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ORIGINAL ARTICLE

Using Near Miss Model to Evaluate the Quality of Maternal Care at a Tertiary Health-Care Center: A Prospective Observational Study

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Abstract

Background Near miss (NM) concept has led to a more comprehensive and better assessment of effect of care on maternal health. It indicates the degree of organ function failure in the wide spectrum of severity.

Methods This was a prospective observational study conducted from July 2015 to Feb 2016. Among women with potentially life-threatening conditions (PLTCs), those fulfilling one or more WHO NM criteria were included and followed up till the final outcome (NM or death). Various critical interventions done in them were associated with the final outcome. Standardized mortality ratio (SMR) was calculated for assessment of overall quality of health care provided.

Results One thousand seven hundred and thirty-nine patients had PLTCs of which 174 (10%) patients were identified as NM. Of 174 patients, 116 patients (66.66%) were discharged in stable condition (group A) and 58 patients (33.34%) died (group B). Hemorrhage (31.8%) was the most frequent complication in group A followed by hypertensive disorders (18.1%) and severe anemia (11.2%). The two most common causes of maternal mortality were hypertensive disorders (27.6%) and hemorrhage (24.1%). Only two critical interventions (assisted ventilation and massive blood transfusion) had significant association with the final outcome. SMR of our center was 1.187 indicating adequate quality of provision of care to the patients.

Conclusion Hemorrhage and hypertensive disorders were the two most common causes of NM and deaths highlighting the importance of their prompt diagnosis and vigorous management. Periodic SMR calculation can be used as an audit to guide us in improving the overall status of maternal health.

Keywords Near miss · Standardized mortality ratio · Critical interventions

Introduction

Introduction of the concept of maternal near miss (NM) has led to a more comprehensive and better assessment of effect of care on maternal health. Maternal NM case is defined as "A woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy" [1]. Maternal mortality ratio is just the tip of iceberg; there are many more females who suffer from serious conditions which can affect them for the rest of their lives. The area of interest has now diverted from the retrospective analysis of conditions causing maternal mortality to early identification and timely management of pregnancy-related complications which can predispose a woman to severe maternal outcome (defined as maternal death or NM irrespective of gestational age or delivery status).

The aim of current study was to evaluate the causes of maternal NM and deaths and to analyze the effectiveness of various lifesaving interventions done to prevent NM patients

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from dying. We also assessed the quality of maternal health care provided by our center by calculating standardized mortality ratio (SMR) using Maternal Severity Index (MSI) model [2].

Methodology

This was a prospective observational study undertaken in the obstetrics department of a tertiary health-care referral center from July 2015 to February 2016. Among women with potentially life-threatening conditions (PLTCs) [3], those fulfilling one or more WHO NM criteria were included. A thorough history of current pregnancy-related complication(s) was obtained. They were then followed up till the final outcome, i.e., near miss or death. Case fatality rate (defined as the proportion of people who die from a specified disease among all individuals diagnosed with that disease over a certain period of time) was also calculated for each PLTC.

Based on the final outcome, patients were divided into two groups—

Group A—Patients who were near miss but improved and were discharged in a stable condition.
Group B—Patients who could not survive the complications and died.

We also associated all critical interventions done in NM patients with the final outcome. Critical interventions analyzed in the current study were massive blood transfusion (BT) of more than 5 whole blood or packed red blood cells (PRBCs), embolization, laparotomy (hysterectomy and other surgical interventions in abdominal cavity, other than cesarean section), dialysis, assisted ventilation and intensive care unit (ICU) admission.

SMR Calculation

SMR of our center was then calculated as a tool for assessment of overall care performance. SMR of <0.5 to 1.24 indicates adequate level of care, whereas SMR of 1.24 to >2 represents inadequate level of care [2]. It was calculated as the number of observed maternal deaths per population size divided by the predicted maternal deaths per population size The predicted number of maternal deaths was calculated as MSI * Population size [2]. Population size corresponds to the number of cases with PLTCs and Severe Maternal Outcome (SMO). SMO is having had a maternal death or maternal near miss irrespective of gestation age or delivery status [3]. MSI of all patients was calculated using MSI calculator available online.

