College of Medicine and Health Sciences
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MATERNAL-FETAL OUTCOME OF INDUCTION OF LABOR AMONG OVERWEIGHT AND OBESE WOMEN.

Dissertation submitted in partial fulfillment of the requirements for the award of degree of master of medicine in obstetrics and gynecology of the University of Rwanda

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LIST OF ABBREVIATIONS

BMI: Body mass index

IOL: Induction of Labor

UW: Underweight

NW: Normal weight

Ob: Obese

CHUK: Centre Hospitaliere Universitaire de Kigali/ Kigali University Teaching Hospital

KH : Kacyiru hospital

NICU: Neonatal intensive care unit

SVD: Spontaneous vaginal delivery

WHO: World health organization

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DECLARATION

I, Stephen AGABA K., hereby declare and certify that the work presented in this dissertation entitled **"MATERNAL-FETAL OUTCOME OF INDUCTION OF LABOR AMONG OVERWEIGHT AND OBESE WOMEN"** is entirely my original work and it has never been presented or submitted in a whole or in part to any other university.

Stephen K. AGABA, MD Signature: ……. Date: …/…./2021

Supervisors:

We, hereby declare that this dissertation has been submitted with our approval as supervisors.

Dr. BAGAMBE Patrick, MD, MMed Signature: …… Date: …../…./2021

Dr. RUZINDANA Kenneth, MD, MMed Signature: …… Date: …../…./2021

DEDICATION

To God the Almighty

To my Family

To my sisters and brothers

To my classmates

I dedicate this work

ACKNOWLEDGEMENT

First of all, my gratitude goes to Dr. BAGAMBE Patrick and Dr Kenneth Ruzindana who accepted to supervise this work. Their patience, availability and meticulous analysis and corrections made to this achievement.

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AGABA Stephen

ABSTRACT

Background: The current global impact of overweight and obesity on maternal and fetal outcomes during pregnancy and delivery is rising. This study aimed at investigating whether maternal obesity adversely affects outcomes of mothers and fetuses after induction of labor in Rwanda.

Methods: The study was a prospective cohort study in nature. Data analysis was done using IBM SPSS version 25. Chi-square test for trends and logistic regression were used to study the differences in management and outcomes among the BMI groups. ANOVA and Kruskal Wallis tests were used to study the continuous data among the BMI groups.

Results: Obese women were 2.1 times to deliver by cesarean section compared to overweight women combined with women with normal BMI (OR=2.13; 95% CI: 1.37-3.29; p=0.001) while overweight and obese women were 3.1 times more likely to deliver by cesarean section as those with normal BMI (OR=3.11; 95%CI: 1.61-5.99; p=0.001). There was no significant difference in birth weights (p=0.260), Apgar scores at 0 minute (p=0.451), Apgar score at 5^{th} minute (p=0.408) and at 10^{th} minutes (p=0.342). Babies born from obese mothers were 2.14 times more likely to be admitted in NICU as those born from overweight and normal BMI women combined (OR=2.14; 95% CI: 1.24-3.69; p=0.006).

Conclusion: Obese and overweight mothers showed to deliver by cesarean section more likely as mothers with normal weight when induced and require more quantity of misoprostol and oxytocin during IOL and babies who were born from obese mothers are more likely admitted in neonatology.

Key words: Maternal obesity, Induction of labor, maternal outcome, neonatal outcome, Cesarean delivery

CHAPTER I: INTRODUCTION

1.1. Background

Overweight and Obesity are described as an abnormal fat accumulation and poses risk to health. Both are categorized according to body mass index (BMI) (1,2). There is an increase in numbers of obesity and overweight in Rwandan population which might be a result of modernization and industrialization growth (3). BMI is weight in kilograms divided by height in meters squared, the latter is classified into six categories to mean underweight (UW), normal weight (NW), overweight (OW) and obesity (OB) (4,5).

Maternal obesity has become an epidemic globally and the rising number of obesity in Rwanda has been observed over the last decade and continues to emerge. The popularity of overweight/obesity in women in Rwanda increased from 13% in 2000 to 16% in 2010 and this has led to a bigger number of women with obesity getting pregnant (3,5).

Induction of labor has been found to be worldwide most performed obstetric procedure and should be considered when vaginal delivery is considered and when immediate delivery is thought to be more beneficial in terms of maternal and fetal outcome compared to waiting for the spontaneous onset of labor (6). Before labor induction is initiated, cervix has to be assessed for consistence, effacement, dilation and position (7).

Usually pregnant women undergo induction either elective or emergency induction of labor due to different obstetric indications. Obese women rarely start spontaneous labor compared to women with normal weight for height, so this make them more likely to reach late term and hence need for induction of labor (8).

Previous studies conducted to determine if there was a difference in oxytocin dose while inducing labor for obese compared to lean women, found that there a significant amount of oxytocin were needed to achieve successful labor induction in obese compared to control group (9). Effect of maternal obesity on first stage of labor has also been evaluated and came up with conclusion that first stage of labor for obese women took longer duration and has slower advancement until 6cm than their non-obese controls (10).

Previous studies have also found that obesity is associated with effects on the pregnant mother and her fetus(es) (11), assisted vaginal delivery and depression have been reported to be linked with

maternal obesity (12)(13)(14), women with BMI of 30 and above are also found to be at an elevated risk of venous thromboembolism it has been also found to be associated with high rates of induction of labor (5) with high failure rates leading to elevated number of cesarean deliveries (15) with postpartum complications like post-operative infections and postpartum fever. Maternal obesity was also found to be associated with fetal macrosomia (2) and higher NICU admissions due to neonatal respiratory distress observed among neonates born to obese mothers (4)(16)(17). However, a study by Tetsuya Kawakita et al stated that obesity is not associated with cesarean section (18).

