Severe maternal outcome among patients with severe pre eclampsia and eclampsia at Muhimbili National Hospital

By

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SEVERE MATERNAL OUTCOME AMONG PATIENTS WITH SEVERE PRE ECLAMPSIA AND ECLAMPSIA AT MUHIMBILI NATIONAL HOSPITAL

By

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A Dissertation submitted in partial fulfillment of the Requirement for the Degree of Master of Medicine in Obstetrics and Gynaecology of the Muhimbili University of Health and Allied Sciences
October, 2018

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance for examination by the Muhimbili University of Health and Allied Sciences a dissertation entitled: **SEVEREMATERNAL OUTCOME AMONG PATIENTS WITH SEVERE PRE ECLAMPSIA AND ECLAMPSIA AT MUHIMBILI NATIONAL HOSPITAL,** In partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynaecology of the Muhimbili University of Health and Allied Sciences**.**

……

Prof. Hans Mgaya. MB; chB, MMED (Supervisor)

Professor in Obstetrics and Gynaecology

MUHAS

Date……..

DECLARATION AND COPYRIGHT

I, **Dr. Jane Rosemary Manyahi,** declare that this dissertation is my own original work, and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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Date …….....…

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Lastly with all the weight I thank the Almighty God for giving me good health and ability to do the study.

DEDICATION

This Dissertation is dedicated to My BELOVED PARENTS, MRS SAIRIS HILARY MANYAHI AND MY LATE FATHER MR AIDAN NDUNGURU MANYAHI, for their unending love and support throughout my life, MAY MY FATHER'S SOUL REST IN ETERNAL PEACE, AMEN.

To my beloved husband Dr Alex Mpeku and our children, you are the reason behind my hardworking and success.

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LIST OF ABBREVIATIONS

MNM	Maternal Near Miss
WHO	World Health Organization
HDP	Hypertensive Disorders in Pregnancy
SMO	Severe Maternal Outcome.
MI	Mortality Index
SMOR	Severe Maternal Outcome Ratio
MNMR	Maternal Near Miss Ratio
MD	Maternal Death
LB	Live Births

DEFINITION OF TERMS-By WHO-Evaluating the quality of care for severe pregnancy complications. 2011

Maternal near miss (MNM) refers to a woman who nearly died but survived a complication that occured during pregnancy, childbirth or within 42 days of termination of pregnancy.

Maternal death (MD) is the death of a woman while pregnant or within 42 days of termination of pregnancy irrespective of duration and site of pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes

Live birth (LB) refers to the birth of an offspring which breathes or shows evidence of life.

Severe maternal outcome (SMO) refers to a life threatening condition (i.e organ dsyfunction), including all maternal deaths.

The case-specific maternal near miss ratio due to pre eclampsia and eclampsia refers to number of maternal near miss cases due to pre eclampsia and eclampsia per 1,000 live births respectively.**(MNMR =MNM/LB).**

The case-specific severe maternal outcome ratio due to severe pre eclampsia/ eclampsia refers to the number of women with life threatening conditions plus maternal death due to sever pre eclampsia/eclampsia (MNM + MD) per 1000 live birth . [SMOR = (MNM + MD)/LB].

The case-fatality ratio due to severe pre eclampsia/ eclampsia will be determined as the proportion of deaths out of the total number of patients presenting with severe pre eclampsia and eclampsia, expressed as a percentage.

The case-specific mortality index due to severe pre eclampsia/eclampsia refers to the number of maternal deaths due to severe pre eclampsia and eclampsia divided by the number of women with life threatening conditions due to severe pre eclampsia/ eclampsia expressed by percentage [MI=MD/ (MNM + MD)].

The case-specific maternal near miss mortality ratio due to severe pre eclampsia/eclampsia **(MNM: 1 MD)** refers to the ratio between maternal near miss cases due to severe pre eclampsia/eclampsia and maternal death due to severe pre eclampsia /eclampsia. Higher ratio indicates better care.

Severe pre eclampsia : Patient presents with : Systolic blood pressure of 160mmHg or higher, or diastolic blood pressure of 110 mmHg or higher in two occasions a least 4 hourly apart while the patient is on the bed, or with features of organ dsyfunction.

Eclampsia: generalised fits in a woman with pre eclampsia, without previous history of epilepsy. Include coma in pre-eclampsia

ABSTRACT

Background: Hypertensive disorders in pregnancy (HDP) is the second most common direct cause of maternal deaths accounting for 14% of maternal deaths worldwide.Severe pre eclampsia and eclampsia are among the HDP which cause significant morbidity and mortality,hence categorized as Maternal Near Miss (MNM).At Muhimbili National Hospital these are the leading causesof maternal deaths (MD) accounting for 19.9% of MD.

Objective: The aim of this study was to determine the proportion of severe maternal outcome among patients with severe pre eclampsia and eclampsia and to determine MNM indices at Muhimbili National Hospital in Tanzania.

Methods: A descriptive cross sectional study was conducted at Muhimbili National Hospital. Women with severe pre eclampsia and eclampsia were recruited for the study. Data was extracted from patient files after admission,and followed up until discharge or death; after discharge was categorized as MNM or death as MD . Such data included: age,parity,gravidity, gestation age,hypertensive disorder, admission to ICU, organ dsyfunction, matenal death, mode of delivery and referral status then filled in a structured check list form.The information extracted was coded,entered cleaned and analysed using Statistical Package for the Social Sciences(SPSS), Version 22. Continous variables was summarized into mean and standard deviation.Categorical were summaized as frequencies and percentage.Outcome indicators were calculated.

Results: During the study period there were 3853 deliveries, whereby 3661were live births.A total of 320 women were recruited in this study, nearly two thirds of women, 199 (62.2%) had severe pre eclampsia while 121 (37.8%) had eclampsia, 310 (96.5%) women had been referred from other health facilities.Seventy one women (22.1%) were found to have severe maternal outcome whereby 63 had MNM with organ dsyfunction and 8 maternal deaths.

