



UNIVERSITY *of*
RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES

SCHOOL OF MEDICINE & PHARMACY

**Evaluation of risks, indications, morbidity and mortality
associated with re-laparotomy after C/S**

A dissertation submitted to the college of medicine and health sciences, school of medicine and Pharmacy in partial fulfillment for the requirement of awards of Master's degree in Obstetrics and Gynecology/ University of Rwanda.

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Declaration

Student's declaration

I, Dr Jean de la Croix MUTABAZI, to the best of my knowledge, hereby declare that this dissertation contains my own work except where specifically acknowledged, and it has been passed through the anti-plagiarism and found to be complaint and this the approved version of the dissertation

Date: December 15th, 2020

Signature: (see hard copy)

Submission authorization

Declaration from main Supervisor after use of Turnitin plagiarism checker, he approves the submission.

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Date: December 15th, 2020

Signature: (See hard copy)

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- May God Bless you All.

Précis

Only Emergency C/S was significantly associated with re-laparotomy. The main indication of re-laparotomy was peritonitis/infections.

EVALUATION OF RISKS, INDICATIONS, MORBIDISRY AND MORTALITY ASSOCIATED WITH RE-LAPAROTOMY AFTER C/S. Jean de la Croix MUTABAZI ,MD¹, Diomede NTASUMBUMUYANGE, MD² Theogene RURANGWA, MD², Urania Maggriples, MD, Associate professor³.

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Authors' contributions

This study was carried out in close collaboration between the authors. The author jcm invented the idea, designed the protocol, collected data and did initial data analysis. The author dn, tr, and um reviewed and gave inputs and guidance on the study design, reviewed the literature and corrected the writing errors and fine touches.

Abstract

Objective: To determine the risk factors, indication, morbidity and mortality associated with re-laparotomy.

Methods: A retrospective descriptive study of all patients who required re-laparotomy after Cesarean Section (CS) at the 3 main referral hospitals in Rwanda from January 2016 to September 2019. Patient demographics, hospital course and complications were extracted from chart review and analysed. Results: There were 909 patients who had re-laparotomy during the study period. Most of the women were less than 30 years old (55.7%), married (73.4%) and 42% were primiparas. The most common indication for the CS was concern for fetal wellbeing (33.8%). Only 19% were repeat CS. Most of the patients were transferred from District Hospitals (96.4%) with only 3% having the original surgery at the referral hospital and 0.6% from private clinics. Infection was the indication in 2/3 of re-laparotomy and hemorrhage in 31.2%. Forty three percent required hysterectomy and 94.9% of the hysterectomies were in patients who were transferred. Transfusion was necessary in 62.9% and massive transfusion in 37%. Additional surgery after the re-laparotomy was performed in 31.9%. Sepsis and maternal death were significantly more likely with emergency vs. elective surgery (13.2 vs. 6.3%, $p=0.009$ and 11.4% vs. 6.3% $p=0.047$, respectively). There were 88 maternal deaths (9.7%); 69% were infectious. Parity was associated with an increased risk of hysterectomy at the time of re-laparotomy ($p<0.01$). Longer delay between CS and re-laparotomy was associated with longer length of stay ($p=0.004$); this association was not seen in women who had their primary CS at a referral hospital ($p=0.311$) while it remained statistically significant for women who had their CS at a District Hospital ($p<0.001$).

Conclusions: There is significant morbidity and mortality in re-laparotomy after C/S. Re-laparotomy was more likely to be associated with emergency CS. No other maternal demographics were predictive of re-laparotomy. The most patients who underwent re-laparotomies were transferred from District Hospitals to the referral hospitals. Improving the quality of surgical care in the District Hospitals is necessary to improve CS outcomes.

Key Words: Re-laparotomy, Cesarean section, risk factors, morbidity and mortality.

