"Maternal near miss in a tertiary care hospital: A Cross Sectional study"

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ABBREVIATIONS

AFLP	Acute fatty liver of pregnancy
HDU	High dependency unit
HELLP	Haemolysis, elevated liver enzymes, low platelet count
ICU	Intensive care unit
LB	Live birth
MD	Maternal death
MI	Mortality index
MNM	Maternal near miss
MNMR	Maternal near miss ratio
PPH	Postpartum hemorrhage
SMO	Severe maternal outcome
SMOR	Severe maternal outcome ratio
WHO	World Health Organization
WLTC	Women with life threatening conditions

ABSTRACT

Title:

Maternal near miss in a tertiary care hospital: a cross sectional study.

Objectives

Primary Objective: To determine the prevalence of maternal near miss due to obstetric complications or maternal disease in a tertiary hospital.Secondary Objective: To determine severe maternal outcome ratio(SMOR), maternal near miss ratio(MNM ratio) and maternal near miss mortality ratio

Materials and methods: A cross-sectional study was conducted in KLES Dr.Prabhakar Kore Hospital and MRC, tertiary care hospital, Belagavi From January 2015 to December 2015, all consecutive cases of maternal near miss (MNM) and maternal death (MD) were included. WHO near miss criteria was considered as standard to include patients for the study

Results: There were 6275 deliveries during the study period of which 6077 were live births, 97 cases were included in the study who fulfilled the WHO near miss criteria. 84 patients of the study population were maternal near-miss cases and 13 were maternal deaths. The mean age among the study group was 21-25 years, Majority of the population were primigravida with term gestation and were unregistered. The statistical analysis of demographic profile showed no significance in the categories of age, parity, and occupation whereas, gestational age, antenatal care and mode of termination of pregnancy in the study population showed statistical significance. The commonest causes of morbidity among the maternal near miss group were Anemia,

hemorrhage and hypertensive disorders, accounting for 44%, 45% and 50% respectively. In the maternal death group it was anemia 69%, hemorrhage 61%, other conditions 46% and infections 15%. Infections and other conditions as a cause were statistically significant. In MD group 46% died with in 24 hours of admission and 53% died after 24 hours of admission. In MNM group 38% had received massive blood transfusion, 13% underwent emergency obstetric hysterectomy, and 16% required ventilator support. Prevalence of MNM was 1.3% near miss incidence is found to be 13.3 per 1000 live births and maternal mortality rate is 213 per 100000 live births. The MNM to MD was 6:1. The maternal mortality index (MI) in this study is 13%.

Conclusion: The near miss incidence in our hospital is 13.3 per 1000 live births and maternal mortality rate is 213 per 100000 live births, which suggests the quality of health and care provided. Registered cases who took regular antenatal visits resulted in maternal near miss and no maternal deaths. Early evaluation and treating the morbidity at its root does prevent maternal death. Timely and prompt referral of high-risk cases to tertiary care centers goes a long way in reducing maternal and perinatal morbidity and mortality. Thus Evaluation of the circumstances surrounding near miss cases could act as proxy for maternal deaths which can be prevented.

Key words: Maternal near miss, maternal mortality, severe maternal morbidity.

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Chapter 1

Introduction

INTRODUCTION

Maternal mortality is one of the important indicators used for the measurement of maternal health. Improvement of maternal health is one of the millennium development goals, MDG 5 with Target 5 A that calls for the reduction of maternal mortality ratio by three quarters between 1990 and 2015.[1,2] Since 1990, though maternal deaths world-wide have dropped by 47%, the number of maternal deaths in developing countries remains high. The global maternal mortality ratio is 210/100,000 births while it is about 240 in developing countries as compared to 14/100,000 in developed countries.[2-4] India has also reported a decline with the figure for 2007-2009 being 212/100 000 births from 398 in 1997-1998 and 301 in 2001-2003.[2,5,6]

Although maternal mortality remains a significant public health problem, maternal deaths are rare in absolute numbers especially within a community, hence that assessment of effects of care is difficult.[2,6]

Progress in the reduction of maternal mortality – a key Millennium Development Goal – has been slow in most countries that have high maternal mortality ratios, and solutions to this global problem are urgently needed.[8]

Worldwide, approximately 800 women die every day from preventable causes related to pregnancy and delivery.[9,10] An additional ten million experience some kind of complication and a further three million neonatal deaths occur every year globally.[9,11,12] Most of these situations are preventable and 99% of maternal deaths occur in developing countries.[9,10] The maternal mortality ratio in Brazil is about 60.1/100,000 live births (LB) and a total of 1,719 deaths were estimated to have occurred in 2010. The main causes of maternal deaths this year were: hypertension

(21.1%), hemorrhage (11.9%), complications of labor (9.6%), sepsis (8.6%), abortion (6.5%) and HIV and infectious disease (5%). Maternal deaths occur asymmetrically and vary according to the region in country and its state of development.[9]

In most places, the study of maternal mortality has become increasingly difficult for several reasons, especially due to its rare occurrence. It is therefore very difficult to do population studies that aim at understanding the reason behind the death of these women.[9,13]

In 2009, the WHO established a set of criteria for SAMM and for NM in order to standardize data and calculate indicators for comparing different settings and identify cases of interest.[9,14] Severe acute maternal morbidity (SAMM) and maternal near miss (NM) are events involved in the biological *continuum* that goes from the normal expected healthy situation of a pregnancy to maternal death.[9,15] NM events are used to study situations where women survived, but nearly died due to a complication during pregnancy, delivery and postpartum and help to reduce maternal mortality by improving maternal health.[9,16,17] Despite these cases having several aspects in common with women who died (especially with the same risk factors), fortunately these events are at least three times more frequent than maternal deaths. SAMM is a condition, more broadly defined, the cases are less serious and represent a situation that precedes the NM situations in severity.[9,14] NM situations are classified according to Table three in Say, Souza and Pattinson paper, are more specific and often represent the stage that immediately precedes maternal death.[9,14]

A systematic review, including 82 studies from 46 countries, demonstrated that the prevalence ranged from 0.04% to 14.98%.[18] Other similar studies found NM incidence ratios of 3.4 cases/1,000 deliveries and 18 cases/1,000 deliveries.[19] A recent

Brazilian multicenter study, which adopted the new SAMM and NM classification from the WHO (2009), analyzed 27 reference maternity hospitals in one year and found 116.3 cases/1,000LB.[9,20]

The maternal mortality ratio (MMR) of India was 254 (2004-2006), which was reduced to 200 (2010).[21,22] India is a signatory to millennium declaration and is committed to achieving the target of millennium development goals by reducing MMR to 100. Known obstacles to reducing the MMR in developing countries, include lack of material and human resources, as well as difficulties in accessing services due to financial, geographical, and cultural limitations. Near-miss cases have similar pathways as maternal deaths, with the advantages of offering a larger number of cases for analysis, greater acceptability of individuals and institutions since death did not occur, and the possibility of interviewing the woman herself. However, there is no definite denominator population in a hospital; the data for total number of deliveries and live births is available, which was used to calculate the maternal mortality and ONM ratios. International studies have reported ONM to maternal death ratios ranging from 5:1[21,23] up to 11:1.[21,24] Worldwide, some studies have described it according to common obstetric disease states, e.g., hemorrhage, preeclampsia,[21,25] whereas others used either criteria related to the response to the disease (e.g., hysterectomy or admission to Intensive Care Unit [ICU]) or specific organ system dysfunction, that is specific criteria of dysfunction or failure of specific organ system.[21,26]

The prevalence of near miss is higher in developing countries and causes are similar to those of maternal mortality namely hemorrhage, hypertensive disorders, sepsis and obstructed labor. Reviewing near miss cases provide significant

information about the three delays in health seeking so that appropriate action is taken. It is useful in identifying health system failures and assessment of quality of maternal health-care.[2]

In any setting, women who develop severe acute morbidity during pregnancy share many pathological and circumstantial factors related to their condition. While some of these women die, a proportion of them narrowly escape death. By evaluating these cases with severe maternal outcomes (both "near-miss" cases and maternal deaths), much can be learnt about the processes in place (or lack of them) to deal with maternal morbidities.[2] In 2007, WHO established a technical working group comprising obstetricians, midwives, epidemiologists and public health-care professionals to develop a standard definition and uniform identification criteria for maternal near-miss cases. With a view to achieving a reasonable balance between the burden of data collection and useful information, with this working[27]

The present study was an attempt to provide an insight into the problem of maternal near-miss and mortality in North Karnataka, India so as to reduce the burden of maternal mortality, maternal near miss has been suggested as a compliment to maternal death. Severe morbidity data are vital for policy planners to know the requirements of essential and emergency obstetric care (EmOC) to manage these. It is also assumed to be a better indicator than maternal mortality alone for designing, monitoring, follow up and evaluation of safe motherhood programs.[28-30]

Chapter 2

Objectives

OBJECTIVES

The objectives of this study were;

Primary Objective:

- To determine the prevalence of maternal near miss due to severe obstetric complications or maternal disease in a tertiary hospital.

Secondary Objective:

- To determine severe maternal outcome ratio (SMOR),maternal near miss ratio (MNM ratio) and maternal near miss mortality ratio

Chapter 3

Review of Literature

REVIEW OF LITERATURE

Near miss is defined as very ill pregnant or recently delivered woman who nearly died but survived a complication during pregnancy, childbirth or within 42 days of termination of pregnancy. SAMM refers to a life-threatening disorder that can end up in near miss with or without residual morbidity or mortality. Women who develop SAMM during pregnancy share many pathological and circumstantial factors related to their condition. Although some of these women die, a proportion of them narrowly escape death. Near miss cases and maternal deaths together are referred to as severe maternal outcome (SMO).

However, there is a lack of uniform criteria for identification of cases of severe obstetric morbidity or maternal near miss. Identification of cases is complex and varies across studies.[31,32] Three major criteria have been mentioned in a review conducted by the WHO, these are described in Table. The review has suggested the use of the organ system dysfunction based criteria supplemented with compatible clinical markers of organ system dysfunction that are feasible for collection in the absence of higher-level amenities based criteria for identifying all severe morbidity and investigating the cause as the most reproducible one across similar areas.[26]

Criteria for identification of near miss cases[2,26]

Criteria	Description	Advantages	Disadvantages
Clinical criteria related to a specific disease entity	Disease specific definitions used for common conditions and clinical criteria defined for severe morbidity. e.g. Pre-eclampsia is a disease and complications such as eclampsia, renal failure and pulmonary edema identify severe cases	Easy to interpret cases can be identified retrospectively	All problems may not be covered
Management specific	Management or intervention to disease. e.g. hysterectomy, blood transfusion or admission to ICU	Simple to use in identification of cases	Depends on other variables such as availability of ICU beds, indications for hysterectomy
Organ system dysfunction or failure	Based on the concept that there is a sequence of events leading from good health to death. Death is preceded by organ dysfunction and organ failure. Markers for organ system dysfunction or failure are specified. e.g. Jaundice in the presence of pre-eclampsia	Allows for identification of critically ill women	Dependent on the existence of a minimum level of care including functioning laboratories and basic critical care monitoring

In another recent review on maternal near miss the authors observed that on using the disease specific criteria a higher percentage of near miss with a wider range of estimate is reported due to variation in the disorders being reported. The management based criteria mostly identifies emergency hysterectomy and intensive care unit (ICU) admissions as the major criteria. This criteria also produces a large variation as it depends on the physical and human resources available and the criteria for admission to ICU used in the institution.[33]

Recently, a WHO Expert Group has suggested a uniform set of identification criteria for maternal near miss cases aiming to facilitate the reviews of these cases. A process of identifying cases with potentially life-threatening conditions in the hospital has been suggested and among these those with organ system failure or dysfunction as per the definition will be included as near miss cases. The causes of these will be aligned with the pathological classification of maternal deaths.[14]

Prevalence of Maternal Near Miss

Due to the wide variation in identification of near miss cases, it has been difficult to make a summary estimate of the prevalence of near miss globally. In the systematic review published in 2004 the prevalence of near miss varied between 0.80% and 8.23% in studies that used disease-specific criteria while the range was 0.38% - 1.09% in the group that use organ-system based criteria. Rates were within the range of 0.01% and 2.99% in studies using management-based criteria.[14] In another, recent review on articles between January 2004 and December 2010 the prevalence rates of maternal near miss varied between 0.6% and 14.98% for disease-specific criteria, between 0.04% and 4.54% for management-based criteria and between 0.14% and 0.92% for organ-based dysfunction based on Mantel criteria. The rates are higher in low-income and middle-income countries of Asia and Africa. Based on meta-analysis, the estimate was 0.42% (95% confidence intervals CI 0.40-0.44%) for the organ dysfunction criteria.[33] Studies from developing countries especially in the African region have reported a high incidence of near miss when compared to the

developed world as can be seen from Table. There are not many studies[2,23,31-42] available from India on maternal near miss as is evident from Table.

Causes of near miss and near miss death ratio[2]

Author	Year	Setting	Criteria	Prevalence	Near miss ratio	Causes of near miss
Baskett and Sternadale J.[31] Canada	1998	Tertiary maternity hospital	hospital Management based	0.7	NA	Hypertension (25)
Waterstone et al.[32] UK	1997-98		Disease specific	1.2	117	Hemorrhage 0.67 Eclampsia and pre eclampsia Severe sepsis
Brace[34] Scotland	2001-02	Maternity units	Disease specific and organ system dysfunction	1.34	49	Hemorrhage 50
Zwart[35] (2008)	Netherlands 2004-06	Population based	Management based	7.1	53	Hemorrhage (4.5/1000) ICU admission (2.7/1000)
Mantel[23] 1998	South Africa 1996	Academic hospitals	Organ system dysfunction	1.09	5	Hemorrhage (26) Hypertension (26) Sepsis (20)
Prual[36] 2000	West Africa multi country1994-96	Maternity units	Disease specific	6.6	29	Hemorrhage (46) Dystocia (30.9)
Kaye[37] 2003	Uganda 2000	Teaching hospital	Organ system dysfunction	10.1	17	Obstructed labor (37) Eclampsia and preeclampsia (18)
Fillipi[38] 2005	Africa 1999-2000	Hospitals at different levels of the health system	Disease specific	8.2	9-108	Hemorrhage (22.7-52.8)
Oladapo[39] 2005	Nigeria 2002-04	Teaching hospital	Disease specific and management based	14.1	4.8	Hemorrhage (30.2)
Khosla[40] 2000	India 1998	Teaching hospital	Disease specific	4.4	7	Hemorrhage (29.9) Hypertension (22.7) Severe anemia (16.4)
Taly[41] 2004	India 2001	Teaching hospital	Disease specific	3.3	31.5	Hemorrhage (34)
Siddiqui[42]	Pakistan	Civil hospital	Disease specific	8.6	5.8	Hemorrhage (33) Hypertension (31) Sepsis (14)

Causes of Maternal Near Miss

The causes of near miss vary in different geographical areas of the world and also there are variations within countries. Hemorrhage, hypertensive disorders, sepsis and obstructed labor are the most important causes in the developing countries as is evident from above Table. Causes of near miss are similar to causes of maternal deaths prevailing in the area. A systematic review to determine the causes of maternal deaths conducted by the WHO recorded wide regional variation. Hemorrhage was the leading cause of maternal deaths in Africa (33.9%) and in Asia (30.8%) while in Latin America and the Caribbean, hypertensive disorders were responsible for 25% deaths. Anemia was reported as an important cause in 12.8% deaths in Asia, 3.7% in Africa and none in the developed countries[43,44] Studies from our country have also reported anemia as an important cause and contributor to maternal mortality and severe maternal morbidity.[45]

Delays in maternal health care

To understand the gaps in access to adequate management of obstetric emergencies leading to severe maternal complications and death three delays have been identified. The first delay is in deciding to seek care by the woman and/or her family as they are unaware of the need for care, this occurs as the danger signs are not recognized or there is lack of support of the family. The second delay is in reaching an adequate health-care facility as the services may not exist or may be inaccessible for reasons such as distance, lack of transport, cost or socio-economic barriers. The third delay occurs in receiving adequate care

at that facility resulting from errors in diagnosis and clinical decision-making, or lack of medical supplies and of staff proficiency in the management of obstetric emergencies.[28-30] In developing countries, about 75% of women with severe obstetric morbidity are in a critical condition upon arrival, underscoring the significance of the first two delays.[24,46] Availability, accessibility, cost of health-care and behavioral factors play an important role in the utilization of maternal health services.[41,43,47,48,49]

