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MATERNAL AND PERINATAL OUTCOME IN MECONIUM-STAINED AMNIOTIC FLUID IN TERM VERTEX PRESENTATION

A prospective cross-sectional study done at CHUK, Muhima and Kibagabaga hospitals from April to June, 2021

Dan Butare, MD

Master of Medicine (Obstetrics and Gynecology) Dissertation
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By

Dan Butare

A Dissertation submitted in partial fulfillment of the requirements for the Degree of Master of Medicine (Obstetrics and Gynecology) of the University of Rwanda.

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CERTIFICATION FOR EXAMINATION

The undersigned certify that they have read and hereby recommend for examination by the University of Rwanda a dissertation entitled '**Maternaland Perinatal outcome in meconium-stained amniotic fluid in term vertex presentation'** in partial fulfillment of the requirements for the Degree of Master of Medicine (Obstetrics and Gynecology) of the University of Rwanda.

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DECLARATION AND COPYRIGHT

I, Dan Butare, declare that this dissertation is my own original work except where specifically acknowledged and it has not been presented to any other University for similar or any other degree award.

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Last but not least, I thank the Almighty God.

DEDICATION

My colleagues, friends and family

ABSTRACT

Objective: To study Maternal and Perinatal outcome in meconium-stained amniotic Fluid.

Materials and Methods: This was a cross-sectional study, conducted in 3 different hospitals in Kigali "one tertiary hospital and 2 districts hospital" (University Teaching Hospital of Kigali (CHUK), Muhima district hospital, and kibagabaga district hospital) over a period of 3months (April to June 2021). The total of 490 pregnant women after 37 completed weeks of gestational with a singleton pregnancy with the cephalic presentation were included in the study, for those 245 pregnant women had meconium-stained amniotic Fluid and the remaining 245 pregnant women had clear amniotic Fluid. Recruited participants were followed till 24hours post-delivery. Microsoft excel was used for Data entry and imported in SPSS version 26 for data analysis we considered $P<0.05$ as Statistical significance.

Results: Out of 490 participants, 385(80.6%) were in the age group between 20-30years of age, 348(71%) had spontaneous labor while 142(29%) were induced. The majority deliver by normal vaginal delivery (NVD) 372(76%), while 118(24%) delivered by c/section. We found the mother who used traditional drugs during pregnancy had a high risk of stained amniotic Fluid 27(77.1%) which was statistically significant. We found low APGAR scores less than 7 after 5min in MSAF group 12(85.7%) than in clear fluid 2(14.3%), a high rate of HIE were seen in meconium-stained Fluid compared to clear fluid 14(87.5%), 2(12.5%) respectively. 3 neonate death were seen in meconium-stained amniotic fluid group in 24hours post follow up, respiratory distress syndrome were statistical significance in MSAF 13(81.2%) than in clear fluid 3(18.8%), there were an increases of NICU admissions in MSAF group than in clear fluid 19(76.0%) 6(24%) respectively.

Conclusion: Meconium-stained amniotic Fluid is associated with an increase in the poor neonatal outcome; "birth asphyxia, and neonatal intensive care unit admissions compared to clear amniotic fluid"

KEY WORDS:

Meconium stained amniotic fluid (MSAF), Term pregnancy, fetal outcomes, Maternal outcomes.

LIST OF ABBREVIATIONS

CHUK: University Teaching Hospital of Kigali

C/Section: Cesarean Section

CTG: Cardiotocography

CMHS: College of Medicine and Health Sciences

FHR: Fetal Heart Rate

HIE: Hypoxic Ischemic Encephalopathy

HCW'S: Health Community Workers

IUFD: Intra-Uterine Fetal Demises

IRB: Institutional Review Board

MSAF: Meconium-Stained Amniotic Fluid

NVD: Normal Vaginal Delivery

NICU: Neonatal Intensive Care Unit

PPH: Postpartum Hemorrhage

ROM: Rupture of Membrane

RDS: Respiratory Distress Syndrome

SPSS: Statistical Package Social Sciences

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CHAPTER I. INTRODUCTION

1.1 Background

Meconium originates from a Greek word "mekonion" which is like poppy juice. Aristotle has discovered that presence of this substance in the amniotic Fluid was similar to the presence of newborn

Meconium-stained amniotic Fluid (MSAF) disquiet feature of fetal compromise which is associated with poor perinatal outcomes; it complicates 8 to 20% of all pregnancies [1,2]

Passing meconium before 34 weeks of gestation is rare and its rate increase after 37 weeks of gestation [3,4].

