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Clinical profile and outcome of term asphyxiated neonates in neonatal ICU of rural India

Manish Rasania
M.D (Paediatrics), Professor, Department of Paediatrics, Smt. B K Shah Medical Institute & Research Center, Sumandeep Vidhyapeeth Deemed to Be University, Contribution – concept, planning, data analysis

Pooja Patel
M.D (Paediatrics), Assistant Professor, Department of Paediatrics, Smt. B K Shah Medical Institute & Research Center, Sumandeep Vidhyapeeth Deemed to Be University, Contribution – data interpretation, literature review, manuscript preparation

Shainy Chandna
M.D (Paediatrics), Consultant Paediatrician, Pinjore, Haryana, India, Contribution – data collection, data analysis

Sunil Pathak
DNB (Paediatrics), Professor, Department of Paediatrics, Dr. N. D. Desai faculty of Medical sciences & Research | Dharmsinh Desai University, Nadiyad, India, Contribution – conceptualization, planning, manuscript preparation

Guntupalli Shravya L.
Resident Doctor, Department of Paediatrics, Smt. B K Shah Medical Institute & Research Center Sumandeep Vidhyapeeth Deemed to Be University, India, Contribution – data collection

Bindesh B. Shah
Resident Doctor, Department of Paediatrics, Smt. B K Shah Medical Institute & Research Center, Sumandeep Vidhyapeeth Deemed to Be University, India, Contribution – data collection

Manan Arora
Resident Doctor, Department of Paediatrics, Smt. B K Shah Medical Institute & Research Center, Sumandeep Vidhyapeeth Deemed to Be University, India

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Corresponding author: *Sunil Pathak*
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***Abstract*---**India contributes to one fifth of global live births and more than a quarter of neonatal deaths. Of the total 6.3 million children who died before age 5years, around 2.76 million were neonates, the highest for any country in the world. In India where traditional practices are commonly followed, perinatal asphyxia is an important cause of immediate and long-term morbidity and mortality. To study clinical profile and immediate outcome of term neonates with birth asphyxia. A prospective observational study was conducted in tertiary care NICU of Vadodara district, Gujarat, from May 2017 to June 2018. Full term asphyxiated neonates were included in the study. Risk factors for birth asphyxia, their clinical profile, course and complications were recorded. Immediate outcome of newborns with birth asphyxia outcome was analysed. Out of the total 2702 term live births during the study period, 45 (2.17 %) neonates were born asphyxiated. Most common risk factors were foetal distress 13 (28.89%), intrauterine growth restriction(IUGR) 8(17.78%), meconium stained liquor (MSL) 5(11.11%) cord around neck 9 20.0%), pregnancy induced hypertension (PIH) 5(11.11%) and prolonged labour 9(20%). 20(44.44%) neonates had moderate asphyxia and 25(55.56%) had severe asphyxia. Major complications developed were hypoxic ischemic encephalopathy (HIE) stage II/III 24(53.33%), shock 37(82.22%), acute kidney injury (AKI) 11(24.44%), sepsis 10(22.23%), asphyxiated lung injury/ transient tachypnoea of newborn (TTN) 6(13.33%), persistent pulmonary hypertension of newborn (PPHN) 6(13.33%), hypocalcemia 11(24.44%), hyponatremia 3 (6.66%) and hyperbilirubinemia 6(13.33%). 38(84.44%) were successfully discharged, 3(6.66%) died and 4(8.88%) left against medical advice in moribund state. HIE stage II/III, sepsis, lower APGAR score at 1 and 5 minutes, refractory shock, AKI and requirement of ventilator support ± CPAP were found to have a higher risk of poor outcome. Adequate antenatal care and early detection of maternal high-risk factors, good antenatal and intrapartum monitoring of foetal well-being, timely intervention of at-risk cases, skilled resuscitation personnel, advanced NICU care set up with well trained staff may reduce the incidence & severity of perinatal asphyxia with improved short term and long-term outcome.