Overall MNMR was 87.4 per1000 live births,54 per 1000 live birth for severe pre eclampsia and 33 per 1000 live births for eclampsia. Overall SMOR was 19.4 while that for severe pre eclampsia was 12 per 1000 live births and that foreclampsiawas 9.5 per 1000 live births.Mortality index was11%; 9% for severe pre eclampsia and 11.4% for eclampsia. Case fatality rate was 2.5%; 2.1 for severe pre eclampsia and 3.3% for eclampsia.

CONCLUSION

There is high proportion of women with severe maternal outcome attributable to severe pre eclampsia and eclampsia, with reduced proportion of maternal deaths as compared to previous studies.This signifiesimprovement of performance in our health facility in dealing with patients with severe morbidities due to severe pre eclampsia and eclampsia, however more effort has to be put to reduce maternal mortality to the acceptable standards.

INTRODUCTION

Background

Worldwide there has been a significant reduction of MMR (Maternal Mortality Ratio) between 1990 to 2015.The MMR dropped by approximately 44% from an estimate of 385 per 100,000 live births to 216 per 100,000 live births. The approximate global life time risk of maternal death dropped considerably from 1 in 73 to 1 in 180 (1).

Developing regions accounted for 99% of global maternal deaths, with Sub Saharan region alone contributing about 66% followed by Southern Asia. The magnitude of MMR reduction differed between regions. Eastern Asia having been observed to have the greatest decline of approximately 72%; Western Asia was observed to have the lowest decline of 43% from 1990 to 2015. Sub Saharan Africa is among the regions with the highest MMR of 546 per 100,000 live births. A woman in Sub Saharan Africa has 1 in 16 chances of maternal death compared to 1 in 4000 in developed regions (1).

Globally, the risk of maternal death due to HDP is approximately 1 in 1700 to 1 in 2100 deliveries. There is a wide variation across regions in the lifetime risk of a woman dying from HDP from 1 in 3800 in developed countries to 1 in 39 in Sub-Saharan Africa (2). Most of the morbidity is concentrated among pregnancies complicated by pre eclampsia or eclampsia, and for every woman who dies; approximately 20 others suffer severe morbidity. Hypertensive disorders in pregnancy complicate up to 10% of pregnancies worldwide, constituting one of the greatest causes of maternal and perinatal morbidity and mortality (3). It’s the second most common direct cause of maternal death accounting for 14.0% of maternal deaths Worldwide, 12.9% in developed countries, 14% in developing countries, and 16% in Sub Saharan regions alone. Hypertensive disorders increase the risk of severe complications by 3 to 25 times, these complications include placental abruption, thrombocytopenia, disseminated intravascular coagulation, acute pulmonary edema, acute kidney injury, cerebrovascular disorders.

These further increase the risk of severe maternal morbidities and mortality. These complications occur more in severe pre eclampsia and eclampsia, hence they are categorized as Maternal Near Miss (4).

Tanzania has shown progress towards improving maternal health, as is shown by a 47% decline in maternal mortality ratio (MMR) from an estimated MMR of 870 per 100,000 live births in 1990 to a MMR of 460 per 100,000 live births in 2010 (5). The progress however has not been consistent, as in 2015-16 MMR as reported by Tanzania demographic and health survey 2015 raised to 556 per 100,000 (6).All the same, this indicates that there is a gap in provision of obstetric and maternal care which needs to be addressed. In Tanzania the commonest direct causes of maternal deaths are haemorrhage, sepsis, hypertensive disorders, abortion complications and obstructed labour. At Muhimbili National Hospital the major causes are pre eclampsia and eclampsia which accounted for 19.9% of maternal deaths, followed by post-partum haemorrhage which accounted for 14.9 % (7).

For many years, evaluation of maternal health care services aimed at improving the quality of obstetric care and has traditionally relied on enquiries into maternal deaths. More recently, review of cases at the very severe end of maternal morbidity spectrum, described as “near miss” those who nearly died, has been found to be a useful complement to investigation of maternal mortality. World Health Organization (WHO) developed a systematic MNM approach. The aim was to facilitate comparisons between different studies, and between countries and regions, in order to have uniformity of reporting and analyzing severe maternal morbidity events, hence address shortcomings in quality of obstetric care and improve pregnancy outcome. It applies organ failure based criteria which reflects critical illness and allow for MNM reviews (4).

WHO recommended that maternal near miss and maternal deaths review to be done every year at different levels of health facilities.It should be implemented in 3 steps, which are baseline assessment or reassessment, followed by situation analysis then intervention.

They identified some severe maternal morbidities to be in MNM criteria which are severe maternal complications which include postpartum haemorrhage, severe pre eclampsia, eclampsia, sepsis or severe systemic infection, ruptured uterus, and severe complications of abortions, critical intervention or intensive care unit admission and organ dysfunction. In hypertensive disorders, severe pre eclampsia and eclampsia, intensive care unit admission and organ dysfunction are categorized as maternal near miss (4). This study involved baseline assessment and situation analysis whereby near miss indicators and selected evidence based interventions were assessed.

The following indicators have been proposed by WHO for evaluation of care in women with severe pregnancy complications. These indicators are severe maternal outcome ratio (SMOR) and the maternal near-miss ratios (MNMR). These are outcome indicators that provide an assessment of how frequently those conditions occurred in the source population. These near-miss indicators provide an estimate of the complexity of care that is required by the population served by the health-care facility in the assessment. Higher ratios over 10 cases per 1000 live births indicate that a substantial proportion of cases will require more complex interventions in order to survive their complications.(4)

The mortality index (MI) and the maternal near-miss mortality ratios (MNM: 1MD) provide an estimate of performance. High mortality index over 20% indicate that the quality of care provided to severe cases may need to be reviewed. If mortality index is low, less than 5% it can be interpreted that the health care facility is performing well in dealing with complex and severe cases. Proportion of women with life threatening conditions (WLTC) coming from other health facilities stratifies the information with regard to at what stage the severe maternal morbidity was identified. This has important implications for the health system because if a very large proportion of over 70% of women is reaching the facility already with a severe maternal morbidity, it indicates that first and second delays may be an issue.

In addition, by examining especially the cases in which a severe maternal outcome occurs during hospital stay, both in terms of SMOR and mortality index, a more specific assessment of intrahospital care can be made (4).

All these indicators are used to evaluate the quality of care to women with MNM in an institution. The near miss approach will be an important tool in evaluation and assessment of the newer strategies for improving maternal health.