The incidence of meconium passage is proportional to the gestational age and it is estimated at 5%, 7-22% and 23-52% for preterm deliveries, term deliveries and post term deliveries respectively. [5,6].

Respiratory distress is 100times more likely to occur in infants born with meconium than infants born in clear Fluid, even in low risk woman for obstetric complications, perinatal mortality is five-fold higher in women with meconium stained amniotic Fluid than women with clear amniotic Fluid [3].

Meconium passage in utero is detrimental in intrapartum and postnatal for well-being of the fetus and the mother [5].

Maternal risk factors to develop meconium staining amniotic Fluid are post-term pregnancy, gestational diabetes mellitus, maternal chronic respiratory diseases, cardiovascular diseases, hypertensive disorders [7].

Fetal risk factors for meconium staining fluid include oligo-hydramnios, fetal growth restriction, and low biophysical profile [7].

Meconium-stained liquor is a sign of fetal compromise which is associated with adverse perinatal outcomes which includes low APGAR score, perinatal death, increase rate of chorio-amnionitis, and high rate of neonatal intensive care admission.[4]

MSAF is one of the reasons for the increase in operative deliveries which includes cesarean delivery[7,8], it increases the rate of maternal complications such as Puerperal endometritis,

intrapartum chorioamnionitis, meconium laden amniotic fluid embolism, wound infection.[2]

There is an association between MSAF and meconium aspiration syndrome as well as neonatal resuscitation.[7]

So far there are two unresolved problems about MSAF: management of labor by an Obstetrician and the immediate postpartum period management of an infant.[9]

Currently, there paucity of literature on the effects of Meconium-stained amniotic Fluid on perinatal outcome for those woman who present with meconium-stained amniotic Fluid

Worldwide, little is known on the effect of meconium on the perinatal outcome to affected women.[3,7,10]

In Africa, there are few studies that have assessed the effect of meconium stained amniotic Fluid on perinatal outcome. [5,11]

In East Africa, there was no single studies done MSAF on maternal and perinatal outcome

In our county, no study has been done on the effect of on perinatal and maternal outcome.

This study has been designed to assess the effect of MSAF on maternal and perinatal outcome in vertex presentation in labor.

This is very important because it is the first study to be done in whole East Africa assessing the effect of MSAF on perinatal outcome.

Currently, little is known about MSAF on perinatal outcome and few studies that on MSAF showed that meconium-stained amniotic is associated with poor neonatal outcome and neonatal intensive care admission, Hypoxic ischemic encephalopathy, respiratory distress syndrome and low APGAR scores.

What is so for not known about MSAF in Eastern Africa its effect on perinatal outcome and maternal complications?

The Current study will address the effect that MSAF presents on perinatal outcome and assess if there is associated maternal complication.

1.2 Research questions;

What is the maternal and perinatal outcome in meconium-stained amniotic Fluid in term vertex presentation?

1.3Objectives

1.3.1 General objective:

Assess the influence of meconium-stained amniotic Fluid (MSAF) on the fetal and maternal outcome.

1.3.2 Specific objective:

1. To assess maternal demographic characteristics among pregnant women with meconium-stained amniotic Fluid.
2. To assess the influence of meconium stained amniotic fluid on the mode of delivery.
3. To assess maternal morbidity and mortality associated with meconium-stained amniotic Fluid.
4. To compare the outcomes among neonates borne in meconium stained amniotic fluid versus those with non-stained amniotic fluid.

CHAPTER II. METHODOLOGY

2.1 Study design:

This was a prospective cross-sectional study for 3 months, done at CHUK, Muhima and Kibagabaga hospitals.

2.2 Study site

We conducted this study in the department of Obstetrics and Gynecology at Kigali University teaching hospital (CHUK), Muhima district hospital, and Kibagabaga district hospital. Those are public busy hospitals which are centrally located in Kigali and have a high maternity patient, population and constitute best places to conduct this study because of high hospital attendance in maternity services.

2.3 Study population

Patients admitted during the study period with a term pregnancy were considered. Recruitment of participants was done by the health care provider (Doctor or Midwife) and when the patient was noticed to have meconium-stained amniotic Fluid she was asked to be enrolled in the study and those who accepted were included and cross-matched with the next patient who has clear Fluid. The recruited Participants were followed till 24 hours post-delivery.