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List of Acronyms and abbreviations

CS: Cesarean Section

R-LACS: Re-laparotomy after Cesarean Section

PPH: Postpartum Hemorrhage

ICU: Intensive Care Unit

WHO: World Health Organization

RMH: Rwanda Military Hospital

CHUK: Centre Hospitalier Universitaire de Kigali

CHUB: Centre Hospitalier Universitaire de Butare

Introduction

Cesarean section (CS) is the most common obstetric surgery and one of the most common surgeries worldwide. Worldwide there is dramatic increase in CS rate in both developed and developing countries.^{1,2} Rising rates of CS have been associated with improvement in perinatal outcomes as well as increased maternal morbidity.³ In 2015, the WHO documented that CS can cause significant and occasionally permanent complications, disability or even death especially in settings that lack the facilities and/or capacity to properly conduct safe surgery and treat surgical complications.⁴ Studies reporting complications of re-laparotomy after CS have shown mortality rates ranging from 0.4% to 3.5% and few studies had shown a high mortality rate.⁴⁻⁶ CS is associated with more complications than vaginal delivery including infection and hemorrhage. In some cases, the complications require surgical intervention. Unfortunately, re-laparotomy is often performed when the patient is unstable and in critical condition. Re-laparotomy is a rare but serious complication of cesarean section. Patients with re-laparotomy often require blood transfusion, admission to ICU, as well as longer hospitalization.^{1,7} The risk of infection increases by 5-fold to 20-fold than vaginal delivery.⁸ There are few studies documenting the rates, causes, and risk factors for re-laparotomy after CS. Many of these studies are limited in numbers and do not highlight the maternal complications and mortality rate.⁹

In an Egyptian study, re-laparotomy complicated 1.04% of CS (n= 26). The main indication for re-laparotomy was bleeding with intra-abdominal bleeding in 41.7%, rectus sheath hematoma in 29.2% and uncontrolled postpartum hemorrhage in 29.2 %. Infections complicated 7.7% of cases. The maternal mortality was 11.5 %.¹ A high mortality rate of 45% was reported from a study in India.⁴

Rwanda has also faced the challenge of increase in CS rate which was 15 % prior to 2010. The highest increase in the CS rate was in the District Hospitals which increased to 45 % in 2011.¹⁰ In Rwanda, morbidity and mortality associated with re-laparotomy after CS is unknown. The aim of this study is to determine the risk factors, indication, morbidity and mortality associated with this rare but serious complication of CS.

Methods

A retrospective descriptive study of patients was performed on all patients who required re-laparotomy after CS at the three main referral hospitals in Rwanda from January 2016 to Sept 2019. Centre Hospitalier Universitaire de Kigali (CHUK) has 2354 annual deliveries with 59.8 % CS. Centre Hospitalier Universitaire de Butare (CHUB) has 2741 annual deliveries with 53.26% CS. Rwanda Military Hospital (RMH) has 1332 annual deliveries with 66.07% CS. In 2016, there were 45,255 CS performed in Rwanda.

Cases were determined by review of the surgical theater logs. The study population was all patients who underwent re-laparotomy after CS within the postpartum period regardless of the site of primary C/S. Women who were on anticoagulants or with a known underlying bleeding disorder were excluded. During the study period, there were 909 patients requiring re-laparotomy.

Data was collected by chart review using a data collection tool and included patient demographics characteristics, whether they were transferred, indication and site location of CS, indication for re-laparotomy, details of the procedure done, preoperative hemodynamic state of patients, interval between CS and re-laparotomy, ICU admission, blood transfusion, morbidities and mortality.

Patient data were entered and analyzed in SPSS version 23. Sepsis, emergency CS and time between CS and re-laparotomy were analyzed in relation to maternal death. Chi-square test was used and p value was set at <0.05 for statistical significant difference. Personal identification was not disclosed in our study.

IRB approval was obtained prior to initiation of the study.