Severe pre eclampsia and eclampsia are the leading causes of severe maternal morbidity and mortality in our institution. Little information was available on severe maternaloutcome due to severe pre eclampsia and eclampsia. This neccesiates the need to determine proportion of severe maternal outcome among patients with severe pre eclampsia and eclampsia and to determine case specific MNM indices at Muhimbili National Hospital by applying the WHO MNM approach.

LITERATURE REVIEW.

Severe Pre-eclampsia and eclampsia are hypertensive disorders of pregnancy that cause significant morbidity and mortality in the fetus and mother both in the developed and developing countries. The case fatality ratio of eclampsia ranges from 0 to 1.8 % in high-income countries to 17.7 % in middle-income countries such as India, which reflects the gap in quality of maternal health care (8).

In African countries, case fatality rate for severe pre eclampsia has been reported variously as low in a study done in Uganda and in Mozambique(9,10), while case fatality rate for eclampsia has been reported as high in a study done in Uganda and in Mozambique.In a study done in Rwanda, maternal death attributable to eclampsia were high while there was no death due to severe pre eclampsia(11).This shows how appropriate management of these HPD in pregnancy can reduce case fatality rate and improve maternal survival.

In Tanzania severe pre eclampsia and eclampsia are among the leading causes of maternal mortality. Studies done in tertiary hospitals in Dar es salaam and Mwanza showed that eclampsia was the leading cause of maternal death accounting for 19.9% of all maternal deaths at Muhimbili National Hospital in Dar es salaam and 26.3% at Bugando Hospital Mwanza (7,12). Case fatality rates due to eclampsia, in studies done in Tanzania showed different results. Studies done at Muhimbili National Hospital showed case fatality rates of 5% in 2006 and 7.7%in 2009(13,14). Another study done in western Tanzania showed case fatality rate due to eclampsia to be 11%(15).

Regarding specific maternal morbidities caused by severe pre eclampsia and eclampsia, there are variations in results in different countries.

A WHO multi country survey showed that coagulopathy/ haematological dsyfunction was the leading morbidity among women with severe pre eclampsia followed by respiratory dsyfunction (16).

This was also reported in a study done in India whereby high proportion of women with severe pre eclampsia were found to have haematological dsyfunction (17). Another study done in Brazil, however showed that abruption placenta was the leading maternal complication followed by coagulopathy (18).

Among patients with eclampsia neorological dsyfunction was the leading morbidity followed by respiratory dsyfunction(16). A study done in Western Tanzania, showed that neorological dsyfunction was the leading morbidity among patients with eclampsia(15).
Another study done in a tertiary hospital in Dar es salaam Tanzania, showed that neurological dsyfunction was the leading cause of death among women with eclampsia followed by pulmonary oedema and respiratory failure (19).

Severe maternal outcome ratio (SMOR) and Maternal near miss ratio (MNMR) are outcome indicators that provide assesment of how frequent those conditions occured and estimate of amount of care that would be needed. In India studies done by Bansal and that by Umadevi showed low MNMR due to pre eclampsia and eclampsia(20,21).Lotufo et al in Brazil also reported low MNMR (22). In Uganda Nakimuli reported high MNMR(9). A study done in Brazil by Zanette et al reported low SMOR(18). A Tanzanian study done at Muhimbili national hospital reported higher MNMR and SMOR (23). Facilities with higher ratio of MNMR or SMOR indicate that substantial proportion of cases will require more complex interventions to survive complications.

Mortality indexand Maternal near miss mortality ratio provide an estimate of performance. Mortality index due to pre eclampsia and eclampsia showed variations of results in different countries. In two studies done in Brazil, one study reported MI of 54.4% while in the other study was 22% due to pre eclampsia and eclampsia(20,21). In Uganda it was reported that MI due to pre eclampsia and eclampsia was low(9), also Zannete et al reported low MI(18).
Facilities with higher motality index of above 20% indicate that more women with life threatening condition are dying, hence quality of care provided to these women need to be reviewed.

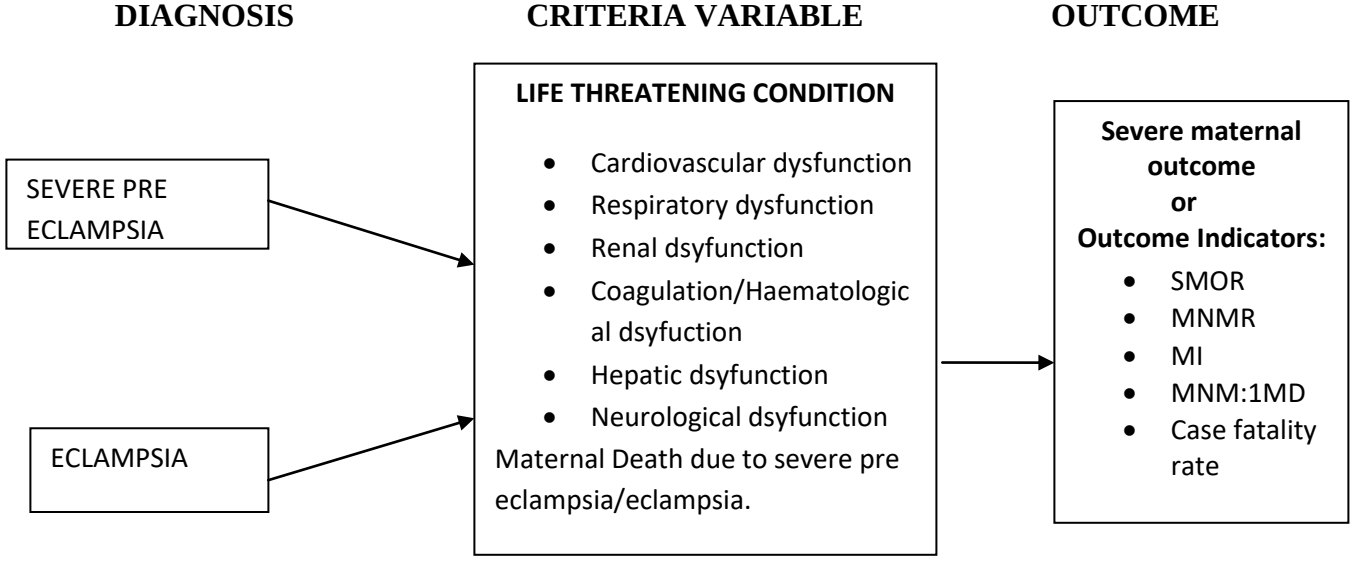
Many countries have adopted and use WHO MNM review but it has some limitations especially in low resource countries. Due to limited resources some of laboratory and management based criteria could not be used.Studies done in Rwanda reported that they could not use the following laboratory criteria: Lactate, PaO2/FiO2 and Ketoacid in urine, also among management criteria, dialysis was not done(11).In Tanzania a rural referral hospital reported that they could perform only two laboratory criteria that is Oxygen saturation and platelets count, while in management criteria they could not perform dialysis for acute renal failure and use of vasoactive drugs. They also modified blood transfusion criteria of more than 5 units to more than one unit (24). Studies done in India and Brazil reported to use all the WHO criteria as their centres had all the laboratory and management criteria needed(25,26). These results make it difficult to compare findings between countries, regions or studies.

