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COLLEGE OF MEDICINE AND HEALTH SCIENCES
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Maternal and perinatal outcomes of expectantly managed cases of severe preterm preeclampsia: A retrospective review at Kigali University Teaching hospital

A Thesis submitted to the School of Medicine and pharmacy as a partial fulfillment for the award of the Degree of Masters of Medicine by the University of Rwanda.

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Kigali, Friday, December 18, 2020

DECLARATION

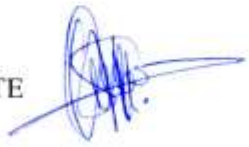
The researcher:

I hereby declare that this dissertation **"Maternal and perinatal outcomes of expectantly managed cases of severe preterm preeclampsia: A retrospective review at Kigali University Teaching hospital"** is my own work and it has not been submitted by any other university for the award of a degree.

Signed

Date 18/12/2020

Dr Odile MUREKATETE



The supervisor:

I hereby declare that this dissertation **"*Maternal and perinatal outcomes of expectantly managed cases of severe preterm preeclampsia: A retrospective review at Kigali University Teaching hospital*"** was submitted for the degree of Master of Medicine in Obstetrics and Gynecology.

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Title: **Maternal and perinatal outcomes of expectantly managed cases of severe preterm preeclampsia: A retrospective review at Kigali University Teaching hospital**

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To my husband and our children got their support in my absence

To my dad and Mum who guided my first steps in life

To God the Almighty for whom I owe my existence, for his love and blessings;

PRECIS

Expectant management of select cases with severe preterm preeclampsia with close monitoring may be done in our setting without compromising maternal status and with better neonatal outcomes.

ABSTRACT.

OBJECTIVE: To assess the outcomes of expectant vs non-expectant management of preterm preeclampsia with severe features and to determine which management modality is appropriate for our clinical settings and the factors that are associated with improved outcomes.

STUDY DESIGN: A retrospective analysis of outcomes in patients with severe preterm preeclampsia admitted with viable pregnancies prior to term at the University Teaching Hospital-Kigali. Patients were stratified by expectant and non-expectant management. Neonatal and maternal complications (composite maternal morbidities including HELLP syndrome, pulmonary edema, eclampsia, and renal insufficiency) were analyzed and neonatal outcomes (were assessed.

RESULTS: There were 203 women who fulfilled study criteria. Thirty nine percent were nullipara and the average maternal age was 30.0 $\pm$ 5.4 years. There were 57 women (28%) who were greater than 34 weeks and were delivered immediately. Of the remaining 146 women, 8 of them were transferred prior to or immediately after delivery, therefore outcome data was available on 138 women, 59 (42.8%) managed expectantly and 79 (57.2%) managed aggressively. There was no difference in the gestational age on admission or delivery between the groups. The average latency period in the expectant management group was 2.76 days $\pm$ 2.8(range 0 to 14). HELLP syndrome was associated with aggressive management (p=0.011). There was significant difference between the median maternal hospital stay in the groups (p=0.003). Expectant management had higher incidence of admission to the neonatal intensive care unit (91.5%% vs 78.5 %, p = 0.045), higher median days of hospitalization in the intensive care unit (20 vs 10 days (p=0.017), but lower incidence of neonatal mortality (31.7% vs. 68.3% p=0.017). Overall neonatal birthweight and gestational age significantly influenced the neonatal

outcome with 92.3% of infants less than 27 weeks ($p<0.001$) and 63.5% of infants less than 1 kg dying ($p=0.021$).

CONCLUSION: Expectant management of women with severe preterm preeclampsia with close monitoring in our setting demonstrated a short latency period enabling the administration of corticosteroids without compromise of maternal status. Women who needed to be aggressively managed because of maternal and fetal indications had worse neonatal outcomes.

