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Original Research Article

Sepsis Bundle Approach in Early Recognition and Timely Management of Sepsis in Obstetric Patients

Nidhi Gupta[1], Shubha Srivastava[2], Aruna Kumar[3], Toshi Bansal[4], Priyanka Kanwaria[5]

[1,4,5]Post Graduate Resident, Department of Obstetrics and Gynaecology, Gandhi Medical College, Bhopal
[2]Associate Professor, Department of Obstetrics and Gynaecology, Gandhi Medical College, Bhopal
[3]Director (Regulation and Policy) Public Health and Medical Education (M.P.)

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Corresponding Author: Dr. Nidhi Gupta
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Abstract:

Objective: To study the maternal outcome using "sepsis bundle approach" in obstetric patient with sepsis or septic shock.

Methods: The present study was an observational study on patients presenting with features of sepsis admitted in hospital for management, fulfilling the inclusion and exclusion criteria. A thorough history and physical examination were done. Investigation including serum lactate and blood culture was done. Patients were managed as per the guidelines of sepsis bundle approach and outcome noted in terms of, application of sepsis bundle approach and outcome, blood culture positivity and organism involved, high serum lactate and mortality, duration of ICU stay.

Results: Majority of women with sepsis were post-partum females (53%) belonged to age range of 20 to 24 years (64.7%) and were of lower middle class. Obstetric causes of sepsis were documented in 40 out of 51 cases. Among them, most common diagnosis associated with sepsis was Purpureal pyrexia. Most of the blood culture came out to be sterile (39.2%) and most common organism observed in blood culture was E.coli (31.3%), followed by Klebsiella. About 29 cases (55.9%) cases required fluid resuscitation in addition to broad spectrum antibiotics, of them, 27 patients recovered and mortality was documented in 2 cases. Maternal mortality due to underlying sepsis was documented in 11.8% cases. Serum lactate and WBC count were raised in 83.3% and 100% cases respectively. The observed association of mortality with comorbidities was statistically significant ($p<0.05$).

Conclusion: Obstetric sepsis and septic shock during pregnancy and postpartum period is one of the major contributors of maternal mortality. Using a standardized protocol can help in early identification of sepsis and immediate management can significantly improve maternal outcome, and help in reducing maternal mortality associated with sepsis.

Keywords: Systemic Inflammatory Response Syndrome (SIRS), Sepsis bundle approach, Maternal sepsis, obstetric mortality, feto-maternal outcome, World Health Organization's Global Sepsis Study (GLOSS).

Introduction

Sepsis in obstetric care is a critical life-threatening condition that poses a significant threat to the health and well-being of not only the pregnant women but also to their unborn child. Maternal sepsis is defined as sepsis with its onset during the pregnancy or post-partum period. It is a severe infection that can rapidly progress, leading to organ failure and even death if not promptly diagnosed and treated. Sepsis has been described in 3 stages namely sepsis, severe sepsis and septic shock. Septic shock can be further categorized into two phases, warm shock, which is compensated hyperdynamic and cold shock, which is uncompensated characterized by decreased cardiac output.[1,2]

Obstetric sepsis used to be one of the main causes of maternal death in the past, before the development of modern medicine and hygiene practices. Globally, maternal sepsis is the third major contributor to maternal mortality after haemorrhage and hypertensive diseases, attributing to 4.7% & 10.7% of maternal deaths in developed and developing countries respectively. In India, maternal mortality ratio has declined from 130 in 2014-2016 to 97 in 2018-20. According to Special bulletin on MMR in India (2018-20), the MMR in Madhya Pradesh (173) is much higher than National MMR (97). [3-5]

The diagnosis of maternal sepsis may be challenging as the typical signs and symptoms of maternal sepsis are masked due to the usual physiologic adaptations of pregnancy. Many management protocols have been used and the latest is "Hour – one – bundle" approach which was initiated in 2018. The utility of

care bundle approach in management of maternal sepsis, reducing obstetric mortality and improving feto-maternal outcome has been clearly established in high-income countries. The data regarding the role of sepsis bundle approach in care of maternal sepsis in low- and middle-income countries is scarce. With the above background, the present study was conducted at our tertiary care centre to analyse the effect of sepsis bundle approach in reducing the maternal morbidly and mortality in obstetric patients.[6-8]

Materials and Methods

The present study was an observational study on patients presenting with features of sepsis in The Department of Obstetrics and Gynaecology, Gandhi Medical College, Bhopal. Study population was all obstetric patients presenting with features of sepsis in the Department of Obstetrics and Gynaecology. The study was conducted for 18 months.