***Keywords*---**birth asphyxia, hypoxic ischemic encephalopathy, acute kidney injury, refractory shock.

Introduction

Perinatal asphyxia refers to a condition during the first and second stage of labor in which impaired gas exchange leads to fetal hypoxemia and hypercarbia. It is identified by fetal acidosis as measured in umbilical arterial blood [1]. WHO defines birth asphyxia as Apgar score of less than 7 at 1 minute of age wherein an Apgar of 4-6 is considered moderate birth asphyxia and a score of 3 or lesser is considered severe birth asphyxia [2]. India contributes to one fifth of global live births and more than a quarter of neonatal deaths. Of the total 6.3 million

children who died before age 5years, around 2.76 million were neonates, the highest for any country in the world. Perinatal asphyxia is a common neonatal problem and contributes significantly to neonatal morbidity and mortality globally amounting to 23% of the total neonatal deaths [3]. In India where traditional practices are commonly followed, perinatal asphyxia plays an important role in the neonatal mortality and morbidity. The most serious complication of birth asphyxia is Hypoxic ischemic encephalopathy. Kimberly et al published in 2011 that around 40-60% of asphyxiated children die by 2 years of age or have severe with chronic neurodevelopmental morbidities including cerebral-palsy, mental retardation and learning disabilities which are not only a burden to the individual and the family unit but also to the community [4]. Although, improvements in neonatal health care in the last decade have caused a decline in the neonatal mortality rate, wide disparities are present depending upon the quality and availability of regional health care delivery systems specially in developing countries. Considering above factors, this study was conducted study the risk factors for birth asphyxia in term neonates. Their clinical profile, course of the ailment, complications and Immediate outcome of neonates with birth asphyxia were analysed.

Material and Methods

This is a prospective observational study conducted in tertiary care NICU of Dhiraj Hospital, SBKS Medical Institute & Research Center situated in the Vadodara district, Gujarat, India catering mainly to the rural and lower income population. The study was conducted from May 2017 to June 2018. Study was commenced after approval from the institutional ethics committee. All the inborn full-term neonates with birth asphyxia were included in this study after taking consent from parents. Exclusion criteria included extramurally born neonates, preterm neonates and those with birth weight less than 1.8kg. A newborn was considered to be asphyxiated when 1-minute Apgar score was less than 7. All the asphyxiated neonates were admitted in NICU and were given standard treatment. Facility of hypothermia management for asphyxiated neonates is not available at our hospital. Phenobarbitone was used as a first line anticonvulsant, followed by levetiracetam and midazolam infusion. A structured proforma was used for recording basic demographic profile, risk factors, complications and immediate neonatal outcome.

Statistical analysis

Data collected was entered in Microsoft excel sheet. It was analysed in the form of percentage, mean & standard deviation; and median and IQR. Relative risk and p value calculation was done to find association between variables. Mann Whitney U test was used to find out p value from median.

Result

During the study period, there were 2362 live births in the hospital. 2072 were term neonates. 45 (2.17%) term neonates were asphyxiated.

Table 1
Demographic profile and antepartum risk factors of neonates with birth asphyxia

List of variables	Frequency (N=45)	Percentage
Gender		
Female Male	17 28	37.78% 62.22%
Weight for Gestational age		
AGA SGA LGA	36 8 1	80% 17.78% 2.22%
Gravida		
Primigravida Multigravida	25 20	55.56% 44.44%
ANC		
Inadequate ANC Adequate ANC	09 36	20% 80%
Mode of Delivery		
Normal Vaginal Delivery Assisted Vaginal Delivery LSCS	33 3 9	73.33% 6.67% 20%
Maternal & Foetal Risk Factors		
PIH	5	11.11%
Maternal diabetes	0	
Maternal smoking	0	
Bleeding PV / APH	1	2.22%
Oligohydramnios	1	2.22%
Multiple gestation	0	
PROM>24 Hours	1	2.22%
Maternal fever / UTI / severe infection	0	
Prolonged / obstructed Labour	9	20%
Cord Around the Neck	9	20.00%
Cord Prolapse	1	2.22%
Fetal Distress	13	28.89%
MSL	5	11.11%
Malpresentation	1	2.22%
SGA / IUGR	8	17.78%
Post maturity	0	
Instrumentation (2 forceps, 1 vacuum)	3	6.67%

*, †, ‡, §, | |, , **, ††, ‡‡

Of 45 asphyxiated neonates, 28 (62.22%) were male and 17 (37.78%) were female. 36 (80%) were AGA and 8 (17.78%) were SGA neonates. 9 (20%) received inadequate ANC. WHO guideline defines adequate antenatal care (ANC) or essential obstetric care as 3 or more antenatal visits along with two doses of tetanus toxoid injection and 100 days of iron and folic acid tablets [5].

