COLLEGE OF MEDICINE & HEALTH SCIENCES

SCHOOL OF MEDICINE & PHARMACY

Department of Obstetrics and Gynecology

Academic year 2019-2020

COMPARISON OF RISK ASSESSMENT OF SCORING SYSTEMS FOR OUTCOME PREDICTION IN OBSTETRICS AND GYNECOLOGICAL EMERGENCY LAPAROTOMIES AT KIGALI UNIVERSITY TEACHING HOSPITAL, RWANDA.

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

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July 10, 2020

Comparison of Risk assessment of scoring systems for outcome prediction in Obstetrics and Gynecological emergency laparotomies at Kigali University Teaching Hospital, Rwanda

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The realization of this thesis has been possible due to the regular collaboration of its authors. Author UJC collected Data and did analysis and preliminary editing. Authors UM, RJD, BP, ND, RS made the edits of the manuscripts and gave their advice of the design for the whole project and have reviewed it entirely before the final copy.

Acknowledgements

This work couldn't have been possible without the passion and love and thougfulness of my mentors and supervisors Professor Urania MAGRIPLES, Dr RUKUNDO Je.an Damascene, Dr Patrick BAGAMBE, Dr Diomede NTASUMBUMUYANGE and Professor Stephen RULISA. I greatly thank them for their tireless efforts during the whole process of realization of this thesis.

I thank also the University of Rwanda and the College of Medicine and Health Sciences, *CMHS* for having contributed enormously to the knowledge I got during my residency program. I thank also University Lecturers who have been always close to us and helping us during our residency program.

I thank the Kigali University Teaching Hospital, *KUTH* administration for having allowed me to conduct this research within its settings.

I thank all patients who accepted to participate in our study.

I thank also my beloved wife **MUKANDORI Alexie** and my daughter **AHABWE NATETE Ange Pearl** for their Love, close charm and encouragements during the realization of this work.

DECLARATION

I, **Dr UZAHABWANIMANA Jean Claude**, 4th year Resident in Gynecology and Obstetrics, declare that this work is original and fully mine, authentic and has never been published anywhere in any conference or scientific meeting and has not been published anywhere before.

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Key Words: Possum, Apache II, morbidity, mortality, surgical scoring, gynecological surgery

ABSTRACT

Objective: Surgical scoring systems have been widely used in medicine mainly to evaluate the severity of diseases and surgical emergency and potentially predict the outcome of those conditions during and after treatment. The purpose of this study

was to evaluate the potential use of Possum and Apache II surgical scores in Obstetrical and gynecological emergency laparotomies at Kigali University Teaching Hospital, and to assess which one of the two systems would be superior at predicting the outcomes of those conditions in Obstetrical and gynecological surgical emergencies.

Methods: A prospective cross-sectional study was performed from September 2019 to April 2020 for patients admitted for emergency explorative laparotomy in the Department of Obstetrics and Gynecology at KUTH. Data entry and data analysis were done using SPSS version 25. Two surgical scoring systems, Apache II and Possum were studied extensively to see their potential use in Ob/Gyn emergency laparotomies; and the two systems were compared with the aim of assessing which one of the two is superior at predicting the outcomes.

Results: There were 178 patients admitted for emergency explorative laparotomies during the study period. Most of the patients (98.9%) were less than 45 years of age. Almost all (97.2%) had medical insurance. The majority of patients (92.7%) were from District Hospitals in the KUTH catchment area. More than a third of the patients were clinically unstable at the time of admission. In all interventions performed, Infections accounted for 57.9% of cases, and hemorrhage for 42.1%. The most common complication was the need for transfusion in 80.9% of cases. The mortality rate in the cohort was 8%. Patients who died had significantly higher APACHE II scores compared to survivors (16.5 versus 9.0, $p<0.001$). This was also seen with POSSUM scores (32.5 versus 22.0, $p<0.001$). There was no significant difference between either APACHE II or POSSUM scores between hemorrhagic or infectious cases. Participants who had APACHE II scores above 15 had a mortality of 42.8% and were 14.6 times more likely to die than those who scored less than 15 (95% CI: 4.4-48.4; $p<0.001$). The POSSUM did

not perform as well. A score greater than 15 was not associated with significant mortality and a score > 30 was associated with 23.3% mortality.