Maternal Near Miss Reviews

Maternal death reviews and verbal autopsies have been the common approaches in investigating barriers to maternal health-care in developing countries. Reviewing near miss cases has the further advantage of having firsthand information from women who have survived in understanding health-seeking behavior. The proportion of women arriving at a health-care facility with SMO provides information about the occurrence of the first delay or second delay and factors contributing to the delays.[2] Understanding of these factors by the health personnel, authorities and policy makers and taking appropriate action to address them would improve utilization of maternal health-care services.[2]

Quality of Care and Maternal Near Miss

Globally, there has been a paradigm shift in the maternal care strategy since the 1990's. According to the World Health Statistics 2011, the proportion of deliveries attended by skilled health personnel have rosen from 58% in 1990 to 68% in 2008 at the global level.[2,50] In India also there has been a policy change with promotion of institutional births, births by skilled birth attendants and

provision of Emergency Obstetric Care.[2,51] The Janani Suraksha Yojana (JSY) a cash incentive scheme has been initiated to promote institutional deliveries. Consequently, the proportion of institutional deliveries has risen from 25.4% in 2001 to38.8% in 2006, 47% in 2007-08 and 72.9% in the recent Coverage Evaluation Survey (CES 2009).[2,52-54] This increase in load on the health facilities may compromise the quality of care due to limited financial resources and trained skilled health personnel available. A recent study on impact of JSY has shown an increase in institutional deliveries among the vulnerable and high-risk cases such as pre-eclampsia, eclampsia, hemorrhage etc., whereas there was no decline in the number of maternal deaths.[55] These are the potentially life-threatening cases that need to be identified and managed to prevent maternal mortality.[2]

The near miss approach has been suggested to evaluate and improve the quality of care provided by the health system. By reviewing near miss cases we can learn about the processes and their deficiencies that are in place for the care of pregnant women. This would result in identifying the pattern of severe maternal morbidity and mortality, strengths and weakness in the referral system and the clinical interventions available and the ways in which improvements can be made.[2,56]

Maternal near miss indicators

Certain maternal near miss indicators have been suggested to evaluate the quality-of-care; namely maternal near miss ratio, which is the ratio of the number of maternal near miss cases and live births. It is an estimation of the amount of care and resources that would be needed in an area or facility. Another important

indicator is maternal near miss mortality ratio which is the ratio of the number of maternal near miss and deaths, higher ratio indicates better care.[56,57] This ratio was calculated in the WHO systemic review on near miss and observed to be lower in resource poor settings in Asia and Africa when compared to that in the developed world.[26] These findings assert the fact that maternal near miss to death ratio can be a useful method to assess the care these cases receive.

Access to good quality EmOC is another key strategy to improve maternal outcome. Studies have shown the availability and access of EmOC to be below the target coverage levels especially among the poor and less educated women in poorly performing states.[2,58,59] The state of Tamil Nadu has been successful in observing a significant decline in maternal mortality due to series of initiatives such as skilled birth attendance for all births and making EmOC more available and accessible. The key lesson learnt from the success is to focus on specific evidence based strategies to reduce maternal mortality.[2,60]

Maternal near miss has emerged as an adjunct to investigation of maternal deaths as the two represent similar pathological and circumstantial factors leading to severe maternal outcome. As the number of maternal near-miss cases is more than the maternal deaths and the cases are alive to directly inform on problems and obstacles that had to be overcome during the process of health-care, they provide useful information on quality of health-care at all levels. Thus, there is a need for application of the maternal near-miss concept for assessment of maternal health and quality of maternal care.[2]

In various countries the morbidity rate of severe obstetric disease is similar (0.8-8.2%).[61] Without a doubt, the fatality ratio is an objective indicator for the quality of obstetric care. It is the ratio between the number of maternal deaths and all cases of women who experienced life-threatening complications. This ratio allows us to compare data from different countries and consequently to evaluate the quality of obstetric health care. Mortality from severe obstetric complications ranges from 0.02 to 37%.[61] Fatality ratio depends on the quality of healthcare. The mortality indicators greatly differ between developed and developing countries. Data in all studies carried out in South Africa, showed that 1 woman from 5 die, in addition to 1 from 3 cases of "near miss".[23,63-64] Life-threatening conditions are fatal for 1 woman from 11 in countries like India and Nigeria.[65,66] In developed countries, this indicator is 10 times less: in Great Britain 1 woman from 118 dies, in France 1 woman from 222, in cases of severe obstetric disease.[67,68] The indicators of severe obstetric morbidity also vary: they depend on the countries' economic social and health care levels: Senegal and Nigeria 48%, Great Britain, Canada, and France 0.07-1.2%.[64,66-69] It is obvious that better obstetric care leads to the incremental decrease of the mortality rate, in addition to the number of cases with severe complications. All studies included hemorrhage, sepsis, and eclampsia. Dystocia and consequent caesarean section are life-threatening complications only in developing countries. In most cases thromboembolism was not included in cases of "near miss" because of the absence of specific diagnostic criteria even though mortality from this disorder remains the highest (30-100%).[61] The prevalence of thromboembolism was evaluated only in Canada and in South and West Africa.[36,62,69] In Canada 3% of

treated cases are lethal, and up to 30% of untreated cases are lethal.[69] In South Africa this rate ranges between 83 and 100% (11, 15, 16).[36,62,63] Hemorrhage. The prevalence of bleeding is the highest (2-3%) in West Africa (all cases of bleeding and blood transfusion were included), Benin, Senegal and Canada (criteria were not defined).[36,68,71,72] Those studies, which have had harsher inclusion criteria, showed a much smaller prevalence of bleeding (<1%). A population study in Great Britain showed that only 0.03% of women lost more than 1500 ml of blood during delivery.[32] Such hemorrhage is 10 times more common in France, and mortality is 3 times higher.[67] In Benin, Nigeria, and India, between 1-2% of deliveries are complicated by hemorrhage, and one woman out of eleven dies as a consequence.[64,66] The differences in prevalence of sepsis in different countries is not large, they largely depend on non-identical levels of obstetric help. In African countries, sepsis is diagnosed ten times more often than in Great Britain, France and Canada (0.1-0.7%).[61] The mortality rate as a result of sepsis clearly illustrates the difference in the quality of medical care: women do not die from sepsis in Canada, Senegal, and France, whereas in Nigeria and South Africa the mortality rate ranges from 50-72%.[61] Half of women suffering from eclampsia in India die, whereas in other countries this complication is treated more efficiently, and mortality ranges from 0 to 18%.[61]

The prevalence of uterine rupture ranges from 0.01 to 1%, however this complication is lethal only for women from West African countries (1 out of 3).[61] Evaluation of obstetric care, outcome and risk factors in studies exploring “near miss” Recently it has become important to evaluate the risk for obstetric complications and the quality of obstetric care in addition to the common practice

of calculating indicators of mortality and morbidity.[61] Schoon and co-authors evaluated cases of "near miss" during a hospital audit. They presented clear conclusions about optimal and insufficient medical care. In 35% of cases medical care was optimal, in 14% of cases this care was insufficient, and in 51% of cases faulty health care was behind poor fate.[62] Vandencruys and colleagues from South Africa compared how special means when applied to improve obstetric care, greatly improved the various indicators. They concluded that 40% of pregnant women were suffering from pregnancyinduced hypertension, and 42% of women who suffered from bleeding were offered incompetent health care.[63] This method of evaluating obstetric care can help to point out worsening indicators, and thus can help change health care strategies (implement new methods of treatment, decentralize hospitals, increase the number of wards in the ICU) and thus to decrease maternal mortality and morbidity. A study carried out in Senegal showed that mortality decreased when labor was attended by a qualified obstetrician rather than by a midwife.[68] A cohort prospective population study was carried out in 6 West African countries and included 20326 deliveries. The importance of 10 prognostic factors was evaluated in foreseeing the possibility of near miss cases. It became evident that the most important factors were: bleeding during labor, high blood pressure, a history of caesarean section, or multifetal pregnancy.[36] Waterstone and coauthors in Great Britain analyzed 331 cases and pointed out certain risk factors for severe obstetric complications: age >34 years, present or previous hypertension, caesarean section, multifetal pregnancy, social status, hospitalization prior to delivery, use of antidepressants and iron preparations.[66] A few researchers evaluated not only the morbidity of

severe obstetric disease but also the long-term complications that may become evident later in life. They concluded that obstetric diseases are closely related to the long-term health of women.[73] It is statistically significant that they are admitted urgently to the hospital ($p<0.001$), have sexual problems ($p<0.001$), are more often treated on an outpatient basis ($p<0.001$). Murphy and coauthors observed 47 women who had been admitted to the ICU for periods ranging from 18 months to 12 years after their discharge. They concluded that 62% of women completely recovered, 32% remained with some degree of disability and 3% died.[74]

Morbidity rate of severe obstetric complications ranges from 0.8 to 8.2%, mortality rate from 0.02 to 37%, however due the fact that in different studies "near miss" cases are defined differently, the methodology and indicators should be compared with caution. The majority of "near miss" cases include severe hemorrhage, sepsis, hypertensive states, and uterine rupture. It is necessary to improve the quality of registration of cases with severe obstetric complications and to develop a clear definition.[61]

Study	Place population	Sample size	Number of cases	Condition	Diagnostic criteria	Comment
Nasrat H A[75] 1998	Medical institution / Village	18842	23	Cases of near miss	Hysterectomy during delivery or in the early postpartum period	
Koeberle P, et al.[76] 2000	Medical institution not defined		46	Cases of near miss	Clear diagnostic and clinical criteria for the diagnosis of obstestetric diseases	
Prual[36] 2000 East African countries	the whole population mixed	20326	1307	Mortality rate of severe obstetric disease	Clear diagnostic and clinical criteria for the diagnosis of obstestetric diseases	
Baskett T F,[77] 1998, Canada, cross-sectional	Medical institution / mixed	76119	55	Cases of "near miss"	Admission to the ICU	
Souza JPD,[78] 2002 cross-sectional	IIIrd level) medical institution not defined	28660	40	Cases of "near miss"	Admission to the ICU	Stillbirths 19%
Sivalingam N,[65] 2002 Malaysia, cross-sectional	medical institution not defined	9932	122	Mortality rate of severe obstetric disease	Admission to the ICU and need for the artificial respiration	30% of women died.
D. J. Murphy,[74] 2002, Great Britain cross-sectional	IIIrd level) medical institution not defined	51756	50	Cases of "near miss"	Admission to the ICU	Perinatal mortality rate 14%
Duffy S,[79] 2001, Ireland, cross-sectional	IIIrd level medical institution / not defined	20800	19	Mortality rate of severe obstetric diseases	Admission to the ICU	
Prual A,[64] 1998, Nigeria, cross-sectional	6 medical institutions / not defined	4081	232	Morbidity of severe obstetric diseases	Diagnosis is based on the clinical diagnosis	
Mantel G D, 1998[23] South Africa, cross-sectional, prospective,[80] 2 year audit	4 medical institutions / not defined	13854 and 26152	588	Morbidity of severe obstetric diseases	Clear diagnostic criteria Classification is based on organ dysfunction and treatment.	
Waterstone M,[32] 2001, Great Britain, population-based prospective, case-control	25 hospitals / mixed	48865	588	Mortality rate of severe obstetric diseases	Clinical diagnosis based on labora- tory findings. Severe hemo rrhage >1500ml or or >4 units of blood or Hb decreases to 40g/l	
Bernis L,[68] 2000, Senegal, population-based prospective, cohort	2 regions / urban	3777	261	Mortality rate of severe obstetric diseases	Criteria according to the clinical diagnosis or intervention	Comparison of obstetric care and indicators in 2 different regions
Khosla A H,[40] 2000, India, cross-sectional	Medical institution / mixed	5124	224	Cases of near miss	Not defined	

Chapter 4.

Methodology

METHODOLOGY

The present study was conducted in the Department of Obstetrics and Gynecology, KLE University's Dr. Prabhakar Kore Hospital and Medical Research Centre, belagavi.

Study design

The study was a cross sectional study

Study period

This study was conducted during the period from January 2015- December 2015

Source of data

All the pregnant woman, during pregnancy or during delivery or within 42 days after delivery getting admitted to the obstetric unit and who fulfill the WHO criteria of near miss. Also all the deaths related to pregnancy that occurred during the study period.

Sample size

All the cases that are getting admitted to obstetric unit, who fullfill the criteria of WHO near miss.

Selection criteria

Inclusion Criteria:

All the pregnant women during pregnancy, during delivery or within 42 days after childbirth who fulfill WHO criteria of near miss.

All the cases of maternal mortality occurred during the study period, where cause of death is pregnancy related or a complication of pregnancy or is aggravated by pregnancy.

WHO CRITERIA OF NEAR MISS

1. Clinical criteria
   Acute cyanosis

   Gasping respiratory rate > 40 or < 6/min

   Shock

   Oliguria

   Non-responsive to fluids or diuretics

   Failure to form clots

   Loss of consciousness lasting >12hrs

   Cardiac arrest,

   Stroke

   Uncontrollable fit

   Total paralysis

   Jaundice in the presence of preeclampsia.

2. Laboratory based criteria
   Oxygen saturation < 90% for >/= 60 min

   PaO^2/FiO^2< 200mmHg

Creatinine >/=300 micromol/l or >/= 3.5mg/dl

Bilirubin >100micromol/l or > 6.0mg/dl

pH< 7.1

Lactate > 5mEq/ml

Acute thrombocytopenia < 50000 platelets/ml

Loss of consciousness and ketoacids in urine.

3. Management based criteria

   Use of continuous vasoactive drugs

   Hysterectomy following infection or hemorrhage

   Transfusion of >=5 units of blood

   Intubation and ventilation for >=60 min not related to anesthesia

   Dialysis for acute renal failure, cardiopulmonary resuscitation

Ethical clearance

Ethical clearance for the present study was obtained from JNMC Institutional Ethics Committee.Ref:MDC/DOME/199 dated 13/11/2014

Informed Consent

All pregnant women, admitted in the obstetric unitand fulfilling the inclusion criteria were explained about the purpose of the study. A written informed consent was obtained from all the participants before the enrollment (Annexure I)

Method of collection of data

After the inclusion criteria was fulfilled, the patients were explained about the study, informed consent was taken and list of questionnaires as described by WHO was filled.Woman who were brought dead or those who diedon arrival at the facility were also included in the study. Maternal mortality occurred during the study period were analyzed.The eligibility was not restricted by the gestational age at which the complications occurred.

Statistical analysis

The data obtained was coded and entered into Microsoft Excel Worksheet. The data was analysed using chi-square test and unpaired t test. A probability value ('p' value) of less than or equal to 0.05 was considered as statistically significant. All statistical calculations were done with the use of the computer programs Microsoft Excel 2013 and SPSS version 20 for Microsoft windows.

MATERNAL NEAR MISS INDICATORS

Maternal near-miss (MNM) Refers to a woman who nearly died but survived a complication that occurred 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 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 Refers to a life-threatening condition (i.e. organ dysfunction), including all maternal deaths and maternal near-miss cases.Women with life-threatening conditions (WLTC) Refers to all women who either qualified as

maternal near-miss cases or those who died (i.e. women presenting a severe maternal outcome). It is the sum of maternal near-miss and maternal deaths (WLTC = MNM + MD). Severe maternal outcome ratio (SMOR) Refers to the number of women with life-threatening conditions (MNM + MD) per 1000 live births (LB). This indicator gives an estimate of the amount of care and resources that would be needed in an area or facility (SMOR = MNM + MD/LB). MNM ratio (MNMR) Refers to the number of maternal near-miss cases per 1000 live births (MNMR = MNM/LB).

Similarly to the SMOR, this indicator gives an estimation of the amount of care and resources that would be needed in an area or facility. Maternal near-miss mortality ratio (MNM: 1 MD) Refers to the ratio between maternal near- miss cases and maternal deaths. Higher ratios indicate better care. Mortality index Refers to the number of maternal deaths divided by the number of women with life-threatening conditions expressed as a percentage (MI = MD/MNM + MD). The higher the index the more women with life-threatening conditions die (low quality of care), whereas the lower the index the fewer women with life-threatening conditions die (better quality of care).

NEAR MISS GLOSSORY:

Acute severe azotemia:

Creatinine ≥300 μmol/l or ≥3.5 mg/dl.