CONCEPTUAL FRAMEWORK

Severe pre eclampsia and eclampsia are among the leading causes of maternal morbidity and mortality worldwide. In this study severe pre eclampsia and eclampsia were the main diagnosis and were considered as maternal near miss.

This study expected to show the occurance of severe maternal outcome among women with severe pre eclampsia and eclampsia. The scheme shows the relationship between the diagnosis, criteria variables and the outcome variables. Severe pre eclampsia and eclampsia are diagnoses, whereas the criteria variables are life threatening conditions which include cardiovascular dsyfunction, respiratory dsyfunction,renal dsyfunction, haematological dsyfunction,hepatic dsyfunction, neurological dysfunction and maternal death.Severe maternal outcome (SMO) is the outcome variable, whereby a patient with severe pre eclampsia / eclampsia who presented with one of the criteria above plus maternal deaths was considered as SMO. The diagnoses were expected to be influenced by the criteria variables for occurance SMO.Outcome indicators was calculated from SMO such as MNMR,SMOR,MI,MNM:1MD and Case fatality rate

Figure 1: CONCEPTUAL FRAME WORK SCHEME



PROBLEM STATEMENT

Severe pre eclampsia and eclampsia are among the leading causes of maternal death and maternal near miss, worldwide. At Muhimbili National Hospital they contributed to high proportion of severe maternal outcome (MNM +MDs) of 24% in 2012 (23).It indicates that there is a gap in provision of obstetric and maternal care which needs to be addressed.This necessiates the need to determine the proportion of severe maternal outcome among women with severe pre eclampsia and eclampsia, and to determine case specific MNM indices,which will help to evaluate quality of care given to these patients, hence intervention can be made to reduce severe maternal morbidity and mortality.

RATIONALE

Due to high proportion of severe maternal outcome (maternal death and maternal near miss) caused by severe pre eclampsia and eclampsia in Muhimbili National Hospital, it is crucial to review MD and MNM among these women . The MNM indices will help to assess how frequently these conditionsoccur so as to provide an estimate ofthe complexity of care and performance that will be required in their management.All these will help to evaluate quality of care provided to these patientswhere by interventions can be made to reduce severe maternal outcome due to severe pre eclampsia and eclampsia. These data can be used as the data for severe maternal outcome among women with severe pre eclampsia and eclampsia and baseline data for continous maternal near miss review in our institution.

RESEARCH QUESTION

What is the proportion of severe maternal outcome and case specific maternal near miss indices among patients with severe pre eclampsia/eclampsia at Muhimbili National Hospital?

OBJECTIVES

Broad objective

To determine proportion of severe maternal outcome and case specific maternal near miss indices among patients with severe pre eclampsia and eclampsia at Muhimbili National Hospital from September 2017to January 2018.

Specific objectives.

The specific objectives of this study are:-

i. To determine proportion of severe maternal outcome among patients with severe pre eclampsia and eclampsia.
ii. To determine case specific MNM indices among patients with severe pre eclampsia and eclampsia

METHODOLOGY

Study Design: It was a descriptive cross sectional study**.**

Study Duration: The study was conducted for the period of four months, from September 2017 to January 2018.

Study Settings: The study was conducted at Muhimbili National Hospital, which is the largest public and tertiary hospital in Tanzania and teaching hospital for Muhimbili University of Health and Allied Sciences. It caters for the population of about 4.4 million Dar es salaam residents.The hospital receives patients from 3 Regional hospitals and other hospitals within the city and upcountry. Being a tertiary hospital it receives many patients with severe morbidities that need specialized care.

Maternity block has six antenatal and postnatal wards, which can accomodate 40 patients each.The labour ward has 17 delivery beds and adjuscent to it is ward 35 which is high dependent unit and maternity ICU with 21 beds. An average of 30 deliveries take place per day. After delivery patients are observed in the labour ward for up to six hours before transfer to the post natal wards.Patients with severe morbidities are delivered in ward 35.The on call team on each day includes one specialist obstetrician/ gynaecologist, three residents, and one intern doctor.

Critically ill patients due to hypertensive disorders and other obstetric conditions are admitted in ward 35. This ward has two units, one is ICU unit where patients who need intensive care including mechanical ventilation are admitted,there are nine beds in ICU, with only five ventilators. The other unit is high dependent unit for patients with life threathening conditions includingsevere pre eclampsia and eclampsia who will not need mechanical ventilation, it has 12 beds. An average of 20 patients with severe pre eclampsia and eclampsia are admitted per week. Management protocols for various conditions are available in the ward for critically ill patients. The following investigations are done to all patients admitted in ward 35: Urine for protein, Random Blood Glucose, Blood slide for malaria parasites, Full blood picture, Serum

Creatinine and Urea and Uric acid, Liver function tests and Serum electrolytes, other investigations are done as needed. Magnesium sulphate is initiated to all patients with severe pre eclampsia and eclampsia, to prevent/ treat convulsion.Antihypertensives are used to control blood pressure. Blood for transfusions is supplied through the hospital's blood bank, but is sometimes insufficient and must be supplemented by the National Blood Bank.Admitting team is responsible for daily morning and evening ward rounds.There is also a team of internsivity and anesthesiologistswho are responsble for intubation of patients who need mechanical ventilation, dailyreviewing and discharging patients from ICU.There is also multiproffesional consultation system where specialists from other departments are called to review patients who need their attention.Patients who need dialysis are sent to the dialysis unit according to their schedules.