Conclusion: While both increased APACHE II and POSSUM are associated with increased mortality in OBGYN emergency laparotomy, the APACHE II score was better in predicting mortality in our settings. The APACHE II score was better in predicting mortality in our settings. Comparing the sensitivity of the two scoring systems, APACHE II scoring system showed to be more sensitive for the outcome with less false positive rate compared to POSSUM scoring system.

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LIST OF ACRONYMS AND ABBREVIATIONS

AKI: Acute Kidney Injury

APACHE II: The Acute Physiology and Chronic Health Evaluation II score

CBHI: Community-based Health Insurance

CI: Confidence Interval

CMHS: College of Medicine and Health Sciences

DIC: Disseminated Intravascular Coagulation

IRB: Institutional Board Review

KUTH: Kigali University Teaching Hospital

OBGYN: Obstetrics & Gynecology

POSSUM: The Physiological and Operative Severity Score for enumeration of Mortality and morbidity

SPSS: Statistical Package for the Social Sciences

UR: University Of Rwanda

USA: United States of America

WHO: World Health Organization

INTRODUCTION

Over the years, the surgical prognosis scores have been widely used in medicine mainly to evaluate and predict potential complications of surgery, and outcomes for a given surgical condition in the postoperative period[1]. These scores have been of critical importance since they help for adequately optimize surgical patients, prepare for post-operative disposition and predict potential intraoperative and postoperative complications for a given surgical pathology. Most of those scores have been unexplored in the Obstetric and Gynecological surgeries, and there is paucity of literature evaluating the use of surgical scoring systems in operative gynecological surgeries worldwide and particularly in East Africa and Rwanda. To date, evaluation, adaptation and validation of those scoring systems have been limited to General Surgery and Surgical Sub-specialties and little is known on how those systems can be practically applied in gynecological surgeries[1,2].

APACHE II and POSSUM scores have been widely used in many clinical studies. The APACHE II is a disease severity classification system, one of many ICU scoring systems.[2,3] It is performed within 24 hours of admission of the patient to an intensive care unit; the score of zero to 71 is computed based on different measurements; the higher scores the more severe disease and a higher risk of death. It was designed to measure the severity of disease for adult patients admitted to intensive care units. It has not been validated for use in young people of 16 years or less. It is has been used in therapeutic decision making as well as predicting morbidity and mortality. The Apache index was previously designed to predict mortality of patients in ICU, but attempts have been made to apply the scoring system to patients with severe trauma, abdominal complications, and acute pancreatitis. The literature suggest that it is possible to use this scoring system to

predict perioperative events in patients who undergo various surgical procedures in various specialties [4–8].

The POSSUM audit system was designed to be easy and rapid to use and have wide application across the general surgical spectrum, both in the elective and emergency settings, and to be applicable in most health care systems[4,9]. It can predict 30 day mortality and morbidity rates. [7] The POSSUM system is a 2-part scoring system that includes a physiological assessment and a measure of operative severity.[4] It is simple and includes variables that are easy to collect. It considers the physiological condition of the patient at admission and the severity of the surgical procedure to predict the rates of morbidity and mortality.[7] The advantages of the APACHE II score is that it has a good prediction index especially for ICU patients but requires a 24-hour follow up and does not consider the extent of the surgical procedures. On the other hand, the POSSUM scoring presents the advantage of including the operative procedure complex and extent of the diseases [7] Patients who undergo emergency surgery in Obstetrics and Gynecology have different demographic characteristic than general surgery patients as they tend to be younger and may also have different physiologic responses especially postpartum which potentially can make scoring systems less accurate. Elaborate scoring systems may also use data that are not readily obtained in resource limited settings such as Rwanda. The aim of our study was to evaluate the potential use of surgical scoring in Obstetrics and Gynecological emergency laparotomies in Rwanda by comparing the APACHE II and POSSUM scoring systems. These scoring systems may allow early identification of high risk patients, and potentially help to predict the perioperative outcomes and allocation of resources. Moreover, the two systems could potentially allow comparison of outcome of severe illness between different centers, and could be useful for stratifying patients in clinical trials.

