTMENT OF SURGERY
COLLEGE OF HEALTH SCIENCES
P. O. Box 19676 - 00202 KNH
NAIROBI
TEL: 2726590 / 2726300 Ext. 43775

ACKNOWLEDGEMENT

I would like to extend sincere appreciation to my supervisors Dr Peter Wambugu and Dr Wyckliffe Kaisha for their guidance, counsel and mentorship towards the completion of this dissertation. More appreciation to the late Dr Wang'ombe Githaiga (may his soul rest in eternal peace) for the supervision and guidance accorded till his demise.

I am sincerely grateful to my colleagues, and teachers for the critique in the process and the immense input in preparation of this dissertation.

Special thanks to the patients involved in this study for voluntarily accepting to participate in the study.

Finally to God for the good health, zeal, and favour towards this accomplishment.

DEDICATION

To my family, my wife Linda, and my great sons Reagan, Raymond and Roy for their support, love, patience, prayers and immense contribution towards this achievement.

ACRONYMS AND ABBREVIATIONS

BMI	Body Mass Index
BPD	Biliopancreatic diversion
DiaRem	Diabetes remission
DSS-II	Second Diabetes Surgical Summit
ERC	Ethics and Research Committee
GLP1	Glucagon Like Peptide 1
HBA1C	Glycosylated Hemoglobin
KNH	Kenyatta National Hospital
LAGB	Laparoscopic Adjustable Gastric Bypass
LSG	Laparoscopic Sleeve Gastrectomy
RYGB	Roux-en-Y gastric bypass
SGLT	Sodium Glucose Transporter
SPSS	Statistical Package for Social Sciences
T2DM	Type Two Diabetes Mellitus
UK	United Kingdom
UON	University of Nairobi
VSG	Vertical sleeve gastrectomy
WHO	World Health Organization

OPERATIONAL DEFINITIONS

1. **T2DM**: Type 2 diabetes mellitus as diagnosed by the attending physician at Kenyatta National Hospital, and as recorded in the patient's file.
2. **Chronic illness**: A long standing disease that the patient has been on management for, including psychiatric conditions, kidney disease, heart disease, pulmonary disease, hyperlipidemia, alcoholism, and hypertension as defined by the attending physician.
3. **Poor sugar control**: Defined by HBa1C levels above 7%.
4. **Newly diagnosed T2DM patient**: Patients recently diagnosed with T2DM who are attending the diabetes clinic for the first time at KNH.

TABLE OF CONTENTS

CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

BACKGROUND

Metabolic surgery refers to a set of gastrointestinal operations performed on the stomach and intestines with the intent to treat diabetes mellitus and metabolic dysfunctions. Studies have shown significant remission of type 2 diabetes mellitus (T2DM) after metabolic surgery and a reduction in comorbidities and associated mortality. Different eligibility criteria have been adopted to determine qualification for surgery. Preoperatively, the diabetes remission score has been devised and validated to assess the likelihood of remission of T2DM with surgery.

The procedures shown to have significant outcomes towards the treatment of T2DM include adjustable band gastrectomy and sleeve gastrectomy among many others.

STUDY OBJECTIVE

The objective of the study was to assess the eligibility of T2DM patients for metabolic surgery, to determine the diabetes remission score and to assess awareness of metabolic surgery for treatment of T2DM at Kenyatta National Hospital (KNH) diabetes/ endocrinology clinic.

STUDY DESIGN AND METHODOLOGY

This was a cross-sectional study at the KNH diabetes/endocrinology outpatient clinic on patients with T2DM being followed up at the clinic who met the inclusion criteria and gave informed consent. Newly diagnosed patients were excluded. Two hundred and nineteen participants were selected using the convenience sampling method and data collection proceeded for a duration of one month from September 2021 to October 2021. A structured data collection sheet was used to collect data which was then entered into data sheets and analysed via IBM Statistics SPSS version 23.0. The participants' heights (m), weights (kg) were taken and the body mass index (kg/m^2) calculated for each patient. Additional data collected included the participants' age, HBA1c levels, presence of any chronic illnesses, the

medication that the participants were on, and responses to a question on awareness of treatment options available for T2DM.

RESULTS

A total of 219 conveniently selected patients in the Diabetes/ Endocrinology department at Kenyatta National Hospital were selected and included in the study. Demographic, clinical, and laboratory data, height, weight, BMI, medication use, and response on awareness of different treatment options for T2DM was entered in the data collection sheet. Frequency, means, standard deviation and median were used to describe the data. The level of significance was set at <0.05. Continuous variables analysed using Mann Whitney U test and categorical variables analysed using Pearson's correlation index. From the study, the average age of participants was 58.98±12.05 years, with age range from 24 to 96 years. Majority of the participants were female (69.4%, n=219). From the study, eligibility for metabolic surgery stood at 10.05% (DSS II). Among the eligible persons, two participants had a DiaRem score of 3-7, two had a DiaRem score of 8-12, four had a DiaRem score of 13-17 while fourteen had a DiaRem score of 18-22. Of those who were eligible, only 36.36% were aware of metabolic surgery as a treatment option for T2DM. There was a statistically significant relationship between body mass index and eligibility for surgery (p=0.000, n=219), but no relationship between age and metabolic surgery (p=0.386, n=219). There was a positive relationship between grade of obesity (p=0.000) as well as awareness of metabolic surgery (p=0.047) and eligibility for metabolic surgery.

CONCLUSION

In Kenyatta National hospital, there is a considerable proportion of patients with T2DM who are eligible for metabolic surgery, with acceptable Diabetes Remission scores. A small proportion of those eligible for metabolic surgery are aware of metabolic surgery as a treatment option for T2DM.

SIGNIFICANCE OF THE STUDY

The study has yielded information on qualification for metabolic surgery, preoperative probability of T2DM remission after metabolic surgery and patients' awareness of metabolic surgery as a treatment for T2DM.

CHAPTER ONE: INTRODUCTION

Metabolic surgery is an evolving discipline that traditionally focused on the management of obesity but has lately gained traction as a treatment for T2DM amongst other metabolic disorders. Metabolic surgery for T2DM is the main focus of this study. T2DM is characterized by progressive failure of beta cells of the pancreas with reduced sensitivity of peripheral cells to insulin. It is often linked to a sedentary lifestyle, being overweight and it mainly affects those over the age of 40 (1).

Traditionally, the management of T2DM has been premised on dietary and lifestyle modification measures alone or together with medication. However, only about a half of T2DM patients are able to achieve their target HBA1c levels on dietary modification and medication (2). Recent studies have shown tremendous improvement of glycaemic levels with metabolic surgery procedures in patients with T2DM although resulting in remission of the disease. This is after procedures such as vertical sleeve gastrectomy, biliopancreatic diversion procedures, Roux- n -Y gastric bypass amongst others (3). Comparing lifestyle modification and medical therapy to metabolic surgery shows surgery to be superior in achieving glycaemic control, resulting in a reduction of medication taken with an attendant reduction in cardiovascular morbidity and mortality (4). Various mechanisms have been described explaining the physiological processes leading to either partial, complete or prolonged remission (5).

Various diabetes remission scores have been developed and validated. These include DiaRem score, and DiaRem 2 score. Preoperatively, these tools estimate the likelihood of T2DM remission after metabolic surgery (6, 7). Therefore, this study assessed the qualification of T2DM patients for metabolic surgery and also assessed their preoperative diabetes remission

score using these tools. It also assessed the awareness of metabolic surgery as a treatment option for T2DM amongst the patients.

CHAPTER TWO

2.1 LITERATURE REVIEW

2.1.1. Metabolic surgery

Metabolic surgery has increasingly gained recognition in academia and major bariatric surgery societies have adopted the word “metabolic” as part of their names (8).

The Interdisciplinary European Guidelines on metabolic and bariatric surgery describes metabolic surgery as the most effective solution to morbid obesity, with studies showing significant reduction in mortality in patients who undergo metabolic surgery as well as reduction of risk of comorbidities associated with metabolic syndromes. It has been advocated for as a means of treatment of T2DM (9).

2.1.2 T2DM

T2DM refers to a metabolic disorder in which the body is not able to make adequate amounts of insulin, or when the body is resistant to actions of insulin, such that the body glucose levels are not controlled resulting in hyperglycaemia. There is a projected increase in cardiovascular complications, retinopathy, neuropathy, and other associated comorbidities, and thus the attendant cost of managing T2DM and its complications (1, 10).

2.1.3. Metabolic surgery and T2DM

About 90% of all cases of diabetes mellitus are T2DM (11). A total population of around 400 million people worldwide is currently affected by T2DM. This is likely to rise to 640 million by 2040 (1).

In the early years, it was noticed that patients with T2DM who underwent metabolic surgery ended up having lower blood sugars with attempts to explain the mechanisms of action (3). Consequently, there has been a deviation from the traditional medicinal management of T2DM with an incline towards metabolic surgery which has been shown to have higher incidences of remission.

Metabolic surgery causes normoglycaemia in about 31–77% of T2DM patients (4). Glycaemic remission rates have been shown to vary with the duration of disease, criteria defining the remission, and the type of surgery done, with over 80% of patients with T2DM who undergo metabolic surgery achieving good sugar control without drugs or with reduced drugs (12). A meta-analysis done comparing the surgical and non-surgical treatment of diabetes mellitus shows metabolic surgery to be the most efficient treatment option for T2DM (13).

Special concern is given to metabolic surgery in the management of T2DM, more so with regards to remission of the disease. Regionally, there is data available in support of the surgery in the treatment of T2DM. In South Africa, at a centre of excellence, there was baseline patient profiling and data analysis 3 years after bariatric surgery. This analysis was done after 840 metabolic surgeries with results as below: One-year remission of T2DM stood at 73.9% in males and 75.1% in females (14). Two-year outcomes were: diabetes mellitus remission was in 81.6% of males and 83.1% of females; hyperlipidemia remission was in 76.8% of males and 72.19% of females; hypertension remission was in 84.8% of males and 74.6% of females; sleep apnea remission was 75.5% in males and 76.8% in females; weight loss at 29% in 3 years. Conclusion from this study was that metabolic surgery is more effective than usual care for diabetes in obese patients (15, 16).

2.1.4 Mechanism of metabolic surgery

Glycaemic improvement after metabolic surgery involves improved beta-cell function with improved insulin secretion, improved peripheral insulin sensitivity, as well as changes in glucose absorption and alteration in adipose tissue morphology. T2DM results from a gradual failure of beta cells, leading to a decrease in the secretion of insulin in a background of increasing insulin resistance. This dysfunction is associated with the loss of sensitivity of beta cells to glucose and impaired secretion of insulin (17). Metabolic surgery has been shown to partly restore beta-cell dysfunction more so in patients with a higher BMI, $\geq 35 kg/m^2$ (18, 19). Consequently, there is an acute initial peak of insulin production, which is an indicator of beta-

cell sensitivity. There is also an augmented increase in post-prandial insulin concentration after metabolic surgery compared to preoperative levels (20).

Metabolic surgery enhances the incretin effect with increased GLP-1 secretion after surgery with improved function of beta cells after surgery (20). In late postoperative periods after a period of three to six months, weight loss helps to augment the sensitivity of peripheral tissues to insulin. As shown in a cohort in Europe, a reduction in BMI by 30% increases insulin sensitivity by about 50% (21).

Short-term effects of biliopancreatic diversion (BPD) include increasing peripheral insulin and hepatic insulin production. Long-term insulin sensitivity is attributed to increased production of anorexigenic hormones in the gut which lead to reduced caloric and food intake as well as early satiety. The hormones include oxyntomodulin, GLP-1, and peptide YY (22). Gastric banding enhances satiety via neural mechanisms, with weight loss being the main contributor towards enhanced insulin sensitivity; while RYGB surgery works by reducing the endo-luminal glucose absorption (23).

In vertical sleeve gastrectomy, a sleeve of the stomach is removed resulting in a structural reduction of cells that express ghrelin and leptin hormones. The hormone ghrelin's effect is thus blunted, as is its importance in increasing appetite, decreasing stomach emptying, regulating energy use, decreasing insulin release as well as decreasing tissue sensitivity to insulin (24). Leptin production is blunted too, with an attendant reduction in its effect of promoting glucose absorption by enhancing GLUT 2 in the jejunum (21).

2.1.5 Merits and demerits of metabolic surgery

There have been arguments on the safety profile of metabolic surgery and the risk associated. The safety profile has been noted to continue improving with the refinement of minimally invasive procedures (laparoscopy) and participation by teams from many disciplines. The

mortality rate associated with these surgeries is comparable to that in procedures such as cholecystectomy or hysterectomy at 0.1-0.5% (25). Other major and minor complications are comparable to other commonly performed elective operations (26).

Like other gastrointestinal operations not associated with T2DM, there are many nutritional complications associated with metabolic surgery including anaemia, hypoproteinaemia, bone demineralization, and these procedures may require lifelong nutritional supplementation. Iron deficiency anaemia, with or without clinical anaemia has been seen in 5-64% of patients who have undergone metabolic surgery (27).

