Evaluating the moderating role of Accredited Social Health Activists home visits and Accompanied Antenatal Care visits on preterm birth and low birth weight in rural Mysore District, India

Sandra Kiplagat, PhD, MS,[1] Anisa Khan, MSc,[2] Diana M. Sheehan,PhD,[1,3,4] Poornima Jaykrishna, BCom,[2] Kavitha Ravi, MSc,[2] Mary Jo Trepka, MD, MSPH,[1,4] Zoran Bursac, PhD,[5] Dionne Stephens, PhD,[6] Karl Krupp, PhD, MSc,[2,7] Purnima Madhivanan, MBBS, MPH, PhD,[2,8,9,10]

[1]Department of Epidemiology, Robert Stempel College of Public Health and Social Work, Florida International University (FIU), Miami, FL

[2]Public Health Research Institute of India, Mysore, Karnataka, India

[3]Center for Research on U.S. Latino HIV/AIDS and Drug Abuse (CRUSADA), FIU, Miami, FL

[4]Research Center for Minority Institutions (RCMI), FIU, Miami, FL

[5]Department of Biostatistics, Robert Stempel College of Public Health and Social Work, FIU, Miami, FL

[6]Department of Psychology, College of Arts and Science Education, FIU, Miami, FL

[7] Division of Public Health Practice and Translational Research

[8]Department of Health Promotion Sciences, Mel & Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ

[9]Division of Infectious Diseases, College of Medicine, University of Arizona, Tucson, AZ

[10]Department of Family & Community Medicine, College of Medicine, University of Arizona, Tucson, AZ

Corresponding Author

Sandra Kiplagat, PhD, MS
Department of Epidemiology
Robert Stempel College of Public Health and Social Work
Florida International University
11200 SW 8th St., Miami, FL, 33199
Email: skipl001@fiu.edu

Abstract

Background

The Indian government established the Accredited Social Health Activists (ASHA) program in 2006 to improve access and healthcare coverage in rural regions. The objective of this study was to examine the moderating role of ASHA home visits and ASHA-accompanied antenatal care visits (ANC) on the relationship between sociodemographic latent classes of pregnant women and preterm birth and low birth weight infants in rural Mysore District, India.

Methods

Utilizing a prospective cohort study conducted between 2011–2014, secondary data analysis was performed among 1540 pregnant women in rural Mysore, India. Latent class analysis was performed to identify sociodemographic distinct patterns. Multivariable logistic regression was performed to examine the moderating effects of ASHA-accompanied ANC visits and ASHA home visits on preterm birth and low birth weight.

Results

Among women who never/rarely had ASHA-accompanied ANC visits, women in Class 1 "low socioeconomic status (SES)/early marriage/multigravida/1 child or more" had higher odds of preterm birth (adjusted odds ratio [aOR]: 2.62, 95% confidence interval [CI]: 1.12–6.12 compared to Class 4 “high SES/later marriage/primigravida/no children.”. Women in Class 3 “high SES/later marriage/multigravida/1 child or more” had higher odds of preterm birth compared to class 4. Women in Class 2 “low SES/later marriage/primigravida/no children” had higher odds of low birth weight infant.

Conclusion

The findings demonstrate that ASHA accompanying women to ANC moderates the risk of preterm births among women in high-risk SES groups. Targeted policies and interventions in improving and strengthening the ASHA program are needed to reduce inequalities in adverse birth outcomes in rural India.

Keywords

Accredited Social Health Activists, Latent Class Analysis, Preterm Birth, Low Birth Weight, India

Introduction

Despite significant strides in advancing maternal and neonatal health, pregnancy and childbirth remains a high risk and vulnerable period. Each year, nearly 2.4 million babies die within the first month of life, and approximately 300,000 women die due to pregnancy and child-birth related complications globally.[1,2] The majority of these deaths are preventable through implementation of interventions along the continuum of care, that is, before conception, prenatal and postnatal care.[3] India has consistently ranked as the country with the highest number of newborn deaths in the past decade.[4] Between 1990 and 2016, the neonatal mortality rates (NMR) in India from preterm birth and low birth weight infants increased from 12.3 per 1000 live births to 13.3 per 1000 live births, predominantly in poorer states and rural regions.[5] In the early 2000s, the National Family Health Survey (NFHS-2)[6] reported a higher NMR in rural India compared to urban India (46.7 per 1000 live births vs. 31.7 per 1000 live births), and the most recent data indicates that this rural-urban disparity has persisted over time.[6] These disparities have been attributed to low socioeconomic status, lack of access to antenatal care (ANC) services, restricted geographical mobility to healthcare institutions, and reduced quality of care.[7]

Due to the existing geographical inequities, the Indian government established the National Rural Health Mission (NRHM) in 2005 to strengthen the healthcare system by increasing institutional delivery access and ANC services coverage among the poorest populations.[8] A major component of the NRHM program is the Accredited Social Health Activist (ASHA) program, which was launched in 2006.[8] The program consists of ASHAs, all-female cadre of frontline health workers who serve as vital intermediaries between the community and the public health system to improve access and healthcare coverage in rural regions.[8] The key roles include counseling and educating pregnant women, supporting healthcare service delivery by conducting home visits, registering women for ANC visits, offering nutritional support, and providing ancillary services such as transportation for institutional delivery.[8] Even

though ASHAs are voluntary workers, they are often rewarded through performance-based incentives by the government for facilitating the utilization of reproductive health services by pregnant women.

Antenatal care services have been specifically recommended by the World Health Organization (WHO) for monitoring, screening, educating, preventing, and treating any pregnancy complications. Timely and appropriate ANC visits are vital in reducing adverse birth outcomes. However, several barriers in accessing ANC services in rural India have been well-documented including low socioeconomic status, limited access to healthcare, restricted geographical mobility, and limited awareness of ANC.[9] A recent national survey indicated that women residing in urban India were more likely to receive the recommended ANC visits compared to those residing in rural areas (66% vs. 45%).[6] Research has shown that ASHAs have been instrumental in increasing ANC visits among marginalized and poor women in rural settings.[10,11] Therefore, ASHAs play an important role in promoting uptake of ANC services among pregnant women in rural India. Since the launch of the program in 2006, nearly one million ASHAs have been trained and deployed throughout India, and it remains one of the largest community health workers program worldwide.[12]

Given the massive expansion of ASHA programs throughout India, it is critical to perform assessments to examine the programs' effectiveness on health outcomes. Previous studies have examined performance assessments on ASHA programs and maternal utilization of health services,[10,13] while less is known about the impact of the ASHAs on birth outcomes. Tripathy and colleagues conducted a randomized clinical trial which revealed that ASHA-supported women groups were associated with decreased neonatal mortality.[14]

Recent studies have documented that preterm birth and low birth weight infants are attributed to multiple co-occurring risk factors compared to single risk factors examined in multivariate analysis.[15,16] Therefore, complex methodological approaches such as latent class analysis have been increasingly adopted to identify high-risk groups of pregnant women. To our knowledge, no studies have utilized person-centered approaches in evaluating the relationship between ASHA visits during pregnancy and birth outcomes i.e., preterm birth and low birthweight in rural India. Therefore, our study sought to

examine the moderating role of ASHA home visits and ASHA-accompanied ANC visits on the relationship between sociodemographic latent classes of pregnant women and preterm birth and low birth weight infants in rural Mysore District, India.

