DEVELOPING A NOMOGRAM FOR ASSESSING NUTRITIONAL STATUS IN SURGICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL

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A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTERS OF MEDICINE IN GENERAL SURGERY, UNIVERSITY OF NAIROBI

STUDENT'S DECLARATION

This dissertation is my original work and has not been submitted elsewhere for any other purpose in any institution. Where other people's work has been used, this has been acknowledged and referenced as per University requirements.

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DEDICATION

This work is dedicated to my parents **Mr. and Mrs. Mose** and my late uncle **Prof. Ombega James** for making this dream possible and walking with me through the entire gamut of emotions during the training.

ACKNOWLEDGMENT

I thank the Almighty God for His grace throughout this program. I am indebted to **Dr. Githaiga Joseph** and **Dr. Ojuka D.K.** for their expert opinion, guidance and constant encouragement that go beyond indispensable levels.

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LIST OF ABBREVIATIONS

KNH	Kenyatta National Hospital
BMI	Body Mass Index
RDW	Red blood cell Distribution Width
CBC	Complete Blood Count
LFT	Liver Function Test
WHO	World Health Organization
UON	University Of Nairobi
SPSS	Statistical Package for Social Sciences
MIC	Malnutrition Inflammatory Complex
CORL-BMI	Combination of Red blood cell distribution width total lymphocyte count and Body Mass index
RBC	Red Blood Cell
RDW	Red Blood Cell Distribution Width
TLC	Total lymphocyte count
RBP	Retinol Binding Protein
EDTA	Ethylenediaminetetraacetic acid
LOH	Length Of Hospital stay

OPERATIONAL DEFINITIONS

Sensitivity: Probability that a test will identify a disease among those with the disease; true positive rate.

Specificity: Probability of those without the disease to have a negative result; true negative rate.

Nomogram: A graphical calculating device representing the relationship between three or more variables by means of a number of scales, so arranged that the values of one variable can be found by simple geometrical constructions e.g. by drawing a straight line intersecting the other scales at the appropriate values.

ABSTRACT

Background: Poor nutritional status in the background of a disease process is associated with a prolonged hospital stay, increased economic burden, and higher morbidity and mortality. Robust nutritional assessment tools exist which have varying accuracy and cost implications. The use of a combination of red cell distribution width, total lymphocyte count and body mass index (CORL-BMI), could be a reasonable alternative in a resource-limited center for assessment of nutritional status.

Objective: This study aimed to develop a tool (CORL-BMI) that can be used in the nutritional assessment of surgical patients at Kenyatta National Hospital (KNH).

Methodology: This was a hospital-based cross-sectional analytic study that was carried out in the surgical wards and theatres (minor and main theatres) of KNH from March 2020 to June 2020. Patients above the age of eighteen years, who met the inclusion criteria and consented, were conveniently recruited. The data collection tool captured; social demographic, clinical information like weight, height and laboratory indices like TLC, CBC and pre albumin levels of participants. Patient characteristics that were categorical were presented as frequencies and percentages, while those that were continous were presented as means with standard deviations. The association between RDW-SD, TLC, and BMI with pre-albumin levels, as well as the association between CORL-BMI and pre-albumin levels was performed using Pearson Correlation. The sensitivity and specifity of CORL-BMI was performed with the use of ROC curve. The prevalence of malnutrtion was determined as a proportion of those with Pre-Albumin levels of less than 18 over the total sample size of the study, and reported as a percentage. The nomogram for assessing risk of malnutrition was generated with the use of R Statistical Software version 3.6.1 after running a logistic regression model to predict the probability of malnutrition. All statistical tests were considered significant where $p<0.05$.

Results: The correlation of CORL-BMI with pre-albumin is moderate. The value of the area under the curve (AUC) has archived statistical significance with p-value < 0.05 with favorable sensitivity and specificity, 74.1% and 21.4% respectively.

Conclusion: This study has demonstrated that utility of a combination of laboratory parameters (TLC and RDW-SD) and physical examination findings (BMI) to generate a nomogram (CORL-BMI) could be used in assessment of nutritional status in resource-limited settings.

Significance: This study introduces a novel alternative tool (CORL-BMI) that could be used for assessing nutritional status in surgical patients that is cheaper and easy to use especially in resource-limited settings.

CHAPTER ONE: INTRODUCTION

1.1 Background

To expedite healing and recovery, good nutritional status is key[1]. In 1859 Florence Nightingale described Crimean soldiers as starving amidst plenty of food, on her realization of the importance of nutrition on patients' clinical outcomes. [2] Malnutrition is an emerging significant factor of patient clinical outcomes across the board; in both medical and surgical fields. Hill et al found that 50% of surgical patients and 20% of medical patients are malnourished upon admission, worse still; it remains to be an unrecognized entity. [3]

The stress of surgery alters the human body physiology by inducing an inflammatory response that increases catabolism predisposing one to malnutrition. A surgical patient presenting in already a malnourished state before surgery is at a higher risk of malnutrition postoperatively if not addressed.[4]

Malnutrition can be assessed using clinical, physical and laboratory parameters. Several tools[5] have been developed to aid in nutritional assessment; DETERMINE checklist and Subjective Global Assessment (SGA)[6] [7] which utilizes clinical assessment only, whereas, Malnutrition Screening Tool (MST)[8], Malnutrition Universal Screening Tool (MUST)[9] and Mini Nutritional Assessment (MNA); utilizes both clinical assessment and anthropometric measures. None of these tools utilizes laboratory parameters.

Obtaining an accurate rate of weight loss may not be possible, laboratory parameters have therefore been used as a rapid and reliable tool to detect malnutrition before clinical signs and symptoms manifest[8]. Some tools (MST[10] MNA[10] MUST[9]) have incorporated both clinical and anthropometric parameters increasing their accuracy of the assessment. Incorporating laboratory parameters may further increase the sensitivity.

The utility of biochemical parameters introduces additional hospital costs, this increases the economic burden and results[11] into poor nutritional assessment and follow-up. This study seeks to develop a tool that combines both anthropometric (BMI) and laboratory parameters (TLC and RDW). Both TLC and RDW are parameters in a basic CBC test, hence no added additional laboratory tests will be required making it a good alternative in a resource-limited setting.

1.2 Statement Problem

The universality of malnutrition is evident, and so is its direct impact on clinical outcome[1 4] and therefore a critical subject to be explored. Malnutrition increases the economic burden both directly and indirectly[11].

Measurement of nutritional status is used to assess the health status of any population. A vast number of tools exist for nutritional assessment, ranging from physical to biochemical tools. Nutritional status is assessed in terms of anthropometric measurement, biochemical assessment, clinical assessment and dietary. Most biochemical tools require additional tests and therefore increasing hospital costs and resulting in poor nutritional assessment and follow up.