2.1.6 Eligibility for metabolic surgery for t2dm treatment

Whereas obesity guidelines in western countries recommend metabolic surgery for the treatment of T2DM, clinical guidelines scantily highlight the role (28, 29). Despite the growing popularity of these surgeries, many patients and practitioners remain largely unaware of their benefits, risks and indications.

In 2011, the International Diabetes Federation Taskforce on Epidemiology and Prevention of Diabetes recommended metabolic surgery as an appropriate treatment for patients with T2DM and obesity who are not adequately controlled using medical treatment, especially when they have other comorbidities.

A report of the expert committee on diagnosis and classification of diabetes mellitus provides for eligibility criterion which includes; age from 18 to 65 years, BMI 25kg/m^2 to 34.9 kg/m^2, and poor control of blood sugars shown by $HBA_1C \geq 7\%$ (30). The UK currently uses the 2014 guidelines by the National Institute for Clinical Excellence (NICE), which recommend metabolic surgery for patients with BMI of 40 kg/m^2; and patients with obesity-associated illness and BMI of 35 and 39.5 kg/m^2 (31). However, patients with a BMI of > 50 kg/m^2 notwithstanding their treatment plan are eligible for metabolic surgery. Additionally, the NICE

guideline recommends metabolic surgery for patients with recent-onset (diagnosis made in a ten-year time frame) T2DM with a BMI of 30-34 kg/m^2. Accelerated assessment for patients with recent-onset disease and BMI ≥35 kg/m^2 is recommended. However, in this cohort, several factors influence the final decision, such as optimization of non-surgical therapy, including pharmacological regimen and lifestyle change.

The 2nd Diabetes Surgery Summit (DSS-II) recommends bariatric surgery even for T2DM patients with class 1 obesity (BMI 30.0-34.9 kg/m^2) if their blood sugar is inadequately controlled with medical treatment and lifestyle modification (12). The guidelines recommend the surgery in T2DM patients with class 2 and class 3 obesity marked by BMI 35.0-39.9 kg/m^2 and more than 40 kg/m^2 respectively no matter the level of glycaemic control. The DSS-II eligibility criterion excludes patients with age above 65 years, patients with severe life-threatening chronic illnesses like cardiopulmonary diseases and final-stage organ failure, metastasized malignant tumors, positive current substance or alcohol abuses, and chronic mental sickness (12).

Traditionally, there has been preponderance towards offering the surgical option only for obese patients. However, research has shown a significant benefit in patients with BMI 25-34.5kg/m^2 with a conclusion that there is no significant difference between obese patients and overweight patients after the surgery (32). Early intervention in low BMI patients has been shown to give better remission rates as glycaemic outcomes are predicted by the duration of disease, BMI and age of the patient.

The algorithm below, in figure 1, was adopted by the 2nd Diabetes Surgery Summit (DSS-II) in 2016 and highlights the management of T2DM patients. It incorporates metabolic surgery into the treatment of T2DM.

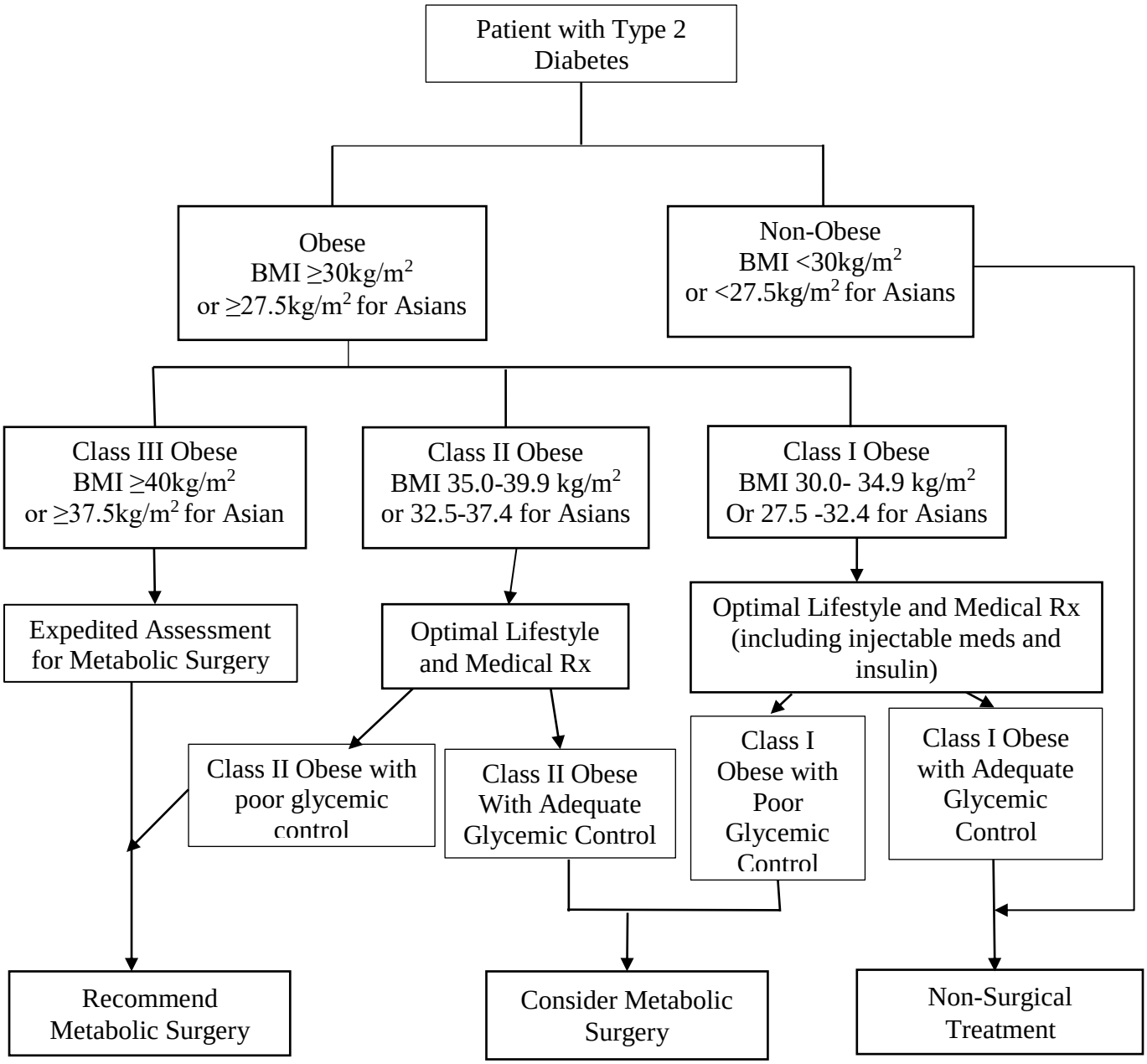

Figure 1: Algorithm for diabetes surgery adopted from Diabetes Surgery Summit II (12)

In a study done by Koliaki et al in Athens assessing eligibility for metabolic surgery among 1167 patients with T2DM, it was found that a significant proportion of the patients-15.3% met the eligibility criteria set out by the DSS-II. Those who were eligible were younger patients who had a shorter duration of T2DM and a higher grade of obesity (33).

2.1.7 Awareness of metabolic surgery as a treatment option for T2DM

Many patients with T2DM are eligible for metabolic surgery as per the Diabetes Surgery Summit (DSS-II) guidelines. However, Koliaki et al. found that amongst the patients who were eligible for metabolic surgery, only about 40% were aware of metabolic surgery as a treatment option for T2DM. The study also found that majority of those who had been informed about metabolic surgery were younger and more obese than those who were not informed (33). The lack of sufficient information among T2DM patients concerning the effectiveness of metabolic surgery indicates a lost opportunity for many eligible patients to experience improved overall well-being and quality of life (34).

Information about metabolic surgery should be part of the treatment options the patients are provided with during decision-making for the most appropriate treatment plan for the patients. Medical professionals' code of practice recommends comprehensive and exhaustive information about a patient's health conditions, risk factors, complications, prevention, and available treatment options (35). Perhaps, medical providers' insufficient knowledge on metabolic surgery as a treatment option, failure to follow eligibility criteria, unfamiliarity with health aspects of the procedure including risks, modalities, and benefits, disinterest in the procedure and post-surgery care has widened the gap in patients' awareness on effectiveness of metabolic surgery (36).

2.1.8 Diabetes remission

Metabolic surgery has been shown to cause remission of disease in many T2DM patients. The definition of remission in this group spans across reduction in medication use, both oral and injectable medication as well as improvement in glycated haemoglobin levels. Metabolic surgery is deemed successful when there is a reduction in insulin usage by 25% or more from the preoperative amount, and by a reduction in oral dose by 50% or more postoperatively. With regards to HBA_1C, metabolic surgery is deemed successful if HBA_1C levels reduce by 0.5% or when the levels are equal to or less than 7% within 3 months of surgery.

Several randomized control trials have shown sustained remission postoperatively ranging between 30-63% of patients. With RYGB, the median disease-free period is 8.3 years with a majority of these patients maintaining significant glycaemic control for at least 5 years to 15 years (36, 37, 38).

2.1.9 DiaRem score

Diabetes remission score (DiaRem score) has been developed to predict the likelihood of resolution of T2DM after surgery. It helps in decision making in the treatment of T2DM both by the physician and the patient. It was described by Still et al (2014) which stratifies risk based on weighted punctuation. Patients are stratified into 5 groups based on age, HBA1C levels, and medication used. The DiaRem score is a sum of individual components and is scored into 5 groups- 0-2, 3-7, 8-12, 13-17, and 18-22 as shown in figure 2 below. There is an inverse relationship between the DiaRem score and the probability of remission of T2DM (6).

The DiaRem score has been validated with data from records showing its ability to predict remission after RYGB surgery. Still CD et al sought to validate DiaRem score in other metabolic surgeries as well and found that the tool is also able to predict remission in LSG, RYGB and LAGB (6). In another study in 2019, it was shown that DiaRem score is able to predict remission to T2DM not only after RYGB surgery but also to LAGB and LSG. It further impresses on the importance of this score in helping to inform a tailored approach to decisions regarding T2DM treatment and also to inform guidelines on the eligibility of patients for surgery (7).

One of the drawbacks of DiaRem score is that it does not consider the duration of diabetes as a component of the score. A longer duration of T2DM confers an increased risk for failure of T2DM remission. A study by Still et al in 2018 proposes DiaRem2 score, which incorporates duration of T2DM into the DiaRem score thus simplifying and increasing the accuracy of prediction of the likelihood of remission of T2DM after metabolic surgery. It also reduces the

classification groups from five as seen in DiaRem score to three. However, the challenge associated with DiaRem2 score is patient subjectivity towards defining the duration since diagnosis of T2DM (38). Highlighted below is the DiaRem score table.

Variable	Score
Age (years)	
<40	0
40-49	1
50-59	2
≥ 60	3
HBA1C (%)	
<6.5	0
6.5 -6.9	2
7.0-8.9	4
≥ 9.0	6
Other diabetes drugs	
No sulfonylureas or insulin-sensitizing agent other than metformin	0
Sulfonylureas or insulin-sensitizing agent other than metformin	3
Treatment with insulin	
No	0
Yes	10
The overall score (sum of the four components)	**0-22**
Probability of remission in each DiaRem score subgroup*	
0-2	87 (83-90)
3-7	66 (61-70)

8-12	32(24-40)
13-17	16 (12-21)
18-22	5 (0-9)
Values are presented as probability (%) with 95% confidence interval *Including both parties and complete remissions HBA1C, glycosylated haemoglobin	

Figure 2: DiaRem score adopted from Still CD et al. Lancet Diabetes Endocrinol 2014.

2.2 STUDY JUSTIFICATION

As highlighted in the literature, there is limited data on eligibility and awareness of metabolic surgery as a treatment option for T2DM. KNH recently performed its first metabolic surgery due to obesity and its uptake remains low, despite being a confirmed treatment of T2DM amongst other metabolic disorders. The increasing prevalence of T2DM in the region and country, and the poor achievement of optimal glycaemic control with medication, dietary and lifestyle adjustment, therefore, means a change of strategy needs to be adopted, and thus metabolic surgery.

There is a paucity of data on metabolic surgery for the treatment of T2DM in the world, the African continent and in the East African region in general to the best of our knowledge and therefore this study seeks to add to the pool of data available on this topic. The study may as well help inform policy decisions on the management of T2DM.

The study will also serve as a basis for improvement of the current practice and to better management of T2DM patients, perhaps offering them a wider range of treatment options and may help inform policy decisions on the management of T2DM.

2.3 STUDY QUESTIONS

1. What is the proportion of T2DM patients who are eligible for metabolic surgery as per the Diabetes Surgical Summit 2 guidelines at the KNH diabetes clinic?
2. What is the Diabetes remission score amongst T2DM patients on follow-up at the KNH diabetes clinic?
3. What proportion of patients on treatment for T2DM at KNH diabetes clinic is aware of metabolic surgery as a treatment option for T2DM?

