

One-Year Follow-Up of Women with Severe Acute Maternal Morbidity (SAMM): A Cohort Study

Shobha A. Alluvala¹ · Nuzhat Aziz¹ · Ashwin Tumkur² · Hari K. Boorugu³

Received: 22 March 2018 / Accepted: 11 July 2018 / Published online: 23 July 2018
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About the Author



Shobha A. Alluvala is a student of DNB in obstetrics and gynaecology, and this prospective study was done with Dr. Nuzhat Aziz, consultant obstetrician and gynaecologist at Fernandez Hospital. She presented a paper on 'Disease Specific Morbidity' data of Fernandez hospital, Hyderabad at APCOG conference in 2016 at Visakhapatnam and won first prize. She is interested in infertility and high-risk pregnancy.

Abstract

Background Some women experience unforeseen complications during pregnancy and childbirth, which may be life threatening; their survival depends on intensive support

and timely interventions. The aim of this study was to assess the long-term prevalence of adverse health conditions and their impact on quality of life in women who had severe acute maternal morbidity (SAMM).

Methods This is a prospective cohort study comprising 43 women with SAMM during 2015 (exposure group) and 43 women who had an uneventful pregnancy and delivery (non-exposure group) during the same study period. Those who consented were given an additional follow-up date for free medical health check at 1 year.

Results The incidence of SAMM during study period was 8.6/1000 births. There were five deaths in the exposure group. Adverse health events were seen in 30 (78.94%) out of 38 survivors. Abnormal lipid profile, thrombocytopenia, cardiac diastolic dysfunction, amenorrhoea, Sheehan and Asherman syndrome were major findings in the exposed group. Four (10.52%) women required re-admission, and eight (20.05%) required additional procedures to confirm screening abnormalities. The exposure group had higher

Shobha A. Alluvala is an obstetrician at Fernandez Hospital. Dr. Nuzhat Aziz is a consultant obstetrician and gynaecologist at Fernandez Hospital. Ashwin Tumkur is a consultant interventional cardiologist at Fernandez Hospital. Hari K. Boorugu is a consultant physician at Fernandez Hospital.

✉ Nuzhat Aziz
drnuzhat@fernandezhospital.com

¹ Department of Obstetrics, Fernandez Hospital, 4-1-1230, Bogulkunta, Abids, Hyderabad 500001, India

² Consultant Interventional Cardiologist, Fernandez Hospital, 4-1-1230, Bogulkunta, Abids, Hyderabad 500001, India

³ Consultant Physician, Fernandez Hospital, 4-1-1230, Bogulkunta, Abids, Hyderabad 500001, India

mean scores on the EPDS scale, incidence of suicidal thoughts and poorer performance in the WHOQOL BREF psychological domain.

Conclusion Health programmes need to focus on maternal health, provide medical treatment and psychological support for a longer duration than the traditional 6 weeks postpartum in women who experience SAMM.

Keywords Severe maternal morbidity · Near miss · Follow-up · Pregnancy · India

Introduction

Severe acute maternal morbidity (SAMM) or maternal near-miss morbidity is defined to include women who experience a life-threatening event during pregnancy or postpartum (up to 42 days after the end of pregnancy) and survive because of the care that they receive. Complications as a result of SAMM and interventions to ensure survival impact the physical, mental and reproductive health of these women. There is a growing body of evidence on the long-term adverse consequences for women's health and socio-economic conditions secondary to severe obstetric complications [1–8]. These consequences may range from abandonment of the woman who has had a hysterectomy and is therefore of no further reproductive use to the family, to lifelong indebtedness due to catastrophic out-of-pocket expenditure for treatment [9–15]. There are few long-term studies on follow-up obstetric care from India. The present study was undertaken to address this gap and assess the long-term prevalence of adverse health conditions and their impact on quality of life in women who had SAMM.

Materials and Methods

A cohort study was conducted at a tertiary referral perinatal institute with 8000 deliveries per annum, between January and December 2015, after an approval by the institutional review board. Women who had experienced SAMM constituted the 'exposure' group. The 'non-exposure' group comprised mothers who had an uneventful pregnancy and delivery during the same study period. A prevalence of adverse outcomes of 5 and 30% in the non-exposure and exposure groups, respectively, and an alpha error of 5% and power of 80% was presumed to determine a sample size. The sample size was estimated to be 43 in each group to prove the hypothesis of increased incidence of adverse events in women with SAMM.

