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CLINICAL ARTICLE

Obstetrics

Maternal and fetal factors associated with stillbirth in singleton pregnancies in 13 hospitals across six states in India: A prospective cohort study

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Abstract

Objective: This study aimed to investigate the incidence of and risk factors for stillbirth in an Indian population.

Methods: We conducted a secondary data analysis of a hospital-based cohort from the Maternal and Perinatal Health Research collaboration, India (MaatHRI), including pregnant women who gave birth between October 2018–September 2023. Data from 9823 singleton pregnancies recruited from 13 hospitals across six Indian states were included. Univariable and multivariable Poisson regression analysis were performed to examine the relationship between stillbirth and potential risk factors. Model prediction was assessed using the area under the receiver-operating characteristic (AUROC) curve.

Results: There were 216 stillbirths (48 antepartum and 168 intrapartum) in the study population, representing an overall stillbirth rate of 22.0 per 1000 total births (95% confidence interval [CI]: 19.2–25.1). Modifiable risk factors for stillbirth were: receiving less than four antenatal check-ups (adjusted relative risk [aRR]: 1.75, 95% CI: 1.25–2.47), not taking any iron and folic acid supplementation during pregnancy (aRR: 7.23, 95% CI: 2.12–45.33) and having severe anemia in the third trimester (aRR: 3.37, 95% CI: 1.97–6.11). Having pregnancy/fetal complications such as hypertensive disorders of pregnancy (aRR: 1.59, 95% CI: 1.03–2.36), preterm birth (aRR: 4.41, 95% CI: 3.21–6.08) and birth weight below the 10th percentile for gestational age (aRR: 1.35, 95% CI: 1.02–1.79) were also associated with an increased risk of stillbirth. Identified risk factors explained 78.2% (95% CI: 75.0%–81.4%) of the risk of stillbirth in the population.

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Conclusion: Addressing potentially modifiable antenatal factors could reduce the risk of stillbirths in India.

KEYWORDS
cohort study, India, risk factors, singleton pregnancies, stillbirth

1 | INTRODUCTION

The global burden of stillbirths remains a significant public health concern, with an estimated 1.9 million babies being stillborn annually.[1] In 2021, the global stillbirth rate reached 13.9 per 1000 total births, with a significant concentration of stillbirths in sub-Saharan Africa and South Asia, collectively accounting for three-quarters of all stillbirths.[1] The emotional implications for affected families, coupled with negative consequences for communities, healthcare providers, and economies, underscores the urgency of addressing this issue.[2]

Despite the profound impact of stillbirths, this issue has received inadequate attention on the global health agenda, particularly in comparison to maternal and child mortality.[3–5] Notably, stillbirth-specific targets were conspicuously absent from the 2030 Agenda for Sustainable Development Goals.

In India, the scale of the problem is particularly alarming, with an estimated 286 482 stillbirths in 2021, consistently ranking the nation first in the absolute number of stillbirths for over two decades.[1,5] This is despite commendable progress made in reducing stillbirth rates over the past two decades, with the rate declining from 29.6 per 1000 births in 2000 to 13.9 per 1000 births in 2019.[5] Recognizing stillbirths as a persistent public health challenge, India launched the India Newborn Action Plan (INAP) with the ambitious goal of reducing the stillbirth rate to less than 10 per 1000 births by 2030.[6]

To date, various types of studies, including population surveillance,[7,8] case series,[9] cross-sectional[10] and case–control studies[11] have explored risk factors or spatial patterns influencing stillbirths in India. One of these studies has identified pregnancy complications such as anemia and hypertensive disorders of pregnancy (HDP) as risk factors amenable to interventions.[10] However, these studies adopted study designs susceptible to bias or were primarily descriptive in nature.

To address these limitations, this study focused on a hospital-based cohort of singleton pregnancies to investigate the incidence of and risk factors for stillbirths in an Indian population. The primary objectives of this study were to calculate overall stillbirth (ante- and intrapartum) rates per 1000 total births in 13 hospitals across six states in India and to investigate the maternal and fetal characteristics associated with stillbirths in this population.

TABLE 1 Characteristics of 13 MaatHRI hospitals.

Maternal care functions	*N* (%)
Skilled staff available 24 h	13 (100.0)
Access to operating theater	13 (100.0)
Functional ambulance available	13 (100.0)
Electricity always available	13 (100.0)
Reliable access to clean water	13 (100.0)
Infection control	13 (100.0)
Partograph use	13 (100.0)
Cardiotocography (CTG) monitors	11 (84.6)
Hand-held dopplers	11 (84.6)
Emergency carts	13 (100.0)
Functional blood bank	12 (92.3)
Anesthetic care (by technicians or anesthetists)	13 (100.0)
Fridge for storage of drugs	13 (100.0)
Neonatal Intensive Care Unit (NICU)	12 (92.3)
Removal of retained products	13 (100.0)
Parenteral oxytocin	13 (100.0)
Parenteral magnesium sulfate	13 (100.0)
Manual removal of placenta	12 (92.3)
Parenteral antibiotics	13 (100.0)

2 | MATERIALS AND METHODS

2.1 | Study design

This study was a secondary data analysis of a hospital-based cohort from the Maternal and Perinatal Health Research collaboration, India (MaatHRI). MaaatHRI has 16 collaborating hospitals in six states in India (Assam, Meghalaya, Maharashtra, Uttar Pradesh, Himachal Pradesh and Chhattisgarh) and 13 of these hospitals participate in epidemiological studies.[12] This cohort study was originally designed to investigate the risk factors for postpartum hemorrhage in an Indian population.

