



UNIVERSITY of
RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES
SCHOOL OF MEDICINE & PHARMACY

DISSERTATION TITLE:

PREDICTING POSTOPERATIVE MORBIDITY AND MORTALITY IN ADULT SURGICAL PATIENTS: VALIDATION OF THE AFRICAN SURGICAL OUTCOMES STUDY SURGICAL RISK CALCULATOR AT UNIVERSITY TEACHING HOSPITAL OF KIGALI (CHUK)

Dissertation submitted for partial fulfillment of the academic requirements for the award of

Master's Degree of Medicine in Anesthesiology

By

Dr TWISUNGANE Protogene

SUPERVISOR: MVUKIYEHE JEAN PAUL, MD

Lecturer of Anesthesiology

Department of Anesthesia, Critical care and Emergency Medicine

College of Medicine and Health Sciences

University of Rwanda

CO-SUPERVISOR:

Prof Marcel DURIEUX, MD, PhD

Department of Anesthesiology

University of Virginia

Kigali, August 2022

DECLARATION AND AUTHORITY TO SUBMIT THE DISSERTATION

Surname and First Name of the Student: **TWISUNGANE PROTOGENE**

Title of the project: '**PREDICTING POSTOPERATIVE MORBIDITY AND MORTALITY IN ADULT SURGICAL PATIENTS: VALIDATION OF THE AFRICAN SURGICAL OUTCOMES STUDY SURGICAL RISK CALCULATOR AT UNIVERSITY TEACHING HOSPITAL OF KIGALI (CHUK)**'.

a. Declaration by the Student

I do hereby declare that this dissertation submitted for partial fulfillment of the requirements for **MASTER'S DEGREE OF MEDICINE IN ANESTHESIOLOGY**, at the University of Rwanda/College of Medicine and Health Sciences/School of Medicine and Pharmacy, is my original work and has not previously been submitted elsewhere.

Also, I do declare that a complete list of references is provided indicating all the sources of the information quoted or cited.

Date and Signature of the Student

August 11, 2022

TWISUNGANE Protogene



b. Authority to Submit the dissertation

In my capacity as a Supervisor, I do hereby authorize the student to submit his dissertation.

Dr MVUKIYEHE Jean PAUL

Signature:



August 18, 2022

Prof Marcel DURIEUX

Signature:



August 18, 2022

ABSTRACT

Background:

Patients in Africa are twice as likely to die after surgery when compared to worldwide. There is still lack of appropriate risk assessment tools to predict postoperative morbidity and mortality at the continent. African Surgical Outcomes Study's Surgical Risk Calculator (ASOS SRC) was shown to be more reliable in the African population. Thus, we aimed to assess the validation of the ASOS surgical risk calculator in a cohort of patients at University Teaching Hospital of Kigali (CHUK)

Methods: Prospective observational cohort study of adult surgical patients at university teaching hospital of Kigali from 1st January to 1st March 2022, data were collected from patients' anesthesia record sheets and medical files. Data from 350 patients were entered in Epidata version 3.1, then exported to Stata 13.0 for analysis. Patients were divided into 2 groups: Exposed (ASOS SRC score ≥ 10) and Unexposed (ASOS SRC < 10).

Results: We recruited 350 patients, of whom the majority were aged 30-69 years (66.3%), Elective and emergent surgeries were nearly equal (51% versus 47.1%). Hypertension was the commonest comorbidity (12.5%) while non-communicable diseases were the commonest indication of surgery (40%). The overall postoperative morbidity rate was 13.7% versus 2.8% of mortality rate and 4.3% of patients required critical care admission. Of all the patients who died had an ASOS SRC score ≥ 10 , nearly 80% of patients discharged had the score < 10 and 60% of patients who remained in the hospital had the ASOS SRC score ≥ 10 . patients with ASOS SRC scores ≥ 10 and more were 17 times more likely to develop post-operative complications than those with a score < 10 (RR=17.12; 95% CI: 7.87-37.25; $p < 0.001$). Our Multivariable logistic regression revealed ASOS SRC score, ASA class and surgery timing to be true predictors of postoperative morbidity and mortality.

Conclusions: The study showed that ASOS Surgical Risk Calculator strongly predicts postoperative morbidity and mortality. Larger sample size studies are needed for results generalization and practice change.

Keywords: ASOS, Postoperative complications, mortality, morbidity, surgery

TABLE OF CONTENTS

Contents

DECLARATION AND AUTHORITY TO SUBMIT THE DISSERTATION.....	ii
ABSTRACT	iv
LIST OF TABLES	vii
LIST OF CHARTS	viii
LIST OF ABBREVIATIONS:	ix
ACKNOWLEDGEMENTS	x
DEDICATION	xi
CHAPTER I. BACKGROUND:	1
RATIONALE OF THE STUDY	2
CHAPTER II. AIM AND OBJECTIVES	3
II.1 RESEARCH QUESTION.....	3
II.2 AIM.....	3
II.3 OBJECTIVES	3
CHAPTER III.METHODS	4
III.1. STUDY DESIGN:	4
III.2. SETTINGS:	4
III.3. STUDY POPULATION:.....	4
III.3.1. INCLUSION CRITERIA.....	4
III.3.2. EXCLUSION CRITERIA	4
III.4.DATA VARIABLES TO BE COLLECTED:.....	5
III.5. SOURCE OF DATA and COLLECTION:	7
III.6. DATA ANALYSIS PLAN AND SAMPLE SIZE CALCULATION:	7
III.7. ETHICS CONSIDERATION:.....	8
III.7.1 Ethical approval	8
III.7.2 Data confidentiality.....	8
III.7.3 Informed Consent.....	8
CHAPTER IV: RESULTS	9
CHAPTER V. DISCUSSION	19

CHAPTER VI. CONCLUSION AND RECOMMENDATIONS	22
REFERENCES:.....	23
APPENDIX 1. DATA COLLECTION TOOL	26
APPENDIX 2. CMHS IRB AND CHUK ETHIC COMMITTEE APPROVAL	30