Severe acute maternal morbidity was defined using the WHO criteria, and 43 consecutive women with the

diagnosis were enrolled with an informed consent for 1-year follow-up. In parallel, 43 women without coexisting medical morbidity who delivered at term during the same time frame and who had no adverse events due to pregnancy were recruited randomly as controls. One-year follow-up with a free medical check and evaluation was explained to all participants. The follow-up visit included a review of history, new complaints, medical or surgical interventions in the post-delivery year, standardized clinical examination and investigations, namely haemogram, urine examination, HIV, HBsAg, HCV, serum creatinine, liver function tests, TSH, prolactin, lipid profile, pelvic organ ultrasound and echocardiogram. The Edinburgh Postpartum Depression Scale (EPDS) and the WHOQOL BREF questionnaire were administered at the follow-up visit and used for the assessment of depression and quality of life, respectively. Both these tools have been validated for use in an Indian population [16, 17]. The 10-question EPDS indicates how the mother has felt during the previous week and is an effective screening tool for postnatal depression. The EPDS score identifies women who are relatively happy (score of < 10), those who have the blues (score of 10–12) and those who are at risk of postnatal depression (score of \geq 13). The WHOQOL BREF produces a quality of life profile. It contains a total of 26 questions and has 4 domains: physical, psychological, social and environmental. The responses are scored using a 5-point Likert scale with higher scores indicating a better quality of life.

The primary outcome was the incidence of depression, QOL and other adverse health events at 1 year after the diagnosis of SAMM and delivery. The secondary outcomes were the immediate adverse health complications they had as they experienced the severe acute maternal morbidity. Adverse health events as the primary outcome was based on the National Institute of Health definition as structural and/or functional abnormality, with the implication that the abnormalities produced had the potential of lowering the quality of life, contributing to a disabling illness or leading to a premature death. In the present study, we included any of the following: mortality, organ-based morbidity, newly diagnosed health problems, hospital admissions, physical impairment, self-reported health issues and additional diagnostic procedures due to abnormal screening results.

The WHO maternal near-miss criteria were used to categorise and subdivide the immediate complications of SAMM. Statistical analysis was done using SPSS (V.22). Categorical variables were expressed as proportions, and continuous variables were expressed as mean (SD). Potential differences between the exposed and non-exposed group were tested using Chi-square or Fisher exact tests for categorical variables and student t test for continuous data. A *p* value of < 0.05 was taken as statistically significant for this study.

Results

Seven thousand eight hundred and twenty-one women gave birth at the study institute in the year 2015. Sixty seven (0.86, 95% CI 0.67, 1.09) of these women (incidence 8.6 per 1000 births) were defined as SAMM. The first consecutive 43 women with a diagnosis of SAMM formed the cohort group. The non-exposed group was a random selection of women who had uneventful pregnancy during the same time period. Unemployed women and referrals from other hospitals were significantly higher in the group with SAMM (see Table 1). Thirty-three (76.74%) of the 43 women with SAMM had preterm births including 11 (25.58%) deliveries before 32 weeks. The mean gestational age at delivery was 33.29 weeks in women with SAMM compared to 38.2 weeks in women without SAMM.

Forty (93.02%) of the 43 women with SAMM experienced the life-threatening event during the antenatal period. All 43 women with SAMM needed ICU admission (mean ICU stay = 2.92 days). Women with SAMM had a significantly higher mean hospital stay compared to women without SAMM (6.02 ± 2.92 vs. 1.3 ± 0.55 , $p < 0.0001$). Three (6.97%) of the women with SAMM had pregnancy loss at < 24 weeks (two in first trimester and the other one in second trimester). The incidence of still births ($n = 6$, 13.95%) was significantly higher in women with SAMM ($p < 0.001$).