Methods

Study Population and Design

We utilized data from the Saving Children Improving Lives (SCIL) project. This was a prospective cohort study conducted between 2011 and 2014 among 1820 pregnant women residing in rural areas in the Mysore District in Karnataka State in Southern India. Approximately 58.5% of Mysore population reside in rural areas, where nearly half of the 3 million people are women.[17] The original SCIL research objective was to examine the feasibility of integrated antenatal care and HIV testing among pregnant women. This was achieved through several initiatives including community education, mobile medical clinics and social mobilization through women self-help groups. For additional details on the study, the protocol was previously published in Kojima *et al.*[18] The institutional review boards of Florida International University in Miami, Florida and Public Health Research Institute of India (PHRII) in Mysore, India approved this study.

Pregnant women living in rural Mysore district received integrated ANC and HIV testing through the mobile medical clinics. During the visit, the pregnant women were informed of the study. The eligibility criteria for the study included pregnant women who resided in the rural areas of Mysore district for more than 6 months. Subsequently, these women who met these criteria enrolled in the study. Voluntary written informed consent in the local language of *Kannada* was obtained from eligible women. The PHRII staff who are trained interviewers in *Kannada*, administered a baseline questionnaire on sociodemographic, medical, and reproductive history. Clinical laboratory examinations on urine, blood and vaginal samples were collected by trained PHRII clinical workers as a part of the antenatal care to screen for sexually transmitted infections including syphilis, hepatitis B, HIV and bacterial vaginosis. The laboratory testing was performed in the PHRII lab after data collection. All women enrolled in the study were followed within 15 days of delivery, and 6 and 12 months after delivery. Data on predictors were

collected during the baseline questionnaire during the antenatal period, and data on outcomes were collected during the first follow-up of the study, which was within 15 days of delivery in the postnatal period. To be included in our study, we only selected women aged 18 years and older and excluded 8% of the sample due to missing data on last menstrual period or missing dates on deliveries (n=40) and infant deaths (n=98). Therefore, the total study sample utilized in the analysis was 1,540.

Study Measures

Outcomes

The outcomes in the study were preterm birth and low birth weight infants. Preterm birth was defined as live births born before 37 weeks according to the last menstrual period[19] Low birth weight infant was defined according to the WHO as an infant born weighing less than 2,500 grams.[20]

Moderators

The moderator variables were: ASHA home visits during pregnancy and ASHA-accompanied ANC visits during pregnancy. ASHA home visits refer to ASHA workers visiting and counseling pregnant women at home during and after pregnancy, recommending antenatal checkups, creating a birth-preparedness checklist, informing safe delivery practices and offering institutional delivery support.[8] ASHA-accompanied ANC visits refers to ASHA workers escorting pregnant women to attend ANC visits in medical clinics.[8] The frequency of ASHA exposure was originally labeled as never, rarely (once in 3 months), occasionally (every two months), and regularly (once a month). Due to limitations associated with sample size in the analysis, the ASHA home visits and ASHA-accompanied ANC visits were categorized as a dichotomous indicator: “never/rarely” and “occasionally/regularly”.

Covariates

The covariates in the study were selected based on prior literature review on maternal obstetric factors.[21] The participant’s age was categorized as (<20 years, 20-24 years, and ≥ 25 years). Delivery location was categorized as home, public health institution (sub-center/district health/primary health center), and private health institution (maternity hospital/private nursing home). Self-reported measures for maternal obstetric characteristics included previous still birth or neonatal loss (yes or no), history of

spontaneous abortion (yes or no), history of induced abortion (yes or no), exposure to passive smoking indoors (yes or no), previous low birth weight infants (yes or no), and frequency of ANC visits (<8 ANC visits and ≥ 8 ANC visits).[22] Baseline sexually transmitted infections (STI) (yes or no) was defined as either having hepatitis B or HIV or bacterial vaginosis.

The presence of chronic diseases was self-reported and included history of hypertension classified as yes or no. Baseline anemia and hypertension were based on physical examination and laboratory results. Anemia was assessed by hemoglobin levels categorized as normal for hemoglobin levels of 11.0g/dl or higher, mild for 10-10.9 g/dl, and moderate/severe as ≤10 g/dl respectively.[23] Hypertension categories were based on measured blood pressure levels as follows: normal (<120/80 mm Hg), pre-hypertension (120–139 mm Hg systolic or 80–89 mm Hg diastolic) and hypertensive categories (≥140 mm Hg systolic or ≥90 mm Hg diastolic). [24]

Statistical Analysis

The predictors in our study were latent classes determined through latent class analysis (LCA) in SAS/STAT v14.2 software. Latent class analysis is a statistical approach utilizing a chosen set of indicators to identify and classify homogeneous un-observed groups.[25] A total of six sociodemographic variables (pregnant women's education, partner education, total household income, age at marriage, primigravida status, and number of children) were selected based on latent class analysis (LCA) to classify women into distinct sociodemographic patterns. The analytical approach included conducting a model comparison approach through testing unconditional models without covariates in the LCA. Subsequently, the model fit was tested using 2 through 6 latent classes. The appropriate selection of latent classes was based on Bayesian Information Criterion (BIC), Adjusted Bayesian Information Criterion (aBIC) and Adjusted Information Criterion (AIC), entropy values, and the interpretability of latent classes. Based on the model fit parameters, the model with four latent classes was selected as the best fitting and most parsimonious model with lowest BIC (445.41), adjusted BIC (321.52), and AIC (237.17) and distinct class separation based on an entropy value of 0.75. The four classes classified as: "low socioeconomic (SES)/early marriage/multigravida/1 child or more", "low SES/later

marriage/primigravida/no children", "high SES/later marriage/multigravida/1 child or more," and "high SES/later marriage/primigravida/no children" were labeled as Class 1–Class 4 respectively.