Keywords: expectant management, outcome, preeclampsia with severe features

LIST OF ABREVIATIONS

WHO= World Health Organization
SBP= Systolic Blood Pressure
DBP= Diastolic Blood Pressure
CHUK= Kigali University Teaching Hospital
HELLP= Hemolysis, Elevated liver enzyme and Low Platelets
PE= Preeclampsia
OR= Odds Ratio
P= P-Value
NICU= Neonatal Intensive Care Unit
LMP= Last Menstrual Period
C/S=Cesarian Section
SVD=Spontaneous Vaginal Delivery
SPSS=Statistical Package for the Social Sciences

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INTRODUCTION

Preeclampsia is a leading cause of maternal and fetal/neonatal morbidity and mortality. It is a condition unique to pregnancy with a broad range of clinical presentation[1]. "Preeclampsia is defined as the presence of systolic blood pressure (SBP) greater than or equal to 140mm Hg or diastolic blood pressure (DBP) greater than or equal to 90 mm Hg or higher, on two occasions at least 4 hours apart in a previously normotensive patient. Severe preeclampsia is defined as an SBP greater than or equal to 160mm Hg or a DBP greater than or equal to 110 mmHg or higher and/or the presence of multi-organ involvement including thrombocytopenia (platelet count less than 100,000/uL), hemolytic anemia, renal dysfunction, impaired hepatic function, pulmonary edema, and/or new onset cerebral or visual disturbances"[2,3].The etiology of preeclampsia is unknown. Theories vary from maternal immunologic intolerance, abnormal placental implantation, genetic, nutritional, and environmental factors to cardiovascular and inflammatory changes [2].

The occurrence of preeclampsia is around 5-14% of all pregnancies globally[4].In the United States, its incidence is between 2% to 6% in healthy, nulliparous women and 10% occur in pregnancies below 34weeks of gestation[5]. The occurrence of preeclampsia in developing countries is estimated to be between 4-18% in the litterature[4]. It is the second most common obstetric cause of stillbirths and early neonatal deaths in these countries; and the second cause of maternal death [6,7].Approximately 25% of all cases of preeclampsia have severe features[2].

Preeclampsia is usually an indication for prompt delivery to prevent maternal and fetal complications. Since the disease progressively get worse and there is no medical treatment, delivery benefits more the mother than the newborn who will face consequences of prematurity.

The risk of prolonging pregnancy is worsening maternal endothelial dysfunction and complications; therefore, a decision to delay delivery must be balanced with the neonatal benefits [8]. In a case series by van Oostwaard et al, of women with severe early onset pre-eclampsia before 26 weeks of gestation, the median prolongation of pregnancy was 5 days (range 0 to 25 days)[4]. The WHO recommends induction of labor for preeclampsia with severe features in a non-viable fetus or one who is less likely to reach viability within one or two weeks[9]. In a viable fetus, expectant management is recommended before 36 weeks provided that uncontrolled maternal hypertension, increasing maternal organ dysfunction, or fetal distress are absent and can be monitored[3,9]. The WHO also outlined expectant management which includes intra-hospital care with steroids. Although some studies have reported that neonates from preeclampsia pregnancies have a reduced incidence of respiratory distress syndrome and intraventricular hemorrhage compared with infants from normotensive pregnancies, a 2017 meta-analysis of randomized trials of antenatal corticosteroid treatment versus no antenatal corticosteroid treatment found no evidence that antenatal corticosteroids are less effective in pregnancies complicated by hypertension. [10–12]

Other components of intra-hospital care include magnesium sulfate, antihypertensive medications, close maternal and fetal monitoring to identify an indication of delivery, and in-utero transfer to a tertiary- level center with neonatal intensive care capacity. The mode of delivery should depend on: gestational age; fetal and cervical status and urgency [2,8]Preeclampsia with severe features has many serious maternal complications some of them are life-threatening[8]. Its consequences are influenced , in part, on the gestational age at onset: early-onset has a poorer prognosis than late-onset [8].

In our settings, we practice both expectant and aggressive management in preterm pregnancies and preeclampsia with severe features but there is no data about whether the criteria established in developed countries are appropriate for our settings. There is no maternal and neonatal outcome data to determine which management modality is appropriate in our setting. The objective of the study was to assess the outcomes of expectant vs non-expectant management of preeclampsia with severe features and to determine which management modality is appropriate for our clinical settings and the factors that are associated with improved outcomes.