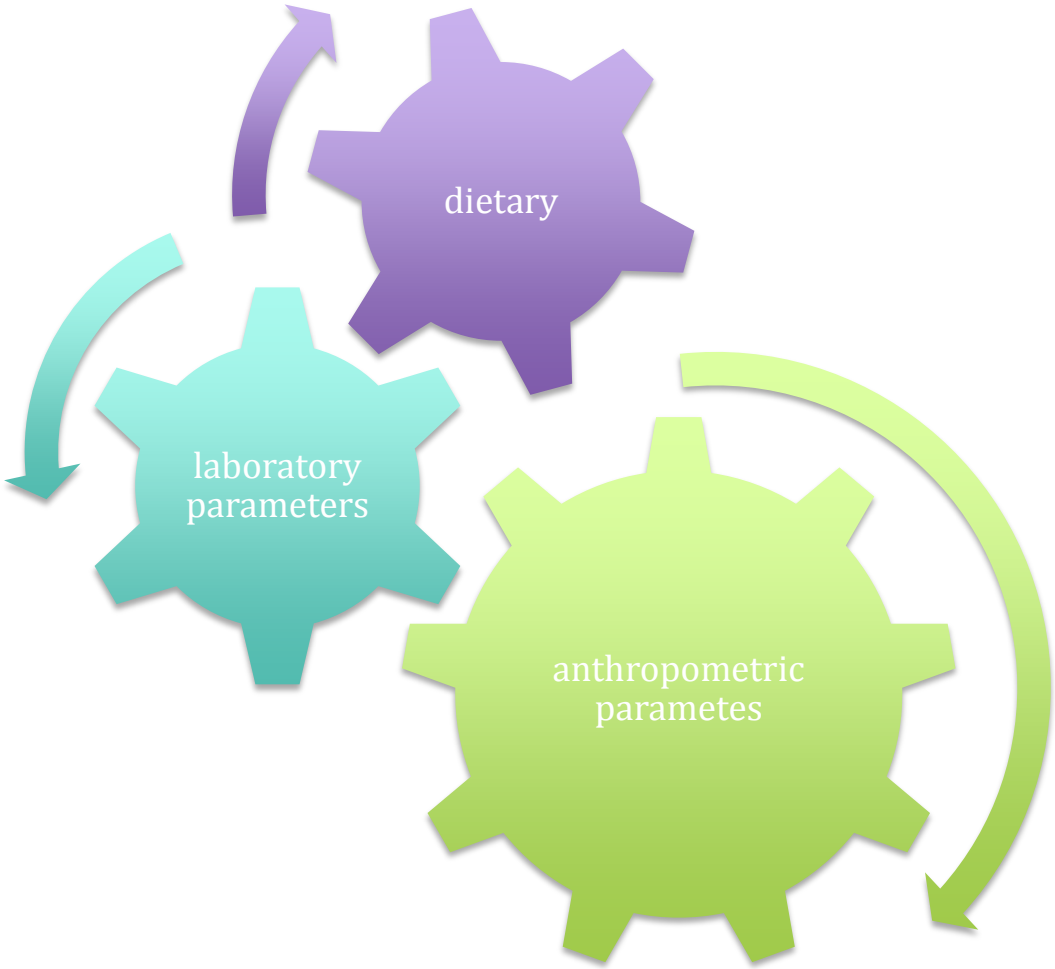

Figure 1: Factors used in assessing nutritional status

CHAPTER TWO: LITERATURE REVIEW

WHO defines malnutrition as insufficiency, surplus or imbalance in the intake of energy and or nutrients in relation to their body requirements. Nutrition is determined by a complex interplay between internal (age, sex, physical activity) and external (socio-economic status, environmental) factors. Malnutrition encompasses over and under nutrition, and it is culpable for most morbidity and mortality in surgical wards. [12] In this study, malnutrition term will be used to imply under nutrition.

2.1 Epidemiology

Malnutrition is a threat to global public health.[13] It takes a toll especially when surgical stress is added resulting in poor healing[14], lowers the immunity making one susceptible to infections, increases hospital costs and prolongs hospital stay[15]. Malnutrition is an emerging significant factor of patient clinical outcomes across the board; in both medical and surgical patients. Hill et al found that 50% surgical patients and 20% of medical patients were malnourished upon admission, worse still, it was unrecognized.[3]

Malnutrition in Kenya is demonstrating an upward trend especially in the pediatric population as elucidated by Ngare D.K. et al. In an observational study done in Kenyatta National Hospital in 2019 by Ali Kariuki and Ojuka D.K. it was demonstrated that 36.2% of patients admitted for elective surgery were malnourished and this negatively impacted on their surgical outcome. [16] Inarguable causes of malnutrition in Africa are poverty and illiteracy.[17] Malnutrition is more prevalent in the hospital setting; considering that 40% of patients are admitted in a malnourished state while 75% have involuntary weight loss during their stay in the hospital, Oliveira et al. In Latin America, hospital malnutrition ranges from 20-50%.[18]

In a WHO meeting in Bangkok November 2018, it was reiterated that malnutrition is demonstrating a high burden and worrying universality with an impact beyond health; as it impacts on the socio-economic development of countries. It was demonstrated that 462 million people worldwide are malnourished. Malnutrition is highlighted in the Sustainable Developmental Goals (SDG) targets of 2030; goal number 2.2. The United Nations aims to end malnutrition by 2030.

A study done in Norway, demonstrated that nutritional assessment is poorly documented in surgical patients, at the time of the study the prevalence was at 39%, these results coincide with the results of Ali Kariuki and Ojuka D. K. (36.2%) done in KNH on elective surgical

patients. A similar study done in New Zealand on the prevalence of malnutrition indicated that it was prevalent in both elective and acute surgical cases.[20]

2.3 Pathophysiology[21]

Malnutrition results from a mismatch between protein-energy requirements and intake. The deficiency is as a result of poor intake, mal-absorption or increased need due to a disease process or surgical stress or trauma. The body adapts to nutrient deficiency by trying to adjust energy store utilization while preserving the protein pool. Plummeting basal metabolism, lessening the secretion of anabolic factors and moderately increasing catabolic hormones, aids in achieving this. Reduced serum protein due to increased catabolism in the disease process or reduction in synthesis, results in low albumin and pre albumins[8], which can be hematologically assessed. Malnutrition state reduces the synthetic factors of the body, resulting in a reduction of the production of essential proteins needed in the immunological system (co-enzymes, complements and immunoglobulins).

2.3.1 RDW

Complete blood count (CBC) is a widely available tool and relatively cheap in the clinical practice, which contains red blood cell distribution width (RDW) among other parameters. RDW has traditionally been used to evaluate different types of anemia's [22]. There exist a robust number of studies on the utility of RDW. RDW has been used to assess prognosis[23] and clinical status of critically ill patients, those with inflammatory disorders, malignancies[24] and cardiac disease, amongst others, particularly in resource-limited settings.

Recent studies have shown that RDW may be a prognostic marker in various tumors and this is strongly associated with the accompanying malnutrition in the disease process e.g. colorectal cancer, renal cell carcinoma, gastric cancer, and breast cancer. Previous studies[25] have shown that RDW correlates with nutrition status markers, such as vitamin D3, transferrin, pre-albumin and albumin.

Vitamin D3 is chiefly responsible for cell proliferation and erythropoiesis in the bone marrow. A bigger percentage of the vitamin D3 is in the bone marrow (75% in the bone marrow and 25% in the blood). Plummeting levels of serum vitamin D3 may result in derangement in bone marrow erythropoiesis. In a meta-analysis of seven trials on 1031 patients done by Lishai Ai et al[23] on patients with hematological malignancies, it elucidated that high RDW is associated with poor prognosis. Increased pre-treatment RDW predicted poor overall survival (HR 2.35, 95% CI 1.70-3.24), poor progress-free survival (HR 2.44, 95% CI 1.70-3.49) and poor event-free survival (HR 3.15, 95% CI1.59-6.25).

In another study done in Germany by Fujita B. et al, it was demonstrated that RDW was elevated in overweight and obese individuals [26].

RDW is a parameter that measures variation in RBC size and volume. In humans, RBC has a diameter ranging from 6 to 8 mm and a thickness of 2mm. The overall volume of an erythrocyte is 80 – 100 fL. Under some circumstances, RBC may decrease or increase their volume to 60 and 150 fL respectively. The degree of heterogeneity of RBCs volume i.e. anisocytosis is conventionally quantified employing an equation in which the standard deviation of RBCs (RDW-SD) volume is divided by MCV and further multiplied by 100 to express it in percentage. The normal ranges of RDW-SD 37-54fL.

2.3.2 Total Lymphocyte Count

Malnutrition is an immune-comprise state hence, it is associated with low total lymphocyte count as demonstrated in a vast number of studies [27] [28] [29]. TLC has been used in assessing malnutrition, however, it may be inaccurate in some conditions for example, in some immune compromise states and viral infections. The normal values ranges of TLC are 1.0 – 3.7*10/3 uL. In a cross-sectional study done in Jakarta Indonesia, it was demonstrated that there was an association between malnutrition and TLC less 1200 cell/mm (p=0.001).[30] In another study done by Tomoko et al in Japan during an annual health check-up, it elucidated that lymphocyte count was notably lower in the underweight cohort with an association of low lymphocyte count (<1500mL) with underweight (OR 1.96, 95% CI 35-2.83). [28]

There is a strong correlation between serum albumin and TLC in a study done in Brazil. In that study, it was concluded that albumin and TLC can be reliably used in assessing nutritional status and determining the prognosis of associated post-operative complications.[31]

In the recent studies, pathogenesis of malnutrition has been associated with inflammation (Malnutrition Inflammation Complex) hence the introduction of the utility of C-reactive protein and total lymphocyte count as markers of nutritional status.

2.3.3 Albumin and Pre-Albumin

In the current practice, biochemical markers of malnutrition in surgical patients include pre-albumin, transferrin, Retinol-Binding Protein (RBP) and nitrogen balance levels. Pre albumin, transferrin, and RBP require additional laboratory tests and follow up of the same tests to evaluate progress, while nitrogen balance requires the collection of 24hr urine, which can be cumbersome. To date, albumin levels are being used as a determinant of nutritional status[32]. However, it is prudent to remember that albumin has an enormous body pool and a prolonged half-life (20days), making it an inaccurate marker. On the other side,

pre albumin has a smaller half-life (2-3days) and lesser serum pool than albumin; therefore it is inarguable that it is a more accurate indicator of protein status. It has a high ratio of essential to nonessential amino acids of any protein in the body making it a discrete indicator for protein synthesis. Unlike albumin, hydration status, stress, and liver diseases[33] do not affect pre albumin. Normal pre-albumin ranges are 18 – 45mg/dl.