MATERIALS AND METHODS

A prospective cross sectional study was performed from September 2019 to April 2020 on patients admitted for emergency explorative laparotomies in the Department of Obstetrics and Gynecology at the Kigali University Teaching Hospital (KUTH). Informed written consent was obtained from the patients or their legal representative if the patients were incapacitated due to the severity of their illness. Ethical clearance was obtained from the IRB of the CMHS / UR (Approval Notice: No 456/ CMHS IRB/ 2019) and Ethical committee of Kigali University Teaching Hospital (Ref.: EC/CHUK/188/2019) prior to the beginning of data collection. All patients with diagnosis of sepsis (peritonitis, tubo-ovarian abscess, and septic abortions), hemorrhage (postpartum hemorrhage requiring explorative laparotomy, and ruptured ectopic pregnancy) and ovarian torsion who were undergoing emergency laparotomies were evaluated for inclusion in our study. Emergency cesarean sections were excluded as they carry low maternal morbidity and mortality.

Demographic and clinical data were collected at the time of admission and throughout the hospital stay by chart review. All data were entered in Microsoft excel spreadsheet then analysis in SPSS version 25, POSSUM and Apache II scores were manually calculated using physiologic data and compared to final outcomes and to each other. The summation of physiological scores done for every single patient on either side (APACHE II score and POSSUM). Of 178 patients, emergency laparotomy were performed with exclusion of all emergency cesarian sections done during our study period. POSSUM is a surgical risk scoring system of morbidity and mortality. APACHE II physiological data used were heart rate, mean arterial pressure, temperature, respiratory rate, potassium, sodium, creatinine (converted from micromole/l to milligram/dl), hematocrit, white blood cells count, Glasgow coma score, chronic health points and the patient age, two physiological

data found not to be applied in our settings and left off (Arterial blood gas and patient oxygenation measurements). The POSSUM physiological data were systolic blood pressure, pulse rate, Glasgow come score, sodium, potassium, urea, hemoglobin, and white blood cell count then patient age, missing data were chest radiograph, and electrocardiogram as they were not done in our settings for emergency laparotomy. The APACHE II has been a good score in comparison to POSSUM as it has many physiological data from the original score. The normality testing of continuous data from APACHE II and POSSUM scores was done using Shapiro Wilk test and the data were not normally distributed (meaning the data were skewed) and hence the non-parametric tests were used to measure the differences in scores between infection and hemorrhage groups where Mann Whitney U test was used. The statistical significance of association or difference set at P value <0.05.

RESULTS

During the study period, there were 178 patients admitted for emergency explorative laparotomy. Demographics are shown in Table 1. Most of patients (98.9%) were less than 45 years of age and the majority of patients were from rural areas. Almost all (97.2%) had community based health insurance and most of them (57.9 %) had infected surgeries. The majority of patients (92.7%) were from District Hospitals in the KUTH catchment area as shown in Table 2. More than one-third of patients were clinically unstable at the time of admission.

Table 3 demonstrates the indications and procedures performed. Infection accounted for 57.9% of cases and hemorrhage for 42.1%. During the emergency explorative laparotomies, a wide variety of procedures were performed as shown in Table 3. The complications are shown in Table 4. The most common complication was the need for transfusion in 80.9% of cases. The mortality rate in the cohort was 8%. Patients who died had significantly higher APACHE II scores compared to survivors (16.5 versus 9.0, $p<0.001$). The range scores of APACHE II in patients who died was 9 to 33 compared to 4 to 23 in the survivors, This was also seen with POSSUM scores where patients who died had a median score of 32.5 (range 28-47) versus survivor median 22.0, (range 12-40); $p<0.001$. (Table 5). On both scores, as the score increases, the mortality and morbidity also are accordingly increased. There were no significant differences of the scores for either APACHE II or POSSUM scores among the hemorrhagic cases in comparison with infections (Table 6). Patients who had the APACHE II scores above or equal to 15 had a mortality of 33.3% and were at 14.6 times greater risk of dying compared to patients who scored less than 15 (OR=14.6; 95%CI: 4.4-48.4; $p<0.001$). POSSUM scores at this cutoff were not predictive of mortality (Table 8). A score greater than 40 had a mortality of 100%. The analysis of sensitivity and specificity of the APACHE II scoring system using receiver operator curve (ROC curve) shows that