Results

A total of 909 patients had re-laparotomy after CS during the period from January 2016 to September 2019. The majority were re-operated at CHUK (56.1%), followed by CHUB (30.5%) and RMH (13.4%). The most common indication was infection including peritonitis (66.4%), followed by hemorrhage (31.1%). Patient sociodemographic data are shown in **Table 1**. Most of these patients were less than 30 years old (55.7%), married (73.4%) and 42% were primiparas. 90% were using community health insurance. Only 27 (2.97%) had their CS in the referral hospital (CHUK, CHUB and RMH), 868 (95.48%) in community hospitals (Provincial and District Hospitals) and 5 (0.55%) had had their cesarean delivery in a private clinic. The rate of hysterectomy was 42.8%. The high rate of hysterectomy was recorded at RMH (57.2%), CHUK (45.3%) and CHUB (31.8%) and this difference was statistically significant among those 3 institutions. Hysterectomy had significantly decreased maternal mortality ($p=0.001$). There was no difference in hysterectomy rate whether the patient was transferred or not (42.9% vs. 42.1%). The predominance of the hysterectomies (94.9%) were in patients who were transferred. Sepsis and maternal death were significantly more likely with emergency vs. elective surgery (13.2 vs. 6.3%, $p=0.009$ and 11.4% vs. 6.3% $p=0.047$, respectively). There were 88 maternal deaths (9.7%); 69% were infectious. There was no difference in maternal death based on the indication of re-laparotomy. Higher parity was significantly associated with hysterectomy ($p < 0.01$). **Table 2** is showing the indications of re-laparotomy in relation of previous indication of CS. The overall ICU admission was 13.1%. ICU admission was associated with maternal mortality ($p < 0.05$). Most of the patients who had re-laparotomy due to infection (93.2%) had hospital stays of more than 10 days; the maximum being 130 days contrary to PPH where only 25% had a length of stay more than 10 days. The higher the number of days between CS to re-laparotomy, the longer the length of hospital stay after re-laparotomy ($p=0.004$) as demonstrated in **Figure 1**. This significance was lost for women who had had CS in referral hospital ($p=0.311$) while it remained statistically significant for women who had had CS at a community hospital ($p=0.000$). Mean hospital stay in days by indications of re-laparotomy is shown in **Figure 2**. Maternal mortality and morbidity in relation to transfusion is shown in **Table 3**. One transfusion was necessary in 62.9% and massive transfusion in 37% of patients. There is no statistical significance on maternal outcome on patients who had any transfusion or massive transfusion. Additional surgery after the re-laparotomy was performed in 31.9%. Most common complications after re-laparotomy are shown in **Table 4**.

Discussion

Bleeding is cited as the most common indication in the literature reviewed.^{1,11,12} A. Gedikbasi et al. found the main indications of R-LACS to be bleeding (74.3%) and infections (20%).¹³ Shiri Shinar et al. also found 88% of R-LACS was due to bleeding where extra uterine injury and sepsis accounts only 12%.¹⁴ J.D. Seffah, in Ghana showed same results as those in India, Poland and Serbia.^{2,9,15,16} In contrast in our study, infection/peritonitis was the predominant indication for re-laparotomy accounting for two-thirds of cases. These results were also demonstrated in a previous study in Rwanda which identified that infection was the most common identified factor in near miss morbidity and mortality.¹⁰ Postpartum infections were associated with high morbidity and mortality and 81% of these infections were after cesarean section. The majority of our patients were from District Hospitals where CS are generally performed by general practitioners with different levels of training. Poor surgical technique, timing of surgery and use of antibiotics as well as delays in treatment of endometritis may be factors contributing to the high rate of infections. Whenever Re-laparotomy is indicated, it poses great morbidity and mortality. In our study, mortality and hysterectomy rate are high but not significantly different from other studies.^{1,2,5,7} The highest hysterectomy rate of 77.78% and mortality rate of 45% were reported in studies in India.^{4,5} Few studies showed no maternal mortality but still maternal morbidity was high.^{9,17} It is interestingly to note that as other studies, sepsis and maternal death were significantly more likely with emergency vs. elective surgery (13.2 vs. 6.3%, $p=0.009$ and 11.4% vs. 6.3% $p=0.047$, respectively), only few studies showed no correlation. There is no other predictive factor.^{1,4,9} Patients who undergo re-laparotomy are often critically ill and unstable; hence there is increased risk of difficulty recovery, ICU admission, prolonged hospital stay, transfusion and further operations. In our study the rate of ICU admission was 13.5% but this may be secondary to the limitations of the number of ICU beds available in our setting. Our results confirmed previous findings in the literature.⁴⁻⁶ This study has not confirmed results from previous studies on most common procedure done during R-LACS, for us it was uterine debridement and hysterorrhaphy repair 44.7% followed by hysterectomy 42.8%. Other researchers found to be suture of the hysterotomy, evacuation of the hematoma, ligation of uterine and hypogastric artery, hysterectomy and debridement and re-suture. This difference is likely explained by the most common cause of R-LACS in Rwanda being infection rather than bleeding.^{4,7,15} Our study did not find any difference in maternal mortality and hysterectomy rate

from all three referral hospitals. Interestingly in our study, hysterectomy was significantly associated with decrease in maternal mortality. Our study also did not find any difference on hysterectomy rate, maternal mortality and hospital length of stay as being associated with referred or none referred patients.