LIST OF TABLES

Table 4. 1 Patients characteristics according to ASOS SRC parameters	9
Table 4. 2 Comorbidities among the study participants.....	10
Table 4. 3 Post-operative complications among the study participants	11
Table 4. 4 ASOS surgical risk calculator scores of the study participants.....	13
Table 4. 5 Association between patients' characteristics and postoperative complications among study participants	16
Table 4. 6 Multivariable logistic regression of predictors of postoperative complications	18

LIST OF CHARTS

Chart 4. 1 State of patients at discharge	12
Chart 4. 2 Status of patients at 30 th day of operation according to ASOS SRC score	14

LIST OF ABBREVIATIONS:

CHUK: Centre Hospitalier Universtaire de Kigali

ASA: American Society of Anesthesiologists

ASOS: African Surgical Outcome Study

ASOS SRC: African Surgical Outcome Study Surgical Risk Calculator

LMICs: Low and Middle-Income Countries

SAS: Surgical Apgar score

M: Male

F: Female

ID: Identity

EPCO: European perioperative clinical outcome

PACU: Post Anesthesia Care Unit

ICU: Intensive Care Unit

HDU: High Dependent Unit

ASA: American Society of Anesthesiologists

COPD: Chronic Obstructive Pulmonary Disease

HIV: Human Immunodeficiency Virus

AIDS: Acquired Immunodeficiency Syndrome

UTI: Urinary Tract Infection

ENT: Ear, Nose and Throat

ACKNOWLEDGEMENTS

The achievement of this work resulted from the effort of many people to whom I am expressing my feelings of gratitude.

This dissertation would have never been accomplished without the tireless guidance and mentorship of Dr MVUKIYEHE Jean PAUL and Prof DURIEUX Marcel; I express my deepest appreciation.

I would like also to express my heartfelt thanks to my beloved mentors Dr NIZEYIMANA Françoise and Prof BANGUTI RUHATO Paulin for their incredible inspiration for me to be my best and for being there to guide me whenever I needed help throughout my training.

I am also thankful to the immeasurable support of the nurses and doctors of the University Teaching Hospital of Kigali and the College of Medicine and Health Sciences at the University of Rwanda and especially the anesthesia postgraduate program for their support during my training.

DEDICATION

To the Almighty God

To my wife: IRATUZI Joselyne

And

My son: SHAMI R.Jason

To my Parents

To my sisters and Brothers

To my classmates and other people who contributed to my training

I dedicate this work.

CHAPTER I. BACKGROUND:

Postoperative complications including death are common after both elective and non-elective surgery. This is often due to poor risk stratification and lack of adequate postoperative patients surveillance¹.

Worldwide, 4.2 million people die every year within 30 days after surgery; 50% of deaths happen in low- and middle-income countries². Advanced age, comorbidity, major and urgent surgery have been identified as important risk factors for postoperative complications and death³. There is an urgent need to improve access to safe surgical treatments for patients in low and middle-income countries (LMICs)⁴.

Even though the global risk for surgical complications is low, still we have high-risk groups of people who develop postoperative complications and poor outcomes⁵.

In a study done in Africa on perioperative surgical outcomes, among 11422 patients recruited, 18.2% developed postoperative complications. The study included multiple surgical disciplines (neurosurgery, orthopedics, general surgery, gynaecology and obstetrics,) and infection was the most common postoperative complication⁶. Postoperative complications are a burden to patients and health systems as they increase health care cost, reduce life expectancy and impair quality of life⁷.

Although there are many tools used to predict postoperative surgical outcomes worldwide, many have been validated based on populations in high-income countries where living conditions are far different from those in LMICs. Therefore, there is a need for studies that predict surgical outcomes in LMICs.

In Rwanda, 2017, a study was completed on validation of Surgical Apgar score (SAS) at a tertiary referral hospital after laparotomy, and 218 patients were recruited. In-hospital mortality and major complications occurred in 19% and 25% of the patients respectively. The Surgical Apgar score only focused on surgical outcomes after laparotomy and did not include other subspecialties of surgery⁸.

The African Surgical Outcomes Study (ASOS) determined that a high number of postoperative complications and deaths in Africa are due to poor postoperative surveillance and a lack of appropriate postoperative disposition for high-risk patients⁹. The ASOS surgical risk calculator score (ASOS SRC) was developed from the ASOS study data. Its purpose was to detect preoperatively which patients were at risk of postoperative complications and may need close monitoring and subsequently early intervention following surgery⁹.

Rwanda did not participate in the ASOS, and there was little data found for surgical risk prediction of postoperative mortality and morbidity.

Addressing the gaps in postoperative care has been poorly investigated in LMICs including Rwanda. There was a need for a tool that helps to predict patients at risk of postoperative complications and deaths. In our study, we aimed to validate the ASOS surgical risk calculator in a cohort of patients at the university teaching hospital of Kigali (CHUK).

RATIONALE OF THE STUDY

Postoperative complications are associated with significant morbidity and mortality. Early identification of high-risk patients is crucial, especially in low-resource environments. The goal of this study is to evaluate the validity of the ASOS surgical risk calculator in predicting postoperative morbidity and mortality.

CHAPTER II. AIM AND OBJECTIVES

II.1 RESEARCH QUESTION

“Does the ASOS surgical risk calculator predict postoperative surgical outcomes at the university teaching hospital of Kigali?”

II.2 AIM

This study aimed to assess the validity of the ASOS surgical risk calculator in predicting postoperative morbidity and mortality in adult surgical patients at university teaching hospital of Kigali (CHUK)

II.3 OBJECTIVES

1. To validate ASOS surgical risk calculator in predicting postoperative morbidity and mortality at CHUK
2. To determine the incidence of postoperative morbidity and mortality at CHUK

CHAPTER III.METHODS

III.1. STUDY DESIGN:

A Prospective observational cohort study

III.2. SETTINGS:

Rwanda is a sub-Saharan country that has approximately 12 million people with 5 tertiary care hospitals. CHUK is the largest and oldest tertiary care hospital, receiving surgical patients primarily referred from the regional and district hospitals. It is located in the center of Kigali City which is the capital of Rwanda. It has 11 operating rooms and 519 beds capacity. It carries operations of different departments including general surgery, ENT, neurosurgery, gynaecology and obstetrics, orthopedics, urology, plastic, maxillofacial and ophthalmology. Postoperatively, patients are admitted to different surgical wards after PACU stay and those in need of critical care support are admitted to ICU (7beds) and HDU (4beds). As a teaching hospital, CHUK also receives a varying number of residents among specialties and medical/nursing students.