The index pregnancy in the exposure group was characterized by very severe morbidity with the need for massive organ support (see Table 2). Almost two-thirds (67.44%) in this group required blood transfusions, with the most frequent WHO near-miss criterion being thrombocytopenia. Jaundice as a near-miss criterion was observed in eight women (18.60%). The causes include four women with acute fatty liver of pregnancy (AFLP), two with intrahepatic cholestasis of pregnancy (IHCP), one

with hepatitis E and the other one woman had intrauterine foetal death (IUFD) which lead to DIC and liver injury. Failure to form clots ($\text{INR} > 1.5$) was observed in ten women (23.25%), which was due to AFLP in two women, IHCP in two, preeclampsia in two, IUFD in two, one each with hepatitis E and abruption. Women with diagnosed epilepsy had status epilepticus in pregnancy which was included under neurological system in the near-miss criterion (2.32%). All 43 women were referred for tertiary medical care. At 1-year follow-up, five of these 43 women had expired. Three deaths were at a tertiary care centre within 42 days of pregnancy termination after referral for renal replacement therapy, and two deaths were reported from home at 3 months after discharge from the tertiary institute. The cause of SAMM in these five women was AFLP ($n = 2$) and pneumonia with respiratory failure, dengue haemorrhagic fever and infective endocarditis in one woman each.

Adverse health events were significantly more in the exposure group in comparison with the non-exposure population (see Table 3) in the remaining 38 mothers. Thirty (78.94%) of the 38 women with SAMM during pregnancy had one or more adverse health events during the follow-up period (see Table 3). Self-reported health problems including weakness and headache were reported by 12 (31.57%) women with SAMM and 2 (4.7%) women without SAMM. The percentage of women who resumed regular menstrual cycles was 68.42 versus 97.67% in the exposure and non-exposure groups, respectively. Amenorrhoea at 1 year was observed in five women, and two of them were diagnosed to have Asherman syndrome, both after surgical interventions for haemorrhage during miscarriage.

The mean EPDS scores were higher in women with severe complications than in the exposure group (mean value of 7.07 vs. 5.67) although the difference was not

Table 1 Group characteristics

Characteristic	Exposure group = 43 No (%)	Non-exposure group = 43 No (%)	<i>p</i> value
Mean age (SD); range	27.67 (4.43); 19–36	27.47 (3.34); 20–35	0.813
Age ≥ 35 years	2, 4.65	1, 2.32	0.500
Unemployed	36, 83.72	22, 51.16	0.001
Non-local	19, 44.18	2, 4.65	< 0.0001
Nulliparous	14, 32.55	14, 32.55	0.5
Termination of pregnancy	3, 6.97	0, 0.00	0.120
Stillbirths	6, 13.95	0, 0.00	0.008

Bold indicate significant *P* values

Unemployment, non locals and stillbirths were significantly high in exposure group

Table 2 Severe acute maternal morbidity as per the WHO criterion

System involved	Total exposure group = 43 (no, %)	Specific criterion	No (%)
Cardiovascular	3, 6.97	Shock, cardiac arrest	1, 2.32
		pH < 7.1, Lactate > 5 mmol/L, 45 mg/dL	0
		CPR, vasoactive drugs	2, 4.65
Respiratory	3, 6.97	Acute cyanosis, gasping, severe tachypnoea, severe bradypnoea	0
		PAO ₂ /FiO ₂ < 200, O ₂ saturation < 90% for > 60 min	0
		Intubation and ventilation not related to anaesthesia	3
Renal	1, 2.32	Oliguria non-responsive to fluids or diuretics	0
		Creatinine > 300 µmol/ml or 3.5 mg/dL	1, 2.32
		Dialysis for acute renal failure	0
Coagulation	31, 72.09	Failure to form clots	10, 23.25
		Platelets < 50,000/ml	21, 48.83
		Massive transfusion of blood or red cells (≥ 5 units)	24, 55.81
Hepatic	8, 18.60	Jaundice in the presence of preeclampsia	0
		Bilirubin > 100 or 6 mg/dL	8, 18.60
Neurological	1, 2.32	Prolonged unconsciousness/coma (lasting > 12 h) stroke, status epilepticus/uncontrollable fits or global paralysis	1, 2.32
Alternative severity proxy	3, 6.97	Haemorrhage or infection leading to hysterectomy	3, 6.97

statistically significant (see Table 4). Nine (23.68%) women with SAMM and 5 (11.62%) of women without SAMM had EPDS scores of more than 13. Suicidal ideations were significantly higher in women with SAMM (7, 18.42%, $p = 0.001$).