Cardiac arrest:

Sudden absence of pulse and loss of consciousness.

Cardiopulmonary resuscitation:

A set of emergency procedures including chest compressions and lung ventilation applied in cardiac arrest victims.

Failure to form clots:

The clinical inability to form clots/disseminated intravascular coagulation. Clinically, absence of clotting from the IV site or suture after 7–10 minutes. It can be assessed by the bedside clotting test (failure of a clot to form after 7 minutes or a soft clot that breaks down easily suggest coagulopathy) or other laboratory tests (acute thrombocytopenia (<50 000 platelets), low fibrinogen (<100 mg/dl), prolonged prothrombin time (>6s, INR>5), or elevated D-dimer (>1000 ng/dl)). The bedside clotting test is a clinical test to assess the clotting status (Instructions: (1) Take 2 ml of venous blood into a small, dry, clean, plain glass test-tube (approximately 10 mm × 75 mm); (2) Hold the tube in your closed fist to keep it warm (+37°C); (3) After 4 minutes, tip the tube slowly to see if a clot is forming. Then tip it again every minute until the blood clots and the tube can be turned upside down; (4) Failure of a clot to form after 7 minutes or a soft clot that breaks down easily suggests coagulopathy

Gasping:A terminal respiratory pattern. The breath is convulsively and audibly caught.

Hysterectomy: In the maternal near-miss context, surgical removal of the uterus following infection or hemorrhage.

Life-threatening condition:A severe health condition usually associated with organ dysfunction. In the maternal near-miss context, a condition that can only result in a near-miss case or in a maternal death.

Massive transfusion: Transfusion of considerable amount of blood or red cells or blood products, i.e. transfusion of ≥5 units of blood or blood components

Metabolic coma:loss of consciousness and the presence of glucose plus ketoacids in urine

Oliguria non-responsive to fluids or diuretics:A urinary output <30 ml/h for 4 hours or <400 ml/24h non-responsive to fluids or diuretics.

Prolonged unconsciousness: Any loss of consciousness lasting more than 12 hours, involving complete or almost complete lack of responsiveness to external stimuli. A state compatible with Coma Glasgow SSevere acidosis:

a blood pH <7.1.

Severe acute hyperbilirubinemia:

Bilirubin >100 μmol/l or >6.0 mg/dl.

Severe acute thrombocytopenia: An acute reduction in the number of platelets in the blood to <50 000 platelets/ml.

Severe bradypnea: Respiratory rate less than six breaths per minute.

Severe hypoperfusion:

Lactate >5 mmol/l or 45 mg/dl. cale<10.

Severe hypoxemia:

Oxygen saturation <90% for ≥60 minutes or PaO2/FiO2< 200. The PaO2/FiO2 index is the relation between the arterial oxygen saturation (PaO2) and the fraction of

inspired oxygen (FiO2). Arterial oxygen saturation is determined by performing an arterial blood gasometry. The inspired oxygen fraction may vary according with patient need and should be recorded at the moment of blood collection for the gasometry. It can be precise (for instance during mechanical ventilation, 0.21–1.00) or estimated (without oxygen supplementation, 0.21; oxygen nasal catheter, 0.25; facial oxygen mask, 0.25–1.0).

Severe tachypnea: Respiratory rate of more than 40 breaths per minute.

Shock:A persistent systolic blood pressure <80 mmHg or a persistent systolic blood pressure <90 mmHg with a pulse rate at least 120 bpm.

Total paralysis: The complete or partial paralysis of both sides of the body. Usually, an extreme neuromuscular global weakness associated with critical illness. This conditions is also known as critical illness polyneuromyopathy

Uncontrollable fit: Refractory, persistent convulsions. Status epilepticus.

Use of continuous vasoactive drugs: The continuous use of any dose of dopamine, epinephrine or norepinephrine. In the context of vasoactive drugs infusion, continuous use refers to the uninterrupted infusion of a solution containing a vasoactive drug. It is opposed to the intermittent or in bolus injection of a vasoactive drug.

Chapter 5

Results

RESULTS

The present one year hospital based crossectional study was conducted from Jan 2015 to Dec 2015 in the department of obstetrics and gynaecology, KLES Dr Prabhakar Kore hospital and medical research center, a tertiary care hospital Belagavi.

Maternal near miss also known as severe acute maternal morbidity (SAMM) . Maternal near miss and maternal mortality are together known as severe maternal outcome (SMO).

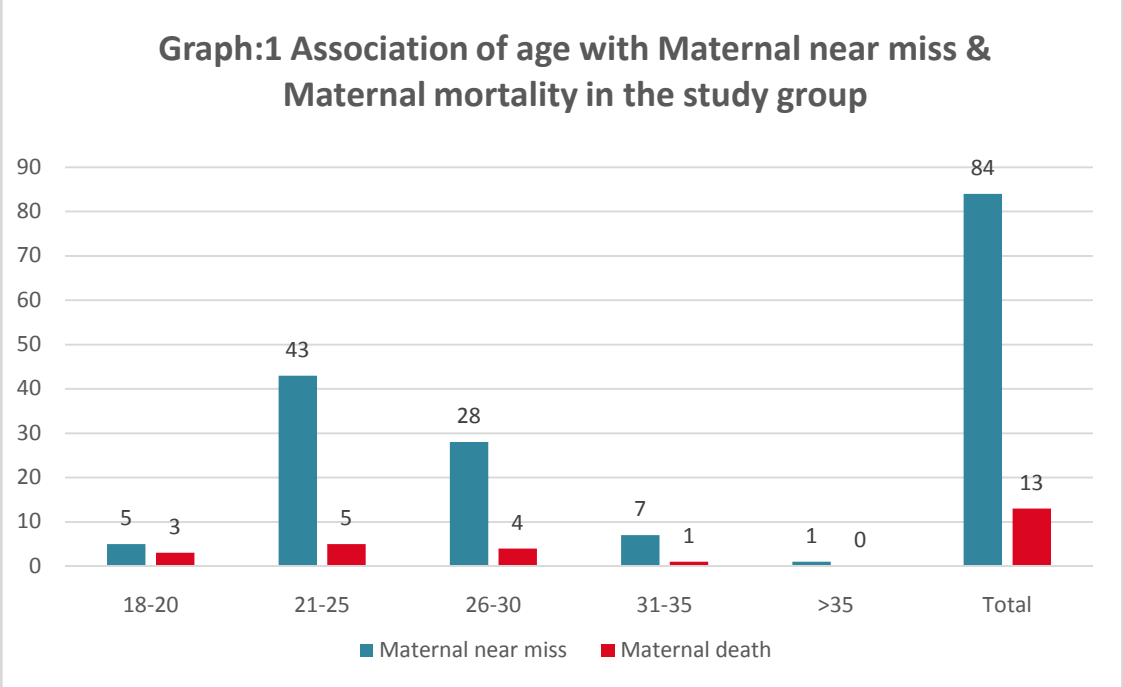
In the given study period of 1 year there were total 6275 number of deliveries conducted, of which 97 patients fulfilled the near miss criteria of WHO. Amongst them there were 84 near miss cases and 13 maternal death cases.

Demographic details in study population were analyzed according to age, parity, gestational age and Antenatal care registration.

The data obtained was tabulated on excel spreadsheet and analyzed using SPSS version 20 statistical software and the final results and observations were tabulated as below.

Table 1. Age distribution in study population

Age groups	Maternal near miss	Percentage	Maternal death	Percentage
18-20	5	5.95	3	23.08
21-25	43	51.19	5	38.46
26-30	28	33.33	4	30.77
31-35	7	8.33	1	7.69
>35	1	1.19	0	0.00
Total	84		13	



In the present study most of the women were aged between 21 to 25 years in maternal near miss (51.1%) as well as maternal death (38.4%) group. However the age distribution in both groups were comparable.p value 0.21, statistically not significant.

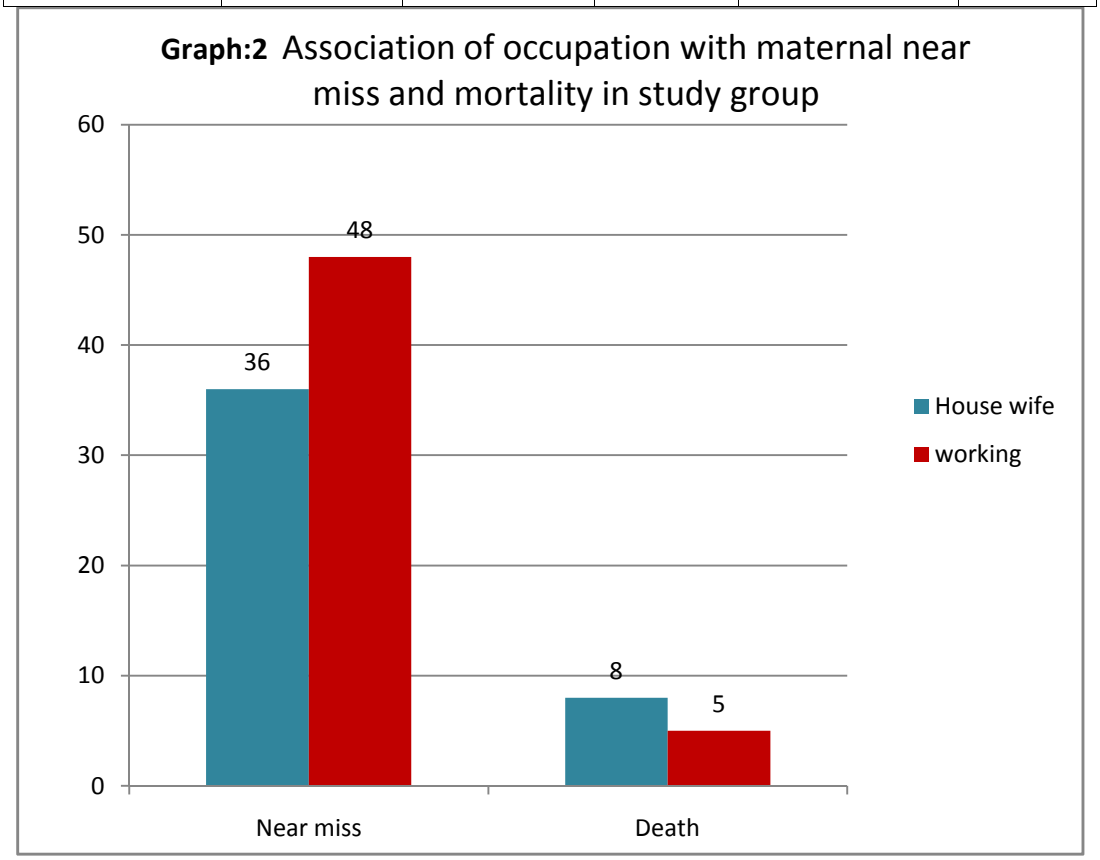
Table 2. Mean Age

Age	MEAN	S.D.
Near Miss	25.33	4.04
Death	25.44	4.26

In this study the mean age group in near miss and maternal death group was around 25 years.

Table 3. Association of occupation with maternal nearmiss and mortality in study group

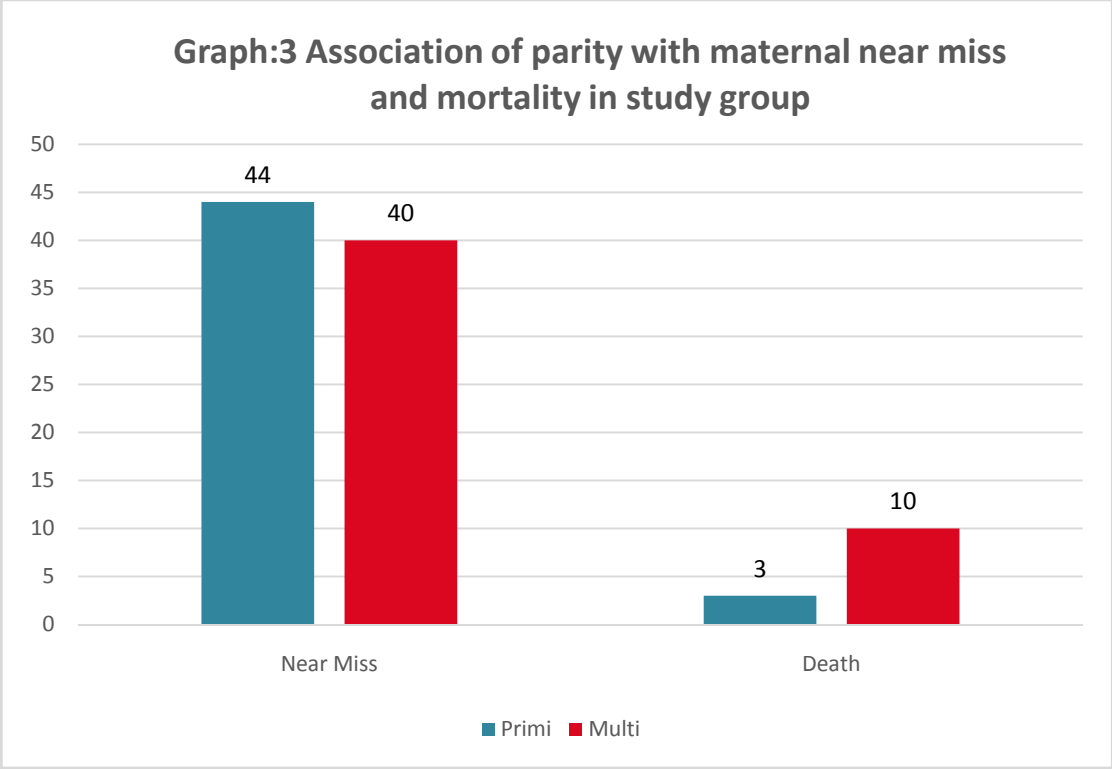
Occupation	Near miss	Percentage	Death	Percentage	Total
House wife	36	42.86	8	61.54	44
working	48	57.14	5	38.46	53



In the present study the 57.1% of near miss cases were working and 61% of the cases from maternal death group were housewives. The p value is 0.208, statistically not significant.

Table 4. Association of parity with maternal near miss and mortality in study group

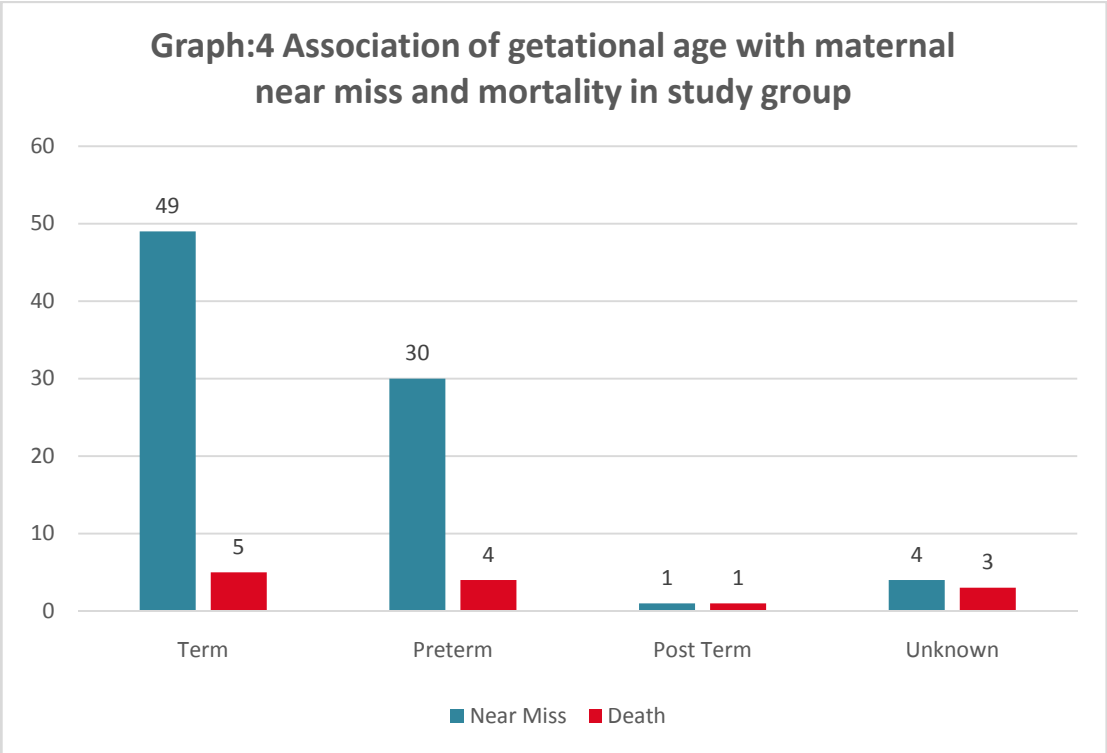
Parity	Near Miss	Percentage	Death	Percentage
Primi	44	52.38	3	23.08
Multi	40	47.62	10	76.92



In the present study 52% of near miss cases were primigravida and 76% of cases in maternal mortality group were multigravida. P value is 0.09 statistically insignificant.