Descriptive statistics were performed to examine the characteristics of the latent classes. Subsequently, univariate analyses were conducted by applying chi-square tests to examine the relationship of the latent classes with the covariates, ASHA home visits, and ASHA-accompanied ANC visits. Unadjusted logistic regression was conducted to examine the association between the latent classes and preterm birth and low birth weight infant (Model 1). In model 2, multivariable logistic regression was conducted to examine the association between the latent classes and preterm birth and low birth weight after adjusting for the covariates.

Subsequently, we performed a moderation analysis of the recommended ASHA components separately to determine their differential effect on the relationship between latent classes and preterm birth and low birth weight infant status. Model 3 included the main effects of the latent classes, ASHA home visits, and the interaction between the two after adjusting for covariates. Model 4 included the main effects of the latent classes, ASHA-accompanied ANC visits, and the interaction between the two after adjusting for covariates. Associations were considered significant at the alpha level of 0.05.

Results

Sample Characteristics

Table 1 displays the sociodemographic patterns of the pregnant women based on the LCA approach. Approximately 40% of the participants and more than half (53%) of their partners had received no more than a primary education. Almost 40% of the women married before they were 18 years of age. More than a third of the women were primigravida, and 53% of women had children. Only 10.8% earned a total monthly household income of 10,000 or more Indian rupees (INR) (approximately USD $170 with 1 USD = 58.9 INR during the data collection period). Table 2 shows univariate analysis of ASHA home visits and ASHA-accompanied ANC visits during pregnancy by the latent classes and the covariates. Approximately 17% of the women reported never/rarely having an ASHA home visit during their pregnancy, while nearly 40% of the women reported never/rarely having ASHA-accompanied ANC

visits. Of those who had never/rarely received ASHA home visits during pregnancy, a higher proportion of those participants belonged to Class 1 "low socioeconomic (SES)/early Marriage/Multigravida/1 Child or More", were older than 20 years of age, delivered in a public/private institution, had a previous stillbirth or neonatal loss, had a history of spontaneous abortion, had mild, moderate and severe anemia levels, and had baseline pre-hypertension and hypertension. Of those who never/rarely received ASHA-accompanied ANC visits, a higher proportion belonged to Class 1, were older than 20 years of age, delivered in a public/private institution, had a baseline STI, had a history of spontaneous abortion, had a previous low birth weight, had baseline pre-hypertension and hypertension, and attended <8 ANC visits.

Multivariable Logistic Regression

Preterm Birth

Table 3 reports the unadjusted odds ratio (OR), adjusted odds ratio (aOR), and 95% confidence intervals (CI) for the association between latent classes and preterm birth. After adjusting for covariates, no significant associations were observed in the relationship between latent classes and preterm birth in models 1, 2 or 3. However, in model 4 which includes the interaction between ASHA-accompanied ANC visits and latent classes, women in Class 1 "low SES/early marriage/multigravida/1 child or more" had higher odds of preterm birth (aOR: 1.83, 95% CI:1.06–3.14) as compared with women in Class 4 "high SES/later marriage/primigravida/no children." In the unadjusted model, the odds of preterm birth were significantly higher among women who never/rarely had ASHA-accompanied ANC visits when compared with those who occasionally/regularly had ASHA-accompanied ANC visits (OR 1.58: 95% CI: 1.09–2.09). However, this association did not remain significant after adjusting for covariates.

No significant interaction was observed in the relationship between latent classes and ASHA-accompanied ANC visits on preterm birth. However, significant differences were observed between the classes—among women who never/rarely had ASHA-accompanied ANC visits: women in Class 1, and Class 3 had higher odds of preterm birth compared to Class 4 (aOR: 2.62, 95% CI: 1.12–6.12 and aOR: 3.47, 95% CI: 1.31–9.15 respectively). Among women who never/rarely had ASHA-accompanied ANC visits, women in Class 2 "low SES/later marriage/primigravida/no children" had a two-fold higher odds

of preterm births (aOR: 2.07, 95% CI: 0.83–5.17) as compared to Class 4; however this was not statistically significant. In contrast, among women who occasionally/regularly had ASHA-accompanied ANC visits, no significant associations were observed among the classes on preterm birth. Additionally, the aORs computed in this group were around 1.00, which were much lower compared to those women who never or rarely had ASHA-accompanied ANC visits. No significant interactions were observed in the relationship between latent classes and ASHA home visits on preterm birth.

Low Birth Weight

Table 4 displays the association between latent classes and low birth weight. After adjusting for covariates, women in Class 2 compared with Class 4 reported higher odds of low birth weight infants in models 1 through 4. No significant interaction was observed in the relationship between latent classes and ASHA-accompanied ANC visits on delivery of low birth weight infants. For both ASHA-accompanied ANC visit strata, women in Class 2 had higher odds of low birth weight infant aOR: 2.26, 95% CI:1.10–4.63 for never/rarely had ASHA accompanied ANC visits and aOR: 2.70, 95% CI:1.27–5.74 for women who occasionally/regularly had ASHA accompanied ANC visits) compared to women in Class 4.

No significant interactions were observed between the latent classes and ASHA home visits on delivery of low birth weight infants. However, among women who occasionally/regularly had ASHA home visits, those in Class 2 had higher odds of having a low birth weight infant (aOR: 2.24, 1.29–3.92) compared with those in Class 4. Moreover, higher odds of low birth weight are displayed in all classes among women who never/rarely had ASHA home visits compared to women who occasionally/regularly had ASHA home visits.

Discussion

Our study findings suggest that among women who never/rarely had ASHA-accompanied visits, those in high-risk SES classes had higher odds of adverse birth outcomes compared with women in lower risk SES classes. ASHA home visits did not moderate the association between SES classes and preterm birth or delivery of low birth weight infant. Most notably, Class 1 “low SES/early marriage/multigravida/1 child or more” was associated with preterm birth, while Class 2 “low SES/later

marriage/primigravida/no children" was associated with low birth weight infant; both were high-risk SES classes.