2.4 Effect of Malnutrition on Surgical Outcome

2.4.1 Clinical Outcome

The effects of malnutrition on physiological function have a significant bearing on the overall clinical outcomes of patients.[1 4] In the early nineteenth century, surgeons noted an increased occurrence of postoperative complications and mortality. A vast number of studies have consequently buoyed this observation. [34]

Undernourished patients develop surgical complications, increasing their hospital stay and mortality, more frequently as compared to normally nourished patients, incurring up to fifty percent more hospital costs. It is challenging to accurately separate the detrimental consequences of malnutrition from the underlying disease process itself, because each can be a cause and/or consequence of the other. However, it is evident that nutrition support notably improves outcomes in these patients; it is, consequently, imperative that malnutrition is recognized promptly and addressed.

2.4.2 Economic Burden

Malnutrition exerts a burden on the nations' economy[11]. According to the British Association of Parenteral and Enteral Nutrition (BAPEN), the overheads linked with disease-related malnutrition in the United Kingdom in the year 2007 were over thirteen billion euros. This was a sum cost of treatment for both the underlying disease and malnutrition. The conceivable budget savings associated with the prevention and treatments of malnutrition are substantial: a one percent saving is equivalent to up to one hundred and thirty million euros per year.

2.4.3 Length of Hospital Stay

Due to associated increased morbidity and poor healing, it summative results in increased hospital stay, which impacts on the country's economy both directly and indirectly.[15] Directly because, affected persons will be away from work, reducing the workforce and indirectly as the protracted hospital stay results into hefty bills to the patient and his family.

2.4.4 Poor and or Delayed Wound Healing

Poor wound healing is associated with delayed collagen synthesis[14], therefore, impeding healing by reducing tensile strength and increasing infection rates. Nutrition and wound healing are intrinsically linked. Malnourished patients have insufficient nutrients to maintain and repair tissues. This leads to reduced 'padding' from fatty tissues, poor skin condition (with low resistance to the effects of shear and pressure) predisposing the patient to development of decubitus ulcer.

2.4.5 Increased Drug Toxicity

The serum albumin concentration is often low in malnutrition; this increases vulnerability to adverse drug reactions associated with protein-bound drugs. The continuous and often approximated weight may result in a drug overdose.[35]

2.5 Nutrition Assessment Tools

There exists an array of nutritional assessment tools with varied sensitivity and specificity. No single parameter can be used independently to assess nutritional status, thus the need to combine different parameters to improve sensitivity. To date, there is no gold standard tool for assessment of nutritional status.

The DETERMINE checklist was developed and validated to assess malnutrition in elderly patients moreover, it utilizes only clinical assessment, therefore, it may not pick malnutrition in its early stages. Furthermore, some questions in the questionnaire may not truly reflect nutritional risk.[36] The SGA tool, is a validated and also utilizes clinical assessment only by combining physical examination and clinical history findings.[6 7] However it is prudent to remember that clinical manifestation develops at advanced stages of malnutrition.

MUST tool is a five-step screening validated tool[9] that incorporates both clinical and anthropometric measurements, but leaves out laboratory parameters. MNA tool; this tool was developed and validated in geriatric patients; notably, it leaves out laboratory parameters.

In a study done on comparison of MUST and MST in assessing nutrition in renal patients, it was found that none of them were sensitive enough to asses nutritional status.[37] The proposed combination of MUST and SGA was found to be a workable recommendation. However, this may be tedious and complex, and still, it does not have a representation of laboratory parameters.

Study on four nutritional assessment tools in Vietnam, NRS-2002 had an excellent performace[38] followed by MST, MUST and finally BMI. A single study done in comparing three screening tools NRS 2002, MUST, MNA-SF with the new ESPEN diagnostic criteria of malnutrition, MUST was found to perform the best in identifying malnutrition (Xiao Jun ye). Studies are revealing conflicting data on the sensitivity of different nutritional assessment tools.

2.6 Anthropometric Parameters

Weight measurements; Weight has a limitation as a nutritional index. For precision, weighing scales require regular servicing and calibration; many do not receive this according to a study done by Chu et al in 1999. Shifting fluid balance with dehydration and edema, differing scales and clothes may mean changes do not reflect the nutritional status. Furthermore, weight measurement cannot differentiate muscle from fat and does not take into account overall body size. A more reliable way of accounting for nutrition than weight measurement is Body Mass Index (BMI); BMI is a term for weight measurements that take account of height. The most commonly used calculation is the Quetelet's index, which is weight in kilograms divided by height in meters squared. BMI of less than 20kg/m2 is considered as nutritional risk, and less than 18kg/m2 is considered as nutritional compromise. In elderly patients, BMI of less than 23kg/m2 is considered to be malnutrition, (Beck and Ovesen 1998). Changes in BMI are demonstrated in advanced stages of malnutrition. Clinical examination is a vital component but while malnutrition produces an array of clinical signs as reiterated by Bond et al 1997; these tend to be subtle and non-specific until malnutrition is advanced. Dependence on clinical signs for nutritional screening may not be effective in the early stages.

Given the prevalence and deleterious consequences of malnutrition, it is pragmatic to utilize available tools and research on more easily available and cheaper yet accurate tools thus the impetus to carry out this study. Anthropometric measures may be less helpful in short term illness when an increase in tissue fluids occurs along with a decrease in cellular mass hence the need to incorporate other parameters from biochemical markers.

2.7 CORL-BMI

In this study, we introduce a nomogram; CORL-BMI. This tool will incorporate both biochemical (TLC, RDW) and an anthropometric parameter (BMI) to increase the accuracy of the assessment of malnutrition. A nomogram is a model that shows relationships between three or more variables, scientifically, it is used to predict different conditions. It allows for the independent contribution of multiple factors to be assimilated to offer a continuous probability prediction for a given outcome. The field of nomography was invented in 1884 by the French engineer Philbert Maurice d'Ocagne. A nomogram consist of a set of scale, one for each variables in an equation, utilizes the known variables to study the unknown ones. Results from a nomogram are obtained by simply drawing one or more lines.

Predictive nomograms have been utilized to aid in the diagnosis and management of patients. In this study three variables (RDW, TLC, BMI) will be correlated with pre albumin as the gold standard. Their strength of correlation will be assessed and a nomogram of the three variables will be developed.

2.8 Knowledge Gap

There is need for a more reliable yet cheap tool to enable assessment and continuous monitoring of nutritional status in surgical patients as this impact greatly on the clinical outcome.

2.9 Conceptual Framework

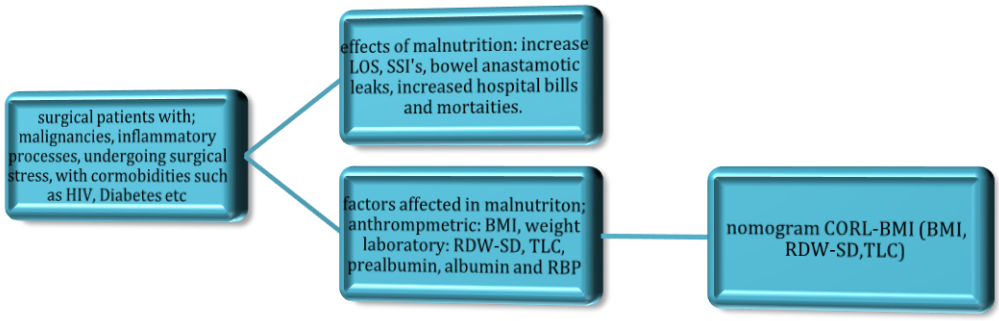

Figure 2: Conceptual Framework

2.10 Study Justification

This study aims to provide an alternative tool for nutritional assessment. Carrying out biochemical tests is expensive, as it requires an additional test that may result in poor nutritional assessment due to costs and ultimately impacting the surgical outcome. We sought to assess the correlation of RDW, TLC, and BMI with pre albumin, and develop a nomogram with these variables. By introducing this novel tool (CORL-BMI), we shall ease nutritional assessment and follow up because it is cheap and easy to use.

2.11 Study Question

Is there a correlation between CORL-BMI and pre-albumin?

2.12 Study Objectives

2.12.1 Broad Objective

To develop a tool for assessing nutritional status in surgical patients by determining the correlation between CORL-BMI (TLC, RDW, and BMI) with pre albumin

2.12.2 Specific Objective

a) To find the association between RDW, TLC, and BMI individually with pre-albumin.

b) To determine the level of association between CORL-BMI with pre albumin.

c) To assess the sensitivity and specificity of CORL-BMI.

2.12.3 Secondary Objective

Determine the prevalence of malnutrition in surgical patients.

2.12.4. Purpose of Study

Offer a cheaper and alternative tool for nutritional assessment and follow up in surgical patients.

CHAPTER THREE: METHODOLOGY

3.1 Study Design

The study design was a cross-sectional analytic, as all parameters regarding the study were taken at the point of admission. It is analytic because RDW, BMI, and TLC are correlated against the gold standard; pre albumin.