Table 5. Association of gestational age with maternal near miss and mortality in study group

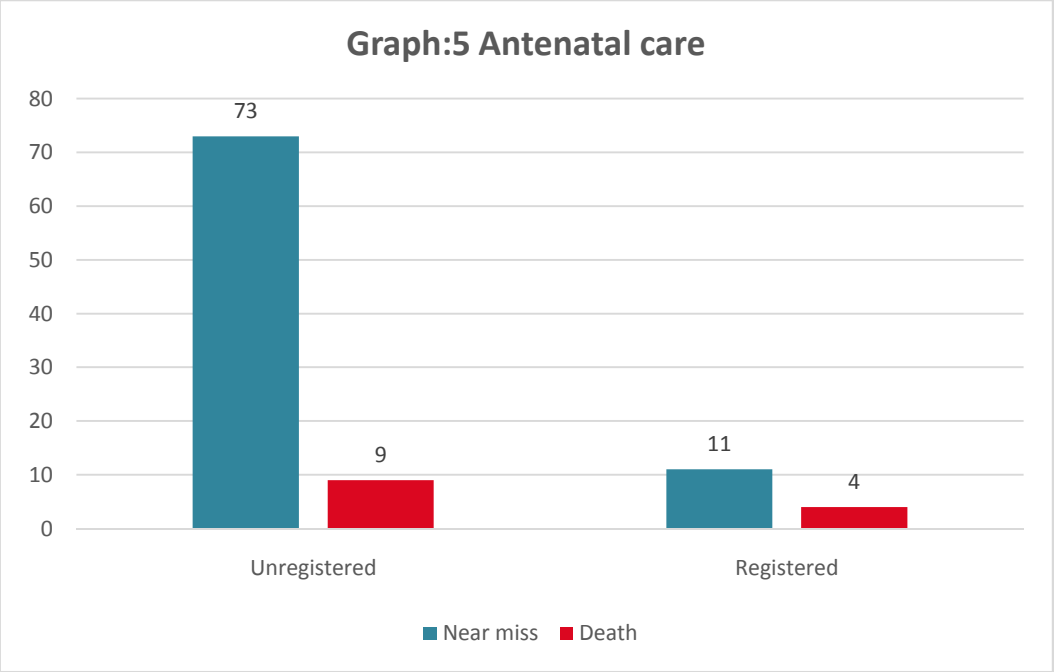
Gestational Age	Near Miss	Percentage	Death	Percentage
Term	49	58.33	5	38.46
Preterm	30	35.71	4	30.77
Post Term	1	1.19	1	7.69
Unknown	4	4.76	3	23.08
Total	84		13	



Major population in our present study were at term gestation 58% and 38% in near miss and mortality group respectively. The gestation age of 4% cases in near miss and 23% cases in maternal mortality group were unknown.p value is 0.045 is statistically significant

Table 6. Antenatal Care

Antenatal care	Unregistered	Registered	Total
Near miss	73	11	84
Death	9	4	13



In the present study population 86.9% of near miss cases and 84.6 % of cases in maternal mortality group were unregistered for antenatal check-up at our institute.P value- 0.021 is statistically significant.

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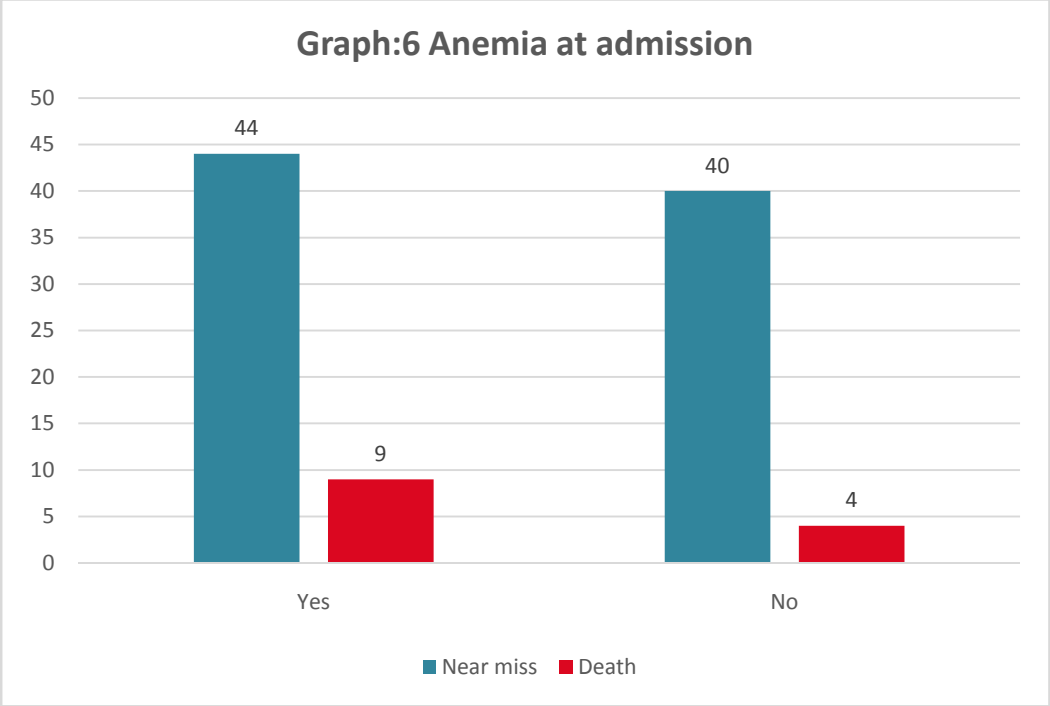
Table 7. Anemia at admission

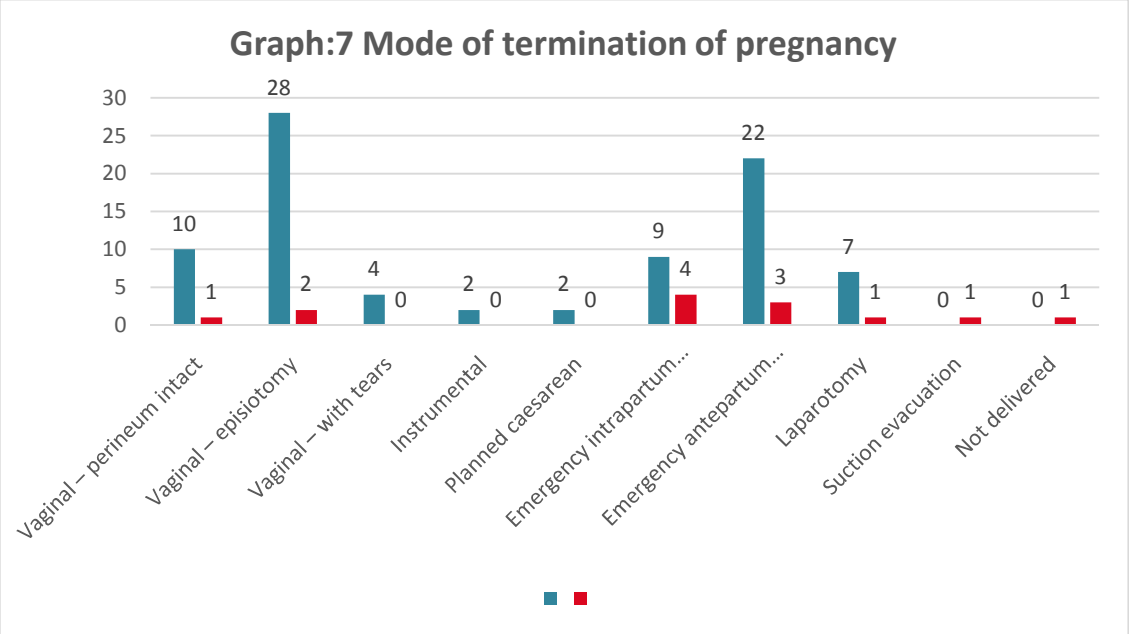
Anemia	Yes	No	Total
Near miss	44	40	84
Death	9	4	13



As anemia is one of the leading cause of morbidity and mortality.52.4% of near miss cases and 69.2% of mortality cases were anaemic at admission.

Table 8.Distribution of mode of termination of pregnancy in study population

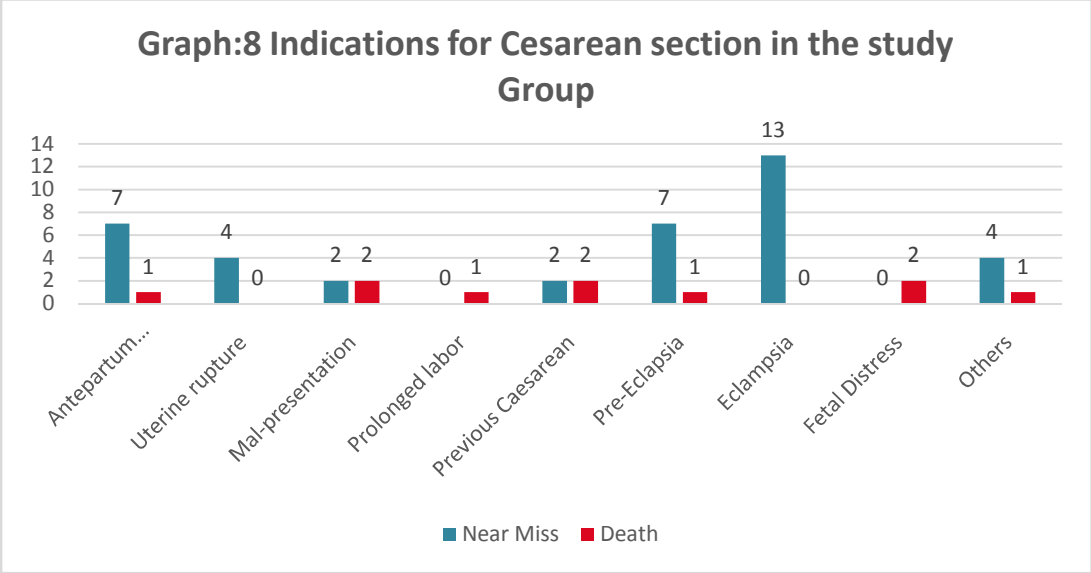
	Near Miss	Percentage	Death	Percentage
Vaginal – perineum intact	10	11.90	1	7.69
Vaginal – episiotomy	28	33.33	2	15.38
Vaginal – with tears	4	4.76	0	0.00
Instrumental	2	2.38	0	0.00
Planned caesarean	2	2.38	0	0.00
Emergency intrapartum caesarean	9	10.71	4	30.77
Emergency antepartum caesarean	22	26.19	3	23.08
Laparotomy	7	8.33	1	7.69
Suction evacuation	0	0.00	1	7.69
Not delivered	0	0.00	1	7.69
Total	84	100	13	100



In the present study 52% patients of near miss group had delivered by vaginal route, 39% of them underwent caesarean section and 8% underwent laparotomy. 23% of the patients of maternal mortality had delivered vaginally, 53% had undergone caesarean section, 7% underwent laparotomy and 7% underwent suction and evacuation.

Table 9. Indications for Cesarean section in the study Group

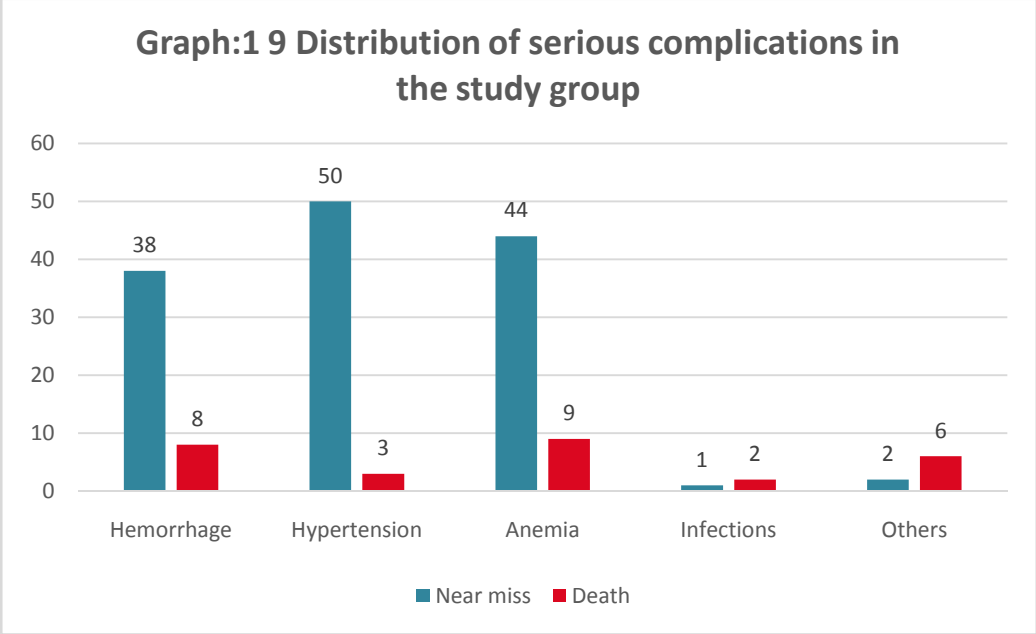
Indications	Near Miss	Percentage	Death	Percentage
Antepartum Hemorrhage	7	8.33	1	7.69
Uterine rupture	4	4.76	0	0.00
Mal-presentation	2	2.38	2	15.38
Prolonged labor	0	0.00	1	7.69
Previous Caesarean	2	2.38	2	15.38
Pre-Eclampsia	7	8.33	1	7.69
Eclampsia	13	15.48	0	0.00
Fetal Distress	0	0.00	2	15.38
Others	4	4.76	1	7.69



15% of the caesarean sections were performed in view of antepartum eclampsia in the near miss group followed by antepartum haemorrhage 8.3% and severe preeclampsia 8.3%. In the mortality group major indication for caesarean section was previous caesarean section and mal-presentation 15.3% and 15.3% respectively.

Table 10.Distribution of serious complications in the study group

Serious complications	Near miss	Percentage	Death	Percentage	P Value
Hemorrhage	38	45.24	8	61.54	0.27
Hypertension	50	59.52	3	23.08	0.01
Anemia	44	52.38	9	69.23	0.25
Infections	1	1.19	2	15.38	0.005
Others	2	2.38	6	46.15	0.0001

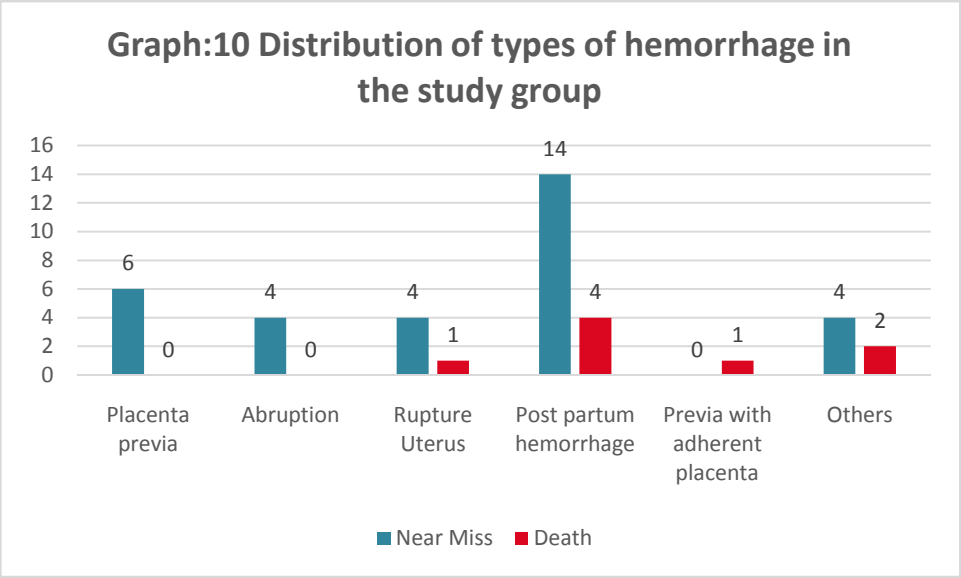


In the present study the major serious complications amongst near miss was hypertensive disorders followed by anaemia accounting for 59.5% and 52.4% respectively whereas in mortality group it was anaemia and haemorrhage 69.2% and 61.5%followed by others which was 46% that includes cardiac diseases and embolic diseases.