Although preterm birth and low birth weight are inextricably linked, the findings of the study demonstrated that distinct risk profiles influence these outcomes differently. Women in Class 1, comprising nearly half of the participants, were characterized by the interplay of risk factors including low SES, early marriage, multigravida, 1 child or more, which have been documented to have higher likelihood of adverse birth outcomes.[26,27] Further, women in Class 2 characterized by co-occurring low SES, later marriage, primigravida and no children were more likely to deliver a low birth weight infant. It has also been posited that the effect of maternal-fetal competition for nutrients among first-time young pregnant women as a risk factor for delivery of low birth weight infant.[28] Moreover, they may have underlying conditions and lack access to antenatal care that may further exacerbate low birth weight. Overall, these two high-risk classes share a common risk factor, low SES. A systematic review conducted by Blumenshine and colleagues reported that socioeconomic disadvantage is the primary risk factor for adverse birth outcomes.[26]

The current study identified the importance of ASHA accompanying women to their ANC visits in moderating the relationship between high-risk classes and preterm birth. Our findings found that among women who never or rarely had ASHA-accompanied ANC visits, women in Class 1 were more likely to have a preterm delivery. The association between co-occurring risk factors including low SES, early marriage, and higher parity and preterm birth has been well-established in prior studies.[26,27] Further, women with previous pregnancy experience may be less inclined to seek antenatal care services and may have opted out of receiving ASHA services.[12] Despite all the disadvantages in Class 1, an ASHA can help overcome those barriers to accessing care, ultimately leading to healthy birth outcomes. Exposure to ASHAs in marginalized and rural communities has demonstrated effectiveness in expanding ANC service coverage, increasing institutional deliveries, increasing access to conditional cash transfers, improving immunization rates, decreasing antenatal anxiety in pregnant women, and reducing perinatal deaths.[14,29,30]

They act as vital support system to encourage and mobilize rural women to engage with healthcare providers during pregnancies.

Surprisingly, among women who never or rarely had ASHA-accompanied ANC visits, women in Class 3 had higher odds of preterm birth compared to Class 4. Women in class 3 were characterized by a distinct profile of high SES, later marriage, multigravida, and 1 child or more. A recent study established that there were no differential effects of ASHA visits based on sociodemographic status.[31] Moreover, the high SES group within this rural community was not wealthy, and it is not comparable to high SES in an Indian urban community or well-resourced setting. Regardless of their socioeconomic status, previous studies shows that women who reside in rural areas have poorer birth outcomes due to lack of equitable access to quality healthcare.[32,33] Additionally, the findings highlight that, nearly half of the women who never/rarely had ASHA-accompanied ANC visits had attended fewer than eight ANC visits which may explain the higher odds of poor birth outcomes. The WHO recommended optimizing systematic low-cost interventions such as antenatal care, community health worker initiatives such as ASHA support in all rural settings that will greatly improve maternal and child health outcomes.[22]

In addition, our study findings revealed that among women who rarely or never had ASHA-accompanied ANC visits, women in Class 2 had higher odds of low birth weight infants. Similar observations were also reported among women who occasionally or regularly had ASHA-accompanied ANC visits. While these findings may seem surprising, women in Class 2 were associated with having low birth weight infants across all four models, and may be a group of women with barriers that were not addressed by ASHAs in this study. Women who are low SES and pregnant for the first time may also lack the appropriate resources and knowledge in seeking reproductive health services. Thus, community health workers, like ASHAs, are vital intermediaries in the mobilizing and facilitating ANC services for primigravida women.[34] Prior studies have shown that primigravida women who tend to seek antenatal care services have healthy birth outcomes.[35] Several community health worker programs that have targeted women have observed increased ANC visits, increased institutional deliveries, and healthy birth outcomes.[10] However, none of the studies has solely focused on primigravida women, particularly

younger women from low-resource settings. Therefore, our findings underscore the need for a targeted outreach by ASHAs geared towards first-time rural mothers to promote healthy birth outcomes.

While the NRHM recommends ASHA home visits as essential services during pregnancy, our study did not find a significant moderating effect of ASHA home visits on the relationship between the latent SES classes and preterm birth. This may be partly explained by the lack of clear guidelines for the minimum number of required home visits and services offered during the ASHA home visits outlined in the policy document.[8] Despite the ASHA program being standardized throughout all states, ASHA training varies depending on the state and the resources available, which could further lead to heterogeneity and inconsistencies of service delivery. A recent systematic review reported that ASHAs negative performance may have been attributed to several inadequacies including, knowledge gaps, limited ASHA training and supervision, challenges with referral, dissatisfaction related to pay, limited coverage, and sub-optimal performance of ASHAs.[12] It is crucial for the NRHM to incorporate strategies to recruit, educate, train, and retain ASHAs to improve healthcare access, quality care and coverage for marginalized and rural pregnant women. Moreover, the government should set up a standard checklist for each visit to ensure standardization throughout the states to promote equitable outcomes. We also found that ASHA home visits had no apparent benefit for women in Class 2. This could be because women in Class 2 were already at a higher risk of low birth weight as shown in all models and hence ASHA home visits were ineffective. It is worth mentioning that while we observed non-significant results, women who never/rarely had ASHA home visits in higher risk SES classes tended to have higher odds of low birth weight infants and preterm birth compared with those who occasionally/regularly had ASHA visits across the same classes. The non-significant results may also be due to reduced statistical power from smaller sample represented in these groups.

Consistent with previous findings, age and previous low birth weight were risk factors for preterm birth and subsequent low birth weight infants respectively.[21] The adjusted analysis did not show significant association of the frequency of ANC visits and preterm birth, this may be as a result of controlling for a number of SES covariates. However, the unadjusted findings indicated that women who

had fewer than eight ANC visits during their pregnancy were significantly more likely to have a preterm delivery. The WHO recently updated its ANC guidelines to a minimum of eight ANC visits as compelling evidence suggested that this can reduce perinatal deaths by up to eight per 1000 live births compared to the prior recommendation of four ANC visits.[22] Therefore, this affirms the important role of updating the Indian antenatal care guidelines to align with the recent WHO recommendation of a minimum of eight ANC visits to promote healthy birth outcomes.[22]

Some limitations were observed in our study. Preterm birth was defined by the gestational age based on the last menstrual period, and there may be degrees of inaccuracy due to the lack of ultrasound assessments to ascertain these measures. Specific measures such as hemoglobin and blood pressure were only assessed during the enrollment of the study in the second trimester, and not throughout the pregnancy. Some measures including short inter-pregnancy intervals and the timeliness for the ANC visits were not included in the survey and may serve as residual confounders. Our study only included women 18 years and older and omitted younger women (<18 years old) who were married and pregnant. Therefore, this may limit the generalizability of the results. The survey questionnaire did not include any assessments done during ASHA home visits and ASHA-accompanied ANC visits to assess the differences observed in our study. However, a distinction between the two is that with ASHA-accompanied ANC visits, pregnant women receive assistance in navigating the medical care system facilitating the identification of pregnancy complications; this assistance with medical care navigation is lacking during home visits.[8] In addition, the three-week training for ASHA workers is inadequate, with ASHA workers performing home visits mainly offer counseling, recommend ANC visits, and facilitate institutional deliveries but do not provide clinical care during home visits.[36] Hence, this may explain why ASHA-accompanied ANC visits were more effective. While the ASHA program is national, the data are from rural Mysore and may have limited generalizability throughout India.