3.2 Study Site

The study was carried out at Kenyatta National Hospital. It is the oldest National, referral, teaching and research hospital of the three Kenyan referral hospitals. It has a large catchment population for the neighboring counties and countries. It was the best site to carry out this study because of the large number and diversity of patients referred here and also because it is a teaching hospital for both University of Nairobi medical school and Kenya Medical Training College (KMTC), with a surgical bed capacity of two hundred and daily twenty-four hour functioning theatres.

3.3 Study Population

3.3.1 Inclusion Criteria

Eligible participants were patients between the age of 18- 50 years[39] admitted in the surgical wards (for both elective and emergent surgeries) and patients who come for minor surgical procedures in minor theatre willing to consent to participate in the study.

3.3.2 Exclusion Criteria

An individual will be excluded from the study if:

- **a)** He/she has hematological or bone marrow disease
- **b)** He/she has liver disease
- **c)** He/she has renal disease
- **d)** He/she is on steroidal treatment
- **e)** He/she has confirmed HIV

3.4 Sampling Size

3.4.1 Sample Size Calculation

Sample size was calculated by Cochran's formula[40] stated as follows:

$$n_0 = \frac{Z^2 pq}{e^2}$$

Where:

N0 = sample size

z_α = standard normal value for two-tailed hypothesis at α level of significance (1.96)

P=Is the estimated proportion of the population which has the attribute in question (0.5)

e^2 = margin of error (0.05)

q=1-p

$N_o = (1.96)^2(0.5)\ (0.5)/(0.05)^2 = 385$

3.4.2 Sampling Technique

Three hundred and eighty five (385) were found to be eligible to participate and, convenient sampling technique was used upon admission to surgical wards or presentation to minor theatre.

3.5 Study Validity

Data quality was ensured through working with a trained research assistant. His role was consenting of participants, data collection and entry. The primary investigator reviewed his work daily for consistency and completeness and plausibility checks done with SMART/ ENA software.

3.6 Study Procedure

3.6.1 Recruitment

Patients meeting the inclusion criteria were recruited at point of admission at the study site. Eligibility was determined by the inclusion and exclusion criteria.

3.6.2 Consenting and Enrolment

Written informed consent was obtained from all eligible and willing to participate in the study. During the consenting process, patients were allowed to choose the preferred language and mode of reading; either the participant reads on his/her own or the study assistant reads aloud for them. A translator was recruited for patients that do not understand both English and Swahili. For the illiterate patients, a witness who was not part of the study was recruited to be present during their consenting process and further request to append his/her signature on the consent form together with the participant. The consent provided details of the study procedure, risks, benefits and confidentiality, voluntarism and contact information.

Patients that met the inclusion criteria were weighed using a salter scale and height measured using a stadiometer. BMI was then calculated manually, and all values entered in a preformed datasheet. Blood samples were then taken using aseptic techniques to do CBC test and determine the pre albumin values.

There was strict surveillance of data collection and entry procedures to minimize the risk of omission biases and transcriptional errors. Participants had venous blood drawn (by the research assistant) using needle gauge 21 or 23 in an aseptic procedure (quantity of blood was five millimeters). The blood was then put in EDTA and plain bottle vacutainers that had patient unique serial numbers, ward number, sampling date and time. The samples in the EDTA bottles were then taken to the hematology laboratory where a designated hematologist for the study analyzed the blood for CBC using an automated analyzer (SYMEX, MODEL DN500). The blood samples in plain vacutainers were put in a cool box and transported to Lancet laboratory by the research assistant for analysis of pre albumin levels.

3.7 Study Variables

3.7.1 Variables

- Age
- Diagnosis
- Weight
- Height
- RDW
- TLC
- Pre albumin
- CORL-BMI

3.7.2 Outcome Measure

- Correlation of RDW, TLC BMI with pre albumin
- Correlation of CORL-BMI with pre albumin
- Sensitivity and specificity of CORL-BMI

3.8 Materials

Pictorial demonstration is seen in *figure 3* below.

- Salter weighing scale
- Standard stadiometer
- Disposable gloves
- Needles gauge 22, 14
- Syringes 10cc
- Vacutainers: plain bottle and EDTA bottle

Figure 3: Materials

3.9 Training Procedure

One research assistant was deployed into the study, he participated in the entire study period; he is a medical student in his sixth year of training in Bachelors of Medicine and Surgery (MBChB). The principal investigator familiarized him with the objectives of the study, nature of data to be collected and how to enter the data in the datasheet. Further, the primary investigator and the research assistant recruited the first fifty study participants and entered the data together, to ensure that the research assistant fully understands his role. Subsequently, the research assistant collected data independently to completion of the study, and the principal investigator duly supervised his work daily for to minimize errors.

3.10 Quality Assurance Procedure

Inclusion criteria were strictly adhered to. Daily meetings were held between the principal investigator and the research assistant to resolve any emerging queries regarding quality control. Stringent training of the research assistant was undertaken inclusive of observation of ethical consideration while interacting with study participants. There was strict surveillance of data collection and entry procedures to minimize the risk of omission biases and transcriptional errors. Participants had venous blood drawn (by the research assistant) using needle gauge 22 or 14 in an aseptic procedure (quantity of blood was five millimeters). The blood was then put into EDTA and plain bottle vacutainers. These vacutainers had patient unique serial numbers, ward number, type of test requested and sampling date and time.

The sample in the EDTA bottle was then taken to the hematology laboratory where a designated hematologist for the study analyzed the blood for CBC using an automated analyzer (SYMEX, MODEL DN500). The samples in plain vacutainers were put in a cool box and transported to Lancet laboratory by the research assistant for analysis of pre albumin levels.

3.11 Ethical Consideration

Approval to conduct the study was obtained from the department of surgery, University of Nairobi (UON) and subsequently KNH/UON ERC before the rollout of the study. Informed consent was sought from patients; confidentiality and privacy was observed by non-disclosure of data to third parties. Those who decline to consent were not discriminated against. Patients had the right to withdraw from the study at any stage. Additionally, permission to carry out the study was sought from KNH administration.

3.12 Data Management

The data recorded on data collecting sheets was checked for accuracy and completeness, and confirmed to be free of error prior to entry into Microsoft Excel 2016 datasheet (appendix 2). It was later exported to Statistical Package for Social Sciences (SPSS) version 23 for analyis. Patient characteristics that were categorical were presented as frequencies and percentages, while those that were continous were presented as means with standard deviations. The association between RDW, TLC, and BMI with Pre-Albumin levels, as well as the association between CORL-BMI and Pre-Albumin levels was performed using Pearson Correlation. The sensitivity and specifity of CORL-BMI was performed with the use of ROC curve.

The prevalence of malnutrtion was determined as a proportion of those with prealbumin levels of less than 18 over the total sample size of the study, and reported as a percentages. The nomogram for assessing risk of malnutrition was generated with the use of R Statistical Software version 3.6.1 after running a logistic regression model to predict the probability of malnutrition. All statistical tests were considered significant where $p<0.05$. The data was subsequently validated for completeness and correctness. Hard copy raw data was kept under lock and key while electronic copy was password protected only accessed by the principal investigator.

3.13 Data Dissemination

Study results will be accessible through the department of surgery University of Nairobi and UON-KNH library, UON repository website, and further published online in peer review journals.

CHAPTER FOUR: RESULTS

4.1 Baseline Characteristics of Participants

Three hundred and eighty five participants (385) were enrolled in the study between the period of March 2020 and June 2020. The mean age of the patients was 38.0 (SD=10.8) years, while the median age was 37.0 (IQR=15) years. The minimum age was 16 years while the maximum age was 72 years; further details are demonstrated in *table 1* below. The demography exhibited a female preponderance of 58.7%. There was a higher prevalence of elective surgical procedures as compared to the emergent surgeries, 74.8% and 25.2% respectively.

Table 1: Age distribution of patients

Age (Years)	Frequency (N)	Percentage (%)
<20	6	1.6
20-29	69	17.9
30-39	154	40.0
40-49	94	24.4
50-59	45	11.7
≥60	17	4.4

The mean BMI of the patients was 23.3 (SD=4.6), while the median BMI was 23.2 (IOQ=5.9) kg/m^2. The minimum BMI was 12.1kg/m^2 while the maximum 42kg/m^2. The rate of under nutrition was 13.5% while the obesity rate was 8.1%. See *table 2* below.

Table 2: Body Mass Index

BMI	Frequency (N)	Percentage (%)
<18.5	52	13.5
18.5-24.9	208	54.0
25-29.9	94	24.4
≥30	31	8.1

The mean TLC of the patients was 2.3 (SD=1.2), while the median TLC was 2.0 (IQR=1.2). The minimum TLC was 0.35 while the maximum TLC was 7.97. The mean RDW-SD of the patients was 48.6 (SD=12.9), while the median RDW-SD was 46.8 (IQR=17.6). The minimum RDW-SD was 27.7 while the maximum was 89.4. The mean pre-albumin of the patients was 26.7 (SD=10.5), while the median pre-albumin was 25.0 (IQR=17). The minimum pre-albumin was 8 while the maximum was 49.