2.4 STUDY OBJECTIVES

2.4.1 Broad Objectives

To determine the eligibility of T2DM patients seen at KNH diabetes clinic for metabolic surgery, their diabetes remission score and their awareness regarding metabolic surgery as a treatment option for T2DM.

2.4.2 Specific Objectives

1. To determine the proportion of T2DM patients who meet the eligibility criteria for metabolic surgery as per the DSS-II guidelines at the KNH diabetes clinic.
2. To determine the preoperative probability of T2DM remission (Diabetes remission score) amongst T2DM patients at the KNH diabetes clinic.
3. To determine awareness of metabolic surgery as a treatment option for T2DM amongst T2DM patients at KNH diabetes clinic.

2.5 CONCEPTUAL FRAMEWORK

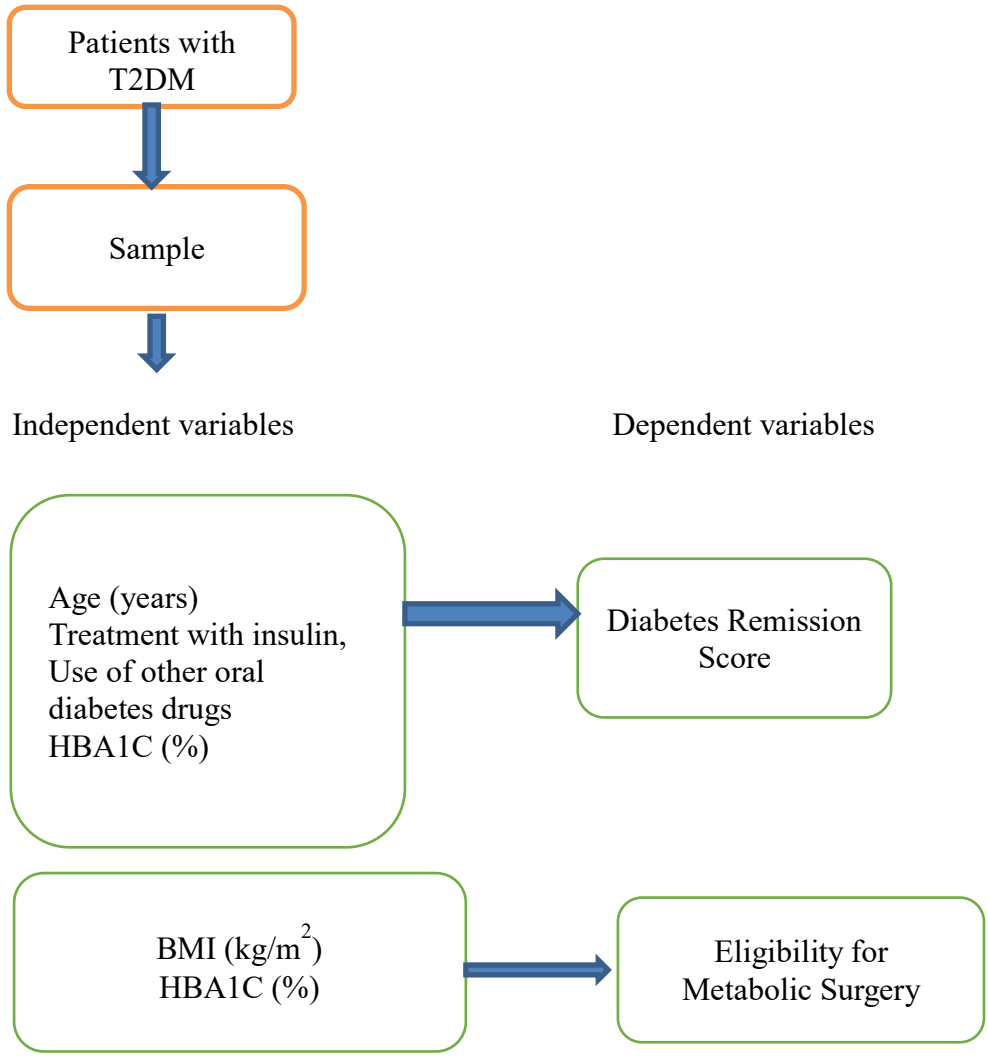

Figure 3: Conceptual framework for the study

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study design

Cross-sectional study design.

3.2 Study setting

The study was carried out at (KNH) diabetes /endocrinology department's outpatient clinic. KNH is a tertiary referral hospital in Nairobi County, Kenya, serving people largely from Nairobi and its environs but also receiving a number of patients referred from other facilities within the country and the Eastern African region, thus with a large catchment area. It is the largest and oldest teaching and referral hospital and was established in 1901. The hospital has a bed capacity of 1,800 with about 400 patients with diabetes mellitus being attended to weekly in the diabetes/endocrinology outpatient clinic that runs daily during the weekdays (39). The hospital has about 22 outpatient clinic, 24 theatres, about 50 wards and the accident and emergency department. On average, 600,000 patients visit the outpatient clinics annually. The study, therefore, provides invaluable information on patients being managed for T2DM bearing in mind the large catchment area.

3.3 Study population

The study population comprised of adult patients who were being followed up for T2DM at the KNH diabetes/ endocrinology outpatient clinic.

3.4 Selection criteria

3.4.1 Inclusion criteria

1. Patients with T2DM attending the KNH diabetes/ endocrinology clinic who agreed to consent.

3.4.2 Exclusion criteria

1. Newly diagnosed T2DM patients.
2. Patients below 18 years as they were not able to consent.

3.5 Sampling method

The convenience sampling method was employed to attain the desired sample size. All patients who fulfilled the criteria and consent to the study were recruited into the study. This was employed on every alternate diabetes clinic days (Monday, Wednesday, Friday).

3.6 Sample size determination

The sample size for this study was calculated using Fischer's formula by Fisher et al (1991).

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n is the required sample size based on a finite population of patients with T2DM.

Z is the value from standard normal distribution corresponding to desired confidence, it is taken to be 1.96 for 95% confidence interval.

P is the proportion of patients eligible for metabolic surgery, put at 15.3% in a study done in Greece (33).

d is the desired precision level at 0.05

$$n = \frac{1.96^2 x\ 0.153(1-0.153)}{0.05^2}$$

$$n = 199$$

Consideration for attrition of data at 10% gave a sample size of **219**

Thus, 219 participants were recruited.

3.7 Study flow

The flow diagram below indicates how the study was conducted.

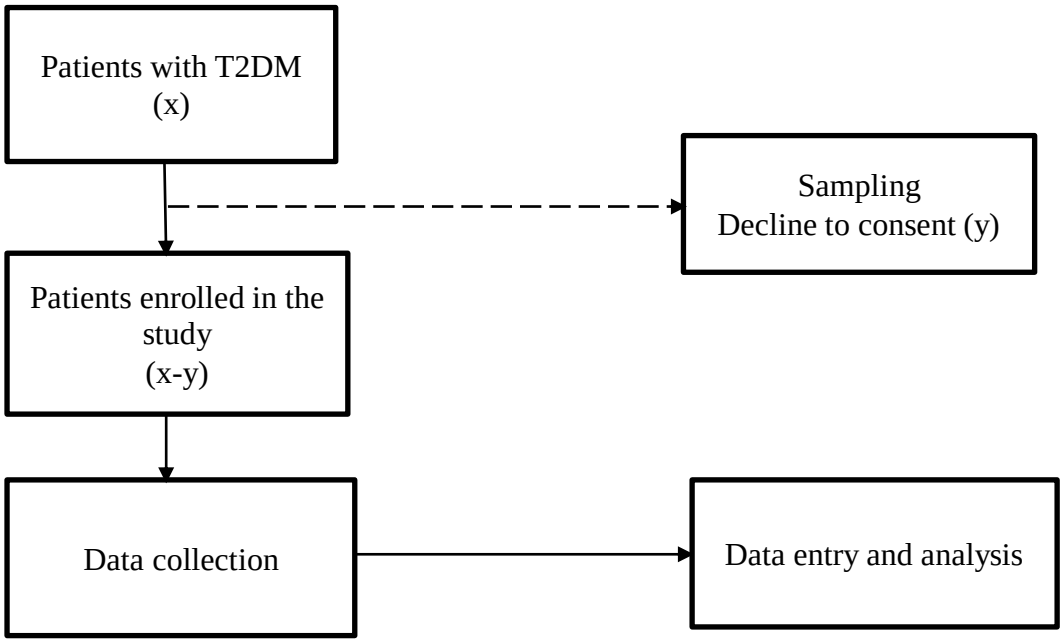

Figure 4: Study flow

3.8 Measures to mitigate against COVID 19

The researcher and research assistants were protected against COVID-19 by observing the guidelines set by the Government of Kenya for mitigating the spread of the disease. They adhered to infection prevention measures such as maintaining proper hand hygiene by hand washing with soap and water and sanitization. They wore 3 ply face masks covering the mouth and nose, observed cough etiquette and used appropriate personal protective equipment. They also observed physical distancing of at least 1.5 meters. Only research assistants who were symptom free were allowed to participate in data collection. The participants were remotely screened for COVID-19 symptoms, and in case anyone was suspected to be having it, they were not directly involved in the study. They were instead referred to the Ministry of health for further diagnosis and possible isolation (40).

3.9 Ethical considerations

The researcher obtained approval and authorization from KNH/UON Ethics and Research Committee (KNH/UON ERC), the department of surgery (UON), and the KNH administration. Pre-consent counselling of all eligible participants was carried out, after which individual informed consents were obtained. The consented participants were then enrolled in the study. Those who declined participation were let to proceed with their treatment and were not denied services because of refusal to consent.

Patient's information was treated with utmost confidentiality and was only used for the intended purpose of this study. There were no invasive procedures involved in the study and the participant did not incur any extra cost. The participants were given unique identifiers to aid in maintaining confidentiality and the data sheets were shredded upon completion of the study.

3.10 Study enrollment

In this study, patients who were on follow up for T2DM in the KNH diabetes/endocrinology outpatient clinic were the target population. The subjects who met the eligibility criteria were

selected. Recruitment was done on Mondays, Wednesdays and Fridays. The objectives of the study and all relevant information regarding the study were explained by the principal researcher and the research assistants to those selected. Those who accepted to consent were taken to a room where they were given a consent form which they read and signed (Appendix II), and were thereafter recruited into the study. An interviewer-guided questionnaire (Appendix I) was administered at this point with clinical information obtained from the patient's records.

3.11 Training and data quality procedures

The questionnaire was presented to the department for approval and later pretested before administration to the participants. The research assistants who were registered information records officers were trained on data collection and handling.

3.12 Data collection and handling

Data was collected by the principal researcher and two research assistants using a questionnaire. The research assistants were taken through the data collection tool to familiarize with it. Each patient recruited into the study was given a special serialized number for purposes of ordering the data collection documents. The data collected was then entered into a Microsoft Excel spreadsheet which was password protected, with the password known to the principal researcher and assistants only.

3.13 Study materials

Study materials used for this study included stationery, storage files, computes, tape measure and a weighing scale.

3.14 Study variables

The independent variables in the study were: Age (years), BMI (kg/m^2), treatment with insulin, treatment with oral hypoglycaemics, HBA_1C (%)

Dependent variables were: Eligibility for metabolic surgery, Diabetes remission score.

Table 1. Study variables

Independent variables	**Dependent variables**
Age (years)	Eligibility for metabolic surgery
Treatment with insulin	Diabetes remission score
Treatment with oral hypoglycaemics	
BMI (kg/m^2)	
HBA_1C (%)	
Chronic illnesses e.g. renal disease, heart disease	

3.15 Data management and analysis

Raw data was entered into an Excel sheet, cleaned and analysed using SPSS for windows IBM version 23. Statistical analysis such as mean, median, and frequency were calculated for all the data. Descriptive statistics about patient demographics and clinical characteristics were represented as tables and graphs. Categorical variables such as the grade of obesity, sex, eligibility for surgery, awareness of metabolic surgery as a treatment and chronic illnesses were presented as absolute numbers (n) and frequencies (%). The awareness of metabolic surgery as a treatment option for T2DM was analysed as a proportion of those patients who are eligible for metabolic surgery.

Discrete quantitative variables such as the DiaRem score were analysed using measures of central tendency such as median and mode. Individual DiaRem score was determined by summing up the individual scores for age, HBA1C, usage of insulin, and usage of other oral hypoglycaemic. The probability of remission was considered amongst the patients who were eligible for metabolic surgery and was deduced as highlighted in the DiaRem score table.

Continuous variables such as weight, height, age and BMI were analysed and presented as means± standard deviation.

Comparisons between groups e.g. age, BMI, glycaemic control, gender, oral hypoglycaemic drugs used, diabetes remission score and awareness of metabolic surgery compared with eligibility for metabolic surgery were performed using non parametric Mann-Whitney-U test for continuous variables. Pearson's Chi square test was applied for categorical variables. In the analysis, the level of significance was set at 0.05. All the results were represented using tables, pie charts and graphs.

3.16 Study limitations

There was a limitation of sample selection bias as KNH, being a national and regional referral hospital largely receives patients referred from facilities all over the country.