It is believed that maternal obesity is highly associated with antenatal and perinatal complications (19). Obesity is also believed to be associated with increased amniotic fluid index, fetal macrosomia, unexplained stillbirths (20)(21) and higher NICU admissions due to the fetal distress (4)(22). A large study conducted in Sweden found that as BMI increases, the rate of fetal death also increases (23).

Therefore, the current study aims to investigate maternal and fetal well-being after inducing labor in women with different body mass indices.

1.2. Research Question

Does maternal obesity adversely affect maternal and fetal outcome after induction of labor in Rwanda

1.3. Objectives

1.3.1. General objective

Assess the impact of overweight and obese on maternal and fetal outcome

1.3.2. Specific objectives

Find out the influence of maternal obesity on maternal outcomes after induction of labor

Assess the influence of maternal weight on fetal outcomes after induction of labor

CHAPTER II: METHODOLOGY

2.1. Study setting

The study was carried out at Kigali University Teaching Hospital (CHUK), Muhima Hospital plus Kacyiru hospital (KH).

Above sites were selected based on different criteria; these hospitals share many things in common: Criteria for inducing labor with Misoprostol or Oxytocin or any other method is the same across these settings and follows the National Obstetric Care Protocol 2020 guideline. Labor monitoring and basic procedures for evaluation of delivery status were similar.

2.2. Study type

This was a prospective cohort study in nature that was conducted from May 1,2021 to June 30, 2021.

2.3. Study population

Our study focused on underweight, normal weight for height, overweight and obese pregnant women with gestational age starting from late preterm up to postdates, admitted in either of the above hospitals for induction of labor. Most of these women were coming for their scheduled visits nevertheless also women undergoing emergency induction of labor were explained about the study and those interested were screened for eligibility.

2.4. Sampling and sample size

The sample size calculation was done using the formula used to estimate a proportion from the population and the study recruited 396 participants and we used consecutive sampling where all the available participants during the study period were enrolled in the study.

2.5. Study procedure

All potential participants visiting hospitals for induction of labor were explained about the current study, weight in kilograms (kg) and height in centimeters (cm) were taken at admission to determine body mass index (BMI) as usual; Gestational age was determined based on either first date of last menstrual cycle for those remembering it or based on Ultrasonography examination. Eligibility check was done in labor suite after patient admission for induction of labor, and then we obtained the informed consent from study participants before the study questionnaire began to

be completed. Illiterate women thumb printed the consent after through explanation of study and study related procedures.

Induction of labor was done after assessing Bishop Score; women with Bishop score of 6 or less were induced with Misoprostol whereas those found to have Bishop score of 7 and above were induced with Oxytocin. As routine practice in all above institutions, regardless of participant's body weight, those who were induced with Misoprostol were give 50mcg per os taken every 4 hours till labor on set while those induced with Oxytocin received 5IU in 500ml of Normal saline, with infusion rate of 8 drops/min where extra 4 drops were added every 30 min till adequate uterine contractions; this was done systematically to each woman who qualified to be induced by either method. Time of administration of prostaglandins was noted, quantity of medications given and time of onset of labor was documented. Study participants were followed up till delivery where delivery time, mode of delivery, neonatal weight, Apgar scores at time zero (0), 5^{th} and 10^{th} minute after delivery, neonatal admission to neonatology were noted. All maternal and fetal outcomes were recorded.

2.6. Inclusion and exclusion criteria

2.6.1. Inclusion criteria

- All pregnant women carrying singleton pregnancy, live fetus, cephalic presentation with no contraindication to vaginal delivery.
- ≥ 18 years old pregnant woman with gestational age of 34weeks and above (≥ 34weeks)
- Able and willing to freely provide informed consent

2.6.2. Exclusion criteria

- Previous cesarean delivery.
- Mentally disabled women
- Not willing to consent

2.7. Data collection

We used paper-based questionnaires to collect information (data) from the patients; these questionnaires were made available to every site's focal persons who were trained about the study and familiar with study questionnaire. Data from these questionnaires were entered electronically at the end of every week in a computer which is password protected.

2.8. Statistical data analysis

Data entry was done using Epidata version 3.1 and IBM SPSS version 25 was used for statistical analysis. Descriptive data were presented as follow: categorical data were presented using frequencies and percentages in tables and continuous data are summarized by mean and median values depending on their distribution and Chi-square test and Logistic regression were used to study the differences in management and outcome among the BMI groups and the ANOVA test and a non-parametric test, Kruskal Wallis test, were used to compare the continuous data among the groups.

2.9. Ethical considerations

We got allowance to conduct study from the University of Rwanda Ethics committee and from Ethics Committees of data collection sites.

CHAPTER III: RESULTS

3.1. Characteristics of study participants

Our study recruited 396 women who presented for a scheduled or emergency induction of labor at CHUK, Muhima, and Kacyiru Hospitals. The mean age for our participants was 29 (± 5.7) years and approximately fifty percent (49.7%; 197/396) of the participants attended secondary school and twenty percent (19.9%;79/396) of them pursued tertiary education. Eighty-five percent (85.1%; 337/396) of the mothers who were recruited in the study were married and the median number of pregnancies was 2 ranging from 1 to 10 pregnancies. Fifty-three percent (52.5%; 208/396) of the participants had their labors induced due to rupture of membranes, twenty-six percent (25.8%; 102/396) were induced due to late term and post term pregnancy (gestational age of 41 weeks and above), fourteen percent (13.9%; 55/396) induced because of preeclampsia whereas five percent (5.3%;21/396) were induced due to reduced fetal movements, remaining three percent (2.5%; 10/396) of our study participants were induced due to oligohydramnios. Considering the body mass index, almost thirty-eight percent (37.6%; 149/396) of the participants were obese, forty-three percent (42.9%; 170/396) were overweight and almost twenty percent (19.4%;77/396) had normal body mass index.