There were 51 Obstetric patients with features of sepsis were observed for the outcome after using '1 hour bundle'.

Inclusion and Exclusion Criteria

Inclusion Criteria

- All Obstetric patients with features of sepsis and septic shock admitted in hospital, in terms of -

1) SEPSIS

   1. Having suspected infection
   2. Having q SOFA score ≥ 2 [RR≥ 22/min, Systolic blood pressure ≤ 100mmHg, Mental status change

2) SEPTIC SHOCK

   1. Having sepsis
   2. Hypotension requiring vasopressor therapy to maintain a mean arterial blood pressure of 65mmHg or greater.
   3. Serum lactate level greater than 4 mmol/L even after adequate fluid resuscitation.

Exclusion Criteria

- Patients in shock due to other causes like-hypovolumic shock, Hemomorrhagic Shock, Cardiogenic shock, Neurogenic Shock etc.
- Patients not willing to participate.

Methodology

After receiving ethical clearance from the institute's ethical committee, all patients who fulfilled the inclusion criteria and agreed to take part in the study were included. Using the information received from the valid proforma, a thorough history pertaining to sociodemographic factors including name, age, address, and socioeconomic status was acquired. A thorough obstetric history regarding place of delivery, home or hospital deliveries, abortion and its method. In addition, pertinent past events, individual histories, and family histories were recorded. Patients underwent per vaginal, systemic, and general physical examinations and investigated according to the protocol. It was also observed that by using sepsis bundle approach as per guidelines, can we decrease the mortality or morbidity. The maternal outcome was noted.

Special emphasis given on –

1. Serum lactate levels
2. Blood culture.

Observations

Table 1: Distribution of Cases According To Age

Age (years)	Number of patients (n=51)	Percentage (%)
20-24	33	64.7%
25-29	9	17.6%
>30	9	17.6%
Mean ± SD	24.88 ± 5.72	

Table 2: Distribution According To Socioeconomic Status

Social economic Status	Number of patients (n=51)	Percentage
Upper	0	0%
Upper Middle	1	1.9%
Lower Middle	20	39.2%
Upper Lower	24	47.1%
Lower	6	11.8%

Table 3: Distribution According To Period Of Gestation

Period Of Gestation	Number of patients (n=51)	Percentage
Post abortion	10	19.6%
Preterm pregnancy (< 36+6 weeks)	11	21.5%
Term pregnancy	3	5.9%
Post vaginal delivery	8	15.7%
Post LSCS	19	37.3%