The p value forhypertension (0.01),infections (0.005) and others (0.0001) are statistically significant.

Table 11.Distribution of types of hemorrhage in the study group

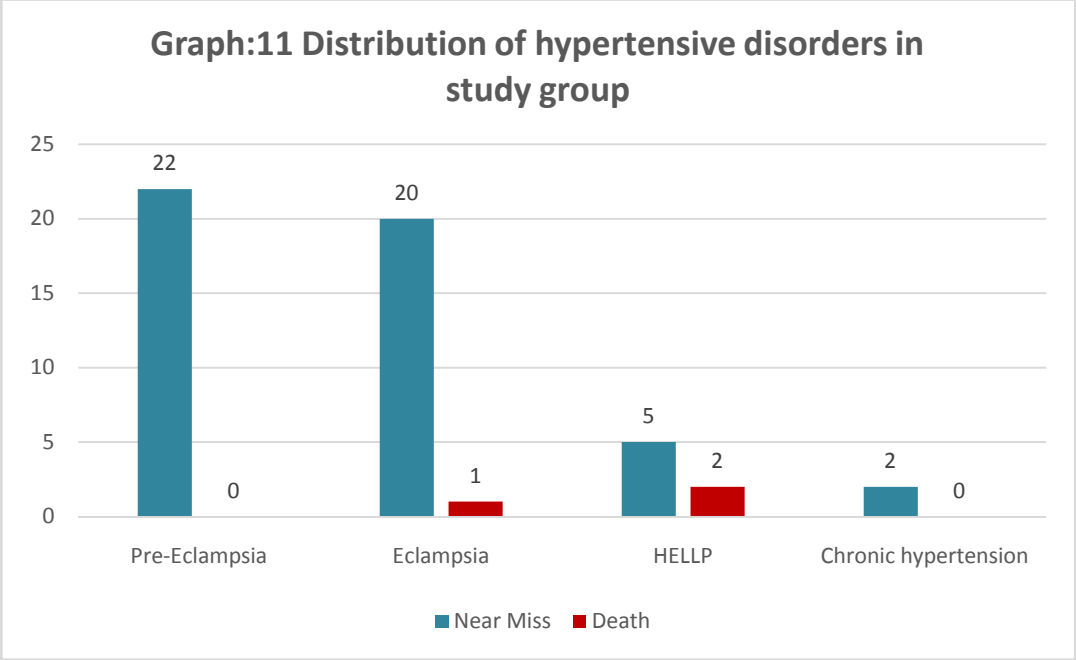
Hemorrhage types	Near Miss	Percentage	Death	Percentage
Placenta Previa	6	7.14	0	0.00
Abruption	4	4.76	0	0.00
Rupture Uterus	4	4.76	1	7.69
Post-partum hemorrhage	14	16.67	4	30.77
Previa with adherent placenta	0	0.00	1	7.69
Others	4	4.76	2	15.38



Haemorrhage is one of the major serious complications seen in our study population. Of which post-partum haemorrhage is the major cause contributing up to 16.6% and 30.7% in near miss and mortality population. P value is 0.04 significant.

Table 12.Distribution of hypertensive disorders in study group

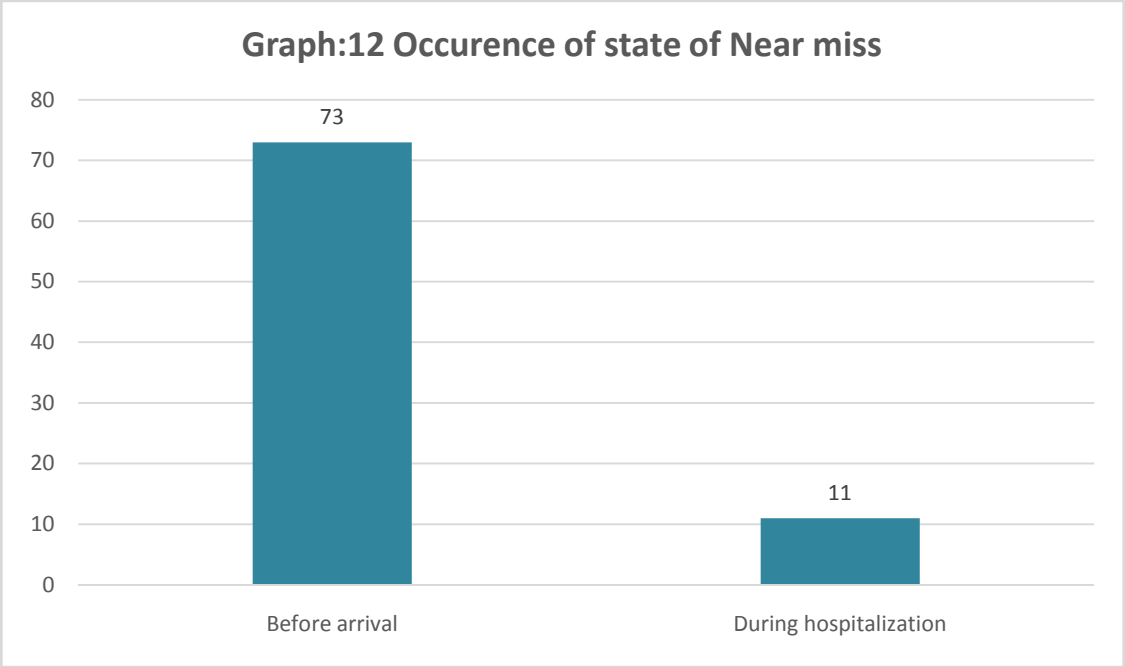
Hypertensive Disorders	Near Miss	Percentage	Death	Percentage
Pre-Eclampsia	22	26.19	0	0.00
Eclampsia	20	23.81	1	7.69
HELLP	5	5.95	2	15.38
Chronic hypertension	2	2.38	0	0.00



In the present study population, hypertensive disorders are one of the major cause of serious complications. Of which eclampsia 23% was seen in near miss group and 7.6% in maternal mortality group.15.3% of the hypertensive population in maternal death and 5.9% in maternal near miss group had HELLP syndrome.

Table 13. Occurence of state of Near miss

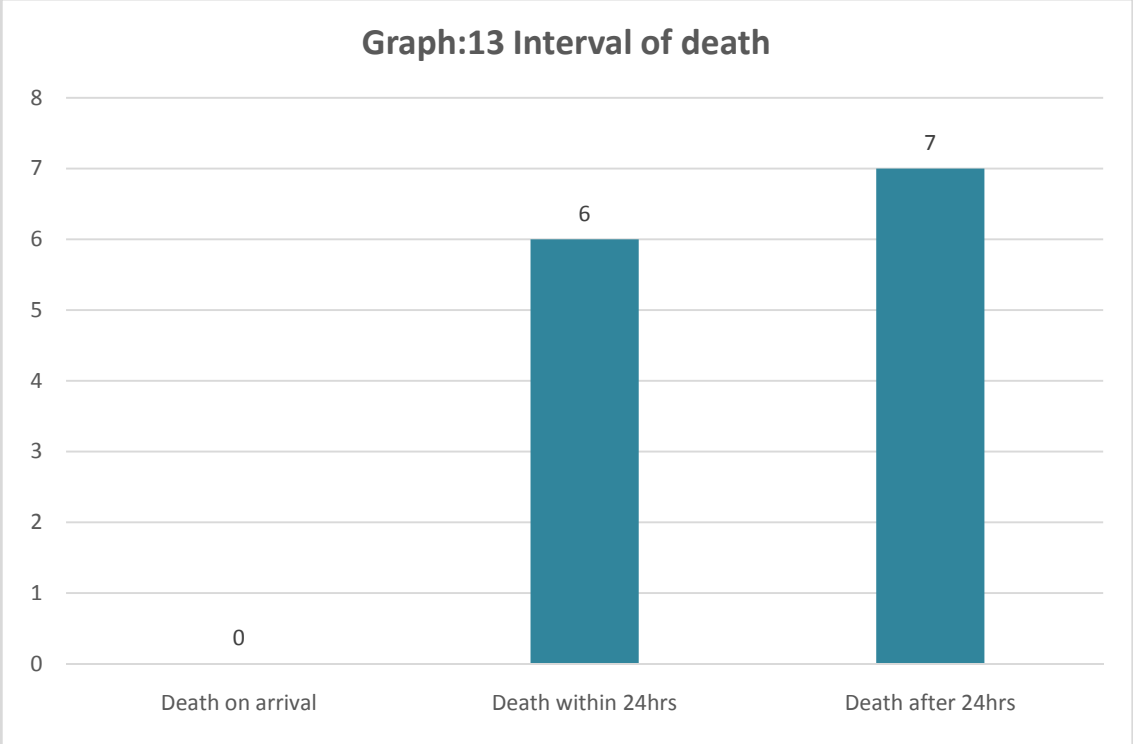
Occurrence of state of near miss	Before arrival	Percentage	During hospitalization	Percentage	Total
Near miss	73	86.90	11	13.10	84



In our present study the state of near miss had occurred in 86% of cases before arrival and 13% during hospitalization.

Table 14. Interval between admission and death

Interval of death	Number	Percentage
Death on arrival	0	0
Death within 24hrs	6	46.15
Death after 24hrs	7	53.85



In our present study there were 13 mortality cases of which 46% of cases died within 24 hours of admission indicating the severity of the clinical condition.

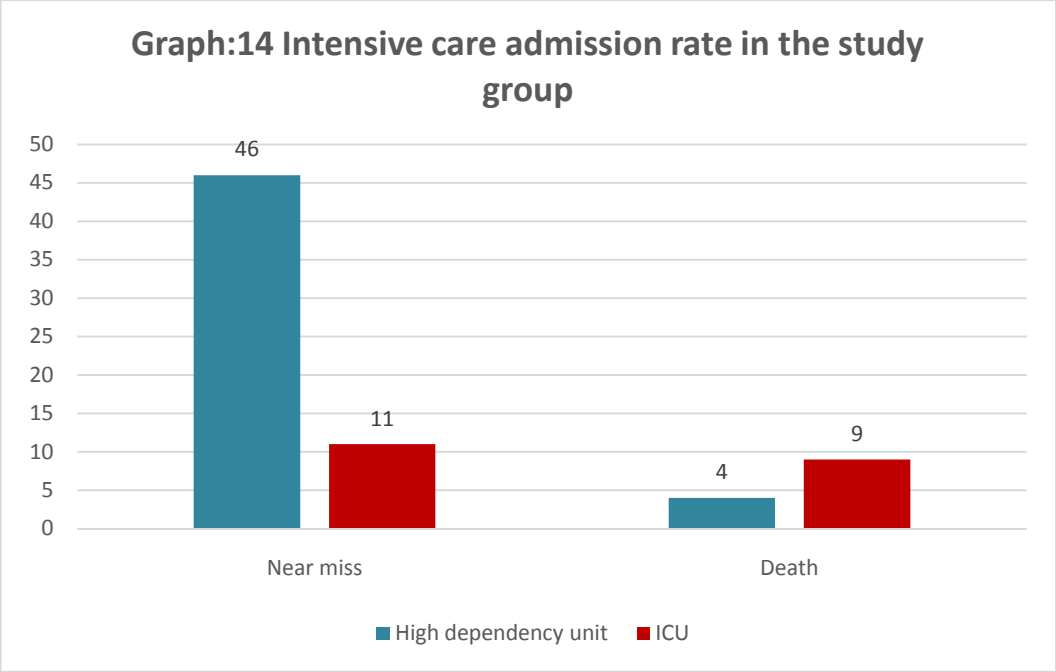
Table 15.Critical interventions done in the study group

Interventions	Near miss	Percentage	Death	Percentage
Massive blood transfusions	32	38.10	10	76.92
Emergency obstetric hysterectomy	11	13.10	1	7.69
Ventilator support	14	16.67	12	92.31
Insertion of CVP line	17	20.24	7	53.85
Inotropic support	3	3.57	3	23.08

In the present study 32% of near miss patients and 76% of death patients had received massive blood transfusion.Emergency obstetric hystrectomy was performed in 13% of MNM and 7% of MD groups (p 0.07). 16% in MNM and 92% in MD required ventilaor support(p 0.001). CVP was inserted in 20% of MNM and 53% of MD group patients (p 0.04). Inotropic support was required in 3% and 23% of the MNM and MD groups respectively. The life saving critical interventions were statistically significant.

Table 16. Intensive care admission rate in the study group

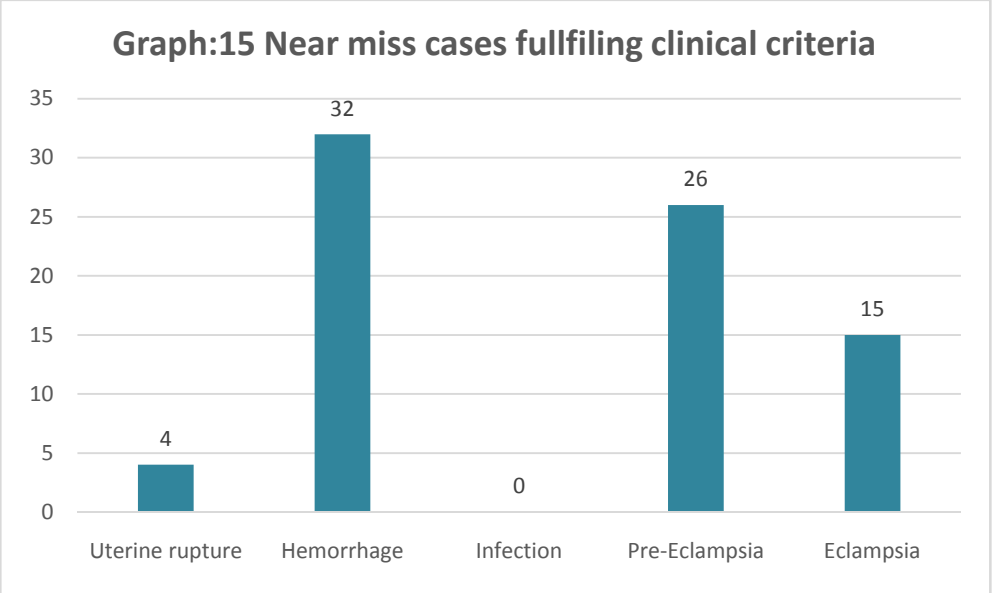
Admission	Near miss	Percentage	Death	Percentage
High dependency unit	46	54.76	4	30.77
ICU	11	13.10	9	69.23



In the present study the admission rate in intensive care unit was high in mortality group 69.2% and 30.7% in near miss group.