The definition of T2DM and other chronic illnesses was taken as defined by the attending physicians.

3.17 Study timelines

Table 2. Table showing the study timelines

ACTIVITY	**SEPT 2020-JAN 2021**	**FEB 2021 – JULY 2021**	**SEP 2021 – OCT 2021**	**DEC 2021-MAR 2022**	**APR 2022**
PROPOSAL DEVELOPMENT					
ETHICAL APPROVAL					
DATA COLLECTION					
DATA ANALYSIS					
PRESENTATION AND SUBMISSION					

3.18 Study closure and results dissemination

The research findings were disseminated to the UON library and KNH/UON Ethics and Research Committee. They were also made available to the participants and will be published online for access by anyone who might require them.

CHAPTER FOUR: RESULTS

4.1 Characteristics of the study population

This was a prospective cross-sectional study research done at KNH endocrinology department, on 219 patients who were on follow-up for treatment of T2DM. The study was conducted between September 15th 2021 to October 15th 2021.

A total of 152 participants (69.4%) were identified as females. The age range for the participants was between 24 and 96 years. Of the participants, 72.1% were on insulin for the management of their T2DM, while 90.4% were on metformin. There were 61.6% of the participants on other oral hypoglycaemics. Results are shown on Table 3.

Table 3: Social demographics and clinical characteristics of participants

SOCIODEMOGRAPHICS	**FREQUENCY**
Age (years)	58.98 ± 12.05
Female (%)	152 (69.4%)
Males	67 (30.6%)
Education level	
Primary	93 (42.5%)
Secondary	82 (37.5%)
Tertiary	39 (17.8%)
BMI (kg/m2)	27.73 ± 4.43
Obesity	
Class 1	53 (24.2%)
Class 2	11 (5%)
Class 3	2 (0.2%)
HBA_1C (%)	7.56 ± 2.35

Drugs	
Insulin	158 (72.1%)
Metformin	198 (90.4)
Other oral hypoglycaemics	135 (61.6)
Other comorbidities	
Congestive heart disease	2 (0.9%)
Chronic kidney disease	1 (0.5%)
Acute heart failure	1 (0.5%)
Psychiatric conditions	1 (0.5%)
Cancer	1 (0.5%)
Chronic liver disease	1 (0.5%)
Alcoholism	4 (1.8%)

4. 1.1 Demographic characteristics

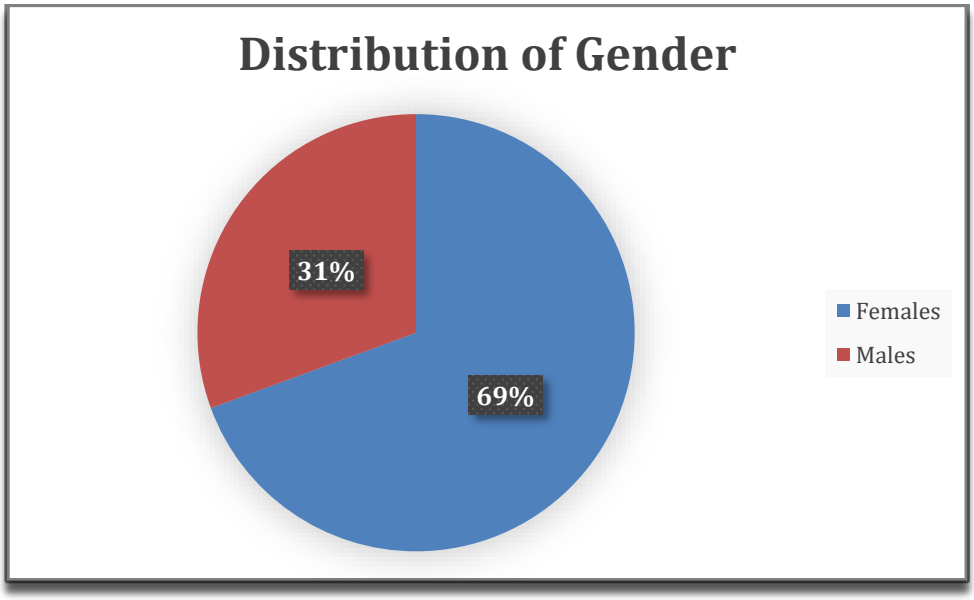

Figure 5. Gender distribution

As shown in the figure 5 above, 152 participants were females, representing 69.4%, while 67 participants were males, representing 30.6% of the participants.

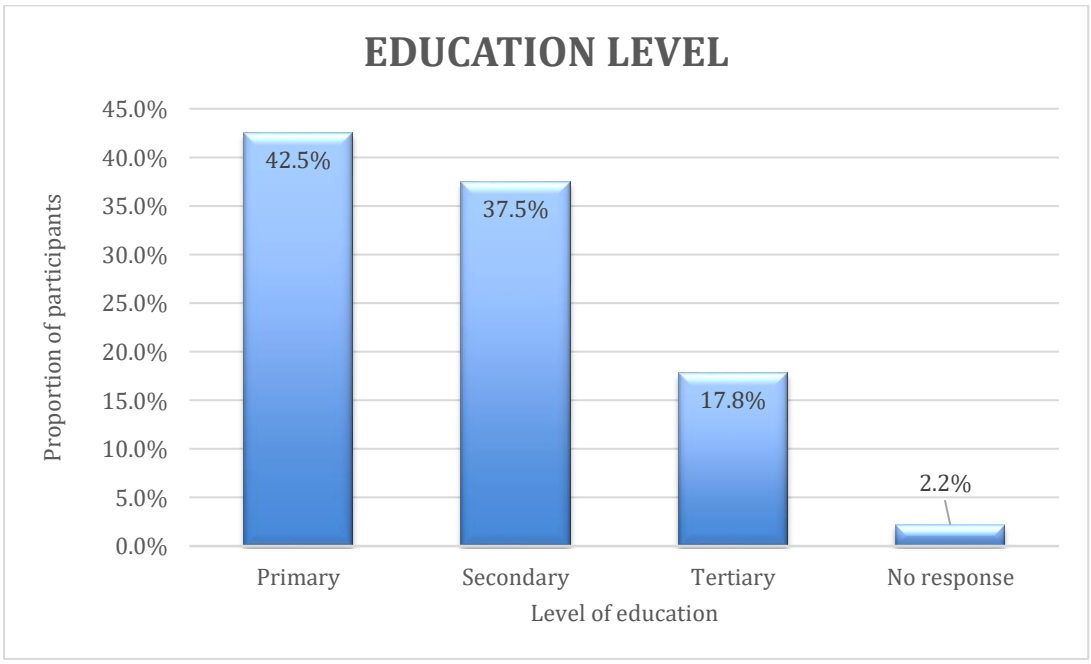

Figure 6. Level of education

Majority of the participants had a primary school level of education (42.5%), followed by 37.4% with a secondary education. Only 17.85% of the participants had a tertiary education. 5 of the participants did not respond to the question (Figure 6).

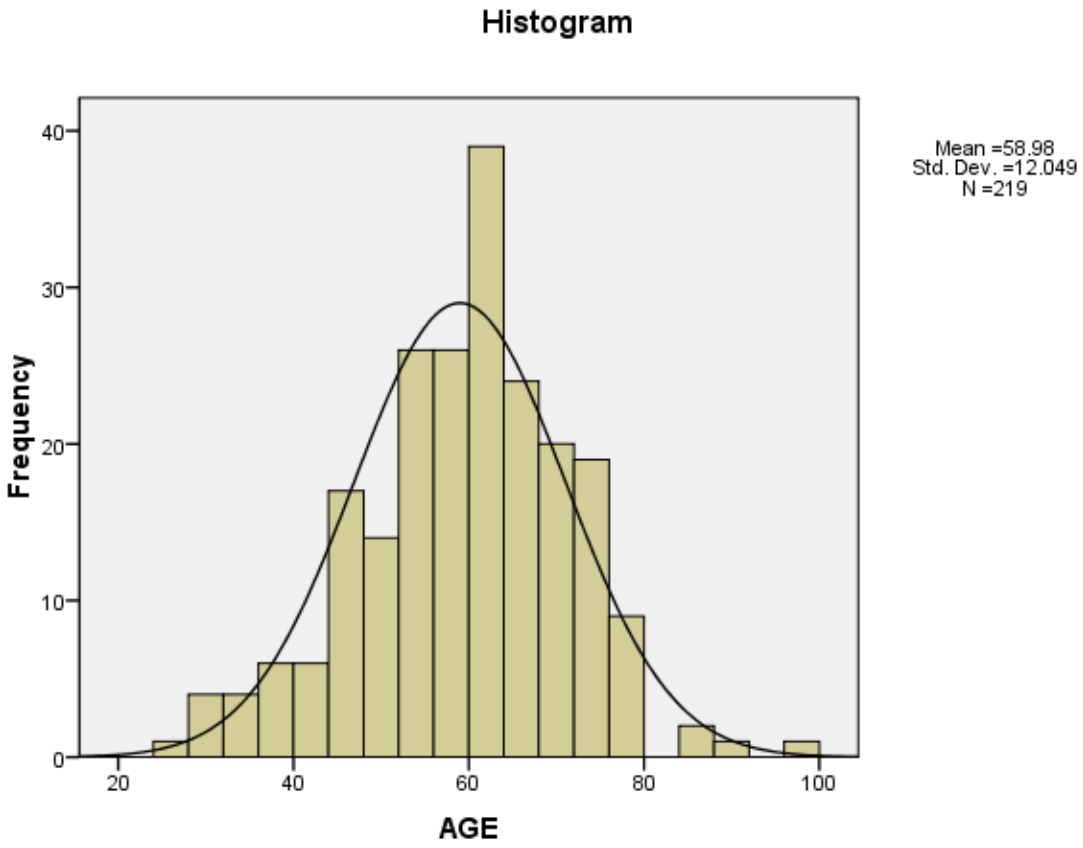

Figure 7. Age of participants

As shown in figure 7 above, the ages of the participants ranged from 24 to 96 years, with the mode at 60 years. The mean age was 58. 98 ± 12. 049 years.

4.2 Eligibility of T2DM patients for metabolic surgery

Only 156 participants were below 65 years and above 18 yrs. All the participants seen were of African descent. There were 7 participants who had chronic illnesses as shown in the table

above. Therefore, only 149 participants met the DSS II requirement for consideration for the metabolic surgery.

Table 4. Patients eligible for metabolic surgery (MS)

Participants (n)	**BMI (kg/m2)**	**HBA1C (%)**	**Eligibility**
106 (71%)	<29.9		Not eligible
33 (22.1%)	30.0-34.9	<7 n=21 >7 n=12	Not eligible Consider MS
9 (6%)	35.0-39.9	<7 n=5 >7 n=4	Consider MS Recommend MS
1 (0.7%)	>39.9	<7 n=1	Recommend MS

As shown in Table 4 above, out of the 149 participants, 71% of participants had BMI less than 29.9 kg/m^2 therefore not qualified for metabolic surgery according to DSS II while 22.1% of participants were in Obesity Class I with a BMI between 29.9 kg/m^2 and 34.9 kg/m^2. Of these, 12 had a HBA_1C above 7% and 21 had a HBA_1C below 7%. Six percent of the participants were in Class II (34.9-39.9kg/m^2), with 4 having a HBA_1C above 7% and 5 with a HBA_1C below 7% while only 1 participant had a BMI above 39.9kg/m^2, with a HBA_1C of 5.2%. Among the obese participants, a total of 22 participants met the eligibility criteria for metabolic surgery as per DSS II. Those with Class 1 obesity, with HBA1c above 7% (12), in class II with HBA_1C less than 7 (5), class II with HBA_1C above 7% (4) and those in Class III, regardless of HBA_1C (1) are considered and recommended for metabolic surgery (Figure 8).