2.4 Selection of study population

2.4.1 Inclusion criteria

- Term pregnancy in vertex presentation without prior uterine scars

2.4.2 Exclusion criteria

- Patient with multiple pregnancies
- The patient who has been diagnosed with fetal congenital Abnormality
- Patient with previous cesarean section
- Breech presentation
- Pregnancy with gestational age which is unknown

- ❖ Intra-uterine fetal death upon admission
- ❖ Patients refusing to take part in the study

2.5 Sample size;

We calculated the sample size using the following formula:

$S = Z^2P (1-P) / E^2$

S: Sample size

Z: Z score (1.96 for 95% confidence interval)

P: Population proportion

E: Margin of error (5%)

Population proportion used was from Ethiopia[2] as no study yet was done in Rwanda = 17.8%.

$$\mathbf{S= \frac{(1.96)^2 \text{ X } 0.178 \text{ X } (1-0.178)}{(0.05)^2} = 224.835 \sim = 225}$$

We also need patients to compare. Therefore, our sample size was doubled

2.6 Study procedures

2.6.1 Data collection

Data were collected using a pretested questionnaire and were kept confidentially in locked keyboard. we adapted and used the questionnaire from a study done by Gregroy E. Halle-Ekane et al. [12]

2.6.2 Data analysis

We used Microsoft excel for data entry and imported in SPSS version 26 for data analysis. The results were presented in tables. We used Chi-square and Fischer's test for the measuring of association and P-value of < 0.05 were used for statistical significance

2.7 Ethical consideration

Before beginning the study ethical approval from Institutional Review Board (IRB) was provided. Permission from concerned hospitals (CHUK and Muhima and Kibagabaga district hospital), were requested before the beginning of the study. The patient's identifiers were not recorded on the data collection form and the data were kept anonymous to keep the patient confidentiality.

2.8 Limitation of the study

All the hospitals in the study were located in Kigali which does not necessarily reflect the picture of the whole country.

CHAPTERIII: RESULTS

3.1 Participants' demographic

In our study, we recruited 490 women, 245 had MSAF while the remaining 245 women had non-MSAF.

Table 1, we can see 395(80.6%) were between age group 20-35years, 282(57.6%) were from Muhima District Hospital and 222(45.3%) had primary education level, 213(43.5%) were housewife, 424(86.5%) married.

Table 1: Demographics of study participants

DEMOGRAPHICS		FREQUENCY(N=490)
HOSPITAL	MUHIMA	282 (57.6%)
	KIBAGABAGA	162 (33.1%)
	CHUK	46 (9.4%)
AGE	<20	20 (4.1%)
	20-35	395 (80.6%)
	>35	75 (15.3%)
EDUCATION	None	87 (17.8%)
	Primary	222 (45.3%)
	Secondary	143 (29.2%)
	University	38 (7.8%)
OCCUPATION	House wife	213 (43.5%)
	Farmer	167 (34.1%)
	Businesswomen	61 (12.4%)
	Student	29 (5.9%)
	Civil Servant	20 (4.1%)
MARITAL STATUS	Married	424 (86.5%)
	Single	66 (13.5%)

3.2 Obstetrical characteristics

Table2, in a total of 490 women, table2; describe parity, gestational age, labor onset, labor duration and mode of delivery. It showed that Most women were multiparous 284(58%), 244(49.8%) were full-term, many women had spontaneous labor 348(71%), 429(87.6%) delivered in less than 12hours, the majority delivered by NVD 372 (76%).

Table 2: Obstetrical characteristics of study participants

OBSTETRICAL CHARACTERISTICS		Frequency N=490
PARITY	Primiparous	206 (42%)
	Multiparous	284 (58%)
GESTATIONAL OF AGE	Early term	205 (41.8%)
	Full term	244 (49.8%)
	Late term	41 (8.4%)
ONSETOF LABOR	Spontaneous labor	348 (71%)
	Induced labor	142 (29%)
DURATION OF LABOR	< 12hours	429 (87.6%)
	12hours-24hours	59 (12%)
	>24hours	2 (0.4%)
MODEOF DELIVERY	NVD	372 (76%)
	C/Section	118 (24%)

3.3 Comparisons of demographic characteristics and traditional drugs between a group with MSAF and without MSAF

Table 3, Illustrate that being single, advancing gestational age and use of traditional medicine during pregnancy were statistically significant with p-value <0.05 in meconium group.