METHODS

A retrospective study of cases of severe preeclampsia from 2015 to 2018 admitted to Kigali University Teaching Hospital (CHUK). CHUK is the main tertiary/referral hospital located in Kigali with approximately 2700 annual obstetric deliveries, 5000 admissions and 12,000 outpatient consultations. During the 3year period, 928 women consulted with hypertension in pregnancy. The criteria for inclusion in the study were: preeclampsia with severe features at less or equal to 36 weeks 6 days gestation (preterm) women or newborn who were referred to other hospital were excluded during the analysis. Severe preeclampsia was defined as: an SBP greater than or equal to 160mm Hg or a DBP greater than or equal to 110 mmHg or higher (recorded at CHUK or at a referring hospital) and/or the presence of multi-organ involvement including thrombocytopenia (platelet count less than 100,000/uL), hemolytic anemia, renal dysfunction, impaired hepatic function, pulmonary edema, and/or new onset cerebral or visual disturbances.

Patients with preeclampsia with severe features admitted with fetal demise were recorded but not included in the analysis of outcomes as they were all delivered expeditiously. Patients who were less than 34 weeks gestation were stratified by whether the initial management was expectant (observation until maternal/fetal indication for delivery) versus aggressive (expeditious delivery based on maternal/fetal status). Outcomes of pregnancies between 34 and 37 weeks were also recorded to provide background prevalence data of preterm severe preeclampsia; they were not included in the stratification analysis as it is standard of care to expeditiously deliver women with severe preeclampsia at those gestational ages.

Data was collected by chart review of maternal and neonatal records as well as review of computer-based software of laboratory results. Maternal and neonatal outcomes were recorded

on a deidentified form and data was coded and entered and analyzed in SPSS version 25. The data were protected with password limited access.

Ethical approval was obtained from the IRB of the University of Rwanda College of Medicine and Health Science and CHUK.

RESULTS

There were 928 with hypertensive disorders on pregnancy during the 3year study period. Two hundred and 3 women (21%) had preterm preeclampsia with severe features and delivered 205 infants. Three quarters of the women were dated by LMP and 22 % of the cohort established dates by an ultrasound at admission. Fifty-seven women (28%) had pregnancies greater than 34 weeks and were delivered expeditiously and 96.4% had good fetal outcomes. There were 146 women who were less than 34 weeks with one twin pregnancy. The predominance (80.8%) were between 28 weeks and 34 weeks. Seven women prior to delivery and one neonate were transferred to other hospitals therefore outcome data is unavailable. Thus, there were 138 mothers and 139 neonates analyzed. An intrauterine fetal demise on admission occurred in 14% of the 928 women (they were not included in the management outcome analysis).

Table 1 shows the demographics of the cohort. The majority of women were between 25-34 years (63.04%). There was no difference in the gravidity, parity or gestational age at admission or delivery between the aggressive and expectant groups. Public hospitals transfers were more likely to be aggressively managed (65.1% vs 35.3%; p=0.001). The mean latency period for expectant management was 2.76 days ±2.8 (range 0-14days) with 23 (38.9%) delivering within the first day and 41 (69.5%) within 3 days following admission (figure 1).

Table 2compares the clinical characteristics between the two groups. Epigastric pain was more common in the aggressively managed group. Otherwise, clinical symptoms did not differ between the 2 groups. Patients with HELLP syndrome were more likely to be aggressively managed p=0.011.

Neonatal outcomes are shown in Table 3.The mean gestational age at birth did not differ between the groups (expectant management 30.7 vs 29.9 weeks in aggressive management), Patients with

intrauterine growth restriction were more likely to be aggressively managed but it did not achieve statistical significance (OR=1.9; p=0.074). Aggressively managed neonates were less likely to be admitted in NICU (78.5% vs 91.5% with OR=2.9; p=0.045) and were more likely to die (OR=2.3; p=0.017).

Table 4 demonstrates the different effects of treatment options on neonatal outcomes. Exposure to Dexamethasone was associated with NICU admission. Among fetuses who received Dexamethasone, 89.6% of them were admitted to the NICU vs 71.7% (OR=4.5; p=0.002). Neonatal death was less likely in the Dexamethasone group (41% vs 62.5%; OR=0.4; p=0.034). Babies born by C/S were more likely to be admitted to the NICU (94.3% vs 50%, OR=14.3; p <0.001). Survival was highly correlated with birth weight (p<0.021) and gestational age (p< 0.001) in both expectant and aggressive management (Table 5).