4.2 Association between RDW-SD, TLC and BMI with Pre-albumin

Pearson correlation coefficient was used to determine the correlations of RDW-SD, TLC and BMI with pre-albumin levels.

4.2.1 Correlation of RDW-SD with Pre-Albumin

The correlation between RDW-SD and Pre-Albumin is moderate (r=-0.398, p<0.01), with the linear regression, *y=61.73+0.49x,* determining the relationship, (where *x* is the independent variable Pre-Albumin, and *y* is the dependent variable RDW-SD). See *figure 4* below.

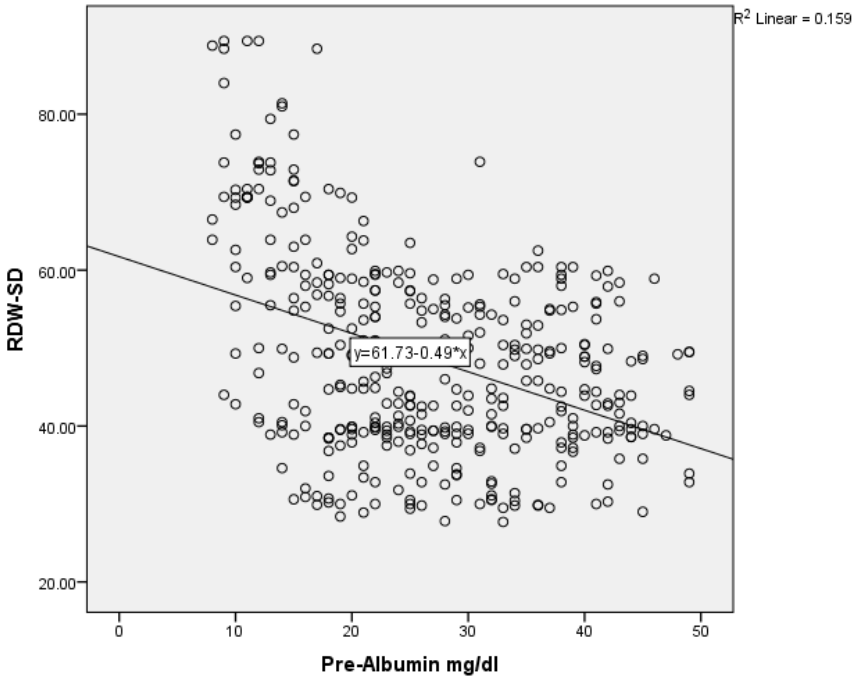

Figure 4: Correlation of RDW-SD with pre albumin

4.2.2 Correlation of TLC With Pre-Albumin

The correlation between TLC and Pre-Albumin is weak (r=-0.201, p<0.001), with the linear regression, *y=2.92+0.02x,* determining the relationship (where *x* is the independent variable Pre-Albumin, and *y* is the dependent variable TLC). See *figure 5* below.

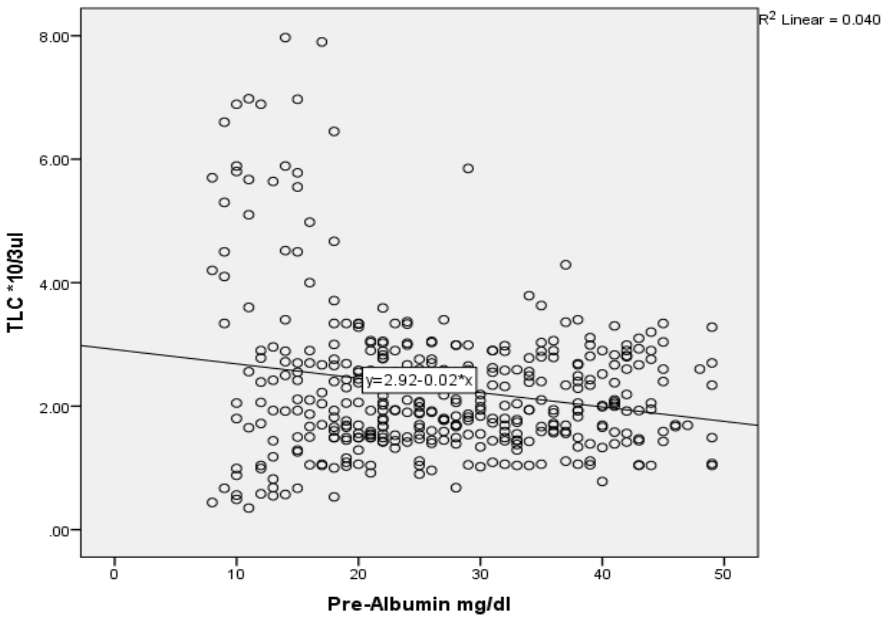

Figure 5: Correlation of TLC with pre albumin

4.2.3 Correlation of BMI with Pre-Albumin

The correlation between BMI and Pre-Albumin is weak (r=0.232, p<0.001), with the linear regression, *y=20.57+0.1x*, determining the relationship (where *x* is the independent variable Pre-Albumin, and *y* is the dependent variable BMI). See *figure 6* below.

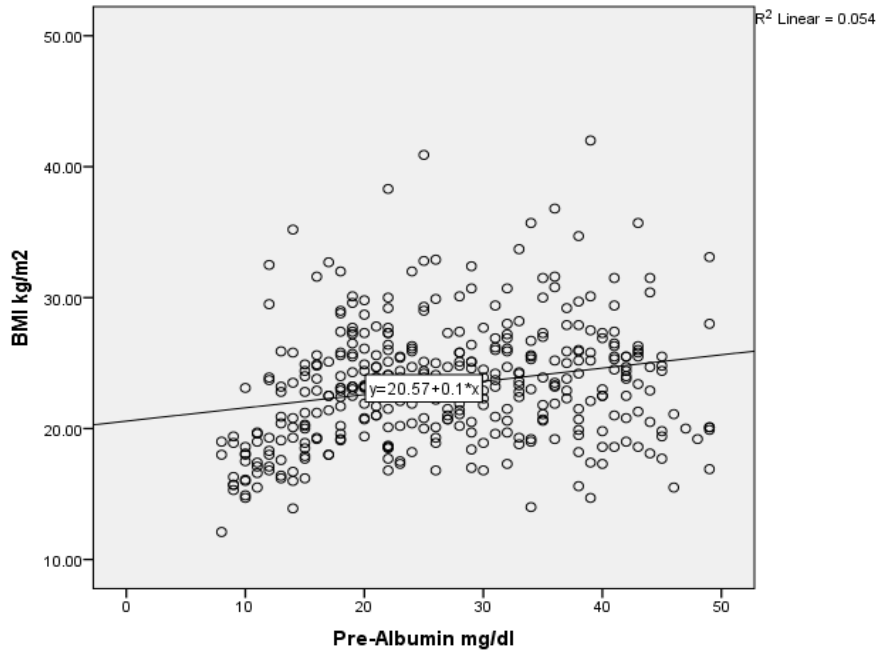

Figure 6:Correlation of BMI with pre albumin

4.3 Association between Various Levels CORL-BMI with Pre-Albumin

The CORL-BMI values were first generated using multiple linear regressions with the independent variables BMI, TLC and RDW-SD as predictors for malnutrition. These generated the linear predictor equation, y=0.357 (BMI) – 0.950 (TLC) – 0.281 (RDW). All predictors were statistically significant with $p<0.05$, and so they were included in the model. The correlation between CORL-BMI and Pre-Albumin is moderate ($r=0.446$, $p<0.001$), with the linear regression, $y=21.42+0.2x$, determining the relationship (where x is the independent variable Pre-Albumin, and y is the dependent variable CORL-BMI). See *figure 7* below.

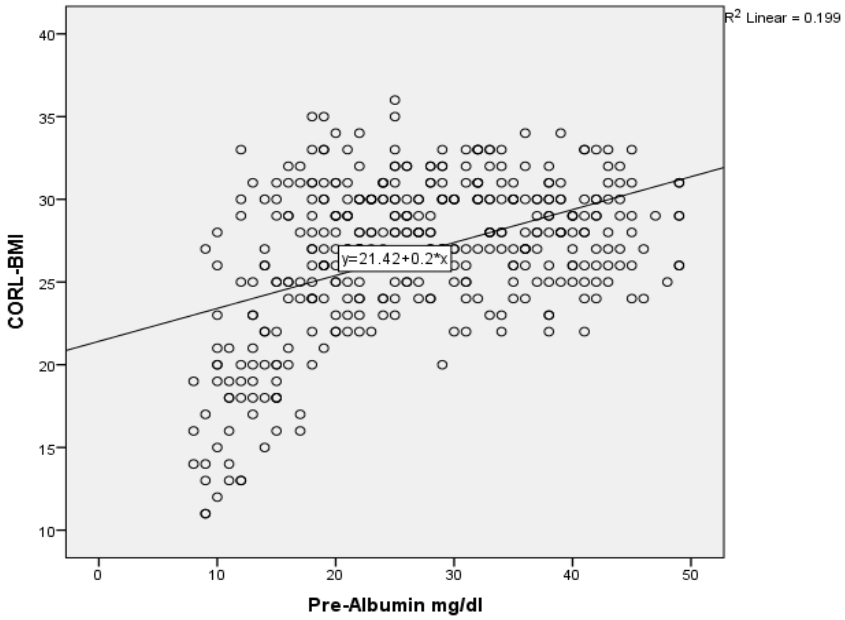

Figure 7: Correlation between CORL-BMI with pre albumin.