III.3. STUDY POPULATION:

All adult patients admitted at CHUK with a planned surgery from 1st January to 1st March 2022.

III.3.1. INCLUSION CRITERIA

All adult (18 years and above) patients coming for either elective or non-elective surgery.

III.3.2. EXCLUSION CRITERIA

- ✓ Patients under 18 years
- ✓ Patients whose surgery is postponed
- ✓ Patients who die intraoperatively
- ✓ Patients whose files are missing or not correctly filled out
- ✓ Patients who decline to participate

III.4.DATA VARIABLES TO BE COLLECTED:

➤ Exposure and Outcome variables:

EXPOSURE VARIABLES (Preoperative variables)	OUTCOME VARIABLES (Postoperative variables)
<ul style="list-style-type: none"> ● Age ● ASA ● Surgery timing ● Surgery severity ● Indication for surgery ● Surgery type ● Smoking status ● Preoperative comorbidity 	<p>Primary outcome:</p> <ul style="list-style-type: none"> ● Postoperative complications ● 30day in-hospital mortality <p>Secondary outcomes:</p> <ul style="list-style-type: none"> ● Critical care admission ● Status at discharge or 30th postoperative in-hospital day (discharged, alive or dead)

➤ Postoperative complications were grouped into Respiratory complications (Pneumonia, ARDS, pulmonary edema, pulmonary embolism, pneumothorax and pleural effusion requiring drainage), Cardiovascular complications (Myocardial infarction, arrhythmia, cardiac arrest, shock, stroke, deep venous thrombosis) and miscellaneous complications (gastro-intestinal bleed, postoperative bleed, acute kidney injury, anastomotic breakdown, surgical site infection (Superficial, Deep or body cavity), urinary tract infection, sepsis, they were defined based on standards for definitions and use of outcome measures for clinical effectiveness research in perioperative medicine : European perioperative clinical outcome (EPCO) definition¹⁰

- Most of the exposure variables were from the ASOS Surgical Risk Calculator card⁹ as shown below:

Age	Points
18-29	0
30-69	+1
≥ 70	+3
ASA	
ASA 1	0
ASA 2	+2
ASA 3	+5
ASA 4 and more	+8
Surgery timing	
Elective surgery	0
Urgent surgery	+3
Emergent surgery	+4
Surgery severity	
Minor	0
Intermediate	+2
Major	+4
Indication for surgery	
Non-communicable disease	0
Cesarean section	-2
Trauma	+1
Infection	+2
Surgery type	
Gynecology/obstetrics	-1
Plastics and breast	+1
Urology	+2
Ear, nose, and throat, gastrointestinal, hepato-biliary, cardiothoracic, vascular	+3
Neurosurgery	+4
All other types of surgery	0
TOTAL ASOS SRC SCORE	

III.5. SOURCE OF DATA and COLLECTION:

Data were collected by the theatre nurse, who received training about the study for 3 days. Preoperative/exposure variables were recorded from the patients' anesthesia record sheets which had parameters of preoperative assessment for ASOS SRC score calculation, and outcome variables were collected from the in-patients medical files on the postoperative 30th day and on discharge day. We collected data for 350 patients from different departments including obstetrics and gynaecology, general surgery, ENT, orthopedics, urology, plastic, neurosurgery, etc....who were operated on during January 2022.

III.6. DATA ANALYSIS PLAN AND SAMPLE SIZE CALCULATION:

a. Sample size estimation:

We calculated the sample size using the Daniel sample size formula ($n = Z^2P(1-P)/d^2$ with Z: the level of confidence of 95% which is the conventional value of 1.96, P: prevalence and d: precision which is known to be 0.05). By integrating the prevalence of 18.2% for postoperative complications in the ASOS study on perioperative patient outcomes in the formula, we found a sample size of 229 patients which was extended to 350 patients to improve the elimination of confounders.

b. Data analysis process:

After the collection of data, patients were divided into 2 groups: Patients with ASOS SRC score < 10 and those with ASOS SRC score ≥ 10 . Collected data were entered into Epidata version 3.1 and then exported to Stata version 13 for analysis. Descriptive categorical data were presented using frequencies and percentages in tables and continuous data was summarized using mean and median depending on their distribution. The difference in mean and/or median scores among groups was tested using a t-test and ANOVA test for normally distributed data and by nonparametric test (Mann Whitney U test for binary outcomes and Kruskal Wallis test for the outcomes with more than 2 categories) for skewed data. The Chi-square test and logistic regression analysis (Relative Risk and 95% confidence intervals) were used to study the relationship between the predictors and outcomes. Statistical significance for the associations was taken at the level of $p < 0.05$.

III.7. ETHICS CONSIDERATION:

III.7.1 Ethical approval

Ethical approval was obtained from College of Medicine and Health Science/Institutional Review Board (No 299/CMHS IRB/2021) and CHUK Ethical Committee (No EC/CHUK/144/2021).

III.7.2 Data confidentiality

- ✓ There was no use of patients' names or hospital identity numbers, and data were stored in a computer protected by a personal principal investigator's password
- ✓ The principal investigator checked the data for completeness

III.7.3 Informed Consent

- ✓ Explanations regarding the study were provided by the investigator or another designed collaborator before signing the consent
- ✓ Patients were enrolled in the study after they (or caretaker for non-competent patients) signed the consent form.

CHAPTER IV: RESULTS

The median age of the participants was 36 years ranging from 20 years to 97 years and the majority of the participants (66.3%) were aged 30-69 years. 40% of the participants were categorized as ASA 1, 52.3% were ASA 2, 5.4% were ASA 3 and only 5 patients were ASA 4 or above. 51% of the operations were elective and 47.1% were emergency operations. 62% of the operations were major and the commonest indication of surgery was non-communicable disease at 40%. This was followed by cesarean section at 26% and infection was the indication in 10% of the operations (Details in table 4.1).