The hospital-based prospective cohort study collected data on births between October 2018 and September 2023 in 13 of the MaatHRI collaborating hospitals that participate in

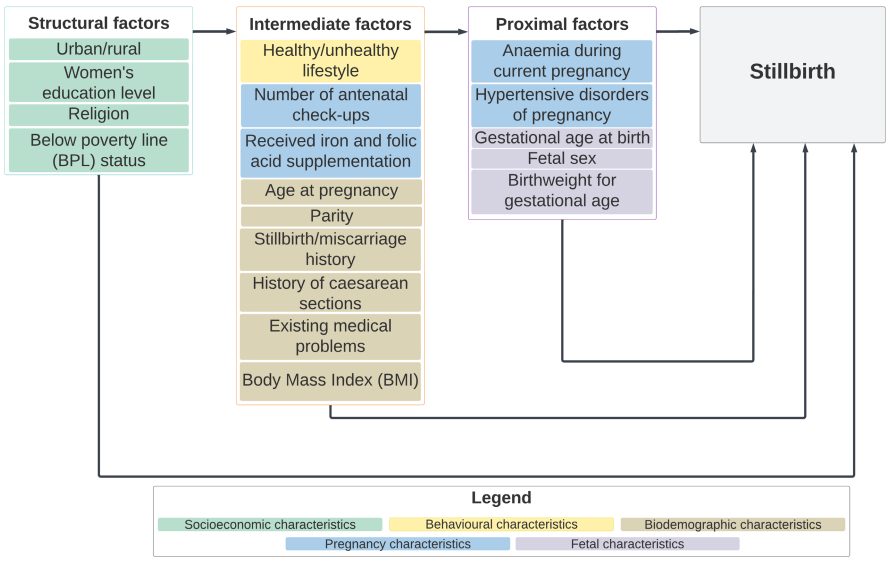

FIGURE 1 Hypothesized relationship between the structural, intermediate and proximal factors and stillbirth.

epidemiological research (9 medical colleges, 4 community hospitals) across six states in India. All 13 hospitals have adequate facilities for providing maternal and newborn care, and Table 1 describes the characteristics of included MaatHRI hospitals. In this cohort study, pregnant women more than 28 weeks of gestational age, aged 18 years or older and planning a vaginal birth in the 13 hospitals were approached to participate. Women were excluded if they were under 18 years of age, if they were unwilling to provide informed consent or were planning a cesarean section at the time of the recruitment.

Out of 10064 women, 99.9% of women ($N = 10056$) consented to participate, and their baseline information including sociodemographic characteristics, previous and current pregnancy problems, medical comorbidities and other pregnancy characteristics were collected by the research nurses. Hemoglobin (Hb) concentration in the third trimester was measured by collecting, processing and analyzing women's blood samples at the time of recruitment and by using their most recent routine Hb record. The women were followed-up during labor and childbirth and up to 48 h postpartum.

2.2 | Inclusion and exclusion criteria

All singleton pregnancies where the outcome of the fetus was available were included in this study. Women with multiple pregnancies and those with missing fetal outcomes, such as due to lost to follow-up were excluded.

2.3 | Outcome variable

The outcome variable was stillbirth, defined as any fetal death that occurred at or beyond 28 completed weeks' of gestation.[13] Stillbirths were categorized into ante- and intrapartum stillbirths and this information was derived from the free text data related to the reasons/indications for cesarean section, induction and augmentation of labor, and/or details of maternal/fetal complications.

2.4 | Exposure variables

Exposure variables were grouped as socioeconomic, behavioral, biodemographic, pregnancy, and fetal characteristics. These variables were selected if there was likely clinical relevance and/or if they were found as significant risk factors for stillbirth in the literature.[7–11,14–16]

For socioeconomic characteristics, below the poverty line (BPL) status was selected as a proxy for assessing income level. The Planning Commission of India defined BPL households as households (average five family members) with a per capita consumption expenditure of Indian Rupees (INR) 816.00 on a monthly basis in rural areas and an expenditure of INR 1000.00 in urban areas using the Tendulkar methodology.[17]

For behavioral characteristics, unhealthy lifestyle during pregnancy was defined as smoking, chewing betel nuts, or consuming tobacco and/or alcohol.

For biodemographic characteristics, women's age at the time of recruitment was categorized into five groups (<20, 20–24, 25–29, 30–34, >34) and age group 20–24 was selected as the reference group to examine the potential associations between teenage pregnancy and stillbirth.

Introduced in 2002, the WHO's Focused Antenatal Care model recommends pregnant women receive at least four comprehensive antenatal check-ups.[18] Thus, the number of antenatal check-ups were categorized into three groups: 0–1, 2–3, and 4 or more, with four or more check-ups serving as the reference group. Levels of severity of anemia were defined using the WHO definition for Hb cutoffs[19]: mild anemia 10–10.9 g/dL, moderate 7–9.9 g/dL, and severe <7 g/dL.