4.4 Sensitivity and Specificity of CORL-BMI

Linear predictor equation, y=0.357 (BMI) – 0.950 (TLC) – 0.281 (RDW) was generated using multiple linear regression of the independent variable and further ROC curves were used to establish sensitivity and specificity of CORL-BMI as seen *figure 8* below. The values for Area Under the Curve (**AUC**) for CORL-BMI are excellent (0.819) with CI ranging from 0.756 – 0.882. see *table 3* below. This finding indicates that the cut-off value is good for evaluation of patients at risk of malnutrition. The value of the area under the curve (**AUC**) has achieved statistical significance with p-values < 0.05, which means it has favorable sensitivity and specificity characteristics.

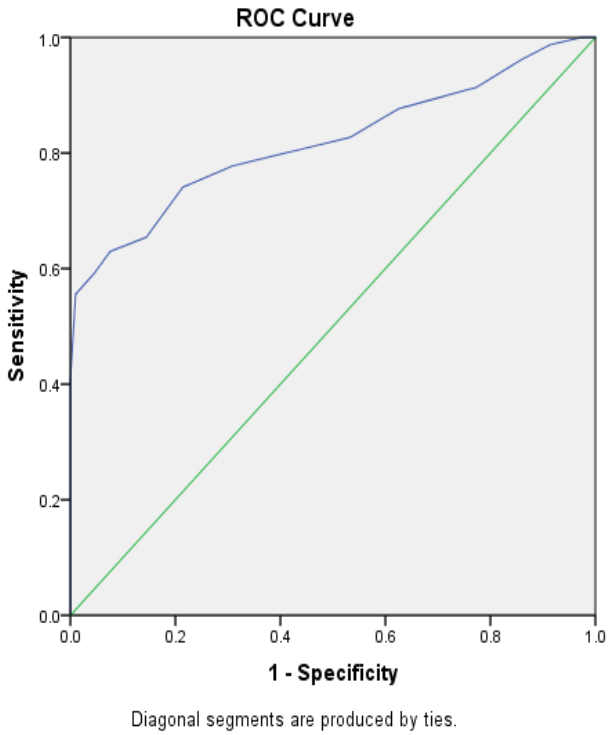

Figure 8: Receiver Operating Characteristic Curve (ROC- curve) for CORL-BMI

Table 3: Area Under the Curve (AUC) for CORL-BMI

Area Under the Curve					
Test Result Variable(s)	**Area**	**Std. Error**	**Asymptotic Sig.**	**Asymptotic 95% Confidence Interval**	
				Lower Bound	**Upper Bound**
CORL-BMI	0.819	0.032	<0.001	0.756	0.882

Table 4:Sensitivity and specificity cut-off values

	Cut off	**Sensitivity**	**Specificity**
CORL-BMI	25.50	74.1%	21.4%

4.5 Prevalence of Malnutrition in Elective Surgical Patients

The incidence of malnutrition in surgical patients undergoing surgical procedures in KNH remains to be remarkable (see *table 5* below) this result coincides with the results of the study done by Ali Kariuki et al. The prevalence of malnutrition depicted on *table 5* was determined using the gold standard; pre-albumin levels.

Table 5:Prevalence of malnutrition

	Frequency (N)	Percentage (%)
Malnourished	81	21.0
Not malnourished	304	79.0

4.6 Nomogram for Assessment of Risk for Malnutrition

A logistic regression model was run with BMI, TLC and RDW-SD as independent predictor variables for the binary dependent outcome varible; malnutrition. The independent predictors were statistically signifacant and so were manntained in the model. The generated equation; y=0.198 (BMI) + 0.291 (TLC) + 0.093 (RDW), as well as the means and standard deviations values for BMI, TLC and RDW were used in the R Statistical software with the additional installaion of the RMS package that contains libraries that facilitate the generation of a nomogram. The RMS package contains several funcions including graphical functions that utilizes the logistic regression parameters and those for the means and standard deviations of BMI, TLC and RDW to generate probability values for the risk of malnutrition and generate the scales and graphical presentation for each parameter. See *figure 9* below.

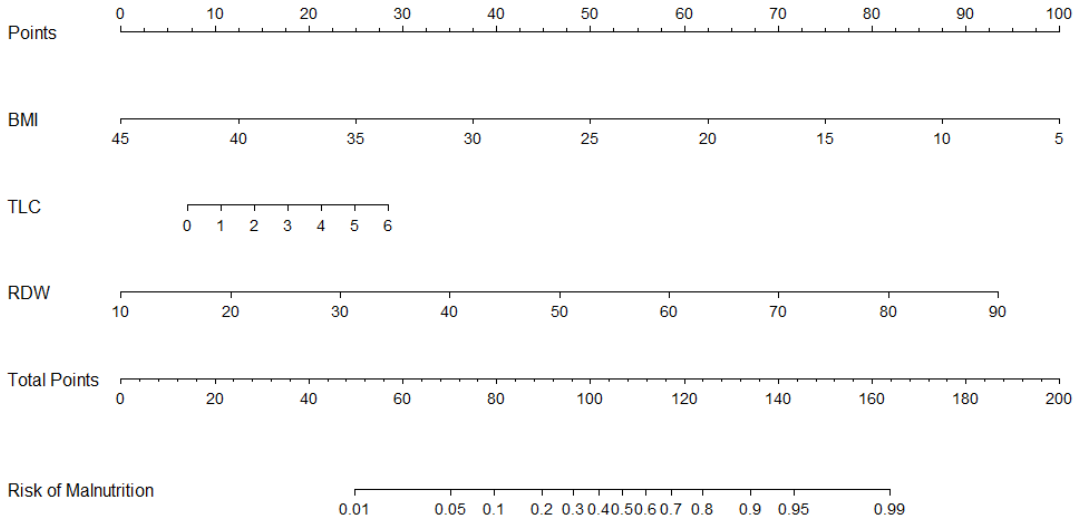

Figure 9: Nomogram for assessing risk of malnutrition

CHAPTER FIVE: DISCUSSION

This study affirms that prevelance of malnutrition amongst elective surgical patients remains to be high, albeit its known associated risk of postoperative complications that increase morbidity and mortality. [1 3 4 15 14] The study done by Ali Kariuki et al found that 36.2% of elective surgical patients were malnourished at the time of admission. Further, in Latin America similar results were reiterated, where malnutrition ranges were 20-50%.[18] While in Norway, the prevelance was found to be 39%. In our study this results are affirmed; 21% elective surgical patietns were malnourished upon admission. This study population had a female prepoderance of 58.7% this could be attributed to the poor treatment seeking behaviours amongst the male gender. The mean age of the patients was 38.0 (SD=10.8) years, while the median age was 37.0 (IQR=15) years. The minimum age was 16 years while the maximum age was 72 years. The study setting being a capital city which is an urban setup, could explain the youthful population of the study participants.

The mean BMI of the patients was 23.3 (SD=4.6), while the median BMI was 23.2 (IOQ=5.9) kg/m^2. The rate of under nutrition was 13.5% while the obesity rate was 8.1%. The correlation of BMI with pre albumin is weak ($P< 0.001$ and $r = 0.232$). It is inarguable that changes in BMI are appreciated in advanced malnutrition while biochemical markers like pre-albumin and albumin are able to detect malnutrition on its onset. Further, pre-albumin has a shorter half-life and less serum pool than albumin making it an accurate marker of protein status hence a more accurate marker. This could explain its weak correlation with BMI as pre albumin is able to pick even the subtle forms of malnutrition. In this study, the average BMI was ranging between 18.5-24.9 of up to 54% of the population, which means a larger population in the study group, was of good nutritional status. The study population had few obese patients rated at 8.1% and malnourished patients i.e. BMI < 18.5 were 13.5%.

Previous studies have demostrated a correlation of RDW with pre-albumin.[25] In our study, the correlation of RDW-SD with pre-albumin was found to be moderate ($p<0.01$ and $r=0.398$), this coincide with a study done by Lishai Ai et al where he noted elevated RDW in persons with malnutrition and advanced haematological malignancies and correlated it with prognosis. We found the correlation between TLC and pre-albumin to be weak with p value <0.001 and $r=0.201$. Correlation between malnutrition and low total lymphocyte has been demostrated in a vast number of studies. [5 27 33 30 31] The poor correlation of TLC with malnutrition could be associated compromised immunity due to the global stressful state occasioned by the infamous COVID-19 that was ongoing during the study period.