Table 4. 1 Patients characteristics according to the parameters of the ASOS Surgical risk calculator

Variables	N	%
Age range		
18-29	92	26.29
30-69	232	66.29
>=70	26	7.43
ASA group		
1	143	40.86
2	183	52.29
3	19	5.43
4 and more	5	1.43
Surgery timing		
Elective	179	51.14
Emergent	165	47.14
Urgent	6	1.71
Surgery severity		
Major	219	62.57
Intermediate	122	34.86
Minor	9	2.57
Indication of surgery		
Non-communicable disease	140	40
C-section	92	26.29
Trauma	81	23.14
Infection	37	10.57
Surgery type		
Gynecology & obstetrics	126	36
ENT/GIT/LIVER/CARDIOTHORACIC/VAS	95	27.14
C		

Urology	32	9.14
Neurosurgery	16	4.57
Plastic	2	0.57
All other types of surgery	79	22.57

Considering the comorbidities among the operated patients, 12.6% of all patients had hypertension, 5.4% had metastatic cancer and 3.4% had HIV infection (details in table 4. 2).

Table 4. 2 Comorbidities among the study participants

Variables	Frequency (n=350)	%
Hypertension	44	12.57
Metastatic cancer	19	5.43
HIV	12	3.43
Diabetes mellitus	10	2.86
Smoking	9	2.57
Asthma	6	1.71
Benign Prostatic Hypertrophy	4	1.14
Hepatitis B	4	1.14
Bladder cancer/tumor	3	0.86
Hepatitis C	2	0.57
Stroke	1	0.29
CKD	1	0.29
Congestive heart failure	1	0.29
Coronary artery disease	1	0.29
Others	21	6.00

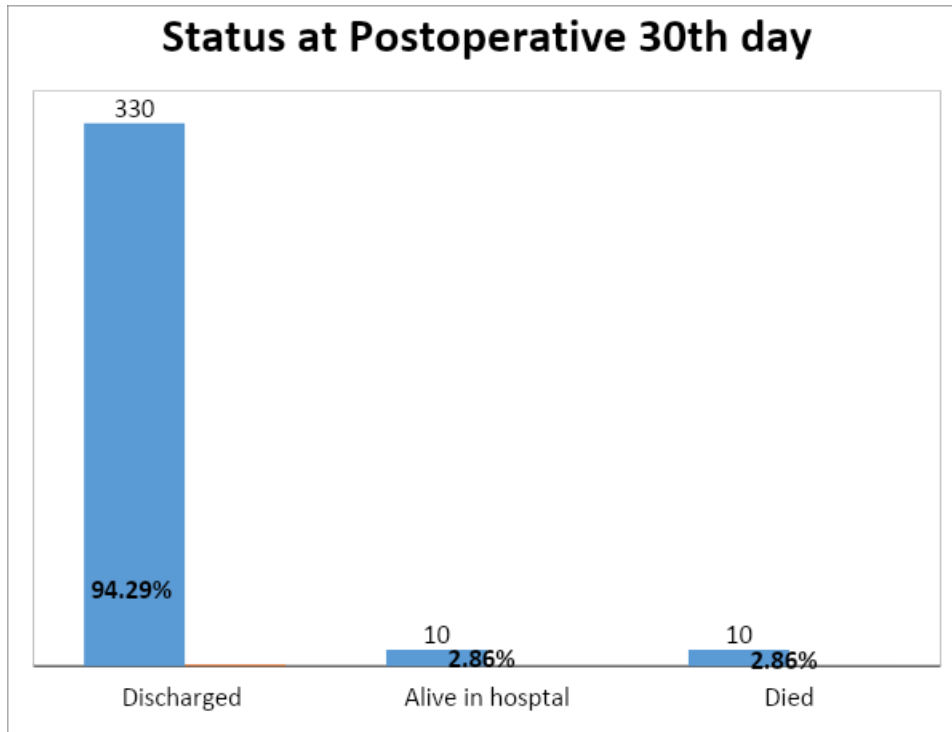
The results of the analysis showed that 13.7% (n=48) of the patients developed at least one postoperative complication where 5.1% had acute respiratory distress syndrome, 4.3% were admitted in critical care and ten patients (2.8%) had pneumonia (More details in table 4.3).

Table 4. 3 Postoperative complications among the study participants

Type of Complication	N	%
Acute respiratory distress syndrome	18	5.14
Critical care admission	15	4.29
Pneumonia	10	2.86
Cardiac arrest	8	2.29
Shock	6	1.71
Acute kidney injury	5	1.43
Anastomotic breakdown	5	1.43
Surgical site infection	5	1.43
Urinary tract infection	3	0.86
GI bleeding	2	0.57
Postoperative bleeding	2	0.57
Pulmonary edema	1	0.29
Pulmonary embolism	1	0.29
Myocardial infarction	1	0.29
At least 1 complication	48	13.71

Considering the outcome of the patients on the 30th day postoperative or at discharge day, the results showed that 10 patients (2.8%) died; another 10 patients (2.8%) were still hospitalized in the hospital while 94.3% of the patients were discharged alive (Chart 4.1).