Gestational age at birth was categorized according to the recommendation by Spong[20] recognizing that the risk of stillbirth can vary even within the "term" pregnancy, with a 5-week gestational age range. Hence, the early term was defined as $37^{0/7}$ to $38^{6/7}$ weeks. Birth weight for gestational age, gender-specific z-scores and centiles were generated using the INTERGROWTH-21st tool.[21]

2.5 | Conceptual framework

Exposure variables were categorized as structural, intermediate and proximal factors informed by the WHO's Commission on Social Determinants of Health (CSDH) conceptual framework[22] and the complex hierarchical inter-relationships between these factors and stillbirth were visualized using a directed acyclic graph (DAG) (Figure 1). Conceptual frameworks are known to provide guidance for statistical analysis and also allow epidemiological studies to take account of the effects of structural and intermediate (more distal) factors.[23]

2.6 | Statistical analysis

The overall stillbirth rate and a confidence interval (CI) per 1000 total births were calculated using the stillbirths and births recorded in the cohort study using Ulm's method.[24]

Frequency distributions for categorical exposure variables and median and interquartile range for continuous exposure variables were compared between stillbirths (overall, ante- and intrapartum) and live births. Univariable analysis using modified Poisson regression models was conducted to observe unadjusted associations between each exposure variable and the outcome.

After initial exploratory analysis, multivariable Poisson regression models were built to estimate adjusted associations between the outcome and exposure variables. Only variables that were associated with the outcome in the univariable analysis at a *P* value of ≤0.05 overall or within the subgroups were included in the regression models using a hierarchical approach starting with the structural factors (model 1), followed by intermediate factors (model 2), and proximal factors (model 3). This was informed by the DAG (Figure 1). Statistical interaction between the women's education level and BPL status was tested for effect modification. Multicollinearity was tested for using the variance inflation factor (VIF). Variables with a value of VIF five or more were not included in the same model. Model prediction was assessed using the area under the receiver-operating characteristic (AUROC) curve.

Patterns and frequencies of missing data were described for exposure variables in Table S1. While there was missing information, the proportion of missingness was very small: almost all the exposure variables had less than 0.4% of missing data, and even the variable with the highest extent of missingness (BMI) had less than 4% of missing data. Therefore, the missing data were presumed to be missing at random and complete-case analysis was used.

All associations were reported as relative risk (RR) or adjusted RR (aRR) with 95% CI and *P* values. All analyses were performed using R version 4.2.2 and RStudio 2023.03.0+386. A two-tailed *P* value ≤0.05 was considered statistically significant.

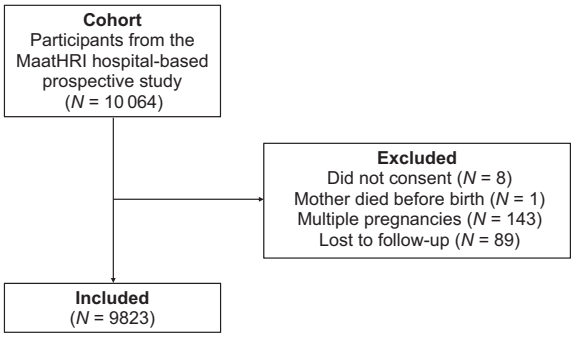

FIGURE 2 Flow diagram of the selection of the study participants.

3 | RESULTS

Based on inclusion and exclusion criteria, 9823 women were eligible for inclusion in the analysis (Figure 2).

There were 216 stillbirths (48 antepartum and 168 intrapartum) in the study population, representing a stillbirth rate of 22.0 per 1000 total births (95% CI: 19.2–25.1). Of these 22.2% were antepartum and 77.8% were intrapartum stillbirths.

Table 2 describes the results of the univariable analysis. Urban/rural and religion from structural factors, unhealthy lifestyle, history of cesarean sections, existing medical problems and BMI category for South Asian from intermediate factors, and fetal sex from the proximal factors had *P* values >0.05 and were excluded from the multivariable analysis. The results of the multivariable analysis are shown in Table 3, and after adjusting for structural, intermediate and proximal factors (full adjustment, model 3), BPL status and parity were not statistically significantly associated with stillbirth.

3.1 | Structural risk factors

Compared with women who had a tertiary or higher level of education (beyond 12th class in the Indian education system), women who could not read or write (illiterate) had almost a three times greater risk of stillbirth when adjusting for only BPL status (aRR: 2.95, 95% CI: 1.84–4.83). After full adjustment for structural, intermediate and proximal factors, the association was attenuated to 1.86 times increased risk of stillbirth (95% CI: 1.13–3.10).

3.2 | Intermediate risk factors

After full adjustment, women who received two or three antenatal check-ups had a 75% increased risk of stillbirth (aRR: 1.75, 95% CI: 1.25–2.47) than women who received four or more check-ups.

TABLE 2 Descriptive statistics of antepartum, intrapartum, and total stillbirths, and live births, and univariate analysis of risk factors associated with stillbirth.