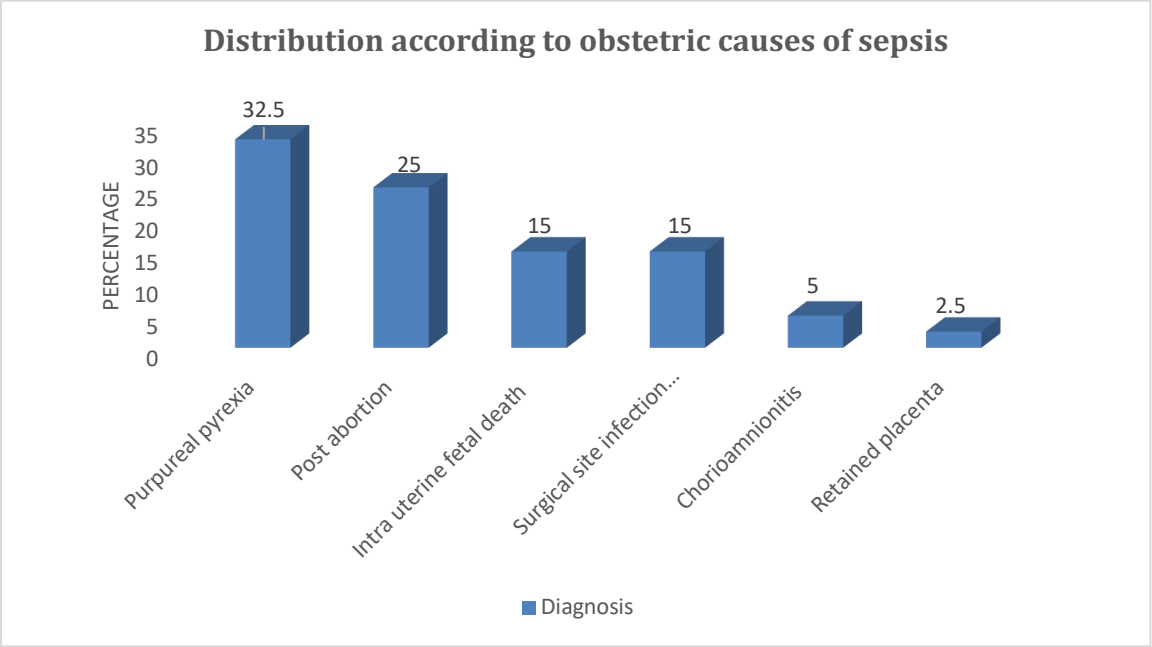

Figure 1: Distribution according to obstetric causes of sepsis

Table 4: Management Using Sepsis Bundle Approach.

Sepsis Bundle approach	Number of patients	%	Patient recovered	Mortality
1.Serum lactate 2.blood culture 3.broadspectrum antibiotics	07	13.7%	07	00
1.Serum lactate 2.blood culture 3.broadspectrum antibiotics 4.fluid resuscitation	29	55.9%	27	02
1.Serum lactate 2.blood culture 3.broadspectrum antibiotics 4.Fluid resuscitation 5.Ionotropic support	15	29.4%	11	04
χ^2	**3.51**			
P value	**0.03**			

Table 5: Distribution According To Length Of ICU Stay

Duration of ICU stay	Number of patients (n=51)	Percentage
<3days	22	43.1%
≥3days	29	56.9%

Table 6: Distribution According To Maternal Mortality Attributed To Sepsis

Mortality	Number of patients (n=51)	Percentage
No	45	88.2%
Yes	6	11.8%

Table 7: Distribution According To Blood Culture

Blood Culture	Number of patients (n=51)	Percentage
Escherichia coli	16	31.3%
Klebsiella	5	9.8%
Methicillin resistant Staphylococcus aureus	4	7.8%
Proteus spp.	2	3.9%
Streptococcus spp.	4	7.8%
Sterile	20	39.2%

Table 8: Correlation Of Investigations Among Maternal Deaths Due To Sepsis.

Investigation	Frequency (n=6)	Percentage	χ^2	P value
Serum lactate ≥4 mmol/L	5	83.3%	**4.39**	**0.04**
WBC count > 20,000/cumm	6	100%	**16.32**	**0.001**
Blood culture positivity	4	66.6%	0.17	0.67