Table 3: Comparison of demographic characteristics, parity, gestational age, and traditional drugs between a group with MSAF and without MSAF

CHARACTERISTICS		**MECONIUM STAINED**		**P-Value**
		YES	NO	
		(n=245)	(n=245)	
AGE	<20	11 (55.0%)	9 (45.0%)	Ref
	20-35	198 (50.1%)	197(49.9%)	0.671
	>35	36 (48.0%)	39 (52.0%)	0.579
EDUCATION	**None**	**51 (58.6%)**	**36 (41.4%)**	Ref
	Primary	109 (49.1%)	113 (50.9%)	0.133
	Secondary	71 (49.7%)	72 (50.3%)	0.187
	University	**14 (36.8%)**	**24 (63.8%)**	0.027
OCCUPATION	Business women	25 (41.0%)	36 (59.0%)	Ref
	Civil Servant	10 (50.0%)	10 (50.0%)	0.481
	Farmer	88 (52.7%)	79 (47.3%)	0.119
	House wife	109 (51.2%)	104 (48.8%)	0.162
	Student	13 (44.8%)	16 (55.2%)	0.730
MARITAL STATUS	Married	202 (47.6%)	222 (52.4%)	0.011
	Single	43 (65.2%)	23 (34.8%)	

PARITY	Multiparous	133 (46.8%)	151 (53.2%)	0.99
	Primiparous	112 (54.4%)	94 (45.6%)	
GESTATIONAL OF AGE	early term	87 (42.4%)	118 (57.6%)	<0.001
	full term	126 (51.6%)	118 (48.4%)	0.03
	late term	32 (78.0%)	9 (22.0%)	Ref
TRADITIONAL MEDICINE USED DURING PREGNANCY	Yes	27 (77.1%)	8 (22.9%)	0.001
	No	218 (47.9%)	237 (52.1%)	

3.4 Mode of delivery

Table4, illustrate that ther e was no difference seen in the mode of delivery. 192(78.4%) delivered by NVD had MSAF verses 180(73.5%) with clear Fluid. 65(26.5%) delivered by c/section, had clear fluid verses 53(21.6%) was in the MSAF group

Table 4: Mode of delivery for study participants

		Mode of delivery		P Value
		C/Section	SVD	
Meconium stained	YES	53(21.6%)	192(78.4%)	0.205
	NO	65(26.5%)	180(73.5%)	

3.5 Maternal morbidity and mortality

Table5, illustrate that PPH was statistically significantly common in meconium group 86.4% verse control group 13.6%, one maternal death was seen in the meconium group.

Table 5: Maternal Morbidity and Mortality for study participants

COMPLICATIONS		Meconium Stained		P-value
		YES	N0	
PPH	YES	19 (86.4%)	3 (13.6%)	0.001
	NO	226 (48.3%)	242 (52.7%)	
MATERNAL DEATH	YES	1 (100%)	0 (0.0%)	1
	NO	244 (49.9%)	245 (50.1%)	

3.6 Neonatal morbidity and mortality.

Table 6, Show that meconium-stained amniotic fluids were associated with Low APGAR, RDS, HIE, and NICU admission.

Table 6: Neonatal morbidity and mortality

NEONATAL MORBIDITY AND MORTALITY CHARACTERISTICS		**MECONIUM STAINED** YES (n=245)	NO (n=245)	**P-Value**
NICU ADMISSION	Yes	19 (76.0%)	6 (24.0%)	0.008
	No	226 (49%)	239 (51%)	
HIE	Yes	14 (87.5%)	2 (12.5%)	0.002
	No	231(48.7%)	243 (51.3%)	
RDS	Yes	13 (81.2%)	3 (18.8%)	0.01
	No	232 (48.9%)	242 (51.1%)	
NEONATAL DEATH	Yes	3 (100%)	0 (0.0%)	0.124
	No	242 (49.7%)	245 (50.3%)	
APGAR 1min	<7	22 (88.0%)	3 (12.0%)	<0.001
	≥7	223 (48.0%)	242 (52.0%)	
APGAR 5min	<7	12 (85.7%)	2 (14.3%)	0.006
	≥7	233 (48.9%)	243 (51.1%)	

CHAPTER IV: DISCUSSION

Meconium-stained Fluid; is a tiresome situation for both obstetricians and pediatricians. Meconium passage sometimes is normal physiology, indicating an acute or chronic hypoxic event that can lead to fetal compromise. It increases NICU admission, which can lead to a long time admission stay. The incidence of MSAF increases with gestational age.
In present study we assessed maternal and perinatal outcomes in patients with term pregnancy in vertex presentation found with meconium-stained amniotic fluid.