The presence of fetal distress (28.89%), cord related problems like cord around neck (20%) & prolapsed cord (2.22%), prolonged / obstructed labor (20%), intrauterine growth retarded neonate (17.78%), PIH (11.11%) and MSL (11.11%) were the major risk factors noted in the study.

Table 2
Resuscitation Required & Severity of Asphyxia

List of variables	Frequency (N=45)	Percentage
Resuscitation required		
Stimulation		
Bag & Mask ventilation	45	100.00%
ET Intubation & ventilation	40	88.89%
Chest Compression	15	33.33%
Adrenaline	00	0.00%
	00	0.00%
APGAR Score at 1 min		
Moderate asphyxia(4 – 6)	20	44.44%
Severe asphyxia (0 – 3)	25	55.56%

*, †, ‡, §, | |, , **, ††, ‡‡

Out of the 45 asphyxiated neonates, 40 (88.89%) required bag and mask ventilation and 15 (33.33%) required endotracheal intubation. As per WHO definition of asphyxia based on 1minute Apgar score, 25 (55.56%) were classified as having severe birth asphyxia & 20 (44.44%) as having moderate asphyxia.

Table 3
Complications in Asphyxiated Neonates

Complication	Frequency (n= 45)	Percentage
HIE		
No HIE	21	46.67%
Stage I HIE	0	0.00%
Stage II HIE	19	42.22%
Stage III HIE	5	11.11%
Shock	37	82.22%
Refractory shock	8	17.78%
AKI	11	24.44%
Non Oliguric AKI	10	22.22%
Oliguric AKI	1	2.22%
Asphyxiated lung injury / TTN	6	13.33%
PPHN	6	13.33%
Metabolic complications		
Hypoglycemia	1	2.22%
Hypocalcaemia	11	24.44%
Hyponatremia	3	6.66%
Hyperkalemia	2	4.44%
Septicaemia	7	15.56%
EOS	3	6.67%

LOS		
NEC	0	0%
Thrombocytopenia	8	17.78%
Moderate	4	8.89%
Severe	4	8.89%
DIC	3	6.67%
Hyperbilirubinemia	6	13.33%

*, †, ‡, §, ||, , **, ††, ‡‡

19 (42.22%) developed HIE stage II. 5 (11.11%) developed HIE stage III. 37 (82.22%) of the neonates went into shock state, of which 8 (17.78%) went in to refractory state of shock requiring either adrenaline or noradrenaline infusion. 11 (24.44%) developed AKI; of which majority (10) had non oliguric AKI. Major metabolic complication was hypocalcemia in 11 (24.44%), followed by hyponatremia and hyperkalemia in 3 (6.67%) & 2 (4.44%) respectively. 7 (15.56%) had early onset sepsis, 3 (6.67%) developed late onset sepsis.

Table 4
Outcome and Duration of Stay

List of variables	Frequency (n=45)	Percentage
Hospital Stay		
< 7 Days	20	44.44%
7 to 14 Days	20	44.44%
> 14 Days	05	11.11%
Outcome		
Discharge	38	84.44%
LAMA in non-moribund state	00	0.00%
LAMA in moribund state	04	8.88%
Death	03	6.66%
Neurological abnormality on discharge (n=38)		
Yes	01	2.63%
No	37	97.37%

*, †, ‡, §, ||, , **, ††, ‡‡

38 (84.44%) participants were discharged. 3 (6.66%) died. 4 (8.88%) left against medical advice, all left in moribund state. Of discharged neonates, 1 (2.70 %) had persistent neurological abnormalities on discharge.

Table 5
Comparison between Various Factors with Outcome

Parameters(N=45)	Poor Outcome (Death + LAMA in moribund state) (N=07)	Good Outcome (Discharged) (N=38)	Relative risk
GENDER			
Female (17) Male (28)	5 (29.41%) 2 (7.14%)	12 (70.59%) 26 (92.86%)	4.12 (95% CI 0.9 – 18.92), p=0.07