There is significant morbidity and mortality in re-laparotomy after CS. Improving the quality of surgical care in the district hospitals is necessary to improve CS outcomes.

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Table 1. Patient Sociodemographic data

		Count	%
Referral hospitals N= 909	CHUB	277	30.5%
	CHUK	510	56.1%
	RMH	122	13.4%
Year the patient was discharged N= 907	2016	248	27.3%
	2017	199	21.9%
	2018	250	27.6%
	2019	210	23.2%
Age Group N= 901	<20	102	11.3%
	21-25	222	24.6%
	26-30	210	23.3%
	31-35	192	21.3%
	>35	175	19.4%
Marital status N= 635	Single	138	21.7%
	Married	466	73.4%
	Cohabitate	21	3.3%
	Divorced/Separated	8	1.3%
	Widowed	2	0.3%
Health Insurance N= 887	None	42	4.7%
	Community Health	799	90.1%
	Private	46	5.2%
Parity N= 902	1	379	42.0%
	2	166	18.4%
	3	149	16.5%
	4	91	10.1%
	>4	117	13.0%

Table 2. indications of Re-laparotomy in relation of previous indication of C/S

Indications for C/S	Indication for Re-Laparotomy			Total
	Bleeding	Infections	Dehiscence/Injury/Fistula	
Unknown	36 (24.2%)	112 (75.2%)	1(0.7%)	149
Repeat C/S	88 (51.5%)	77(45%)	6(3.5%)	171
Foetal Indications				
NRFHR	40(18.7%)	170(79.4%)	4(1.9%)	214
Malpresentation	24(35.3%)	43(63.2%)	1(1.5%)	68
Oligo/Poly/an- amnios	7(58.3%)	5(41.7%)	0	12
IUFD	3(100%)	0	0	3
Twin Pregnancy	0	5(100%)	0	5
Cord Prolapse	0	3(100%)	0	3
PPROM	0	1(100%)	0	1
Total	74(24.2%)	227(74.2%)	5(1.6%)	306
Uterine Indications				
Arrested labour	24(16.4%)	118(80.8%)	4(2.7)	146
Failed induction	11(25.6%)	31(72.1%)	1(2.3%)	43
Uterine rupture	20(54.1%)	16(43.2)	1(2.7%)	37
Uterine Myoma	1(100%)	0	0	1
Total	56(24.7%)	165(72.7%)	6(2.6%)	227
Haemorrhagic Indications				
Placenta Previa	8(57.1%)	6(42.9%)		14
Placenta abruption	4(66.7%)	2(33.3%)		6
Placenta accreta spectrum	9(100%)	0		9
Total	21(72.4%)	8(27.6%)		29
Maternal Indications				
Pre- eclampsia/Eclampsia	6(42.9%)	8(57.1%)		14
Chorioamnionitis	0	1(100%)		1
Active Herpes Infection	0	1(100%)		1
Total	6(37.5)	10(62.5%)		16
Maternal Request	1(20%)	3(60%)	1(20%)	5

Table 3. Maternal morbidity and mortality in relation to transfusion

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		Infections vs PPH							
		PPH				Infections			
		Transfusion Categories				Transfusion Categories			
		Any Transfusion		Massive Transfusion		Any Transfusion		Massive Transfusion	
		Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
Sepsis and Wound Infections	No	68	97.1%	152	93.8%	225	90.4%	25	83.3%
	Yes	2	2.9%	10	6.2%	24	9.6%	5	16.7%
Hospital stay in Ranges	<=4	21	31.8%	69	46.3%	4	1.7%	1	3.4%
	5-10	27	40.9%	49	32.9%	10	4.2%	1	3.4%
	>10	18	27.3%	31	20.8%	223	94.1%	27	93.1%
Maternal Death	No	67	95.7%	138	85.7%	221	89.1%	25	83.3%
	Yes	3	4.3%	23	14.3%	27	10.9%	5	16.7%