DISCUSSION

Women with preterm preeclampsia have a significant risk of medically-indicated premature birth; however, in selected cases, delaying delivery when preeclampsia is diagnosed before 34 weeks improved the neonatal outcomes, without major harm to the maternal health.

Among all patients with severe PE, 42.8% qualified for expectant management; this is in agreement with a previous study by Hall, et al in which 49% qualified for expectant management[13].

In our study, expectant management had a mean latency period of only 2.76 days, which is lower than that reported in studies from developed countries where the latency has been reported to range between 4 and 36 days. [14,15–18] This is likely secondary to the severity of disease on presentation and that delays in presenting for care as well as transfer to a tertiary institution are common. The latency was calculated from the time of admission to the referral hospital and did not account for time prior to transfer. Maternal complications such as HELLP syndrome were more common in the aggressive management group which is similar to the literature.[19,20,21,22,23] There was no significant difference in maternal mortality rate between the 2 groups as there were only 3 deaths in the entire cohort. The small number of complications made comparisons between the groups not possible.

In terms of neonatal outcomes, aggressive management had a lower incidence of admissions to the neonatal intensive care unit and a lower median NICU stay. The fewer NICU admissions and decreased stay were secondary to the higher perinatal mortality noted in the aggressive group. This differs from finding Sibai et al.[15] The severity of disease that necessitates aggressive management contributes to the poor outcomes as preeclampsia is a disease of the placenta and leads to significant fetal compromise, This was also shown by Oettle et al. [24,25]. The increased

perinatal complications seen in aggressive management might be explained by early gestational age, low birth weight, and the consequences of poor oxygenation and acidemia of the fetus as well as termination of pregnancy in previable fetuses.[24,25] It is likely a reflection of the degree of placental dysfunction that is present at admission. When we compared major complications such as respiratory distress syndrome, necrotizing enterocolitis, and intraventricular hemorrhage, we found that the difference in complications in both the groups were not statistically significant. The factors for survival were predicted by birth weight and gestation age in both expectant and aggressive management which was consistent with a study done by Oettle et al.

The limitations of this study are that it is retrospective and that data are collected by chart review and are limited by the degree of documentation. In addition, the latency period was calculated from the day of admission at the referral hospital and did not include the time a woman had spent at a referring hospital and that patients are transferred secondary to complications therefore our patient population is skewed to more severe cases. Moreover, our findings are limited to a single facility and may not be generalized nationwide. Due to lack of NICU beds, some women were transferred to other referral hospital and hence their outcomes were not known. To overcome this limitation, patients without outcome data were not included in the data analysis. The strength of this study is in comparison of two different groups exposed to a disease and compared the outcome and all women fulfilling the criteria were recruited. A more detailed multicenter prospective study would reflect better the current situation and generate recommendation on when and to who expectant management should be offered.

Expectant management with close monitoring in Rwanda is a viable option enabling steroids to be administered. Clinicians should carefully balance the risks versus benefits of aggressive management in women with severe PE before 34-weeks' gestation to achieve optimal outcomes

for both the mother and baby. Appropriate counseling about outcomes based on gestational age and birthweight may better inform parents of the risks involved.