In this study, the authours analyzed three variables TLC, RDW and BMI that are affected in malnutrition, further correlated them with pre-albumin and generate a nomogram as reiterated in the results section. Correlation between CORL-BMI with pre-albumin was moderate ($p<0.001$ $r=0.446$). Area under the curve for CORL-BMI is excellent, this is indicative that the cut-off values can be used for evaluating malnutrition. The value under the curve has archived statistical significance with p value < 0.05. CORL-BMI has a sensitivity of 74.1% and specificity of 21.4%.

5.1 Example on How to Interpret the CORL-BMI Nomogram

What is the probability of malnutrition in a patient with BMI of 20 (normal), TLC value of 5.5(elevated) and RDW-SD of 62(elevated)?

On each corresponding scale of TLC, RDW and BMI vertical lines are drawn to meet the point scale. The three values on the point scale are noted and summed up, this figure is then idenfied on the total scale, and another vertical line is drawn from this point downwards to meet the risk of malnutrition scale as shown in *figure 10* below.

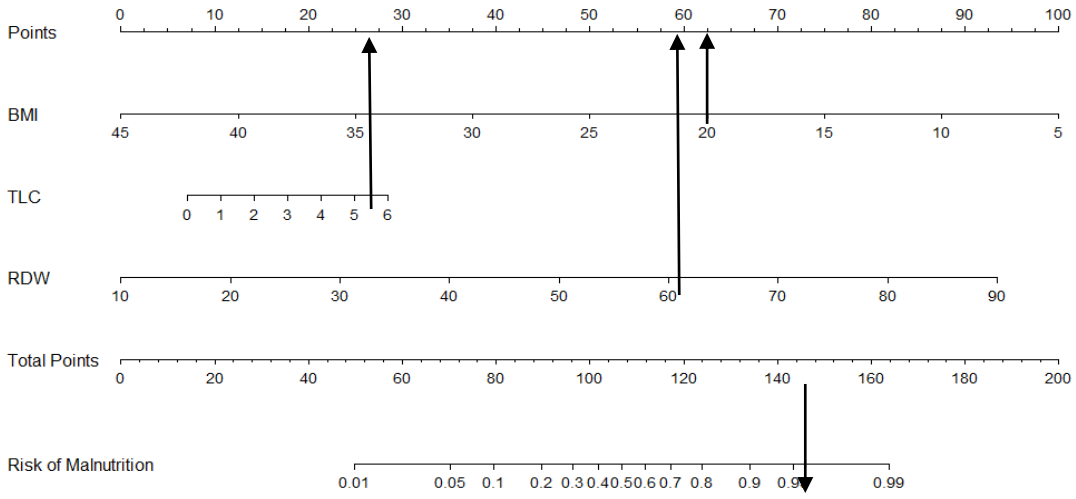

Figure 10: Example of how to use the CORL-BMI scale

The value on the risk of malnutrition scale determines the probability of risk of malnutrition; in this example the probability of malnutrition is 96%.

5.2 Study Limitations

a) This was a hospital-based study thus these results cannot be generalized to any other population. Due to the nature of study design (cross-sectional study) it is possible that the trend of malnutrition could differ if other study designs and employed.

b) Patients who could not speak Swahili and English and had no available translator for his/ her language were excluded as getting informed consent was mandatory for this study.

c) The study took place during the COVID-19 era; it is possible that only the very sick patients participated in the study as most elective surgical procedures (non malignancy cases) were postponed indefinitely in the study site.

CHAPTER SIX: RECOMMENDATIONS AND CONCLUSION

6.1 Conclusion

This novel nomogram (CORL-BMI), has acceptable specificity and sensitivity and it moderately correlates with pre-albumin levels hence it can be utilised as a clinical aid scoring tool to determine the risk of malnutrition in resource-limited centres.

6.2 Recommendations

Further studies are recommended to validate this novel tool in different settings. We further recommend additional variables to be added to this nomogram to increase its strength of correlation inorder to enhance its accuracy.

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STUDY TIMELINE

This study will be undertaken for nine months following approval. Should the participants reach the sample size required before the stipulated time lapses, the study will be terminated.

Statistical analysis and write up of the study report will three months

Activity	**JULY 2019**	**AUG 2019**	**SEPT 2019**	**4th Quarter 2019**	**1st Quarter 2020**	**APRIL 2020**	**MAY 2020**
Proposal development							
Ethical approval							
Data collection							
Data analysis							
Dissertation submission							

BUDGET

ITEM	AMOUNT IN KSH
Research fee for KNH/UON ERC	2,000
Stationary	30,000
Pre albumin test	480,000
Statistician	20,000
Research assistant	10,000
TOTAL	542,000

APPENDICES

Appendix I: Consent Form (English Version)

"DEVELOPING A NOMOGRAM FOR ASSESSING NUTRITIONAL STATUS IN SURGICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL"

Part 1 Information Sheet

My name is Dr. Mose Moraa a postgraduate student PGY 4 at the University of Nairobi School of Medicine. I am carrying out a study on the development of a nomogram for assessing malnutrition. This will be determined by data collected from patients and their laboratory results.

Objectives of Study

This study aims to assess the association of hematological (RDW and TLC) and biochemical (pre-albumin) markers of nutrition both individually and summatively, with the ultimate goal of developing a nomogram for assessing nutritional status in surgical patients

Voluntariness of Participation

I am inviting you to participate in my study. You are free to agree immediately or later after reconsidering your decision or even decline. You will be allowed to ask questions at your convenience

Benefits

There is no monetary or any other form of other than contributing to medical research. There will be no added benefit to the participant for taking part in this study. The results of this study may introduce a novel tool of nutrition assessment that is cheaper and easily available

Risks

Participants shall at no time be exposed to any health risk. Anthropometric measurement does not entail any health risk. Blood sampling will be taken in an aseptic technique

Costs

The principal investigator shall undertake all the expenses of the study.

Confidentiality

Confidentiality will be ensured. Participants' names will not appear in any research document, they will be identified with study numbers. Your personal information will not be shared in any forum. All data collected will be used for research purposes only.

Study Procedure

The patients that meet the inclusion criteria and will have consented will be weighed using a salter scale and height measured using a stadiometer. Further, a blood sample of five millimeters will be drawn from them and taken to the hematology and biochemistry laboratories.

Right to Withdraw From the Study

Participants are allowed to withdraw from the study without any consequences whatsoever.

Queries

Any queries concerning this study should be directed to the following people

Principal investigator:

Dr. Mose Moraa
Department of surgery school of medicine, University of Nairobi
PO BOX 19676-00202
NAIROBI
0711756643

Supervisors:

Dr. Githaiga Joseph
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0722-322246

KNH/UON ETHICS AND RESEARCH COMMITTEE
020-276300 ext 4435

Consenting

Part 2 Consent Certificate

I ……. of …….. study number……..do hereby freely consent to take part in the study conducted by Dr. Mose Moraa. be included in this study on, after being satisfactorily explained to verbal and/ or written form. by the researcher.

I have been informed and fully understand that my participation is voluntary and I am free to withdraw my consent at any time without being discriminated in care

The nature of the study has been fully explained to me by Dr. ……. I have not been promised any material gain to participate

Sign/ thumbprint…… date …….

Statement by a witness if the participant is illiterate

I have witnessed the accurate reading

I confirm that the individual has given consent freely

Name of witness…….

Signature……. Date……..

Statement by Researcher

I have read out the information sheet to the participant and to the best of my ability I have made sure the participant understands the following

1. all information given will be stored in absolute confidentiality
2. Refusal to participate or withdrawal from the study will not compromise the quality of care
3. I confirm that the participant was given a platform to ask questions and they were answered to the best of my ability
4. I confirm that the participant voluntarily

Dr. Mose Moraa

Signature…….…… Date……..…….

Appendix II: Consent Form (Swahili Version)

Maelezo Kwa Kiswahili.

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI
SWALA LA UTAFITI: "DEVELOPING A NOMOGRAM FOR ASSESSING NUTRITIONAL STATUS IN SURGICAL PATIENTS".

Fomu hii ya makubaliano ni kwa wale wanaolazwa katika majumba ya upausaji katika hopitali kuu la Kenyatta. Ninakualika kuwa ujitolee kwa hiari yako, kuwa, mmoja wa wale watakaofanyiwa utafiti huu.

Mtafiti mkuu Dkt. Mose Moraa

Kituo; Kitivo cha utatibu, idara ya upasuaji Chuo Kikuu cha Nairobi

Fomu hii ya makubaliano ina sehemu tatu:

1) Habari itakayokusaidia kukata kauli
2) Fomu ya makubaliano (utakapoweka sahihi)
3) Ujumbe kutoka kwamtafiti
4) Utapewa nakala ya fomu hii.