Chart 4. 1 **Status of patients at discharge or postoperative 30th day**



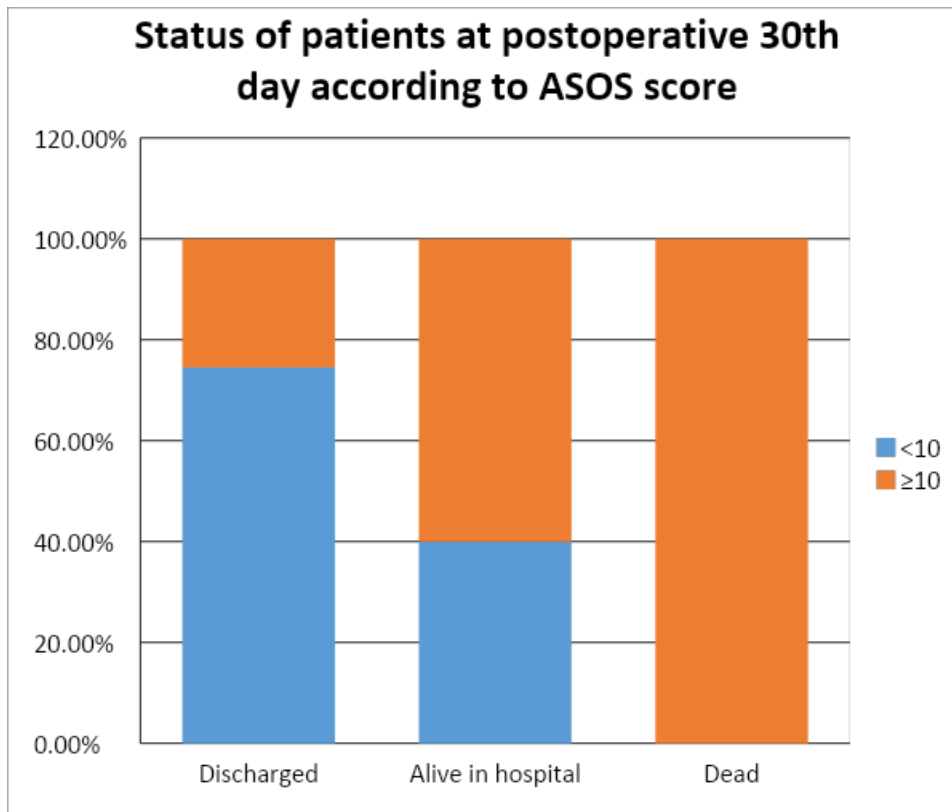
Considering the ASOS surgical risk calculator scores among the patients recruited in this study, among 48 patients who had postoperative complications, the majority of patients who sustained complications (43%) had ASOS SRC scores ranging between 13 and 18, 25% had the scores ranging between 7 and 12, 20.8% had the scores of at least 19 while only 10% of them had scored less than 6. When considering the individual ASOS surgical risk calculator scores, all participants (100%) who scored 19 and more developed severe post-operative complications compared to 55.3% of those who scored from 13 to 18 who developed severe post-operative complications, 7.0% of those who scored 7 to 12 and 3.8% of those who scored 6 and less (see table 4.4).

Table 4. 4 ASOS surgical risk calculator scores of the study participants

ASOS SRC score	Number of patients (n=350)	Number of patients with complications (n)	% of complications (n=48)	% of complications (n=respectively ASOS SRC group)
<6	132 (37.71%)	5	10.42%	3.79%
7 to 12	170 (48.57%)	12	25.00%	7.06%
13-18	38 (10.86%)	21	43.75%	55.26%
≥19	10 (2.86%)	10	20.83%	100%

When comparing the status of patients at postoperative 30th day versus ASOS SRC Score, we found that all the patients who died had an ASOS SRC score ≥ 10 , nearly 80% of patients discharged had the score < 10 and 60% of patients who remained in the hospital had the ASOS SRC score ≥ 10 . (Details in Chart 4.2)

Chart 4. 2 Status of patients at 30th day of operation according to ASOS SRC score



Bivariate analysis of patients' characteristics and postoperative complications among study participants.

The risk of postoperative complications increased with age where patients who were aged 70 years and above were 4.8 times more likely to have postoperative complications than those aged 18-29 years (RR=4.88, 95% CI:1.69-14.1, p=0.003). The risk of having postoperative complications also increased with the ASA class where patients in ASA class 2 were 3.97 times more likely to have postoperative complications than those who were in ASA class 1 (RR=3.97; 95% CI: 1.47-10.71; p=0.007) while those in class 3 were 103 times more likely to have complications than those in class 1 (RR=103.5, 95% CI: 25.0-427.6; p<0.001). Patients who underwent emergent operations were 6.8 times more likely to have postoperative complications than those who underwent elective operations (RR=6.84; 95% CI: 3.09-15.12; p<0.001). Patients who underwent major surgeries were 7.4 times more likely to have post-operative complications as those who underwent intermediate surgeries (RR=7.42; 95% CI: 2.59-21.19; p<0.001).

Patients who were operated on with infection-related indications were 5 times more likely to have postoperative complications than those who were operated on for baby delivery (RR=5.04; 95% CI: 1.85-10.7; p=0.002). Patients who underwent neurosurgery operations were 16.7 times more likely to have postoperative complications as those who underwent gynecological and obstetric operations (RR=16.71; 95% CI: 5.04-55.4; p<0.001) and those who underwent ENT, GIT, cardiothoracic surgeries were 4.6 times more likely to have postoperative complications as those who underwent gynecology and obstetrics operations (RR=4.64; 95% CI: 2.05-10.51; p<0.001). Patients who had at least one comorbidity were 2.1 times more likely to have complications as those who did not have comorbidities (RR=2.14; 95% CI: 1.14-3.96; p=0.018). Patients who smoked were 5.4 times more likely to have postoperative complications than those who did not smoke (RR=5.4; 95% CI: 1.39-20.88, p=0.015).

When considering ASOS surgical risk calculator score, patients who scored 10 or more were 17 times more likely to develop postoperative complications than those who scored less than 10 (RR=17.12; 95% CI: 7.87-37.25; p<0.001) (more details in Table 4.5 below).

Table 4. 5 Bivariate analysis of patients' characteristics and postoperative complications among study participants