EPDS scores were studied for women with perinatal loss (6) and compared with women who had a live birth (31) in women with SAMM as a subgroup analysis. The mean EPDS scores were found to be significantly higher in women with perinatal loss (11.66 ± 7.78 vs. 6.29 ± 4.97 , $p = 0.034$), without any significant difference in diagnosis of depression (3, 50% vs. 6, 19.35%, $p = 0.14$) or suicidal ideations (2, 33.33% vs. 5, 16.12%, $p = 0.315$). Women with SAMM had poorer scores on the WHOQOL domains than women without SAMM although this evidence was statistically significant only in the psychological domain (see Table 4).

Discussion

The 8.6/1000 incidence of SAMM in our series was higher than the reported incidence from developed countries and lower when compared to Indian data (11–17/1000) [18, 19]. The five maternal deaths (11.62%) in the 1-year follow-up were much higher when compared to other follow-up series, reflecting the inability of these women to sustain healthcare over a longer period of time. All these women were referrals, belonged to lower socio-economic status and less educated. In a similar follow-up series at

Burkina Faso, only 6 women had died in a cohort of 337 women with SAMM (2%) [12].

The prevalence of adverse health outcomes at 1 year after a life-threatening event was very high, reiterating the need for long-term follow-up. The adverse outcomes were diverse involving various organ systems. Although there was no physical impairment, the loss of the uterus after peripartum hysterectomy was a significant reproductive impairment in three young women. All the women who were re-admitted had an uneventful recovery subsequently. An interesting finding in the exposure group was an abnormal lipid profile in 13.5%, and this warrants further research on its role as a precursor of cardiovascular disease. Sheehan's syndrome is a well-recognised complication of severe hypotension following PPH, and this small series had one woman giving an incidence of 2.63%.

Several women with SAMM had self-reported ill health and varied physical symptoms such as myalgia and weakness. It is likely that these symptoms were a consequence of anaemia, which affected most women in this group, or an effect of the psychological stress they underwent during the life-threatening crisis. Women who experience SAMM had a postpartum depression prevalence rates of 23.68% in comparison with the global prevalence rates of 10–15 and 20–25% in India [16]. There was no statistical difference in the incidence of depression across the groups using a EDPS cut-off score of 13 but women with perinatal loss had a higher mean score of 11.66 and 50% incidence of depression, with suicidal thoughts being

Table 3 Adverse health outcomes at 1-year follow-up

Organ-based morbidity	Exposure group = 38 No (%)	Non-exposure group = 43 No (%)	<i>p</i> value
Haematological	11, 28.94	6, 13.95	0.055
Anaemia (< 11 gm/L)	7, 18.42 [2, 5.26]	6, 13.95 [3, 6.79]	0.402 [0.559]
Thrombocytopenia (< 100,000/cumm or < 10 ⁹ /L)	4, 10.52	0, 0.00	0.044
Cardiovascular system	5, 13.15	0, 0.00	0.019
Abnormal 2D echocardiogram	4, 10.52 [3, 7.89]	0, 0.00 [0, 0.00]	0.044 [0.049]
Hypertension, BP > 140/90 mmHg	2, 5.26 [1, 2.63]	0, 0.00 [0, 0.00]	0.217 [0.469]
Abnormal lipid profile	[5, 13.15]	[0, 0.00]	[0.019]
Central nervous system	1, 2.63	0, 0.00	0.469
Sheehan syndrome	[1, 2.63]	[0, 0.00]	[0.469]
Endocrine	10, 26.3	6, 13.95	0.089
Hypothyroidism (TSH > 5 mIU/L)	7, 18.42 [4, 10.52]	5, 11.62 [5, 11.62]	0.206 [0.579]
Hyperprolactinaemia (> 20 µg/L)	[3, 7.89]	[1, 2.32]	[0.262]
Gastrointestinal	1, 2.63	0, 0.00	0.469
Hyperbilirubinaemia (> 1.2 mg/dL or 20 µmol/L)	[1, 2.63]	[0, 0.00]	[0.469]
Reproductive	12, 31.57	0, 0.00	< 0.001
Abnormal pelvic organ scan	9, 23.68	0, 0.00	< 0.001
Asherman syndrome	2, 5.26	0, 0.00	0.217
Polycystic ovarian disease	7, 18.42	2, 4.65	0.052
Irregular cycles	4, 10.52	0, 0.00	0.044
Amenorrhoea	5, 13.15	0, 0.00	0.019
Hysterectomy	3, 7.89	0, 0.00	0.098
Re-admission to hospital in this 1 year	4, 10.52	0, 0.00	0.044