Nevertheless, there were several strengths in our study. This study is a prospective cohort study with a rich dataset to assess the measure of temporality between exposure and outcomes of interest. This study is one of the few studies that has utilized latent class analysis to examine the co-occurrence of risk

factors among pregnant women in low-resource settings. Specifically, this analysis offers a robust analytical approach to examine sociodemographic class patterns that may not be accounted by traditional multivariable regression analyses. Lastly, this study examined the moderating role of ASHA home visits and ASHA-accompanied ANC visits during pregnancy which has not been previously studied.

Conclusion

ASHA services are truly essential among rural women in India to increase antenatal care to prevent adverse birth outcomes and promote successful and thriving healthy pregnancies. The findings demonstrate that ASHA accompanying pregnant women to ANC moderates the risk of preterm births among women in high-risk SES groups. No significant interaction was observed in the relationship of ASHA home visits on preterm birth and low birth weight in high-risk groups. Targeted policies and interventions are needed to improve and strengthen the ASHA program to recruit, educate, train, and retain ASHAs to promote quality-care home visits, and encourage ANC visits, ultimately reducing inequities in preterm birth and low birth weight in rural India.

Conflict of Interest

The authors declare that have no conflicts of interest.

References

1. Liu L, Oza S, Hogan D, et al. Global, regional, and national causes of under-5 mortality in 2000–15: an updated systematic analysis with implications for the Sustainable Development Goals. *The Lancet*. 2016;388(10063):3027-3035.
2. World Health Organization. Newborns: Improving survival and well-being. World Health Organization Accessed December 10, 2020.
3. Bhutta ZA, Das JK, Bahl R, et al. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? *The Lancet*. 2014;384(9940):347-370.
4. UNICEF. Newborn and child health: Let's end preventable deaths and ensure Every Child ALIVE. Accessed December 10, 2020. https://www.unicef.org/india/what-we-do/newborn-and-child-health
5. Fadel SA, Rasaily R, Awasthi S, et al. Changes in cause-specific neonatal and 1–59-month child mortality in India from 2000 to 2015: a nationally representative survey. *The Lancet*. 2017;390(10106):1972-1980.
6. International Institute of Population Health Sciences. *National Family Health Survey (NFHS-4)*. 2016. rchiips.org/nfhs/NFHS-4reports/Karnataka.pdf
7. Saikia N, Singh A, Jasilionis D, Ram F. Explaining the rural–urban gap in infant mortality in India. *Demographic Research*. 2013;29:473-506.
8. National Health Mission. About Accredited Social Health Activists. Accessed December 10, 2020. https://nhm.gov.in/index1.php?lang=1&level=1&sublinkid=150&lid=226
9. Munuswamy S, Nakamura K, Seino K, Kizuki M. Inequalities in use of antenatal care and its service components in India. *Journal of Rural Medicine*. 2013:2877.
10. Agarwal S, Curtis SL, Angeles G, Speizer IS, Singh K, Thomas JC. The impact of India's accredited social health activist (ASHA) program on the utilization of maternity services: a nationally representative longitudinal modelling study. *Human resources for health*. 2019;17(1):68.
11. Lyngdoh T, Neogi SB, Ahmad D, Soundararajan S, Mavalankar D. Intensity of contact with frontline workers and its influence on maternal and newborn health behaviors: cross-sectional survey in rural Uttar Pradesh, India. *Journal of Health, Population and Nutrition*. 2018;37(1):2.
12. Scott K, George AS, Ved RR. Taking stock of 10 years of published research on the ASHA programme: examining India's national community health worker programme from a health systems perspective. *Health research policy and systems*. 2019;17(1):29.
13. Paul PL, Pandey S. Factors influencing institutional delivery and the role of accredited social health activist (ASHA): a secondary analysis of India human development survey 2012. *BMC Pregnancy and Childbirth*. 2020;20(1):1-9.
14. Tripathy P, Nair N, Sinha R, et al. Effect of participatory women's groups facilitated by Accredited Social Health Activists on birth outcomes in rural eastern India: a cluster-randomised controlled trial. *The Lancet Global Health*. 2016;4(2):e119-e128.
15. Shaw SH, Herbers JE, Cutuli J. Medical and psychosocial risk profiles for low birthweight and preterm birth. *Women's Health Issues*. 2019;29(5):400-406.
16. Hendryx M, Chojenta C, Byles JE. Latent Class Analysis of Low Birth Weight and Preterm Delivery among Australian Women. *The Journal of Pediatrics*. 2020;218:42-48. e1.
17. Mysore District : Census 2011 data. https://www.census2011.co.in/census/district/263-mysore.html

18. Kojima N, Krupp K, Ravi K, et al. Implementing and sustaining a mobile medical clinic for prenatal care and sexually transmitted infection prevention in rural Mysore, India. *BMC infectious diseases*. 2017;17(1):189.
19. World Health Organization. Born too soon: the global action report on preterm birth. 2012;
20. World Health Organization. *Low birthweight: country, regional and global estimates*. 2004. 9280638327.
21. Blencowe H, Cousens S, Chou D, et al. Born too soon: the global epidemiology of 15 million preterm births. *Reproductive health*. 2013;10(1):S2.
22. World Health Organization. *WHO recommendations on antenatal care for a positive pregnancy experience*. 2016. 9241549912.
23. World Health Organization. *Haemoglobin concentrations for the diagnosis of anaemia and assessment of severity*. 2011.
24. Barbara M. Seventh Report of the Joint National Committee (JNC 7) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: National Heart, Lung, and Blood Institute, National High Blood Pressure Education Program. *Retrieved May*. 2006;
25. Lanza ST, Collins LM, Lemmon DR, Schafer JL. PROC LCA: A SAS procedure for latent class analysis. *Structural equation modeling: a multidisciplinary journal*. 2007;14(4):671-694.
26. Blumenshine P, Egerter S, Barclay CJ, Cubbin C, Braveman PA. Socioeconomic disparities in adverse birth outcomes: a systematic review. *American journal of preventive medicine*. 2010;39(3):263-272.
27. Simkhada B, Teijlingen ERv, Porter M, Simkhada P. Factors affecting the utilization of antenatal care in developing countries: systematic review of the literature. *Journal of advanced nursing*. 2008;61(3):244-260.
28. Mukhopadhyay P, Chaudhuri R, Paul B. Hospital-based perinatal outcomes and complications in teenage pregnancy in India. *Journal of health, population, and nutrition*. 2010;28(5):494.
29. Bhushan NL, Krupp K, Jaykrishna P, et al. The association between social support through contacts with Accredited Social Health Activists (ASHAs) and antenatal anxiety among women in Mysore, India: a cross-sectional study. *Social Psychiatry and Psychiatric Epidemiology*. 2020:1-11.
30. Kiplagat S, Coudray MS, Ravi K, et al. Evaluating a Conditional Cash Transfer Scheme in a Maternal Health Care Utilization Program Among Rural Pregnant Women in Mysore District, India. *Women's Health Reports*. 2020;1(1):159-166.
31. Seth A, Tomar S, Singh K, et al. Differential effects of community health worker visits across social and economic groups in Uttar Pradesh, India: a link between social inequities and health disparities. *International journal for equity in health*. 2017;16(1):46.
32. Dongarwar D, Salihu HM. Place of Residence and Inequities in Adverse Pregnancy and Birth Outcomes in India. *International Journal of Maternal and Child Health and AIDS*. 2020;9(1):53.
33. Amjad S, MacDonald I, Chambers T, et al. Social determinants of health and adverse maternal and birth outcomes in adolescent pregnancies: a systematic review and meta-analysis. *Paediatric and perinatal epidemiology*. 2019;33(1):88-99.