Table 1: Baseline characteristics of study participants (n=396)

Characteristics	Frequency	%
Age		
Mean ± SD	29.0 ± 5.7	
Educational background		
No formal education	22	5.6
Attended primary school	98	24.7
Attended secondary school	197	49.7
Attended university	79	19.9
Marital status		
Married	337	85.1
Single	51	12.9
Divorced	7	1.8
Widowed	1	0.3
Number of pregnancies		
Median (Min-Max)	2 (1-10)	
Primigravida	170	42.9
Parity 1-4	183	46.2
Parity >4	43	10.9
Indication for induction of labor		
PPROM/PROM	208	52.5
Gestational age >=41 weeks	102	25.8
Pre-eclampsia	55	13.9
Oligohydramnios	10	2.5
Reduced fetal movements	21	5.3
BMI (Mean ± SD)	**28.5 ± 4.9**	
Normal	77	19.4
Overweight	170	42.9
Obese	149	37.6

3.2. Effect of maternal obesity on maternal outcomes

There was a statistically significant difference in median initial Bishop scores among BMI groups where mothers with normal BMI had slightly low Bishop scores compared to overweight and obese mothers ‹2.0 (2.0-4.0) →3.0 (2.0-4.0) →3.0 (2.0-4.0) P=0.02›. The obese and overweight women required high quantity of Misoprostol with a median of 100 micrograms compared to normal weight mothers for their height who had a median Misoprostol quantity of 50 micrograms ($p<0.001$). There was difference in time required to reach 6 centimeters of dilatation (active phase of labor) among obese mothers compared to overweight and mothers with normal BMI where obese mothers required a median of 14.5 hours to reach the active phase compared to a median of 8 hours for overweight and 8.5 hours for mothers with normal weight for height ($p<0.001$). Considering women who delivered eutocically, the median labor duration varied across different BMI groups, 5 hours for obese, 4 hours for overweight and 2 hours for normal weight for height women ($p<0.001$). Thirty-five percent of primiparous mothers delivered by Cesarean section compared to 28.3% of the multiparous ones who delivered by Cesarean section ($p=0.138$).

Fifty-six percent (56.2%; 82/146) of the obese mothers delivered by spontaneous vaginal delivery compared to sixty-nine percent (69.4%;118/170) of the overweight mothers and Eighty-three percent (82.5%; 66/80) of the mothers with normal BMI ($p=<0.001$). Obese women delivered by cesarean section at forty-two percent (41.8%; 61/146) compared to thirty percent (30%; 51/170) of overweight women and fifteen percent (15%; 12/80) of women with normal BMI with statistical significance ($p<0.001$). The methods used to induce labor were equally distributed across the body mass index groups ($p=0.611$). Eight of 23 (34.8%) obese women who were induced with oxytocin required at least 10 UI, while all 23 overweight women who were induced with oxytocin required 5 UI and one of 4 women with normal BMI required 10 UI ($p=0.008$). See details in table 2.

Table 2: Comparison of management and labor outcomes among study participants' BMI groups (n=396; ‹NW=80, OW=170, OB=146›)

Management and labor outcome	Normal (BMI:18.5-24.9)	Overweight (BMI:25.0-29.9)	Obese (BMI: ≥30.0)	P value
Initial Bishop score				
Median (IQR)	2.0 (2.0-4.0)	3.0 (2.0-4.0)	3.0 (2.0-4.0)	0.02
Quantity of Misoprostol in mcg				
Median (IQR)	50 (50-100)	100 (50-150)	100 (50-200)	<0.001
Time for 6cm of cervix dilation in hours				
Median (IQR)	8.5 (6.0-13.0)	8.0 (5.0-14.5)	14.5 (6.8-18.25)	<0.001
Duration of labor in hours				
Median (IQR)	2.0 (2.0-4.0)	4.0 (3.0-5.0)	5.0 (4.0-6.0)	0.001
Delivered by SVD				
Yes	66 (82.5%)	118 (69.4%)	82 (56.2%)	<0.001
No	14 (17.5%)	52 (30.6%)	64 (43.8%)	
Operative vaginal delivery				
Yes	2 (2.5%)	0 (0.0%)	2 (1.4%)	0.078
No	78 (97.5%)	170 (100%)	144 (98.6%)	
Cesarean section				
Yes	12 (15.0%)	51 (30.0%)	61 (41.8%)	<0.001
No	68 (85.0%)	119 (70.0%)	85 (58.2%)	
Indication of C/S				
Failure of induction	3 (6.8%)	15 (34.1%)	26 (59.1%)	
NRFHR	7 (12.5%)	23 (41.1%)	26 (46.4%)	
Prolonged labor	1 (7.7%)	8 (61.5%)	4 (30.8%)	0.415
Maternal request	0 (0.0%)	2 (100%)	0 (0.0%)	
Other	2 (15.5%)	4 (30.8%)	7 (53.8%)	
Method of Induction of labor				
Misoprostol				
Yes	73 (91.3%)	148 (87.1%)	130 (89.0%)	0.611
No	7 (8.8%)	22 (12.9%)	16 (11.0%)	
Oxytocin				
Yes	8 (10.0%)	17 (10.0%)	17 (11.6%)	0.877
No	72 (90.0%)	153 (90.0%)	129 (88.4%)	
Combined Misoprostol and oxytocin				
Yes	1 (1.3%)	5 (2.9%)	2 (1.4%)	0.527
No	79 (98.8%)	165 (97.15%)	144 (98.6%)	
Quantity of oxytocin				
5 UI	3 (75.0%)	23 (100%)	15 (65.2%)	0.008
≥10 UI	1 (25.0%)	0 (0.00%)	8 (34.8%)	