Variables	Patients with postoperative complications	Patients without postoperative complications	RR (95% CI)	p
Age range				
18-29	9 (9.78%)	83 (90.22%)	Ref	
30-69	30 (12.93%)	202(87.07)	1.37 (0.62-3.01)	0.434
>=70	9 (34.62%)	17 (65.38%)	4.88 (1.69-14.1)	0.003
ASA group				
1	5 (3.50%)	138(96.50)	Ref	
2	23 (12.57%)	160(87.43)	3.97 (1.47-10.71)	0.007
3	15 (78.95%)	4 (21.05%)	103.5 (25.0-427.6)	<0.001
4 and more	5 (100%)	0 (0.0%)		
Surgery timing				
Elective	8 (4.47%)	171 (95.53%)	Ref	
Urgent	0 (0.0%)	6 (100%)		
Emergent	40 (24.24%)	125 (75.76%)	6.84 (3.09-15.12)	<0.001
Surgery severity				
Minor	0 (0.0%)	9 (100%)		
Intermediate	4 (3.28%)	118 (96.72%)	Ref	
Major	44 (20.09%)	175 (79.91%)	7.42 (2.59-21.19)	<0.001
Indication of surgery				
C-section	8 (8.70%)	84 (91.30%)	Ref	
Non-communicable disease	18 (12.86%)	122 (87.14%)	1.55 (0.64-3.73)	0.328
Trauma	10 (12.35%)	71 (87.65%)	1.48 (0.55-3.95)	0.435
Infection	12 (32.43%)	25 (67.57%)	5.04 (1.85-1.70)	0.002
Surgery type				
Gynecology & obstetric	9 (7.14%)	117 (92.86%)	Ref	
Plastic	0 (0.0%)	2 (100%)		
Urology	2 (6.25%)	30 (93.75%)	0.86 (0.18-4.22)	0.859
ENT/GIT/LIVER/CARDIO	25 (26.32%)	70 (73.68%)	4.64 (2.05-10.51)	<0.001
THORACI/VASC	9 (56.25%)	7 (43.75%)	16.71(5.04-55.4)	<0.001

All other types of surgery	3 (3.80%)	76 (96.20%)	0.51 (0.13-1.96)	0.328
Smoking				
Yes	4 (44.44%)	5 (55.56%)	5.4 (1.39-20.88)	0.015
No	44 (12.90%)	297 (87.10%)	Ref	
Having at least 1 comorbidity				
Yes	21 (20.59%)	81 (79.41%)	2.12 (1.14-3.96)	0.018
No	27 (10.89%)	221 (89.11%)	Ref	
ASOS Surgical risk calculator score				
<10	9 (3.60%)	241(96.40)	Ref	
≥10	39 (39.0%)	61 (61.0%)	17.12 (7.87-37.25)	<0.001

In the multivariable logistic regression, the ASA class, surgery timing and ASOS surgical risk calculator score showed to be the true predictors of postoperative complications (Details in table 4. 6).

Table 4. 6 Multivariable logistic regression of predictors of postoperative complications

Predictors	RR	p value	95% CI	
ASA class				
1	Ref			
2	3.995729	0.01	1.384658	11.53054
3	36.97667	<0.001	7.942802	172.14
4 and more				
Surgery timing				
Elective	Ref			
Urgent				
Emergent	3.199407	0.013	1.274988	8.028472
ASOS SRC score				
<10	Ref			
>=10	7.655601	<0.001	3.248056	18.04409
Constant	0.0071515	<0.001	0.0018648	0.0274256

Model fitness testing:

The final model was tested for fitness using Hosmer-Lemeshow goodness-of-fit test and we found that the model fits very well with the Hosmer-Lemeshow $X^2=2.29$ and $p =0.8079$.The ROC regression model was done with all AUC values different for all the predictors and with the $p=0.009$

CHAPTER V. DISCUSSION

This study demonstrates how the ASOS surgical risk calculator can be an important tool to use during preoperative evaluation of adult surgical patients to limit the burden of postoperative complications and burdens on patients and health care systems. By surveying preoperative patients' ASOS SRC scores, adequate postoperative surveillance and resources can be allocated to patients in the categories that were found to have high risk of postoperative complications. The study found that of the 48 patients who developed post-op complications, 43% had ASOS SRC scores from 13-18, 25% had ASOS SRC from 7-12, 20.8% had scores of 19, and 10% had scores less than 6. Notably, patients with an ASOS SRC score of 19 or greater had a 100% risk of postoperative complications, compared to a 55.3% risk of postoperative complications in individuals with ASOS SRC scores between 13 and 18. Again our study showed that 100% of patients who died and 60% of patients who stayed longer in the hospital had ASOS surgical risk scores above 10, this shows that a score lesser than 10 was more protective as almost 80% of patients with this score were discharged within 30days after surgery. Overall, patients who scored 10 or more on the ASOS SRC were found to be 17 times more likely to develop postoperative complications(**RR: 17.12,95% CI: 7.87-37.25, P value:<0.001**).

In comparison to the 2017 study on validation of Surgical Apgar score (SAS) to predict postoperative complications, which was limited to patients undergoing laparotomy⁸, this study incorporated data from various specialties and surgical procedures from different medical fields. Compared to another prior study done in Africa where 11422 patients were recruited, 18.2% of patients developed postoperative complications and 2.1% of patients died⁶, this study found that 13.7% of patients developed at least one postoperative complication and 2.8% died. This difference could be due to the smaller sample size in our study⁹. Our results are similar to those of other study done in Ethiopia which reported postoperative morbidity of 12.5% and in-hospital mortality of 2.5%, however contrary to our study, it revealed cigarette smoking to be a strong risk factor for postoperative complications and in-hospital mortality(AOR=4.02,CI:1.86-8.66)⁵. Again our study found that the most common complication was acute respiratory distress syndrome (5.1%) and pneumonia has 2.8% where they can overlap each other, in other many studies infection was the most common complication and lead to significant poor postoperative outcome¹¹⁻¹³.

When looking at the need for critical care admission, the study done by M.Vester-Anderson et al on a cohort of 2904 patients found that ICU admission was 4.8% ¹⁴, and this finding is similar to our study which found a critical care admission rate of 4.3%.

Our study found that the commonest comorbidities included Hypertension, cancer and HIV/AIDS with 12.5%, 5.4% and 3.4% respectively. Same findings were seen during another study done by Bruce Biccard et al which revealed that hypertension and HIV/AIDS were the most common comorbidities⁶.

In our study we found that after multivariate logistic regression, ASOS SRC score, ASA Class and Surgery timing were the true predictors of postoperative morbidity and in-hospital mortality. These findings were similar to those found in a systematic review done in the Netherlands (Annelies et al,2015) where the most predicting factors of surgical outcomes included ASA class, emergency surgery and functional status¹⁵. Another review was done for risk assessment tools to predict postoperative outcomes and identified emergency surgeries to be associated with higher morbidity¹⁶. Our confounders were comorbidities, smoking and advanced age, this is different from many other studies where they were highly associated with poor surgical outcomes^{5,5,17}.