In present study, MSAF was common in women aged between 20-35years; similar results of other several studies are in line with our findings [3,11,13], it is also correlated with the study done by Mundhra R, Agarwal M, Gregory E. Halle-Ekane et al [3,12]**.** Despite being common findings, that remains unclear in other studies, the fact that in the present study more participants without meconium was also in these age range, we believe that the findings can be explained by peak of female fertility is within the same age range.

In present study, the majority delivered by spontaneous vaginal delivery, which is in line with the study done, Dr. Vidya A Thobbi et al and Mohapatra V, Misra S et al [7,13]; maybe this can be explained as the majority in our study were admitted in an active phase of labor and the fetal monitoring using Cardio-tocography (CTG) or fetoscope by observing fetal heart rate (FHR) kept reassuring and close monitoring of the materno-fetal in labor suite was well done. Several results from other studies done by Nadia Mohammad, lemi belay tolu and Sarika Thakare et al.[6,11,15], showed C/Section as the common mode of delivery in meconium-stained Fluid. This high rate of C/Section was explained by infant rescue due to abnormal fetal heart rate and partly a reflection of obstetricians on managing this labor.
In present study, a low APGAR score of less than seven was seen in the meconium-stained group 88%, similar to the study done by Demisew Amenu Sor et al.[16],which showed low APGAR score of 88% in MSAF group but much higher compared to the study done by lemi belay tolu, and Patil Kamal P et al.[11,16], Persistent low APGAR score at 5minute score found in our study may be explained by having limited resuscitation resources.
In present study, NICU admission was high in the meconium-stained amniotic fluid group compared to clear amniotic Fluid. This was similar to other different studies done by,

Mundhra R, Agarwal M, et al., and Patil Kamal P et al. [3,16], which also showed a high rate of NICU admission in MSAF group.

Our study found that Hypoxic Ischemic Encephalopathy (HIE) was significantly high in the MSAF group at 87.5%. This was quite similar but high to the study done by Vineeta Gupta, B.D. Bhatia et al, 24.5% [18], and Hemali PankajbhaiVaghela et al 19.2% [4].

In present study, patients who had PPH 86.4% was found in the MSAF group, which is statistically significant, similar to study done by Carlo bouche et al and Fang Z et al [19,20].

In present study, we also found statistical significance in none educated MSAF group versus those who complete university; this may be explained by as you become educated the likelihood for understanding is high compared to none educated, we did not find any studies discussing education levels, and this was an incidental finding.

CHAPTER V. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions:

Meconium-stained amniotic Fluid is a predictor of poor neonatal outcome; 87.5% of neonates with MSAF had HIE compared to 12.5% in the control group. 76% of neonates were admitted to NICU compared to 24% without MSAF. This highlights that MSAF can affect the fetal outcome, which can lead to high morbidity and mortality.

The Discovery of a pregnant woman with risk to have or who has meconium allows fetal observation and early intervention to reduce a poor neonatal outcome. Hence decreasing fetal morbidity and mortality

5.2 Recommendations:

- Good collaboration between obstetrician and pediatrician and optimal labour preparedness and neonatal care are important and to achieve this regular training of the concerned healthcare personnel is very necessary

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ANNEXES

Annex 1: QUESTIONNAIRE

Maternal and Perinatal outcomes in Meconium-Stained Amniotic Fluid

Patient Code…….

A. Maternal characteristics

1. Age(years)……

1. Level of Education
- ☐ None
- ☐ Primary
- ☐ Secondary
- ☐ University

2. Marital Status…….
3. Occupation……
4. Gravity…….
5. Parity…….
6. Weight (Kg)……
7. Height (m)…….
8. BMI (kg/m2) ……
9. Gestational Age (weeks)……

10. Medical illness during pregnancy

- ☐ None
- ☐ Chronic hypertension
- ☐ Preeclampsia/Eclampsia
- ☐ DM
- ☐ HIV
- ☐ Malaria
- ☐ Anemia
- ☐ Others….

11. Drug Use

- ☐ Yes
- ☐ No
- ☐ If yes; which.....