Table 17.Near miss cases fulfilling clinical criteria

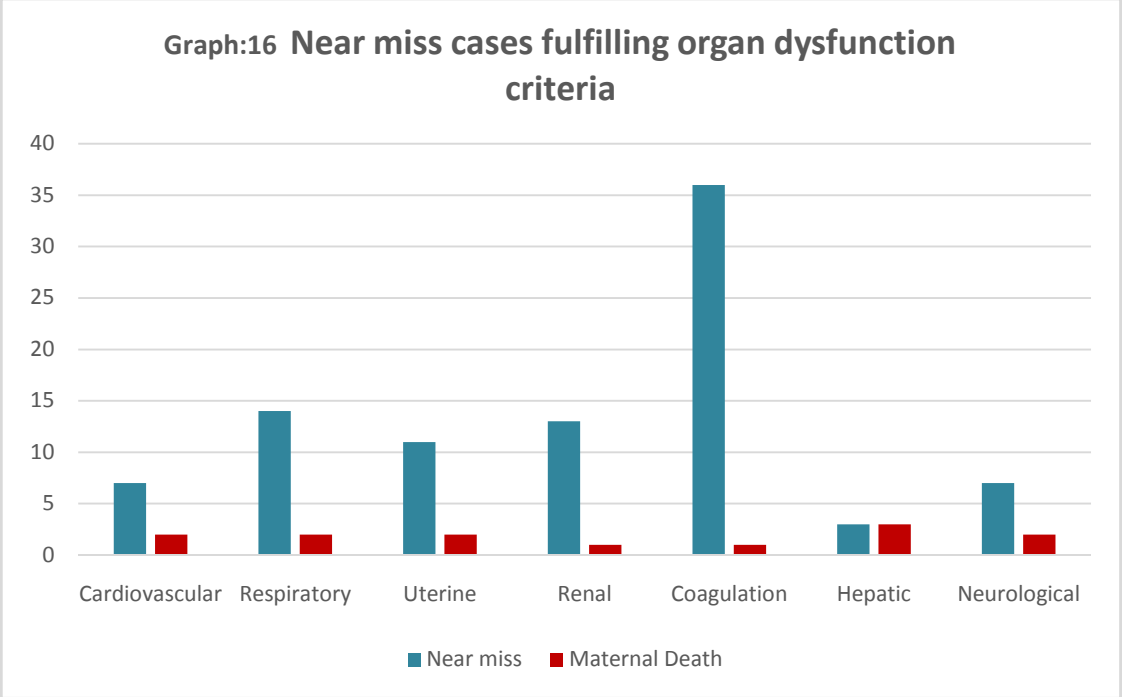
Clinical criteria	Near Miss	Percentage
Uterine rupture	4	4.76
Hemorrhage	32	38.10
Infection	0	0.00
Pre-Eclampsia	26	30.95
Eclampsia	15	17.86



In our present study 38% of patients with haemorrhage, followed by 30% of patients with pre eclampsia are the major causes fulfilling clinical criteria of WHO near miss.

Table 18.Near miss cases fulfilling organ dysfunction criteria

Organ dysfunction	Near miss	Percentage	Maternal Death	Percentage
Cardiovascular	7	8.33	2	15.3
Respiratory	14	16.67	2	15.3
Uterine	11	13.10	2	15.3
Renal	13	15.48	1	7.6
Coagulation	36	42.86	1	7.6
Hepatic	3	3.57	3	23.0
Neurological	7	8.33	2	15.3



In our present study 42% of patients with coagulation dysfuntion, followed by 16% of patients with respiratory dysfunction are the major causes fulfilling organ dysfunction criteria of WHO near miss.

Maternal Near Miss Indicators	
Prevalence	1.3%
Maternal near-miss ratio (per 1000 live births)	14.1
Maternal near-miss to mortality death ratio	6 : 1
Mortality index	13%
Severe maternal outcome ratio (per 1000 live births)	15.9 per 1000 LB

Chapter 6

Discussion

DISCUSSION

The analysis of maternal death has long been used for the evaluation of women's health and the quality of obstetric care. The need to assess the quality of obstetric care in any center is paramount to understand the improvement resulting from investments in its maternity services. As the maternal mortality rate declined in the developed countries, maternal near miss was considered and guidelines to select a patient under this category were given by WHO working group. In due course assessment on health care facilities by maternal near miss was found to be equally effective. In this context, strengthening health systems and services to provide optimal care for women during pregnancy and childbirth is crucial, particularly to those women experiencing acute pregnancy related complications[81].

In the last twenty years, the concept of maternal near miss has been explored in maternal health as an adjunct to maternal-death confidential enquiries, women who nearly died but survived complications. The WHO definition enables a common ground for the implementation of maternal near miss assessments across countries and allows international comparison to be carried out.

The WHO criteria for pregnancy related life threatening conditions were found to be highly associated with maternal deaths. Survivors of the WHO pregnancy related life-threatening conditions could be accurately classified as maternal near miss cases. A severity score representing the total number of life threatening conditions present in each case and a mathematical model describing the relationship between severity markers and maternal deaths have been developed[83].

Scoring systems have been used to evaluate severity and outcome of critically ill patients since many years. APACHE, SAPS and SOFA systems are among the most commonly used ones. Some of these systems are extensively used for intensive care benchmarking and quality of care assessment. Notwithstanding, these systems have been developed based on general critical care populations from developed countries. In these reference populations, obstetric patients were largely omitted or underrepresented, either

because pregnant women were excluded or because maternal deaths were rare events in the countries where these systems were developed. Another issue that should be acknowledged is that the physiological changes of pregnancy affects some of the markers used by general severity scoring systems leading to over estimation of severity. Owing to this the performance of these systems of obstetric population is challenged, particularly in developing countries. The WHO criteria for pregnancy related life threatening conditions are part of a strategy promoted by WHO for assessing and improving quality of maternal health care. These criteria are used in the identification of maternal near miss cases in clinical audits and other near miss studies[85].

Obstetric near miss or severe acute maternal morbidity is gaining interest internationally as a new indicator of the quality of obstetric care following maternal statistics. Near miss describes a patient with an acute organ system dysfunction, which, if not treated appropriately, could result in death. It has also been described as a situation of lethal complication during pregnancy, labor or puerperium in which the woman survives either because of medical care or just by chance. Pattinson described this theory, as “the sequence from good health to death in pregnant woman is a clinical insult, followed by a systematic inflammatory response, organ failure and finally death. By viewing pregnancy and its potential outcomes as a continuum, beginning at normal pregnancy and concluding with maternal death, the number which can be studied meaningfully can be increased by examining the group of outcomes closest to death.” The death to severe morbidity ratio reflects the standard of maternal care. Near miss cases have similar pathways as maternal deaths, with the advantages of offering a larger number of cases for analysis, greater acceptability of individuals and institutions since death did not occur, and the possibility of interviewing the women herself.

This cross sectional observational study was conducted in the department of obstetrics and gynecology, of KLES Dr. Prabhakar Kore Hospital and medical research center, a tertiary care hospital in Belagavi, Karnataka for a period of twelve months from

January 2015 to December 2015. For identifying near miss cases the WHO's criteria for near miss was applied. All the patients getting admitted to our obstetric unit and fulfilling the WHO'S near miss criteria were analyzed. Patient characteristics such as age, parity, antenatal booking status and details of disease specific conditions and their outcome were recorded in a semi-structured proforma and the outcome was evaluated using statistical analysis.

During the study period of twelve months there were 6275 number of deliveries of which 6077 were live births. We had a study population of 97 who were fulfilling the near miss criteria; amongst them there were 87 near miss cases and 13 maternal mortality cases. Similarly there was a study conducted in Manipur, for twelve months where there were 5553 no of live births, 22 near miss cases and 5 mortality cases [81]. There was another study made in Telangana, for a study period of 12 months in which 2409 deliveries were conducted, of these 2385 were live births. Total no of near miss cases in their population was 22 and deaths were 2 [82]. This difference in number of deliveries could be due to patient load, ours is a tertiary care referral hospital with 24-hour critical obstetric care.

Maternal age distribution in the given study population were distributed more in the age group of 21 to 25 years i.e. 51% in near miss population and it was comparable with maternal death group which also had majority of the cases falling in the particular age group. In our study we had only 1 case of elderly gravida of more than 35 years in the near miss group and none in maternal death group, which was statistically insignificant. The mean age for our study group in both near miss and maternal mortality was 25.3 years. Similarly, the study population of the one study conducted in Telangana, the majority of study population were belonging to the age group of 20-25 years in both the near miss and maternal mortality group with no statistical significance.[82] According to the results of one study conducted in Assam majority of the near miss cases 37.9% and mortality cases 47.1% were in the age group of 15-20 years followed by 23% of mortality group with age more than 30 years[83]. According to a study conducted in Brazil it was found that greater population in greater limits of reproductive age, with highest observed among adolescents from 10 to 14 years and among

women over 35 years and it was statistically significant[53]. Here we can see the greater number of the population distribution in the extremes of the ages and are facing a serious complications indicating that early marriage, teenage pregnancy, lack of sex education, illiteracy, poverty is the root cause of these such events.

57.1% of the near miss population in our study were working and majority of the maternal mortality group of 61% were housewives and when analyzed statistically it was found to be not significant. There were no studies which compared the occupation of the women in near miss and mortality. In our study though it is not statistically significant, there is a need to throw some light in this area to know if they are any occupation related aggravating factors complicating the pregnancy.

52% of the near miss group in our study population were primigravida with 58% of them being at term, 76.9% of the population of maternal mortality were multigravida, which also includes grand multigravida with 38.4% being term. The parity status in my study was statistically insignificant. According to a study conducted in Rajasthan the parity status was similar to ours and was also not statistically significant[85]. The gestational age in the near miss and mortality group, majority were in the postpartum period. Similar results regarding parity were observed in a study conducted in Manipur, which was statistically insignificant [81]. This discrepancy in the gestational age when they are facing morbidity or mortality tell us that, if it is during antenatal period it is mainly due to irregular antenatal checkups, non compliance, lack of awareness, illiteracy or low socio economic status. If it is in the postpartum period then it tells us that it could be due to an unattended delivery, home delivery, delivery in a place with no adequate facilities or late referral to secondary center.

In our present study 73 out of 84 near miss cases and 9 out of 4 maternal mortality cases were unregistered for antenatal checkup at our hospital which accounts for 86% and 69% of near miss and maternal mortality respectively. In a study conducted in Assam showed that 92% of near miss cases were unregistered while all the death cases were unregistered[83]. A

similar study done in Telangana concluded that 81% of the study population were unregistered cases [82]. According to a study made in brazil the mortality and morbidity amongst population who were unregistered was high but not statistically significant [53]. Similarly, in a study conducted in Iran the morbidity and mortality in referred population was insignificant because 97% population undergo institutional deliveries and were registered[86]. This major disparity in western literature and the one in developing countries is credited to illiteracy, low socioeconomic status, approaching traditional folk medicine, unawareness, delay in deciding to seek care, or unavailability of appropriate transport facilities.

In the near miss group 52% had delivered by vaginal route, 39% of them had undergone caesarean section. In the caesarean section group of near miss population most of them underwent emergency antepartum caesarean section and 8.3% underwent laparotomy. In mortality group 23% of patients delivered by vaginal route and 53.8% had undergone caesarean section. In the caesarean section group majority were emergency Intrapartum caesarean section, 7.6% had undergone laparotomy and 7.6% underwent suction and evacuation. The p value was statistically significant. A study done in brazil concluded that the near miss rate was more in cases with previous caesarean section especially antepartum caesarean section. It was observed that the near miss rate is rising with the rising trends of cesarean sections. It was also greater in instrumental delivery[53]. In a study conducted in Telangana mortality and morbidity rate was high in a group delivered by caesarean section[82]. Similarly, in a study conducted in Iran concluded that rate of near miss was higher in a group who underwent caesarean section and it was statistically significant[86].

In the present study the indications for caesarean sections were analyzed, 15% of the caesarean sections were performed in view of antepartum eclampsia in the near miss group followed by antepartum hemorrhage and severe preeclampsia 8.3% and 8.3% respectively. In the mortality group major indication for caesarean section was previous caesarean section and mal-presentation of 15.3% and 15.3% respectively. The p value was significant. In a Brazilian

study it was similarly stated that the indication for caesarean section rate was a previous

Serious Complications	This Study	Study 1[81]	Study 2[82]	Study 3[86]

cesarean section[53].

In present study the serious complications which complicated pregnancy and lead to the state of near miss were hypertensive disorders, anemia and hemorrhage which are 59%, 52% and 45% respectively. In the maternal death group, the leading serious complications which lead to critical state were anemia, hemorrhage, other causes and infections in the range of 69%, 61%, 46% and 15% respectively. The p value was statistically significant for hypertensive disorders of pregnancy, infections and other causes. In infections there were conditions like septicemia, pyelonephritis and other systemic infections. Under other pathologies we had cardiac diseases, coagulation disorders like thrombosis, amniotic fluid embolism or gaseous embolism. 15% had infection of which one patient had developed bilateral multidrug resistant pneumonia and died, another patient was referred in a state of severe sepsis and had died. 46.15% under maternal death group were categorized under other pathologies of which 1 patient had cardiac disease in pregnancy with end stage disease, another patient had pulmonary embolism, 2 patients were diagnosed with Acute Fatty Liver of Pregnancy with Hepato-Renal failure, another had fulminant Hepatitis E infection. Similarly, in a study conducted in Assam hemorrhage, eclampsia and anemia were responsible for 42%, 39% and 18% of cases respectively[83]. Another study concluded hemorrhage as leading serious complication followed by hypertensive disorders[81]. One other study in Chhattisgarh had hemorrhage as the leading cause of morbidity accounting for 43% and in mortality group it was eclampsia accounting for 31%[87].

Hemorrhage	44%	40%	33%	46%
Hypertensive Disorders Of Pregnancy	59%	22%	56%	31%
Anemia	52%	4%		
Infections	1%	9%		0.8%
Other Conditions	2%	9%		76%

COMPARISION OF SERIOUS COMPLICATIONS IN MATERNAL NEAR MISS IN OTHER STUDIES:

In this study hemorrhage which is among the serious complications in the near miss group, 16% of it was contributed by postpartum hemorrhage followed by placenta previa which is 7%. Whereas, in the mortality category the leading cause was contributed by postpartum hemorrhage again accounting for 30% followed by other causes which accounts to 15%. The other causes include bleeding due to coagulopathies, disseminated intravascular coagulopathy. Another study from Brazil in which type of hemorrhage was analyzed the leading cause was abruptio placenta accounting for 16%[53]. This disparity between the type of hemorrhage leading to morbidity and mortality is because, in this study, which is conducted in a tertiary care hospital which receives the referral patients, unregistered and delivered outside institute cases involving faulty techniques of delivery or home delivery or late referral or may be hemorrhage after delivery could not be controlled within available little resources, where as in the study conducted in brazil most of the deliveries were institutional.

The next leading cause of serious complication which was hypertensive disorders of pregnancy were analyzed it was found that the leading cause was preeclampsia and eclampsia accounting for 26% and 23% respectively in morbidity group, where as in the mortality group there were no pre-eclampsia cases, but leading cause was by HELLP Syndrome accounting to 15% followed by eclampsia which were 7%. Similar study concluded that eclampsia 48%

was the leading cause for morbidity[82]. Similar study done in Gwalior also concluded eclampsia as the major cause for morbidity accounting to 51% of their mortality cases.

The development of state of near miss can be a gradual process of deterioration from health or it can be sudden deteriorating condition. In either case identification and in prompt and vigorous treatment is necessary. In this study the state of near miss had already set in, in 86% of patients before arrival to the hospital and 13% of the patients developed near miss state during the period of hospitalization. This huge number of population is contributed by the ones who had irregular antenatal checkups, or patients who were not compliant with previous advice and few high-risk cases. Similar study concluded that 65% of the patients had developed the state of near miss before arrival at the health care facility[88].

The step after near miss is maternal mortality and hence it is very important for early recognition of this near miss state and to take appropriate actions. About 46% of the mortality group who were referred to this institute died within 24 hours of admission and 53% of the population died in next 24 hours after admission. In a similar study 64% of the patients died within 24 hours from admission. The particular parameter is important to understand the cause, whether it was delay in seeking care or a delay in identifying the condition or a delay in receiving appropriate care in the primary hospital and referred in the critical condition.

In this study certain critical lifesaving interventions were evaluated like massive blood transfusions, which according to WHO is defined as five or more packed red blood cells transfusion. 38% of near miss group received massive transfusions and 79% in of the patients in the mortality group. Similarly, in one study the massive transfusion rate was 28% in near miss group and a mention about it is was not done in relation to the mortality group[53]. In other similar study 45% of the population required massive blood transfusion in the near miss group[82]. This may also show the quality of care provided.

COMPARISION OF CRITICAL INTERVENTIONS IN MATERNAL NEAR MISS WITH OTHER STUDIES:

INTERVENTIONS	THIS STUDY	STUDY 1[84]	STUDY 2[86]	STUDY 3 [82]
Massive Blood Transfusion	38%	24%	3.4%	45%
Emergency Obstetric Hystrectomy	13%	18%	2%	13%
Ventilator Support	16%	6%		27%
Cvp Insertion	20%		0.4%	
Inotropic Support	3%	9%		

In this study emergency hysterectomy as a life saving procedure was performed in 13% of near miss group and 8% among the mortality group. In a similar study it was 13% in near miss population[82]. In other study emergency obstetric hysterectomy was performed in 7% of near miss population[88].