WEIGHT FOR GESTATIONAL AGE			
SGA (8) AGA (36) LGA (1)	3 (37.5%) 4 (11.11%) 0	5 (62.5%) 32 (88.89%) 1	3.38 (95% CI 0.93 – 12.21), p=0.064
PARITY			
Primi (25) Multi (20)	5 (20%) 2 (10%)	20 (80%) 18 (90%)	2.0 (95% CI 0.43 – 9.24), p=0.37
ANTENATAL CARE			
Inadequate ANC (9) Adequate ANC (36)	1 (11.11%) 6 (16.67%)	8 (88.89%) 30 (83.33%)	0.67 (95% CI 0.09 – 4.86), p=0.69
MODE OF DELIVERY			
Instrumentation / LSCS (12) Normal Delivery (33)	3 (25%) 4 (12.13%)	9 (75%) 29 (87.87%)	2.06 (95% CI, 0.54 - 7.9), p=0.29
SEVERITY OF ASPHYXIA			
Severe Asphyxia (25) Moderate Asphyxia (20)	6 (24%) 1 (5%)	19 (76%) 19 (95%)	4.8 (95% CI 0.63 – 36.68), p=0.13
HIE STAGING			
Stage III (5) Stage II (19)	3 (60%) 4 (21.05%)	2 (40%) 15 (78.95%)	2.85 (95% CI 0.92 – 8.8), p=0.07
Stage II / III HIE (24) No HIE (21)	7 (29.17%) 0 (0%)	18 (70.83%) 21(100%)	12.69 (95% CI 0.77 – 209.95), p=0.076
SEPTICEMIA			
Yes (10) No (35)	4 (40%) 3 (8.57%)	6 (60%) 32 (91.43%)	4.67 (95% CI 1.24 – 17.5), p=0.02
Acute Kidney Injury			
Yes (11) No (34)	5 (45.45%) 2 (5.8%)	6 (54.54%) 32 (94.11%)	7.72 (95% CI, 1.73 -34.3), p=0.007
SHOCK			
Refractory Shock requiring adrenaline / noradrenaline (8) Shock requiring dopamine / dobutamine / both (29)	5 (62.5%) 2 (6.9%)	3 (37.5%) 27 (93.1%)	9.06 (95% CI 2.15 – 38.29), p=0.003
Need of inotropes (37) No need of inotropes (8)	7 (18.92%) 0 (0%)	30 (81.08%) 8 (100%)	3.55 (95% CI 0.22 – 56.64), p=0.37
RESPIRATORY SUPPORT			
Ventilator with or without CPAP (18) CPAP alone (11)	7 (38.89%) 0 (0%)	11 (61.11%) 11 (100%)	9.47 (95% CI 0.59 – 151.19), p=0.11
Need of CPAP / Ventilator / both (29) No need of CPAP / Ventilator (16)	7 (24.14%) 0 (0%)	22 (75.86%) 16 (100%)	8.5 (95% CI 0.52 – 139.81), p=0.13

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Relative risk of poor outcome was statistically significant in asphyxiated neonates with sepsis compared those without sepsis (p value 0.02), those with AKI compared to not having AKI (p value 0.007) and those having refractory shock (p

value 0.003). relative risk of poor outcome was statistically mildly significant in female neonates compared to male, SGA neonates compared to AGA, neonates having HIE stage III compared to HIE stage II, neonates having HIE stage II or III compared to no HIE.

Table 6
Correlation of Various Parameters with Outcome

Parameter	Poor outcome (n=7)	Good outcome (n=38)	P value
Gestational age	38.71 (0.7)*	38.03 (0.28)*	0.0001
Birth weight	2.46 (0.43)*	2.62 (0.35)*	0.29
APGAR at 1 minutes	2.71 (0.7)	3.71 (1.23)	0.044
APGAR at 5 minutes	5.14 (0.99)*	6.47 (1.6)*	0.04
Male	2 (28.57%)	26 (68.42%)	0.048
Female	5 (71.43%)	12 (31.58%)	0.048
AGA	4 (57.14%)	32 (84.21%)	0.1
SGA	3 (42.86%)	5 (13.16%)	0.06
Normal Delivery	4 (57.14%)	29 (76.32%)	0.3
LSCS /Instrumental	3 (42.86%)	9 (23.68%)	0.3
HIE II	4 (57.14%)	15 (39.47%)	0.39
HIE III	3 (42.86%)	2 (5.26%)	0.004
HIE II / III	7 (100%)	17 (44.74%)	0.008
No HIE	0 (0%)	21 (100%)	<0.0001
Sepsis	4 (57.14%)	6 (15.79%)	0.017
Acute Kidney Injury	5 (71.43%)	6 (15.79%)	0.001
Refractory shock	5 (71.43%)	3 (7.89%)	0.0001
Shock requiring dopamine / dobutamine / both	2 (28.57%)	27 (71.05%)	0.03
Need of inotropes	7 (100%)	30 (78.95%)	0.19
No need of inotropes	0 (0%)	8 (21.05%)	0.19
Average duration of stay (days)	7.86 (10.12)*	8.55 (5.40)*	0.79
	4 (2-7)**	7 (5-10)**	0.12#
Ventilator ± CPAP	07 (100%)	11 (28.95%)	0.0005
CPAP alone	0 (0%)	11 (28.95%)	0.11
No Ventilator / CPAP	0 (0%)	16 (42.11%)	0.03
Average duration of Ventilator ±CPAP	6.71 (8.89)*	3.41 (1.92)*	0.04
	3 (2 – 5.5)**	2 (2 – 5.5)**	0.82#