Statistical Analysis

Statistical analysis was performed using SPSS software (version 22, SPSS Inc., Chicago, IL, USA). Categorical data were compared using chi-square analysis with Yates correction and Fischer's extract. P value ≤ 0.05 was considered statistically significant with 95% confidence interval.

Results

Four thousand eight hundred twenty-two patients were admitted during the study period of which 1739 (36.1%) patients had PLTCs. Among them, 174 (10%) patients fulfilled one or more WHO NM criteria. On follow-up, 116 patients survived the complication and were discharged in stable condition (group A) and 58 patients died (group B) (Fig. 1).

Baseline Characteristics

The mean age of patients in both the groups was comparable. Neither parity nor the delivery status had significant association with the final outcome ($p>0.05$). The percentage of adequately booked and supervised patients (at least one antenatal visit in each trimester) in group A and group B was 88.8% and 70.6% respectively; the difference was found to be statistically significant ($p=0.02$). The presence of one or more previous cesarean sections (25.8% in group A and 5.1% in group B) was significantly associated with the final outcome ($p<0.001$). On comparing the mode of delivery, it was noted that the vaginal route was the most common mode of delivery in both the groups (48.3% vs. 48.2% in group A

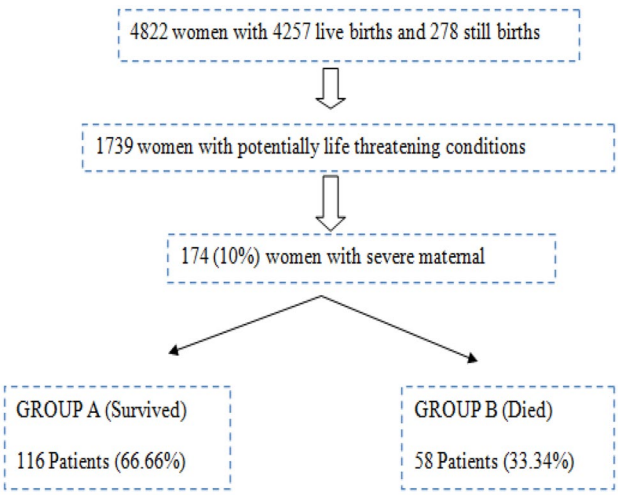

Fig. 1 Flow diagram showing the total number of patients included along with the final outcome

and group B, respectively), and the difference was, however, statistically insignificant ($p = 0.65$) (Table 1).

Causes of Maternal Near Miss and Deaths (Table 2)

The PLTCs included were hemorrhage, infections, hypertensive disorders, abortions, ectopic pregnancies and other complications.

Hypertensive disorder, hemorrhage and hepatic disorders were the three most frequent PLTCs affecting 729 (41.9%), 441 (25.3%) and 210 (12.1%) patients, respectively. Hemorrhage (31.8%) was the most frequent complication in NM group followed by hypertensive disorders (18.1%) and severe anemia (11.2%). The two most common causes of maternal mortality were hypertensive disorders (27.6%) and hemorrhage (24.1%). Systemic sepsis and hepatic diseases constituted the third most common complication leading to maternal death (each contributing 10.3%) (Fig. 2).

Hypertensive Disorders

Preeclampsia (30%) was the predominant etiology followed by chronic hypertension (6.3%) and eclampsia (5.5%), respectively. Of 729 patients with hypertensive disorders, 21 patients (2.9%) became NM and 16 patients (2.2%) died. Eclampsia was the most common cause in NM group (11.2%) among hypertensive disorders followed by preeclampsia (6%) and chronic hypertension (0.8%). Eclampsia (13.8%) was also the leading cause of death with a case fatality rate (CFR) of 8.3% followed by preeclampsia (12.1%) and chronic hypertension (1.7%) with a CFR of 1.3% and 0.9%, respectively.

Hemorrhage

Postpartum hemorrhage (PPH) was the most common PLTC (8.5%) and the most common cause of NM (12.1%) among hemorrhage with a CFR of 6.1%. The most common cause of PPH was atonic PPH followed by trauma. Seven patients (4.7%) with PPH who were not responding to medical management ultimately underwent peripartum hysterectomy. Second most common cause of NM in hemorrhage was abruption (mainly toxemic) and placenta accreta (requiring peripartum hysterectomy due to excessive bleeding), each constituting 7.7% of NM patients. There were two cases (0.1%) of rupture uterus of which one was referred to us in hemorrhagic shock as NM. Both of them had successful uterine repair and were discharged under stable condition.