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Index 1: Tables and Figures

Table 1. *Demography*

Variables	Total (n=138)	Management group		P value
		Expectant(n=59)	Aggressive (n=79)	
Age (Mean ± SD) years	30.0 ± 5.4	29.6 ± 5.2	31.0 ± 5.3	0.139
Groups				
<25	19	12 (63.2%)	7 (36.8%)	
25-29	36	18 (50.0%)	18 (50.0%)	0.104
30-34	51	17 (33.3%)	34 (66.7%)	
≥35	32	12 (37.5%)	20 (62.5%)	
Referring institution				
Public	109	38 (34.9%)	71 (65.1%)	
Private	17	11 (64.7%)	6 (35.3%)	0.001
Home	12	10 (83.3%)	2 (16.7%)	
Gravidity				
G1	43	21 (48.8%)	22 (51.2%)	
G2-G4	79	31 (39.2%)	48 (60.8%)	0.6
≥G5	16	7 (43.8%)	9 (56.3%)	
Mean ± SD	2.6 ± 1.6	2.5 ± 1.8	2.7 ± 1.5	0.56
Parity				
Nulliparous	54	27 (50%)	27 (50%)	
Primiparous	41	17 (41.5%)	24 (58.5%)	0.464
Multiparous	31	10 (32.2%)	21 (67.7%)	
Grand multiparous	12	5 (41.7%)	7 (58.3%)	
Mean ± SD	1.2 ± 1.0	1.1 ± 1.0	2.4 ± 1.3	0.574
Gestational age at admission				
Mean ± SD in weeks	30.0 ± 2.6	30.4 ± 2.0	29.7 ± 2.9	0.152
Gestational age at delivery				
Mean ± SD in weeks	30.3 ± 3.2	30.7 ± 3.7	29.9 ± 2.8	0.193

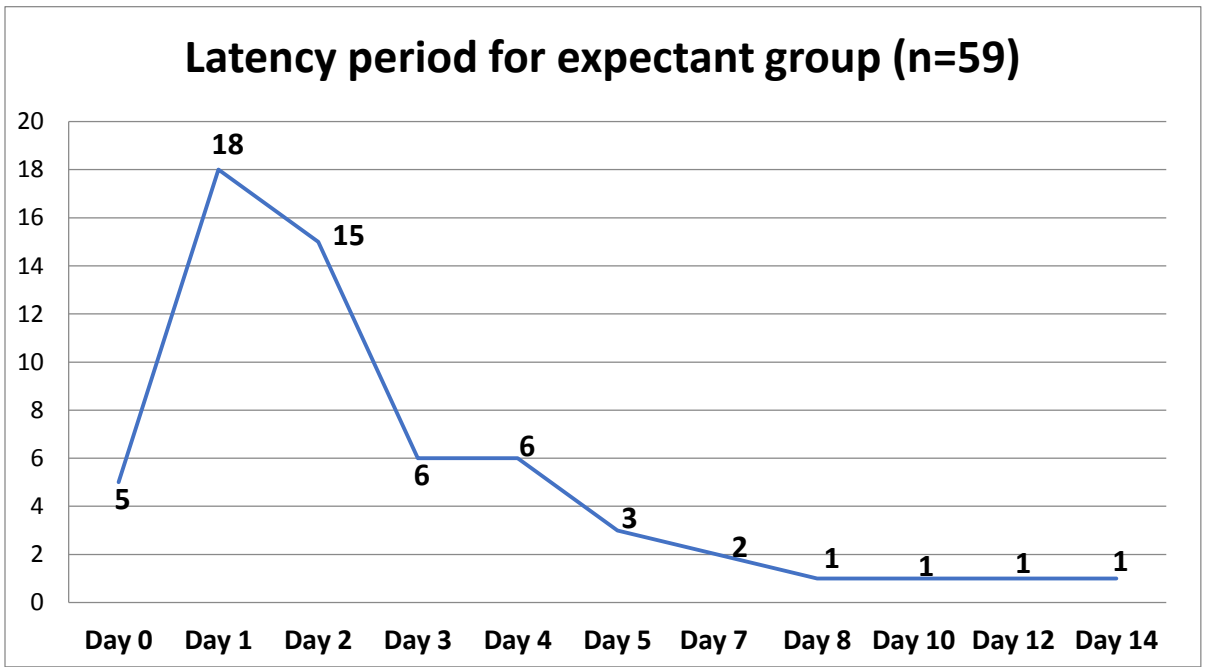

Figure 1. Latency period in expectant management

Table 2: Characteristics of the patient who underwent expectant management and aggressive management