34. Okuga M, Kemigisa M, Namutamba S, Namazzi G, Waiswa P. Engaging community health workers in maternal and newborn care in eastern Uganda. *Global health action*. 2015;8(1):23968.
35. Tuladhar H, Dhakal N. Impact of antenatal care on maternal and perinatal utcome: a study at Nepal medical college teaching hospital. *Nepal journal of Obstetrics and Gynaecology*. 2011;6(2):37-43.
36. Evaluation of Accredited Social Health Activists (ASHA) (2015).

Table 1: Description of sociodemographic characteristics of rural pregnant women in Mysore District that were used to determine class membership overall and by class (n=1540)

Characteristics	Total N=1540 (%)	Class 1: Low SES, Early Marriage, Multigravida, 1 Child or More n (%) 710 (46.1%)	Class 2: Low SES, Later Marriage, Primigravida, No Children n (%) 354 (23.0%)	Class 3: High SES, Later Marriage, Multigravida, 1 Child or More n (%) 214 (13.9%)	Class 4: High SES, Later Marriage, Primigravida, No Children n (%) 262 (17.0%)	P-value
Pregnant Woman's Education						<0.0001**
Primary Education or Less (≤8 years)	603 (39.2%)	406 (57.2%)	176 (49.7%)	21 (9.8%)	0 (0.0%)	
Secondary Education (9-10 years)	629 (40.8%)	268 (37.8%)	178 (50.3%)	92 (43.0%)	91 (34.7%)	
Upper Secondary and Higher (>10 years)	308 (20.0%)	36 (5.1%)	0 (0.0%)	101 (47.2%)	171 (65.3%)	
Partner's Education						<0.0001**
Primary Education or Less (≤8 years)	817 (53.1%)	493 (69.4%)	246 (69.5%)	15 (7.0%)	63 (24.1%)	
Secondary Education (9-10 years)	478 (31.0%)	183 (25.8%)	89 (25.1%)	97 (45.3%)	109 (41.6%)	
Upper Secondary and Higher (>10 years)	245 (15.9%)	34 (4.8%)	19 (5.4%)	102 (47.7%)	90 (34.4%)	
Age at Marriage						<0.0001**
<18 years	603 (39.2%)	432 (60.9%)	140 (40.0%)	5 (2.3%)	26 (9.9%)	
≥ 18 years	937 (60.8%)	278 (39.2%)	214 (60.5%)	209 (97.7%)	236 (90.1%)	
Primigravida						<0.0001**
No	969 (62.9%)	710 (100.0%)	33 (9.3%)	214 (100.0%)	12 (4.6%)	
Yes	571 (37.1%)	0 (0.0%)	321 (90.7%)	0 (0.0%)	250 (95.4%)	

Children						<0.0001**
No	723 (47.0%)	66 (9.3%)	354 (0.0%)	41 (19.2%)	262 (100.0%)	
Yes	817 (53.0%)	644 (90.7%)	0 (0.0%)	173 (80.8%)	0 (0.0%)	
Monthly Household Income (In Indian Rupees) (1 USD = 58.9 INR)						<0.0001**
<4000 Indian Rupees	554 (36.0%)	337 (47.5%)	149 (42.1%)	30 (14.0%)	38 (14.5%)	
4000-10,000 Indian Rupees	819 (53.2%)	320 (45.1%)	185 (52.3%)	159 (74.3%)	155 (59.2%)	
>10,000 Indian Rupees	167 (10.8%)	53 (7.5%)	20 (5.7%)	25 (11.7%)	69 (26.3%)	

Table 2: Description of maternal obstetric covariates among rural pregnant women in Mysore District by ASHA home visits and ASHA-accompanied ANC visits n=1540)

Characteristics	ASHA Home Visits Never/Rarely n=258 (16.9%)	ASHA Home Visits Occasionally/ Regularly n=1273 (83.2%)	P-value	ASHA ANC Visits Never/Rarely n=612 (39.7%)	ASHA ANC Visits Occasionally/ Regularly n=928 (60.3%)	P-value
Latent Classes			0.1391			0.4133
Class 1	131 (50.8%)	575 (45.2%)		303 (44.5%)	403 (47.4%)	
Class 2	32 (12.4%)	230 (18.1%)		122 (17.9%)	140 (16.5%)	
Class 3	59 (22.9%)	293 (23.0%)		167 (24.5%)	185 (21.8%)	
Class 4	36 (14.0%)	175 (13.8%)		89 (13.1%)	122 (14.4%)	
Age Categories			0.8109			0.2133
<20 years	58 (22.5%)	303 (23.8%)		174 (25.6%)	187 (22.0%)	
20-24 years	165 (64.0%)	813 (63.9%)		428 (62.9%)	550 (64.7%)	
≥ 25 years	35 (13.6%)	157 (9.3%)		79 (11.6%)	113 (13.3%)	
Delivery Location			0.2455			0.2629
Home	4 (1.6%)	8 (0.6%)		6 (0.9%)	6 (0.7%)	
Sub-center/ Primary Health Center/District Health	137 (53.3%)	652 (51.4%)		366 (54.0%)	423 (50.0%)	
Maternity Hospital/Private Nursing Home	116 (45.1%)	607 (47.9%)		306 (45.1%)	417 (49.3%)	
Baseline Sexually Transmitted Infections			0.4719			0.0054*
No	239 (93.7%)	1161 (92.4%)		632 (94.8%)	768 (91.0%)	