3.3. Impact of maternal weight on fetal outcome

The neonatal birth weights were not different across BMI groups (p=0.260), and also the Apgar scores at 0 minute (p=0.451), Apgar score at 5^{th} minute (p=0.408) and at 10^{th} minute (p=0.342) were not different statistically. Twelve percent (12.5%) of neonates born from mothers with normal BMI developed respiratory distress syndrome compared to 12% of babies born from overweight women and 16.4% of babies born from obese women (p=0.457). Among the two babies born from shoulder dystocia, one was from a mother who was overweight and the other one was from the mother with obesity. Neonates born from obese mothers were more likely to be admitted in neonatology unit compared to those born from overweight and normal weight for height mothers. 22.6% of newborns from obese women, 12% from overweight mothers and 12.5% of the babies from mothers with normal BMI (p=0.021). See details in table 3.

Table 3: Comparison of neonatal outcomes among participants' BMI groups

Neonatal outcome	Normal (BMI:18.5-24.9)	Overweight (BMI:25.0-29.9)	Obese (BMI: ≥30.0)	P value
Birth weight				
Mean ± SD	3.1 ± 0.6	3.2 ± 0.4	3.2 ± 0.04	0.260
APGAR score				
APGAR score at 0 minute				
Median (IQR)	9 (9-9)	9 (8-9)	9 (8-9)	0.451
APGAR score at 5th min				
Median (IQR)	10 (10-10)	10 (9-10)	10 (9-10)	0.408
APGAR score at 10th				
Mean ± SD	9.6 ± 0.1	9.8 ± 0.1	9.6 ± 0.06	0.342
Neonatal complications				
RDS				
Yes	10 (12.5%)	20 (11.8%)	24 (16.4%)	0.457
No	70 (87.5%)	150 (88.2%)	122 (83.6%)	
Admission in neonatology				
Yes	10 (12.5%)	20 (11.8%)	33 (22.6%)	0.021
No	70 (87.5%)	150 (88.2%)	113 (77.4%)	

SD: Standard Deviation; RDS: Respiratory Distress Syndrome; IQR: Interquartile range; BMI: Body mass index

3.4. Comparison of the maternal and fetal outcomes among normal BMI vs combined overweight and obese

There was a difference in the quantity of Misoprostol required among the groups ($p<0.001$) and for the duration of labor ($p<0.001$) in the overweight women combined with obese women compared to women with normal BMI. The overweight and obese women were less likely to deliver by spontaneous vaginal delivery compared to normal weight for height women (OR=0.36; 95%CI: 0.19-0.68; p=0.001) and overweight combined with obese women were 3.11 times more likely to deliver by cesarean section as women with normal BMI (OR=3.11; 95%CI: 1.61-5.99; p=0.001).

Table 4: Comparison of the maternal and fetal outcomes among normal BMI vs combined overweight and obese

Management and labor outcome	Body weight		OR (95%CI)	P value
	Normal	Overweight & Obese		
Quantity of Misoprostol				
Median (IQR)	50 (50-100)	100 (50-200)		<0.001
Time for 6cm of cervix dilation in hours				
Median (IQR)	9 (6-14)	12 (5-17)		0.062
Duration of labor in hours				
Median (IQR)	2.0 (2.0-4.0)	5.0 (3.0-6.0)		<0.001
Misoprostol				
Yes	73 (91.3%)	278 (88.0%)	0.70 (0.30-1.63)	0.412
No	7 (8.8%)	38 (12.0%)		
Oxytocin				
Yes	8 (10.0%)	34 (10.8%)	1.08 (0.48-2.44)	0.844
No	72 (90.0%)	282 (89.2%)		
Delivered by SVD				
Yes	66 (82.5%)	200 (63.3%)	0.36 (0.19-0.68)	0.001
No	14 (17.5%)	116 (36.7%)		
Operative vaginal delivery				
Yes	2 (2.5%)	2 (0.6%)	0.25 (0.3-1.79)	0.167
No	78 (97.5%)	314 (99.4%)		
Cesarean section				
Yes	12 (15.0%)	112 (35.4%)	3.11 (1.61-5.99)	0.001
No	68 (85.0%)	204 (64.6%)		
RDS				
Yes	10 (12.5%)	44 (13.9%)	1.13 (0.54-2.36)	0.74
No	70 (87.5%)	272 (86.1%)		
Admission in NICU				
Yes	10 (12.5%)	53 (16.8%)	1.41 (0.68-2.91)	0.353
No	70 (87.5%)	263 (83.2%)		

RDS: Respiratory distress syndrome; SVD: Spontaneous vaginal delivery; IQR: Interquartile range