Variables	Management group		OR (95% CI)	P value
	Expectant	Aggressive		
Pulmonary Edema				
Yes	3 (50.0%)	3 (50.0%)	0.7 (0.14-3.7)	0.714
No	56 (42.4%)	76 (57.6%)		
Acute Kidney Injury				
Yes	7 (36.8%)	12 (63.2%)	1.3 (0.48-3.6)	0.575
No	52 (43.7%)	67 (56.3%)		
Liver failure				
Yes	1 (33.3%)	2 (66.7%)	1.5 (0.1-17.0)	0.74
No	58 (43.0%)	77 (57.0%)		
Stroke				
Yes	0 (0.0%)	2 (100%)	3.8 (0.2-81.4)	0.388
No	59 (43.3%)	77 (56.6%)		
Seizures				
Yes	1 (100%)	0 (0.0%)	0.2 (0.009-6.1)	0.392
No	58 (42.3%)	79 (57.7%)		
DIC				
Yes	1 (100%)	0 (0.0%)	0.2 (0.009-6.1)	0.392
No	58 (42.3%)	79 (57.7%)		
Headache				
Yes	16 (45.7%)	19 (54.3%)	0.85 (0.4-1.8)	0.682
No	43 (41.7%)	60 (58.3%)		
HELLP syndrome				
Yes	10 (42.9%)	29 (57.1%)	2.9 (1.3-5.6)	0.011
No	49 (50.0%)	49 (50.0%)		
Placental abruption				
Yes	6 (54.5%)	5 (45.5%)	0.6 (0.2-2.0)	0.414
No	53 (41.7%)	74 (58.3%)		
Preterm labor				
Yes	0 (0.0%)	5 (100%)	8.9 (0.48-164.3)	0.141
No	59 (44.7%)	73 (55.3%)		
Epigastric pain				
Yes	20 (31.7%)	43 (68.3%)	2.3 (1.2-4.6)	0.017
No	39 ((52.0%)	36 (48.0%)		
Death				
Yes	1 (33.3%)	2 (66.7%)	1.5 (0.13-17.0)	0.74
No	58 (43.0%)	77 (57.0%)		
Maternal hospital stay				
Median (Min-Max) days	9.0 (3-31)	7.0 (2-53)		0.003

Table 3:Neonatal Outcomes

Variables	Management group		OR (95% CI)	P value
	Expectant	Aggressive		
Fetal growth restriction				
Yes	19 (35.1%) (	37 (64.9%)	1.9 (0.9-3.8)	0.074
No	40 (48.7%)	42 (51.2%)		
Intrauterine fetal demise				
Yes	0 (0.0%)	4 (100%)	7.0 (0.3-134.3)	0.191
No	59 (44.0%)	75 (56.0%)		
NICU admission				
Yes	54 (46.6%)	62 (53.4%)	0.3 (0.11-0.9)	0.045
No	5 (22.7%)	17 (77.3%)		
Perinatal Outcome				
Dead	20 (31.7%)	43 (68.3%)	2.3 (1.12-4.6)	0.017
Alive	39 (52.0%)	36 (48.0%)		
Neonatal complications				
Yes	56 (44.5%)	70 (55.5%)	0.46 (0.11-1.8)	0.279
None	3 (27.3%)	8 (72.7%)		
Neonatal hospital stay				
Median (Min-Max) days	20.0 (0-69)	10 (0-218)		0.017

Table 4. Association of Neonatal admission, maternal characteristics and management

Variables	NICU admission		OR (95% CI)	P value
	No	Yes		
Dexamethasone				
Yes	11 (10.4%)	95 (89.6%)	4.5 (1.7-11.8)	0.002
No	11 (34.4%)	21 (65.6%)		
Mode of delivery				
Cesarean Section	6 (5.7%)	100 (94.3%)	14.3 (5.0-40.1)	<0.001
SVD	16 (50.0%)	16 (50.0%)		
Plan for delivery				
Expectant	5 (8.5%)	54 (91.5%)	2.9 (1.0-8.5)	0.045
Aggressive	17 (21.5%)	62 (78.5%)		
HELLP Syndrome				
Yes	6 (15.4%)	33 (84.6%)	1.1 (0.4-2.9)	0.892
No	16 (16.2%)	83 (83.8%)		
Transfer				
Yes	20 (15.9%)	106 (84.1%)	1.06 (0.2-5.2)	0.942
Home	2 (16.7%)	10 (83.3%)		
Primigravida				
Yes	7 (16.3%)	36 (83.7%)	0.9 (0.3-2.5)	0.942
No	15 (15.8%)	80 (84.2%)		