if we consider the cut off APACHE II score of 16.5, fifty percent of the participants with death as outcome are correctly presumed to die (sensitivity) and with 5% of the participants who survived were falsely presumed to die (false positive) (Fig 1). The analysis of sensitivity and specificity of the POSSUM scoring system using receiver operator curve (ROC curve) shows that if we consider the cut off POSSUM score of 30.5, fifty percent of the participants with death as outcome are correctly presumed to die (sensitivity) and with 14% of the participants who survived were falsely presumed to die (false positive) (Fig 2). Comparison of sensitivity for two scoring systems using the ROC curves, APACHE II scoring system showed to be more sensitive for the outcome with less false positive rate compared to POSSUM scoring system.

DISCUSSION

This study compared APACHE II and POSSUM score systems originally used in general surgery patients for perioperative mortality and morbidity prediction in predicting perioperative complications patients undergoing gynaecological emergency laparotomies.

Most of our patients were less than 45 years of age, and this very different from a study done by Trial A. et al, where the median age was 69 years[10] but our study had included diseases of reproductive age such as PPH, ectopic pregnancy and post cesarean complications, therefore, the median age was shifted towards the reproductive age bracket.

While it is documented the higher risk of mortality with increasing age in adult community, our results did not show a significant relationship between age and risk of dying. This is in agreement to study in England that studied the mortality among women undergoing surgical management of uterine or ovarian cancer and rejected the age as a predictor of morbidity[11] but contrary to the finding in India and Netherlands that demonstrated a significant higher risk of mortality among surgical patient as the age increases[12,13]. Similarly to data among general surgery patients and other gynaecologic operations[1,2,14–16], our study has demonstrated higher scores both in APACHE II and POSSUM as predictive of subsequent morbidity and mortality. However, our results have shown higher sensitivity in predicting perioperative outcome when APACHE II was used compared to POSSUM score despite the great consideration of physiologic status when POSSUM is used. This could be explained by the known overestimation of mortality by POSSUM even though it has showed better accuracy than APACHE II in oesophageal surgery[14].

In our study, the most frequent complication was the need of blood transfusion as our patients were referred from district hospital for management of complications

of the primary operation such as post-operative hemorrhage, infection both which are associated with poor patient's tolerance of extra blood loss during re-laparotomy and hence need to be transfused peri-operatively. Similar complications were observed at a university hospital in UK summarizing that the risk influenced by patient's health and clinical status correlate with postoperative outcomes[17] and also similar to the findings in Brazil where surgical complications were: local wound infection and systemic infection like pneumonia, sepsis, respiratory failure and massive bleeding needing reoperation[7]. This also could explain the high rate of death in early the first 48 hours as a possibly due to the critical status of patients at admission with higher APACHE score as a function of poor prognosis.

In our study, we noticed that infections accounted for 57.9% of cases and there were few comorbidities in our young cohort in contrast to study from Nigeria stating that the presence of organ dysfunction, age above 50 years and comorbidities were independent risk factors and diffuse peritonitis in this group had a mortality of 47% and 10-15% of patients needed re-exploration for persistence and recurring sepsis and mortality in the group was considered.[18] Another study in South Africa patients with perforated peptic ulcer by Scheien M et al. reported mortality of zero in patients with scores below 11 points and 35% mortality rate in patients with APACHE II scores above 11.[15] Patients who had the APACHE II scores above or equal to 15 had a mortality of 33.3% and were at 14.6 times greater risk of dying compared to patients who scored less than 15 (OR=14.6; 95%CI: 4.4-48.4; $p<0.001$). POSSUM scores at this cutoff were not predictive of mortality. From these findings, Apache II is much better at predicting the outcomes of gynecological procedures than Possum when both are compared in this study. These tools can be used to predict the perioperative and post-operative outcomes in gynecological procedures as widely applied for general surgery. The APACHE II had a significant prediction of outcome among gynecology surgical

patients even though it was parameters such as blood gazes were not included. This suggest that APACHE II can be modified and adapted for use in settings with limited laboratory panels and still maintains better predictions compared to the alternative POSSUM. The study limits arisen while calculating our scores, some variables were missing on either side APACHE II and POSSUM, since those parameters were not being done in the hospital. This induces scores calculations modification for both Possum and apache II score numbers. Most emergency obstetric patients are young and without chronic disease therefore it is important to see whether the scoring systems are applicable to this population. Also, baseline mortality in OBGYN is lower thus making the cut-offs used in other subspecialties difficult to extrapolate to this population.