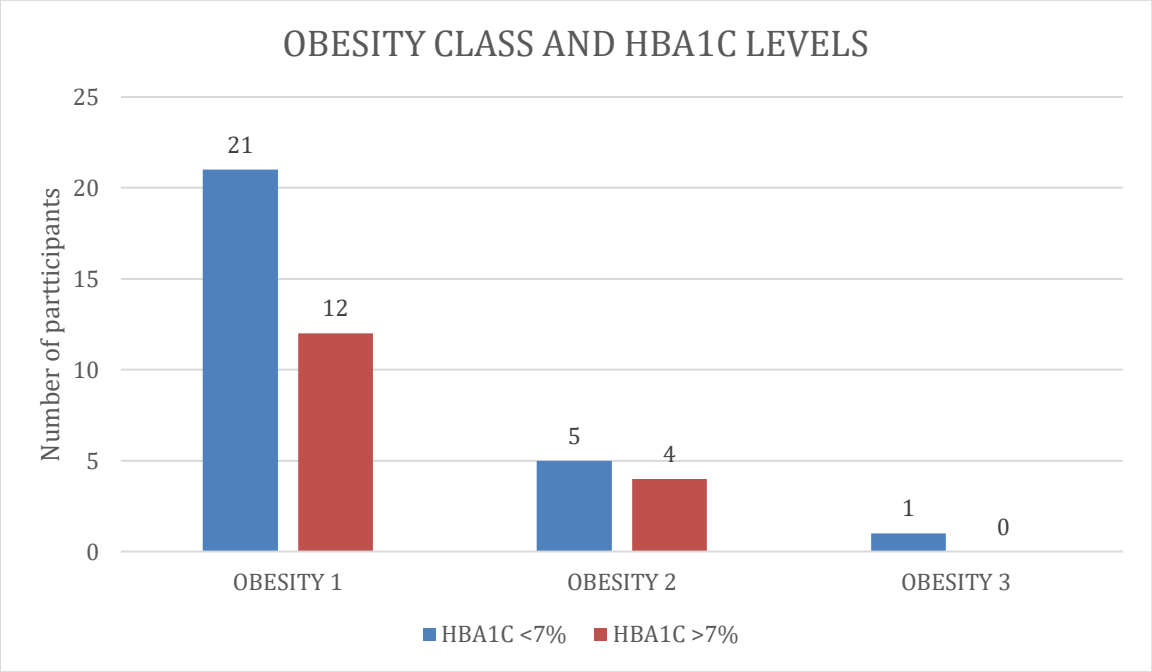

Figure 8. Obesity class and respective HBA1C levels

The bar-graph in Figure 9 below shows the relationship between level of education, age, class of obesity and HBA1c with eligibility for metabolic surgery. Eligibility is highest amongst participants of a primary and secondary education level. It is highest in the ages between 51-60 years, higher in class I obesity, and in participants with HBA1c levels between 7-10%. Proportionately more females are eligible for metabolic surgery at 68%.

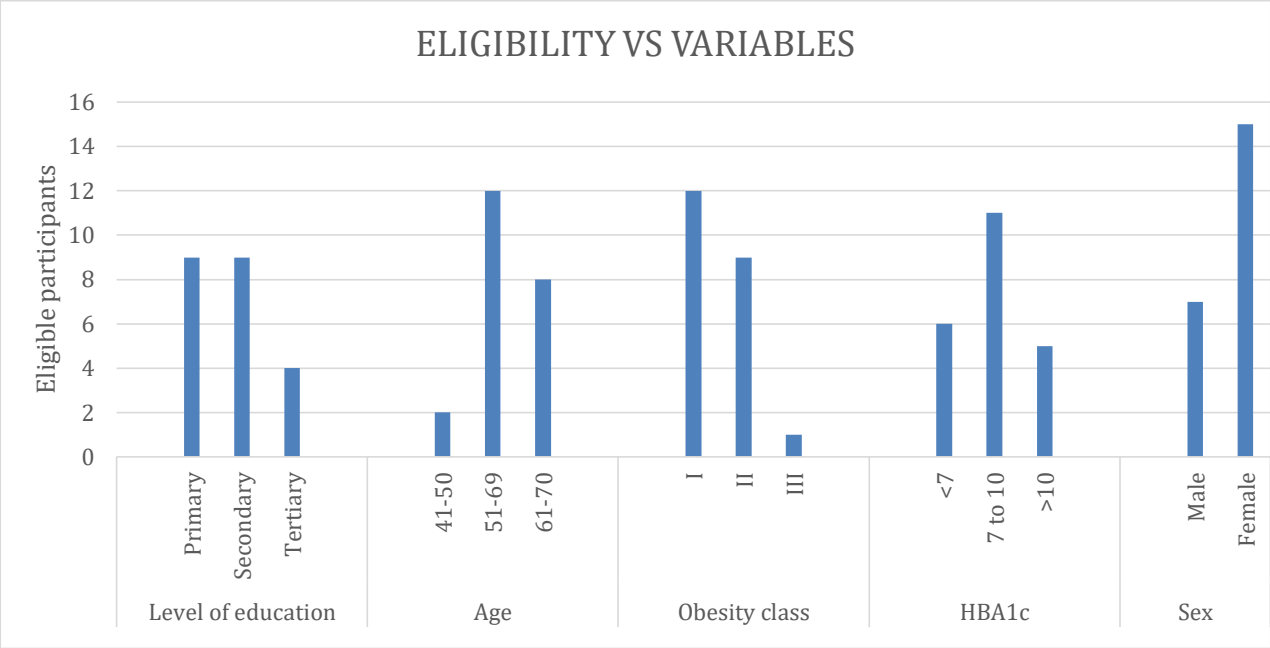

Figure 9. Eligible participants vs different variables

4.3 Diabetes Remission Score

Only 153 participants had a BMI below 29.9kg/m^2 (non-obese). There were 53 participants with Class I obesity (24.2%), 11 participants had Class II obesity (5%) while 2 participants (0.2%) had class III obesity (Figure 10).

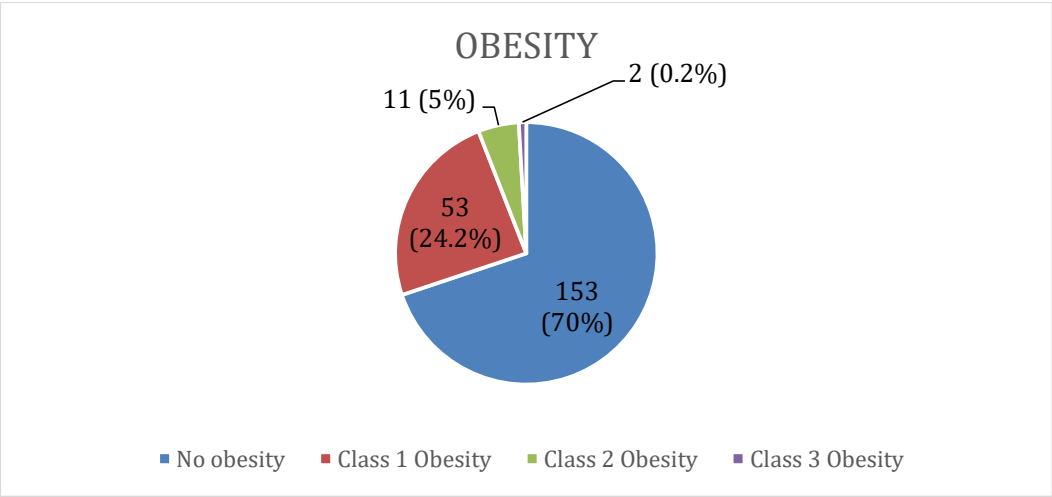

Figure 10. Obesity classes

Majority of the participants were on metformin 198(90.4%), with 158 (72.1%) on insulin, either alone or in combination. Only 135 participants were on other oral hypoglycaemics other than metformin, representing 61.6% of the participants (Figure 11).

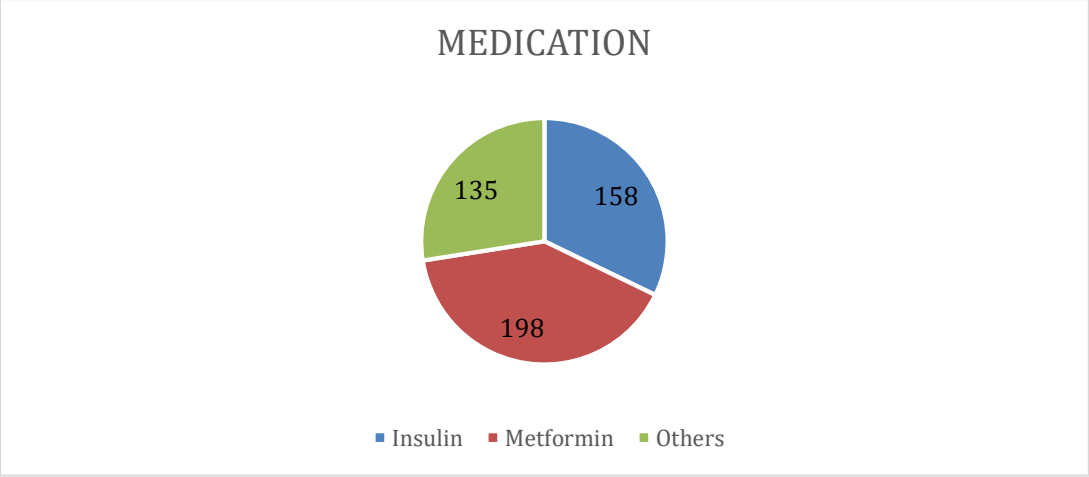

Figure 11. Diabetes 2 treatment options

As shown in Figure 12 below, none of the eligible participants had a DiaRem score of 0-2. Amongst the eligible participants, 2 participants had a DiaRem score of 3-7; 2 had a DiaRem score of 8-1; 4 had a DiaRem score of 13-17 while 14 had a DiaRem score of 18-22. This represents a probability of remission of 87%, 66%, 32%, 16% and 5% respectively.

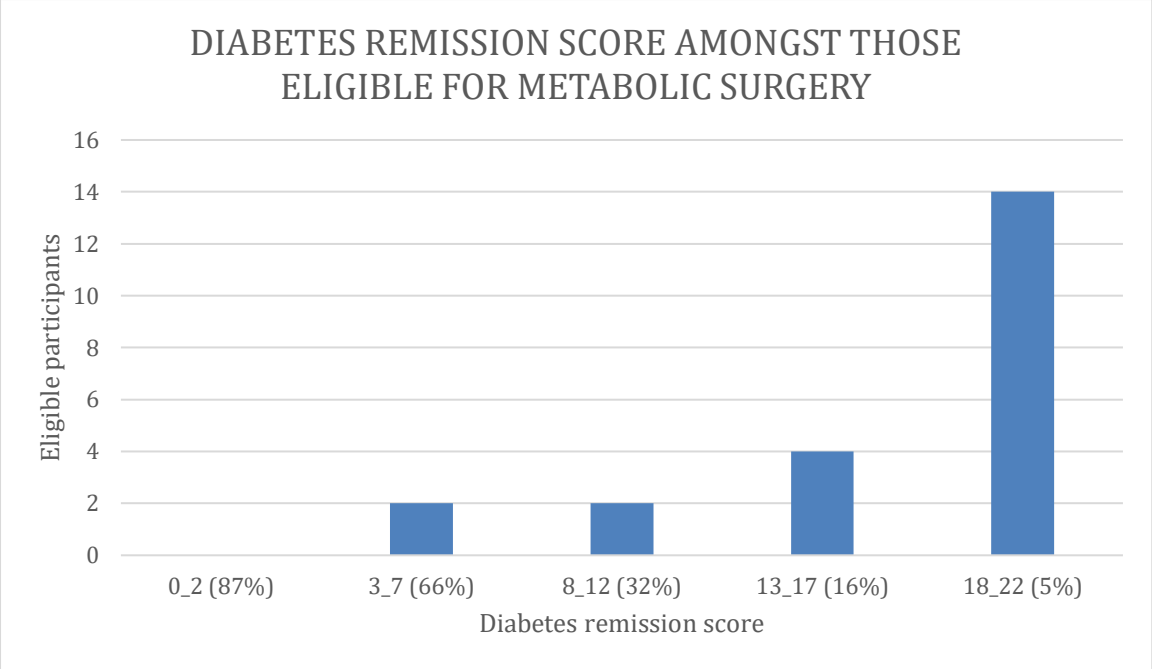

Figure 12. Diabetes remission score amongst those eligible for metabolic surgery

4.4 Awareness of metabolic surgery as a treatment option for T2DM

As highlighted in the figure 13 below, of the 22 participants who qualified for metabolic surgery, 18 responded to being aware of pharmaceutical treatment as treatment of choice for T2DM, with 5 pointing towards use of herbal medication. There were 8 participants who acknowledged knowledge of metabolic surgery as a treatment option for T2DM while 2 participants alluded to no intervention for the treatment of T2DM. There was overlap of responses amongst some participants with regard to the treatment option. Overall, 36.36% of those who qualified for metabolic surgery were aware of metabolic surgery as a treatment option for T2DM.

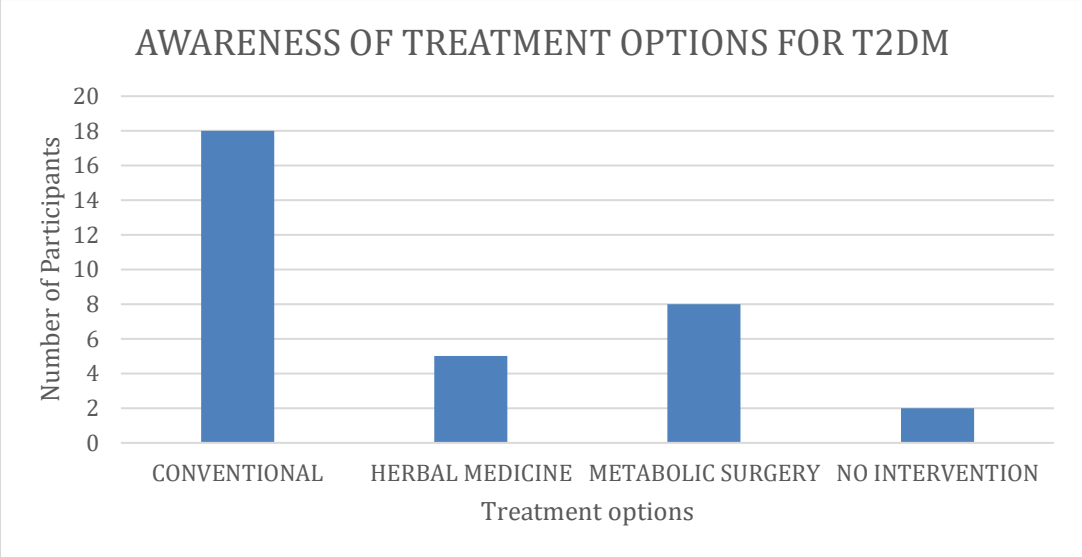

Figure 13: Number of participants aware of various treatment options

There was more awareness of metabolic surgery in the age groups 51-60 and 61-70, amongst participants of primary level of education, those with class II obesity, and those with HBA1C level between 7-10%. Proportionately more females (62%) are aware of metabolic surgery as a treatment option for T2DM as opposed to males (38%) as shown in Figure 14 below.