The numbers in parentheses indicate the newly diagnosed problems at the 1-year follow-up which were not present at the time of occurrence of SAMM

Table 4 EPDS and WHOQOL scores

Outcome	Exposure group <i>N</i> = 38 Mean scores (SD)	Non-exposure group <i>N</i> = 43 Mean scores (SD)	<i>p</i> value
Prevalence of depression at 1 year after delivery (EPDS)			
Mean EPDS score (SD)	7.07 (5.69)	5.67 (5.06)	0.244
Possible depression (<i>n</i> , %)	1, 2.63	3, 6.97	0.356
Depression (<i>n</i> , %)	9, 23.68	5, 11.62	0.127
Suicidal ideations (<i>n</i> , %)	7, 18.42	0, 0	0.001
Quality of life at 1 year after delivery			
Physical life (SD)	65.86 (14.36)	70.84 (17.51)	0.169
Psychological life (SD)	68.11 (17.17)	75.47 (14.59)	0.040
Social life (SD)	79.05 (17.25)	83.58 (11.24)	0.476
Environmental life (SD)	74 (19.9)	80.33 (15.84)	0.160

reported in a third of these women. There was a greater tendency for the non-exposure group to be at the lower end of the scale (< 10). This implies that the women with SAMM may represent an at-risk group, more so if they have suffered a perinatal loss. These findings may reflect a need for emotional support as they recover from the acute life-threatening event. WHOQOL BREF questionnaire revealed poorer quality of life in the exposure group with

statistically significant difference in the psychological domain only again reinforcing the need for psychological support. Long-term morbidity and mortality in India is dependent on access, affordability and availability of healthcare and quality of follow-up services. NFHS-4 (National Family Health Survey, India), for the year 2015–16, has immediate postnatal coverage indicator (2 days) and antenatal care, reported as 62.4% (within

2 days of delivery) and 21% full antenatal care (4 visits, one TT, and iron folic acid for at least 100 days) for India, and 81.8 and 42.2% for Telengana [20]. This study indicates the need for longer duration of postpartum care especially for women with morbidity during pregnancy. This will require a change in current policy that focuses heavily on antenatal care with a short duration of postpartum care. Maternal mortality data would not capture all these deaths which occurred after 42 days of delivery, even though the death was a direct cause of pregnancy.

Strengths of this study were 1-year follow-up in Indian settings and no dropouts. Non-availability of certain investigations such as serum prolactin and echocardiogram at the time of the index pregnancy for the exposure group and lack of baseline organ evaluation tests for the non-exposure group limited comparison with the 1-year assessment. Despite these limitations, this study provides important evidence of adverse health conditions a year after presumed complete recovery from the severe acute morbidity.

Conclusions

The incidence of mortality in these women, the new problems diagnosed a year later and the impact on reproductive health are salient findings of this study. Maternal health programmes have paid little attention to interventions beyond the postpartum period. A national programme to provide for follow-up of these women with medical treatment and psychological support is vital. The results of this study highlight the need for health programmes to focus on maternal health not only in the first 6 weeks postpartum but also beyond for all women with SAMM.

Acknowledgement The authors acknowledge and thank all the women who consented to participate in this study.

Funding The Fernandez Hospital Educational and Research Foundation funded this study, for the laboratory and radiological investigations for the study and non-exposure group. The funding agency had no role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

Compliance with Ethical Standards

Conflict of interest Authors SAA, NA, AT and HKB declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were done after an informed consent and were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The Fernandez Hospital ethical committee (Reg No. ECR/933/Inst/TG/2017) reviewed and approved the protocol (Protocol Ref. No. 32_2014, 19 January 2015 at Fernandez Hospital, Hyderabad, India).

Informed Consent Informed consent was obtained from all individual participants included in the study.

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