3.5. Comparison of the maternal and perinatal outcomes among obese vs combined overweight and normal weight women

Among the BMI groups, there was a difference in the quantity of Misoprostol required ($p<0.001$), time to reach the active phase ($p<0.001$) and the duration of labor ($p<0.001$) between the obese women and overweight women combined with normal weight for height women. Women who were obese were less likely to deliver by SVD ($p<0.001$) but they were 2.13 times more likely to deliver by cesarean section compared to overweight and normal weight for height mothers combined (OR=2.13; 95% CI: 1.37-3.29; p=0.001). Babies born from obese women were 2.14 times more likely to be admitted in NICU as those born from overweight and normal weight for height women combined (OR=2.14; 95% CI: 1.24-3.69; p=0.006)

Table 5: Comparison of the maternal and fetal outcomes among obese vs combined overweight and normal weight women

Management and labor outcome	Body weight		OR (95%CI)	P value
	Normal and overweight	obese		
Quantity of Misoprostol				
Median (IQR)	100 (50-150)	100 (50-200)		<0.001
Time for 6cm of cervix dilation in hours				
Median (IQR)	10.0 (6.0-16.0)	14.0 (6.0-18.0)		<0.001
Labor duration in hours				
Median (IQR)	4.0 (2.0-5.0)	5.0 (4.0-6.0)		<0.001
Method of Induction of labor				
Misoprostol				
Yes	73 (91.3%)	278 (88.0%)	0.94 (0.49-1.79)	0.846
No	7 (8.8%)	38 (12.0%)		
Oxytocin				
Yes	8 (10.0%)	34 (10.8%)	1.18 (0.62-2.28)	0.609
No	72 (90.0%)	282 (89.2%)		
Delivered by SVD				
Yes	184 (73.6%)	82 (56.2%)	0.46 (0.29-0.71)	<0.001
No	66 (26.4%)	64 (43.8%)		
Operative vaginal delivery				
Yes	2 (0.8%)	2 (1.4%)	1.72 (0.24-12.3)	0.589
No	248 (99.2%)	144 (98.6%)		
Cesarean section				
Yes	63 (25.2%)	61 (41.8%)	2.13 (1.37-3.29)	0.001
No	187 (74.8%)	85 (58.2%)		
Neonatal complications				
RDS				
Yes	30 (12.0%)	24 (16.4%)	1.44 (0.81-2.58)	0.216
No	220 (88.0%)	122 (83.6%)		
Admission in NICU				
Yes	30 (12.0%)	33 (22.6%)	2.14 (1.24-3.69)	0.006
No	220 (88.0%)	113 (77.4%)		

CHAPTER IV: DISCUSSION

Our findings indicate that both obese and overweight women were more likely to deliver by cesarean section compared to normal BMI women ($p<0.001$) with a difference that is statistically significant and our results are in accordance from the results of studies done by other researchers who reported that obese mothers had higher rates of cesarean section and adverse perinatal outcomes compared to mothers with normal BMI (1,2,4,8,11,14,24–31) but different from the results from the study done by Tetsuya et. al (31)(32).

In our study there was a difference in total duration of latent phase labor for obese mothers compared to overweight women and those with normal weight for height ($p<0.001$) our result is different from the results from the study done by Karen et al. in Denmark (28) and the study done by Arrowsmith et. al (24) but in accordance with the results from the study done by Shayna et. al (32) and other studies (8,20,25).

In our study, there was no difference in method of induction of labor across groups among overweight and obese women compared to normal BMI women but obese women induced with oxytocin, required more quantity of oxytocin compared to overweight women and women with normal BMI with a statistically significant difference ($p=0.008$). Our findings are in accordance with the results from the study done by Meg et.al (9).

Birth weight of babies born from either overweight or obese women was not different from that of those born from women with normal body mass index in our study even though all 4 macrosomic neonates who were recorded in our study were born from obese women; this is not similar to findings of the study done by Elizabeth et.al who showed super-obesity to be more likely associated with macrosomia (29), results from the study done by Nicole et. al. (33) and results from the study done by Shayna et. al. (32). The study by Baron et al. also found that neonates born from obese mothers were more likely to be macrosomic (26). Other researchers also reported the same findings (14,27).

Our results showed significant difference in neonatology admission of babies born from obese women (23%) mainly due to respiratory distress and fetal macrosomia compared to babies born from overweight women (12%) and normal weight for height women (13%). Our results are in accordance with the results of the study done by Elizabeth et al. (29) and other studies which also

found that babies of obese mothers are more likely to be admitted in neonatology unit and that they have high risk of poor neonatal outcomes (4,26).

Our findings showed no difference in the Apgar scores at time 0, 5^{th} and 10^{th} minute after birth in babies born from mothers with abnormal weight for their height as those from women having normal weight for height which was in accordance with the results from Arrowsmith et al. who reported no difference in Apgar scores across all BMI groups (24). Our result is different from the results from other studies (25–27).

Our results showed that there is no difference in shoulder dystocia across groups which is in accordance with the results from Arrowsmith et al. who reported that shoulder dystocia cases were similar across the groups (24).

In our study we had no opportunity to look at the effect of inducing underweight pregnant women in relation to maternal and fetal outcome, simply due to lack of underweight women in the recruited subjects. Thus, this brings the need for a large study that could include all the BMI categories.

CHAPTER V: CONCLUSION AND RECOMMENDATIONS

5.1. Conclusion

Obese and overweight women showed to be more likely to deliver by cesarean section when induced for labor and require more quantity of Misoprostol and oxytocin during induction of labor, their labor tend to be slow compared to that of normal BMI women, and babies who were born from obese women had more chance to be admitted in neonatology.

There is no difference in neonatal birth weight, Apgar scores and respiratory distress syndrome among overweight and obese mothers compared to women with normal body mass index though we recorded only 4 macrosomic babies and all were born from obese women.