Table 4. Complications of Re-laparotomy

DIC	7	0.8%
AKI	7	0.8%
Sepsis and Wound Infections	109	12.0%
Bladder Injury/ureteric injury	41	4.5%
Bowel Injury	15	1.7%
Further Operations	290	31.9%
ICU admission	123	13.5%
Maternal Death	88	9.7%

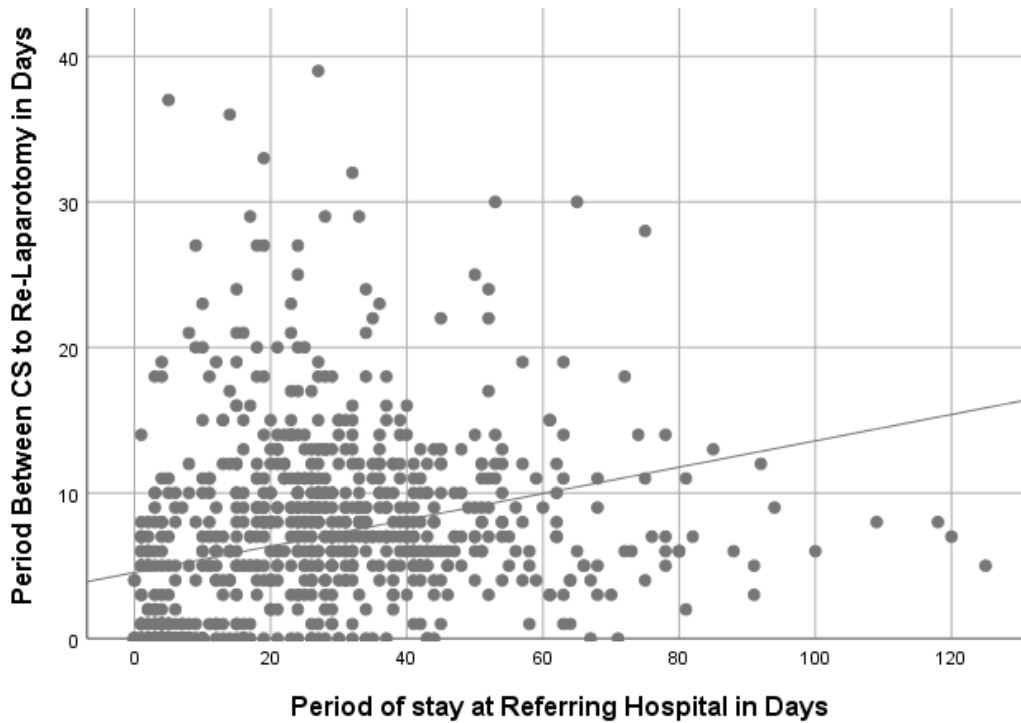


Figure 1. Time from C/S to re-laparotomy in relation to hospital stay after re-laparotomy

The higher the number of days between CS to relaparotomy, the longer the patient will stay in hospital after relaparotomy $n=889$, $p\text{-value}=0.004$ but this significance was lost for women who had had CS in referral hospital ($p\text{-value}=0.311$) while it remained statistically significant for women who had had CS at a community hospital ($p\text{-value}=0.000$).