Yes	16 (6.3%)	95 (7.6%)		35 (5.3%)	76 (9.0%)	
Previous Stillbirth or Neonatal Loss			0.3094			0.7281
No	245 (95.0%)	1226 (96.3%)		653 (95.9%)	818 (96.2%)	
Yes	13 (5.0%)	47 (3.7%)		28 (4.1%)	32 (3.8%)	
History of Spontaneous Abortion			0.0200*			0.7388
No	222 (86.1%)	1156 (90.8%)		611 (89.7%)	767 (90.2%)	
Yes	36 (14.0%)	117 (9.2%)		70 (10.3%)	83 (9.8%)	
History of Induced Abortion			0.7157			0.3863
No	251 (97.3%)	1233 (96.9%)		663 (97.4%)	821 (96.6%)	
Yes	7 (2.7%)	40 (3.1%)		18 (2.6%)	29 (3.4%)	
Passive Smoking			0.3453			0.2726
No	206 (79.8%)	1048 (82.3%)		566 (83.1%)	688 (80.9%)	
Yes	52 (20.2%)	225 (17.7%)		115 (16.9%)	162 (19.1%)	
Previous Low Birth Weight			0.0521			0.1873
No	200 (77.5%)	1052 (81.8%)		547 (80.3%)	705 (82.9%)	
Yes	58 (22.5%)	221 (17.4%)		134 (19.7%)	145 (17.1%)	
Frequency of ANC Visits			0.0340*			<0.0001**
<8 visits	118 (19.3%)	140 (15.2%)		335 (49.2%)	275 (32.4%)	
≥ 8 visits	492 (80.7%)	781 (84.8%)		346 (50.8%)	575 (67.7%)	
Baseline Anemia Status			0.4840			0.2216
Normal (>11 g/dl)	59 (22.9%)	312 (24.5%)		156 (22.9%)	215 (25.3%)	

Mild (10.0-10.9 g/dl)	47 (18.2%)	262 (20.6%)		150 (22.0%)	159 (18.7%)	
Moderate/Severe (≤ 9.9 g/dl)	152 (58.9%)	699 (54.9%)		375 (55.1%)	476 (56.0%)	
History of Hypertension			0.8859			0.0120*
No	253 (98.1%)	1250 (98.2%)		662 (97.2%)	841 (98.9%)	
Yes	5 (1.9%)	23 (1.8%)		19 (2.8%)	9 (1.1%)	
Baseline Hypertension			0.0058*			<0.0001**
Normal (<120/80 mm Hg)	171 (66.3%)	743 (58.4%)		452 (66.4%)	462 (54.4%)	
Pre-hypertension (120-139 mm Hg/ 0r 80-89 mm Hg)	76 (29.5%)	499 (39.2%)		208 (30.5%)	367 (43.2%)	
Hypertension (>140/>90 mm/Hg)	11 (4.3%)	31 (2.4%)		21 (3.1%)	21 (2.5%)	

**-<0.0001 *-<0.05

Table 3: Logistic Regression Models Examining the Interaction of ASHA and Latent Classes on Preterm Birth in rural Mysore District

Characteristics	Model 1	Model 2	Model 3: Predictors and ASHA Home Visits Interaction	Model 4: Predictors and ASHA ANC visits Interaction
	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)
Class				
Class 1 vs. Class 4	**1.79 (1.10–2.91)***	1.68 (1.00–2.83)	1.87 (0.91–3.83)	**1.83 (1.06–3.14)***
Class 2 vs. Class 4	1.35 (0.78–2.34)	1.35 (0.76–2.39)	1.67 (0.78–3.58)	1.45 (0.80–2.62)
Class 3 vs. Class 4	1.51 (0.83–2.75)	1.63 (0.85–3.12)	2.00 (0.87–4.60)	1.75 (0.90–3.43)
Age				
<20 years vs. ≥ 25 years	1.35 (0.78–2.35)	**1.92 (1.03–3.57)***	**1.94 (1.04–3.60)***	**1.89 (1.02–3.51)***
20-24 years vs. ≥ 25 years	1.21 (0.74–2.00)	1.46 (0.85–2.52)	1.46 (0.85–2.52)	1.45 (0.84–2.50)
Delivery Location				
Home vs Private Health Institution	2.66 (0.71–10.02)	1.73 (0.43–6.91)	1.73 (0.43–6.99)	1.79 (0.45–7.14)
Public vs. Private Health Institution	1.18 (0.86–1.60)	1.07 (0.77–1.48)	1.07 (0.77–1.48)	1.07 (0.77–1.48)
Baseline Sexually Transmitted Infection				
Yes vs. No	1.36 (0.79–2.34)	1.36 (0.78–2.37)	1.37 (0.78–2.39)	1.36 (0.78–2.37)
History of Neonatal Loss or Still Birth				
Yes vs. No	1.27 (0.61–2.61)	1.13 (0.53–2.39)	1.14 (0.54–2.42)	1.13 (0.53–2.39)
History of Spontaneous Abortion				
Yes vs. No	1.40 (0.88–2.23)	1.02 (0.58–1.79)	1.02 (0.58–1.80)	1.04 (0.59–1.83)
History of Induced Abortion				
Yes vs. No	0.64 (0.23–1.79)	0.50 (0.17–1.48)	0.51 (0.17–1.51)	0.51 (0.17–1.51)
Passive Smoking				
Yes vs. No	1.08 (0.73–1.60)	1.05 (0.70–1.59)	1.05 (0.70–1.59)	1.07 (0.71–1.61)
Previous Low Birth Weight				
Yes vs. No	**1.60 (1.12–2.29)***	1.38 (0.88–2.17)	1.37 (0.87–2.15)	1.37 (0.87–2.15)
Anemia				
Mild vs. Normal	0.59 (0.35–1.00)	**0.56 (0.33–0.96)***	**0.56 (0.33–0.96)***	**0.56 (0.33–0.96)***
Moderate/Severe vs. Normal	1.13 (0.78–1.62)	1.09 (0.75–1.59)	1.10 (0.75–1.60)	1.10 (0.75–1.60)