5.2. Recommendations

To Health providers

-Health care providers should monitor closely obese and overweight women who are on induction of labor for possible cesarean sections and counselling should be done prior to induction of labor.

-Educate women in consultations during antenatal care visits about weight regulation and the effect of obesity and/or overweight on both mother and fetus's outcome.

To the community

-Effort should be put to avoid being Overweight or Obese especially among pregnant women

in improving the outcomes of pregnancy.

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ANNEXES

Data collection tool

INFORMED CONSENT	
INFORMED CONSENT	
1. Has the informed consent form for enrolment been signed?	☐ Yes ☐ No
DEMOGRAPHIC DATA	
3. In which hospital have you come to deliver?	☐ CHUK ☐ KH ☐ Muhima Hospital
4. What is your date of birth?	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY) ☐ Unknown
4a. If date is unknown, what is the presumed age?	__ __ Years
5. Matrimonial status	☐ Single ☐ Married ☐ Divorced
6. Did you go to school; what is your highest education?	☐ Did not go to schooling ☐ Did not complete primary school ☐ completed primary school ☐ Did not complete secondary school ☐ Completed secondary school ☐ Tertiary school

OBSTETRIC HISTORY: *Now we are going to discuss with you about how many pregnancies you have had, how many of them went to term, delivered preterm, miscarriages, living children and mode of delivery*	
7a. How many pregnancies have you had so far?	__ __ __
7b. in those, how many reached term and delivered spontaneously?	__ __ __ __ __ / __ __ __ / __ __ __ __

8. At what gestational age is this pregnant according to her LMP or Ultrasonography?	__ __ *W* __ *D*
9a. Is the patient admitted for Induction of labor? 9b. If yes, Specify reason for IOL:	☐ Yes ☐ No ☐ Hypertension ☐ Gestational diabeetes melitus ☐ Preeclampsia ☐ Other, specify:
PHYSICAL EXAMINATION: BMI calculation and Cervical assessment for Bishop score	
10. Patient's weight in kilograms (KG)	__ __ __
11. Patient's height in centimetres	__ __ __
12. What is her BMI based on the above	__ __. __
13. What is the baseline or initial Bishop score?	__ __
14. About methods used to induce labor, tick all that apply: ☐ Cytotec ☐ Oxytocin infusion ☐ Transcervical foley's catheter ☐ Laminaria japonicum ☐ combined methods (transcervical foley's catheter plus cytotec)	
15. What was the quantity of Cytotec utilized?	__ __ __mcg
16. What was the quantity of Oxytocin given?	__ __ __IU
17. Time of initiation of induction of labor	__ __ :__ __
18. Time when cervix is 6cm dilated (Active phase of labor)	__ __: __ __

19. What was the time interval in hours between start of IOL to Active phase of labor (cervix dilated to 6cm)	__ __ __Hrs
20. What was duration of labor?	__ __ __Hrs
MODE OF DELIVERY AND NEONATAL OUTCOME	
20. Did participant deliver eutocically?	☐ Yes ☐ No
21. Did participant have operative vaginal delivery?	☐ Yes ☐ No
22. Did participant undergo caesarean section?	☐ Yes ☐ No
23. If yes, what was the indication for caesarean section? *Choose one that apply*.	☐ Failure of induction of labor ☐ None reassuring fetal heart rate ☐ Prolonged labor ☐ caesarean section for maternal request
NEONATAL OUTCOME SECTION.	
24. What is birth weight of the baby?	__.__KG
25. What are the APGAR score at 0, 5th, and 10th minute respectively?	__, __ , __
26. Did neonate suffer or experience any of the following during or after birth?	☐ Respiratory distress ☐ Shoulder dystocia ☐ Birth trauma: Specify: ---------- ☐ Chorioamnionitis ☐ Other, specify:
27. Was the neonate admitted in Neonatology?	☐ Yes ☐ No

Completed by:	Date: _____/_____/_____
Reviewed by:	Date: _____/_____/_____
Data entry by:	Date: _____/_____/_____
Investigator sign-off:	Date: _____/_____/_____

Consent form: ENG & KINYA

PARTICIPANT INFORMATION SHEET

Title: "MATERNAL-FETAL OUTCOME OF INDUCTION OF LABOR AMONG OVERWEIGHT AND OBESE WOMEN. A COMPARATIVE STUDY"

This informed consent form is for patients who will be recruited for participating in the study, entitled **"Maternal-Fetal Outcome Of Induction Of Labor Among Overweight And Obese Women. A Comparative Study"**.

The main investigator is Agaba K. Stephen, a student from University of Rwanda, doing Master of Medicine in obstetrics and gynecology.

Part I: Information Sheet

Introduction

Agaba K. Stephen, a student from University of Rwanda, doing Master of Medicine in obstetrics and gynecology is doing a research project on **Maternal-Fetal Outcome of Induction of Labor among Overweight and Obese Women. A comparative study**. We are going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can freely ask them.

Purpose of the research

The study aims to identify the maternal-fetal outcome of induction of labor among overweight and obese women.

I am requesting you to be a part of this research because you are among the pregnant mothers who are going to be on induction of labor. Before agreeing to participate in this study, it is important that you know the purpose of this study and knowing the nature of the questions. Don't hesitate to request clarifications if information is unclear.

Maternal-Fetal Outcome of Induction of Labor among Overweight and Obese Women. A comparative study

The researcher is interested in knowing the maternal and fetal outcomes of induction of labor among overweight and obese women.

Questions are about?