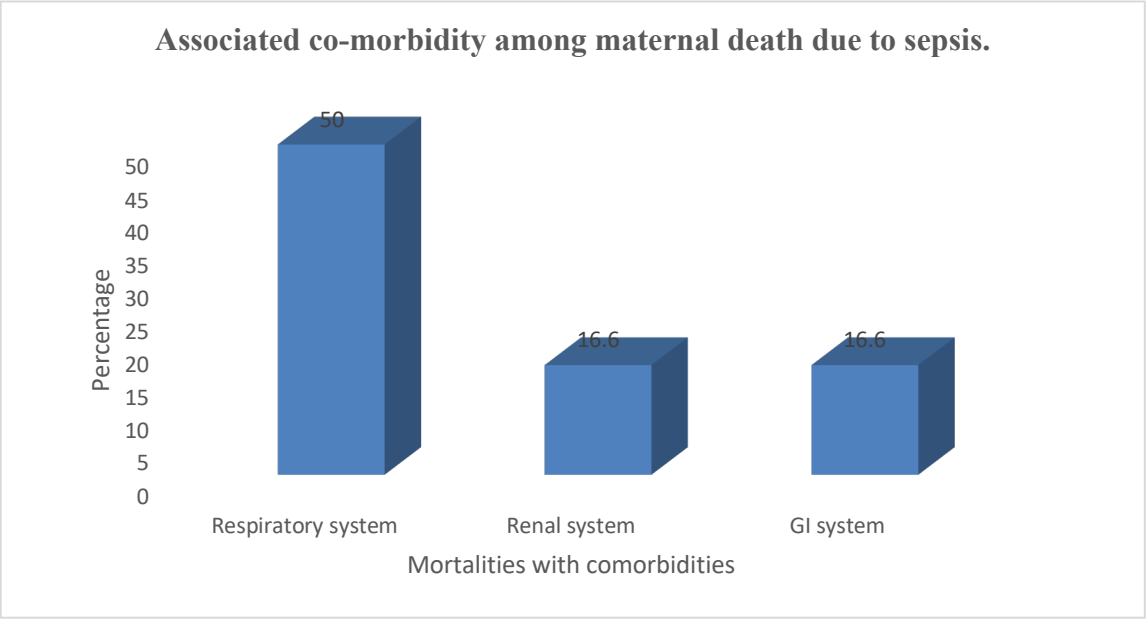

Figure 2: Associated co-morbidity among maternal death due to sepsis.

Results

- Mean age of patients enrolled in our study was 24.88±5.72 years and majority of them belonged to age range of 20 to 24 years (64.7%). About 47.1% cases belonged to upper lower socioeconomic class whereas 39.2% belonged to lower middle socioeconomic class. Only 11.8% and 1.9% cases belonged to lower and upper middle class respectively.
- Majority of women with sepsis were post-partum females (53%) out of them, post LSCS cases contributed to 37.3% of the study population and postnatal cases following normal vaginal delivery contributed to 15.7% of the cases. Among them, most common diagnosis associated with sepsis was Purpureal pyrexia in 32.5% cases, followed by Post abortion sepsis (25%).
- Serum lactate levels were less than 2 mmol/L in 11.8% cases whereas serum lactate levels were more than 4 mmol/L in 60.8% cases.
- Most common organism observed in blood culture was E. coli (31.3%), followed by Klebsiella (9.8%), streptococcus spp. (7.8%) and MRSA (7.8%). Proteus spp. was observed in 3.9% cases. Blood culture was sterile in 39.2% cases.
- In our study, 7 (13.7%) patients were managed with broad spectrum antibiotics based upon sepsis bundle approach and all of them recovered. About 29 cases (55.9%) cases required fluid resuscitation in addition to broad spectrum antibiotics, of them, 27 patients recovered, and mortality was documented in 2 cases. About 15 cases required ionotropic support, of them 11 cases recovered, and 4 cases succumbed to death.
- Duration of ICU stay was up to and more than 3 days in 56.9% cases with sepsis whereas it was less than 3 days in 43.1% cases.
- Maternal mortality due to underlying sepsis was documented in 11.8% cases in our study out of them, 5.9%, 3.9% and 1.9% were postpartum, post abortion and antenatal cases respectively. Out of 51 cases we encountered death in 6 patients. Serum lactate and WBC count were raised in 83.3% and 100% cases respectively. Blood culture came out to be positive in 66.6% cases. Mortality was significantly associated with serum lactate levels of more than 4 mmol/L and WBC count of more than 20000/cu.mm ($p<0.05$). However, no such association was observed with blood culture positivity ($p>0.05$).

Statistical Analysis

Data was compiled using MsExcel and analysed using IBM SPSS software version 20. Categorical variables were expressed as frequency and proportion whereas numerical variables were expressed as mean and standard deviation. Association of outcome with various parameters was assessed using

chi square test. P value of less than 0.05 was considered statistically significant.