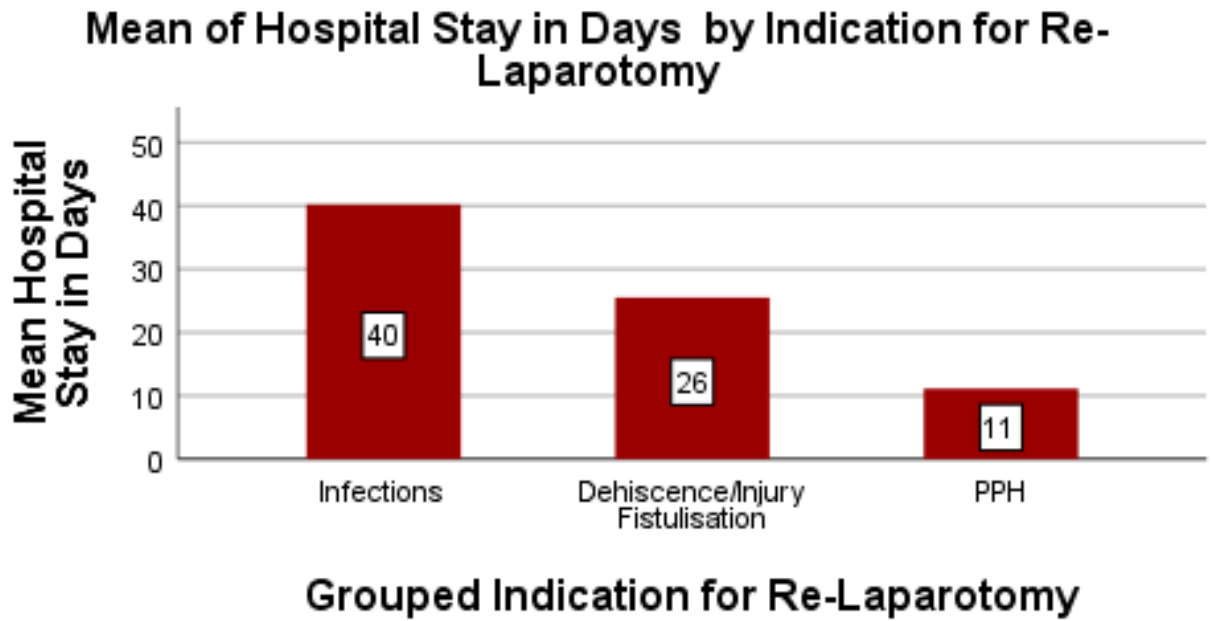


Figure 2. Mean hospital stay by indications of Re-laparotomy

ANNEXES

1.DATA COLLECTING TOOL

DATA COLLECTING TOOL.

Title of the study: _____

- | | | | | | | | | | | |
|--|--------------|--------|-------|-------|--------|-------|--------|--------|-------|--|
| <ol style="list-style-type: none"> 1. Year _____ 2. Study ID : _____ 3. Age _____years 4. Marital status <ol style="list-style-type: none"> 1. Single 2. Married 3. Cohabitate 4. Divorced/separated 5. Widowed 5. Residence district : _____ 6. Level of education <ol style="list-style-type: none"> 1. No formal education 2. Primary 3. Secondary 4. Univeristy 7. Health insurance <ol style="list-style-type: none"> 1. None 2. Community health insurance 3. Employment insurance (RSSB, MMI, UAP, SORAS,) 8. Wealth quintile (Ubuhehehe) <ol style="list-style-type: none"> 1. Category 1 2. Category 2 3. Category 3 4. Category 4 5. AHA/HCR 6. Not yet categorized 9. Parity : _____ 10. Number of antenatal cares _____ 11. Medical history <table border="0" style="margin-left: 20px;"> <tr> <td>1. HIV (STI)</td> <td>1. Yes</td> <td>0. No</td> </tr> <tr> <td>2. DM</td> <td>1. Yes</td> <td>0. No</td> </tr> <tr> <td>3. HTN</td> <td>1. Yes</td> <td>0. No</td> </tr> </table> 12. BMI. (ht-----, cm; wt-----kgs) 13. Number of previous cesarean deliveries: _____ 14. Category of cesarean delivery <ol style="list-style-type: none"> 1. Emergency 2. Elective 15. Indication of cesarean section <ol style="list-style-type: none"> 1. Unknown 2. Repeat C/S 3. Arrested labor 4. NRFHR 5. Failed induction 6. Malpresentation 7. Maternal request 8. Other. Specify..... 16. Place where C/S was done <ol style="list-style-type: none"> 1. Referral hospital of admission | 1. HIV (STI) | 1. Yes | 0. No | 2. DM | 1. Yes | 0. No | 3. HTN | 1. Yes | 0. No | <ol style="list-style-type: none"> 2. Provincial Hospital 3. District Hospital 4. Private clinic 17. period between C/S to re-laparotomy: ____d 18. Transferred: <ol style="list-style-type: none"> 1. Yes 0. No 19. Transferring Hospital _____ 20. Length of stay at referring hospital: ____d 21. Interval between admission and re-laparotomy transferred patients ____days 22. Blood Pressure before operation <ol style="list-style-type: none"> 1. Hypertensive 2. Normotensive 3. Hypotensive 4. Non-recordable 5. Not recorded 23. Before operation was the patient on: <ol style="list-style-type: none"> 1. Pressors 2. Oxygen 3. Intubation 4. ATB before Re-laparotomy 24. Hb level before operation _____(g/dl) 25. Indication for re-laparotomy <ol style="list-style-type: none"> 1. Intra-abdominal bleeding 2. PPH 3. Peritonitis 4. Other specify..... 26. Procedure done during re-laparotomy <ol style="list-style-type: none"> 1. Hysterectomy 2. B-lynch 3. Hysterorrhaphy repair 4. Wash out 5. Debridement and BOGOTA BAG plac 27. Number of re-laparotomies: _____ 28. Complications <ol style="list-style-type: none"> 1. IUC admission 2. Any transfusion 3. Massive transfusion 4. DIC 5. AKI 6. Sepsis, wound infection 7. Bladder/Ureter injury 8. Bowel injury 9. Further operations 29. Hospital stay: ____days 30. Maternal mortality <ol style="list-style-type: none"> 1. Yes 0. No |
| 1. HIV (STI) | 1. Yes | 0. No | | | | | | | | |
| 2. DM | 1. Yes | 0. No | | | | | | | | |
| 3. HTN | 1. Yes | 0. No | | | | | | | | |