	Antepartum stillbirths (*N* = 48)	Intrapartum stillbirths (*N* = 168)	Total stillbirths (*N* = 216)	Live births (*N* = 9607)	Univariable analysis using total stillbirths as the outcome compared with live births	
					RR (95% CI)	*P* value
Structural factors						
Urban/rural						
Urban/suburban	9 (18.8%)	29 (17.3%)	38 (17.6%)	1419 (14.8%)	1 (Ref)	-
Rural	39 (81.3%)	139 (82.7%)	178 (82.4%)	8188 (85.2%)	0.82 (0.58–1.17)	0.255
Women's education level						
Tertiary or above (beyond 12th class)	9 (18.8%)	18 (10.7%)	27 (12.5%)	1628 (16.9%)	1 (Ref)	-
Up to secondary school (6–12th class)	17 (35.4%)	73 (43.5%)	90 (41.7%)	5070 (52.8%)	1.07 (0.71–1.67)	0.761
Up to primary school (5th class)	13 (27.1%)	41 (24.4%)	54 (25.0%)	2002 (20.8%)	**1.61 (1.02–2.59)**	**0.043**
Illiterate	9 (18.8%)	36 (21.4%)	45 (20.8%)	874 (9.1%)	**3.00 (1.88–4.89)**	**<0.001**
Religion						
Hindu	38 (79.2%)	119 (70.8%)	157 (72.7%)	7059 (73.5%)	1 (Ref)	-
Muslim and others	10 (20.8%)	49 (29.2%)	59 (27.3%)	2548 (26.5%)	1.04 (0.77–1.39)	0.796
Below poverty line (BPL) status						
No	14 (29.2%)	45 (26.8%)	59 (27.3%)	3195 (33.3%)	1 (Ref)	-
Unknown	10 (20.8%)	21 (12.5%)	31 (14.4%)	1594 (16.6%)	1.05 (0.67–1.61)	0.819
Yes	24 (50.0%)	102 (60.7%)	126 (58.3%)	4818 (50.2%)	**1.41 (1.04–1.93)**	**0.031**
Intermediate factors						
Unhealthy lifestyle[a]						
Never	27 (56.3%)	116 (69.0%)	143 (66.2%)	6185 (64.4%)	1 (Ref)	-
Gave up during/prior to pregnancy	3 (6.3%)	11 (6.5%)	14 (6.5%)	353 (3.7%)	1.69 (0.93–2.82)	0.062
Current	18 (37.5%)	41 (24.4%)	59 (27.3%)	3069 (31.9%)	0.83 (0.61–1.12)	0.243
Number of antenatal check-ups (*N*)						
Median [Q1, Q3]	3.00 [2.75,4.00]	3.00 [2.00,3.00]	3.00 [2.00,4.00]	3.00 [3.00,4.00]		
Number of antenatal check-ups						
4 or more	16 (33.3%)	39 (23.2%)	55 (25.5%)	4199 (43.7%)	1 (Ref)	-
2–3	27 (56.3%)	104 (61.9%)	131 (60.6%)	4624 (48.1%)	**2.13 (1.56–2.94)**	**<0.001**
0–1	5 (10.4%)	25 (14.9%)	30 (13.9%)	784 (8.2%)	**2.85 (1.81–4.41)**	**<0.001**
Duration of iron and folic acid supplementation						
More than 180 days	0 (0%)	2 (1.2%)	2 (0.9%)	283 (2.9%)	1 (Ref)	-
90–180 days	21 (43.8%)	97 (57.7%)	118 (54.6%)	7492 (78.0%)	2.21 (0.70–13.38)	0.266
Less than 90 days	22 (45.8%)	44 (26.2%)	66 (30.6%)	1482 (15.4%)	**6.08 (1.91–37.01)**	**0.012**
None	5 (10.4%)	25 (14.9%)	30 (13.9%)	350 (3.6%)	**11.25 (3.40–69.55)**	**<0.001**
Women's age (years)						
Median [Q1, Q3]	25.0 [21.0,29.0]	26.0 [22.0,29.3]	25.5 [22.0,29.0]	24.0 [21.0,28.0]		
Women's age						

TABLE 2 (Continued)