CONCLUSIONS

While both increased APACHE II and POSSUM scores are associated with increased mortality in OBGYN emergency laparotomy, the APACHE II score was better in predicting mortality in our settings. Comparing the sensitivity of the two scoring systems, APACHE II scoring system showed to be more sensitive for the outcome with less false positive rate compared to POSSUM scoring system.

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Table 1: Baseline characteristics and outcome of the patients enrolled in the study

Variables	n (%)	Died	Recovered	P value
Age				
≤45 years	176 (98.9)	14 (8.0%)	162 (92.0%)	1
>45 years	2 (1.1)	0 (0.0%)	2 (100%)	
Residence				
Urban	79 (44.4)	5 (6.3%)	74 (93.7%)	0.583
Rural	99 (55.6)	9 (9.1%)	90 (90.9%)	
Marital status				
Single	99 (55.6)	10 (10.1%)	89 (89.9%)	
Married	78 (43.8)	4 (5.1%)	74 (94.9%)	0.328
Widower/separated/divorced	1 (0.6)	0 (0.0%)	1 (100%)	
Economic status				
cat1	20 (11.2)	3 (15.0%)	17 (85.0%)	
cat2	43 (24.2)	5 (11.6%)	38 (88.4%)	0.187
cat3	115 (64.6)	6 (5.2%)	109 (94.8%)	
Education				
Primary	108 (60.7)	12 (11.1%)	96 (88.9%)	
Secondary	64 (36.0)	2 (3.1%)	62 (96.9%)	0.259
University	4 (2.2)	0 (0.0%)	4 (100%)	
No formal education	2 (1.1)	0 (0.0%)	2 (100%)	
Insurance				
CBHI	173 (97.2)	14 (8.1%)	159 (91.9%)	1
Private	3 (1.7)	0 (0.0%)	3 (100%)	
None	2 (1.1)	0 (0.0%)	2 (100%)	
Parity				
Primiparous	57 (32.0)	6 (10.5%)	51 (89.5%)	
Multiparous	121 (68.0)	8 (6.6%)	113 (93.4%)	0.381
Surgery class				

Clean Infected	75 (42.1) 103 (57.9)	3 (4.0%) 11 (10.7%)	72 (96.0%) 92 (89.3%)	0.157
Hospital stay [median (min-max)]	7.0 (1-66)	7.0 (1-57)	3.5 (1-66)	0.312
GCS [mean (SD)]	14.8 (1.0)	13.5 (3.3)	14.9 (0.3)	<0.001
APACHE II [mean (SD)]	10.3 (4.8)	18.9 (6.9)	9.6 (3.8)	<0.001
POSSUM [mean (SD)]	23.7 (6.9)	34.1 (6.2)	22.8 (6.2)	<0.001

Table 2: Origin and general status of the patients enrolled in our study on admission

Variable	N	%
Origin of the patient		
DH	165	92.7
Referral hospital	5	2.8
Private	5	2.8
Home	2	1.1
Provincial Hospital	1	0.6
Status of the patient at admission		
Stable	114	64.0
Unstable	62	34.8
Intubated	1	0.6
Oxygen	1	0.6

Table 3: Indications and type of operations done to the patients enrolled in the study

Variable	N	%
Indication of the operation		
Peritonitis	71	39.9
Ruptured ectopic pregnancy	41	23.0
Postpartum hemorrhage	25	14.0
Tubo-ovarian abscess	18	10.1
Septic abortion	14	7.9

Twisted ovarian cyst	9	5.1
Operation done		
Hysterorrhaphy	63	35.4
Salpingectomy	44	24.7
Washout	25	14.0
Hysterectomy	23	12.9
Abscess drainage	17	9.6
Cystectomy	6	3.4

Table 4: Distribution of complications related among our study participants

Complications	**N**	**%**
Transfusions		
Any transfusion	109	61.2
Massive transfusion	35	19.7
Acute kidney injury	5	4.3
Bowel injury	3	2.6
Bladder injury	2	1.7
DIC	1	0.9
Sepsis and wound infection	1	0.9