Questions are addressed to women presented for labor and childbirth at CHUK, Rwanda Military hospital, King Faisal hospital, and Kacyiru hospital. Those questions are related to the maternal outcome and fetal outcomes after induction of labor. The time required to respond on the planed questions is less than 10 minutes.

Who do I want to talk to?

I want to talk to patients who presented for labor and childbirth in the department of obstetrics and gynecology on induction of labor. It is voluntary participation; there is no push and no law. If you don't want to participate, you don't have to explain why.

When you agree to participate:

- ✓ You sign/ write your names that prove that you have accepted to participate in this study.

If there are questions that you don't feel comfortable to answer, you are free to skip.

Right to refuse or withdraw

You are allowed to stop your participation at any time

Incentives

There are no any incentives for your time, your participation is voluntary.

Confidentiality

Your names, and other information shared will not be shared with anybody than the research team.

Dissemination of results

The outcome from this research will be used to improve quality of care of women presenting for labor and childbirth who will go for induction of labor. There is no personal interest or direct benefit for the researcher.

Who is conducting this research?

This research is led by a student from University of Rwanda, doing his Master of Medicine in obstetrics and gynecology.

Who to contact

If you want more information about project, you can contact the researcher on the following contacts:

Agaba K. Stephen**: Phone number: + (250) 788357866 or at email: agabask@gmail.com**

My Supervisor ;

Dr Patrick Bagambe: + (250) 788302804; email: patrickgatsinzi.pg@gmail.com

Dr Kenneth Ruzindana: Tel: +(250) 788642551; Email: kenru20@gmail.com

Chairperson of IRC-CMHS, Dr Stephan Jansen on phone number + (250) 788563311

Ifishi y'amakuru ku uwitabira ubushakashatsi: KWINJIRA MU BUSHAKASHATSI

Izina ry'Ubushakashatsi: "UBUSHAKASHATSI BUGAMIJE GUSUZUMA UBUZIMA BW'ABANA N'ABYEYI NYUMA YUKO UMUBYEYI AHAWE IBISE.

Ayamakuru yagenewe umuntu wese uzitabira buno bushakashatsi bwavuzwe haruguru bwitwa **"Maternal-Fetal Outcome Of Induction Of Labor Among Overweight And Obese Women. A Comparative Study"**. Mundimi z'Amahanga

Ubushakashatsi burakorwa na Agaba K. Stephen, Umunyeshili urimo gusoza metirize muri Kaminuza y'Urwanda mu ishami ry'ubuvuzi kugitsina Gore.

Ubushakashatsi bugamije iki

Hagamijwe gusuzuma ubuzima bw'ababyeyi n'abana bavutse kubabyeyi babyibushye cyane, ababyibushye bigereranyije na abatananutse kandi bakaba batanabyibushye.

Urashishikarizwa kwitabira ubushakashatsi kubera ko utwite kandi ukaba ugiye guhabwa ibise. Mbere yo kwemera kwitabira ubushakashatsi, ningenzi kubanza ukamenya intego y'ubushakashatsi, mugihe kandi ugize ikibazo icyo aricyo cyose kumakuru uhawe, usabwe kutubaza.

Ibibazo bibazwa bigamije iki?

Ibibazo birebana n'ubushakashatsi bibazwa abagore batwite baje guhabwa ibise bari mu rwererero kubitaro bikurikira; KFH, CHUB, CHUK, RMH na Kacyiru DH. Ibyibibazi byerekeye ku kumenya ubuzima bw'umwana nyuma yo kuvuka, ubuzima bw'umubyeyi wibarutse nyuma yo guhabwa ibise. Igihe gitegenyijwe gusubiza ibibazo muzabazwa ntikigera kuminota 10.

Ninde ubazwa ibibibazo?

Hazabazwa umugore utwite uri murwererero waje guhabwa ibise. Kwitabira ubushakashatsi ni ubushake ntagahato; ubaye udashaka kugirara uruhare mubushakashatsi; ntawakubaza gusobanura impamvu wanze.

Niwemera kugira uruhare mubushakashatsi:

- ✓ Urasinya/wandika amazina yawe nkikimenyetso ko wemeye kwitabita ubushakashatsi. Hari ibibazo udashaka gusubiza kumpamvu zawe bwite, wemerewe kubyihorera.

Uburenganzira ku kutitabira cyangwa kuva mu ubushakashatsi

Ufite uburenganzira bwo kutitabira cyanwa ukava mubushakashatsi igihe icyo aricyo cyose

Ikiguzi

Kwitabira ubushakashatsi nubushake, ntakiguzi uhabwa kubera igihe wakoresheje mubikorwa by'ubushakashatsi.

Ibanga

Amazina yawe, n'andi makuru agaragaza uwitabiriye ntazasaranganwa n'undi muntu uwariwe wese keretse abakore muri ubu bushakashatsi.

Isaranganywa ry'amakuru avuye mubushakashatsi

Ibizava mubushakashatsi bizadufasha kunoza ubuvuzi kubagore batwite baje guhabwa ibise ngo babyare. Ntanyungu cyangwa indonke umushakashatsi ategerejemo.

Ninde urigukora ububushakashatsi?

Ubushakashatsi burigukorwa n'umunyeshuli wiga muri Kaminuza y'Urwanda mu ishami ryita kubuvuzi bwa abagore.