Study Population

All women with severe pre eclampsia and eclampsia admitted during the study period .

Inclusion Criteria:

1.**Severe pre eclampsia** : A patient who presents with : Systolic blood pressure of 160mmHg or higher, or diastolic blood pressure of 110 mmHg or higher in two occasions a least 4 hours apart while the patient is on the bed, or with features of organ dsyfunction.

2**. Eclampsia**: generalised fits in a woman with pre eclampsia, without previous history of epilepsy. Include coma in pre-eclampsia

Criteria for Severe maternal outcome

Maternal deathdue to severe pre eclampsia/eclampsia.

Maternal near miss due to severe pre eclampsia /eclampsia which will fulfill at least one of the clinical, laboratory or management criteria representing life thratening condition, which are as follows:

Life-threatening conditions (organs dysfunction)- clinical and laboratory criteria

• Cardiovascular dysfunction— Shock, cardiac arrest (absence of pulse/ heart beat and loss of consciousness), use of continuous vasoactive drugs, cardiopulmonary resuscitation.

• Respiratory dysfunction — Acute cyanosis, gasping, severe tachypnea (respiratory rate >40 breaths perminute), severe bradypnea (respiratory rate <6 breaths per minute), intubation and ventilation not related to anaesthesia, severe hypoxemia (O2 saturation <90% for ≥60 minutes)

Renal dysfunction— Oliguria non-responsive to fluids or diuretics, dialysis for acute renal failure, severe acute azotemia (creatinine ≥300 μmol/ml or ≥3.5 mg/dl)

• Coagulation/haematological dysfunction— Failure to form clots, massive transfusion of blood or red cells (≥5 units), severe acute thrombocytopenia (<50 000 platelets/ml)

• Hepatic dysfunction — Jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia (bilirubin >100 μmol/l or >6.0 mg/dl)

• Neurological dysfunction — Prolonged unconsciousness (lasting ≥12 hours)/coma (including metabolic coma), stroke, uncontrollable fits, total paralysis

Critical interventions or intensive care unit use- Management criteria

• Admission to intensive care unit

Sample Size

Sample size was calculated using prevalence of severe maternal outcome due to severe pre eclampsia and eclampsia (maternal deaths plus near miss cases) from the previous study on maternal near miss and death and their association with caesarian section compications done by Helena Litorp at Muhimbili National hospital in 2012(23)

Prevalance of SMO due to severe pre eclampsia and eclampsia by Litorp et al in 2012 at MNH =24%

Sample size was calculated by the formular below

$$n = \frac{z^2 p(100 - p)}{\varepsilon^2}$$

n=maximum sample required

z=level of confidence in this study is 95% therefore z=1.96

E= maximum likely error which is 5%

P= prevalence of MNM

Therefore $n=1.96^2$ x 24(100- 24)/5^2

n=280 When adjusted to 10% non-response rates =380 /0.9 = 311

n=311

Sample size =311

Sampling Technique

Consecutively sampling was used for the study whereby all women with severe pre eclampsia/eclampsia who were admitted during time of study were consecutively recruited until the sample size was reached. They were identified from daily review of admission books in ward 35 andadmitting wards.

Data Collection

All women with severe pre eclampsia and eclampsia were identified on daily basis by Principal researcher through daily review of admission books in ward 35 and admitting wards. Where inclusion criteria were met, the researcher recruited the patients and followed them during hospitalization until their discharge or death.

A structured check list was filled which included: patients particulars such as age ,parity ,gravidity,gestation age,referral status ,mode of delivery, hypertensive disorder: severe pre

eclampsia or eclampsia. Critical intervention: admission to ICU and maternal outcome organ dsyfunction and matenal death. This data was obtained from patients files, in case of missing information or doubt the facility medical staff was questioned.

Organ dsyfunction was diagnosed using laboratory results which were obtained from patient's file or computer data base. Once women are discharged, they were considered to have survived and constituted a near miss case, those who died constituted maternal death. Any maternal death due to severe pre eclampsia and/or eclampsia, which occured before being recruited in the study was also included. A woman with severe pre eclampsia/eclampsia who presented with a least one of the organ dsyfunctionwas considered as MNM with organ dysfunction ,together with maternal death they constituted SMO.

Data Analysis

The collected data were coded, entered, cleaned and analyzed using SPSS Statistical software version 22. Categorical variables were summarized as frequencies and percentage.Continous variables were summarized into mean and standard deviation(such as age and gestation age at delivery).Contingency tables were formed, theoutcome variables formed the row in the tables.These included mode of delivery,placental abruption, maternal death,organ dsyfnction,severe maternal outcome.The exposure variables were presented in columns.These variables were severe pre eclampsia and eclampsia. A cross tabulation was obtained with row percentages.

Proportion of Severe maternal outcome among patients with severe Pre eclampsia and eclampsia were obtained by summation of all maternal death due to severe pre eclampsia/eclampsia and patients with severe pre eclampsia/eclampsia with any organ dsyfunction**.**

The outcome indicators were calculated using total number of live births during study period, number of maternal deaths and maternal near miss due to severe pre eclampsia/ eclampsia in the same period. These indicators are as follows;

- Case specific maternal nearmiss ratio due to pre eclampsia and eclampsia were calculated by the number of maternal near miss cases due to pre eclampsia and eclampsia per 1,000 live births.
- Case specific severe maternal outcome ratio due to severe pre eclampsia/ eclampsia determined as the number of women with life threatening conditions(organ dysfunction)plus maternal deathdue to severe pre eclampsia/eclampsia (MNM + MD) per 1000 live birth.
- Case fatality rate due to severe pre eclampsia/ eclampsia was determined as the proportion of deaths out of the total number of patients presenting with severe pre eclampsia and eclampsia, expressed as a percentage.
- Case specific mortality index due to severe pre eclampsia/eclampsia wasdetermined as the number of maternal deaths due to severe pre eclampsia and eclampsia divided by the number of women with life threatening conditions due to severe pre eclampsia/ eclampsia expressed as percentage.
- Case specific maternal mortality ratio due to severe pre eclampsia/eclampsia (MNM: 1 MD) determined as the ratio between maternal near miss cases due to severe pre eclampsia/eclampsia and maternal death due to severe pre eclampsia /eclampsia.