Table 5: Association of the outcome of POSSUM and APACHE II scores

Scoring	**Final**	**N (%)**	**Mean**	**Median**	**P value**

system	outcome		(SD)	(Min-Max)	
APACHE II	Died	14 (7.9)	18.9 (6.9)	16.5 (9-33)	<0.001
	Survived	164 (92.1)	9.6 (3.8)	9.0 (4-23)	
POSSUM	Died	14 (7.9)	34.1 (6.2)	32.5 (28-47)	<0.001
	Survived	164 (92.1)	22.8 (6.2)	22.0 (12-40)	

Table 6: Comparison of the APACHE II and POSSUM scores between hemorrhage and infectious group

Scoring system	Class of condition	N (%)	Median (IR)	Min-Max	P value (Mann Whitney U test)
APACHE II	Hemorrhage	75 (42.1)	9 (5)	4 to 23	0.179
	Infection	103 (57.9)	9 (6)	4 to 33	
POSSUM	Hemorrhage	75 (42.1)	21 (9))	13-40	0.139
	Infection	103 (57.9)	24 (10)	12 to 47	

Table 7: Observed mortality rates according to APACHE II and POSSUM

Scoring system	N	Outcome		Mortality rate
		Alive	Dead	
APACHE II score				
0-5	20	20 (100%)	0 (0.0%)	0.0%
6 to 10	83	82 (98.8%)	1 (1.2%)	1.2%
11 to 15	54	50 (92.6%)	4 (7.4%)	7.4%
16-20	12	8 (66.7%)	4 (33.3%)	33.3%
>20	9	4 (44.4%)	5 (55.6%)	55.6%
POSSUM score				
11-20	66	66 (100%)	0 (0.0%)	0.0%
21-30	82	75 (91.5%)	7 (8.5%)	8.5%
31-40	28	23 (82.1%)	5 (17.9%)	17.9%
>40	2	0 (0.0%)	2 (100%)	100%

Table 8: Association of POSSUM and APACHE II scores with mortality

Score	Outcome		OR (95% CI)	p value
	Died	Recovered		
POSSUM				
5 to 14	0 (0.0%)	11 (100%)		
15-49	14 (8.4%)	153 (91.6%)	2.2 (0.12-38.8)	0.597
APACHE II				
5 to 14	5 (3.4%)	146 (96.6%)		
15-49	9 (33.3%)	18 (66.7%)	14.6 (4.4-48.4)	<0.001

Figure 1: Receiver operator curve (ROC) for APACHE II scores

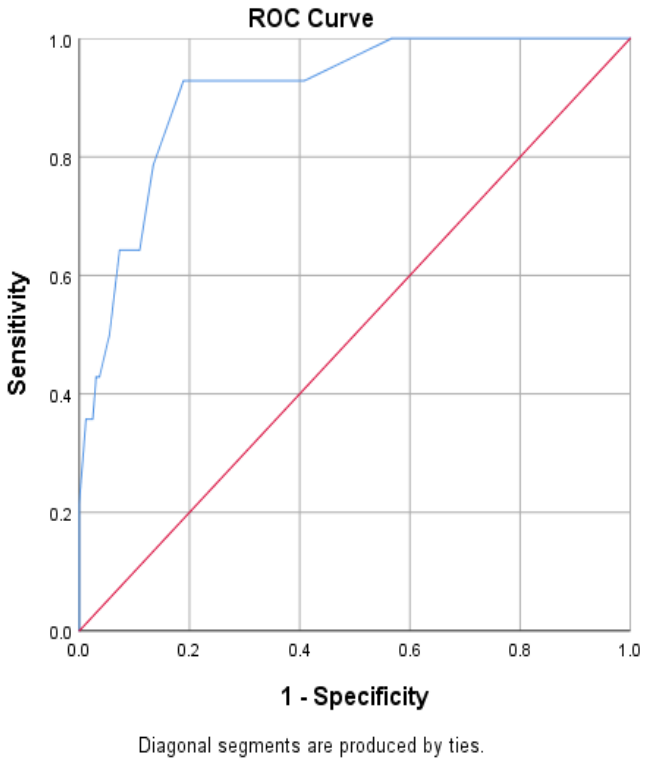
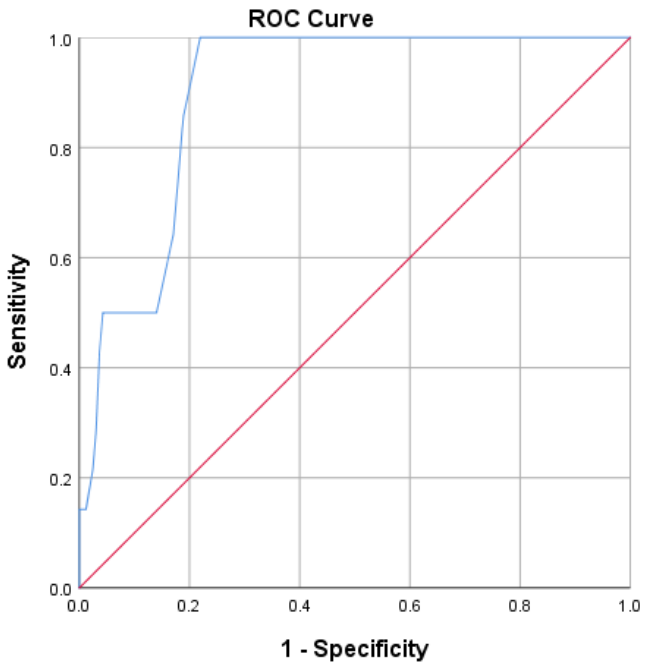