Infection

Systemic sepsis was the leading etiology comprising 1.6% of PLTCs and 7.7% of NM patients. Of 28 patients with systemic sepsis, 15 (53.6%) patients presented to us as pyoperitoneum post-cesarean section (CS). Only one CS was performed at our center, and others were referred in the postoperative period. Of these, eight patients underwent laparotomy while others were managed conservatively. Ultimately, nine (60%) patients survived the complication and six (40%) patients expired due to septicemia with multi organ failure (CFR—21.4%). Fourteen patients had puerperal endometritis, all of which were successfully managed with antibiotics.

Table 1 Comparison of baseline characteristics between the two groups

Characteristics	Group A (survived) *N* (%)	Group B (died) *N* (%)	*p* value
Age (in years) (mean ± SD)	26.4 ± 5.08	26.19 ± 4.47	0.48
Parity			
Primipara	44 (37.9%)	24 (41.37%)	0.67
Two or more deliveries	72 (62.1%)	34 (58.63%)	0.52
Delivery status			
Antenatal	68 (58.6%)	40 (68.9%)	0.21
Postpartum	48 (41.4%)	18 (31.1%)	0.16
	30 (25.8%)	3 (5.1%)	–
Booking status			
Adequately booked at our center	5 (4.3)	2 (3.4)	0.27
Adequately booked at outside hospital	98 (84.5)	39 (67.2)	**0.02**
Inadequately booked	2 (1.7)	1 (1.7)	0.42
Unbooked	16 (27.6)	11 (9.5)	**0.04**
One or more LSCS	30 (25.8%)	3 (5.1%)	**< 0.001**

Bold signifies statistical significance

Table 2 Frequency of potentially life-threatening conditions, near miss and maternal deaths

Disorders	Potentially life-threatening conditions *N* (%)	Group A (survived) *N* (%)	Group B (died) *N* (%)	Case fatality rate (%)
Hemorrhagic disorder				
Placenta previa	122 (7.0)	0 (0)	1 (1.7)	0.8
Accreta/increta/percreta	27 (1.5)	9 (7.7)	1 (1.7)	3.7
Abruption	130 (7.4)	9 (7.7)	3 (5.2)	2.3
Rupture uterus	2 (0.1)	1 (0.8)	0	0
Postpartum hemorrhage	148 (8.5)	16 (13.7)	9 (15.5)	6.1
Other obstetrical hemorrhage	12 (0.7)	2 (1.7)	0	0
Total	441(25.3)	37 (31.9)	14 (24.1)	3.2
Infections				
Puerperal endometritis	14 (0.8)	1 (0.8)	0 (0)	0
Pyelonephritis	2 (0.1)	0 (0)	0 (0)	0
Influenza like illness	10 (0.6)	0 (0)	0 (0)	0
Sepsis and other systemic infection	28 (1.6)	9 (7.7)	6 (10.3)	21.4
Total	44 (2.5)	10 (8.6)	6 (10.3)	13.6
Hypertensive disorders				
Chronic hypertension	111 (6.3)	1 (0.8)	1 (1.7)	0.9
Preeclampsia (except eclampsia)	522 (30)	7 (6.0)	7 (12.1)	1.3
Eclampsia	96 (5.5)	13 (11.2)	8 (13.8)	8.3
Total	729 (41.9)	21 (18.1)	16 (27.6)	2.2
Abortion and ectopic pregnancy				
Abortion-related hemorrhage	2 (0.1)	0 (0)	0 (0)	0
Abortion-related infection	11 (0.6)	1 (0.8)	1 (1.7)	9.09
Ectopic pregnancy	58 (3.3)	3 (2.5)	1 (1.7)	1.7
Total	71 (4.1)	4 (3.4)	2 (3.4)	2.8
Other complications				
HIV positive or AIDS	27 (1.5)	0 (0)	0 (0)	0
Severe anemia	53 (3.0)	13 (11.2)	3 (5.2)	5.6
Malaria or dengue	6 (0.3)	2 (1.7)	0 (0)	0
Embolic disease	1 (0.05)	0 (0)	1 (1.7)	100
Cancer	6 (0.3)	1 (0.8)	1 (1.7)	16.6
Heart disease	78 (4.4)	7 (6.0)	2 (3.4)	2.5
Lung disease	36 (2.1)	2 (1.7)	1 (1.7)	2.7
Renal disease	23 (1.3)	8 (6.8)	2 (3.4)	8.7
Hepatic disease	210 (12.1)	11(9.4)	6 (10.3)	2.8
Others	4 (0.3)	0 (0)	4 (6.8)	100
Total	1739	116	58	3.3