Ninde twakwiyambaza

Ugize ikibazo icyo aricyo cyose cyangwa hari amakuru arenzeho waba ukeneye kubijyanye n'ububushakashatsi, wakwiyambaza aba bakurikira:

Agaba K. Stephen**: Phone number: + (250) 788357866 or at Email: agabask@gmail.com**

My Supervisors ;

Dr Patrick Bagambe: Phone number: + (250) 788302804; Email: patrickgatsinzi.pg@gmail.com

Dr Kenneth Ruzindana: Phone number +(250) 788642551; Email: kenru20@gmail.com

Chairperson of IRC-CMHS, Dr Stephan Jansen on phone number + (250) 788563311

Outcome of Induction of Labor in Obese & Overweight women (Maternal fetal outcome)

Participant Identification Number **Participant Initials** **Protocol version 0.1 dated 28/04/2021**

ENROLMENT INFORMED CONSENT FORM

Before you sign this consent form (or give your thumbprint or special mark, if you are unable to read), make sure of the following:

- You have read the enrolment participant information sheet (dated 28/04/2021), or someone has read it to you.
- You have been given a copy of the enrolment participant information sheet (dated28/04/2021).
- This study has been explained to you.
- You have had your questions answered.
- You understand you can ask more questions at any time and that you can withdraw at any time from the study process.
- You understand your study records will be available to the Obstetricians and Midwives in this hospital and other groups of people.
- You agree to join the study.

PARTICIPANT CONSENT FOR STUDY ENROLMENT

My signature (or thumbprint) below confirms that I freely agree to **join** this study.		
Participant's Name	**Participant's Signature/Thumbprint**	**Date**

PRINCIPLE INVESTIGATOR

As Principle Investigator, or properly delegated by the Principle Investigator, I have fully informed the participant of all aspects of the study.		
Investigator/Designee Name	**Signature**	**Date**

Outcome of Induction of Labor in Obese & Overweight women
(Maternal fetal outcome)

(Ubushakashatsi bugamije gusuzuma uburyo umubiri wabagore bafite ukabije wakira ihabwa ry'ibise igihe cyo kubyazwa.)

Participant Identification Number **Participant Initials** **Protocol version 0.1 dated 28/04/2021**

IFISHI YO KWEMERA KUBUSHAKE KWITABIRA UBUSHAKASHATSI

Mbere yo gushyira umukono (cyangwa igikumwe cg ikimenyetso kihariye, niba utabasha gusoma) kuri iyi fishi yo kwemereraho, banza umenye ko ibi bikurikira byakozwe:

- Wasomye ifishi ikubiyemo amakuru agenewe uwitabira ubushakashatsi (yo kuwa 28/04/2021), cyangwa hari umuntu wayagusomeye.
- Wahawe ikopi y'ifishi ikubiyemo amakuru agenewe uwitabira ubushakashatsi (yo kuwa 28/04/2021).
- Wasobanuriwe ubu bushakashatsi.
- Wahawe ibisubizo ku bibazo wabajije.
- Wasobanuriwe ko ushobora kubaza ibindi bibazo igihe icyo aricyo cyose kandi ko igihe icyo aricyo cyose ushobora no kuva mu gikorwa cyo kwitabira ubushakashatsi.
- Wasobanuriwe ko amakuru y'ubushakashatsi akwerekeyeho azaba afitwe n'abaganga n'ababyaza bakora muri ibibitaro n'andi matsinda y'abantu.
- Wemeye kwitabira ubushakashatsi.

KWEMERA KWITABIRA UBUSHAKASHATSI

Umukono wanjye (cyangwa igikumwe) nshyize mugice gikurikira n'uguhamya yuko nemeye kwitabira ntagahato Ubushakashatsi bugamije gusuzuma ubuzima bw'umwana na nyina nyuma y'ihabwa ry'ibise kubagore batwite bafite umubyibuho ukabije.)		
Amazina y'uwitabira ubushakashatsi	**Umukono/igikumwe cy'uwitabiriye ubushakashatsi**	**Itariki**

UHAGARARIYE UBUSHAKASHATSI

Nk'uhagarariye ubushakashatsi cyangwa uwo yagenye kumuhagararira, nahaye uwitabiriye amakuru yose arebana n'ibikorwa byose bijyanye n'ubushakashatsi.		
Uhagarariye ubushakashatsi cyangwa umuhagarariye	**Umukono**	**Itariki**

IRB approval

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 28th /April /2021

Dr AGABA Stiven
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 136/CMHS IRB/2021

Your Project Title ***"Maternal Featal Outcome of Induction of labour among Overweight and Obese women; a comparative study"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
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 23rd April 2021, **Approval has been granted to your study.**
Please note that approval of the protocol and consent form is valid for **12 months**.

Email: researchcenter@ur.ac.rw P.O Box 3286 Kigali, Rwanda www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the 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 28th April 2021

Expiration date: The 28th April 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

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

11th Jun,2021 *Ref.:EC/CHUK/071/2021*

Review Approval Notice

Dear Stephen Agaba,

Your research project: ***"Maternal fetal outcome of induction of labor in overweight and obese women. A comparative study. "***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 11th Jun,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=377&&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

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 "

REPUBLIC OF RWANDA

Kigali, May18th 2021

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AGABA Stephen

Re: Your request for clearance and final approval of the research project

Dear Stephen

Reference made to your letter received on 7th May 2021 request to conduct a study entitled: *Maternal fetal outcome of induction of labor among overweight and obese women. A comparative study at Muhima hospital*

I would like to inform you that your request to conduct this data collection at Muhima district hospital is approved and at the end the administration of hospital shall need to be given the final report of your study.

Yours sincerely,

MANIRAGUHA YEZE Aimée Victoire

Chief Ethic Committee

MUHIMA HOSPITAL - ETHIC COMMITTEE -

Cc:
- Clinical Director
- Head of Gyneco-obstetric department