Ethical Clearance .

The ethical clearance for the study was obtained from the Senate Research and Publication Committee of Muhimbili University of Health and Allied Sciences (MUHAS). Permission to conduct the study was granted from Executive Director of Muhimbili National Hospital where the study was conducted. Data was collected and extracted from patient's records without identification of the subject. A structured check list was filled usingpatient's recordsand therefore inclusion did not interfere with the management of the patient. Considering the precautions above, individually obtained informed consent was not required.

Ethical Consideration

Data was treated confidentially, patient was identifying by folder number and filled form was kept on a locked cabinet only accessible to principal investigator . During follow up of the patients, the principal investigator worked together with admitting team by consulting them regarding treatment and participated in some of the procedures so as to make sure these patients received necessary care and treatment.

RESULTS

During the study period there were 3853 deliveries, whereby 3661were live births.A total of 320 women were recruited in this study, whereby 310(96.9%) women were referred from peripheral hospitals. They presented with severe pre eclampsia and eclampsia, 199(62.2%) and 121(37.8%) respectively. Mean age was 27.1±6.31 years, more than two thirds, 247(77.2%) were aged 19–35 years. High proportion of women were primigravida and para1-2 with 136(42.5%) and 129(40.3%) respectively. Mean gestational age at delivery was 34.0±3.5 weeks; majority of them hadpremature delivery at GA of 28-36 weeks 225(70.3%). Out of 320 pregnant women 27(8.4%) were admitted to ICU. All women with severe pre eclampsia and eclampsia received Magnesium Sulphate for prevention and treatment of convulsions.

Table 1: Distribution of maternal characteristics among women with severe pre eclampsia and eclampsia at MNH (N=320)

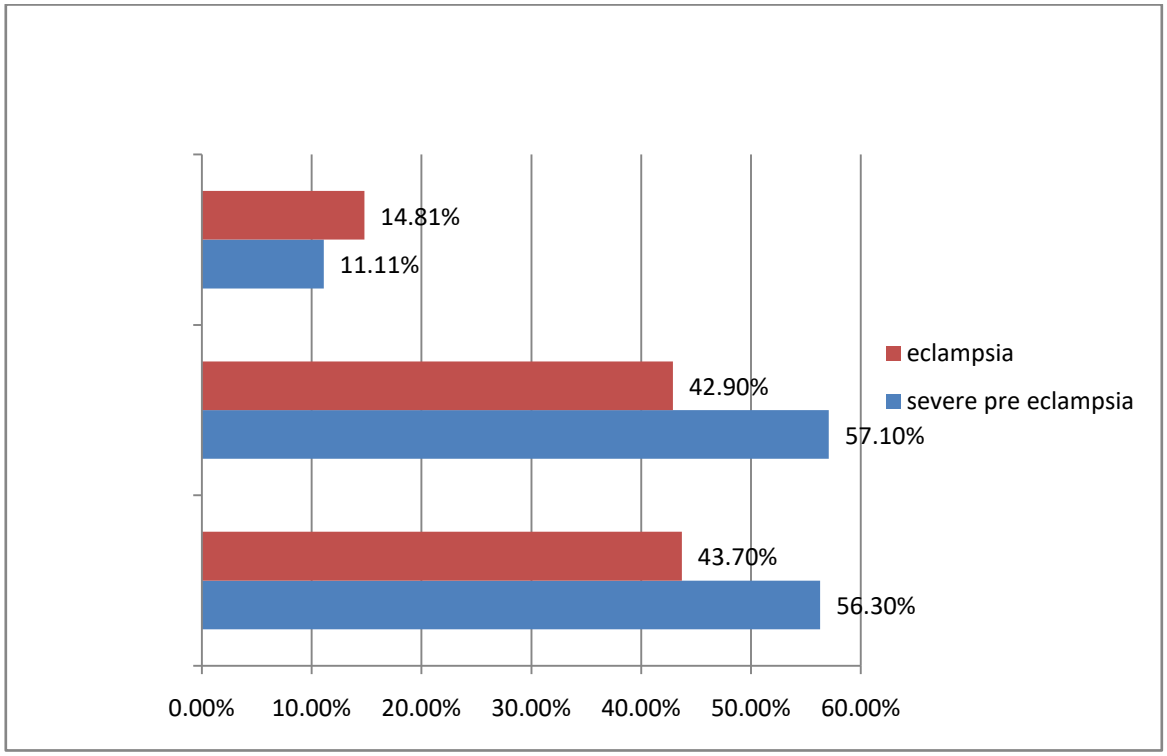
Maternal characteristics	Frequency (%)
Age group (years)	
<19	38 (11.9)
19-35	247 (77.2)
more 35	35 (10.9)
Parity	
0	136 (42.5)
1-2	129 (40.3)
3-4	47 (14.7)
≥5	8 (2.5)
Gravidity	
1	117 (36.6)
2-4	171 (53.4)
≥5	32(10.0)
Gestational age at delivery	
<28 weeks	15 (4.7)
28-36 weeks	225 (70.3)
≥37 weeks	80 (25)

***Mode of delivery**	
Vaginal delivery	157 (49.4)
Caesarian section	161 (50.6)
Admission to ICU	
Yes	27 (8.4)
No	293 (91.6)
Referral status	
Yes	310 (96.9)
No	10 (3.1)
Hypertensive disorders	
Severe pre eclampsia	199 (62.2)
Eclampsia	121(37.8)

***n=318**

Two (0.6%) women died undelivered.

Figure 2: Distribution of Severe maternal outcomes among patients with severe pre eclampsia and eclampsia.