Abortion and Ectopic Pregnancy

Fifty-eight patients had ectopic pregnancies (including both ruptured and unruptured). Four patients (7.7%) with ruptured ectopic pregnancy presented to us as near miss in shock with massive hemoperitoneum. Three patients were successfully saved with immediate surgery and BT; however, one patient who was referred to us in gasping state expired. Eleven patients who had abortion-related complications were successfully managed with conservative treatment. However, two patients presented to us in septic shock with rupture uterus and gut injury following illegal abortion attempted by an untrained health worker. Both underwent immediate laparotomy with uterine repair and diversion ileostomy; however, one patient died on third postoperative day due to septicemia and multiorgan dysfunction.

Other Complications

Of 210 patients with hepatic diseases, 59.7% patients had viral hepatitis. Among these 210 patients, 11 (5.2%) patients became NM and 6 (2.9%) patients expired. It was seen that 73% of NM patients with hepatic dysfunction were HEV positive and 78.6% of patients who expired were suffering

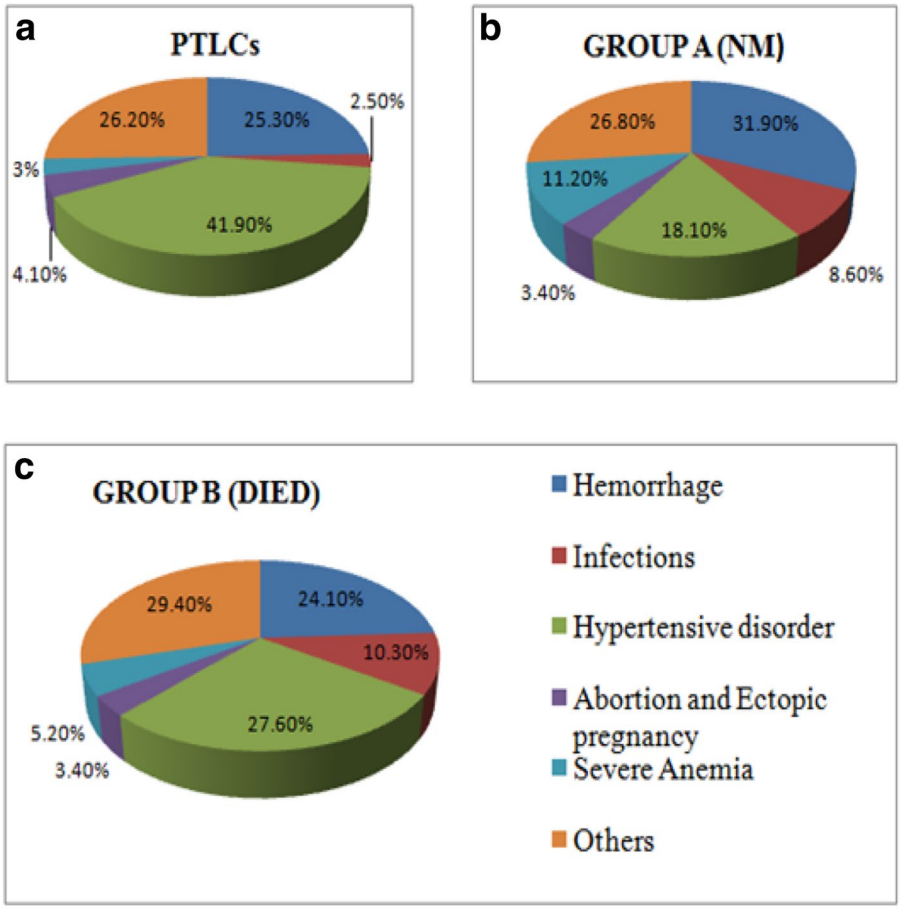

Fig. 2 Percentage of various disorders in **a** total (PLTCs), **b** group A (NM) and **c** group B (died)