Table 5: Factors that influence the neonatal outcome

Variables	Neonatal outcome		OR (95% CI)	P value
	Dead	Alive		
Gestational age				
<27	24 (92.3%)	2 (7.7%)	22.2 (4.9-98.7)	<0.001
28-33	40(35.1%)	73 (64.9%)	Ref	
Birth weight				
<1000g	34(64.2%)	19 (35.8%)	6.9 (1.3-36.1)	0.021
1000-1499g	25 (41.7%)	35 (58.3%)	2.8 (0.5-14.6)	0.207
1500-1999g	3 (18.7%)	13 (81.3%)	0.9 (0.1-6.7)	0.937
≥2000g	2 (20.0%)	8 (80.0%)	Ref	
Dexamethasone at admission				
Yes	43 (40.6%)	63 (59.4%)	0.41 (0.18-0.9)	0.034
No	20 (62.5%)	12 (37.5%)	Ref	

Index 2: Data collection form

I. DEMOGRAPHICS

Age……...

Transfer: Yes/No Hospital……, Days of admission……

Gravity:

Parity:

GA on admission:

How dates established (LMP, US before 20 weeks, US on admission):

Previous preeclampsia:

Family history of preeclampsia:

History of chronic hypertension:

Medications on admission:

II. SIGNS, SYMPTOMS AND VITALS

Signs and symptoms	**Yes**	**No**
Headache		
Epigastric pain		
Blurred vision		
Oliguria		
Hemoptysis		
VITALS	**admission**	**Control**
BP		
PULSE		
SPO2		
RR		

III. LABS

Labs	**1st**	**2nd**	**3rd**	**4th**
Hb				
Platelets				
AST				
ALT				
UREA				
CREAT				
LDH				
INDIRECT BILIRIBIN				
CLOTTING TIME				

IV. COMPLICATIONS OF PRE-ECLAMPSIA WITH SEVERE FEATURES AT

Complications	At admission	During expectant management	Management and latency period
Pulmonary edema			
AKI			
Liver failure or rupture			
stroke			
seizures			
ASCITIS			
Hypertensive encephalopathy			
DIC			
Placental abruption			
Persistent headache; epigastric pain			
Visual aberrations			
HELLP Sx			
Preterm labor			
PPROM			
Maternal request for immediate delivery			
Laboratory abnormalities; ▪ ASAT or ALAT increase >2 times in 6 to 12hrs ▪ Decrease platelets<100000			
Ventilator (number of days)			
ICU admission (number of days)			
Death			
Non reassuring fetal status; ▪ non stress test ▪ Biophysical profile ▪ Olygohydroamnios ▪ Persistent absent or reversed diastolic flow			
Fetal growth restriction			
IUFD			
Maternal length of hospital stay			

ADMISSION AND DURING EXPECTANT MANAGEMENT

V. FETAL CHART QUESTIONNAIRE

Gestation age on admission:…….
Gestational age at delivery:…….
Weight:…….
Apgar:……..
Hospital duration:……..
NICU admission:……..
Number of NICU days:……..
Mode of delivery:……..
Induction: Yes/ No
Failed induction Yes/No

Complications:

- NEC
- IVH
- RDS
- OTHERS SPECIFY

OUTCOMES:

- DEAD
- ALIVE

Index3: IRB Approval

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES
DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, the 23rd /January/2020

Dr MUREKATETE Odile
School of Medicine and Pharmacy, CMHS, UR

Notice of Renewal of Approval for Research Project: No029 /CMHS IRB/2020

Your Project title ***"Retrospective Review of Maternal and Perinatal Outcomes of Expectant Management of Preterm Severe Preeclampsia At CHUK"*** has been evaluated by CMHS Institutional Review Board.

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

You are responsible for fulfilling the following requirements:

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

Sincerely,

Date of Approval: The 23rd January 2020

Expiration date: The 23rd January 2021

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

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