Out of 320 women 71 women presented with SMO (63 MNM with organ dysfunction and 8 maternal deaths), whereby 56.3% had severe pre eclampsia while43.7% had eclampsia. Severe pre eclampsia had high proportion of organ dysfunction of 57.1%. Eclampsia had high proportion of MD as compared to severe pre eclampsia.**(Figure 2).**

Table 2: Distribution of severe maternal outcomes among women with severe pre eclampsia and eclampsia at MNH (N=320)

Maternal outcomes	Severe pre eclampsia	Eclampsia	Total
Placenta abruption			
Yes	12(70.6)	5(29.4)	17
No	187(61.7)	116(38.3)	303
Maternal death			
Yes	4(50.0)	4(50.0)	8
No	195(62.5)	117(37.5)	312
Cardiovascular dysfunction			
Yes	4(66.7)	2(33.3)	6
No	195(62.1)	119(37.9)	314
Respiratory dysfunction			
Yes	5(55.6)	4(44.4)	9
No	194(62.4)	117(37.6)	311
Renal dysfunction			
Yes	9(42.9)	12(57.1)	21
No	190(63.5)	109(36.5)	299
Hellp syndrome			
Yes	34(58.6)	24(41.1)	58
No	165(63.0)	97(37.0)	262
Neurologicaldysfunction			
Yes	0(0.0)	8(100.0)	8
No	199(63.8)	113(36.2)	312

***Organ dysfunction**			
Yes	36(57.1)	27(42.9)	63
No	163(63.4)	94(36.6)	257
SMO			
Yes	40(56.3)	31(43.7)	71
No	159(63.9)	90(36.1)	249

***Organ dysfunction=total number of women with organ dsyfunction**

HELLP syndrome was the leading dysfunction whereby 58(18.1%) of participants presented with it. (**Table 2).**

Table 3: Maternal morbidity and mortality indicators among women with severe pre eclampsia and eclampsia at MNH

Indicator	Indices calculations	Overall ratio	Hypertensive Disorder	Case specific ratio
Case specific maternal near miss ratio (MNMR) (per 1000 LB)	MNM/LBX1000	87.4	S.Preeclampsia Eclampsia	54 33
Case specific severe maternal outcome (SMOR) ratio(per 1000 LB)	(MNM+MD)/LBX1000	19.4	S.Preeclampsia Eclampsia	12 9.5
Mortality index (MI) (as percentage)	MD/(MNM+MD)X100	11	S.Preeclampsia Eclampsia	9 11.4
Case fatality rate (CF) (as percentage)	MD/Total number of pts with severe pre eclampsia and eclampsia X 100	2.5	S.Preeclampsia Eclampsia	2.1 3.3
Case specific maternal near miss mortality ratio	MNM:1MD	40:1	S.Preeclampsia Eclampsia	50:1 30:1

LB=Live Birth

During the study period there were 3661 live births. Overall maternal near miss ratio was87.4 .Overall case fatality rate was 2.5% whereby severe pre eclampsia accounted for 2.1% while eclampsia accounted for 3.3% respectively. **(Table 3).**

DISCUSSION

Severe pre eclampsia and eclampsia are hypertensive disorders in pregnancy which cause significant proportion of maternal morbidity and mortality in developing countries, including Tanzania. Index study is one of thestudies describing maternal morbidity and mortality due to severe pre eclampsia and eclampsia by applying WHO MNM approach.

A high proportion of women presented with severe morbidties due to hypetensive disorders but they survived.This was indicated byhigher MNMR found in the index study.These findingswere similar to those in a previous study done at Muhimbili National Hospital(23). A low MNMR washowever reported in studies done in Brazil, India and Uganda(9,21,22).The difference could probably be due to the fact that in our study more than 90% of women were referred from peripheral facilities with morbidities already,compared to 20% to 64%in the above studies.It could also be due to difference of quality of care for hypertensive disease in pregnancy in different settings,as they had high proportion of MD as compared to MNM. The care in our facility, being a tertiary facility, is likely to be more appopriate than that offered in peripheral facilities,hence explaining the high proportion of MNM casescoming from these facilities but they survived. Also this shows that severe pre eclampsia and eclampsia occurs more frequently in our facility and more care is needed to manage these patients,hence reduce severe maternal outcome among these patients.

In the current study severe maternal outcome ratio was19.4 per 1000 live births, whereby severe pre eclampsia accounted for higher ratio than eclampsia.WHO recommends SMOR below 10 per 1000 live births. High SMOR in this study indicates that substantial proportion of women required more complex intervention in order to survive their complications. Despite the interventions some women died from their complications, this shows that more effort has to be put to save lives of these patients with severe maternal morbidities.Ninty percent (90%) of these participants were referred from peripheral health facilities or from home already with complications, this explains the high SMOR.

The results are comparablewith the findings from previous study conducted at Muhimbili National Hospital (23). Studies done in Uganda,however reported low SMOR(9).

Mortality index (MI)provides an estimate on how a health facility is performing in dealing with complex and severe cases.WHO recommends mortality index of below 5% .In this study it was found to behigh; mortality index of 11%. Similar findings were reported in studies done in Uganda and Brazil(9,18). Umadevi and Lotufo et al in Brazilreported very high maternal mortality index of more than two to five foldof the MI in this study (20,21).This demonstrates thata high proportion of critically ill women in low resource settings die from their complications.The mortality index found in this study is higher than WHO recommendations but low when you compare with the findings of above studies in the low resource settings.We have a well organized and functioning obstetric ICU and high dependant unit ,and this could explain on improvement of performance in caring of criticaly ill patients, but more effort needs to be put to reduce maternal deaths to the recommended standards.

In this study the overall case fatality was low, even lower compared to previous studies done in Muhimbili National Hospital in 2006 and 2009 (13,14) and other studies done in Uganda, Rwanda and Mozambique(9–11).This implies that substantial proportion of patients with severe morbidities survived the complication,hence reduction of maternal deaths among these patients. Attention is needed for eclampsia as it still has high case fatality rate and mortality index.

Maternal Near Miss Mortality ratio is the ratio of MNM per one maternal death: higher ratio indicates better care.In this study it was found thatin every fourty women with severe pre eclampsia/eclampsia one woman died.Thisimpliesthat high proportion of patientswith severe marternal morbiditysurvived these complications.This indicates better care provided to these patients in our facility as explained above. These findings are contrary to previous study done in Muhimbili National Hospital(23) and other African countries Uganda, Rwanda and Mozambique which had low ratio ofaround 20:1(9–11).