Figure 2: Receiver operator curve (ROC) for POSSUM scores



Diagonal segments are produced by ties.

Figure 3: Summary of variables and calculations for APACHE II score.

Physiologic variable	Points								
	+4	+3	+2	+1	0	+1	+2	+3	+4
Temperature	≥41	39-40.9		38.5-38.9	36-38.4	34-35.9	32-33.9	30-31.9	≤29.9
Mean Arterial Presssure	≥160	130-159	110-129		70-109		50-69		≤49
Heart rate (/min)	≥180	140-179	110-139		70-109		55-69	40-54	≤39
Respiratory rate (/min)	≥50	35-49		25-34	12-24	10-11	6-9		≤5
Sodium (mEq/L)	≥180	160-179	155-159	150-154	130-149		120-129	111-119	≤110
Potassium (mEq/L)	≥7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		≤2.5
Creatinine (mg/dl)	≥3.5	2-3.4	1.5-1.9		0.6-1.4		<0.6		≤
Hematocrit (%)	≥60		50-59.9	46-49.9	30-45.9		20-29.9		≤2.5
WBC (x1000/mm3)	≥40		20-39.9	15-19.9	3-14.9		1-2.9		<1
GCS	Score = 15 minus actual Gcs								
Chronic health points (emergency postop)	5 points for emergency postop 2 points for elective postop								
Age points (years)	≤ 44=0, 45 to 54=2, 55 to 64= 3, 65 to 74=5, ≥75=6								

Figure 4: Summary of variables and calculations for POSSUM score (modified)

Variable	score			
	1	2	4	8
Age	<60	61-70	>71	None
Systolic BP(mmhg)	110-130	131-170 100-109	>171 90-99	 <89
Pulse rate (bpm)	50-80	81-100 40-49	101-120	>121 <39
GCS	15	12-14	9-11	<8
Urea	<7.5	7.6-10	10.1-15	>15.1
Sodium	>136	131-135	126-130	<125
Potassium	3.5-5	3.2-3.4 5.1-5.3	2.9-3.1 5.4-5.9	<2.8 >6
Haemoglobin	13-16	11.5-12.9 16.1-17	10-11.4 17.1-18	<9.9 >18.1
WBC	4-10	10.1-20 3.1-3.9	>20.1 <3	

ANNEXES

Study Participation Consent form

Please read carefully this consent agreement before you participate in this study.

Purpose of the study: Comparison of Risk assessment of scoring system for outcome prediction in Obstetrics and gynecological emergency laparotomies at CHUK.

Your contribution to the study: you are required to complete the questionnaire provided asking information about you or your patient. Your participation to the study is absolutely voluntary.