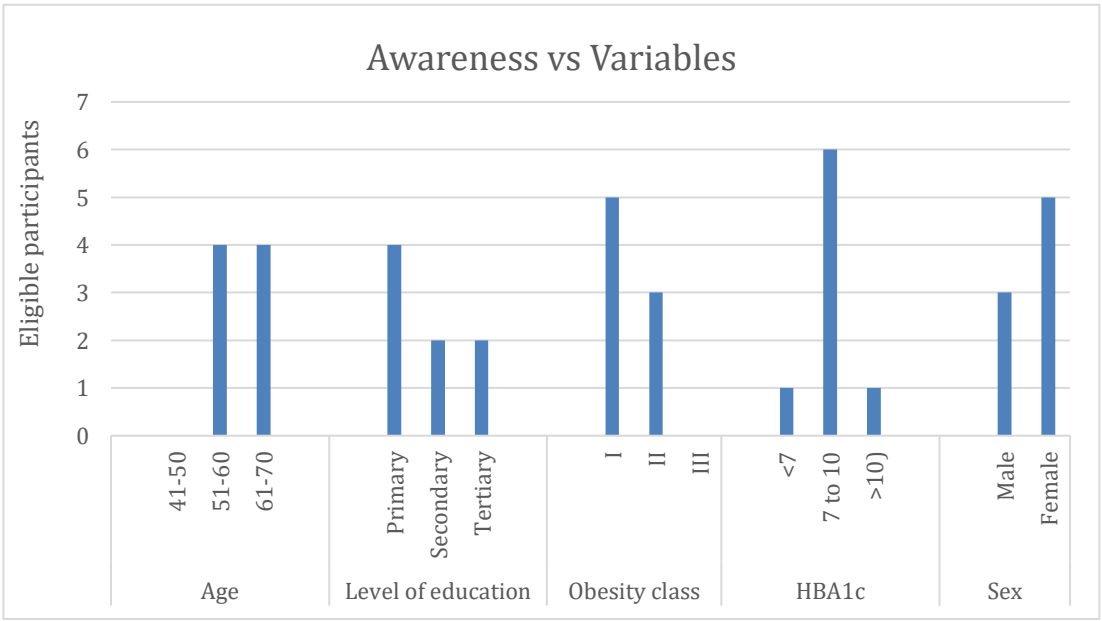

Figure 14: Awareness of metabolic surgery against different variables

4.5 Correlation analysis

4.5.1 Pearson's correlation index

Pearson's correlation index was used to analyse the relationship between continuous variables and eligibility for metabolic surgery. Whereas there was a statistically significant relationship between BMI and eligibility for surgery (p= 0.000), there was no statistically significant relationship between age and eligibility for metabolic surgery (p=0.386). The results are shown in Table 5.

Table 5. Relationship of age and BMI with eligibility for metabolic surgery

Variable	**n**	**Pearson's correlation**	**Significance (2 tailed)**
Age	219	0.059	0.386
BMI	219	-0.529	0.000

Correlation is significant at 0.05 level (2 tailed)

4.5.2 Mann Whitney U test

This statistical test was used to analyse the relationship between categorical variables and eligibility for metabolic surgery. A statistically significant relationship was observed between the grade of obesity and eligibility for metabolic surgery (p=0.000). There was a positive relationship between awareness of metabolic surgery as a treatment option for T2DM and eligibility for metabolic surgery (p=0.047). There was no statistically significant relationship between sex and eligibility for metabolic surgery (p=0.896). Mann Whitney U results are shown in Table 6 below.

Table 6. Relationship between grade of obesity and awareness of metabolic surgery with eligibility for metabolic surgery

Categories	**Group**	**n**	**Z**	**P**
Grade of obesity	1 2	53 11	-3.774	0.000
Awareness of metabolic surgery	Aware Not Aware	44 178	-1.990	0.047
Gender	Male Female	67 152	-0.131	0.896

Results are significant at 0.05 level (2 tailed)

CHAPTER FIVE

5.1 DISCUSSION

Metabolic surgery has been advocated for as a means of treatment of T2DM (8). It has been shown to result in T2DM remission with achievement of good sugar control without drugs or with reduced drugs. Studies have shown that metabolic surgery is more effective than usual care for diabetes mellitus in obese patients (12, 13, 14, 15, 16).

Different criteria have been adopted by different regions. Recommendation for eligibility include the Report of Expert Committee on diagnosis and classification of diabetes mellitus (30), NICE guidelines in the UK and Diabetes Surgical Summit II, 2016 (12, 31).

The objective of this study was to determine the eligibility of T2DM patients for metabolic surgery according to the DSS II eligibility criteria. We also set out to determine the diabetes remission score amongst the participants who were eligible for metabolic surgery. Also, the study sought to answer the question on awareness of metabolic surgery amongst patients on treatment for T2DM.

The data analysed suggests that there is a considerable proportion of participants who were eligible for metabolic surgery. According to the study, 22 out of 219 (10.05%) of the participants met the eligibility criteria for metabolic surgery as per DSS II (12). This is slightly lower than the findings in a study by Koliaki et al who found an eligibility of 15.3 % of participants in Greece (n=1167) (33). This difference could be explained by a local population that is less obese due to the African diet as opposed to the Western diet in Greece. Literature has shown a higher prevalence of obesity in Greece with 20% of males and 15% of females having obesity, while in Kenya the obesity statistics show that 2.8% of males and 11.1% of females have obesity (41, 42)

Genetic factors have been shown to have a big role in regulating body weight, accounting for up to 40-90% of population weight variants. There has been shown to be an increase in heritable risk of obesity due to underlying genetic factors in Greece (43). Progressive deviation from the traditional African diets and adoption of more refined foods, use of wheat products, increased use of cooking fats and oils, physical inactivity amongst others have been shown to contribute to increasing prevalence of obesity in Africa (44). Therefore, the proportion of eligible participants is likely to rise as the local population continually adopts a Western diet with an attendant increase in obesity. The eligible proportion as per DSS II is a wider net and is more expanded as compared to previously employed NICE criteria that excluded participants with a BMI <35kg/m^2, strictly considering those with BMI above 40kg/m^2 and those with BMI of 35-39.9kg/m^2 but with obesity associated illness (31). More recent studies have even expanded the eligibility criteria further to include BMI even as low as 25kg/m^2, highlighting a probability of an even larger eligible population (32). There has been a demonstrable benefit of metabolic surgery prioritisation in these patients as there is an attendant reduction in cardiovascular complications, reduction in mortality as well as a role in prevention of T2DM itself.

The average age for those eligible for surgery from the study was 58.98±12.05 years, a young age, perhaps explained by the exclusion of participants above 65 years of age (about 30%) from metabolic surgery. The proportion of patients excluded also points towards a lost earlier opportunity to offer them a potential remission-inducing treatment. The eligible patients were noted to have a higher body mass index, higher grade of obesity (in line with the DSS II eligibility criteria) and were more aware of metabolic surgery as a treatment option for T2DM. In this study, there was no relationship between eligibility for metabolic surgery and age. Koliaki et al observed eligibility for surgery to be related to younger participants who had a higher grade of obesity (33). The higher body mass index and higher grade of obesity had a

direct relationship with eligibility as they are components of the defining criteria for eligibility (12).

Of those who were eligible, the average diabetes remission score is 16.55 indicating an overall 16% 5-year probability of diabetes remission after undergoing metabolic surgery. Amongst the eligible participants, 2 participants had a DiaRem score of 3-7 with a probability of remission of 66%. 2 participants had a DiaRem score of 8-12 with a probability of remission of 32%. 4 participants had a DiaRem score of 13-17 with a 16% probability of remission while 14 participants had a DiaRem score of 18-22 with a 5% probability of remission. These results are conflicting to a South African study that established a 2 year average remission of 81.6% in males and 83.1% in females (15, 16). Our study was silent on the duration of T2DM, a parameter that could have impacted on the probability of remission. A longer duration of disease implies an increased risk of failure of T2DM, thus a recommendation, to, perhaps perform a study putting into consideration the duration of diabetes may alter this probability score (38). The challenge with this, however is the subjectivity that comes in determining the duration of disease as this largely depends on the patients recall and memory (38). The study done by Koliaki et al considered the duration of T2DM in the computation of the remission score with the adDiaRem score in this study showing that 35% of the participants displayed a favourable adDiaRem score of <10 (33).

Despite the above noted opportunity to achieve T2DM remission, the data suggests that awareness of metabolic surgery amongst the eligible persons is low at 36% while in Koliaki et al, this stood at 40%, encompassing younger and more obese participants (33). Inadequate information and awareness indicates a lost opportunity for eligible participants to better their quality of life and well-being while reducing long-term complications of T2DM. (34). There should be consideration for incorporation of information about metabolic surgery as a treatment option in the different T2DM review clinics to enable a more enhanced and informed decision

making by the patients so as to fully benefit from the available treatment options. Discussing all available treatment options is a requirement in patient care, and as such, healthcare providers are obliged to give all the available treatment options (35). However this may not be possible where healthcare providers themselves are unaware of metabolic surgery as a treatment option for T2DM (36), and could in part, be contributing to the high gap in patient awareness on metabolic surgery and its effectiveness. An aggressive campaign should thus be adopted, targeting both the treating physicians and the T2DM patients aiming to boost their awareness of metabolic surgery. The misconception that metabolic surgery is a preserve for the morbidly obese denies the younger and less obese persons an opportunity for the life changing surgery, directly losing an opportunity for diabetes remission and probably robbing them of later-day quality of life which could be different were they to adopt metabolic surgery (33).

Despite the demonstrated benefits, there is low uptake of metabolic surgery with KNH only undertaking its first metabolic surgery about a year ago. The low uptake may be due to fear associated with surgery, anaesthesia and other operative risks. A study done in KNH shows that 30.7% of preoperative patients have fear of surgery, 37.3% have fear of anaesthesia, and 44.1% have fear of not waking from anaesthesia (45). From a healthcare financing point of view, though, the long-term health benefits and cost savings resulting from metabolic surgery may far much outweigh the prohibitive cost of surgery. A study to this effect may help elaborate on cost benefit analysis of metabolic surgery.

While the study has provided insight into our local population, more research on this topic needs to be done, assessing eligibility in a larger population, and also assessing uptake of metabolic surgery in the country and region. A formal and structured follow up and maintenance of a database may also need to be encouraged for documenting long term outcome of metabolic surgery in our setting.

Amongst the limitations of this study is that it is a cross-sectional, single centre study. It does not put into consideration the duration of T2DM in assessing probability of remission and has a limitation in determination of the optimal medical treatment or lifestyle modification prior to considering qualification for metabolic surgery. However, the study has the strength of adding to the limited pool of data on metabolic surgery, especially with regards to eligibility for surgery as per DSS II. It also underpins the need for enhancing awareness and advocating for uptake of metabolic surgery both to the treating physicians and to the populace in view of its innumerable benefits.

5.2 CONCLUSION

As obesity, T2DM and other metabolic disorders are on the rise, novel means of treatment outside the traditional medical treatment need to be explored, and metabolic surgery, perhaps, needs to be incorporated into national treatment guidelines of T2DM.

While there is a scanty write-up on this topic, few centres have done research on eligibility for metabolic surgery, diabetes remission score and awareness of metabolic surgery amongst participants on treatment for T2DM. We sought to address these questions in our study. This study has demonstrated that indeed, many patients on treatment for T2DM at Kenyatta National Hospital qualify for metabolic surgery for treatment of the diabetes mellitus. A significant proportion of those who qualify for metabolic surgery have good diabetes remission scores and would benefit in terms of achieving remission of T2DM were they to undergo metabolic surgery. There is a drawback in the sense that only a small proportion of persons on treatment for T2DM are aware of metabolic surgery as a treatment option for T2DM.

5.3 RECOMMENDATIONS

1. Public health policies can be adopted to increase awareness of metabolic surgery as a treatment option for T2DM amongst other metabolic disorder amongst the populace, including healthcare providers.