Discussion

Maternal sepsis is one of the common causes associated with maternal morbidity and mortality, which also poses a significant threat to the health and well-being of unborn neonates. All normal physiologic measures of pregnancy coincide with the Systemic Inflammatory Response Syndrome (SIRS) criteria, which have low specificity for identifying sepsis in all patient categories. Second, the obstetric population is not included in the modern definition of sepsis for the general population. Lastly, there is currently no definition of obstetric sepsis that covers the ante-, intra-, and postpartum phases of pregnancy. Hence maternal sepsis and obstetric infections must be studied furthermore as critical aspects of maternal health.[7-9]

For tackling the high maternal morbidity and mortality associated with sepsis, it is important to identify the developing sepsis early and initiate appropriate management as early as possible. To improve the feto-maternal outcome, use of sepsis bundle approach within one hour of admission has been recommended in patients presenting with clinical features suggestive of sepsis or septic shock. The goal of the sepsis bundle approach is to decrease the morbidity and mortality associated with sepsis in obstetric patients by identifying sepsis early and starting treatment on time. Sepsis bundle approach includes 5 measures i.e. measurement of serum lactate levels, obtaining blood culture before initiating antibiotics, administration of broad spectrum antibiotics, fluid resuscitation and inotropic agents. We used sepsis bundle approach to identify and manage mothers with sepsis. We aimed to analyse the effect of sepsis bundle approach in reducing the maternal morbidly and mortality in obstetric patients.[10]

Sociodemographic: The mean age of women was 24.88±5.72 years. Majority of our study participants belonged to age group of 20 to 24 years. Out of 51 cases, majority of patients belonged to lower socioeconomic strata (upper lower- 47.1% and lower 11.8%). These findings were concordant with the findings of Panda SR et al, in which majority of patients with maternal sepsis belonged to age range of 2 to 35 years (73.91%) and 64.13% cases with sepsis belonged to lower socioeconomic status. Similarly, mean age of patients presenting with obstetric sepsis in a study of Saif KM et al was 27.3±4.9 years. The findings of our study were also supported by the findings of Tiwari P et al, in which mean age of patients with obstetric sepsis was 24.7±4.0 years and 60.2% of the patients belonged to 20 to 25 years of age. About 90.2% patients with sepsis belonged to low socioeconomic class. However, the mean age of obstetric patients with sepsis in a study of Ray A et al was 31 years and 70% of the cases belonged to 20 to 40 years of age. Maximum patients in a study of Kumari A et al with sepsis admitted in obstetric care unit belonged to more than 35 years of age (60%). Lin L et al reported Sepsis to be associated with risk factors such as low socioeconomic status, poor nutrition, and older pregnant mothers.[12-17]]

Period of Gestation: Out of 51 cases, 53% cases were post-partum cases. Amongst all cases, 19.6% cases were associated with abortion. Similarly, in a study of Saif KM et al (2013), majority of cases (61.2%) with sepsis presented in postpartum period whereas 38.8% cases with sepsis were antepartum cases. Our study findings were also supported by the findings of Kumari A et al (2018), where, about 58% cases were postnatal, 20% of them were post abortal and 22% cases were antenatal. Kvalvik SA et al (2024) also assessed maternal sepsis in their study and documented that 72% of the cases with maternal sepsis were postpartum, 11% were intrapartum, 11% were antepartum and 6% were postabortal. In a study of Lin L et al (2021), 55% cases with sepsis were antepartum, 42% were postpartum and 2.9% were intrapartum cases. According to them, first and second trimester was associated with higher risk of sepsis ($p<0.05$). [12-18]

Investigations: Procalcitonin, lactate, total leukocyte count, and C-reactive protein are the sepsis biomarkers that are most used in clinical practice. An elevated TLC can also be a common outcome in postpartum women because of the physiological leukocytosis during pregnancy and the aftermath of delivery. When venous lactate levels exceed 2 mmol/L, critical care intervention is required. Goyal P et al (2020) documented that serum lactate levels at 0, 24, and 48 hours were significantly higher in cases of the Intensive Care Unit (ICU) group's that of the Non-ICU group, with values of 6.00±2.46 mmol/l vs 3.25±1.92 mmol/l, 4.44±2.24 mmol/l vs 2.91±1.77 mmol/l, and 5.65±2.91 mmol/l vs 2.99±1.93 mmol/l, respectively. The group that survived had much less lactic acid than the group that died (3.79±0.32 mmol/l versus 7.3±0.56 mmol/l). For predicting ICU admission, a cut-off of 3.8 mmol/l with an area under the curve of 0.814 offers an 84% sensitivity and a 68% specificity. On the other hand, the sensitivity and specificity of Lactic acid value of 4 mmol/l was 78% and 68.1% respectively for ICU admission. In a study of Yousuf S et al , serum lactate levels were assessed in 19 out of 396 patients and among them, serum lactate levels were raised (>4mmol/L) in 12 cases. Ray A et al documented serum lactate levels to be independent predictor of mortality in patients with sepsis. Guwalani P et al observed a significant association of serum lactate level of more than 4 mmol/L with high mortality rate amongst patients with sepsis.[16-19]]