2. IRB APROVAL



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COLLEGE OF MEDICINE AND HEALTH SCIENCES
DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 23rd /August/2019

Dr MUTABAZI Jean de la Croix
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 429/CMHS IRB/2019

Your Project Title *“Evaluation of Risks, Indications, Morbidity and Mortality Associated with Re-Laparotomy after C/S”* 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. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asimwe-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 16th August 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. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,



Date of Approval: The 23rd August 2019

Expiration date: The 23rd August 2020

Professor GAHUTU 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

3. ETHIC COMMITTEE APPROVAL



CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Ethics Committee / Comité d'éthique

August 20th, 2019

Ref.: EC/CHUK/ 153 /2019

Review Approval Notice

Dear Dr.Mutabazi Jean de la Croix

Your research project: "Evaluation of risks,indications,morbidity and mortality associated with re-laparotomy after C/S,CHUK from January 2014 to September,2019"

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 20th August 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 renewal.

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>>

B.P. :655 Kigali- RWANDA www.chk.rw Tél. Fax : 00 (250) 576638 E-mail :chuk.hospital@chukigali.rw

4. CHUB ETHIC COMMITTEE APPROVAL



CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

CENTRE HOSPITALIER UNIVERSITAIRE
DE BUTARE (CHUB)
OFFICE OF DIRECTOR GENERAL

Huye, ... 19/11/2019

N° Ref: CHUB/DG/SA/11/...../2019

Jean de La Croix MUTABAZI
University of Rwanda
Phone: +250788457987
Email: mujeancroix@gmail.com

Dear Mutabazi,

Re: Your request for Data collection

Reference made to your letter requesting for permission to collect data within University Teaching Hospital of Butare for your research study entitled "*Evaluation of risks, indications, morbidity and mortality associated with re-laparotomy after C/S*"; and based to the approvals: No: RC/UTHB/085/2019 from our Research - Ethics committee and No: 429/CMHS IRB/2019, from CMHS Institution Review Board we are pleased to inform you that your request was accepted. Please note that your final document will be submitted in our Research Office.

Sincerely,

Dr. Augustin SENDEGEYA
Director General of CHUB

Cc:

- Ag Head of Clinical Education and Research Division
- Ag Director of Research
- Chairperson of Research-Ethics Committee
- Ag Research officer

CHUB

E-mail : info@chub.rw
Website: www.chub.rw

B.P : 254 BUTARE
Hotline: 2030

5. RMH ETHIC COMMITTEE APPROVAL



CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

CENTRE HOSPITALIER UNIVERSITAIRE
DE BUTARE (CHUB)
OFFICE OF DIRECTOR GENERAL

Huye, ... 19/11/2019

N° Ref: CHUB/DG/SA/11/...../2019

Jean de La Croix MUTABAZI
University of Rwanda
Phone: +250788457987
Email: mujeancroix@gmail.com

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Sincerely,

Dr. Augustin SENDEGEYA
Director General of CHUB



Cc:

- Ag Head of Clinical Education and Research Division
- Ag Director of Research
- Chairperson of Research-Ethics Committee
- Ag Research officer

CHUB

E-mail : info@chub.rw
Website: www.chub.rw

B.P : 254 BUTARE
Hotline: 2030