Interpretations/Implications

The ASOS surgical risk calculator is a useful tool to detect preoperatively which patients are at high risk of postoperative complications and in need of close monitoring. Patients screened preoperatively and are found to have an ASOS SRC score of greater than 10 can be identified as patients who may need increased surveillance during the postoperative period. These results build on existing evidence of the validity of the ASOS SRC score in predicting morbidity and mortality in adult surgical patients and can be a useful tool in preventing postoperative complications by identifying patients that may need enhanced postoperative surveillance. The implication of this research is the potential to increase postoperative surveillance for high-risk patients, which could ultimately lead to a decrease in postoperative mortality and morbidity.

Limitations

Data sampling is one of the apparent limitations of this study. Due to a limited sample size of only 350 patients and a single-center study, our findings cannot be generalizable to the entire population of Rwanda. Additionally, data was only collected over a limited period of 2 months, and data collection over an extended period would provide a better indication of the validity of the ASOS SRC. Furthermore, the distribution of patients in each score category was skewed towards lower ASOS SRC scores as the majority of patients in the study had ASOS SRC scores in the ranges of <6 (37.71%) and from 7-12(48.57%). Because of the small sampling of patients with ASOS SRC scores from 13-19 (13.72%), it is difficult to predict whether higher ASOS SRC scores are truly associated with a higher risk of postoperative complications. Additionally, our study did not evaluate intraoperative factors which could also have biased our results.

CHAPTER VI. CONCLUSION AND RECOMMENDATIONS

Conclusion:

The study showed that the ASOS Surgical Risk Calculator strongly predicts postoperative morbidity and mortality. Larger sampled studies are needed for results generalization and practice change.

Recommendations/Forward-looking statement:

Further research is needed utilizing a larger sample size to establish the validity of the ASOS SRC and be more generalizable to the entire population of Rwanda. Furthermore, the replication of this study with a more extended data collection period will allow for more robust analysis and validation of the ASOS SRC. Future studies should also include patients with more comorbidities (higher ASA Class) to have a better distribution of patients with higher ASOS SRC scores compared to patients with lower ASOS SRC scores. We recommend also further studies which include intraoperative factors for better elimination of confounding factors.

REFERENCES:

1. Du Toit L, Kluyts HL, Gobin V, et al. The African Surgical OutcomeS-2 (ASOS-2) Pilot Trial, a mixed-methods implementation study. *South Afr J Anaesth Analg*. Published online January 24, 2019;14-23. doi:10.36303/SAJAA.2019.25.1.2173
2. Nepogodiev D, Martin J, Biccard B, et al. Global burden of postoperative death. *The Lancet*. 2019; 393(10170):401. Doi: 10.1016/S0140-6736(18)33139-8
3. Pearse RM, Moreno RP, Bauer P, et al. Mortality after surgery in Europe: a 7 day cohort study. *The Lancet*. 2012; 380(9847):1059-1065. Doi: 10.1016/S0140-6736(12)61148-9
4. Hewitt-Smith A, Bulamba F, Olupot C, et al. Surgical outcomes in eastern Uganda: a one-year cohort study. *South Afr J Anaesth Analg*. 2018; 24(5):122-127. doi:10.1080/22201181.2018.1517476
5. Bayissa BB, Mummud M, Miressa F, Fekadu G. Postoperative Complications and Associated Factors Among Surgical Patients Treated at a Tertiary Hospital, Eastern Ethiopia: A Prospective Cohort Study. *Open Access Surg*. 2021; Volume 14:37-46. doi:10.2147/OAS.S320506
6. Biccard BM, Madiba TE, Kluyts HL, et al. Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. *The Lancet*. 2018; 391(10130):1589-1598. Doi: 10.1016/S0140-6736(18)30001-1
7. Global patient outcomes after elective surgery: prospective cohort study in 27 low-, middle- and high-income countries. *Br J Anaesth*. 2016; 117(5):601-609. doi:10.1093/bja/aew316
8. Ngarambe C, Smart BJ, Nagarajan N, Rickard J. Validation of the Surgical Apgar Score After Laparotomy at a Tertiary Referral Hospital in Rwanda. *World J Surg*. 2017; 41(7):1734-1742. Doi: 10.1007/s00268-017-3951-5
9. Kluyts HL, le Manach Y, Munlemvo DM, et al. The ASOS Surgical Risk Calculator: development and validation of a tool for identifying African surgical patients at risk of severe

- postoperative complications. *Br J Anaesth.* 2018; 121(6):1357-1363. doi:10.1016/j.bja.2018.08.005
10. Jammer I, Wickboldt N, Sander M, et al. Standards for definitions and use of outcome measures for clinical effectiveness research in perioperative medicine: European Perioperative Clinical Outcome (EPCO) definitions: A statement from the ESA-ESICM joint taskforce on perioperative outcome measures. *Eur J Anaesthesiol.* 2015; 32:88-105. doi:10.1097/EJA.000000000000118
 11. Alves A, Panis Y, Manton G, Slim K, Kwiatkowski F, Vicaut E. The AFC Score: Validation of a 4-Item Predicting Score of Postoperative Mortality after Colorectal Resection for Cancer or Diverticulitis. *Ann Surg.* 2007; 246(1):91-96. doi:10.1097/SLA.0b013e3180602ff5
 12. Kulemann B, Fritz M, Glatz T, et al. Complications after pancreaticoduodenectomy are associated with higher amounts of intra- and postoperative fluid therapy: A single centre retrospective cohort study. *Ann Med Surg.* 2017; 16. doi:10.1016/j.amsu.2017.02.042
 13. Roche JJW, Wenn RT, Sahota O, Moran CG. Effect of comorbidities and postoperative complications on mortality after hip fracture in elderly people: prospective observational cohort study. *BMJ.* 2005; 331(7529):1374. doi:10.1136/bmj.38643.663843.55
 14. Vester-Andersen M, Lundstrøm LH, Møller MH, Waldau T, Rosenberg J, Møller AM. Mortality and postoperative care pathways after emergency gastrointestinal surgery in 2904 patients: a population-based cohort study. *Br J Anaesth.* 2014; 112(5):860-870. doi:10.1093/bja/aet487
 15. Visser A, Geboers B, Gouma DJ, Goslings JC, Ubbink DT. Predictors of surgical complications: A systematic review. *Surgery.* 2015; 158(1):58-65. doi:10.1016/j.surg.2015.01.012
 16. Eamer G, Al-Amoodi MJH, Holroyd-Leduc J, Rolfson DB, Warkentin LM, Khadaroo RG. Review of risk assessment tools to predict morbidity and mortality in elderly surgical patients. *Am J Surg.* 2018; 216(3):585-594. doi:10.1016/j.amjsurg.2018.04.006