2. Recommendation to perform future research in different geographical regions in order to solidify the findings on eligibility, and the probability of T2DM remission with metabolic surgery.
3. Incorporating metabolic surgery into training of medical students and post graduate students undertaking training in surgery and internal medicine, as well as updating practitioners of emerging trends in management of T2DM and other metabolic disorders through Continuous Medical Education.
4. Incorporation of metabolic surgery into protocols of management of T2DM and advocating for national health insurance reimbursements for metabolic surgery.

REFERENCES

1. International Diabetes Federation. Diabetes Facts & figures [Internet]. [cited 2020 Dec 12]. Available from: https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html.
2. Del Cañizo-Gómez FJ, Moreira-Andrés MN. Cardiovascular risk factors in patients with type 2 diabetes: Do we follow the guidelines? Diabetes research and clinical practice. 2004 Aug 1;65(2):125-33. Available from doi: 10.1016/j.diabres.2003.12.002.
3. Pories WJ, Swanson MS, MacDonald KG, Long SB, Morris PG, Brown BM, Barakat HA, DeRamon RA, Israel G, Dolezal JM. Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus. Annals of surgery. 1995 Sep;222(3):339. Available from: doi: 10.1097/00000658-199509000-00011
4. Cummings DE, Arterburn DE, Westbrook EO, Kuzma JN, Stewart SD, Chan CP, Bock SN, Landers JT, Kratz M, Foster-Schubert KE, Flum DR. Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial. Diabetologia. 2016 May 1;59(5):945-53.
5. Buse JB, Caprio S, Cefalu WT, Ceriello A, Del Prato S, Inzucchi SE, McLaughlin S, Phillips GL, Robertson RP, Rubino F, Kahn R. How do we define cure of diabetes?. Diabetes care. 2009 Nov 1;32(11):2133-5.
6. Still CD, Wood GC, Benotti P, Petrick AT, Gabrielsen J, Strodel WE, Ibele A, Seiler J, Irving BA, Celaya MP, Blackstone R. Preoperative prediction of type 2 diabetes remission after Roux-en-Y gastric bypass surgery: a retrospective cohort study. The lancet Diabetes & endocrinology. 2014 Jan 1;2(1):38-45.

7. PRIME PubMed | Performance of the DiaRem Score for Predicting Diabetes Remission in Two Health Systems Following Bariatric Surgery Procedures in Hispanic and non-Hispanic White Patients [Internet]. [cited 2020 Dec 12]. Available from: https://www.unboundmedicine.com/medline/citation/28717860/Performance_of_the_DiaRem_Score_for_Predicting_Diabetes_Remission_in_Two_Health_Systems_Following_Bariatric_Surgery_Procedures_in_Hispanic_and_non_Hispanic_White_Patients_.
8. Cummings DE, Cohen RV. Beyond BMI: the need for new guidelines governing the use of bariatric and metabolic surgery. The lancet Diabetes & endocrinology. 2014 Feb 1;2(2):175-81.
9. Fried M, Yumuk V, Oppert JM, Scopinaro N, Torres AJ, Weiner R, Yashkov Y, Frühbeck G. Interdisciplinary European guidelines on metabolic and bariatric surgery. Obesity facts. 2013;6(5):449-68.
10. Azevedo M, Alla S. Diabetes in sub-saharan Africa: kenya, mali, mozambique, Nigeria, South Africa and zambia. International journal of diabetes in developing countries. 2008 Oct;28(4):101.
11. Goyal R, Jialal I. Hyperphosphatemia. StatPearls [Internet]. 2020 Nov 21. Available from: http://www.ncbi.nlm.nih.gov/books/NBK513253/.
12. Rubino F, Nathan DM, Eckel RH, Schauer PR, Alberti KG, Zimmet PZ, Del Prato S, Ji L, Sadikot SM, Herman WH, Amiel SA. Metabolic surgery in the treatment algorithm for type 2 diabetes: a joint statement by international diabetes organizations. Surgery for Obesity and Related Diseases. 2016 Jul 1;12(6):1144-62.
13. Wu GZ, Cai B, Yu F, Fang Z, Fu XL, Zhou HS, Zhang W, Tian ZQ. Meta-analysis of bariatric surgery versus non-surgical treatment for type 2 diabetes mellitus. Oncotarget. 2016 Dec 27;7(52):87511.

14. Van der Merwe MT, Fetter G, Naidoo S, Wilson R, Drabble N, Gonçalves D, Mahomedy Z. Baseline patient profiling and three-year outcome data after metabolic surgery at a South African centre of excellence. Journal of Endocrinology, Metabolism and Diabetes of South Africa. 2015;20(3):115-26.
15. Schauer PR, Kashyap SR, Wolski K, Brethauer SA, Kirwan JP, Pothier CE, Thomas S, Abood B, Nissen SE, Bhatt DL. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. New England Journal of Medicine. 2012 Apr 26;366(17):1567-76.
16. Mingrone G, Panunzi S, De Gaetano A, Guidone C, Iaconelli A, Nanni G, Castagneto M, Bornstein S, Rubino F. Bariatric–metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial. The Lancet. 2015 Sep 5;386(9997):964-73.
17. Ferrannini E, Mingrone G. Impact of different bariatric surgical procedures on insulin action and β-cell function in type 2 diabetes. Diabetes care. 2009 Mar 1;32(3):514-20.
18. Buchwald H, Estok R, Fahrbach K, Banel D, Jensen MD, Pories WJ, Bantle JP, Sledge I. Weight and type 2 diabetes after bariatric surgery: systematic review and meta-analysis. The American journal of medicine. 2009 Mar 1;122(3):248-56.
19. Hofsø D, Jenssen T, Bollerslev J, Ueland T, Godang K, Stumvoll M, Sandbu R, Røislien J, Hjelmesæth J. Beta cell function after weight loss: a clinical trial comparing gastric bypass surgery and intensive lifestyle intervention. European journal of endocrinology. 2011 Feb 1;164(2):231-8. Available from: doi: 10.1530/EJE-10-0804
20. Kashyap SR, Daud S, Kelly KR, Gastaldelli A, Win H, Brethauer S, Kirwan JP, Schauer PR. Acute effects of gastric bypass versus gastric restrictive surgery on β-cell function and insulinotropic hormones in severely obese patients with type 2 diabetes. International journal of obesity. 2010 Mar;34(3):462-71.

21. Muscelli E, Mingrone G, Camastra S, Manco M, Pereira JA, Pareja JC, Ferrannini E. Differential effect of weight loss on insulin resistance in surgically treated obese patients. The American journal of medicine. 2005 Jan 1;118(1):51-7. Available from: https://www.amjmed.com/article/S0002-9343(04)00658-8/pdf.
22. le Roux CW, Aylwin SJ, Batterham RL, Borg CM, Coyle F, Prasad V, Shurey S, Ghatei MA, Patel AG, Bloom SR. Gut hormone profiles following bariatric surgery favor an anorectic state, facilitate weight loss, and improve metabolic parameters. Annals of surgery. 2006 Jan;243(1):108.
23. Baud G, Daoudi M, Hubert T, Raverdy V, Pigeyre M, Hervieux E, Devienne M, Ghunaim M, Bonner C, Quenon A, Pigny P. Bile diversion in Roux-en-Y gastric bypass modulates sodium-dependent glucose intestinal uptake. Cell metabolism. 2016 Mar 8;23(3):547-53.
24. Lv Y, Liang T, Wang G, Li Z. Ghrelin, a gastrointestinal hormone, regulates energy balance and lipid metabolism. Bioscience reports. 2018 Oct 31;38(5).
25. Birkmeyer JD, Finks JF, O'Reilly A, Oerline M, Carlin AM, Nunn AR, Dimick J, Banerjee M, Birkmeyer NJ. Surgical skill and complication rates after bariatric surgery. New England Journal of Medicine. 2013 Oct 10;369(15):1434-42.
26. Aminian A, Brethauer SA, Kirwan JP, Kashyap SR, Burguera B, Schauer PR. How safe is metabolic/diabetes surgery? Diabetes, Obesity and Metabolism. 2015 Feb;17(2):198-201.
27. del Villar Madrigal E, Neme-Yunes Y, Clavellina-Gaytan D, Sanchez HA, Mosti M, Herrera MF. Anemia after Roux-en-Y gastric bypass. How feasible to eliminate the risk by proper supplementation? Obesity surgery. 2015 Jan;25(1):80-4.

28. Kasama K, Mui W, Lee WJ, Lakdawala M, Naitoh T, Seki Y, Sasaki A, Wakabayashi G, Sasaki I, Kawamura I, Kow L. IFSO-APC consensus statements 2011. Obesity surgery. 2012 May;22(5):677-84.
29. UK NC. Obesity: Identification, Assessment and Management of Overweight and Obesity in Children, Young People and Adults.
30. Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the expert committee on the diagnosis and classification of diabetes mellitus. Diabetes Care. 2003 Jan;26 Suppl 1:S5-20
31. Desogus D, Menon V, Singhal R, Oyebode O. An examination of who is eligible and who is receiving bariatric surgery in England: secondary analysis of the Health survey for England dataset. Obesity surgery. 2019 Oct;29(10):3246-51.
32. Huang CK, Shabbir A, Lo CH, Tai CM, Chen YS, Houng JY. Laparoscopic Roux-en-Y gastric bypass for the treatment of type II diabetes mellitus in Chinese patients with body mass index of 25–35. Obesity surgery. 2011 Sep;21(9):1344-9.
33. Koliaki C, Tzeravini E, Papachristoforou E, Severi I, El Deik E, Karaolia M, Noutsou M, Thanopoulou A, Kountouri A, Balampanis K, Lambadiari V. Eligibility and Awareness Regarding Metabolic Surgery in Patients With Type 2 Diabetes Mellitus in the Real-World Clinical Setting; Estimate of Possible Diabetes Remission. Frontiers in Endocrinology. 2020 Jun 5;11:383.
34. Pareek M, Schauer PR, Kaplan LM, Leiter LA, Rubino F, Bhatt DL. Metabolic surgery: weight loss, diabetes, and beyond. Journal of the American College of Cardiology. 2018 Feb 13;71(6):670-87.
35. Rubin JK, Hinrichs-Krapels S, Hesketh R, Martin A, Herman WH, Rubino F. Identifying barriers to appropriate use of metabolic/bariatric surgery for type 2 diabetes treatment: policy lab results. Diabetes Care. 2016 Jun 1;39(6):954-63.

36. Halpern B, Mancini MC. Type 2 diabetes and metabolic surgery guidelines and recommendations should urgently be unified. Acta Diabetologica. 2021 Apr;58(4):531-6.
37. Sjöström L, Peltonen M, Jacobson P, Ahlin S, Andersson-Assarsson J, Anveden Å, Bouchard C, Carlsson B, Karason K, Lönroth H, Näslund I. Association of bariatric surgery with long-term remission of type 2 diabetes and with microvascular and macrovascular complications. Jama. 2014 Jun 11;311(22):2297-304.
38. Still CD, Benotti P, Mirshahi T, Cook A, Wood GC. DiaRem2: incorporating duration of diabetes to improve prediction of diabetes remission after metabolic surgery. Surgery for Obesity and Related Diseases. 2019 May 1;15(5):717-24.
39. Mwavua SM, Ndungu EK, Mutai KK, Joshi MD. A comparative study of the quality of care and glycemic control among ambulatory type 2 diabetes mellitus clients, at a Tertiary Referral Hospital and a Regional Hospital in Central Kenya. BMC research notes. 2016 Dec;9(1):1-8. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4702345/.
40. KNH-UON ERC- GUIDELINES ON CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC | KNH-UoN Ethics and Research Committee [Internet]. [cited 2021 Jan 8]. Available from: https://erc.uonbi.ac.ke/basic-page/knh-uon-erc-guidelines-conduct-research-during-covid-19-pandemic.
41. World Health Statistics 2015. Geneva: World Health Organisation; 2015
42. DB Panagiotakos et al. 2004. Epidemiology of Overweight and Obesity in a Greek Adult Population: the ATTICA Study
43. Yiannis Vasilopoulos et al. 2013. VDR TaqI is associated with obesity in the Greek population. National Library of Medicine.

44. Edward Michieka, Benjamin Moranga. 2018. The rise of non communicable diseases in Kenya: an examination of the time trends and contribution of the changes in diet and physical inactivity. Journal of epidemiology and global health.
45. Chanda et al. 2012. Assesement of preoperative anxiety amongst patients presenting for elective surgery at the KNH. University of Nairobi.

STUDY BUDGET

BUDGET ITEM	**AMOUNT (KSH.)**
Research fee for KNH-ERC	2,000
Statistician consultation fee	35,000
Stationery;(a) Printing (b) Photocopying (c) Binding (d) Pens Face Masks Sanitizers	15,000 20,000 10,000 1,000 5,000 5,000
Research assistants fee @30,000 each (two assistants)	60,000
Miscellaneous (10% of total)	15,000
Total	**168,000**

Budget justification

The budget estimates are set at prevailing market rates.