from acute fatty liver of pregnancy. Severe anemia was found in 53 (3%) patients of which 13 (24.5%) were NM requiring massive blood transfusions. Three (5.7%) patients presented to us in congestive cardiac failure and could not be salvaged. Cardiac diseases constituted 4.4% of patients with potentially life-threatening conditions with a CFR of 2.5%. Among 23 patients with renal disorders, two patients (CFR—8.7%) died due to pulmonary edema secondary to fluid overload. Among malignancies, one patient died in antenatal period at 27 weeks of gestation due to familial adenomatous polyposis associated advanced stage colorectal cancer. Four patients died due to rare complications—meningitis (one patient), more than 90% thermal burns injury (one patient), H1N1 virus-related complications (one patient) and probable drug-induced reaction (one patient).

Critical Interventions and Outcome

Patients in both the groups were also compared on the basis of various critical interventions done to save maternal lives, i.e., ICU admission, assisted ventilation, laparotomy, embolization, dialysis and massive BT.

The most common intervention done in group A was assisted ventilation (45.7%) followed by massive BT (34.5%) and ICU admission (25.9%). In group B, assisted ventilation (98.3%), ICU admission (36.2%) and dialysis (29.3%) were the three most common interventions done to save maternal lives. Thirty-nine patients who underwent surgical intervention included 23 hysterectomies (58.9%) and 16 laparotomies for other indications. Of the six interventions done, only two interventions (assisted ventilation and massive BT) were found to be significantly associated with the final outcome (Table 3). In group A, 53 patients (45.7%) received assisted ventilation while in group B, 57 patients (98.2%) received assisted ventilation with a statistically significant difference. Forty patients (34.48%) in group A and 11 patients (18.9%) in group B received massive BT; the difference was found to be statistically significant ($p = 0.034$).

SMR

Total MSI of entire population (1739) calculated using online MSI calculator was 4884.4%. Average MSI of population (total MSI/population size—4884.4/1739) was 2.808%. Predicted numbers of deaths (calculated as average

Table 3 Association of critical interventions with the final outcome

Intervention	Total (N)	Group A (yes/no)	Group B (yes/no)	*p* value
ICU admission	51	30/86	21/37	0.158
Assisted ventilation	110	53/63	57/1	**< 0.001**
Laparotomy	39	27/89	12/46	0.704
DSA and embolization	6	2/58	4/112	0.829
Dialysis	43	26/90	17/41	0.32
Massive blood transfusion	51	40/76	11/47	**0.034**

Bold signifies statistical significance

MSI of the population × population size—0.02808 × 1739) were 48.83. Actual numbers of deaths were 58. Hence, SMR (actual number of deaths/predicted number of deaths—58/48.83) was 1.187 indicating adequate quality of care of patients at our center.

DISCUSSION

Severe acute maternal morbidity (SAMM) and maternal NM are events involved in the biological continuum that goes from the normal expected healthy situation of a pregnancy to maternal death [4].

In the current study, mean age, parity, delivery status and mode of delivery were comparable in both the groups and hence did not affect the final outcome. The percentage of adequately booked and supervised patients was much higher in patients who became NM as compared to those who died, indicating the importance of adequate antenatal care in prevention of maternal deaths. Although vaginal delivery was the most common mode of delivery in both the groups, it is worth mentioning that the number of women who underwent one or more cesarean sections in previous pregnancies was significantly more in NM group as compared to those who expired. The probable explanation is that the presence of one or more cesarean sections in previous pregnancies adds to the surgical morbidity due to adhesion formation and subsequent risk of injury to the surrounding structures. Hence, the patient is at increased risk of developing surgery-related complications and becoming NM in subsequent pregnancy; however, the condition alone is not severe enough to cause maternal death. Hence, it is of utmost importance to critically scrutinize the indication of each cesarean section.