There were eight maternal deaths whereby four were due to severe pre eclampsia and the other four were due to eclampsia, all were referred from peripheral health facilities with severe morbidities. Two women died undelivered, one had severe pre eclampsiawith concealed abruption placenta while the other one had eclampsia with Hellp syndrome and respiratory dysfunction. Six women had multiple organ dysfunctions. Hellp syndrome was the leading morbidity followed by acute kidney injury, respiratory, neurological and cardiovascular dysfunctions, all were admitted in ICU. Dialysis was done to those who had acute kidney injury.This shows that high proportions of women with SMO were referred from peripheral health facilities. Those who presented with very critical condition died despite of the care they received, as it was seen that half of MDs had short duration of hospital stay, however as a tertiary hospital it's our duty to make sure they survive. Out of nine women with respiratory dysfunction one woman died, this shows the importance of respiratory support by early intervention with intubation and continuous ventilation. There is a need to have adequate number of ventilators in ICU. Some patients with severe pre eclampsia were admitted in general maternity wards due to low capacity of high dependent unit; monitoring these patients in general wards is difficult, hence resulted in more morbidities to these patients.Our high dependentunitneeds to be expanded to accommodate all patients with severe maternal morbidities so as they can receive appropriate care and reduce maternal mortality. The fact that 8.4% of women were admitted in ICU and all MDs were admitted in ICU shows that critical intervention was provided to those women who needed it.

Strength of this study is that womenwere recruited after admission and followed up to the day of discharge or death.This enabled the principal invesigator to have up to date data.The limitation of this study was that, there were no reagents for renal function tests for two weeks during study period. Blood samples of women with clinical presentation of acute kidney injury were sent to MuhimbiliOrthopedic Institute (MOI)for the tests. Hence some of women with no symptoms of acute kidney injury missed these investigations.

CONCLUSION

There is high proportion of women with severe maternal outcome amongpatients withsevere pre eclampsia and eclampsia, with reduced proportion of maternal deaths as compared to previous studies.This signifies improvement of performance in our health facility in dealing with patients with severe morbidities due to severe pre eclampsia and eclampsia. More effort however has to be put to reduce maternal mortality to the recommended standards.A high proportion of women with severe morbidities had been referred from peripheral health facilities.

RECOMMENDATIONS

There is need to strengthen maternal health care services especially in peripheral health facilities, to be more effective in detecting women who are at risk for hypertensive disorders and provide proper management with regular follow up.

These findings highlight the feasibility of implementing facility based continuous surveillance system for severe maternal morbidity from which data to improve intervention can be generated.

Expand high dependent unit in our facility to accommodate all patients with severe maternal morbidities, also to add ventilators in ICU.

Future studies should be directed to assess long term morbidities due to severe pre eclampsia and eclampsia, hence determine the burden attributable to these HPD in pregnancy.

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APPENDIX

MATERNAL NEAR MISS AND MORTALITY DATA COLLECTION TOOL

ADOPTED FROM WHO - EVALUATING THE QUALITY OF CARE FOR SEVERE PREGNANCY COMPLICATIONS DOCUMENT.

IDENTIFICATION:

INDIVIDUAL IDENTIFICATION CODE:……

AGE:…….

PARITY……

GRAVIDITY ……..

GESTATION AGE :…….

1. **SEVERE COMPLICATIONS/ POTENTIALLY LIFE THREATENING CONDITION**

   a) Severe pre eclampsia

   0.No …… 1.Yes…….

   b) Eclampsia

   0. No…….1. Yes……..

2. **INTERNSIVE CARE USE**

   a) Admission to intensive care unit 0. No…… 1.Yes

3. **ORGAN DSYFUNCTION AND LIFE THREATENING CONDITION**

   C0- Cardiovascular dysfunction— Shock, cardiac arrest (absence of pulse/ heart beat and loss of consciousness), use of continuous vasoactive drugs, cardiopulmonary resuscitation.(0.No……. 1.Yes……)

   C1- Respiratory dysfunction — Acute cyanosis, gasping, severe tachypnea (respiratory rate >40 breaths perminute), severe bradypnea (respiratory rate <6 breaths per minute), intubation and ventilation not related to anaesthesia, severe hypoxemia (O2 saturation <90% for ≥60 minutes) (0.No……1.Yes…….)

C2- Renal dysfunction— Oliguria non-responsive to fluids or diuretics, dialysis for acute renal failure, severe acute azotemia(creatinine ≥300 μmol/ml or ≥3.5 mg/dl) (0 No……1.Yes……..)

C3- Coagulation/haematological dysfunction— Failure to form clots, severe acute thrombocytopenia (<50 000 platelets/ml) (0.No …….1.Yes…….)

C4- Hepatic dysfunction — Jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia(bilirubin >100 μmol/l or >6.0 mg/dl), orabnormallyelevatedblood concentration of liver enzymes ASAT and ALAT to twice normal. (0.No…1.Yes…)

C5- Neurological dysfunction — Prolonged unconsciousness (lasting ≥12 hours)/coma (including metabolic coma), stroke, uncontrollable fits, total paralysis (0.N0……1.Yes…..)

4. **MATERNAL DEATH**

   a)- Death during pregnancy or within 42 days of termination of pregnancy. (0.No……1.Yes…….)

MATERNAL AND PERINATAL INFORMATION

5. Date of admission……
6. Date of delivery or uterine evacuation……
7. Date of hospital discharge or death…….
8. Mode of delivery

   1= Vaginal delivery

   2= Caesarian section

9. Gestational age at delivery
10. Abortion (0.N0…..1.Yes….)

11. Status of the infant
    I. ALIVE……
    II. SBF……
    III. SBM……
    Body weight ……, Apgar score at 5th minute…….
12. Baby died within 7th day of life if still in hospital
    (0.No…….1. YES…….)

PROCESS INDICATORS.

13. About condition at arrival in the health facility and the referral process, specify
    (0=No…. 1= Yes…..)
    Women referred from other health facility…….
14. Timing of complication
    I. Prior admission
    II. After admission
15. About use of interventions, please specify whether the woman receive any of the following : (0= No 1= Yes)
    Anticonvulsant: Magnesium sulphate…….