12. Previous history

- ☐ None
- ☐ Stillbirth
- ☐ IUFD
- ☐ Abortion
- ☐ Others……

B. Labor Characteristics

1. Onset of labor

- ☐ Spontaneous
- ☐ Induced

2. Time of rupture of membranes(ROM)

- ☐ Before the onset of labor
- ☐ After the onset of labor

3. Duration of ROM before delivery (mins)……
4. Duration of Labor (hrs)……
5. Meconium Stain

- ☐ YES
- ☐ NO

6. Stage of labor at diagnosis of MSAF

- ☐ Latent phase
- ☐ Active phase

7. Mode of Delivery

- ☐ Spontaneous vaginal delivery (SVD)
- ☐ Instrumental
- ☐ Caesarean Section (CS)

8. Indications for operative delivery…….
9. Maternal complications……
10. Temperature (0C) ……

C. Neonatal Characteristics

1. Sex……

2. Mode of New-born resuscitation…….

3. APGAR Score (1^{st}/5^{th}min) ……

4. Birth Weight (kg)…….

5. Perinatal Complications …….

6. Time of birth to the onset of complication (mins)……

APPENDICES

CONSENT TO PATICIPATE IN THE RESEARCH STUDY MATERNAL AND PERINATAL OUTCOME IN MECONIUM -STAINED AMNIOTIC FLUID IN VERTEX PRESENTATION

INTRODUCTION

Dear participant, thank you for taking part in our study maternal and perinatal outcome in meconium-stained amniotic Fluid in vertex presentation.
The current study is designed to assess maternal and perinatal outcome to all patients admitted in time flame period.

PARTICIPATION IN THE STUDY

Participating in this study is a full and free consent. No one will be forced to take part in the study. Apart from the researcher, no one else will have access to the data of participants; and in any case no patient's information will be divulgated to any third party.

RESEARCHER TEAM

The current research on maternal and perinatal outcome in meconium stained amniotic Fluid in vertex presentation; is being conducted by Dan BUTARE resident in Obstetrics and Gynecology in the School of Medicine at the University of Rwanda. The current study is supervised by Dr. Diomede NTASUMBUMUYANGE as a Lecturer at the college of Medicine and health sciences at the University of Rwanda.

WHO WILL PARTICIPATE IN THE STUDY

Having consented to take part in the study and fulfilling the following condition:

Patient admitted in labor ward for labor monitoring and delivery with vertex presentation gestation age between 37wks+0days and 41wks+6days.

WHO IS NOT ALLOWED TO TAKE PART IN THE STUDY

- Patient with multiple pregnancies.

- Patient who has been diagnosed with fetal congenital Abnormality.
- Patient with previous cesarean section.
- breech presentation,
- pregnancy with unknown gestational age
- intrauterine fetal death upon admission

RISKS OF PARTICIPATING IN THIS STUDY

As the current study doesn't involve any clinical intervention to the patients, there is no anticipated risk to the people participating in the study. Confidentiality is warranted during and after the study period.

INTERESTS FOR THE PARTICIPANT

There are no financial interests for participating in this study. As stated above, the purpose of this research is to assess maternal and perinatal outcome in meconium stained amniotic Fluid in vertex presentation. Therefore, there is no direct benefit for the participating patients. However, we hope that by assessing maternal and perinatal outcome in meconium stained amniotic Fluid in vertex presentation, will help us for future perspectives in helping Rwandan to get adequate information and health institutions will be notified to influence and design future strategies aiming at improving the labor monitoring and delivery for our women.

CONFIDENTIALITY

As with any other type of research, the current research will not reveal any personnel detail or the disease condition of the patient/partner to anyone apart from the researcher team.

PERSON OF CONTACT

For any query about this research, please kindly contact us on the following e-mail address: butare40@gmail.com or the following phone number: +250 788896877

Supervisor: Dr. Diomede NTASUMBUMUYANGE Email: muyangediomede@gmail.com

Tel: +250 788334988

CONSENT

I hereby assert that I was explained thoroughly the purpose of this research, and I confirm that I was given sufficient amount of time to think about my participation in the study. I was assured about my privacy, and confidentiality was warranted by the researcher team. I confirm that I

have chosen to participate in this study without financial motivation and my participation was not in any case forced by my treating doctor/ nurse or the researcher team.

Names	Signature	Date
……	…….	
……..	……..	