In this study 16.67% of near miss group required ventilator support other than anesthetic causes and complications and 92% in mortality group an important finding indicating the severity of the clinical condition. In a similar study 28% of the near miss population required ventilator support[82].

In this study CVP was inserted in 20% of near miss group and 53% of mortality groups. The mention about the same has not done in other refered articles.

In the current study 3% of the near miss population and 23% of the mortality population were on inotropic support. Similar study in Brazil showed 9% of the near miss populations were on inotropic support[53].

In this study, the study area is divided to 3 levels of care, standard maternity ward, the obstetric high dependency unit and the intensive care unit. The HDU is differentiated from ICU in ways of care, an obstetrician who understands physiology of pregnancy and disease process will be the best person in charge of the situation with the support team consisting of an intensivist, physician, and anesthetist, pediatrician and a trained maternity nurse. In the ICU high-end care is delivered under a dedicated intensivist, the obstetrician role is only if a delivery seems imminent[89]. 54.76% of near miss and 30.77% of the mortality group were treated in HDU. 13% of near miss cases and 9% of mortality cases were admitted in the ICU. In a similar study 50% of study population required ICU admission[82].

In this study under the organ dysfunction criteria of near miss, 42% was contributed by the coagulation dysfunction in the maternal near miss group, followed by, respiratory system, renal organ dysfunction and liver dysfunction which were 16%, 15% and 3% respectively. In the maternal death group, the leading cause of organ dysfunction was hepatic organ dysfunction accounting for 23%, followed by cardio vascular, respiratory, uterine and neurological dysfunction which were 15.3%. A study conducted in Iraq had cardiovascular dysfunction as the leading cause contributing to 55% which is followed by uterine and multiorgan dysfunction which were 53% and 49 % respectively among MNM group. Renal

and hepatic dysfunction were accounting for 4% and 3% respectively. In MD group the leading cause was multiorgan failure followed by respiratory and cardiovascular dysfunction which were 56%, 50% and 43% respectively. This major disparity in the organ dysfunction is because in the developing countries hemorrhage is a leading serious complication which unattended would lead to a severe morbidity. Underestimation of blood loss,giving inappropriate resuscitation, or delay in the transport of sick patients would further deteriorate the clinical condition.

MNM Indicators	This study	Study1[89]	Study2[87]	Study3[90]	Study4[81]	Study5[82]
SMO	97	145	58	880	27	24
SMOR	15.9	5.69	17	166	4.8	10
NM:MD	6:1	9:1	2:1	2.6:1	4.4:1	11:1
MI	13%	11%	32.7%	28%	18%	8.3%

The prevalence of MNM in this study was 1.3%, the SMOR was 15.9 per 1000 LB. The near miss to mortality ratio was 6:1 and the mortality index was 13%.

MNM incidence was calculated as number of near miss cases per 1000LB is 14.1/1000 and MMR is 213/100,000.higher the near miss to mortality ratio and lower the mortality index, better is the health care.

COMPARISION OF MATERNAL NEAR MISS RATE AND MMR WITH OTHER STUDIES

STUDIES	MNM/1000 LB	MMR/100,000
STUDY 1[90]	120/1000	4684/100,000
STUDY 2[82]	9.2/1000	83/100,000
THIS STUDY	14.1/1000	213/100,000

The comprehensive obstetric care available at this hospital, as witnessed from this study has made maternal mortality an unusual event. Data collected on MNM helps us to identify priorities in health care system more rapidly than maternal deaths. It will also help health care providers and policy makers to design strategies to improve maternal health services.

Chapter 7

Summary

SUMMARY

- The present cross sectional study was conducted in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period of one year from Jan 2015 to Dec 2015. During the study period a total of 6275 deliveries were conducted, of which 6077 were live births, of them 97 patients were taken into the study who fulfilled the WHO criteria of near miss. Amongst them 84 were maternal morbidity or near miss cases and 13 were maternal mortality cases.
- The objective of the study was to determine the prevalence of maternal near miss due to severe obstetric complications or maternal disease in a tertiary care hospital and to determine severe maternal outcome ratio (SMOR), maternal near miss ratio (MNM ratio) and maternal near miss mortality ratio.
- The statistical analysis of demographic profile showed no significance in the categories of age (p-0.21), parity (p-0.09), and occupation (p-0.20) whereas, gestational age (p-0.045), antenatal care (p-0.021) and mode of termination of pregnancy (p-0.04) in the study population showed statistical significance
- In the study population 86% in MNM and 84% in MD were unregistered. The registered patients who were part of the study group had irregular antenatal checkups and were noncompliant to treatment.
- Gestational age analysis showed term gestation among 58% in MNM and 38% in MD group, preterm gestation in 35% and 30%, and post term among 1% and and 7% in MNM and MD population respectively.
- Mode of termination of pregnancy when analyzed in the present study showed 52% of patients in MNM and 23% of patients in MD group delivered vaginally, caesarean section conducted in MD group were 53% and among the MNM group it was 39%. 15% of the caesarean sections were done in view of antepartum eclampsia in MNM group, where as in MD group previous caesarean section was the major indicator.
- Major serious complications were, hypertensive disorders 59%, anemia 52% and hemorrhage 45% in MNM group. In the MD group it was anemia 69%, hemorrhage 61%, other conditions 15% and infections 15%. Other conditions were cardiac disease, embolic

diseases like thrombosis, amniotic fluid embolism or gaseous embolism and infections included septicemia, pyelonephritis, other systemic infections, HIV and Hepatitis.

- The p value was statistically significant in hypertensive disorders of pregnancy (p-0.01), infections (p-0.005) and other conditions (p-0.0001).
- Hemorrhage in MNM group, is contributed by postpartum hemorrhage 16% followed by placenta previa 7%, in the MD group the leading cause was postpartum hemorrhage accounting 30% followed by other conditions 15%. The other conditions included bleeding due to coagulopathies or disseminated intravascular coagulopathy.
- Hypertensive disorders of pregnancy were analyzed, preeclampsia and eclampsia accounted for 26% and 23% respectively in MNM group. In MD group leading cause was HELLP Syndrome 15% followed by eclampsia 7%.
- The state of near miss had developed in 86% of patients before arrival to the hospital and 13% of the patients had developed near miss condition during the period of hospitalization.
- In MD group 46% expired within 24 hours of admission and 53% of the patients expired after 24 hours of admission.
- In this study critical interventions like massive blood transfusions done were 38% in MNM group and 79% in MD group.
- Emergency obstetric hysterectomy as a lifesaving procedure was performed in 13% of MNM group and 8% among MD group.
- Among the MNM group 16.6% of the population required ventilator support for reasons other than anesthetic causes and complications and 92% required ventilator support in MD group.
- CVP was inserted in 20% of MNM group and 53% of MD group.
- 3% of the MNM population and 23% of the MD population were on inotropic support.
- In this study 54% of near miss cases received care at HDU and 30% among MD group. 13% of MNM group and 69% of MD group needed ICU admission.
- In this study 38% followed by 30%, 17% and 4% of MNM population had hemorrhage,

preeclampsia, eclampsia and uterine rupture respectively.

- In organ dysfunction criteria, coagulation disorders 42%, followed by respiratory, renal and uterine dysfunctions 16%, 15% and 13% respectively were noted in MNM population and in MD group it was majorly hepatic 23% followed by cardiovascular 15%, respiratory 15%, uterine 15% and neurological dysfunction 15%.
- The prevalence of MNM in this study was 1.3%, the incidence of near miss cases was 13 per 1000 live births. The total numbers of women with severe maternal outcome (SMO) were 97, and the severe maternal outcome ratio (SMOR) is 15.9 per 1000 live births.
- In the present study the maternal near miss to mortality ratio was 6:1. The maternal mortality index (MI) in this study conducted at this institute is 13% which indicates better quality of care.

Chapter 8

Conclusion

CONCLUSION

As the maternal mortality is declining, maternal near miss will help us to assess the quality of service and will suggest the dearth in the quality of health care delivered that requires concentrated efforts to overcome the deficiencies Maternal mortality is the tip of iceberg, there is a large base of severe acute maternal morbidity, the identification and analysis of which is essential to know the true story of complications. The mother, here, survives in near miss situations to tell the story.

Mere availability of obstetric care cannot achieve reduction in maternal mortality and morbidity. The services must be accessible, affordable and with prime focus on the quality of services provided by health professional. The gap between availability of health facilities and its outreach to poor pregnant woman must be bridged. Skilled attendance at birth, institutional delivery, access to emergency obstetric care and functional timely referral can reduce substantial burden of trivial complications of pregnancy and childbirth.

The prevalence of MNM in this study is 1.3%.

According to this cross sectional study the incidence of near miss cases is 14/1000LB. The total number of women with severe maternal outcome (SMO) were 97 which refers to the life threatening conditions that woman face and the severe maternal outcome ratio (SMOR) is 15.9/1000, which denotes further improvement in maternal health care services.

In the present study the maternal near miss to mortality ratio was 6:1. Higher the ratio better the care delivered.

The maternal mortality index (MI) in this study conducted at this institute is 13%, which indicates better quality of care. Lower the index better is the survival prognosis for the woman associated with life threatening conditions.

Evaluation of the circumstances which surround near miss cases could act as proxy for maternal deaths, hence maternal near miss indicators can be used to evaluate the current status of health facilities rendered at medical center in management.

Chapter 9

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10.

Annexure I

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mrs _____ we are requesting you to enroll yourself in study titled "MATERNAL NEAR MISS IN A TERTIARY CARE HOSPITAL:A CROSS SECTIONAL STUDY" conducted by Dr. _____ Post Graduate in M.S. Obstetrics And Gynecology under the guidance of Dr. _____ Professor and Head Of the Department, Department of Obstetrics And Gynecology , J.N. Medical College, Belgaum under KLE university, Belgaum.

Respected Madam, we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

The purpose of research is to "MATERNAL NEAR MISS IN A TERTIARY CARE HOSPITAL: A CROSS SECTIONAL STUDY"

Procedure Involved:

If you agree to enroll yourself in my study, you will be interviewed regarding your present, past and family history, then you will be clinically examined in detail and investigated accordingly.

Risks and Benefits:

The benefits of taking part in this research are that it will help to improve quality of care. There are no observable risks associated with the study.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E.S hospital.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients.

Questions:

In case you have any questions related to the study,you can contact Dr. _____ Department of Obstetrics And Gynecology, KLES Hospital and

MRC, phone number: _____ or Dr. _____ Professor, and Head Of the Department of Obstetrics And Gynecology, KLES Hospital and MRC, Belgaum phone number: _____

If you have any queries about your rights as a study subject, you may callDr. _____, Prof. & Head of Pathology as Chairperson of J. N. Medical College Institutional Ethics Committee on Human Subjects Research, Phone No. ____ext-____ at J. N. Medical College, Belgaum or phone number:

_____

Consent for participation in research trial

I, _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read form in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Date:

Witness Name: _____ Signature: _____ Date:

Investigators Name: _____ Signature: _____

Date:

Place: _____

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr. /Mrs. _____ we are requesting you to enroll your daughter/wife/daughter-in-law in study titled "MATERNAL NEAR MISS IN A TERTIARY CARE HOSPITAL: A CROSS SECTIONAL STUDY" conducted by Dr. _____Post Graduate in M.S. Obstetrics And Gynecology under the guidance of _____ Professor and Head Of the Department, Department of Obstetrics And Gynecology, J.N. Medical College, Belgaum under KLE university, Belgaum.

Respected Sir/Madam, we request you to enroll your daughter/wife/daughter-in-law to participate in our study as she is eligible for participating in the study. During the study you will be asked some questions regarding her present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

The purpose of research is to "MATERNAL NEAR MISS IN A TERTIARY CARE HOSPITAL: A CROSS SECTIONAL STUDY"

Procedure Involved:

If you agree to enroll your daughter/wife/daughter-in-law in my study, you will be interviewed regarding her present, past and family history, then she will be clinically examined in detail and investigated accordingly.

Risks and Benefits:

The benefits of taking part in this research are that it will help to improve quality of care. There are no observable risks associated with the study.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E.S hospital.

Privacy and Confidentiality:

The only people to know that your daughter/wife/daughter-in-law is a research subject are members of the research team. No information about her or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose her identity. Any information that is obtained in connection with this study and that can be identified with her will remain confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients.

Questions:

In case you have any questions related to the study, you can contact Dr.

Department of Obstetrics And Gynecology, KLES Hospital and MRC, phone number: or Dr. Professor, and Head Of the Department of Obstetrics And Gynecology, KLES Hospital and MRC, Belgaum phone no:

If you have any queries about your rights as a study subject, you may callDr. , Prof. & Head of Pathology as Chairperson of J. N. Medical College Institutional Ethics Committee on Human Subjects Research, Phone No. ext- at J. N. Medical College, Belgaum or phone number: .

Consent for participation in research trial

I the legal guardian, _____ voluntarily agree for the participation of my daughter/wife/daughter-in-law as a subject of study. By signing this consent form I'm not giving up any of my legal rights, I may withdraw from the study anytime. I'm signing the consent form after having read or been read form in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name: _____

Signature or the Left Thumb Print of Subject: _____

Date :

Witness Name: _____ Signature: _____ Date:

Investigators Name: _____ Signature: _____

Date:

Place: _____

ಸಂಶೋಧನೆ ಅಭ್ಯಾಸ ಕ್ರಮದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಸಲುವಾಗಿ ಒಪ್ಪಿಗೆ

ನಾವು "ಮೆಟರನಲ್ ನಿಯರ ಮಿಸ್ ಇನ್ ಎ ಟೆಲ್ಟಿಯೇರಿ ಕೇರ ಹಾಸ್ಪಿಟಲ್ ಅಕ್ರಾಸ್ ಸೆಕ್ಷನಲ್ ಸ್ಟಡಿ" ಈ ಅಭ್ಯಾಸ ಕ್ರಮದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ವಿನಂತಿ ಪೂರ್ವಕವಾಗಿ ಕೇಳಿಕೊಳ್ಳುತ್ತೇವೆ. ಮೇಲಿನ ಪ್ರೊಗ್ರಾಮವನ್ನು ಡಾ॥ ಪೋಸ್ಟ್ ಗ್ರ್ಯಾಜುವೇಟ್ ಅಬಸ್ಟೇಟ್ರಕ್ಸ್ ಮತ್ತು ಜಾಯನೇಕಾಲಜಿ ನಲ್ಲಿ ಎಮ್. ಎಸ್ ಇವರ ವತಿಯಿಂದ ತಜ್ಞ ಡಾ॥ ಪ್ರೋಪೇಸರ್, ಹೆಡ್ ಡಿಪಾರ್ಟಮೆಂಟ, ಡಿಪಾರ್ಟಮೆಂಟ ಅಬಸ್ಟೇಟ್ರಕ್ಸ್ ಮತ್ತು ಜಾಯನೇಕಾಲಜಿ ಜೆ.ಎನ್. ಮೆಡಿಕಲ್ ಕಾಲೇಜು ಬೆಳಗಾವಿ, ಕೆ.ಎಲ್.ಇ. ಯುನಿವರ್ಸಿಟಿ ಇವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ನಡೆಸಲಾಗುತ್ತಿದೆ.

ಮಾನ್ಯನೀಯ ಮೆಡಮ್

ನೀವು ಈ ಅಭ್ಯಾಸ ಕ್ರಮದಲ್ಲಿ ಭಾಗವಹಿಸಿ ನಿಮಗೆ ಈ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ವಿಚಾರಿಸಲಾಗುವುದು. ಅದರ ಉತ್ತರ ಮತ್ತು ತಕರಾರುಗಳನ್ನು ನಿಮ್ಮ ತಿಳುವಳಿಕೆಯ ಪ್ರಕಾರ ಉತ್ತರಿಸಬೇಕು.

ನೀವು ಸಂಶೋಧನೆ ಅಭ್ಯಾಸ ಕ್ರಮದಲ್ಲಿ ಸ್ವಇಚ್ಛೆಯಿಂದ ಭಾಗವಹಿಸಬೇಕಾಗಿದ್ದು, ನೀವು ಅಭ್ಯಾಸ ಕ್ರಮದಲ್ಲಿ ಭಾಗವಹಿಸಿರಿ ಇಲ್ಲವೇ ಭಾಗವಹಿಸದಿದ್ದಲ್ಲಿ ಜೆ.ಎನ್. ಮೆಡಿಕಲ್ ಕಾಲೇಜಿಗೆ ಯಾವುದೇ ತರಹದ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ನೀವು ಇಚ್ಛಿಸಿದ್ದಲ್ಲಿ ಯಾವುದೇ ವೇಳೆಯಲ್ಲಿ ನೀವು ಭಾಗವಹಿಸಿದ ವೇಳೆಯಲ್ಲಿ ಸ್ವತಂತ್ರವಾಗಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು.