	Antepartum stillbirths (*N* = 48)	Intrapartum stillbirths (*N* = 168)	Total stillbirths (*N* = 216)	Live births (*N* = 9607)	Univariable analysis using total stillbirths as the outcome compared with live births	
					RR (95% CI)	*P* value
<20	4 (8.3%)	11 (6.5%)	15 (6.9%)	852 (8.9%)	0.92 (0.51–1.56)	0.781
20–24	19 (39.6%)	59 (35.1%)	78 (36.1%)	4090 (42.6%)	1 (Ref)	-
25–29	16 (33.3%)	56 (33.3%)	72 (33.3%)	3167 (33.0%)	1.19 (0.86–1.64)	0.292
30–34	6 (12.5%)	25 (14.9%)	31 (14.4%)	1139 (11.9%)	1.42 (0.92–2.12)	0.102
>34	3 (6.3%)	17 (10.1%)	20 (9.3%)	359 (3.7%)	**2.82 (1.68–4.51)**	**<0.001**
Parity (*N*)						
Median [Q1, Q3]	0 [0,1.00]	0 [0,1.00]	0 [0,1.00]	0 [0,1.00]		
Parity						
Nulliparous	27 (56.3%)	111 (66.1%)	138 (63.9%)	6429 (66.9%)	1.01 (0.75–1.38)	0.945
Para 1–2	18 (37.5%)	41 (24.4%)	59 (27.3%)	2779 (28.9%)	1 (Ref)	-
Para 3 or more	3 (6.3%)	16 (9.5%)	19 (8.8%)	399 (4.2%)	**2.19 (1.27–3.59)**	**0.003**
Stillbirth/miscarriage history						
No	11 (22.9%)	46 (27.4%)	57 (26.4%)	2810 (29.2%)	1 (Ref)	-
Never pregnant	27 (56.3%)	106 (63.1%)	133 (61.6%)	6250 (65.1%)	1.05 (0.77–1.44)	0.767
Yes	10 (20.8%)	15 (8.9%)	25 (11.6%)	533 (5.5%)	**2.25 (1.38–3.56)**	**<0.001**
History of cesarean sections						
No	17 (35.4%)	55 (32.7%)	72 (33.3%)	2846 (29.6%)	1 (Ref)	-
Never pregnant	27 (56.3%)	106 (63.1%)	133 (61.6%)	6250 (65.1%)	0.84 (0.64–1.13)	0.248
Yes	4 (8.3%)	7 (4.2%)	11 (5.1%)	487 (5.1%)	0.90 (0.45–1.62)	0.732
Existing medical problems						
No	45 (93.8%)	164 (97.6%)	209 (96.8%)	9288 (96.7%)	1 (Ref)	-
Yes	3 (6.3%)	4 (2.4%)	7 (3.2%)	318 (3.3%)	0.98 (0.42–1.92)	0.955
BMI category for South Asian						
<18.5	7 (14.6%)	49 (29.2%)	56 (25.9%)	2487 (25.9%)	1.10 (0.79–1.51)	0.555
18.5–22.9	30 (62.5%)	78 (46.4%)	108 (50.0%)	5297 (55.1%)	1 (Ref)	-
23–24.9	8 (16.7%)	17 (10.1%)	25 (11.6%)	892 (9.3%)	1.36 (0.86–2.07)	0.162
≥25	2 (4.2%)	8 (4.8%)	10 (4.6%)	561 (5.8%)	0.88 (0.43–1.59)	0.690
Proximal factors						
Severity of anemia						
Normal (≥11 g/dL)	3 (6.3%)	13 (7.7%)	16 (7.4%)	1463 (15.2%)	1 (Ref)	-
Mild (10–10.9 g/dL)	7 (14.6%)	20 (11.9%)	27 (12.5%)	1169 (12.2%)	**2.09 (1.14–3.96)**	**0.020**
Moderate (7–9.9 g/dL)	28 (58.3%)	77 (45.8%)	105 (48.6%)	5845 (60.8%)	1.63 (0.99–2.87)	0.068
Severe (<7 g/dL)	10 (20.8%)	58 (34.5%)	68 (31.5%)	1130 (11.8%)	**5.25 (3.13–9.36)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)						
No	42 (87.5%)	145 (86.3%)	187 (86.6%)	8777 (91.4%)	1 (Ref)	-
Yes	6 (12.5%)	23 (13.7%)	29 (13.4%)	830 (8.6%)	**1.62 (1.07–2.35)**	**0.016**
Gestational age at birth (weeks)						
Median [Q1, Q3]	35.0 [33.0,38.0]	37.0 [34.8,39.0]	37.0 [34.0,39.0]	39.0 [38.0,40.0]		

(Continues)

TABLE 2 (Continued)

	Antepartum stillbirths (N = 48)	Intrapartum stillbirths (N = 168)	Total stillbirths (N = 216)	Live births (N = 9607)	Univariable analysis using total stillbirths as the outcome compared with live births	
					RR (95% CI)	P value
Gestational age at birth						
Preterm ($28^{0/7}$ to $36^{6/7}$ weeks)	30 (62.5%)	66 (39.3%)	96 (44.4%)	1401 (14.6%)	**5.13 (3.77–7.01)**	**<0.001**
Early term ($37^{0/7}$ to $38^{6/7}$ weeks)	8 (16.7%)	35 (20.8%)	43 (19.9%)	2484 (25.9%)	1.36 (0.92–1.98)	0.112
Full term ($39^{0/7}$ to $40^{6/7}$ weeks)	9 (18.8%)	60 (35.7%)	69 (31.9%)	5452 (56.8%)	1 (Ref)	-
Late/post term (≥$41^{0/7}$ weeks)	1 (2.1%)	6 (3.6%)	7 (3.2%)	270 (2.8%)	2.02 (0.84–4.10)	0.076
Fetal sex						
Male	27 (56.3%)	87 (51.8%)	114 (52.8%)	5083 (52.9%)	1 (Ref)	-
Female	21 (43.8%)	81 (48.2%)	102 (47.2%)	4524 (47.1%)	1.01 (0.77–1.31)	0.970
Birth weight for gestational age (percentile)						
Median [Q1, Q3]	25.9 [0.398,69.2]	4.01 [0.120,29.6]	6.83 [0.143,39.2]	13.6 [2.92,36.0]		
Birth weight for gestational age						
<10th percentile	19 (39.6%)	93 (55.4%)	112 (51.9%)	4146 (43.2%)	1.46 (1.11–1.93)	**0.007**
10 to 90th percentile	24 (50.0%)	69 (41.1%)	93 (43.1%)	5075 (52.8%)	1 (Ref)	-
>90th percentile	5 (10.4%)	4 (2.4%)	9 (4.2%)	354 (3.7%)	1.38 (0.65–2.58)	0.359

Abbreviations: BMI, body mass index; RR, relative risk. Bold: statistically significant (P value ≤0.05).

[a]Smoking, chewing betel nuts, tobacco consumption, alcohol consumption.

Women who did not take any iron and folic acid supplementation during pregnancy had more than seven times increased risk of stillbirth than women who took them for more than 180 days (aRR: 7.23, 95% CI: 2.12–45.33). Women's age was also associated with stillbirth. The relationship with age was linear with a 6% increase in risk for every 1 year increase in age (aRR: 1.06, 95% CI: 1.03–1.09, *P* value ≤0.001). However, when we examined age as a categorical variable, women aged 35 years or older had a significantly higher risk of stillbirth compared with age group 20–24 (aRR: 2.28, 95% CI: 1.28–3.87). Finally, women with stillbirth/miscarriage history had more than a two-fold increase in risk of stillbirth (aRR: 2.17, 95% CI: 1.32–3.48) than women who did not have a history of stillbirth/miscarriage.

3.3 | Proximal risk factors

Women who had severe anemia had more than three times the risk of stillbirth (aRR: 3.37, 95% CI: 1.97–6.11) than women who did not. Having HDP increased the risk of stillbirth by 1.59 times (95% CI: 1.03–2.36). Preterm birth and early term birth increased the risk by 4.41 times (95% CI: 3.21–6.08) and 1.63 times (95% CI: 1.09–2.39), respectively. Lastly, infants with birth weight below the 10th percentile for gestational age had a 1.35 times higher risk of stillbirth (95% CI: 1.02–1.79) than infants with birth weight between the 10th to 90th percentile for gestational age.

3.4 | Performance of multivariable models

Figure 3 shows the AUROC curve for model 1 (adjusting for structural factors only), model 2 (adjusting for structural and intermediate factors) and model 3 (fully adjusted including proximal factors). Together, the structural and intermediate factors accounted for 70.2% (95% CI: 66.5%–73.9%) of the variance in the data. With the addition of the proximal factors, this increased to 78.2% (95% CI: 75.0%–81.4%).

4 | DISCUSSION

This study showed that the stillbirth rate in 13 hospitals across six states in India was 22.0 per 1000 total births (95% CI: 19.2–25.1) and 77.8% of all stillbirths occurred intrapartum. Women's illiteracy (not being able to read or write) was a significant structural risk factor. Significant immediate risk factors included receiving less than four antenatal check-ups, not taking any iron and folic acid supplementation during pregnancy, being aged 35 or older and having a history

TABLE 3 Multivariable analysis of risk factors for stillbirth.

	Model 1: Adjusted for structural factors[a]		Model 2: Adjusted for structural and intermediate factors[b]		Model 3: Adjusted for structural, intermediate and proximal factors[c]	
Variable/level	**aRR (95% CI)**	***P* value**	**aRR (95% CI)**	***P* value**	**aRR (95% CI)**	***P* value**
Structural factors						
Women's education level						
Tertiary or above (beyond 12th class)	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Up to secondary school (6–12th class)	1.05 (0.69–1.65)	0.816	1.08 (0.71–1.70)	0.731	1.00 (0.66–1.59)	0.982
Up to primary school (5th class)	1.48 (0.93–2.40)	0.102	1.29 (0.80–2.13)	0.309	1.01 (0.62–1.68)	0.977
Illiterate	**2.95 (1.84–4.83)**	**<0.001**	**2.30 (1.41–3.83)**	**0.001**	**1.86 (1.13–3.10)**	**0.016**
Below poverty line (BPL) status						
No	1 (Ref)	-	1 (Ref)	-	1 (Ref)	-
Unknown	1.13 (0.72–1.75)	0.574	0.93 (0.59–1.44)	0.756	0.90 (0.57–1.40)	0.645
Yes	1.36 (0.99–1.88)	0.058	0.95 (0.69–1.33)	0.766	0.87 (0.63–1.22)	0.416
Intermediate factors						
Number of antenatal check-ups						
4 or more			1 (Ref)	-	1 (Ref)	-
2–3			**1.75 (1.26–2.47)**	**0.001**	**1.75 (1.25–2.47)**	**0.001**
0–1			1.48 (0.90–2.39)	0.114	1.43 (0.87–2.32)	0.149
Duration of iron and folic acid supplementation						
More than 180 days			1 (Ref)	-	1 (Ref)	-
90–180 days			2.11 (0.66–12.83)	0.299	1.97 (0.62–12.03)	0.343
Less than 90 days			**4.88 (1.50–30.05)**	**0.029**	**4.19 (1.28–25.83)**	**0.049**
None			**8.91 (2.63–55.71)**	**0.003**	**7.23 (2.12–45.33)**	**0.008**
Women's age						
<20			0.86 (0.47–1.45)	0.590	0.82 (0.45–1.40)	0.493
20–24			1 (Ref)	-	1 (Ref)	-
25–29			1.27 (0.91–1.77)	0.158	1.22 (0.87–1.71)	0.242
30–34			1.52 (0.97–2.35)	0.062	1.47 (0.93–2.28)	0.088
>34			**2.42 (1.36–4.12)**	**0.002**	**2.28 (1.28–3.87)**	**0.003**
Parity[d]						
Nulliparous			1.17 (0.84–1.64)	0.349	1.16 (0.83–1.63)	0.384
Para 1–2			1 (Ref)	-	1 (Ref)	-
Para 3 or more			1.12 (0.62–1.93)	0.694	1.22 (0.68–2.10)	0.486
Stillbirth/miscarriage history[d]						
No			1 (Ref)	-	1 (Ref)	-
Never pregnant			1.36 (0.97–1.93)	0.083	1.40 (1.00–1.99)	0.056
Yes			**2.34 (1.43–3.73)**	**<0.001**	**2.17 (1.32–3.48)**	**0.002**
Proximal factors						
Severity of anemia						
Normal (≥11 g/dL)					1 (Ref)	-
Mild (10–10.9 g/dL)					**1.92 (1.05–3.65)**	**0.039**
Moderate (7–9.9 g/dL)					1.39 (0.84–2.45)	0.229
Severe (<7 g/dL)					**3.37 (1.97–6.11)**	**<0.001**
Hypertensive disorders of pregnancy (HDP)						

(Continues)

TABLE 3 (Continued)

Variable/level	Model 1: Adjusted for structural factors[a] aRR (95% CI)	*P* value	Model 2: Adjusted for structural and intermediate factors[b] aRR (95% CI)	*P* value	Model 3: Adjusted for structural, intermediate and proximal factors[c] aRR (95% CI)	*P* value
No					1 (Ref)	-
Yes					**1.59 (1.03–2.36)**	**0.028**
Gestational age at birth[e]						
Preterm (28^{+0} to 36^{+6} weeks)					**4.41 (3.21–6.08)**	**<0.001**
Early term (37^{+0} to 38^{+6} weeks)					**1.63 (1.09–2.39)**	**0.015**
Full term (39^{+0} to 40^{+6} weeks)					1 (Ref)	-
Late/post term (≥41^{+0} weeks)					2.00 (0.83–4.06)	0.083
Birth weight for gestational age[e]						
<10th percentile					**1.35 (1.02–1.79)**	**0.038**
10 to 90th percentile					1 (Ref)	-
>90th percentile					0.96 (0.45–1.82)	0.919

Abbreviations: aRR, adjusted relative risk; CI, confidence interval. Bold: statistically significant (P value ≤0.05).

[a]Women's education level, BPL status.

[b]Women's education level, BPL status, number of antenatal check-ups, duration of iron and folic acid supplementation, women's age, parity *or* stillbirth/miscarriage history.

[c]Women's education level, BPL status, number of antenatal check-ups, duration of iron and folic acid supplementation, women's age, parity *or* stillbirth/miscarriage history, severity of anemia, hypertensive disorders of pregnancy (HDP), gestational age at birth *or* birth weight for gestational age.

[d]Due to high collinearity between parity and stillbirth/miscarriage history, these variables were not included in the same model together.

[e]Birth weight for gestational age was calculated using gestational age at birth, therefore, these variables were not included in the same model together.

of stillbirth or miscarriage. Additionally, having anemia, experiencing HDP, preterm birth, early term birth and birth weight below the 10th percentile for gestational age were significant proximal risk factors.

The stillbirth rate of 22.0 per 1000 total births in the study population was substantially higher than the 2019 estimate for India's overall stillbirth rate of 13.9 per 1000 total births.[1] This contrast is noteworthy, considering these births occurred in a hospital setting and did not include home births or planned cesarean sections before the third trimester. This could be because nine out of 13 MaatHRI hospitals (69.2%) where the study population was recruited, were medical colleges, which typically serve a higher proportion of high-risk women compared with community hospitals. It is also possible that the estimate for India overall could be a consequence of undercounting.

The majority of the stillbirths were intrapartum (77.8%) having occurred after the onset of labor and prior to birth. Considering that intrapartum stillbirths are more closely related to various measures of obstetric care than antepartum stillbirths,[25] further investigation into the quality of care received by women who experienced intrapartum stillbirths through a stillbirth review process would be beneficial. Such reviews can generate learning to inform the action plans and allow facilities to consider where the changes should be made to improve the quality of care they provide, enabling positive short- and medium-term outcomes, and ultimately reducing preventable stillbirths.[26]

Similar to the findings of Altijani et al. from an analysis of data from 886 505 Indian women from the annual health survey,[10] our study identified women's illiteracy as significantly associated with an increased risk of stillbirth. However, our findings also highlight that improving access to high-quality antenatal care and better management of pregnancy and fetal complications has the potential to attenuate or eliminate the risk of stillbirth associated with socioeconomic inequalities, such as those related to women's low education levels and low-income status.

More importantly, this study emphasizes that several of the major risk factors for stillbirth are potentially modifiable. For instance, ensuring that women receive at least four antenatal check-ups and take iron and folic acid supplementation during pregnancy were identified as interventions that could significantly reduce the risk of stillbirth in India. Pregnancy complications such as having anemia in the third trimester and HDP were also reported as major risk factors that greatly increase the risk of stillbirth, consistent with findings from other studies.[27-31] These complications are also potentially amenable to interventions to enhance their management.

Despite routine iron supplementation being available at no cost to women,[32] overall 84.9% of the cohort had anemia (Hb < 11 g/dL) and 12.2% had severe anemia (Hb < 7 g/dL). Furthermore, even after adjusting for the effects of iron and folic acid supplementation, anemia remained a significant risk factor for stillbirth, and this was especially critical for women with severe anemia who experience over a

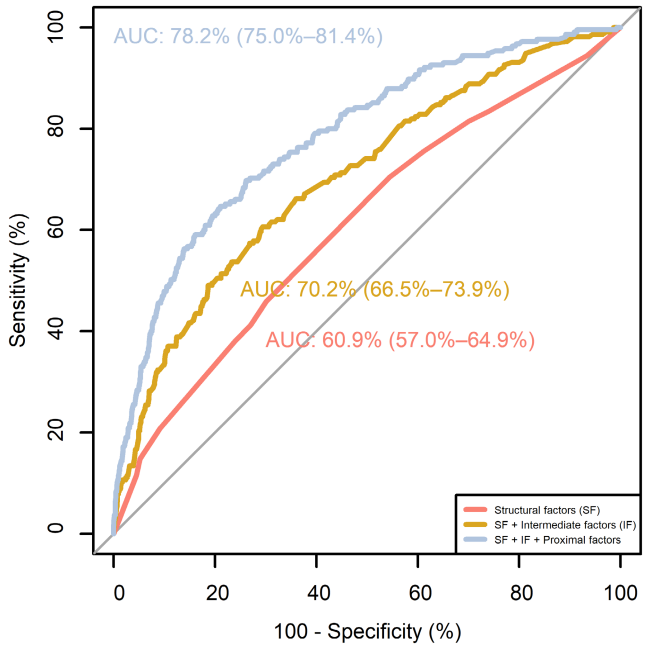

FIGURE 3 Area under the receiver-operating characteristic (AUROC) curve for structural, intermediate and proximal factors.

three-fold increased risk of stillbirth compared with women without anemia.

This suggests that low Hb levels do not necessarily translate into iron deficiency anemia and addressing anemia (especially severe anemia) with iron supplementation alone may not be effective in addressing this important risk factor for stillbirth in India. Understanding the underlying causes of anemia is crucial to developing targeted treatment strategies. The complex, multifactorial relationship between iron supplementation and anemia and risk of stillbirth supports MaatHRI's recent study findings, which emphasized the importance of using iron biomarkers and not relying solely on Hb measurement to facilitate tailored prevention, control, and treatment activities for managing anemia during pregnancy.[33]

Additionally, further analysis should be conducted to explore early term birth (37^{+0} to 38^{+6} weeks) and birth weight below the 10th percentile for gestational age as risk factors for intrapartum stillbirth. While the association between preterm birth and stillbirth is relatively well established,[7,10,34,35] research on the relative risk of intrapartum stillbirth associated with early term birth is limited. Smith[36] suggests there was a 2.2 times increased risk of intrapartum stillbirth at 37 weeks' gestation compared with 38 weeks', while Trudell et al.,[37] advocate for early term birth for small for gestational age pregnancies to minimize the risk of stillbirth. Therefore, it is unclear whether childbirth at early term is beneficial or harmful, especially for small for gestational age babies.

Finally, proximal factors which include pregnancy and fetal characteristics emerged as the important predictors of stillbirth, as evident in the AUROC curve analysis. This finding aligns with the study by Horwood et al.,[38] which found that proximal factors were the primary predictors when focusing on risk factors for maternal mortality in the Indian population. Proximal factors are more likely to be tackled with quality improvement of clinical care, therefore, these findings reinforce the importance of high-quality antenatal care and the availability of basic emergency obstetric care to improve maternal health in India, ultimately supporting efforts to reduce both maternal mortality and the stillbirth rate.

4.1 | Strengths and limitations

The main strength of the present study is that it employed a large prospective design, allowing examination of the relationship between maternal and fetal factors associated with stillbirth. The prospective cohort study design, in combination with an appropriate statistical analysis method, allowed this study to assess the relative risk of identified risk factors associated with stillbirth in India. The findings are potentially generalizable to the wider Indian population as data were collected from 13 hospitals across six states in India, characterized by varying socioeconomic contexts, healthcare facilities, food habits, prevalence of malnutrition and anemia among pregnant women and the burden of pregnancy complications. Rigorous and standardized methodologies were utilized to minimize bias and enhance the validity and reliability of the findings.

Given the limited number of stillbirths and especially the small number of antepartum stillbirths ($N=48$), conducting a subgroup analysis to examine risk factors for ante- and intrapartum stillbirths separately was not feasible. A deeper understanding of the differences between the two subgroups' risk factors can contribute meaningfully to shaping India's policy focus regarding prevention, and future studies should seek to enhance the current knowledge. Another limitation of this study relates to the cohort's original research focus, which did not center specifically on stillbirth. The exclusion of women who were planning to undergo a cesarean section at the time of recruitment, therefore, may have introduced selection bias. There is a need for cautious interpretation before extending the study's findings to this particular subgroup.

5 | CONCLUSION

Our findings emphasize the significance of addressing modifiable factors to reduce the risk of stillbirths in India. Improving access to high-quality antenatal care and enhancing the management of pregnancy complications, including the availability of emergency obstetric care, are vital steps toward achieving this goal. The study also highlights the importance of understanding the underlying causes of anemia to develop targeted treatment strategies, recognizing the complex, multifactorial relationship between iron supplementation and anemia. Furthermore, our findings emphasize the need for further investigation into intrapartum stillbirths and the quality of obstetric care provided during labor. By providing obstetric staff and policymakers with practical data and insights, this study could support strategic planning to reduce stillbirths in the Indian population

and achieve the proposed INAP target. As we move forward, these insights can inform the planning of targeted interventions and policies aimed at reducing stillbirth rates, ultimately advancing maternal and fetal health in India.

AUTHOR CONTRIBUTIONS

YYB developed the concept and design for the study, obtained, analyzed and interpreted the data, and wrote the first draft of the manuscript. RD is the MaatHRI Project Manager who supervised data collection, contributed to the interpretation of the data, and reviewed the paper critically for important intellectual content. MN developed the concept and design for the study, is the chief investigator of the MaatHRI projects from which the dataset was used, contributed to the interpretation of the data, edited the first draft of the paper and reviewed it critically for important intellectual content. JJK contributed to the development of the concept and design for the study, and the interpretation of the data, edited the first draft of the paper and reviewed it critically for important intellectual content. AKB, SC, SSC, GD, SK, PK, PM, BM, AR, SR, IR, CSV, AV and FZ contributed equally and their names are included in the alphabetical order of their last name. They contributed to the development of the concept and design for the study, are collaborators and investigators of the MaatHRI project from which the dataset was generated, contributed to the interpretation of the data, and reviewed the paper critically for important intellectual content. All authors gave final approval of the current version of the paper to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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CONFLICT OF INTEREST STATEMENT

All authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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