Benefits for participation: No direct incentives or other financial benefits for participating in this study. The long-term benefits will be to have local evidence based data that might help policymakers to make an improvement to healthcare system planning strategies.

Risks associated with participation in the study: risk associated with participating in this study would be the disclosure of information provided but confidentiality measures are put in place and the data will only be available to

investigators and will be used only for the purpose of this study. Questionnaire will be anonymous without any personal identifier.

Confidentiality: Data provided by respondents will be kept anonymous, confidential and only handled by study investigators.

Right to refuse to participate: You have right to refuse to participate in this study without any consequence either personal or professional.

Right to withdrawal: you have the full right to stop your participation in the study at any step and anytime.

If any other concern, contact person and address are provided below:

Contacts

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Butare University Teaching Hospital

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CMHS IRB CONTACTS

Chairperson: +250788 490 522

Secretary: +250788563311

Agreement

I hereby, agree to participate in the research study described above.

Names and signature:……..

Date: ……

Questionnaire

Data collection questionnaire

1. Age ……. years

1. 15- 20
2. 21-35
3. ≥ 36

2. Parity

1. 1
2. 2

3. ≥ 3
4. none

3. Residence……province.

1. Urban
2. Rural

4. Health insurance

1. none
2. Community based health insurance
3. Private (RSSB, MMI, UAP, SORAS , BRITAM, …..)

5. Marital status

1. Single
2. Married
3. Divorced/ Separated/widowed

6. Social economic status

a) Category 1 c) Category 3
b) Category 2 d) Category 4

7. Education level

i. Primary
ii. Secondary
iii. University iv. None

8. Medical History

a) HIV b) Anemia c) DM d) HTN e) Infection
f) BMI (ht……. wt ….) g) Cardiac disease

9. Reference from:

1. Referral hospital 2. Other referral hospital 3. Provincial hospital 4. District

hospital 5. Private clinic 6. Home

10. Hemodynamic status at admission

a) Stable b) unstable c) intubated d) vasopressors e) Oxygen

11. Laboratory results before laparotomy:

Hb : plts : Hct : wbc : urea : creatinine : K : Na :

12. Indication for laparotomy

1. Ruptured ectopic pregnancy
2. Twisted ovarian cyst
3. Postpartum Hemorrhage
4. Peritonitis
5. Tubovarian Abscess
6. Septic abortion

13. Procedure done during laparotomy

7. Hysterectomy
8. Hysterorrhaphy
9. Washout
10. Abscess drainage
11. Salpingectomy
12. Salpingoophorectomy
13. cystectomy
14. Estimated blood loss: ……..ml

14. Complications

1. Any transfusion
2. Massive transfusion
3. Disseminated Intravascular Coagulopathy

4. Acute Kidney Injury
5. Sepsis and wound infection
6. Bladder injury
7. Bowel injury
8. Further operations ……..
9. none

15. Outcomes

a) Improved b) Recovered c) ICU d) Discharged e) died

16. Vital signs at admission

BP: HR: T: GCS: RR:
SPO2:

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

November 11st, 2019 **Ref.: EC/CHUK/188/2019**

Review Approval Notice

Dear Dr.Jean Claude Uzahabwanimana

Your research project: **"Comparison of risk assessment of scoring system for outcome prediction in obstetrics and gynaecological emergency laparatomies at CHUK"**

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 8th November 2019 to evaluate your protocol of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your protocol.

You are required to present the results of your study to CHUK Ethics Committee before publication.

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

Yours sincerely,

Dr.RUSINGIZA KAMANZI Emmanuel

The Chairperson, Ethics Committee,

University Teaching Hospital of Kigali

<<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>>

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 12th/September/2019

Dr UZAHABWANIMANA Jean Claude
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 456/CMHS IRB/2019

Your Project Title ***"Comparison of Risk Assessment of Scoring System For Outcome Prediction In Obstetrics And Gynecological Emergency Laparotomies At CHUK, Rwanda"*** has been evaluated by CMHS Institutional Review Board.

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

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 11th September 2019, **Approval has been granted to your study.**

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

You are responsible for fulfilling the following requirements:

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

Sincerely,

Date of Approval: The 12th September 2019

Expiration date: The 12th September 2020

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

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