ಸಂಶೋಧನೆಯ ಉದ್ದೇಶ :

"ಮೆಟರನಲ್ ನಿಯರ ಮಿಸ್ ಇನ್ ಎ ಟೆಲ್ಟಿಯೇರಿ ಕೇರ ಹಾಸ್ಪಿಟಲ್ ಅಕ್ರಾಸ್ ಸೆಕ್ಷನಲ್ ಸ್ಟಡಿ" ಅಂತಾ ಇರುತ್ತದೆ.

ಕಾರ್ಯ ವಿಧಾನವನ್ನು ಹಾಕಿಕೊಳ್ಳುವುದು :

ನೀವು ಈ ಅಭ್ಯಾಸ ಕ್ರಮದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ಕೊಟ್ಟಿದ್ದಲ್ಲಿ, ನಿಮ್ಮ ಈಗಿನ ಹಾಗೂ ಹಿಂದಿನ ಕುಟುಂಬದ ಇತಿಹಾಸ (ಚರಿತ್ರೆ) ಬಗ್ಗೆ ಸಂದರ್ಶನ

ಗುಪ್ತತೆ :

ಕೇವಲ ಕೆಲವೇ ಜನರಿಗೆ ನೀವು ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಸದಸ್ಯರಾಗಿದ್ದರ ಬಗ್ಗೆ ಈ ಗುಂಪಿನಲ್ಲಿ ಗೊತ್ತಿದ್ದು ಇರುತ್ತದೆ. ಯಾವುದೇ ಪರಿಸ್ಥಿತಿಯಲ್ಲಿ ನಿಮ್ಮ ಮಾಹಿತಿ ಬಗ್ಗೆ

ಸಿಗುವುದಿಲ್ಲ. ಒಂದು ವೇಳೆ ನಿಮಗೆ ಗಾಯ ಇತ್ಯಾದಿ ವಾಗಿದ್ದಲ್ಲಿ, ಹೆಡ್ ಡಿಪಾರ್ಟಮೆಂಟ, ಡಿಪಾರ್ಟಮೆಂಟ ಅಬಸ್ಟೇಟ್ರಕ್ಸ್ ಮತ್ತು ಜಾಯನೇಕಾಲಜಿ ಇವರನ್ನು ಸಂಪರ್ಕಿಸ ಬಹುದು.

संशोधन अभ्यासक्रमात भाग घेण्यास कबूली :-

आम्ही "मॅटरर्नल निअर मिस इन ए टर्टियेरी केअर हॉस्पीटल : ए क्रॉस सेक्सनल स्टडीसाठी" तुम्हाला या अभ्यासक्रमात भाग घेण्यास विनंती करत आहोत. वरील प्रोग्रॉम डॉ. तेजस्वी रेड्डी पोष्ट ग्रॅज्युऐट मध्ये एम. एस. ऑब्सट्रेट्रीक्स व

स्वइच्छेने सहभाग / व मागे घेणे :-

या अभ्यासक्रमातील सहभाग व स्वइच्छेच्या असून जर तुम्हाला आमचे भाटग

नुकसान भरपाई :-

या अभ्यासादरम्यान जर तुम्हाला कांही ईजा जखम झाल्यास उपचार के. एल.

कबुली पत्र

संशोधन परीक्षेत सहभाग घेण्यास कबूली मी .....स्वत:हून या अभ्यासक्रमात भाग घेण्यास, या अभ्यासाचा विषय म्हणून मी कबूल आहे. मी हे कबूलीपत्र सही करत आहे. मी माझे कुठलेही वैयक्तीक अधिकार सोडून दिलेले नाहीत मी या अभ्यासक्रमातून केंव्हाही माझा सहभचक्ष पुर्णपणे वाचून माझ्या मातृभाषेत वाचून कबूली दिलेली आहे व यामधील जबाबदारी व फायदा या पश्नाचे उत्तर दिलेले आहे.

पेशंटचे नांव :----------

सही अंगठा :----------

साक्षिदाराचे नांव :---------- सही

तपास करणाऱ्याचे नांव : ---------- सही

स्थळ :-

तारीख :-

11.

Annexure II

PROFORMA

1. Patient Name
2. Town
3. Village
4. District
5. Admission Date
6. Admission Time
7. Op no
8. Ip no
9. Admission Mode - a) self referred
   b) Referred from other facility

If referred

i) Name of referring facility
ii) Date of arrival at referring facility
iii) Time of arrival at referring facility

If readmitted

a) Date of readmission
b) Time of readmission
c) Preceding record number

10. Age (years)
11. Status - a) Married
    b) Single
    c) Widowed

12. Woman's occupation

13. Partner's occupation

14. Number of Pregnancies

15. Number of Live births

16. Number of Stillbirths

17. Does the women have a history of Caesarean or abdominal scar? - a) Yes

b) No

18. Does the women have a history of abortion? - a) Yes

b) No

19. Does the women have any scheme? - a) Yes

b) No

20. Did the women receive antenatal care? a) Yes

b) No

21. Reason for admission - a) Normal delivery

b) Complicated delivery

c) Extra-uterine Pregnancy

d) Other complication during delivery

e) Elective caesarean

f) Abortion, miscarriage, or post-abortion complication

g) Postpartum complication

22. Was the fetal heart beat audible upon admission?

a) Yes

b) No

c) Not perceived

d) Not measured

23. Date of delivery or end of pregnancy

24. Time of delivery or end of pregnancy

25. Gestational age - a) Estimated at term

b) Estimated pre-term

c) Estimated Post-term

d) Unknown

If known _____ weeks of amenorrhea

_____ month of amenorrhea

If abortion, miscarriage or extra-uterine pregnancy: go to question 30

26. Mode of delivery – a) Vaginal – perineum intact

b) Vaginal – episiotomy

c) Vaginal – with tears

d) Instrumental – vacuum / forceps

e) Planned caesarean

f) Emergency Intrapartum caesarean

g) Emergency antepartum caesarean

h) Laparotomy for uterine rupture

I) Unknown

Were the following interventions done?

27. External Version - a) Yes b) No

28. Hysterectomy - a) Yes b) No

29. Blood Transfusion - a) Yes b) No

If Yes

30. Number of units required

31. Number of units transfused

32. Was a complication identified during hospitalization?

a) Yes

b) No

Specify (summarize main events):

33. Vital status of woman at discharge - a) alive

b) Dead

34. Date of discharge or death of woman

35. Time of discharge or death of woman

If alive

36. Mode of exit - a) normal discharge

b) Left against medical advice

c) Escaped

If dead

37. Time of death - a) Dead on arrival

b) Dead between arrival and admission

c) Dead in the first 24hrs

d) Dead after 24hrs

B) SERIOUS COMPLICATIONS

38. Hemorrhage – a) Yes b) No

i) Placenta Praevia

ii) Placenta accreta / increta / percreta

iii) Retro-placental hematoma

iv) Other obstetric hemorrhage

v) Hemorrhage during delivery (no other specification)

vi) Uterine rupture

vii) Postpartum hemorrhage (no other specification)

39. Hypertension – a) Yes b) No

i) Pre-eclampsia

ii) Eclampsia

iiI) HELLP

iv) Chronic hypertension

40. Anemia (Hb< 11g/dl) - a) Yes b) No

i) Hemoglobin level (g/dl)

Unknown

41. Infection - a) Yes b) No

i) Unspecified infection

ii) Puerperal endometritis

iii) Pyelonephritis

iv) Septicemia

v) Peritonitis

vi) Other systemic infection

42.Dystocia - a) Yes b) No

i) Uterine pre-rupture

ii) Prolonged labour

iii) Foeto-pelvic disproportion

43. Other pathologies - a) Yes b) No

i) HIV / AIDS

ii) Embolic diseases (thrombosis / amniotic fluid or gaseous embolism

iii) Heart disease

iv) Sickle-cell disease

v) Other (specify):

C) NEW BORN

44. Total number of newborns

Newborn 1	Newborn 2
45a. Presentation i) Cephalic ii) Breech iii) Transverse / face / brow iv) Other (Specify:	58b.Presentation i) Cephalic ii) Breech iii) Transverse / face / brow iv) Other (Specify :
46a. Sex i) Female ii) Male iii) Unknown	59b. Sex i) Female ii) Male iii) Unknown
47a. Birth weight:	60b. Birth weight:
48a. Alive or stillborn? i) Alive ii) Fresh stillbirth iii) Macerated stillbirth iv) Still birth (not specified) v) Unknown	61b. Alive or stillborn? i) Alive ii) Fresh stillbirth iii) Macerated stillbirth iv) Still birth (not specified) v) Unknown

49a. If stillborn, cause of stillbirth	62b. If stillborn, cause of stillbirth
50a. Apgar at 5min: i) Unknown	63b. Apgar at 5min : i) Unknown
51a. Neonatal complications? i) Yes ii) No	64b. Neonatal complications? i) Yes ii) No
52a. Neonatal complications Specify:	65b.Neonatal complications Specify:
53a. Birth trauma – a) Yes b) No if yes, specify :	66b. Birth trauma – a) Yes b) No if yes, specify :
54a. Baby referred to another facility ? - a) Yes b) No	67b. Baby referred to another facility ? – a) Yes b) No
55a. Admitted to special care or intensive care unit ? a) Yes b) No	68b. Admitted to special care or intensive care unit? a) Yes b) No
56a. If yes, number of days :	69b. If yes, number of days :
57a. Vital status at discharge i) Alive ii) Dead in first 24 hrs iii) Dead after 24 hrs	70b. Vital status at discharge i) Alive ii) Dead in first 24 hrs iii) Dead after 24 hrs

iv) Dead (timing not specified) v) Unknown	iv) Dead (timing not specified) v) Unknown
58a. If dead, cause of death	72b. If dead, cause of death
59a. Date of discharge, referral or death of baby :	72b. Date of discharge, referral or death of baby :

D) CAESAREANS & LAPAROTOMIES

60. Date and time of decision of intervention:

61. Date and time of intervention:

62. **Indication for caesarean or laparotomy**

a) Foeto-pelvic disproportion – a) Yes b) No

If Yes i) Small or deformed pelvis

ii) Foetalmacrosomia

iii) Unspecified disproportion

b) Severe antepatumhemorrhage - a) Yes b) No

If Yes i) Placenta Praevia

ii) Retro-placental hematoma

iii) Yes (no specification)

c) Uterine rupture or pre-rupture - a) Yes b) No

If Yes i) Uterine rupture

ii) Uterine pre-rupture

d) Malpresentation - a) Yes b) No

If Yes i) Transverse

ii) Oblique

iii) Brow

iv) Face with posterior chin / “enclaved” face

v) Arm or shoulder

e) Poor progression of labour - a) Yes b) No

If yes i) Prolonged labour

ii) Failed induction

iii) Other

iv) Yes (no specification)

f) Previous caesarean – a) Yes b) No

g) (Pre-)eclampsia – a) Yes b) No

If yes i) Eclampsia

ii) Pre-eclampsia

h) Foetal indication – a) Yes b) No

If yes i) Foetal distress

ii) Cord prolapse

iii) Cord around neck

iv) Intra-uterine growth retardation

i) Breech presentation – a) Yes b) No

j) Psychosocial indications – a) Yes b) No

If Yes i) Yes, maternal request

ii) Yes, “previous” pregnancy

k) Other – a) Yes b) No

specify _____

Indication not specified

Quality of care indicators for caesareans & laparotomies of uterine rupture

63. Before the surgery

a) Was the hemoglobin level checked ?– i) Yes ii) No

b) Was the foetal heart beat checked just before the anaesthesia ? – i) N/A (stillborn)

ii) Yes

iii) No

c) Was prophylactic antibiotics prescribed? – i) Yes ii) No

If yes

64. During the surgery, was prophylactic oxytocin administered? – a) Yes b) No

65. During the first 2hrs post surgery, did someone monitor **every 30 minutes**? a) yes b)no

66. Morbidity during or after caesarean

i) Blood transfusion

ii) Wound infection

iii) Puerperal fever

iv) Evacuation of haematoma

v) Secondary postpartum hemorrhage

vi) Severe postpartum hemorrhage

vii) Septicemia

viii) Hysterectomy

67. Severe incidents linked to caesareans

i) Admission for over 1 week due to post-surgical infection

ii) Anaesthetic accident

iii) Accident of blood transfusion

iv) Uterine artery pierced

v) Accident of other organs

vi) Return to operating room

vii) Other specify

_____

_____

68. Caesarean after failed instrumental delivery – a) Yes

b) No

E) MATERNAL NEAR-MISS

69. Is the woman considered to be in a state of near-miss?

i) Yes – according to clinical criteria (AUDOBEM)

ii) Yes – according to organ dysfunction criteria (WHO)

iii) Yes - anaemia

iv) No

70. When did the state of near-miss occur ?

i) Before arrival at the facility

ii) During hospitalization

71. Did the woman require intensive care?

i) Yes ii) No iii) Unknown

Clinical criteria

72. Uterine rupture & pre-rupture

i) Dystocia with rapid maternal pulse or foetal distress AND sub-pubic tenderness or bandl ring

ii) Diagnosis of rupture / pre-rupture in medical record

iii) Dystocia with shock or cardiac arrest

iv) Dystocia requiring laparotomy

73. Hemorrhage

i) Hemorrhage with state of shock

ii) Hemorrhage with cardiac arrest

iii) Hemorrhage with laparotomy

iv) Haemorrhage with blood transfusion

74. Infections

i) Temp >38,0° or <36,5 or obstetric infectious seat AND jaundice or state of shock or cardiac arrest

ii) Diagnosis of septicemia in medical record

75. Severe pre-eclampsia

i) Diastolic BP ≥ 110 mm Hg or Proteinuria / albuminuria +++ AND hyper reflectivity or headache or blurred vision or oliguria or high abdominal pain or pulmonary edema or jaundice

76. Eclampsia

i) Diastolic BP ≥ 90 mm Hg or proteinuria/albuminuria ++ AND convulsions or coma

Organ dysfunction criteria

77. Cardiovascular dysfunction

i) Shock

ii) Cardiac arrest

iii) Severe hypo perfusion (lactate > 5mmol/l or 45mg/dl)

iv) Severe acidosis (pH <7.1)

v) Use of continuous vasoactive drugs

vi) Cardio-pulmonary resuscitation

78. Respiratory dysfunction

i) Acute cyanosis

ii) Gasping

iii) Severe tachypnea (respiratory rate/min >40)

iv) Severe bradypnea(respiratory rate/min <6)

v) Severe hypoxaemia (O_2 saturation < 90% for ≥60 min or PaO_2/FiO_2<200)

vi) Intubation& ventilation not related to anaesthesia

79. Uterine dysfunction

i) Haemorrhage or dysfunction leading to hysterectomy

80. Renal dysfunction

i) Oliguria non responsive to fluids or diuretics

ii) Severe acute azotemia (creatinine> 300 umol/ml or >3.5 mg/dl)

iii) Dialysis for acute renal failure

81. Coagulation dysfunction

i) Failure to form clots

ii) Severe acute thrombocytopenia (<50,000 platelets/ml)

iii) Massive transfusion of blood or red cells (≥ 5 units)

82. Hepatic dysfunction

i) Jaundice in the presence of pre-eclampsia

ii) Severe hyperbilirubinemia

83. Neurological dysfunction

i) Prolonged unconsciousness or coma lasting > 12 hrs

ii) Stroke

iii) Status epilepticus / uncontrollable fits

iv) Total paralysis

Anaemia Criteria

84. Severe anaemia

i) Hemoglobin level < 4g/dl OR hematocrit level < 12%

OR

ii) Haemoglobin level 4-7g/dl; or haematocrit level < 20%

OR

iii) Cutaneo-mucosal pallor

AND

i) State of shock (cold sweat + thready pulse + cold extremities + tachycardia)
ii) Difficulty breathing
iii) Blood transfusion performed
iv) Blood transfusion requested