*, †, ‡, §, ||, , **, ††, ‡‡ (*Values represented as mean (standard deviation), **Values represented as median (IR), #Mann Whitney U test)

Mean gestational age was 38.71 (0.7) in neonates with good outcome, as against mean gestational age of 38.03 (0.28) in neonates with poor outcome; p value 0.0001. Mean Apgar at both 1 minute and 5 minutes both were statistically significant between those with poor outcome and good outcome; lower the score more likely poor outcome. Female neonates, those with HIE stage III or combined HIE III or II, sepsis, AKI, shock, need of ventilator with or without CPAP were

significantly more associated with poor outcome. SGA neonates are marginally more associated with poor outcome with p value of 0.06; mildly significant. Male neonates, neonates without development of HIE, neonates not in need of ventilator or CPAP are statistically significantly associated with good outcome. Both duration of hospital stay and duration of ventilation with or without CPAP were not much different between those with poor outcome and good outcome.

Discussion

During the study period, there were 2362 live births in the hospital. 2072 were term neonates. 45 (2.17%) term neonates were asphyxiated. This prevalence is lesser than that of studies conducted in Ethiopia (29%), Japan (0.4%), Egypt(4.5%) and United Kingdom(2%) [6-9]. Similarly, within India a study from Uttarakhand has reported a birth asphyxia incidence of 18.5% [10]. In comparison, a study from Andhra Pradesh has reported an incidence of 6.6 % [11]. This vast disparity in the prevalence can be attributed to the differences in availability of health services and quality of health services, as also socioeconomical and educational background of the people in a particular country or region. One of the reasons for low incidence in the present study could be that only full term asphyxiated neonates were included in the study. A male preponderance was noted in the present study where in 62.22% of the asphyxiated neonates were males. Further, 73.33% were normal vaginal delivered, 6.67% were assisted vaginal delivered and 20.00% were LSCS delivered This is similar to findings of an Iranian study which noted that 64% were males and 36% were female; where in common mode of delivery in asphyxiated neonates was spontaneous vaginal delivery in 44.39%. 32.14% were LSCS delivered and 23.47% were assisted vaginal delivered [12].

In an observational prospective study from Maharashtra, India; the most common maternal risk factor observed was PIH followed by oligohydramnios, multiple gestation, PROM, DM and UTI. IUGR was the most common fetal risk factor followed by fetal distress, MAS and malpresentation. Furthermore, they noted that 1/3rd of neonates requiring resuscitation were born to unbooked mothers [13]. We also found a similar pattern of risk factors in our study wherein foetal distress (28.89%), cord around neck (20.00%), intrauterine growth retardation (17.78%) and meconium-stained liquor (11.11%) were the most common foetal risk factor and prolonged labour (20%) and PIH (11.1%) were the most frequent maternal risk factors encountered. Similarly, in a study by Gebrihiwot et al. in northern Ethiopia prolonged labour, presence of meconium and preeclampsia were determinant as risk factors for asphyxia [14]. In a study by Abdo et al in south Ethiopia, factors that were significantly associated with birth asphyxia included mothers aged ≥35, primigravida, prolonged second stage of labour, preterm birth, meconium stained amniotic fluid and tight nuchal cord [15].