Sehemu ya Kwanza: Ukurasa wa habari

Kitambulizi

Jina langu ni Dkt. Mose Moraa. Mimi ni daktari ninayesomea uzamili katika idara ya upasuaji Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, "development of nomogram for nutritional assesment" Dhamira ya utafiti huu itawezekana kupitia kujaza dodoso utakalopewa nakisha kufuatiliwa au mgonjwa wako kufuatiliwa hadi atakaporuhusiwa kwenda nyumbani.

Lengo La Utafiti

Nia ya utafiti huu ni kudhibiti uhusiano kati ya vipimo vya hematologia na biokemia vinayo husika katika kupima lishe, na kujaribu kuzindua 'nomogram' mpya ya kupima lishe.

Faida

Utafiti huu hautaku gharimu zaidi ya matibabu yako ya kawaida. Vilevile, hakuna malipo yoyote au fidia utakayo pokea kutokana na kujiunga kwako katika utafiti huu. Ushiriki wako kutachangia katika Nyanja ya utafiti wa sayansi tiba; matokeo ya tafiti hii yatapelekea kuanzishwa kwa chombo maalum cha makadirio ya lishe chenye bei nafuu na rahisi kupatikana.

Hasara

Mshriki hatokuwa kwennye hatari yoyote ya kiafya kwa kushiriki. Vipimo vyote ni salama na upimaji damu utafwata vigezo stahili za kuzuia maambukizi ya magonjwa.

Gharama

Mtafiti mkuu ndiye atakayeingia gharama zote za tafiti hii.

Haki ya Kujiondoa Katika Tafiti

Washiriki / mshiriki ana haki ya kujitoa kwa hiari pasipo kutegemea athari / shida yoyote.

Usiri

Hali ya usiri utazingatiwa. Majina ya washiriki hayataonekana popote katika nyaraka za tafiti, washiriki watatambulika kwa tarakimu/ nambari maalum. Taarifa binafsi hazitasambazwa popote. Taarifa zote zitatumika kwa shughuli za tafiti tu.

Ina ya Vielekezo

Wagonjwa watakao kidhi vigezo vya kuingia katika tafiti pamoja na kutoa idhini ya ushiriki watapimwa uzito na urefu na pia kutolewa sampuli ya damu kiasi cha milimita tano ambayo itapimwa katika maabara za hematolojia na biokemia.

Maswali

Maswali yoyote yataelezwa kwa watu wafwatao:

Mtafiti Mkuu:

Dkt. Mose Moraa
Idara ya upasuaji, Shule Ya Afya, Chuo Kikuu cha Nairobi,
SLP 19676 KNH, Nairobi 00202.
Simu: 0722 952883

Wahadhiri husika:

Dkt Ojuka D K
MBCh.B, M.MED (Gen Surg.), PHD
Mhadhiri mkuu,
SLP 19676 KNH, Nairobi 00202.
Simu: # 0202726300

Dkt. Githaiga Joseph
(MB.Ch.B, MMED (Gen Surg.)
SLP 19676 KNH, KNH, Nairobi 00202.
Simu: # 020 272 6300

Sehemu ya Pili: Fomu ya makubaliano

Nimeelezewa utafiti huu kwa kina. NakubaIi kushiriki katika utafiti huu kwa hiari yangu. Nimepata wakati wakuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki_____

Sahihi ya mshiriki_____Tarehe_____

Kwa wasioweza kusoma na kuandika:

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi_____ Alama ya kidole cha gumba mshiriki

Sahihi la shahidi_____

Tarehe _____

SEHEMU YA TATU: Ujumbe kutoka kwa mtafiti

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo:

- Kutoshiriki au kujitoa kwenye utafiti huu hakutadhuru kupata kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa kusaidia utambuzi wa shida zinazotokana na saratani ya matiti

Ninathibitisha kuwa mshiriki alipewa nafasi yakuuliza maswali na yote yakajibiwa vilivyo. Ninahakikisha kuwa mshiriki alitoa ruhusa bila ya kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti_____

Tarehe_____

Appendix III: Data Collection Tool

1. Study Number. ……..

2. BIODATA

   A) AGE

   B) SEX

3. DIAGNOSIS …….

4. COMORBIDITY

5. ANTHROPOMETRIC PARAMETERS

   A) HEIGHT
   ……
   B) WEIGHT

   C) BMI ……

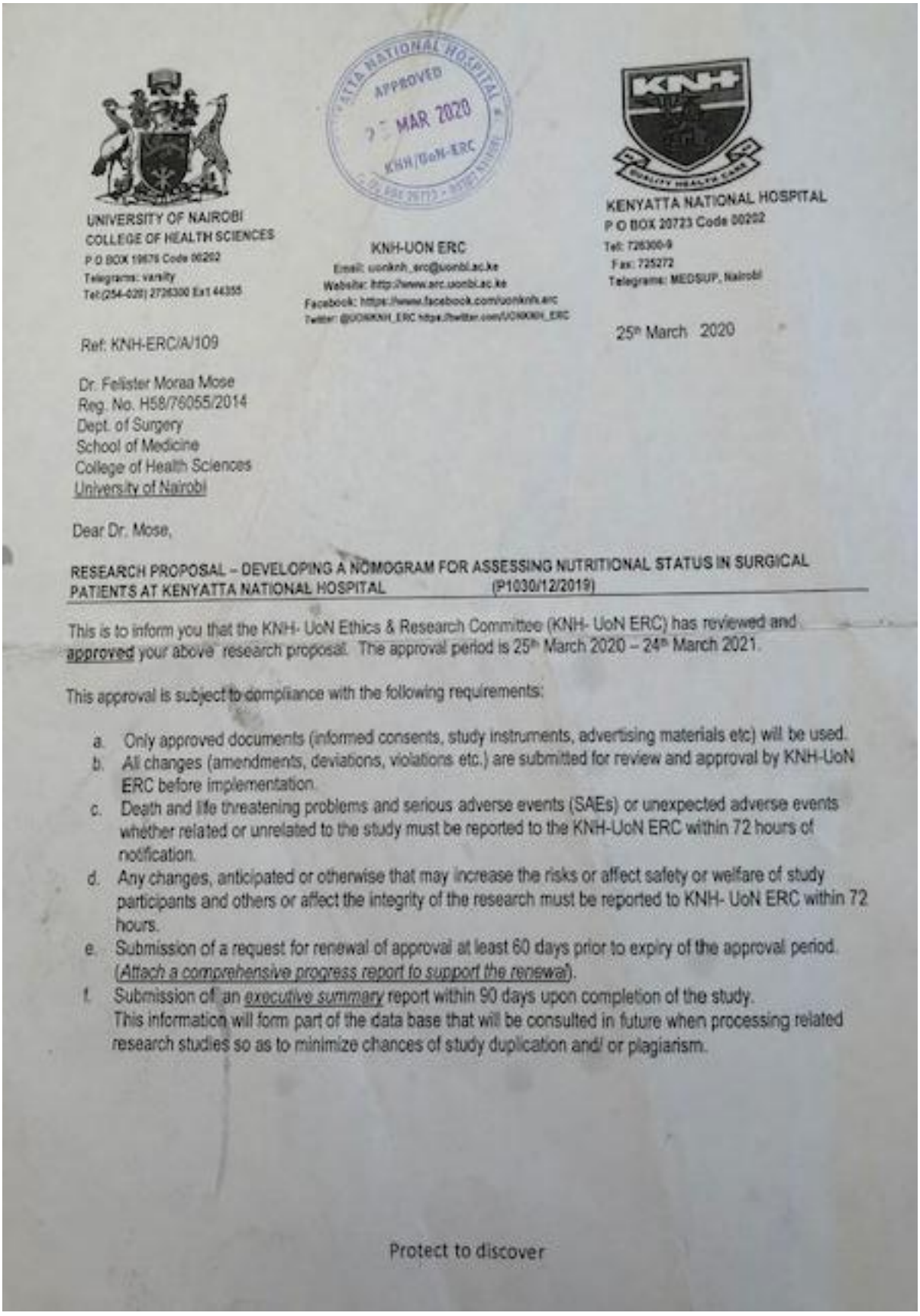
6. LABORATORY PARAMETERS;

   A) TOTAL LYMPHOCYTE COUNT

   B) RED BLOOD CELL DISTRIBUTION WIDTH

   C) PRE ALBUMIN

Appendix IV: KNH/UON-ERC Letter of Approval



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KENYATTA NATIONAL HOSPITAL - APPROVED 25 MAR 2020 - KNH/UoN-ERC

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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/109

25th March 2020

Dr. Felister Moraa Mose
Reg. No. H58/76055/2014
Dept. of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Mose,

RESEARCH PROPOSAL – DEVELOPING A NOMOGRAM FOR ASSESSING NUTRITIONAL STATUS IN SURGICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL (P1030/12/2019)

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 25th March 2020 – 24th March 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. 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.
d. 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.
e. 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*).
f. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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Appendix V: Plagiarism Certificate


Turnitin Originality Report

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