Hemorrhage was the leading cause of maternal NM in the present study followed by hypertensive disorders. Similar results were shown by various other studies as well [5, 6]. In terms of specific conditions, PPH was the most common cause of NM as well as maternal deaths followed by eclampsia. 5.1% of patients with hypertensive disorders and 11.6% of patients with hemorrhage fulfilled the WHO NM criteria on admission. Among them, 43.2% of patients suffering from hypertensive conditions and 27.4% of patients with hemorrhage ultimately expired. Hence, females with hypertensive disorders less often presented as NM in comparison with hemorrhage but once they became NM, they carried a higher risk of mortality in comparison with hemorrhage. This highlights the significance of immediate delivery along with vigorous management of hemodynamic parameters and other associated complications without any delay in patients with hypertensive disorders who present as NM in order to prevent them from dying. Although the two most common causes of maternal mortality were hypertensive disorders and hemorrhage, the highest CFR (21.4%) was seen with systemic sepsis. Also, 53.6% of patients who developed systemic sepsis were those who underwent cesarean section. This signifies the need of critically evaluating the indication of each cesarean section, following proper aseptic precautions during surgery, identifying general as well as procedure-related specific risk factors for the development of postoperative infection.

In a large cross-sectional study by Souza et al. [3], hemorrhage (51.55%) followed by hypertensive disorders (29.8%) were the two most common causes of severe maternal outcome, similar to our study. Another study from Nigeria [7] also concluded that obstetric hemorrhage (39.0%) and hypertensive disorders (24.0%) were the two most frequent complications causing SMO. Eclampsia accounted for twice the number of deaths caused by PPH. However, in the present study, PPH (15.5%) was the leading cause of mortality followed by eclampsia (13.8%). Most of the patients with PPH who died were referred late to our institute in a grave condition and hence could not be salvaged. This underlines the importance of rapid response team and protocol-driven care in all health-care centers for successful management of PPH. In another study from Uganda [8], the predominant etiology of NM was severe preeclampsia followed by PPH. Uterine rupture caused the highest case fatality (17.9%), followed by eclampsia (17.8%). In our study, Case fatality rate of uterine rupture was 0% as all cases of uterine rupture were immediately diagnosed on admission and were taken up for surgery without any delay.

In the present study, we also associated various critical interventions done to save maternal lives with the final outcome. Critical interventions defined by WHO include BT,

interventional radiology and laparotomy [9]. Based on our experience, we also included dialysis, assisted ventilation and ICU care for analysis. We found that only two interventions (assisted ventilation and massive BT) were found to have significant association with the final outcome. Others did not have much impact on the survival of NM patients.

In a study from Nepal [10], it was seen that ICU admission (72.5%) was the most frequent critical intervention required followed by massive BT (40%) in NM patients. Only 13.8% of patients requiring ICU admission died suggesting a favorable impact on maternal outcome. In our study, 41.2% of patients receiving ICU care expired with no significant effect on final outcome. In another study from Iraq, 55.7% women had BT, 36.8% women underwent laparotomy and 34.4% women received ICU care [11]. The authors found that shortage of ICU beds was a limiting factor and contributed to high mortality of women presenting with organ dysfunctions.

The main limitation of the current study was its duration and sample size. More data collection over a few years will provide a better and more comprehensive information about the maternal health status. However, this is probably the first study in India which has used SMR model to assess its quality of care.

Conclusion

Correct and timely detection of complications in NM women and their appropriate treatment at the right time is the most critical step to reduce maternal mortality and upgrade the overall health status of women. Each NM woman should be evaluated in detail to diagnose underlying pathology with prompt institution of management strategies to save her from the claws of death. Also, periodic estimation of SMR can be used as an audit for the efficiency of health care provided by quantifying the level of performance and hence can serve as a guide in improving the overall status of maternal health.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflicts of interest.

Informed Consent An informed written consent was obtained from patients/relatives after fully explaining the nature and purpose of study.

Ethics Approval The study was reviewed and approved by the institute's ethics committee, PGIMER, Chandigarh, on 11/9/2015 (Reference Number-NK/2210/MD/9907–08).

Research Involving Human Participants and/or Animals It was an observational study and does not involve research on human participants or animals.

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