APPENDICES

APPENDIX I: DATA COLLECTION FORM

Serial No ……

1. Age (years) [ ]
2. Sex
    a. Male [ ]
    b. Female [ ]
3. Level of education
    a. Primary [ ]
    b. Secondary [ ]
    c. Tertiary [ ]
4. Investigations
    a. HBA1C (%) …….
5. Measurements
    b. Weight (kg) …….
    c. Height (m) …….
    d. BMI (kg/m^2) …….
6. Obesity class
    a. I (30-34.9kg/m^2) [ ]
    b. II (35-39.9kg/m^2) [ ]
    c. III ($\geq$ 40kg/m^2) [ ]
7. Other chronic illnesses
    a. Congestive heart disease [yes] [no]
    b. Chronic kidney disease [yes] [no]
    c. Acute heart failure [yes] [no]

d. Psychiatric illnesses [yes] [no]

e. Chronic alcoholism and substance abuse [yes] [no]

f. Cancer [yes] [no]

g. Chronic lung diseases [yes] [no]

8. Use of Anti- Diabetes Medication

a. Insulin [yes] [no]

b. Metformin [yes] [no]

c. Other oral medicine except metformin [yes] [no]

9. The following are ways of treating type 2 diabetes mellitus

a) Conventional medication [yes] [no]

b) Herbal medication [yes] [no]

c) Surgery of intestines and stomach (metabolic surgery) [yes] [no]

d) Not taking medication [yes] [no]

Thank you.

APPENDIX II: STATEMENT OF CONSENT

English version

PARTICIPANT INFORMATION AND CONSENT FORM
ADULT CONSENT FOR ENROLLMENT IN THE STUDY

Title of Study: Metabolic surgery for treatment of type 2 diabetes mellitus: Eligibility, diabetes remission score and awareness in a Kenyan Tertiary Hospital.

Principal Investigator\and institutional affiliation: Dr Francis Kimere Kaara
H58/7012/2017. School of Medicine, Department of Surgery- University of Nairobi

Co-Investigators and institutional affiliation: ……
Supervisors: Dr. Joseph Githaiga, Dr. Peter Wambugu, Dr. Wyckliffe Kaisha

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

WHAT IS THIS STUDY ABOUT?

The researchers listed above are interviewing individuals who are on treatment for Type 2 Diabetes Mellitus. The purpose of the interview is to find out whether the participants qualify for metabolic surgery for treatment of the diabetes. Participants in this research study will be asked questions about their knowledge of metabolic surgery as a treatment option for diabetes mellitus. Participants will also have measurements of their height and weight and further information will be deduced from the files.

There will be approximately 219 participants in this study conveniently chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 5 minutes. The interview will generally assess knowledge of metabolic surgery as a treatment option for type 2 diabetes mellitus.

After the interview has finished, your height and weight will be taken and the readings documented.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include to give you feedback on the overall findings from the study.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free health information. We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand how many of our patients qualify for metabolic surgery and the chance of cure after undergoing the surgery. This information is a contribution to science and will go a long way in influencing policy on management 0f type 2 diabetes mellitus.

WILL BEING IN THIS STUDY COST YOU ANYTHING? No

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

Not applicable

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.
For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.
The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

This proposal has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm. The contact information is given below if you wish to contact any of them for whatever reason;

1. Secretary, KNH/UoN-ERC
   P.O. Box 20723 KNH, Nairobi 00202
   Tel 7263009
   Email: uonknh_erc@uonbi.ac.ke

   University of Nairobi research supervisors:

2. DR JOSEPH GITHAIGA
   MBChB (U.O.N), M.Med Surgery (U.O.N)
   Department of Surgery, School of Medicine, University of Nairobi
   P.O. Box 19676 KNH, Nairobi 00202

3. DR PETER WAMBUGU
   MBChB (U.O.N), M.Med Surgery (U.O.N)
   Department of Surgery, School of Medicine, University of Nairobi
   P.O. Box 19676 KNH, Nairobi 00202

   4. DR WYCKLIFFE KAISHA
   MBChB (U.O.N), M.Med Surgery (U.O.N)
   Department of Anatomy, School of Medicine, University of Nairobi
   P.O. Box 19676 KNH, Nairobi 00202

Principal researcher:

1. Dr. FRANCIS KIMERE KAARA
   Department of Surgery, School of Medicine, University of Nairobi
   P.O. Box 36153, 00200 Nairobi.
   Mobile phone: 0720675361

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counsellor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me.

I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to have (define specimen) preserved for later study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name: _____

Participant signature / Thumb stamp _____

Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____Date: _____

Signature_____

Role in the study: _____

For more information contact _____

Witness Printed Name (If witness is necessary, a witness is a person mutually acceptable to both the researcher and participant)

Name _____

Contact information _____

Signature /Thumb stamp: _____

Date _____

Kiswahili Version:

UJUMBE WA MSHIRIKI NA FOMU YA IDHINI

IDHINI YA MTU MZIMA YA KUSHIRIKISHWA KWA UTAFITI

Mada: Ustahiki, alama ya uwezekano wa kupona Kisukari baada ya upasuaji na pia uelewaji wa upasuaji kama njia ya kutibu ugonjwa wa Kisukari.

Mtafiti mkuu: Dkt Francis Kimere Kaara, kutoka shule ya Elimu ya Afya, Idara ya Upasuaji, Chuo Kikuu cha Nairobi.

Msaidizi wa utafiti:……..

Waalimu wakuu: Dr. Joseph Githaiga, Dr. Peter Wambugu, Dr. Wyckliffe Kaisha

Mwanzo

Ningependa kukueleza kuhusu utafiti unaofanywa na watafiti waliotajwa hapa juu. Nia ya fomu hii ya idhini ni kukupa ujumbe ambao utahitaji kukuwezesha kuamua iwapo utakubali kushirikishwa kwa utafiti.

Kuwa huru kuuliza maswali yoyote kuhusu huu utafiti, nini kitakachofanyika kwa utafiti, faida na madhara ya kushiriki kwenye utafiti, haki yako kama mshiriki na chochote kile ambacho hakieleweki. Ukishaelewa kabisa, unawezaamua kushirikishwa kwa utafiti au la. Ukikubali kushirikishwa, nitakuuliza utie sahihi yako kwa hii fomu. Ni vizuri uelewe kwamba i) nia yako ya kushiriki ni kwa hiari yako ii)unaweza kuamua kujitoa kwenye utafiti bila kupeana sababu yoyote iii) kuamua kutoshiriki hakutaadhiri matibabu yako katika hospitali hii. Baada ya kushiriki, tutakupatia nakili ya hii fomu ili uweke kwa rekodi zako.

Tunaweza kuendelea? Ndio La

Utafiti huu umeidhinishwa na The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

Utafiti huu unahusu nini?

Watafiti walioandikwa hapa juu kwenye fomu wanafanya utafiti kuhusu matibabu ya ugonjwa wa kisukari. Nia kuu ni kubaini iwapo washiriki wanahitimu kwa upasuaji wa kutibu ugonjwa wa kisukari. Washiriki katika utafiti huu wataulizwa maswali kuhusu uelewaji wao kuhusu upasuaji kama njia moja ya kutibu kisukari. Watachukuliwa vipimo vya kilo na kimo, na kisha rekodi za faili zitaangaliliwa.

Kutakuwa na takriban washiriki 219 kwa huu utafiti. Tunakusihi utupe idhini ya kushiriki kwenye utafiti huu.

Ni nini kitakachofanyika ukikubali kushirikishwa kwa huu utafiti

Utaulizwa maswali na mtafiti kwa takribani muda wa dakika 5. Maswali yatakua kuhusu uelewaji wa njia ya upasuaji kama njia mojawapo ya kutibu ugonjwa wa kisukari. Baadaye, utapimwa kilo na kimo na vipimo vingine kusomwa kutoka kwa faili yako. Pia tutauliza utupatie namba zako za mawasiliano iwapo kutakuwa na haja ya kufuatiliza ama kukujulisha kuhusu matokeo ya huu utafiti.

Kuna faida kushiriki kwenye huu utafiti?

Faida ambayo utapata kushiriki kwa huu utafiti ni kwamba utapata maelezo na wosia wa afya njema, na pia utafanikiwa kujua kuhusu njia za kisasa za kutibu ugonjwa wa kisukari.

Utafiti huu utakugharimu chochote? La

Na iwapo una maswali mengine kwa siku zijazo

Uko huru kuuliza maswali hata bada ya leo. Unaweza kuuliza watafiti kupitia kwa simu/ ujumbe kwa namba zilizipo hapa chini kwa ukurasa.

Kwa ujumbe Zaidi haswa kuhusu haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Mwenyekiti/ Mwandishi Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. Iwapo mawasiliano haya yatakuwa kuhusu huu utafiti, watafiti watakurejeshea gharama yako ya kupiga simu.

Maamuzi mengine

Kushirikishwa kwako katika huu utafiti ni kwa hiari yako. Unaweza kukataa kuendelea kwenye huu utafiti na unaweza kujiondoa kwa utafiti huu wakati wowote bila kupoteza huduma yoyote.

Unaweza kuuliza maswali yoyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu kwa mtafiti mkuu ama mkuu wa idara ya upasuaji katika chuo kikuu cha Nairobi ama walimu wasimamizi wa utafiti ukitumia nambari za simu zifuatazo;

Katibu wa utafiti,
Hospitali kuu ya Kenyatta na Chuo Kikuu cha Nairobi,
Sanduku la Posta 20723 KNH,
Nairobi 00202.
Nambari ya simu 726300-9.

Walimu wakuu wa Chuo kikuu cha Nairobi:

1. DR JOSEPH GITHAIGA,
MBChB (UON), M.Med Surgery (UON),
Sanduku la Posta 19676 KNH,
Nairobi 00202.

2. DR PETER WAMBUGU,
MBChB (U.O.N), M.Med Surgery (U.O.N)
Sanduku la Posta 19676 KNH,
Nairobi 00202.

3. DR WYCKLIFFE KAISHA
MBChB (U.O.N), M.Med Surgery (U.O.N)
Department of Anatomy, School of Medicine, University of Nairobi
P.O. Box 19676 KNH, Nairobi 00202

Mtafiti

1. DR FRANCIS KIMERE KAARA,
Idara ya Upasuaji ya Shule ya Afya – Chuo kikuu cha Nairobi,
Sanduku la Posta 36153 00200,
Nairobi.
Numbari ya simu: 0720675361

Sehemu ya pili – Idhini ya mgonjwa.

Nimesoma ujumbe ulioko kwenye maandishi haya na nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Francis Kimere kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu yangu au mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na hata madaktari wenyewe na kwa kuendeleza elimu.

Nimekubali kushiriki kwa utafiti huu ndio la

Nimekubali kupeana anwani zangu kwa mawasiliano baadaye ndio la

Jina…….

Sahihi/ama alama ya kidole cha gumba ……..

Tarehe……

Sehemu ya tatu – Dhibitisho la mtafiti

Hii nikuidhinisha ya kwamba nimemueleza msimamizi wa mshiriki (mgonjwa) kwenye utafiti kuhusu utafiti huu na pia nimempa nafasi ya kuuliza maswali. Ninaamini kwamba ameelewa na ameweka sahihi kwa hiari yake bila kushurutishwa na mtu yeyote.

Jina ……

Sahihi……Tarehe……

Nafasi katika utafiti……

Shahidi- iwapo kuna haja ya shahidi

Jina la shahidi……

Sahihi…….

Tarehe……

TABOLIC SURGERY FOR TREATMENT OF TYPE 2 DIABETES
ELLITUS: ELIGIBILITY, DIABETES REMISSION SCORE AND
AWARENESS IN A KENYAN

14% SIMILARITY INDEX | 11% INTERNET SOURCES | 10% PUBLICATIONS | 2% STUDENT PAPERS

PRIMARY SOURCES

1	e-sciencecentral.org Internet Source	1%
2	"Gastric Bypass", Springer Science and Business Media LLC, 2020 Publication	1%
3	link.springer.com Internet Source	1%
4	"The ASMBS Textbook of Bariatric Surgery", Springer Science and Business Media LLC, 2020 Publication	1%
5	Erepository.uonbi.ac.ke Internet Source	1%
6	"Obesity, Bariatric and Metabolic Surgery", Springer Science and Business Media LLC, 2016 Publication	1%
7	journal.acibadem.edu.tr	

itel
SHOT ON A36

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/278

2nd August , 2021

Dr. Francis Kimere Kaara
Reg. No.H58/7102/2017
Dept. of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 02 AUG 2021 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Dear Dr. Kaara

RESEARCH PROPOSAL: METABOLIC SURGERY FOR TREATMENT OF TYPE 2 DIABETES MELLITUS: ELIGIBILITY, DIABETES REMISSION SCORE AND AWARENESS IN A KENYAN TERTIARY HOSPITAL (P121/03/ 2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above research proposal. The approval period is 2nd August 2021 – 1st August 2022.

This approval is subject to compliance with the following requirements.

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
vii. Submission of an executive summary report within 90 days upon completion of the study.