In a study of Lin L et al , blood culture revealed growth of micro-organisms in 72.5% cases, and most common micro-organism associated with obstetric sepsis was Escherichia coli (36.2), followed by Staphylococcus (11.6), enterococcus (5.8%), group A staphylococcus (4.3%) and group B staphylococcus (1.4%).[50] Culture positivity rate in a study of Yousuf S et al (2022), culture positivity rate was 59.1% and most common organism associated with sepsis was E.coli (20.45%), followed by group A staphylococci (11.36%), Klebsiella (6.8%), Pseudomonas (6.81) and Acitenobacter (6.81). Other micro-organisms were Staphylococcus (4.54) and MRSA (2.27). Guwalani P et al reported culture positivity in 23 out of 52 patients with sepsis and E. Coli was the most common micro-organism associated with maternal sepsis (8 out of 23), followed by Klebsiella (7 out of 23). [20-21]

Management Protocol as a Part of Sepsis Bundle Approach and its Impact on Outcome: Out of 51 cases, only 07 cases with sepsis were managed with broad spectrum antibiotics alone whereas 29 cases with lactate levels above 4 mmol/L or hypotension and MAP above 65 mmHg were managed with fluid resuscitation in addition to broad spectrum antibiotics. About 15 patients had MAP below 65mmHg and hence were given inotropic support in addition to fluid resuscitation and antibiotics. Yousuf S et al had similar findings. According to the World Health Organization's Global Sepsis Study (GLOSS), the mortality rate from sepsis in low-income (LIC) and low-middle-income (LMIC) nations ranges from 7 to 14.8%. This is much higher than the 1.1% death rate in upper middle-income (UMIC) countries. [20,21]

Our study is first kind of prospective study in India assessing the utility of sepsis bundle approach in reducing maternal mortality. According to Ahmed SI et al, implementation of FAST-M bundle resulted in decline in maternal mortalities by 9.4% due to sepsis. Lin L et al reported maternal mortality rate of 11.59%, which was concordant with the findings of present study. Most common cause of mortality in a study of Saif KM et al was sepsis (24%) in obstetric ICU, which was much higher as compared to our study, which could be tackled by judicious use of broad-spectrum antibiotics. In present study, length of ICU stay was more than 3 days in 56.9% cases whereas length of hospital stay was more than 7 days in 68.6% cases. Median duration of hospital stay in a study of Lin L et al was 11 days in patients with sepsis, which was much higher in cases with no sepsis (8 days; $p<0.05$). Mean length of ICU stay in a study of Saif KM et al was 2.3±0.9 days. The length of hospital stay was more than 10 days in 19 out of 43 cases in a study of Goyal P et al.[18-21]

Conclusion: Obstetric sepsis and septic shock during pregnancy and postpartum period is one of the major contributors of maternal mortality. Though use of sepsis bundle approach and collection of samples for lactate and blood culture assessment and initiating antibiotics within 1 hour is challenging, improving care and results requires standardizing screening, establishing maternal early warning criteria using a maternal sepsis bundle as we are the tertiary care centre and most of the cases were referred and antibiotics were given already. Due to late and multiple referrals, local infection progresses to bacteraemia, sepsis and septic shock leads to increase risk of maternal morbidity and mortality. However, early identification of sepsis and immediate management can significantly improve maternal outcome, and help in reducing maternal mortality associated with sepsis.

Declarations:

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Availability of data and material: Department of Obstetrics and Gynaecology, Gandhi Medical College, Bhopal

Code availability: Not applicable

Consent to participate: Consent taken

Ethical Consideration: There are no ethical conflicts related to this study.

Consent for publication: Consent taken

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