17. Schoenfeld AJ, Ochoa LM, Bader JO, Belmont PJJ. Risk Factors for Immediate Postoperative Complications and Mortality Following Spine Surgery: A Study of 3475 Patients from the National Surgical Quality Improvement Program. *JBJS*. 2011; 93(17):1577-1582. doi:10.2106/JBJS.J.01048

APPENDIX 1. DATA COLLECTION TOOL

Data Collection instrument (adapted from ASOS Study questionnaire and ASOS surgical risk calculator):

I. ASOS Surgical Risk Calculator CARD

STUDY ID: **Age:** **Gender:** M F **Current smoker:** Yes No

Age	Points
18-29	0
30-69	+1
≥ 70	+3
ASA	
ASA 1	0
ASA 2	+2
ASA 3	+5
ASA 4 and more	+8
Surgery timing	
Elective surgery	0
Urgent surgery	+3
Emergent surgery	+4
Surgery severity	
Minor	0
Intermediate	+2
Major	+4
Indication for surgery	
Non-communicable disease	0
Cesarean section	-2
Trauma	+1

Infection	+2
Surgery type	
Gynecology/obstetrics	-1
Plastics and breast	+1
Urology	+2
Ear, nose, and throat, gastrointestinal, hepato-biliary, cardiothoracic, vascular	+3
Neurosurgery	+4
All other types of surgery	0
TOTAL ASOS SRC SCORE	

II. COMORBIDITIES (you can tick more than one)

- | | |
|----------------------------------|--------------------------|
| Diabetes mellitus | Asthma/COPD |
| Hypertension | Chronic kidney disease |
| Stroke/transient ischemic attack | Congestive heart failure |
| HIV/AIDS | Metastatic cancer |
| Cirrhosis | Coronary artery disease |
| | Others: |

III. ANESTHESIA TECHNIQUE (Tick all that apply)

- General anesthesia Spinal/Epidural anesthesia Sedation Nerve block

IV. POSTOPERATIVE COMPLICATIONS

A. RESPIRATORY

- ☒ Pneumonia
- ☒ Acute respiratory distress syndrome
- ☒ Pulmonary edema
- ☒ pulmonary embolism
- ☒ Pneumothorax
- ☒ Pleural effusion (requiring drainage)

B. CARDIOVASCULAR

- ☒ Myocardial infarction
- ☒ Arrhythmia
- ☒ Cardiac arrest
- ☒ Shock (distributive, hypovolemic, cardiogenic, obstructive)
- ☒ Stroke
- ☒ Deep venous thrombosis

C. MISCELLANEOUS COMPLICATIONS

- ☒ Gastro-intestinal bleed
- ☒ Postoperative bleed
- ☒ Acute kidney injury
- ☒ Anastomotic breakdown
- ☒ Surgical site infection (Superficial, Deep, or body cavity)
- ☒ UTI

Sepsis

Others:

V. Critical care admission to treat postoperative complications:

Yes No Lack of ICU/HDU bed

- Number of days in critical care after surgery:

1-5 days 6-10days 11-20days 21-30th day

- Number of days in hospital after surgery:

1-5 days 6-10days 11-20days 21-30th day

VI. Status at hospital discharge or 30th postoperative in-hospital day:

Alive Discharged in critical care Dead

APPENDIX 2. CMHS IRB AND CHUK ETHIC COMMITTEE APPROVAL



UNIVERSITY OF
RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES
DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 29th /September /2021

Dr Twisingane Protogene
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 299/CMHS IRB/2021

Your Project Title *“Predicting post-operative morbidity and mortality in adult surgical patients: validation of African surgical outcomes study surgical risk calculator at Kigali university teaching hospital (KUTH)”* has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof. Kato J. Njiruwa	UR-CMHS	X		
Dr Stefan Jansen	UR-CMHS	X		
Dr Brenda Asimwe-Kateera	UR-CMHS	X		
Prof. Ntagwirira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayunga N. Egide	UR-CMHS	X		
Mr Kanyons Maurice	UR-CMHS		X	
Prof. Muryanshugore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gashoma Darius	UR-CMHS	X		
Dr Donatilla Makamata	UR-CMHS	X		
Prof. Kyamanywa Patrick	UR-CMHS		X	
Prof. Condo Umutesi Jeanne	UR-CMHS		X	
Dr Nyiranzinyonye Lantia	UR-CMHS	X		
Dr Nkpanzihigo Emmanuel	UR-CMHS		X	
Sr Mulihali Marie Josse	CHUK	X		
Dr Mudonge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 29th September 2021.
Approval has been granted to your study.
Please note that approval of the protocol and consent form is valid for 12 months.



Email: researchcenter@ur.ac.rw P.O Box 2284 Kigali, Rwanda

www.ur.ac.rw

You are responsible for fulfilling the following requirements:

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

Sincerely,



Date of Approval: The 29th September 2021

Expiration date: The 29th September 2022

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

Cc:

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



Review Approval Notice

Dear **TWISUNGANE PROTOGENE**,

Your research project: **"PREDICTING POST-OPERATIVE MORBIDITY AND MORTALITY IN ADULT SURGICAL PATIENTS: VALIDATION OF THE AFRICAN SURGICAL OUTCOMES STUDY SURGICAL RISK CALCULATOR AT KIGALI UNIVERSITY TEACHING HOSPITAL (CHUK)"**

from 1st January 2022 to May 2022

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 30th Dec.2021 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

APPROVED
10/12/2021
ETHICS COMMITTEE
CHUK

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link: www.chuk.rw/research/fullreport/?appid=505&&chuk.

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

Yours sincerely,

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

[Signature]
ETHICS COMMITTEE
CHUK



Scan code to verify

"University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations"