RISK FACTORS FOR RE-LAPAROTOMY AFTER CESAREAN SECTION AND ASSOCIATED MATERNAL MORTALITY AND NEAR-MISS EVENTS AT KNH

AN EXPLORATORY CASE-CONTROL STUDY

DR BARE ABDULLAHI

H58/33441/2019

RESIDENT, DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY,

UNIVERSITY OF NAIROBI.

SUPERVISORS: DR ROSE KOSGEI

DR DIANA ONDIEKI

THIS DISSERTATION IS SUBMITTED IN PARTIAL FULFILLMENT OF THE AWARD OF DEGREE OF MASTERS OF MEDICINE IN OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF NAIROBI.

DECLARATION

This dissertation is undertaken as a part of the fulfillment of the Masters of Medicine in Obstetrics and Gynecology and is my original work and has not been undertaken and presented for a degree in any other University.

DR. BARE ABDULLAHI

STUDENT, MASTERS OF OBSTETRICS AND GYNAECOLOGY

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF NAIROBI.

Signed: _____  _____ Date: 10.06.2022

CERTIFICATE OF SUPERVISION

DR ROSE KOSGEI

MBCHB MOI UNIVERSITY ELDORET, MMED OBS/GYN(UON), MSC IN CLINICAL TRIALS(LSTHM),

CONSULTANT OBSTETRICIAN AND GYNECOLOGIST,

SENIOR LECTURER,

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY,

UNIVERSITY OF NAIROBI.

Signature……  ……. ..Date ……09/06/2022…….

DR DIANA ONDIEKI

MBCHB (UON), MMED OBS/GYN (UON), MSC EPIDEMIOLOGY(LSHTM),

CONSULTANT OBSTETRICIAN AND GYNECOLOGIST,

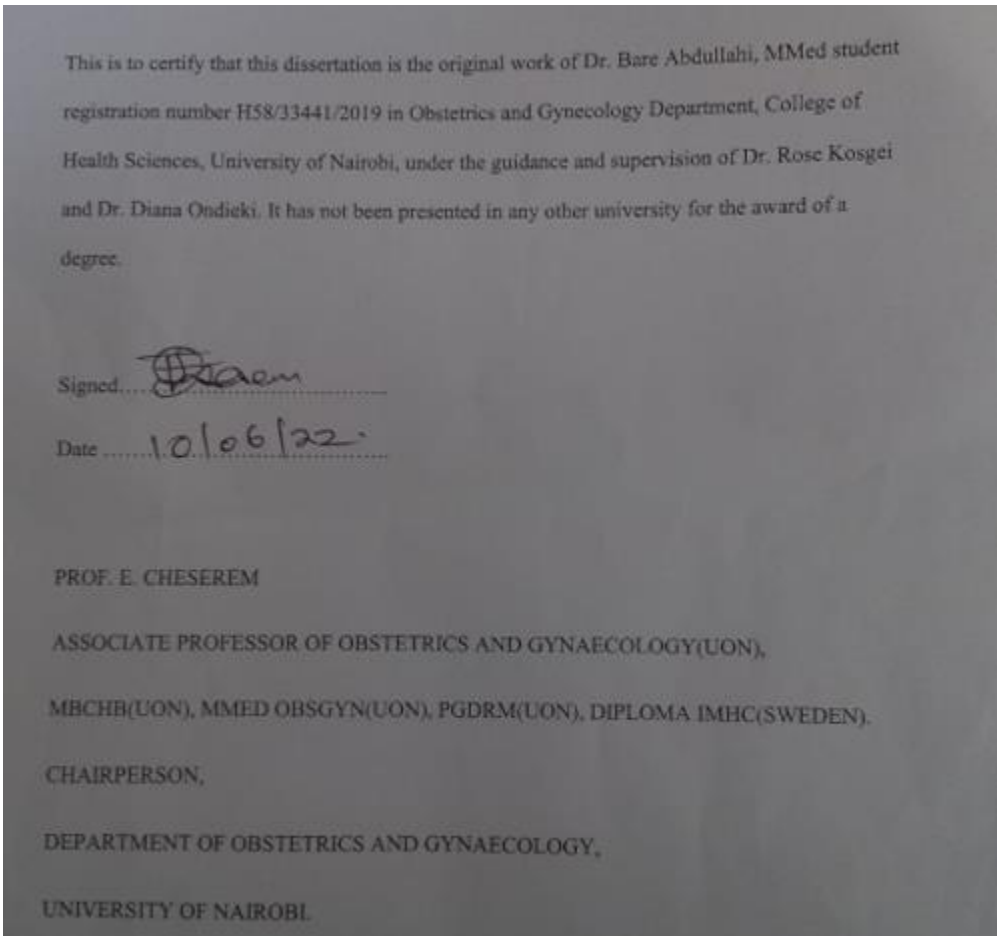
LECTURER,

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY,

UNIVERSITY OF NAIROBI.

Signature ……  ……Date …09/06/2022……

CERTIFICATE OF AUTHENTICITY



This is to certify that this dissertation is the original work of Dr. Bare Abdullahi, MMed student registration number H58/33441/2019 in Obstetrics and Gynecology Department, College of Health Sciences, University of Nairobi, under the guidance and supervision of Dr. Rose Kosgei and Dr. Diana Ondieki. It has not been presented in any other university for the award of a degree.

Signed.....

Date ..10/06/22.

PROF. E. CHESEREM

ASSOCIATE PROFESSOR OF OBSTETRICS AND GYNAECOLOGY(UON),

MBCHB(UON), MMED OBSGYN(UON), PGDRM(UON), DIPLOMA IMHC(SWEDEN).

CHAIRPERSON,

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY,

UNIVERSITY OF NAIROBI.

DEDICATION

This book is dedicated to my dear wife, Hamdia Ali, thank you for your unwavering support and encouragement, toward this journey, I cannot thank you enough. To my daughter Maryam and my son Ibrahim who were a source of happiness. To my entire family, thank you for your prayers and endless support and encouragement, without you, this will not have been possible.

ACKNOWLEDGMENTS

I wish to sincerely thank my supervisors, Dr. Rosse Kosgei and Dr.Diana Ondieki, for their support, and guidance throughout the study period. I am forever grateful.

I would like to also acknowledge my statistician, who helped a lot and who through him I learned a lot.

To the consultants, lecturers, and registrars in the department of Obstetrics and Gynaecology, for your input and support during the study period.

To my research assistant, this study would not have been possible were it not for your willingness to participate and work extra hours toward the timely completion of the study

LIST OF ABBREVIATIONS

AARI	Average annual rate increase
ANC	Antenatal care
BMI	Body mass index
CS	Cesarean Section
DIC	Disseminated intravascular coagulation
Dhs	Demographic health survey
ICU	Intensive care unit
KNH	Kenyatta National Hospital
MNM	Maternal near miss
PPH	Post-partum hemorrhage
UON	University of Nairobi
RH	Reproductive Health
R-LACS	Re-laparotomy after cesarean section
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Re-laparotomy: Operation performed within 60 days after the initial surgery, the purpose being to manage previous surgery complications, achieve hemostasis, and to clear intra-abdominal hematoma or abscess.

Maternal near-miss: Is defined by WHO as **"**A woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy".

Shock: State of tissue and cellular hypoxia due to either reduced oxygen delivery, increased oxygen consumption, inadequate oxygen utilization, or combinations of these processes.

Hypovolemic shock: Rapid body fluid loss that may result in multiple organ failures due to inadequate circulating volume and subsequent inadequate tissue perfusion.

Placenta accreta spectrum(PAS): Formerly called morbidly adherent placenta**,** refers to abnormal trophoblast invasion into the myometrium and sometimes to or beyond the serosa. It includes 3 subtypes:

- **placenta accreta**- Anchoring of chronic villi to the myometrium rather than decidua basalis.
- **Placenta increta**- Anchoring placental villi penetrate into the myometrium
- **placenta percreta**- Anchoring placental villi penetrate through the myometrium to the uterine serosa or adjacent organs.

Uterine atony: Failure of the uterus to contract following delivery.

Macrosomia: Refers to fetal weight above 4000g.

PPH: Refers to blood loss of more than 500mls following vaginal delivery and more than 1000mls after CS.

LIST OF FIGURES

LIST OF TABLES

TABLE OF CONTENTS

ABSTRACT

Background

Cesarean section (CS) delivery is on the rise worldwide and now accounts for more than one in five deliveries, this trend is expected to rise and by 2030 nearly 29% of total deliveries are likely to be through CS.

In LMIC maternal mortality following CS delivery is 100 times higher than in HIC. One of the short-term and rare complications of CS is re-laparotomy after CS (R-LACS). There are few studies on R-LACS in obstetric literature.

In Kenya, there is no study that looked at R-LACS, its therefore necessary to study the risk factors for R-LACS and associated maternal mortality(MM) and near-miss event(MNM) in the Kenyan content so as to improve the quality of care for CS patients and to reduce MM and MNM event associated with R-LACS.

Objectives: To determine risk factors for re-laparotomy after cesarean section and associated maternal mortality and near-miss events at KNH between 1st of January 2012 to 31st of December 2021.

Methodology: This was an exploratory case-control study(1:2 ratio). The data obtained were analyzed using SPSS version 26. We used Chi-square test of association/Fisher's exact test and independent samples T-test/Mann Whitney U test for categorical and continuous variables respectively, to determine the risk factor for R-LACS. A binary logistic regression was then carried out for each significant factor. Finally, all the significant risk factors were modeled using a backward stepwise multivariable logistic regression. This yielded the adjusted odds ratios with

their corresponding 95% confidence intervals for the significant risk factors for re-laparotomy following CS delivery.

The maternal mortality and near-miss events were summarized using frequency(n) and percentages and then compared between the 2 groups (cases and controls group) using Chi-square test of association/fisher's exact test. Binary, as well as multivariable logistic regression, was carried out.

Results: During the study period, 82 patients who underwent re-laparotomy following CS delivery were compared to 164 patients who did not undergo re-laparotomy after CS at KNH. The mean age for the cases was 31± 6.6 years versus 29 ± 5.9 years for the controls, which was statistically with a p-value of 0.022**.** Age above 35 years was associated with higher odds of R-LACS as compared to age less than 25 years, with OR 2.52 (95% CI =1.09-5.80). In backward stepwise multivariable logistic regression we noted; history of one previous scar (aOR = 2.91(95% CI 1.01-8.43), fetal macrosomia (aOR = 7.08 (95% CI 1.27-39.42), Preeclampsia with severe features (aOR = 9.17(95% CI 2.58-32.55), long operative duration of index CS delivery (aOR = 4.00(1.14-14.06),PPH (aOR19.31(95% CI 6.57-56.75),adhesions(aOR 3.65(95% CI 1.45-9.18) and need for blood transfusion (aOR 42.75(95% CI 10.33-177.01) to be independent risk factor for R-LACS.

There were 4% (3cases) of maternal mortality in patients who underwent R-LACS versus none in those who did not undergo re-laparotomy after CS. 60% of patients who underwent R-LACS experienced MNM events as opposed to only 2% in the control group. 11% of the cases experienced more than three MNM events,while none in the control group. Patients who underwent R-LACS had higher odds of experiencing MNM events as compared to those who did not undergo re-laparotomy, with aOR= 81.81(95% CI 23.64-283.17).

Conclusion: Patients who have had; one previous scar, macrosomia, preeclampsia with severe features, long operative duration of index CS delivery, PPH, adhesions and need for blood transfusion during or just after CS are at higher risk of re-laparotomy following CS delivery. The maternal mortality following R-LACS was 4%. Patients who underwent R-LACS following CS had 82 folds of experiencing at least one maternal near-miss event.

Recommendations: Patients with risk factors for R-LACS should be identified during ANC, followed closely, and be operated on by the most senior surgeon.

We recommend prevention and reduction of primary CS delivery, this will eventually lead to a lower repeat CS delivery rate.

Keywords: Re-laparotomy, cesarean section, risk, maternal mortality, near-miss.

CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

Caesarian section (CS) is a major procedure performed in day-to-day obstetric practice (1). It is a lifesaving procedure when medically indicated and prevents maternal and neonatal death. The rate of CS is increasing both in LMIC and HICdue to many factors such as maternal characteristics (extremes of ages, Obesity e.t.c), maternal request, labor induction, and epidural anesthesia(2–4).

From 1990 to 2014, the global CS rate increased from 6.7% to 19.1%, representing a 12.4% absolute increase and an average annual rate increase (AARI) of 4.4%. Countries that showed the

highest increase are the middle-income(MIC) countries with 14.6points (from 6.3% to 20.9%, AARI of 5.1%), followed by the high-income countries (HIC) with an absolute increase of 12.7points (14.5% to 27.2%, AARI of 2.6%), the low-income countries (LIC) the rate of CS rose by 4.2% (from 1.9% to 6.1%, AARI of 5%) (5).

South America has the highest CS rate with 42.9%, while Africa has the lowest rate of CS (7.3%), Egypt has the highest at fifty-two percent, and west Africa lowest at 3% (5).

In Kenya, similarly, there's a rise of CS rate from 4 % in 2003 to about 9 % in 2014, though still below the recommended WHO target (6–8). Two regions were noted to have a CS rate of above 15% (Nairobi county with 20.7% and former central province with 15.7%)

WHO recommends a CS rate of 10-15% (9), despite the rise of CS rate over 20%, this rise was not shown to be associated with a reduction in maternal and neonatal mortality rate (5,9,10).

Despite the improvement and advances in the; techniques, blood transfusion, anesthesia, and routine antibiotic use (2), CS just like any other operation is not without complications both in the short and long term, sometimes associated with the risk of maternal mortalities threefold that of vaginal delivery (11). One of the short-term complications is re-laparotomy after CS (R-LACS) (1).

R-LACS is considered a near-miss event with huge implications on the patient(12), some studies have reported maternal mortalities following re-laparotomy post-CS ranging from 2.9% to 33% (1,13,14). R-LACS, therefore, requires a good clinical decision, and early detection of patients who may require re-laparotomy after CS, since it may be the last and only resort to save the life of the patient (15). Some of the indications of re-laparotomy after CS are; intra-abdominal hemorrhage, hemodynamic shock, and PPH among others (1,13,16,17).

In 2018 Gedikbasi et al noted that there were only 3 descriptive studies on R-LACS in literature (1). In light of the very few studies published on R-LACS, this study aims to investigate the risk factors for re-laparotomy after CS and associated mortality and near-miss events at KNH between the 1st of January 2012 and the 31st of December 2021.

1.2 LITERATURE REVIEW

1.2.1 RISK FACTORS FOR RE-LAPAROTOMY

(a) Socio-demographic characteristics

Maternal socio-demographic characteristics differences and CS delivery have been examined in length by different studies both in LIC and HIC. Advanced maternal age was found to be associated with a higher rate of CS, though the rate of CS differed in different studies (18,19). Similarly, Penfield et al in USA showed a lower CS rate in young adolescent mothers, while the CS rate increased with the age of the mother in a linear fashion (20). Similar findings were reported by Nilsen et al in Tanzania and Manyeh et al in Ghana (21,22). Spek et al in Kenya equally, found that the CS rate increased with maternal age, the CS rate was thirteen percent for those less than 20 years while for those over 40 years the CS rate was over twenty-seven percent (23).

A study by Arunda et al, on CS delivery and associated sociodemographic factors in Tanzania and Kenya found that Women from urban, who were from richer families, well-educated, and employed were found to have a higher rate of CS delivery as compared to the once from rural, uneducated or up to primary level and from the middle class (24). Juma et al, in Kenya, similarly found that women who had formal employment had a higher rate of CS as compared to those who

did not have formal employment which was statistically significant(25). However, Spek et al in Kenya found that the majority of women who had CS were housewives while only Eleven percent of those who had CS were professionals (23).

Several studies on risk factors for R-LACS found that, the mean age for patients who underwent re-laparotomy after CS was between 25-35 years (1,13,17,26–28). Reham et al found that age over 30 years and low-socioeconomic status to be a significant risk for R-LACS (13). Similarly, Peker et al in Turkey found the mean age for patients who underwent R-LACS was 33 years while the control was 29 years which was statistically significant, similar findings were also reported by Levitt et al in Israel where age was found to be a significant risk factor for R-LACS (mean age for the cases 34 years and controls 31 years P< 0.001) (27). However, age was not found to be a risk factor for re-laparotomy after CS in 2 studies by S. Shinar et al and Ashwal et al (2,29). In 2013 Biswas et al did a study in Bangladesh on R-LACS and found that all the patients (55cases) who underwent re-laparotomy were housewife and their mean age was 25 (28).

There are few studies on R-LACS in literature (1,4). Similarly, in sub-Saharan Africa, there are few studies on this topic and none of the studies looked at the risk factors for R-LACS (30,31). In Kenya, there is no study on R-LACS, and little is known on the level of education, occupation which is particularly important for LMIC, this study therefore will look at the sociodemographic characteristic of the CS patients, in order to identify any association between sociodemographic factors and risk for R-LACS in the Kenyan context.

.

(b)Clinical characteristics

Repeat CS deliveries were found to be associated with adverse maternal outcomes. There's an increased risk of; abnormal placentation, uterine rupture, maternal near-miss, placenta previa, and PPH associated with previous CS delivery (32–34). Peker et al, 2019 in Turkey did a study on risk factors for R-LACS and noted that previous CS delivery was a risk factor for R-LACS (35), similar findings were also reported by; Akkurt et al, 2018 in Turkey (36), as well as Kessous et al, 2012 in Israel (37). However, contrary to the above studies, some studies that have looked at risk factors for R-LACS have shown that previous CS delivery did not increase the risk of re-laparotomy following CS delivery (2–4).

Several studies have examined the risk of CS complications versus the experience of the operating surgeon, in some studies, no difference was found between the surgeon's experience and CS complications (38,39), while another study found that CS performed by registrars had higher odds of complications with OR of 2.4 (40). Levin et al and Ashwal et al found that CS performed by the chief surgeon had a higher rate of re-laparotomy after CS as compared to the study group, one possible explanation was that CS performed by the chief surgeon were deemed probably complex requiring the attention of most senior surgeon (3,29). However, S.Shinar et al did a study on risk factors for re-laparotomy after CS and found that surgeon experience didn't influence the risk of re-laparotomy after CS(2).

In a systematic review and meta-analysis done in 2017, that compared maternal and fetal complications in regards to elective versus emergency CS delivery, women who had EMCS were at higher risk of re-operation as compared to those who had an elective cesarean delivery (41). Similarly, some studies which evaluated the risk factors for re-laparotomy after CS, found that

patients who had EMCS had a higher risk for R-LACS as compared to those who had elective CS (3,29,36). However, contrary to the above studies EMCS was not found to be a risk factor for re-laparotomy after CS in a study by Levitt et al (27).

A survey by WHO in 2020, on the adverse maternal outcome associated with the type of anesthesia administered during CS delivery inLMIC, found that local anesthesia was associated with lower odds of an adverse maternal outcome as compared to general anesthesia which had higher odds of; maternal death, maternal near-miss and ICU admission (42). However, Gori et al, 2007 and Thangaswamy et al, 2018 did not find any association between type of anesthesia and adverse pregnancy outcome (43,44). S. Shinar et al did a study in Israel on risk factors for R-LACS and found that general anesthesia was a significant risk factor for re-laparotomy following CS delivery (2), similar results were also reported by Levitt et al in Israel (27).

Peled et al, 2011 did a study on the time of CS delivery and associated adverse maternal outcome after unscheduled CS delivery and found that CS done during the night shift were associated with a higher adverse maternal outcome as compared to the CS performed during daytime (29). Contrary to the findings of the above study, Makori et al, 2015 in Kenya, did a similar study and found no difference in outcome between CS done during the day and those performed during night shift (45).

Peker et al 2019 in Turkey, did a study on risk factors for re-laparotomy after CS and noted that patients who underwent re-laparotomy were mostly patients who had CS during off-hours (16:00hrs to 08:00 am) as compared to those whose who did not require re-laparotomy, this difference was statistically significant (35). However, two other studies by; Shinar et al (2) and Ashwal et al (29), found that time of CS did not increase the risk of re-laparotomy after CS.

Long operative duration in a repeat CS delivery was found to be associated with adverse maternal outcomes, as well as a risk factor for post-operation CS delivery complications in a study done by Rottenstreich et al in 2018 (46). Similarly, Wolfe et al found that a long operative period of CS delivery was associated with adverse maternal outcomes (47). S.Shinar et al 2012 in Israel did a study on R-LACS and found, the long operative period of CS to be a risk factor for R-LACS(2). These findings were also shared by other studies that found a long operative period of CS to be a significant risk factor for R-LACS (3,27,29,36).

Adhesions following previous pelvic surgery are common, leading to maternal morbidity, mortality as well as re-operation after CS delivery (48). Ashwal et al in Germany did a study on risk factors for R-LACS and found that adhesion during CS delivery was a significant risk factor for R-LACS (29). Similarly, surgical difficulties during initial CS, sometimes requiring additional intervention and call for assistance were found to be a risk factor for R-LACS (36,49).

High birth order was found to be a significant risk factor for poor maternal outcomes following CS delivery in a study by Rowaily et al in Saudi Arabia (50). Peker et al in Turkey, found that patients who had re-laparotomy after CS had a higher parity as compared to those who did not undergo re-laparotomy, which was statistically significant (35), similar findings were also reported by kessous et al in Israel (37). However other studies found no difference in parity between the patients who underwent R-LACS and those who did not undergo re-operation after CS delivery (2,4,29).

In systematic review and meta-analysis in 2021, found that early gestational age CS delivery was associated with maternal intra-operative and post-operative complications (51). Likewise, Kessous et al in Israel found that preterm CS delivery was associated with a higher rate of R-LACS as opposed to the controls (37). However, 4 other studies found no difference in gestational age

between the group who underwent re-laparotomy after CS and those who did not undergo R-LACS (2,3,27,35).

A systematic review and meta-analysis in 2019 on the adverse outcome associated with fetal macrosomia, found that fetal macrosomia was associated with adverse maternal outcomes (PPH, risk of CS delivery, Obstetrics anal sphincter injuries) as well as poor neonatal outcomes (52). Turkmen et al also found that fetal macrosomia was associated with serious adverse maternal outcomes (53). Ahmed E. et al in Egypt did a study on risk factors for re-laparotomy after CS and found that fetal macrosomia above 4kg was a significant risk factor for R-LACS (4). However, Peker et al in Turkey found that fetal weight was not associated with the risk of R-LACS (35), this finding was also supported by a study done in Israel (2).

Twin gestation was found to be associated with adverse maternal outcomes as opposed to singleton pregnancies delivered via CS (54), S. Shinar et al in Israel did a study in 2012 on risk factors for R-LACS and found that twin gestation was higher in patients who underwent re-laparotomy after CS than the controls groups, although this difference was not found to be statistically significant (2). Contrary to the above-cited studies, other studies that assessed the risk factors for re-laparotomy after CS found that twin gestation did not risk the risk for R-LACS (3,29).

Female fetal sex was found to be associated with atonic PPH and the need for blood transfusion (55). While Liu et al in China found that male fetal sex was found to be associated with adverse pregnancy outcomes (56). The sex of the fetus was also found to be a risk for R-LACS, S. Shinar et al in Israel, found that female fetal sex to be a risk factor for R-LACS (2), while a similar study by Akkurt et al in Turkey, found that the sex of fetus did not increase the risk of R-LACS(36).

Lugobe et al in Uganda looked at the risk of developing adverse pregnancy in patients with hypertensive disorders during pregnancy (HDP), and found that; PPH, need for ICU admission, need for laparotomy, and hysterectomy were some of the adverse outcomes associated with HDP (57). Sambu et al in Kenya did a study on the adverse outcome associated with eclampsia and similarly found that; abruption placenta, PPH, maternal death, and cerebral hemorrhage were some of the adverse maternal outcomes associated in patients with eclampsia (58). Levin et al in Israel found that hypertensive disorders in pregnancy was higher in patients who underwent re-laparotomy after CS, however, this was not found to be statistically significant(3), contrary to the above study finding, other studies found, that preeclampsia with severe features to be a risk factor for R-LACS(4,36,37).

Placental abruption(AP) is an obstetric emergency and associated with adverse maternal outcomes (59), Mukherjee et al also noted that AP is associated with severe maternal outcomes (60). Similarly, Gedikbasi et al in Turkey found that AP was a significant risk factor for R-LACS with an odds ratio of 15 (1). Akkurt et al in Turkey also found that placental abruption was higher in patients who underwent R-LACS than those who did not undergo re-operation after CS delivery (36). This finding was supported by two studies done in Israel by Levin et al with an odds ratio of 17 (3) and Kessous et al with an odds ratio of 4 (37), which demonstrated that AP was a significant risk for R-LACS. However, Levitt et al in Israel found that AP did not increase the risk of R-LACS (27).

Uterine rupture is an Obstetric emergency and is associated with adverse maternal outcomes (61). Astatikie et al in Ethiopia found that uterine rupture was associated with a higher rate of severe maternal outcomes and with approximately seven percent of maternal death (62). Mrema et al in Tanzania likewise found that uterine rupture was associated with adverse maternal outcomes with

2/3 of the patients who had uterine rupture requiring hysterectomy, while 10 cases of the patients eventually required re-operation. Fortunately, there was no maternal mortality in this study associated with uterine rupture (63). Kessous et al in Israel did a study on risk factors for R-LACS and found that uterine rupture was an independent risk for R-LACS after CS with an odds ratio of 22 (37).

Pencole et al, 2021, did a study on risk factors for re-laparotomy after CS for intra-abdominal hemorrhage and noted that tachycardia above 120 beats/min was the strongest predictor of re-laparotomy for intra-abdominal hemorrhage, followed by hypotension (SBP <90mmHg) as the second commonest predictor of re-laparotomy for intra-abdominal hemorrhage(49). Similar findings was reported by peker et al, where post-operative pulse rate was high in patients who underwent re-laparotomy compared to the controls, this difference was statistically significant, whereas the post-operative systolic and diastolic blood pressure were low in patients who underwent re-laparotomy after CS as opposed to the control group (35). Blood loss during the CS preceding re-laparotomy was also found to be a risk factor for re-laparotomy after CS (35), Peker et al found that the mean blood loss for patients who underwent re-laparotomy after CS was 1987mls as compared to 359mls in the control group (35) which was statistically significant. Similarly, Pencole et al found that blood loss above 500mls during initial CS was a significant risk factor for re-laparotomy after CS for intra-abdominal hemorrhage (49). Peker et al also noted that the need for blood replacement was significantly higher in patients who underwent re-laparotomy after CS as compared to the controls, on average 4 units of blood were transfused in the re-laparotomy group as compared to the controls group that did not required blood transfusion after the CS delivery (35).

Placenta previa(P.P) is a well-known major cause of obstetrics hemorrhage and one of the causes of adverse maternal outcomes in LMIC. It complicates about 0.3 to 1.5% of pregnancies. PP can lead to catastrophic hemorrhage leading to D.I.C and maternal mortality(64). Kollmann et al, 2015 in Austria did a study on P.P and found that placenta previa was associated with adverse maternal outcomes such as; APH at 42%, PPH at 7%, anemia at 30%, and hysterectomy at 5 %(65).

Alsammani et al, 2021 in Sudan did a descriptive prospective study on maternofetal outcome in patients with placenta previa and found that; twenty-three percent of patients who had P.P hysterectomy was performed, and unfortunately with six cases of maternal death (66). Ahmed et al 2014, Egypt did a prospective case-control study on risk factors for R-LACS and found placenta previa to be a risk factor for R-LACS with OR of 6.9(4). Similarly, Kessous et al found placenta previa to be a risk factor for R-LACS with OR 14.4 (37).

Postpartum hemorrhage (PPH) is also a known major cause of maternal mortality worldwide (67). A systematic review of maternal mortality and near-miss events secondary to PPH done in 2017 found PPH mortality index was approximately 7%. The mortality index was highest in LMIC (68). In Kenya, PPH is also the most common cause of maternal mortality contributing to about 57% of all maternal mortality (69). Kessous et al in Israel 2009, did a study on risk factors for R-LACS and found PPH with OR 58.8 to be a significant risk factor for R-LACS(37). Similar findings were also reported by levitt et al in Israel 2015 (27).

Obesity is a precursor and a known risk factor for chronic diseases like HTN, DM and is associated with adverse pregnancy outcomes, especially in pregnant women with a BMI of 40kg/ m2 were found to be at increased risk of CS delivery and Pregnancy-related complications (70). Similarly, obesity was found to be a major cause of maternal mortality in a confidential inquiry report done between 2000 and 2002 done in the U.K (71). S. Shinar et al did a study in Israel on risk factors

for R-LACS and found that patients who delivered through CS with a BMI of above 25Kg/ m^2 were less likely to be re-operated after CS through this was not statistically significant (2). Contrary to the above study, Reham et al in Egypt noted that higher BMI was a significant risk factor for R-LACS (13).

Re-laparotomy following CS delivery is considered a maternal near-miss event, studies on this particular topic are scant in literature (4), more so in sub-Saharan Africa which contributes to over 2/3 of worldwide maternal mortalities (72). The few studies in this region on R-LACS did not look at the risk factors for R-LACS (30,31). In Kenya, no similar study was done, this study will therefore look at the risk factor for re-laparotomy following CS delivery and associated maternal mortality and maternal near-miss event in the Kenyan context, in order to improve the quality of care for CS patients and reduce adverse maternal outcomes associated with R-LACS, in line with WHO directives of 2015, where all countries are expected to reduce their MMR by 2/3 using 2010 MMR as the baseline (73).

1.2.2 Maternal mortality and near-miss events associated with R-LACS

(a) Maternal mortality

Maternal mortality remains to be very high worldwide, unfortunately, in 2017, it's estimated that about 295,000 women died from pregnancy-related complications. The vast majority of this death about 94% were from low-resource settings and most were due to preventable causes (73). Sub-Sahara Africa alone accounted for two-thirds (196,000) of maternal death (72).

In Kenya, the maternal mortality ratio according to 2014 KDHS was 362 deaths per 100,000 live births (74). This figure is still high but fortunately, there is a decline in the maternal mortality ratio from 678 deaths per 100,000live births since 2003 (8).

In 2015, WHO published a direction-setting report toward ending preventable maternal mortality by 2030 under the SDGs. The recommendation was; to reduce global MMR by < 70 deaths per 100,000 live births, countries are expected to reduce their MMR by 2/3 from their 2010 figure as the baseline and by 2030 no country should have MMR twice higher than the expected global target of 70 MMR (73).

Given the high maternal mortalities and the global goal of reducing maternal mortality and improving quality of care, several studies have looked at maternal mortalities associated with re-laparotomy after CS (1,2,4,27). In 2011, Akther et al did a prospective study in Bangladesh on re-laparotomy after CS delivery and found that patients who underwent R-LACS had a high maternal mortality rate of 33% (14). While in 2016, M. Reddy et al did a study on risk factors for re-laparotomy after CS in India and found that patients who underwent re-laparotomy after CS had a maternal mortality rate of 9.5% (26). Similarly, Gedikbasi et al in Turkey reported one case of maternal death following re-laparotomy after CS (2.9%). However, five other studies, 2 in Turkey and 3 in Israel fortunately did not report any maternal mortality in patients who had R-LACS (2,27,35–37).

In Africa, there are few studies, done on re-laparotomy after CS delivery and only 2 in sub-Saharan Africa (30,31). Reham et al in Egypt did a cross-sectional study in 2017 on R-LACS, the maternal mortality following R-LACS was 5% (8cases). Similarly, Ahmed et al 2014 did a study in Egypt on the risks, indications, and management options of R-LACS, he reported high maternal mortality of 11.5% following R-LACS (4).

Seffah et al in Ghana did a retrospective descriptive study in Ghana on R-LACS and reported 9% (4cases) of maternal mortality in patients who underwent re-laparotomy after CS (30). However, Fazari et al did a descriptive cross-sectional prospective study in Sudan and found a high maternal death following R-LACS,6cases (17.6%) (31).

(b) Maternal near-miss events

Assessment of women with maternal near-miss (MNM) events may help in reducing this complication and to a large extent reduce maternal mortality. In order to improve the quality of care and reduce maternal morbidity and mortality (75), WHO developed a standard definition for maternal near-miss, based on 3 set criteria; disease entity, intervention, and organ dysfunction (76). However this tool was found to be not fully applicable to low-resource settings, Tura et al did a study on "Adaptation of WHO MNM Tool for use in sub-Saharan Africa" and found that out of the 25 parameters in the WHO MNM tool, 6 were found not to be applicable in sub-Saharan Africa and low-resource settings (77).

Maternal death was generally used to gauge the quality of maternal care and the health system caring for these women (78). However, it's estimated that for every maternal death from a pregnancy-related cause, 20 to 30 other women experience maternal near-miss events (78,79). The use of maternal near-miss as an indicator of maternal health and quality of care is being encouraged and promoted as well (76). In 2019, a systematic review and meta-analysis on the global prevalence of maternal near-miss events found that "18.67 per 1000 live birth of the general of the world suffered from maternal near-miss based on WHO criteria"(80). Similarly, Goldenberg et al did a study on maternal near-miss in 7 low-resource countries, 4 of which were in Africa, and reported a 4% incidence of maternal near-miss events (81). In Kenya, Owolabi et al did a study in

2018 on the incidence of MNM, this was findings from 54 referral hospitals., the MNM in this study was 7.2/1000 live birth, and the MNM events was compared to maternal death and found that 20 MNM events for every maternal death (69). Similarly, Mwebia Wk et al did a study on MNM events after the introduction of free maternity services in Embu county referral hospital in Kenya, in 2018, and found; severe PPH and preeclampsia with s.features to be the leading cause of MNM (82). A similar finding was also reported by, Owiti et al who did a study on MNM and mortality at KNH in 2019 and found hemorrhage to be the leading cause of MNM at KNH(83).

Akkurt et al did a study in Turkey on risk factors for R-LACS and related MNM and found that forty-seven percent (22cases) of patients who underwent re-laparotomy experienced MNM events (36). Similar findings were reported by Levit et al in Israel, where 47 % of patients who underwent R-LAC required I.C.U admission (27), while Gedikbasi et al in Turkey also noted that 5.7 % of the patients who underwent R-LACS I.C.U admission (1).

Ahmed et al in Egypt did a study on risk factors for R-LACS and found that; 26.9% of patients who underwent R-LACS required I.C.U admission, 11.5% developed D.I.C while 7.7% had cardiac arrest, unfortunately, 46% of the patients subtotal was done (4). Two studies done in sub-Saharan Africa similarly reported MNM events; Seffah et al in Ghana reported that 39% of patients who underwent R-LACS required hysterectomy (30), while Fazari et al in Sudan reported that the majority of patients who underwent R-LACS required blood transfusion; 58% of the patients who underwent R-LACS required at least 1-5 units of blood, 27% required 6-10 units, 9% required 11-15 units and 6% required 16-20 units. 11% of the patients who underwent R-LACS developed renal failure and required dialysis, one case because of the massive transfusion developed pulmonary edema. Unfortunately, 15% of the patients who were re-operated after CS hysterectomy was performed so as to save their life and as the last resort (31).

R-LACS is a maternal near-miss event, associated with adverse maternal outcomes (12), the literature on this subject is not well explored, especially in sub-Saharan Africa, a region with a high burden of maternal mortality (30,31,72). In Kenya, no similar study was done, therefore this study will identify any risk factor associated with R-LACS, in order to improve the quality of care for CS patients and reduce maternal mortality and near-miss events associated with R-LACS.

1.3 Conceptual framework

This study examined the presence of risk factors for re-laparotomy following CS delivery for patients who delivered through CS at KNH and at the same time required re-laparotomy after CS within 7 days. Maternal mortality and near-miss events between the two groups were compared as well. The relationship between independent variables and dependent variables is illustrated in the conceptual framework below. The risk factors (independent variables) can be classified into socio-demographic and clinical characteristics. The dependent variable was re-laparotomy post-CS delivery and associated maternal mortalities and near-miss events. The relationship between the sociodemographic characteristics and clinical characteristics is unidirectional. Advanced maternal age was found to be associated with a higher rate of CS, similarly, women from the urban regions, well-educated and employed tend to have a higher rate of CS delivery.

The risk of preeclampsia is higher in young pregnant women as well as those above 35 years of age. The relationship between sociodemographic characteristics and R-LACS is unidirectional, age over 30 years and low socio-economic was found to be a risk factor for R-LACS. Similarly,

clinical characteristics and R-LACS is unidirectional, patients who had; repeat CS delivery, CS performed by the chief surgeon, and longer duration of CS operation were found to have a higher rate of R-LACS.

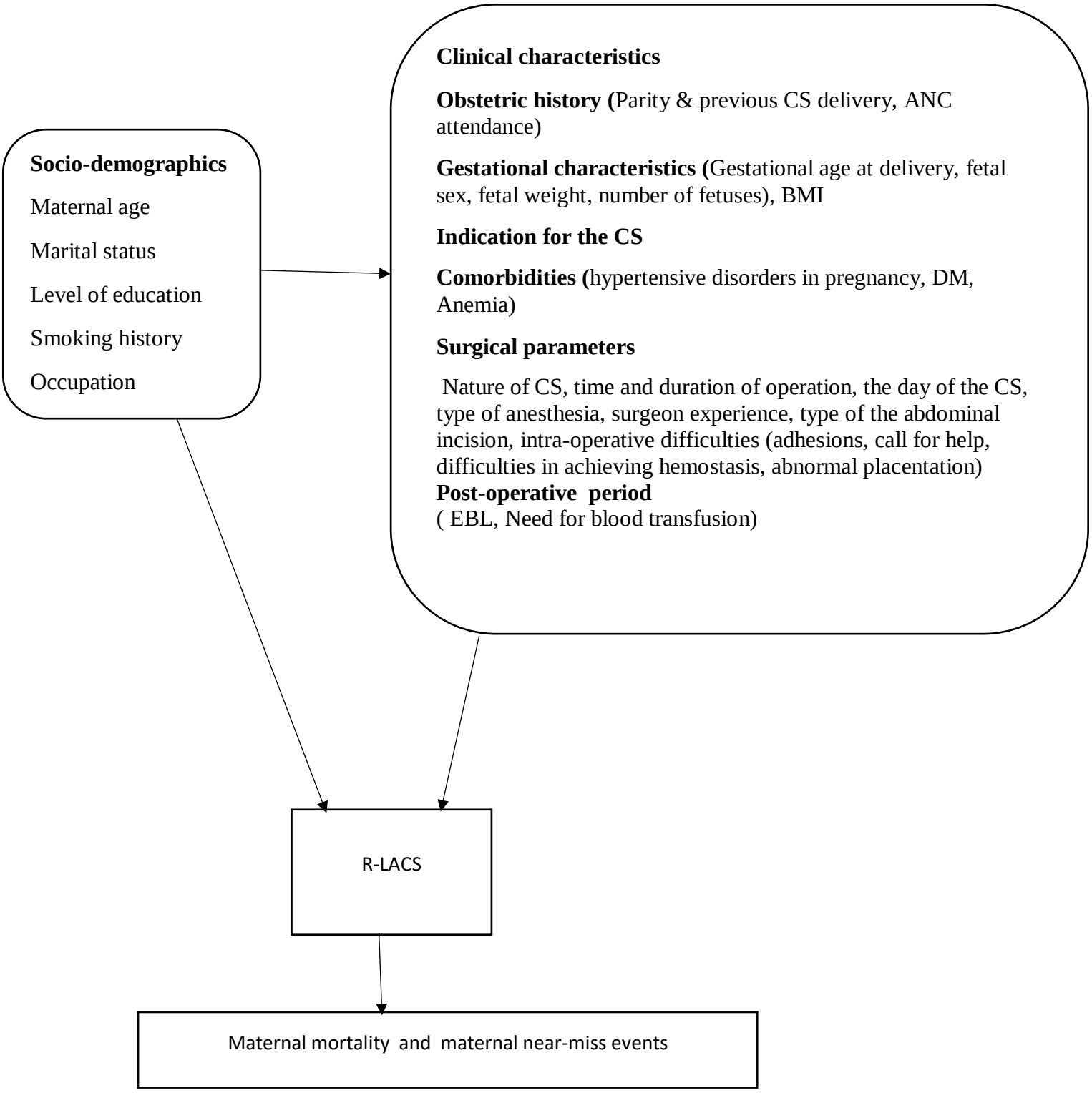


Figure 1: Conceptual framework

1.4Justification

The rate of CS has increased throughout the world, however, the safety of the operation has improved but it is still a major operation and associated with risk and complications both in the short and long term (84,85).

Re-laparotomy is one of the early post-operative period complications, with a huge impact on the patients and the medical team (11). Although a rare complication, it is associated with an increased need for blood transfusion, hysterectomy, long hospital stay, maternal mortality, and MNM events (1,30,37).

There are few studies published on risk factors for R-LACS and the literature on this subject are few and inconsistent (36). Gedikbasi et al reported in 2008 that there were only 3 descriptive studies on re-laparotomy after CS in literature (1).

Worldwide about 810 women die each day due to pregnancy and childbirth-related complications, which are mostly preventable(86). Kenya has a high maternal mortality rate of 362 per 100,000 live birth(87). By 2030, countries are expected to reduce MMR in line with SDG 3 to less than seventy per 100,000 births, and no country is expected to have more than twice the global average of MMR (86). There is no data available on risk factors for re-laparotomy and maternal outcomes associated with it locally. hence the need to identify the; risk factors, maternal morbidity, and mortality associated with re-laparotomy following CS, in order to avoid unnecessary operations, improve the quality of care as well as decrease maternal morbidity and mortality following CS delivery.

1.5 Research question

What are the risk factors for re-laparotomy after cesarean section and the associated maternal mortality and near-miss events at KNH within the first seven days?

1.6 Objectives

1.6.1 Broad objectives

To determine the risk factors associated with re-laparotomy following CS and the associated maternal mortality and near-miss events at KNH within the first seven days.

1.6.2 Specific Objectives

Among patients who undergo CS at KNH;

1. To determine the sociodemographic factors associated with re-laparotomy
2. To determine the clinical factors associated with re-laparotomy
3. To compare the maternal near-miss events and maternal mortality between patients who underwent re-laparotomy versus those who did not.

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study design

This was an exploratory case-control study. Patients who have undergone re-laparotomy at KNH between 1st of January 2012 to 31st of December 2021 within 7days post-CS served as the cases, for each case, we selected two patients who were operated on (CS) same period as the cases but did not require re-laparotomy within seven days of the CS (control) to give a ratio of 1:2. We used the record of patients and no actual patient participated in the study.

2.2 Study site and setting

This study was carried out at Kenyatta National Hospital(KNH), the oldest hospital and the largest teaching and referral both in Kenya and East Africa. Located in Nairobi, the capital city of Kenya, about 3 km from the city center, founded in 1901, covers an area of 45.7 hectares and with over 1900 bed capacity. The hospital serves as a teaching facility for both University of Nairobi and Kenya medical training institute. The hospital has a health information department that was established in the early 1970s, which receives high volumes of both outpatient files over 500,000, and inpatients files over 170,000 per year. The department is currently in the process of computerization of both inpatient and outpatient data. The Obstetric unit has 3 combined antenatal and postnatal wards (GFA, GFB,1A), a labor ward,2 maternity theatres, and one dedicated C.C. U (GFB CCU).

Labor ward, postnatal and antenatal wards, and maternity theatres are usually managed by; 2 residents in Obstetrics and Gynecology, Medical Officers, Medical Officers Interns, and midwives. A consultant Obstetrician and Gynecologist is always on Call to give assistance and guidance.

2.3 Study Population

The study populations were patients who delivered through CS at KNH between the 1st of January 2012 to the 31st of December 2021. The cases were patients who delivered through CS at KNH and required re-laparotomy after CS within 7 days of delivery, while those who delivered through CS and did not undergo re-laparotomy within seven days served as the controls. We used records of patients who either underwent or did not undergo re-laparotomy within 7 days after CS delivery.

Inclusion criteria

1. Patients who delivered through CS at KNH and required re-laparotomy following CS delivery within 7 days of delivery (cases)
2. Patients who delivered through CS at KNH but did not undergo re-laparotomy after CS within 7 days of delivery (controls).

Exclusion criteria

1. Patients who delivered through CS at KNH but re-laparotomy following CS delivery done after 7 days of delivery.
2. Patients with a known history of bleeding disorders who delivered through CS at KNH and required re-laparotomy after CS within 7 days of delivery
3. Files of Patients who delivered through CS at KNH, with incomplete data.
4. Patients who had CS done at another facility but referred to KNH for re-laparotomy

5. Patients who had CS done at KNH but the date of re-laparotomy after CS is not indicated.

2.4 Sample size and sampling procedure.

2.4.1 Sample size calculation

We used the Kelsey et al (88) formula for sample size calculation. The following assumptions from a study conducted by Kessous et al (37), were considered during the sample size calculation. The study found that uterine rupture was a risk factor for R-LACS, the proportion of uterine rupture was 0.3 % in the controls and 6.3 % in the cases. This was statistically significant with a p-value of < 0.001

$$N_{Kelsey} = \frac{\left(z_{\alpha/2} + z_{\beta}\right)^2 p(1-p)(r+1)}{r(p_0 - p_1)^2}$$

Variable Notations:

α The probability of type I error (significance level) is the probability of rejecting the true null hypothesis =0.05

β The probability of type II error (1 – the power of the test) is the probability of failing to reject the false null hypothesis =0.20. The power of this study is 80% (0.8)

P The mean of $\mathbf{P_0}$ and $\mathbf{P_1}$

$\mathbf{P_0}$ The proportion of the cases with uterine rupture was 6.3%

$\mathbf{P_1}$ The proportion of the controls with uterine rupture was 0.3%

r The ratio of controls to cases. r=2

N_{Kelsey} Required sample size for the population one group using Kelsey formula.

Using Kessous et al (37), the uterine rupture proportion was 0.3 % in the controls and 6.3 % in the cases, this gave us a sample size of 74 and 147 for the cases and controls respectively.

Provision for missing and incomplete data with a 10% margin of error gives us a final sample size of 82 records for the cases and 164 records for the controls. A total of 246 records of patient files retrieved from KNH records office were analyzed.

2.4.2 Sampling procedure

We used a consecutive sampling technique to identify records of the cases going back from the 31st of December 2021 until the desired sample size is obtained. However, for the controls, we used a stratified random sampling method to partition the sample into strata according to each year from 2012 to 2021. Within each stratum, we did randomization to select files per year.

Study flow chart

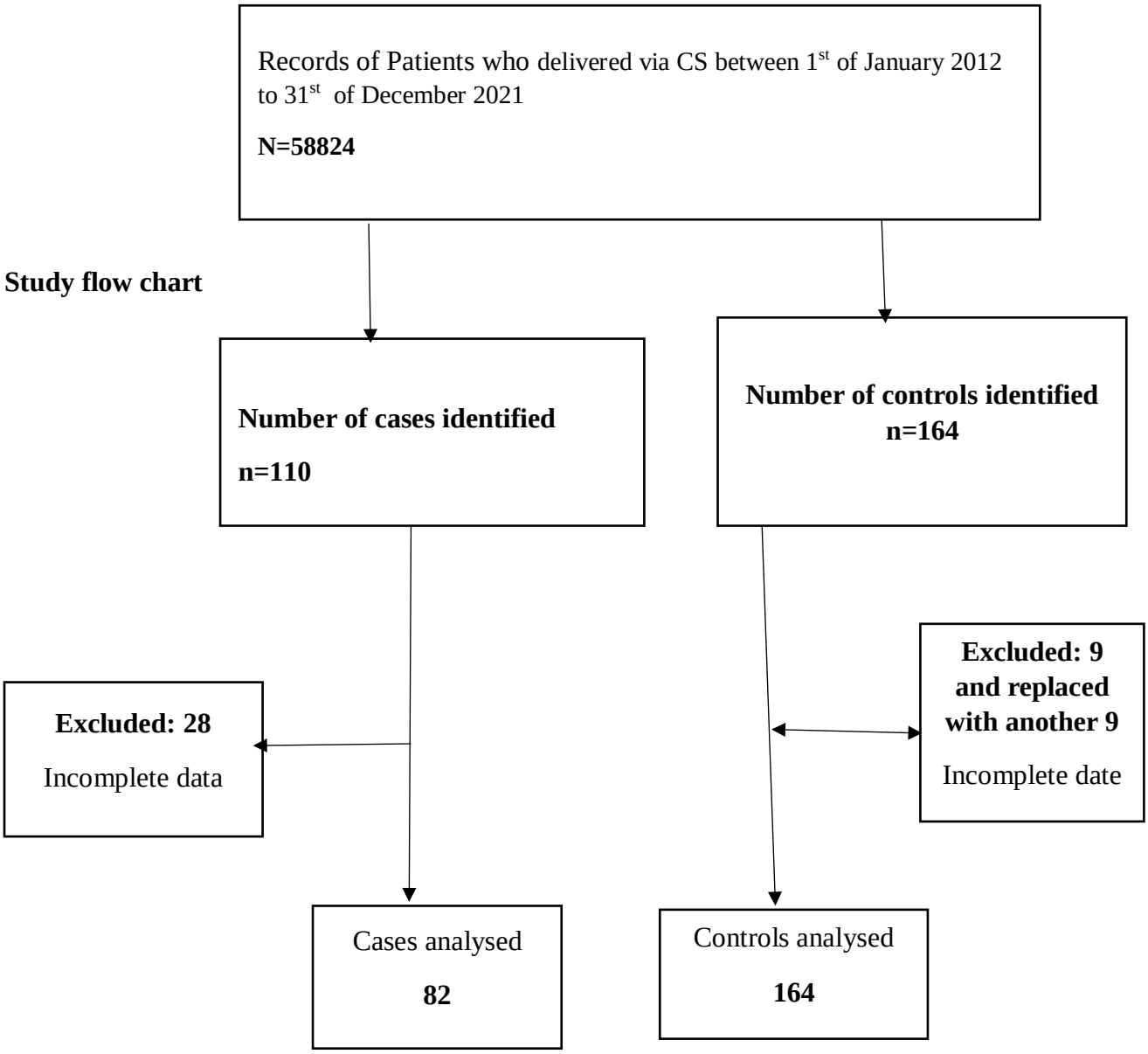


Figure 2: Study flow chart

2.5 Data collection tool and procedure

The data for this study were collected from patients' files using the data entry form in appendix 1, designed to contain questions on both dependent and independent variables. The study instrument was tested before data collection to correct for ambiguity and misinterpretation of the questions.

The data collection instruments reflected the objectives of the study so as to ensure the validity of the study. For the maternal near-miss events that occurred in the cases and controls group, we used the WHO maternal near-miss event tool to collect data (12).

We identified and captured the inpatient number of all patients who underwent re-laparotomy after CS in the register of the following units; maternity theatre, main theatre, post-natal wards (GFA, GFB, and 1A), GFB CCU, and acute gynecology unit (1D) from 31st of December 2021. Files for patients who underwent re-laparotomy (cases) were retrieved from the central registry (the health record at KNH) with the help of patient IP no. As for the control group, we used a stratified random sampling technique. Relevant information was collected for the study based on the dependent and independent variables.

2.5 Study Variables

Table 1: study variable

SPECIFIC OBJECTIVES	EXPOSURE VARIABLE	OUTCOME VARIABLE	SOURCE OF DATA
To compare Sociodemographic characteristics	1. Maternal age 2. marital status 3. Level of education 4. Smoking history 5. Occupation	R-LACS	Patients files
To compare clinical characteristics	1. parity, previous CS, ANC history 2. Gestational age, fetal sex, fetal weight, number of fetuses, BMI 3. Indication of CS 4. Surgical parameters (Nature of CS, time and duration of the operation, day of the CS, type of anesthesia, surgeon experience, type of incision), intra-operative difficulties (adhesions, call for help, difficulties in achieving hemostasis, and abnormal placentation) 5. Post-Operative period; EBL, need for blood transfusion	R-LACS	Patients files
To compare maternal mortality and near-miss events	Those who underwent R-LACS versus those who did not	Maternal death and near-miss events	Patients files

2.7 Data collection and Quality control

Data was collected by the Principal investigator (PI) with the help of two research assistants (2 nurses) using a structured questionnaire in appendix 1. The research assistants were trained on data collection, confidentiality, and techniques for extraction of data accurately, first, they observed and then collected the data under supervision. Similarly, during the data collection period, the research assistants were supervised by the PI on regular basis, to ensure all the relevant information is collected as required.

The PI and the two research assistants reviewed medical records of the selected files and collected data on the risk factors for re-laparotomy following CS and associated maternal mortalities and near-miss events with the help of the data entry form in appendix 1.

we then entered the data into MS Excel software, and validation and cleaning were performed.

The patient's information was kept in a private laptop and encrypted to ensure privacy and confidentiality.

The filled data entry form was kept in a safe and confidential place and was only accessible to the principal investigator. Data were kept in a private laptop and protected using a password and backed up using an external hard drive to ensure privacy and confidentiality. Data will be destroyed at the end of the study through shredding.

On completion of the data entry, data was then exported into a statistical package (SPSS-Version 26) for analysis.

2.8 Data Analysis

The data obtained was analyzed using SPSS version 26

Objectives 1 and 2: Descriptive statistics such as means, standard deviations, counts, and proportions were used to describe the sociodemographic and clinical characteristics of the study participants who underwent re- laparotomy and those who did not. To compare the 2 groups, we used the Chi-square test of association/Fisher's exact test and independent-sample T-test/Mann Whitney U test for categorical and continuous variables respectively. A P-value of < 0.05 showed statistical significance.

A binary multivariable logistic regression was used to evaluate the association between re-laparotomy and the clinical characteristics of patients while adjusting for sociodemographic characteristics. This gave us crudes odds ratio and corresponding confidence intervals. A P-value of less than 0.05 was considered statistically significant.

Finally, all the significant risk factors were modeled using a backward stepwise multivariable logistic regression. This yielded the adjusted odds ratios with their corresponding 95% confidence intervals for the significant risk factors for re-laparotomy following CS delivery. A P-value of less than 0.05 was taken to be statistically significant.

Objective 3: The maternal mortality and near-miss events were summarized using frequency(n) and percentages and then compared between the 2 groups (cases and controls group) using Chi-square test of association/fisher's exact test. Binary, as well as multivariable logistic regression was carried out. A p-value of less than 0.05 was considered statistically significant.

2.9 Study results Dissemination and Closure

The study result, as well as the findings of this study, will be presented to the Department of Obstetrics and Gynecology. The findings of the study will also be presented at conferences and during continuous medical education (CME).

The findings of the study will be sent to peer-review journals for publication.

2.10 Ethical consideration

This study was approved by KNH/UON ethics and research Committee. Similarly, we received permission to collect data from KNH departments of Obstetrics and Gynecology as well as KNH records office.

2.11 study strength

To the best of our knowledge, this is the first study in sub-Saharan Africa on risk factors for R-LACS as well as one of the few that compared maternal mortality and MNM events between the patients who underwent R-LACS versus those who did not.

We were able to evaluate multiple risk factors since we used a case-control study.

2.12 Study limitation

Due to the retrospective nature of the study, we were not able to get some data such as BMI

There's no coding for re-laparotomy cases after CS at KNH, there's a likelihood of missing some files. For patients who underwent re-laparotomy after CS in KNH maternity theatre, there is an incident book, where patients who develop compilations post-CS are recorded, including the patients who required re-operation after CS delivery, inpatient number, the nature of the complication, and the management is well captured. With the help of the inpatient number from

the incident book in maternity theatre, we were able to retrieve files of patients who underwent R-LACS in maternity theatre from the records office at KNH. As for the patients who required re-laparotomy after CS while in the postnatal wards, we went through the inpatient register of different Obstetrics units; GFA, GFB, 1A, GFB CCU, 1D, and main theatre, we captured the inpatient number of patients who underwent R-LACS within 7days from 31st of December 2021 going backward until the desired sample size is achieved. With help of the inpatient number of patients who underwent R-LACS, we retrieved the files of those patients from KNH records office.

CHAPTER THREE: RESULTS

During the study period, there were 157,629 total deliveries, out of this 58,824 were CS deliveries representing 37.3% of the total deliveries.We noted a gradual increase in CS rate from 40.5% in 2012 to 54% in 2021, representing a 13.5% increase in CS rate over a 10-year study period. The high CS rate is way above the WHO recommended CS rate, this is a major concern but this could be because KNH (study site), is the biggest referral hospital in Kenya, and complicated obstetrics cases from all over the country are referred to KNH. During the data collection process, we identified 110 files of patients who underwent R-LACS at KNH, we excluded 28 files because of missing data (i.e theatre notes, biodata, and obstetrics history) and analyzed 82 files. However, for the controls we selected 164 files, we then excluded 9 files due to incomplete data and replaced them with another 9 files.

3.0: Risk factors for re-laparotomy following CS delivery at KNH

3.1: Socio-demographic characteristics of Patients who underwent re-laparotomy after CS versus those who did not undergo relaparotomy at KNH

Table 2: socio-demographic characteristics of the patients who underwent re-laparotomy versus those who did not undergo re-laparotomy at KNH following CS delivery

		Case N=82 n(%)	**Control N= 164 n(%)**	**Crude odds ratio 0R(95% CI)**	**P-value**
Age (Mean ± SD)		31 ± 6.67	29 ± 5.90		
Age groups	<25	18(22)	43(26)	Ref	
	25-35	44(54)	102(62)	1.03(0.54-1.98)	0.928
	>35	20(24)	19(12)	2.52(1.09-5.80)	**0.03**
Education	None	4(5)	4(2)	Ref	0.225
level	Primary	20(24)	50(30)	0.40(0.09-1.76)	0.37
	Secondary	33(40)	64(39)	0.52(0.12-2.19)	0.416
	Tertiary	25(30)	46(28)	0.54(0.13-2.36)	
Marital	Single	11(13)	39(24)	Ref	0.066
status	**Married**	70(85)	125(76)	1.99(0.96-4.12)	1
	Divorced	1(1)	0(0)	-	
Occupation	Unemployed	49(60)	114(70)	Ref	
	Employed	33(40)	50(30)	1.54(0.88-2.67)	0.128

Table 2 shows the sociodemographic characteristics of the study participants. The mean age for the cases was 31± 6.6 years versus 29 ± 5.9 years for the controls**.** Age above 35 years was associated with higher odds of undergoing R-LACS as compared to those who were aged less than 25 years, with OR of 2.52 (95% CI =1.09-5.80).There was no significant difference in the level of education between the cases and controls. However, those who were married had a higher

rate of re-laparotomy (85%) as compared to the controls (76%). Forty percent of the patients who underwent R-LACS were employed versus 30% of the controls.

3.1.1: Clinical characteristics of Patients who underwent re-laparotomy after CS versus those who did not undergo relaparotomy at KNH

Table 3: Obstetrics characteristics of patients who underwent re-laparotomy versus those who did not undergo re-laparotomy after CS at KNH

		Case N=82 n(%)	**Control N= 164 n(%)**	**0R(95% CI)**	**P-value**
Parity	primipara	14(17)	53(32)		
	Multipara	64(78)	107(65)	2.26(1.16-4.41)	**0.016**
	Grand multipara	4(5)	4(2)	3.79(0.84-17.07)	0.083
Previous CS	No	35(43)	111(68)	Ref	
	Yes	47(57)	53(32)	2.81(1.63-4.86)	**<0.001**
Previous CS	0	35(43)	111(68)	Ref	
	1	30(37)	35(21)	2.72(1.47-5.04)	**0.002**
	2	10(12)	15(9)	2.11(0.87-5.13)	0.098
	≥3	7(9)	3(2)	7.40(1.82-30.16)	**0.005**
ANC	Not indicated				0.825
	≥4	8(10)	16(10)	1.12(0.42-2.93)	
	<4	48(59)	90(55)	Ref	0.557
		26(32)	58(35)	1.19(0.67-2.13)	
Gestation age	<37	17(21)	23(14)	0.62(0.31-1.25)	0.181
	≥37	65(79)	141(86)	Ref	
Fetal weight	<4kg	71(87)	160(98)	Ref	
	≥4kg	11(13)	4(2)	6.20(1.91-20.13)	**0.002**
The number of fetuses	singleton	75(91)	162(99)	Ref	
	Twins	7(9)	2(1)	7.56(1.53-37.26)	**0.013**
Fetal sex	Male	36(44)	100(61)	Ref	
	Female	45(55)	63(38)	1.98(1.16-3.40)	**0.013**
	Both(twins)	1(1)	1(1)	2.78(0.17-45.58)	0.474

Table 3 shows, the obstetric characteristics of the study participants.

The majority(78%) of the cases were multiparous as compared to the control(65%). Multiparous women had a two-fold increase in the risk of undergoing R-LACS as compared to the

primigravidas. However,we did not find any significant difference between the cases and controls on the grand multipara

More than half (57%) of the patients who underwent R-LACS had a history of previous CS delivery as compared to those who didn't undergo R-LACS with only 37%. History of previous CS delivery was associated with an increased risk of undergoing re-laparotomy after CS with OR 2.81(95% CI 1.63-4.86) as compared to those without previous history of CS delivery. When we further sub-classified the number of previous CS delivery, we noted that the cases had a higher rate of one previous scar (37% cases versus 21% controls) as well as a higher rate of 3 or more previous CS deliveries(9% cases versus 2% control), however, for two previous CS delivery there was no difference the 2 groups. Patients with a history of one previous CS delivery had a higher odds of undergoing re-laparotomy after CS (OR 2.72(95% CI 1.47-5.04) as compared to the controls, this was statistically significant with a p-value of 0.002. Similarly, those who had three or more previous scars had a seven-fold increase in the risk of re-laparotomy (OR 7.40 (95% CI 1.82-30.16) compared to the controls. There was no significant difference between the cases and controls on; gestational age at delivery as well as the number of ANC attendance.

The patient who underwent re-laparotomy after CS delivery had more fetuses who were; macrosomia(13% cases versus 2% control), female fetal sex (55% cases versus 38% control), and twins (9% cases versus 1% control). Patients who had; twin pregnancies, fetal female sex, and macrosomic were associated with an eight-fold (OR 7.56 (95% CI 1.53-37.26), three-fold(OR 1.98(95% CI 1.16-3.40), and a six-fold (OR 6.20(95% CI 1.91-20.13) increased risk of undergoing re-laparotomy after CS respectively as compared to the controls.

Table 4: Comorbidities of patients who underwent re-laparotomy versus those who did not undergo re-laparotomy following CS delivery at KNH

		Case N=82 n (%)	**Control N= 164 n(%)**	**0R(CI)**	**P-value**
Gestational HTN	No	81(99)	164(100)	Ref	-
	Yes	1(1)	0(0)	-	
Chronic HTN	No	82(100)	162(99)	Ref	-
	Yes	0(0)	2(1)	-	
Preeclampsia without severe features	No	80(98)	162(99)	Ref	
	Yes	2(2)	2(1)	2.03(0.28,14.64)	0.485
Preeclampsia superimposed on chronic HTN	No	81(99)	164(100)	Ref	1
	Yes	1(1)	0(0)	-	
Preeclampsia with severe features	No	63(77)	156(95)	Ref	
	Yes	19(23)	8(5)	5.88(2.45,14.13)	**<0.001**
Eclampsia	No	79(96)	164(100)	Ref	-
	Yes	3(4)	0(0)	-	
Pre-gestational diabetes	No	82(100)	164(100)		
Gestational Diabetes	No	82(100)	163(99)	Ref	1
	Yes	0(0)	1(1)	-	
Anemia	NO	65(79)	118(72)	Ref	
	Mild	17(66)	44(27)	0.70(0.37-1.33)	0.275
	Moderate	0(0)	2(1)		
	severe	0(0)	0(0)		

Table 4 shows the comorbidities of the study participants. The patients who underwent R-LACS had a higher rate of preeclampsia with severe features (23% cases vs 5% control). Patients with preeclampsia with severe features were associated with a higher odds of 5.88 (95% CI 2.45,14.13) of undergoing R-LACS as compared to the controls. Four percent of patients who underwent re-laparotomy after CS had eclampsia as compared to none in the control group. However, there was no difference between the cases and controls on other comorbidities such as; gestational HTN,

chronic HTN, preeclampsia superimposed on chronic HTN, pre-gestational diabetes, gestational diabetes as well as Anemia.

Table 5: Indications for CS delivery in patients who underwent re-laparotomy versus those who did not undergo re-laparotomy at KNH

Indication for CS delivery		Cases N=82 n(%)	Controls N=164 n(%)	OR(95% CI)	P value
APH	No	78(95)	162(99)	Ref	
	Yes	4(5)	2(1)	8.36(0.92,76.04)	0.059
Abnormal placentation	None	68(83)	159(97)	Ref	
	Placental Previa	9(11)	4(2)	5.26(1.57,17.67)	**0.007**
	Placenta accreta	5(6)	1(1)	11.69(1.34,101.96)	**0.026**

Table 5, above shows indications for CS delivery for both the cases and control, we found that 5% of patients who underwent re-laparotomy after CS had APH as compared to 1% in the control group. Patients who underwent R-LACS had a higher rate of; placenta previa(11% cases versus 2% control) and placenta accreta spectrum (6% cases versus 1%), associated with a five-fold(OR 5.26(95% CI 1.57-17.67) and twelve-fold(OR 11.69(95% CI 1.34-101.96) increased risk of re-laparotomy after CS delivery respectively.

Table 6: surgical parameters of patients who underwent re-laparotomy versus those who did not undergo re-laparotomy after CS at KNH

		Case N=82 n(%)	**Control N= 164 n(%)**	**C0R(95%CI)**	**P-value**
Nature of CS	Elective	4(5)	16 (10)	Ref	
	Emergency	78(95)	148(90)	2.11(0.68-6.52)	0.196
Day of CS	Weekday	58(71)	123(75)	Ref	
	Weekend	24(29)	41(25)	1.24(0.69-2.25)	0.475
Time of CS	08:00hrs—18:59hrs	37(45)	82(50)	Ref	0.471
	19:00hrs—07:59hrs	45(55)	82(50)	1.22(0.72-2.07)	
Duration of CS	≤45	10(12)	51(31)	Ref	**0.002**
	>45	72(88)	113(69)	3.25(1.55-6.81)	
Type of anesthesia	General	8(10)	4(2)	4.32(1.26-14.82)	**0.02**
	Local(spinal)	74(90)	160(98)	Ref	
Surgeon experience	Resident	81(99)	161(98)	Ref	
	Consultant	1(1)	3(2)	0.66(0.07-6.47)	0.723
Type of abdominal incision	Pfannenstiel incision	69(84)	138(84)	Ref	1
	SUMI incision	13(16)	26(16)	1.00(0.48-2.07)	
Adhesions	No	60(73)	150(91)	Ref	
	Yes	22(27)	14(9)	3.93(1.89-8.18)	**<0.001**
Call for help	No	80(98)	164(100)	Ref	-
	Yes	2(2)	0(0)	-	
Difficulties in hemostasis	No	65(79)	155(95)	Ref	
	Yes	17(21)	9(5)	4.50(1.91-10.63)	**0.001**
Blood loss	<1000	54(66)	159(97)	Ref	
	≥1000	28(34)	5(3)	16.49(6.06-44.84)	**<0.001**
Blood Transfusion	No	37(45)	160(98)	Ref	
	Yes	45(55)	4(2)	48.65(16.47-143.73)	**<0.001**

Table 6, shows the surgical parameters of the study participants. The patients who underwent re-laparotomy following CS delivery had a higher rate of; CS delivery duration of more than 45 minutes(88% cases vs 69% control) with a three-fold increased risk of re-laparotomy, OR 3.25(95% CI 1.55-6.81), general anesthesia as the mode of anesthesia (10% vs 2%) with three-time risk of undergoing re-laparotomy, OR 4.32 (95% CI 1.26-14.82), peritoneal adhesions(27% cases vs 9% control) associated with higher odds of re-laparotomy(OR 3.93(95% CI 1.89-8.18), difficulty in achieving hemostasis during CS delivery(21% cases vs 5% control) associated with

higher odds(OR 4.5 (95% CI 1.91-10.63) of undergoing re-laparotomy after CS as well as PPH (34% cases vs 3% control) associated with a seventeen-fold increased risk of re-laparotomy after CS (OR16.49 (95%CI 6.06-44.84). Similarly, more than half(55%) of patients who underwent R-LACS required blood transfusion during or just after CS as compared to only 2% and was associated with 49 fold increased risk of re-laparotomy after CS(OR 48.65(95% CI 16.47-143.73).

CS delivery performed during weekends and during night shifts had a higher rate of re-laparotomy as compared to the controls, although this was not statistically significant. However, there was no difference between the cases and controls on; type of abdominal incision, surgeon experience as well as call for help during CS delivery.

Table 7: Backwards Stepwise Multivariable logistic regression of the significant risk factors for re-laparotomy following CS delivery

	aOR(95%CI)	**P-value**
Previous history of one CS delivery	2.91(1.01-8.43)	**0.049**
Fetal weight >4kg	8.52(2.12-34.24)	**0.003**
Preeclampsia with severe features	10.59(3.99-28.09)	**<0.001**
Duration of cs >45 mins	3.18(1.32-7.67)	**0.01**
Adhesion	3.65(1.45-9.18)	**0.006**
Blood loss >1000	19.31(6.57-56.75)	**<0.001**
Need for blood transfusion	47.95 (15.27-150.56)	**<0.001**

Table 7, shows significant risk factors for re-laparotomy after multivariable logistic regression. When we did backward stepwise multivariable regression, we noted; one previous scar (aOR 2.91(95% CI 1.01-8.43), fetal macrosomia (aOR 8.52(95% CI 2.12-34.24), preeclampsia with severe features (aOR 10.59(95% CI 3.99-28.09), long operative duration of index CS delivery

(aOR 3.18(95% CI 1.32-7.67), peritoneal adhesions (aOR 3.65(95% CI 1.45-9.18), need for blood transfusion (aOR 47.95 (95% CI 15.27-150.56), as well PPH (aOR 19.31(95% CI 6.57-56.75) as the independent risk factor for R-LACS following CS delivery.

Figure 3: The time interval between CS delivery and re-laparotomy in patients who underwent re-laparotomy

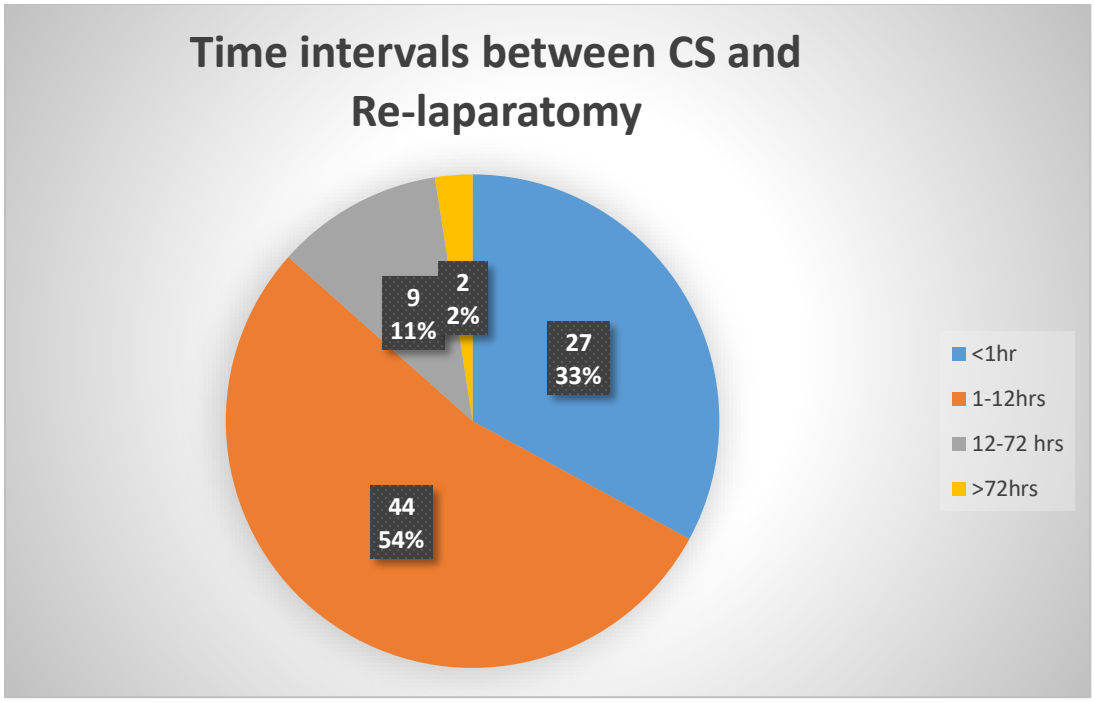


Figure 3 above shows the time interval between CS delivery and re-laparotomy after CS delivery, 87% of cases,re-laparotomy was performed within 12 hours. In eleven percent of the cases, re-laparotomy was performed within 72 hours while in two percent of the cases re-laparotomy was performed after 72hours of the CS delivery

Figure 4: Indication for re-laparotomy following CS delivery at KNH

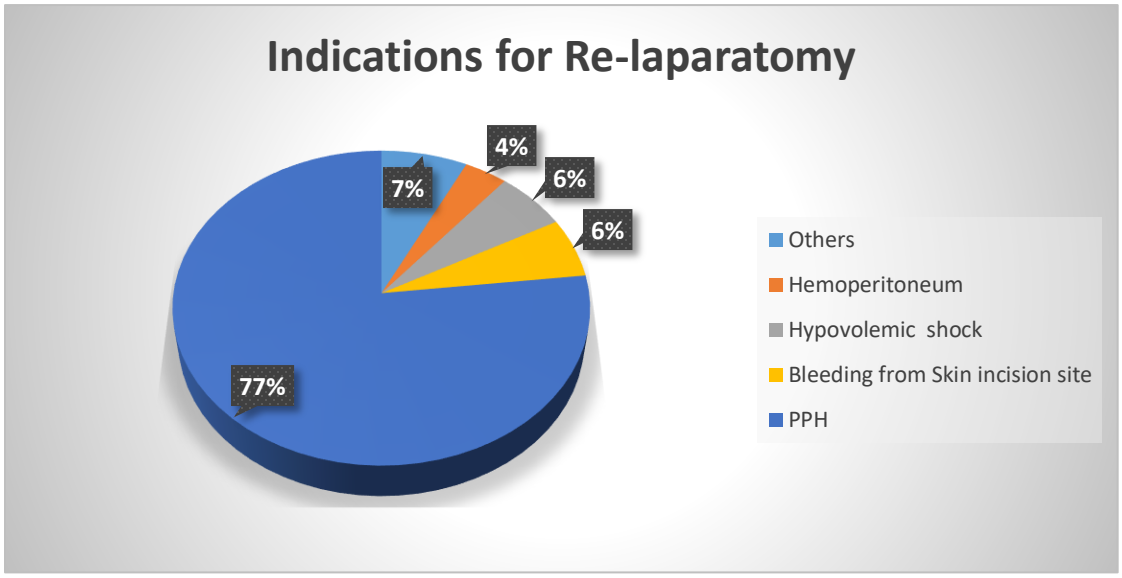


Figure 4, above shows the indication for re-laparotomy after CS delivery, the main indication for re-laparotomy after CS was PPH at 77% followed by hypovolemic shock and bleeding from the skin incision site with 6% respectively. Six of the patients who underwent R-LACS hemoperitoneum was the main indication at 6%.

3.2: Maternal mortality and maternal near-miss events of patients who underwent re-laparotomy after CS versus those who did not undergo re-laparotomy.

Table 8: Maternal near-miss events that occurred in patients who underwent re-laparotomy versus those who did not undergo re-laparotomy at KNH using the WHO MNM event tool

Near Miss Event	Case N=82 n(%)	Controls N=164 n(%)
Shock	37(45)	0(0)
Hysterectomy following infection or hemorrhage	23(28)	2(1)
Transfusion of ≥ 5 units of blood	10(12)	0(0)
Intubation and ventilation for ≥ 60 min not related to anesthesia	10(12)	0(0)
Use of continuous vasoactive drugs	6(7)	1(1)
pH <7.1	3(4)	0(0)
Cardiac arrest	2(2)	1(1)
Uncontrollable fit/total paralysis	2(2)	0(0)
Creatinine ≥ 300 μmol/l or ≥ 3.5 mg/dl	2(2)	0(0)
Cardio-pulmonary resuscitation	2(2)	0(0)
Acute cyanosis	1(1)	0(0)
Jaundice in the presence of pre-eclampsia	1(1)	0(0)
Oxygen saturation <90% for > 60 min	1(1)	0(0)
Bilirubin >100 μmol/l or > 6.0 mg/dl	1(1)	0(0)
Acute thrombocytopenia (< 50,000 platelets/ml)	1(1)	0(0)
Loss of consciousness and ketoacids in urine	1(1)	0(0)

Table 8 shows maternal near-miss events that occurred in the cases and controls.

Fortey five percent of patients who underwent R-LACS developed hypovolemic shock as compared to none in the control group. Hysterectomy was performed in 28% of patients who underwent R-LACS, versus only 1% in the controls,22% of the cases partial hysterectomy was

formed, and 6% of the patients who underwent re-laparotomy after CS total hysterectomy was performed. 10% of the patients who underwent R-LACS received more than or equal to 5 units of blood as compared to none in the control group. Similarly, 10% of the cases required intubation following R-LACS versus none for the controls. Seven percent of patients who underwent re-laparotomy after CS required continuous use of vasoactive drugs as compared to one percent in the control group. Four percent of patients who underwent re-laparotomy developed metabolic acidosis versus none in the control. Two percent of patients who underwent re-laparotomy developed cardiac arrest and AKI injury respectively. Fortunately, none of the patients who underwent re-laparotomy developed AKI.

Table 9: Comparison of maternal near-miss events of the study participants

		Case N=82 n(%)	**Control N= 164 n(%)**
MNM	No	33(40)	160(98)
	Yes	49(60)	4(2)
MNM events	0	33(40)	160(98)
	1-3	40(49)	4(2)
	> 3	9(11)	0(0)
I.C.U admission	NO	70(85)	164(100)
	YES	12(15%)	0(0)

Table 9, shows a Comparison of maternal near-miss events of the study participants. 60% of patients who underwent re-laparotomy after CS experienced at least one maternal near-miss event as compared to 2% in the control. 11% of patients who underwent R-LACS experienced more than 3 maternal near-miss events as compared to none in the control group. Twelve cases(15%) of patients who underwent R-LACS required I.C.U as compared to none in the control group.

Table 10: Bivariate and multivariable analysis of maternal near-miss events that occurred in patients who underwent re-laparotomy versus those who did not undergo re-laparotomy

	Maternal Near Miss Event					
	Yes N= 53 n(%)	No N= 193 n(%)	OR (CI)	P-value	aOR(95%CI)	P-value
R-LACS	49(92)	33(17)	59.39(20.05,175.93)	<0.001	81.81(23.64-283.17)	<0.001
No R-LACS	4(8)	160(83)	Ref		Ref	

Table 10, above shows bivariate as well as multivariable analysis of maternal near-miss that occurred in the cases and the controls. Patients who underwent R-LACS had an 82-fold increased risk of experiencing maternal near-miss as compared to those who did not undergo re-laparotomy, this was statistically significant with a p-value of less than 0.05.

Table 11: comparison of maternal mortality of the study participants

		Case N=82 n(%)	**Control N= 164 n(%)**	**P-value**
Maternal mortality	No	79(96)	164(100)	**0.036**
	Yes	3(4)	0(0)	

Table 11 shows a comparison of maternal mortalities in the cases and controls. There were 3 cases (4%) of maternal mortalities for the patients who underwent re-laparotomy following CS as compared to none for those who did not undergo re-laparotomy. All the three maternal mortalities following R-LACS were referrals from peripheral facilities.

CHAPTER FOUR: DISCUSSION

This study aimed to determine the risk factors for re-laparotomy following CS delivery and associated maternal mortality and near-miss at KNH. The mean age for patients who underwent R-LACS was 31 ± 6.67 years for the cases versus 29 ± 5.90 years for the controls. Similar findings were reported by Peker et al in Turkey(35). In our study, we found that a history of one previous CS delivery was an independent risk factor for R-LACS, associated with a three-fold increased risk of re-laparotomy after CS delivery. Similar findings were also reported by other studies (35–37). However, on further analysis, we did not find a history of two and three previous scars to be a significant risk factor for re-laparotomy after multivariable logistic regression. This was contrary to a study by Akkurt et al in Turkey who found previous CS delivery of three or more to be significant for re-laparotomy following CS delivery(36).

Our data showed that peritoneal adhesions was associated with a four-fold increased risk of re-laparotomy following CS delivery, this was statistically significant with a p-value of 0.006. These findings are in concordance with Ashwal et al (29) as well as Huras et al (94) studies, which also found peritoneal adhesion during CS delivery to be a significant risk factor for re-laparotomy following CS delivery. However, we were not able to classify the type of adhesion due to the retrospective nature of the study.

In our study, we found a longer operative duration of CS delivery to be a significant risk factor for re-laparotomy following CS delivery, similar to other studies by; S.Shinar et al in Israel (2) and Akkurt et al in Turkey (36) who found long operative duration to be a risk factor for R-LACS.

We also found that fetal macrosomia was a significant risk factor for re-laparotomy following CS delivery, associated with an eight-fold increased risk of re-laparotomy,this was similar to a study by Ahmed et al in Egypt (4). In our study we noted, preeclampsia with severe features was associated with a nine-fold increased risk of re-laparotomy following CS delivery, similar findings were shared by four other studies (4,36,37,49). In our study PPH was an independent risk factor for re-laparotomy following CS delivery and was associated with a 19-fold increased risk of re-laparotomy following CS delivery. This was similar to the findings by Pencole et al in France, 2021(49), and Peker et al in Turkey, 2020 (35). We also found blood transfusion during or just after CS was significant risk factor for re-laparotomy following CS delivery. This was similar to study by Peker et al in Turkey(35).

In our study, unfortunately, there were 3 cases(4%) of maternal mortality following R-LACS as compared to none in the control group. A similar maternal mortality rate was reported by Gedikbasi et al in Turkey(1). However, our maternal mortality rate was lower as compared to other studies by; Akther et al in Bangladesh 2011 (14), with a maternal mortality rate of 33 %, and M. Reddy et al reported maternal mortality following R-LACS of 9.5% (26). This could be due to, over 85% of our patient's R-LACS was performed within 12 hours, early recognition of complications, and appropriate intervention hence better outcome, as compared to Akther et al where R-LACS was performed between 1- 7 days in most of the cases (14). The other possible explanation could be, in our study we excluded CS deliveries done elsewhere but re-laparotomy done at KNH since in our study we were looking at the intra-operative findings of index CS delivery. However, there was no report of maternal mortality following R-LACS in several other studies (2,27,35–37), this could be due to differences in settings and level of management, and our study had a higher sample size.

In our study 60% of the patients who underwent R-LACS experienced maternal near-miss events as compared to only 2% in the control group, this rate was higher compared to Akkurt et al (36) in Turkey in which only 47% of patients who underwent R-LACS experienced MNM events. The higher rate could be because our sample size for patients who underwent R-LACS was almost twice their number.11% of the cases experienced more than 3 MNM events but none in the none in the control group. Similarly,15% of our patients who underwent re-laparotomy after CS required I.C.U admission compared to none in the control group. Other studies reported a higher rate of I.C.U admission; Levitt et al at 47% (27) and Ahmed et al in Egypt at 47% (4). This difference could be due to differences in settings, and levels of care. However, Gedikbas et al reported a lower rate of 5.7% I.C.U admission following R-LACS in Turkey(1), this difference could be due to the fact that in our study, our sample size was three times that of the study by Gedikbasi et al.

In our study 28% of the patients who underwent R-LACS, a hysterectomy was performed, a higher rate was reported by Ahmed et al in Egypt at 46% (4), this difference could be due to the difference in the level of care, study population and study setting. However, Fazari et al in Sudan reported a lower rate of hysterectomy following R-LACS after CS of 15% (31). This could be due to, in our study we had a higher sample size.We noted that Patients who underwent R-LACS following CS delivery had 82 folds risk of experiencing MNM events as compared to those who did not undergo R-LACS.

Conclusion

The main risk factors for re-laparotomy following CS were; one previous scar, macrosomia, preeclampsia with severe features, long operative duration of index CS delivery, PPH, adhesions and need for blood transfusion during or just after CS delivery. The maternal mortality following R-LACS was 4%. Patients who underwent R-LACS following CS had an 82-fold increased risk of experiencing maternal near-miss events

Recommendation

1. Patients with risk factors for R-LACS can be identified during ANC, followed closely, and to be operated on by the most senior surgeon and preferably during day time.
2. We recommend prevention and reduction of primary CS delivery, this will eventually lead to a lower repeat CS delivery rate.

STUDY BUDGET AND JUSTIFICATIONS

S/N	ITEM	QUANTITY	UNIT COST (KSHS)	TOTAL COST (Ksh)
1	AIRTIME	5	500	2,500
2	PHOTOCOPIES,SCANNING,PRINTING	100	100	10,000
3	DATA BUNDLES	10	1000	10,000
4	RESEARCH ASSISTANT	2	10,000	20,000
5	STATISTICIAN	1	30,000	30,000
6	PUBLICATION FEES	3	5000	15,000
	TOTAL			87,500

STUDY TIMELINE

	March 2021	**April 2021**	**May 2021**	**June 2021**	**July 2021**	**Aug 2021**	**Sept 2021**	**Oct 2021**	**Nov 2021**	**Dec 2021**	**Jan 2022**	**Feb 2022**	**March 2022**	**April 2022**	**May 2022**
Concept note development															
Proposal development															
Proposal Presentation to the Department															
Ethical Approval															
Data collection															
Data analysis															
Result presentation, dissemination and close out															

References

1. Gedikbas A, Akyol A, Asar E, Bingol B, Uncu R, Sargin A, et al. Re-laparotomy after cesarean section: Operative complications in surgical delivery. Arch Gynecol Obstet. 2008;278(5):419–25.

2. Shinar S, Hareuveni M, Ben-tal O, Many A. Relaparotomies after cesarean sections : risk factors , indications , and management. Pubmed. 2013;41(July 2006):567–72.

3. Levin I, Rapaport AS, Satzer L, Maslovitz S, Lessing JB, Almog B. Risk factors for relaparotomy after cesarean delivery. Int J Gynecol Obstet [Internet]. 2012;119(2):163–5. Available from: http://dx.doi.org/10.1016/j.ijgo.2012.05.037

4. Raagab AE, Mesbah YH, Brakat RI, Zayed AA. Re-laparotomy After Cesarean Section : Risk , Indications and Management Options. PMC [Internet]. 2014;43–5. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4272472/

5. Betrán AP, Ye J, Moller A, Zhang J, Gülmezoglu AM. The Increasing Trend in Caesarean Section Rates : Global , Regional and National Estimates : 1990-2014. Pubmed [Internet]. 2016;1–12. Available from: https://pubmed.ncbi.nlm.nih.gov/26849801/

6. Dhs M, Macro ICF. Kenya. 2008; Available from: https://dhsprogram.com/pubs/pdf/fr229/fr229.pdf

7. Survey H. Kenya. 2003; Available from: https://dhsprogram.com/publications/publication-fr151-dhs-final-reports.cfm

8. Survey H. Kenya. 2014; Available from: https://dhsprogram.com/pubs/pdf/fr308/fr308.pdf

9. A P Betran , M R Torloni , J J Zhang , A M Gülmezoglu WWG on CS. WHO Statement on Caesarean Section Rates €. BJOG [Internet]. 2015;123(5):667–70. Available from: https://obgyn.onlinelibrary.wiley.com/doi/10.1111/1471-0528.13526

10. Uribe-leitz T, Azad T, Shah N, Semrau K. Relationship Between Cesarean Delivery Rate and Maternal and Neonatal Mortality. Pubmed. 2015;94305(21):2263–70.

11. Zelop C, Heffner LJ. The downside of cesarean delivery: Short- and long-term complications. Clin Obstet Gynecol. 2004;47(2):386–93.

12. The WHO near-miss approach for maternal health. WHO [Internet]. 2011;34. Available from: http://apps.who.int/iris/bitstream/handle/10665/44692/9789241502221_eng.pdf;jsessionid=22D439F96B5812D7EA8167C1FCBC7E6C?sequence=1

13. Elkhateeb R, Din Mahran AE El, Sanad AS, Bahaa HA, Ibrahim MH. Re-Laparotomy after Caesarean Section at a Tertiary Hospital in Egypt: Cross Sectional Study. Gynecol Obstet [Internet]. 2017;07(03):3–7. Available from: https://www.researchgate.net/publication/315993141_Re-Laparotomy_after_Caesarean_Section_at_a_Tertiary_Hospital_in_Egypt_Cross_Sectional_Study

14. Akther R, Hossain T, Rashid M. Relaparotomy After Cesarean Delivery: A Prospective Study. J Dhaka Med Coll. 1970;20(1):57–62.

15. Rather SY, Sultana S, Anim ZA. Indications for Relaparotomy in Cesarean Section in a Tertiary Care Hospital of a Developing Country. IJSRP [Internet]. 2015;5(10):47–9. Available from: http://www.ijsrp.org/research-paper-1015.php?rp=P464710

16. Seal SL, Kamilya G, Bhattacharyya SK, Mukherji J, Bhattacharyya AR. Relaparotomy after cesarean delivery : Experience from an Indian teaching hospital. Pubmed [Internet]. 2007;33(6):804–9. Available from: https://pubmed.ncbi.nlm.nih.gov/18001446/

17. Khan N, Kolasseri S. Relaparotomy after caesarean section: an analysis of the risk factors, indications and outcome. Int J Reprod Contraception, Obstet Gynecol. 2015;4(3):575–80.

18. Peipert JF, Bracken MB. Maternal age: An independent risk factor for cesarean delivery. Obstet Gynecol [Internet]. 1993;81(2). Available from: https://pubmed.ncbi.nlm.nih.gov/8423950/

19. Kozinszky Z, Orvos H, Zoboki T, Katona M, Wayda K, Pál A, et al. Risk factors for cesarean section of primiparous women aged over 35 years. Acta Obstet Gynecol Scand. 2002;81(4).

20. Penfield CA, Lahiff M, Pies C, Caughey AB. Adolescent Pregnancies in the United States: How Obstetric and Sociodemographic Factors Influence Risk of Cesarean Delivery. Am J Perinatol. 2017;34(2).

21. Nilsen C, Østbye T, Daltveit AK, Mmbaga BT, Sandøy IF. Trends in and socio-demographic factors associated with caesarean section at a Tanzanian referral hospital, 2000 to 2013. Int J Equity Health. 2014;13(1).

22. Manyeh AK, Amu A, Akpakli DE, Williams J, Gyapong M. Correction to: Socioeconomic and demographic factors associated with caesarean section delivery in Southern Ghana: evidence from INDEPTH Network member site. BMC Pregnancy Childbirth. 2019;19(1).

23. Van Der Spek L, Sanglier S, Mabeya HM, Van Den Akker T, Mertens PLJM, Houweling TAJ. Socioeconomic differences in caesarean section - Are they explained by medical need? An analysis of patient record data of a large Kenyan hospital. Int J Equity Health. 2020;19(1).

24. Ochieng Arunda M, Agardh A, Asamoah BO. Cesarean delivery and associated socioeconomic factors and neonatal survival outcome in Kenya and Tanzania: analysis of national survey data. Glob Health Action. 2020;13(1).

25. Juma S, Nyambati V, Karama M, Githuku J, Gura Z. Factors associated with caesarean sections among mothers delivering at Mama Lucy Kibaki Hospital, Nairobi, Kenya between January and March, 2015: a case-control study. Pan Afr Med J. 2017;28.

26. Reddy M, Reddy M. Risk factors for relaparotomy after caesarian section: a study in a tertiary care hospital. Int Surg J. 2016;3(4):1983–6.

27. Levitt L, Sapir H, Kabiri D, Ein-Mor E, Hochner-Celnikier D, Amsalem H. Re-laparotomy following cesarean delivery - Risk factors and outcomes. J Matern Neonatal Med [Internet]. 2016;29(4):607–9. Available from: http://dx.doi.org/10.3109/14767058.2015.1012065

28. Biswas SP, Halder S, Shirin FB. Indication and outcome of relaparotomy after caesarean section. Bangladesh Med J Khulna. 2013;45(1–2):19–23.

29. Ashwal E, Yogev Y, Melamed N, Khadega R, Ben-Haroush A, Wiznitzer A, et al. Characterizing the need for re-laparotomy during puerperium after cesarean section. Arch Gynecol Obstet. 2014;290(1):35–9.

30. Seffah JD. Re-laparotomy after Cesarean section. Int J Gynaecol Obs [Internet]. 2005; Available from: 15733877

31. Fazari AB, Eldeen NS, Mohammed W, Muror M, Gailii E. Re-Laparotomy after Caesarean Section at Omdurman Maternity Hospital-Khartoum, Sudan. Open J Obstet Gynecol. 2015;05(08):448–54.

32. Kietpeerakool C, Lumbiganon P, Laopaiboon M, Rattanakanokchai S, Vogel JP, Gülmezoglu AM. Pregnancy outcomes of women with previous caesarean sections: Secondary analysis of World Health Organization Multicountry Survey on Maternal and Newborn Health. Sci Rep [Internet]. 2019;9(1). Available from: https://www.nature.com/articles/s41598-019-46153-4

33. Kalisa R, Rulisa S, van Roosmalen J, van den Akker T. Maternal and perinatal outcome after previous caesarean section in rural Rwanda. BMC Pregnancy Childbirth. 2017;17(1).

34. Kongwattanakul K, Thamprayoch R, Kietpeerakool C, Lumbiganon P. Risk of Severe Adverse Maternal and Neonatal Outcomes in Deliveries with Repeated and Primary Cesarean Deliveries versus Vaginal Deliveries: A Cross-Sectional Study. J Pregnancy. 2020;2020.

35. Peker N, Yavuz M, Aydın E, Ege S, Bademkıran MH, Karacor T. Risk factors for relaparotomy after cesarean section due to hemorrhage: a tertiary center experience. J Matern Neonatal Med [Internet]. 2020;33(3):464–70. Available from: https://doi.org/10.1080/14767058.2019.1677599

36. Medicine N. ST Corresponding author : Mehmet Ozgur Akkurt. J Matern Fetal Neonatal Med [Internet]. 2018;7058. Available from: https://pubmed.ncbi.nlm.nih.gov/30235958/

37. Kessous R, Danor D, Weintraub YA, Wiznitzer A, Sergienko R, Ohel I, et al. Risk factors for relaparotomy after cesarean section. J Matern Neonatal Med. 2012;25(11):2167–70.

38. Nielsen TF, Hokegard KH. Postoperative cesarean section morbidity: A prospective study. Am J Obstet Gynecol. 1983;146(8):911–6.

39. Hawrylyshyn PA, Bernstein P, Papsin FR. Risk factors associated with infection following cesarean section. Am J Obstet Gynecol. 1981;139(3):294–8.

40. Hadar E, Melamed N, Tzadikevitch-Geffen K, Yogev Y. Timing and risk factors of maternal complications of cesarean section. Arch Gynecol Obstet. 2011;283(4):735–41.

41. Yang XJ, Sun SS. Comparison of maternal and fetal complications in elective and emergency cesarean section: a systematic review and meta-analysis. Arch Gynecol Obstet. 2017;296(3).

42. Lumbiganon P, Moe H, Kamsa-ard S, Rattanakanokchai S, Laopaiboon M, Kietpeerakool C, et al. Outcomes associated with anaesthetic techniques for caesarean section in low- and middle-income countries: a secondary analysis of WHO surveys. Sci Rep. 2020;10(1).

43. Gori F, Pasqualucci A, Corradetti F, Milli M, Peduto VA. Maternal and neonatal outcome after cesarean section: The impact of anesthesia. J Matern Neonatal Med. 2007;20(1).

44. Thangaswamy CR, Kundra P, Velayudhan S, Aswini LN, Veena P. Influence of anaesthetic technique on maternal and foetal outcome in category 1 caesarean sections – A prospective single-centre observational study. Indian J Anaesth. 2018;62(11).

45. Arnold AA, Ch MMB. THE EFFECT OF TIME OF DAY OF UNSCHEDULED CAESERIAN SECTIONS ON PERINATAL AND MATERNAL OUTCOMES IN

KENYATTA NATIONAL HOSPITAL , NAIROBI , KENYA A Dissertation Submitted in Partial Fulfillment for The Award of Master of Medicine In Obstetrics and Gynecology. 2015; Available from: http://erepository.uonbi.ac.ke/bitstream/handle/11295/94467/Makori, Anching'a A_unscheduled caeserian sections on perinatal and maternal.pdf?sequence=5

46. Rottenstreich M, Sela HY, Shen O, Michaelson-Cohen R, Samueloff A, Reichman O. Prolonged operative time of repeat cesarean is a risk marker for post-operative maternal complications. BMC Pregnancy Childbirth. 2018;18(1).

47. Wolfe HM, Gross TL, Sokol RJ, Bottoms SF, Thompson KL. Determinants of morbidity in obese women delivered by cesarean. Obstet Gynecol. 1988;71(5).

48. Poole JH. Adhesions following cesarean delivery: A review of their occurrence, consequences and preventative management using adhesion barriers [Internet]. Vol. 9, Women's Health. 2013. Available from: https://pubmed.ncbi.nlm.nih.gov/24007252/

49. Pencole L, Mandelbrot L, Lepercq J. 425 Risk factors of relaparotomy for intra-abdominal hemorrhage after cesarean delivery. Am J Obstet Gynecol. 2021;224(2):S272.

50. Al Rowaily MA, Alsalem FA, Abolfotouh MA. Cesarean section in a high-parity community in Saudi Arabia: Clinical indications and obstetric outcomes. BMC Pregnancy Childbirth. 2014;14(1).

51. Cerra C, Morelli R, Di Mascio D, Buca D, di Sebastiano F, Liberati M, et al. Maternal outcomes of cesarean delivery performed at early gestational ages: a systematic review and meta-analysis. Vol. 3, American journal of obstetrics & gynecology MFM. 2021.

52. Beta J, Khan N, Khalil A, Fiolna M, Ramadan G, Akolekar R. Maternal and neonatal complications of fetal macrosomia: systematic review and meta-analysis. Vol. 54, Ultrasound in Obstetrics and Gynecology. 2019.

53. Turkmen S, Johansson S, Dahmoun M. Foetal Macrosomia and Foetal-Maternal Outcomes at Birth. J Pregnancy. 2018;2018.

54. Vogel JP, Torloni MR, Seuc A, Betrán AP, Widmer M, Souza JP, et al. Maternal and Perinatal Outcomes of Twin Pregnancy in 23 Low- and Middle-Income Countries. PLoS One [Internet]. 2013;8(8). Available from: https://pubmed.ncbi.nlm.nih.gov/23936446/

55. Funaki S, Ogawa K, Ozawa N, Okamoto A, Morisaki N, Sago H. Differences in pregnancy complications and outcomes by fetal gender among Japanese women: a multicenter cross-sectional study. Sci Rep [Internet]. 2020;10(1). Available from: https://pubmed.ncbi.nlm.nih.gov/33139809/

56. Liu Y, Li G, Zhang W. Effect of fetal gender on pregnancy outcomes in Northern China. J Matern Neonatal Med. 2017;30(7).

57. Lugobe HM, Muhindo R, Kayondo M, Wilkinson I, Agaba DC, McEniery C, et al. Risks of adverse perinatal and maternal outcomes among women with hypertensive disorders of pregnancy in southwestern Uganda. PLoS One. 2020;15(10 October).

58. Tyaa.Sambu DS. Maternal and Perinatal Outcome in Patients With Eclampsia At Kenyatta National Hospital. 2011; Available from: http://erepository.uonbi.ac.ke/bitstream/handle/11295/64191/Sambu_Maternal and perinatal outcome in patients with eclampsia at Kenyatta national hospital.pdf?sequence=8

59. Lokhande V, Jadhav K, Kadam M, Rawte S. Study of Maternal and Foetal Outcome in Abruptio Placentae. Int J Med Sci Clin Invent. 2021;8(01).

60. Mukherjee S, Bawa AK, Sharma S, Nandanwar YS, Gadam M. Retrospective study of risk factors and maternal and fetal outcome in patients with abruptio placentae. J Nat Sci Biol Med. 2014;5(2).

61. Dadi TL, Yarinbab TE. Estimates of Uterine Rupture Bad Outcomes Using Propensity Score and Determinants of Uterine Rupture in Mizan-Tepi University Teaching Hospital: Case Control Study. J Pregnancy. 2017;2017.

62. Astatikie G, Limenih MA, Kebede M. Maternal and fetal outcomes of uterine rupture and factors associated with maternal death secondary to uterine rupture. BMC Pregnancy Childbirth. 2017;17(1).

63. Mrema S, Massinde A, Matovelo D, Kihunrwa A, Rumanyika R, Kidenya B. Fetomaternal outcomes in patients with Uterine Rupture managed at Bugando Medical Centre, Tanzania: 5-year review of cases. Res Sq [Internet]. 2019;1–19. Available from: https://www.researchsquare.com/article/rs-8063/v1

64. Wasim T, Bushra N, Riaz S, Iqbal HI. Fetomaternal outcome in patients with placenta previa. Pakistan J Med Sci. 2020;36(5).

65. Kollmann M, Gaulhofer J, Lang U, Klaritsch P. Placenta praevia: Incidence, risk factors and outcome. J Matern Neonatal Med. 2016;29(9).

66. Alsammani MA, Nasralla K. Fetal and Maternal Outcomes in Women With Major Placenta Previa Among Sudanese Women: A Prospective Cross-Sectional Study. Cureus.

2021;

67. Carroli G, Cuesta C, Abalos E, Gulmezoglu AM. Epidemiology of postpartum haemorrhage: a systematic review. Vol. 22, Best Practice and Research: Clinical Obstetrics and Gynaecology. 2008.

68. Maswime S, Buchmann E. A systematic review of maternal near miss and mortality due to postpartum hemorrhage. Vol. 137, International Journal of Gynecology and Obstetrics. 2017.

69. Owolabi O, Riley T, Juma K, Mutua M, Pleasure ZH, Amo-Adjei J, et al. Incidence of maternal near-miss in Kenya in 2018: findings from a nationally representative cross-sectional study in 54 referral hospitals. Sci Rep [Internet]. 2020;10(1):1–10. Available from: https://doi.org/10.1038/s41598-020-72144-x

70. Machado LSM. Cesarean section in morbidly obese parturients: Practical implications and complications. Vol. 4, North American Journal of Medical Sciences. 2012.

71. Brettingham M. Depression and obesity are major causes of maternal death in Britain. BMJ. 2004;329(7476).

72. WHO. WHO maternal mortality paper. WHO [Internet]. 2019; Available from: https://apps.who.int/iris/bitstream/handle/10665/329886/WHO-RHR-19.20-eng.pdf

73. World Health Organization. Regional Office for the Western Pacific. (2016). Sustainable development goals (SDGs) : Goal 3. Target 3.1 : By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births [poster]. WHO Regiona. WHO [Internet]. Available from: https://apps.who.int/iris/handle/10665/208272

74. KDHS. 2014 KDHS Key Findings. Spanish J Rural Dev. 2015;6.

75. Souza JP, Gülmezoglu AM, Vogel J, Carroli G, Lumbiganon P, Qureshi Z, et al. Moving beyond essential interventions for reduction of maternal mortality (the WHO Multicountry Survey on Maternal and Newborn Health): A cross-sectional study. Lancet. 2013;381(9879).

76. Souza P, Say L, Pattinson RC. Best Practice & Research Clinical Obstetrics and Gynaecology Maternal near miss – towards a standard tool for monitoring quality of maternal health care q. Pubmed. 2009;23:287–96.

77. Tura AK, Stekelenburg J, Scherjon SA, Zwart J, van den Akker T, van Roosmalen J, et al. Adaptation of the WHO maternal near miss tool for use in sub-Saharan Africa: An International Delphi study. BMC Pregnancy Childbirth. 2017;17(1).

78. Nanda G, Switlick K, Lule E. Accelerating Progress towards Achieving the MDG to Improve Maternal Health : A Collection of Promising Approaches [Internet]. 2005. 1–13 p. Available from: http://www.worldbank.org/hnppublications.

79. Reichenheim ME, Zylbersztajn F, Moraes CL, Lobato G. Severe acute obstetric morbidity (near-miss): A review of the relative use of its diagnostic indicators. Vol. 280, Archives of Gynecology and Obstetrics. 2009.

80. Abdollahpour S, Miri HH, Khadivzadeh T. The global prevalence of maternal near miss: A systematic review and meta-analysis [Internet]. Vol. 9, Health Promotion Perspectives. 2019. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6875559/

81. Goldenberg RL, Saleem S, Ali S, Moore JL, Lokangako A, Tshefu A, et al. Maternal near

miss in low-resource areas. Int J Gynecol Obstet. 2017;138(3).

82. Ogutu MWOFNPKROAKP 2; KAKO, GN1 OKMG. CHANGES IN PATTERN OF MATERNAL NEAR MISS MORBIDITY AFTER INTRODUCTION OF FREE MATERNITY POLICY IN A COUNTY HOSPITAL IN KENYA: A QUASI EXPERIMENTAL STUDYNo Title. JOGECA. 2018;30(2).

83. D MJOM. Describing the causes of Near-Miss Maternal Morbidity and Mortality at Kenyatta National Hospital , Nairobi. 2009;59. Available from: http://erepository.uonbi.ac.ke/bitstream/handle/11295/25333/Owiti_Describing The Causes Of Near-Miss Maternal Morbidity And Mortality At Kenyatta National Hospital, Nairobi.pdf?sequence=5

84. Rubin GL, Peterson HB, Rochat RW, McCarthy BJ, Terry JS. Maternal death after cesarean section in Georgia. Am J Obstet Gynecol [Internet]. 1981;139(6):681–5. Available from: http://dx.doi.org/10.1016/0002-9378(81)90485-3

85. Liu S, Liston RM, Joseph KS, Heaman M, Sauve R, Kramer MS. vaginal delivery at term R esearch. MAJ [Internet]. 2007;176(4):455–60. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1800583/

86. New global targets to prevent maternal deaths [Internet]. WHO. 2021 [cited 2022 Feb 23]. Available from: https://www.who.int/news/item/05-10-2021-new-global-targets-to-prevent-maternal-deaths

87. Kenya mortality rate declines, CAS Health says – MINISTRY OF HEALTH [Internet]. 2020 [cited 2022 Feb 23]. Available from: https://www.health.go.ke/kenya-mortality-rate-declines-cas-health-says/

88. Kelsey et al. Table 12-15. In: Methods in observational epidemiology [Internet]. 1996. Available from: https://global.oup.com/academic/product/methods-in-observational-epidemiology-9780195083774?cc=us&lang=en&

89. Radoń-Pokracka M, Adrianowicz B, Płonka M, Danił P, Nowak M, Huras H. Evaluation of pregnancy outcomes at advanced maternal age. Open Access Maced J Med Sci. 2019;7(12):1951–6.

90. Mahato V, Shrestha P, Bhattarai P. Advanced Maternal Age and Pregnancy Outcome at Manipal Teaching Hospital: Cross-sectional Analytical study. Nepal J Med Sci. 2021;6(1):20–5.

91. Pawde AA, Kulkarni MP, Unni J. Pregnancy in Women Aged 35 Years and Above: A Prospective Observational Study. J Obstet Gynecol India. 2015;65(2):93–6.

92. Arlier S, Seyfettinoğlu S, Yilmaz ES, Nazik H, Adıgüzel C, Eskimez E, et al. Incidence of adhesions and maternal and neonatal morbidity after repeat cesarean section. Arch Gynecol Obstet. 2017;295(2).

93. Saban A, Shoham-Vardi I, Yohay D, Weintraub AY. Peritoneal adhesions during cesarean delivery are an independent risk factor for peri-partum hemorrhagic complications. Eur J Obstet Gynecol Reprod Biol [Internet]. 2020;251:188–93. Available from: https://doi.org/10.1016/j.ejogrb.2020.05.044

94. Huras H, Radon-Pokracka M, Nowak M. Relaparotomy following cesarean section – a single center study. Eur J Obstet Gynecol Reprod Biol [Internet]. 2018;225:185–8. Available from: https://doi.org/10.1016/j.ejogrb.2018.04.034

95. Abalos E, Cuesta C, Carroli G, Qureshi Z, Widmer M, Vogel JP, et al. World Health Organization Multicountry Survey on Maternal and Newborn Health. BJOG [Internet]. 2014;121:14–24. Available from: www.bjog.org

96. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels J, et al. Global causes of maternal death: A WHO systematic analysis. Lancet Glob Heal. 2014;2(6).

97. Khan KS, Wojdyla D, Say L, Gülmezoglu AM, Van Look PF. WHO analysis of causes of maternal death: a systematic review. Lancet. 2006;367(9516).

98. Eyelade OR, Adesina OA, Adewole IF, Adebowale SA. Blood Transfusion Requirement During Caesarean Delivery: Risk Factors. Ann Ibadan Postgrad Med [Internet]. 2015;13(1):29–35. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26807084%0Ahttp://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC4715370

APPENDIX

APPENDIX 1:DATA ENTRY FORM

STUDY TITLE: RISK FACTORS FOR RE-LAPAROTOMY AFTER CESAREAN SECTION AND ASSOCIATED MATERNAL MORTALITY AND NEAR-MISS EVENTS AT KNH.

An exploratory retrospective case-control study

DATE:

Risk factors

1. **Socio-demographic Characteristics**

Number assigned: …….

cases	
controls	

a) **Maternal age: ……years**

b) **Education level:(mark √)**

None	
primary	
Secondary	
Tertiary	

c) Marital status: (mark √)

Single	
Married	
Divorced	
Widowed	

d) Body mass index(BMI) (weight (kg) / height (m)^2) ……

e) Smoking history

Yes……

No……...

f) Occupation: (√)

Employed	
unemployed	

2. Clinical characteristics

a) Obstetrics history

i) Parity…….

ii) The number of Previous Caesarean delivery …….

iii) The number of Antenatal clinic attendance(ANC)…….

b) Gestational Characteristics

i) Gestational age at delivery…….

ii) Fetal sex…….

iii) Fetal weight……

iv) The number of fetuses…….

c) Indication of Cesarean delivery …….

d) Comorbidities

	YES	**NO**
Gestational HTN		
Chronic HTN		
Preeclampsia		
Preeclampsia superimposed on chronic HTN		
Preeclampsia with severe features		
Eclampsia		
Pre-gestational DM		
Gestational DM		
Anemia (Hb before operation)		

e) Surgical parameters

Nature of Cesarean delivery	**Emergency**	
	Elective	
Duration of Cesarean delivery	**<45 mins**	
	≥45 mins	
Time of Cesarean delivery	**08:00hrs—19:00hrs**	
	19:00hrs—08:00hrs	
Day of Cesarean delivery	**weekdays**	
	weekends	
Type of anesthesia	**Local(spinal)**	
	General	
Surgeon experience	**Resident**	
	Consultant	
Type of abdominal incision	**Horizontal**	
	vertical	

	YES	**NO**
Adhesions		
Call for help		
Difficulties in achieving hemostasis		
Abnormal placentation		

f) Post-operative (post-op) period

Estimated blood loss…….

Blood transfused(units) …….

3. Maternal mortality and maternal near-miss events

a) Maternal mortality

Yes……..

NO …….

b) Maternal near-miss (WHO Maternal near-miss tool) (12) **(√)**

Clinical criteria	YES	NO
Acute cyanosis		
Gasping		
Respiratory rate > 40 or <6/min		
Shock		
Oliguria non responsive to fluids or diuretics		
Failure to form clots		
Loss of consciousness lasting more than 12 h		
Cardiac arrest		
Stroke		
Uncontrollable fit/total paralysis		
Jaundice in the presence of pre-eclampsia		
Laboratory-based criteria		
Oxygen saturation < 90% for > 60 min		
PaO2/FiO2 < 200 mmHg		
Creatinine ≥ 300 μmol/l or ≥ 3.5 mg/dl		
Bilirubin > 100 μmol/l or > 6.0 mg/dl		
pH <7.1		
Lactate > 5 mEq/ml		
Acute thrombocytopenia (<50,000 platelets/ml)		
Loss of consciousness and ketoacids in urine		
Management based criteria		
Use of continuous vasoactive drugs		
Hysterectomy following infection or hemorrhage		
Transfusion of ≥ 5 units of blood		
Intubation and ventilation for ≥ 60 min not related to anesthesia		
Dialysis for acute renal failure		
Cardio-pulmonary resuscitation		

APPENDIX 2: DUMMY TABLES

1.0: Distribution of descriptive characteristics of women studied to assess risk factors for re-laparotomy at KNH

		Cases		Controls			
		n	**%**	**n**	**%**	**OR(CI)**	**P-value**
Age							
Marital status	Single						
	Married						
Education	None						
	Primary						
	Secondary						
	Tertiary						
Smoking History	Yes						
	No						
Occupation	Employed						
	Unemployed						

2.0 Clinical characteristics

a) Obstetrics and Gestational characteristics

		Cases		Control			
		n	%	n	%	OR(CI)	P-value
Parity							
Nulliparous							
Pimipara	1						
Multipara	2-4						
Grand multipara	≥5						
No of Previous cesarean section	0						
	1						
	2						
	≥3						
ANC history							
	<4 visits						
	≥4 visits						

Gestational Age (weeks)							
	< 37						
	≥37						
Fetal Weight							
	< 4000grs						
	≥ 4000grs						
Fetal sex	Male						
	Female						
Number of fetuses							
	1						
	2						
	3						
Body mass index							
Underweight (< 18.5 kg/m²**)**							
Normal (18.5kg/m² to< 25kg/m²)							
Overweight (25kg/m² to < 30kg/m²**)**							
Obese ≥ 30kg/m²							

b) Indication of cesarean section

	Cases		**Controls**			
	n	**%**	**n**	**%**	**OR(CI)**	**P-value**

c) Comorbidities

		Cases		Controls			
		n	**%**	**n**	**%**	**OR(CI)**	**P-value**
Chronic hypertension							
Gestational hypertension							
Preeclampsia							
Preeclampsia surimposed on chronic Hypertension							
Preeclampsia with severe features							
Eclampsia							
Pregestational Diabetes							
Gestational diabetes mellitus (GDM)							
Anemia(hb g/dl)	**Severe Anemia** Hb<7g/dl						
	Moderate Anemia Hb 7-8 g/dl						
	Mild Anemia Hb 9-10.9g/dl						
	Normal ≥ 11g/dl						

d) Surgical parameters

	cases		**controls**			
	n	**%**	**n**	**%**	**OR(CI)**	**P-value**

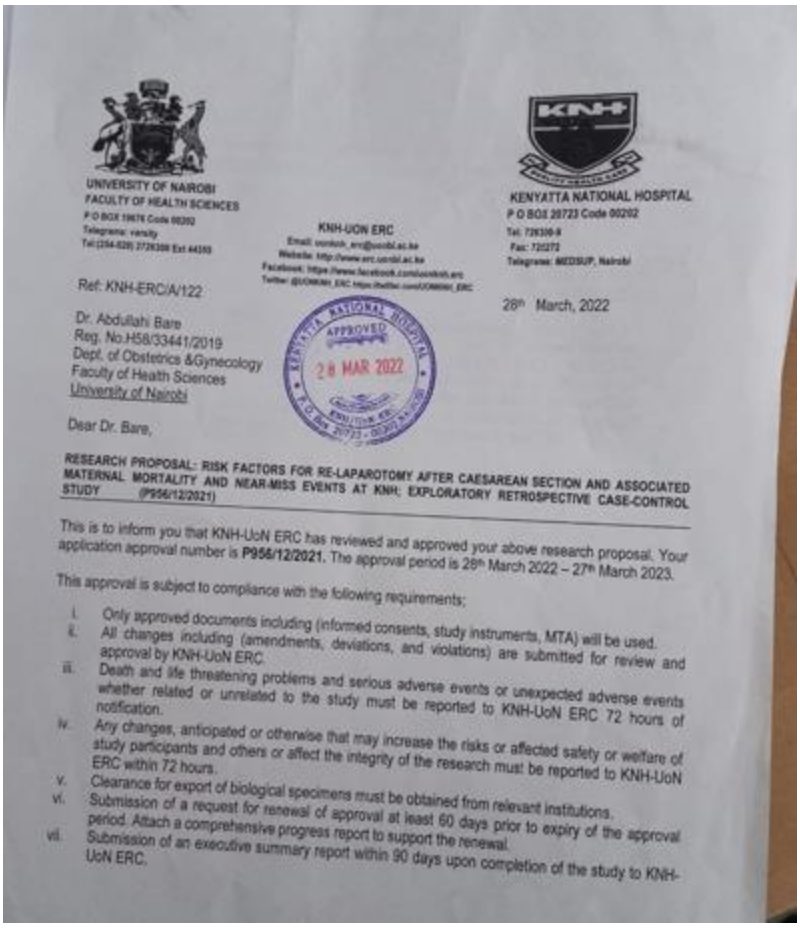
Nature of cesarean section	Emergency						
	Elective						
Time of cesarean section	07:00hrs – 1900hrs						
	19:00— 07:00hrs						
Day of cesarean section	weekday						
	weekend						
Duration of cesarean section	< 45 min						
	≥45 min						
Type of anesthesia	Local(spinal)						
	General						
Surgeon experience	Resident						
	Consultant						
Type of abdominal Incision	Horizontal						
	Vertical						
Adhesions							
Call for help							
Difficulty achieving hemostasis							
Abnormal placentation							

e) POST-OP, EBL, and units of blood transfused

		Cases		Controls		OR(CI)	
		n	**%**	**n**	**%**		**P-value**
Estimated blood loss(EBL)(mls)	<1000mls						
	≥1000mls						
Blood transfused (units)	1-2 units						
	3-4 units						
	5-10 units						
	>10units						

3.0 Comparison of Maternal mortality and maternal near-miss event between cases and the control group

	Cases		Controls		OR(CI)	
	n	**%**	**n**	**%**		**P-value**
Maternal mortality						
Maternal near-miss event						



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

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

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

Ref: KNH-ERC/A/122

28th March, 2022

Dr. Abdullahi Bare
Reg. No:H58/33441/2019
Dept. of Obstetrics &Gynecology
Faculty of Health Sciences
University of Nairobi

APPROVED
28 MAR 2022

Dear Dr. Bare,

RESEARCH PROPOSAL: RISK FACTORS FOR RE-LAPAROTOMY AFTER CAESAREAN SECTION AND ASSOCIATED MATERNAL MORTALITY AND NEAR-MISS EVENTS AT KNH: EXPLORATORY RETROSPECTIVE CASE-CONTROL STUDY (P956/12/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P956/12/2021.** The approval period is 28th March 2022 – 27th March 2023.

This approval is subject to compliance with the following requirements:

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

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Obstetrics and Gynecology, UoN
Supervisors: Dr. Rose Kosgei,, Dept. of Obstetrics and Gynecology, UoN
Dr. Diana Ondieki, Dept. of Obstetrics and Gynecology, UoN