AMASEZERANO Y'UBUSHAKASHATHSI

Tunejejwe no kwemera kwanyu kwinjira muri buno bushakashatsi. Ububushakashatsi bugamije kumenya ingarukaza meconium k'umugore utwite ndetse n'umwana atwite.

IBIJYANYE NO KWINJIRA MURI BUNO BUSHAKASHATSI

Nkuko bigenda mu bushakashatsi bwose, kwinjira muri buno bushakashatsi ni uburenganzira bw'umurwayi utugana. Nta na rimwe byemewe kwinjira muri buno bushakashatsi kugahato. Nta makuru akwerekeyeho ndetse n'ay'uburwayi bwawe azigera atangarizwa undi muntu uretse twebwe abashakashatsi na muganga wa kuvuye, nta na rimwe amazina yawe, aho ukomoka, cyangwa aderesi yawe bizigera bigaragazwa ku muntu uteri muri ubu bushakashatsi.

ABAGIYE GUKORA BUNO BUSHAKASHATSI

Abagiye gukora buno bushakashatsi ni abaganga bavura indwara z'abagore aribo Dr.BUTARE Dan, umunyeshuri mu mwaka wa nyuma muri gynecology/ UR, Dr.Diomede NTASUMBUMUYANGE wo muri kaminuza y'u Rwanda aka ba n'umuganga w'indwara z'abagore.

NINDE WEMEREWE KUJYA MURI UBU BUSHAKASHATSI

Umugore wese utwite inda iri hejuru y'ibyumweru 37 kugeza ku byumweru 41 n'iminsi itandatu (37 weeks+0day – 41weeks+6days).

NINDE UTEMEREWE KUJYA MURI BUNO BUSHAKASHATSI.

Umugore utwite impanga.

Umugore utwite ariko umwana atwite afite umusembwa.(fetal congenital malformation)

Umugore utwite ariko wabazweho.

Umugore utwite ariko umwana yicaye.(breech)

Umugore utwite ariko utazi igihe aheruka mu mihango.

Umugore utwite ariko umwana ya mupfiriyemo munda.

Umugore utwite udashaka kujya mu bushakashatsi.

UKO UBUSHAKASHATSI BUZAKORWA

Umurwayi aje kwivuza/ ku byara muri serivisi y'indwara z'abagore ku bijyanye ni nda atwite, umushakashatsi hamwe n'abaganga bo mu bitaro umurwayi arimo bazabanza bamusobanurire ibijyanye na buno bushakashatsi. Nyuma umurwayi/ umubyeyi utwite azabazwa niba yemera kujya muri buno bushakashatsi noneho na byemera ahabwe urupapuro agomba kudusinyiraho ko abyemeye.

IBYAGO WAGIRA WINJIYE MURI BUNO BUSHAKASHATSI

Nku ko twabisobanuye haruguru nta kintu na kimwe tuzakora k'umurwayi/umubyeyi utwite muri buno bushakashatsi.

Amakuru yerekeye umurwayi/ umubyeyi utwite nta muntu n'umwe utari mu bushakashatsi uzigera ayamenya kuko azakomeza kugirwa ibanga mu gihe cy'ubushakashatsi na nyuma yaho. Bityo rero nta ngaruka tubona kwinjira muri buno bushakatsi bya gutera nk'umurwayi/umubyeyi utwite.

INYUNGU WAKURAMO

Ubu bushakashatsi ntagobugamije inyungu y'amafaranga. Icyo bugamije ni uku menya ingarukaza meconium ku mubyeyi utwite mu gihe cyo ku byara ndetse n'umwana atwite, ndetse na nyama ho gato mu masaha 24 amaze ku byara ndetse n' umwana. Bityo rero nta nyungu ya ko kanya ku barwayi/ umubyeyi utwite. Gusa twizeranezako ubushakashatsi buzaduha amakuru kw'ngaruka z'umubyeyi utwite wanje ku byara n'umwana atwite .bityo tukazakuramo amakuru ya kunganira buryo itanga servisi cyangwa ku menya kare ingaruka zaterwa na meconium.

KUGIRIRWA IBANGA

Nku ko twabibasobanuriye, ububushakashatsi nta na rimwe buzagaragaza umwirondoro w'umurwayi /umubyeyi cyangwa uburwayi bwe ku wundi muntu uteri muri bano bashakashatsi. Haba mu gihe ububushakashatsi burimo gukorwa na nyumayaho nta na rimwe umwirondoro wawe cyangwa uburwayi bwa we buzigera bugaragarizwa undi muntu utari muri aba bashakashatsi.