In the present study, CNS involvement was seen in 53.33%, renal involvement in 24.44%, metabolic involvement in 26.66% and respiratory involvement in 26.66% and shock with probable CVS involvement in 82.22%. In comparison, P. Shah et al noted CNS involvement in 88%, renal involvement in 70% and CVS involvement in 62% [16]. In the present study, 44.44% had moderate birth asphyxia and 55.56% had severe birth asphyxia on the basis of Apgar score at 1 minute. Out of

neonates with moderate birth asphyxia, 25% had Stage II HIE, 75% had no HIE, and none developed HIE stage III. Out of the severe asphyxiated neonates, 56% had stage II HIE, 20% had Stage III HIE and 24% had no HIE. All the neonates who progressed to HIE stage III had severe asphyxia. In a study by Uchennaet al of total 161 asphyxiated newborns, APGAR scores were suggestive of severe asphyxia in 10%, moderate asphyxia in 22%. Sarnat stages were stage III in 24%, stage II in 52%, stage I in 25% [17].

In our study, 84.44% were successfully discharged, 6.66% died and 8.88% left against medical advice in moribund state. Poor immediate outcome in the form of death & LAMA in moribund state was in 15.56%. In a study by Rakesh Kumar et al, 70.79% of inborn asphyxiated neonates were discharged successfully [10]. In a study by Amritanshu et al , 10% of asphyxiated babies were expired [18]. In a study by Gebrihiwot et al, case fatality rate of perinatal asphyxia was 37.5% [14]. We analysed and compared various parameters for risk of poor outcome, as also any association of parameter with either poor or good outcome. Low APGAR score at 1 and 5 minutes of life was found to be statistically significantly associated with poor outcome, p value 0.02 [19]. A statistically significant risk of poor outcome was noted in neonates who developed HIE stage II/III in the present study. Similar findings were noted in a study from Bihar wherein they found the presence of HIE II/III to be a risk factor for mortality [18]. A study from Cameroon also noted that high Sarnat scores were related to high risk of mortality [20].

We found that neonates who had refractory shock were shown to have a 9 times higher risk of poor outcome as compared to neonates without refractory shock; and this was statistically significant. (p=0.003). Presence of shock and in particularly refractory shock was found to have significant association with poor outcome; p value 0.03 and 0.0001 respectively. In a study by Amritanshu et al from Bihar, India; the presence of hypotension was found to be a predictor of poor outcome. The same study also found that birth injury, cord accidents, hypothermia, hypoglycaemia and hypoxemia were significantly associated with a risk of poor outcome and mortality [18]. Similarly, the development of sepsis was found to be related to a higher risk of poor outcome and this difference was found to be statistically significant with a p value of 0.01. Presence of AKI was also significantly related with poor outcome, p value 0.001. Need for ventilation with or without CPAP was a statistically significant risk factor for poor outcome (p value 0.005). Marginally increased risk of poor outcome were noted among SGA neonates, p value 0.06.

Surprisingly, we noted that even though males have a higher risk of developing birth asphyxia; immediate outcome was far better than females. In comparison Rakesh Kumar et al. did not find the sex of the neonate to be a significant predictor of outcome [10]. In this study Apgar score was used to diagnose asphyxia, and to classify severity of asphyxia. Inability to perform routine cord blood gases in the asphyxiated neonates due to limited resources was a limitation of our study. As also a modest sample size was the limiting factor for the study. We aimed for immediate neonatal outcome, and so long-term neurodevelopmental monitoring was not included.

Conclusion

Birth asphyxia remains a major cause of morbidity and mortality in India, especially in rural areas. Important risk factors associated with birth asphyxia are prolonged labour, PIH, foetal distress, cord around neck, MSL and intrauterine growth retardation. Presence of HIE stage II / III, shock, sepsis, AKI and need of ventilator with or without CPAP are associated with poor immediate outcome. Apart from high immediate mortality, serious and debilitating long term sequelae are of great concern. Prevention of birth asphyxia is necessary. Adequate antenatal care and early detection of maternal high-risk factors, good antenatal and intrapartum monitoring of foetal well-being, timely intervention of at risk cases, skilled resuscitation personnel, advanced NICU care set up with well trained staff may reduce the incidence & severity of perinatal asphyxia with improved short term and long-term outcome. The results of this study will help policy makers and program designers to focus on the areas to be looked after more vigilantly.

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