UBURYOZWE

Gusinya cyangwa kudasinya ayamasezerano nti bikuraho uburenganzira wari usanganywe bwo kuvurwa cyangwa se ngo bikongerere uburegazare. Nta ni cyo bihindura ku burenganzira n'inshingano z'abashakashatsi.

NINDE WABAZA IGIHE UGIZE IKIBAZO

Niba ugize ikibazo ku bijyanye n'ububushakashatsi twandikire kuri: butare40@gmail.com cyangwa uduhamagare kuri numero +250788896877.

Cyangwa wahamagara umugezunzi w'ububushakashatsi: numero +250 788334988

AMASEZARANO

Ndemezako n'umvise neza icyo buno bushakashatsi bugamije, ndemeza kandi konabonye umwanya uhagije wo ku bitekerezaho. Nizeyeneza kandi ko amakuru yose anyerecyeyeho azagirwa ibanga n'abashakashatsi. Ndemera ko ninjiye muri buno bushakatsi kandi ko kwemera kujya muri ububushakashatsi nta nyungu y'amafaranga kandi ko nta gahato nashyizweho na muganga umvura cyangwa n'abashakashatsi.

Amazinay’umurwayi umukono itariki

……..
…… ……

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 1st /March /2021

Dr Butare Dan
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 059/CMHS IRB/2021

Your Project Title ***"Obstetric and Perinatal Outcome in Meconium Stined Amniotic Fluid in Vertex Presentation"*** has been evaluated by CMHS Institutional Review Board.

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

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 27th January 2021, **Approval has been granted to your study.**

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

You are responsible for fulfilling the following requirements:

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

Sincerely,

Date of Approval: The 1st March 2021

Expiration date: The 1st March 2022

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

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

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Ethics Committee / Comité d'éthique

14 Apr 2021 Ref :EC/CHUK/048/2021

Review Approval Notice

Dear Butare Dan,

Your research project: ***"Obstetrical and perinatal outcome in meconium stained amniotic fluid in vertex presentation "***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 14,Apr,2021 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:www.chuk.rw/research/fullreport/?appid=333&&chuk.

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

Yours sincerely,

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

ETHICS COMMITTEE
CHUK

Scan code to verify

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

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

REPUBLIC OF RWANDA

Kigali, April 8th 2021

KIGALI CITY
NYARUGENGE DISTRICT
MUHIMA HOSPITAL
P.O. BOX 2456 KIGALI
Tél. /Fax : +252 50 37 7
E-mail : muhima.hospital@moh.gov.rw

Dan BUTARE

Re: Your request for clearance of carrying out the research project

Dear Dan

Reference made to your letter received on 16th March 2021 requesting a clearance of carrying out the research project entitled: *Obstetric and Perinatal outcome in meconium stained fluid in vertex presentation at Muhima District hospital*

I would like to inform you that your request is approved and at the end of your project the administration of Muhima hospital shall need to be given the final report of your research.

Yours sincerely,

MANIRAGUHA YEZE Aimée Victoire

Chief Ethic Committee

MUHIMA HOSPITAL
ETHIC COMMITTEE

Cc:
- Clinical Director
- Head of department

Received

HOPITAL KIBAGABAGA
Date d'arrivée: 23/05/21
N° d'enregistrement: 328
A traiter par:

Ref: - clinical director for analysis
24/05/2021
Dr N. [illegible]

Dan BUTARE, MD

University of Rwanda

School of medicine and pharmacy

Obgyn resident/PGYIV

CELL: +250 788896877

E-mail: butare40@gmail.com

TO:

The members of CHUK ethical committee

The members of MUHIMA DH ethical committee

The members of KIBAGABAGA DH ethical committee

Dear member,

RE: requesting for clearance of carrying out the research project

I would like to request for clearance for my research project, **entitled obstetric and perinatal outcome in meconium stained amniotic fluid in vertex presentation.**

It has been approved in our department, as well as in university of Rwanda /IRB committee.

The project will be carried out in three health facilities CHUK and MUHIMA DISTRICT HOSPITAL, and KIBAGABAGA HOSPITAL.

This request is regards of the project of my research.

Awaiting with respect your favorable answer.

Yours faithfully,

Dan BUTARE.

Dr Diomede NTASUMBUMUYANGE.

Hod/obstetrics & Gynecology/ CHUK