History of Hypertension				
Yes vs. No	1.59 (0.60–4.23)	1.17 (0.41–3.28)	1.14 (0.40–3.20)	1.04 (0.37–2.93)
Hypertension				
Pre-hypertension (120-139 mm Hg/ 0r 80-89 mm Hg) vs. Normal	1.18 (0.86–1.62)	1.27 (0.91–1.78)	1.30 (0.93–1.81)	1.28 (0.92–1.78)
Hypertension (>140/>90 mm/Hg) vs. Normal	**2.16 (1.01–4.64)***	2.18 (0.97–4.90)	2.17 (0.96–4.89)	2.21 (0.98–4.97)
Antenatal Checkups				
<8 visits vs. ≥ 8 visits	**1.48 (1.09–2.01)***	1.36 (0.98–1.89)	1.35 (0.98–1.87)	1.36 (0.98–1.88)
ASHA Home Visits During Pregnancy				
Never/Rarely vs. Occasionally/Regularly	**1.58 (1.09–2.29)***	1.52 (0.97–2.38)	1.47 (0.92–2.36)	
ASHA-accompanied ANC Visits				
Never/Rarely vs. Occasionally/Regularly	1.11 (0.82-1.51)	0.95 (0.65–1.39)		1.10 (0.75–1.61)
INTERACTIONS				
Class*ASHA Home Visits				
Class 1 vs. Class 4*ASHA Home Visits (Never/Rarely)			2.14 (0.58–7.90)	
Class 2 vs. Class 4*ASHA Home Visits (Never/Rarely)			2.35 (0.59–9.40)	
Class 3 vs. Class 4*ASHA Home Visits (Never/Rarely)			2.76 (0.63–12.03)	
Class 1 vs. Class 4 *ASHA Home Visits (Occasionally/Regularly)			1.63 (0.93–2.85)	
Class 2 vs. Class 4*ASHA Home Visits (Occasionally/Regularly)			1.19 (0.63–2.29)	
Class 3 vs. Class 4*ASHA Home Visits (Occasionally/Regularly)			1.45 (0.70–2.96)	
Class*ASHA-accompanied ANC Visits				
Class 1 vs. Class 4*ASHA-accompanied ANC Visits (Never/Rarely)				**2.62 (1.12–6.12)***
Class 2 vs. Class 4*ASHA-accompanied ANC Visits (Never/Rarely)				2.07 (0.83–5.17)
Class 3 vs. Class 4*ASHA-accompanied ANC Visits (Never/Rarely)				**3.47 (1.31–9.15)***
Class 1 vs. Class 4*ASHA-accompanied ANC Visits (Occasionally/Regularly)				1.28 (0.67–2.43)
Class 2 vs. Class 4*ASHA-accompanied ANC Visits (Occasionally/Regularly)				1.02 (0.49–2.11)
Class 3 vs. Class 4*ASHA-accompanied ANC Visits (Occasionally/Regularly)				0.88 (0.37–2.14)

CI, confidence intervals; OR, odds ratio; Bolded point estimates indicate statistical significance at P <0.05*
Model 2: Adjusted for age, delivery location, baseline STI, history of neonatal loss or still birth, history of spontaneous abortion, history of induced abortion, passive smoking, previous low birth weight, anemia, history of hypertension, hypertension, ANC visits, ASHA home visits during pregnancy and ASHA-accompanied visits.

Model 3: Adjusted for age, delivery location, baseline STI, history of neonatal loss or still birth, history of spontaneous abortion, history of induced abortion, passive smoking, previous low birth weight, anemia, history of hypertension, hypertension, ANC visits, ASHA home visits during pregnancy and interaction of classes and ASHA home visits during pregnancy.
Model 4: Adjusted for age, delivery location, baseline STI, history of neonatal loss or still birth, history of spontaneous abortion, history of induced abortion, passive smoking, previous low birth weight, anemia, history of hypertension, hypertension, ANC visits, ASHA home visits during pregnancy and interaction of classes and ASHA-accompanied ANC visits.
Class 1: “Low SES, Early Marriage, Multigravida, 1 Child or More”, Class 2 “Low SES, Later Marriage, Primigravida, No Children”, Class 3 “High SES, Later Marriage, Multigravida, 1 Child or More” and Class 4 “High SES, Later Marriage, Primigravida, No Children”

Table 4: Logistic Regression Models Examining the Interaction of ASHA and Latent Classes on Low Birth Weight in rural Mysore District

Characteristics	Model 1	Model 2	Model 3: Predictors and ASHA Home Visits Interaction	Model 4: Predictors and ASHA ANC Visits Interaction
	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)	Adjusted OR (95% CI)
Class				
Class 1 vs. Class 4	**1.75 (1.08–2.84)***	1.31 (0.78–2.18)	1.57 (0.70–3.57)	1.30 (0.78–2.18)
Class 2 vs. Class 4	**2.83 (1.71–4.71)***	**2.46 (1.46–4.15)***	**3.11 (1.35–7.13)***	**2.47 (1.47–4.17)***
Class 3 vs. Class 4	1.13 (0.60–2.12)	0.89 (0.45–1.75)	0.75 (0.25–2.26)	0.88 (0.44–1.73)
Age				
<20 years vs. ≥ 25 years	1.08 (0.67–1.75)	0.99 (0.58–1.71)	1.02 (0.59–1.74)	1.00 (0.58–1.71)
20-24 years vs. ≥ 25 years	0.85 (0.55–1.32)	0.97 (0.60–1.54)	0.98 (0.61–1.57)	0.97 (0.61–1.55)
Delivery Location				
Home vs Private Health Institution	1.45 (0.31–6.74)	1.55 (0.32–7.49)	1.53 (0.31–7.48)	1.55 (0.32–7.52)
Public vs. Private Health Institution	1.31 (0.97–1.75)	1.27 (0.93–1.73)	1.28 (0.94–1.74)	1.27 (0.93–1.73)
Baseline Sexually Transmitted Infection				
Yes vs. No	1.41 (0.85–2.34)	1.48 (0.87–2.51)	1.50 (0.88–2.53)	1.49 (0.88–2.51)
History of Neonatal Loss or Still Birth				
Yes vs. No	**1.92 (1.04–3.55)***	1.65 (0.86–3.17)	1.67 (0.87–3.21)	1.65 (0.86–3.18)
History of Spontaneous Abortion				
Yes vs. No	1.31 (0.84–2.06)	0.96 (0.56–1.66)	0.95 (0.56–1.64)	0.96 (0.56–1.65)
History of Induced Abortion				
Yes vs. No	0.70 (0.28–1.79)	0.65 (0.25–1.77)	0.62 (0.23–1.67)	0.65 (0.24–1.75)
Passive Smoking				
Yes vs. No	**1.46 (1.03–2.07)***	1.37 (0.95–1.99)	1.37 (0.94–1.98)	1.37 (0.95–1.99)
Previous Low Birth Weight				
Yes vs. No	**1.74 (1.24–2.43)***	**2.17 (1.41–3.34)***	**2.21 (1.44–3.40)***	**2.19 (1.42–3.37)***
Anemia				
Mild vs. Normal	0.97 (0.64–1.47)	0.95 (0.62–1.47)	0.95 (0.61–1.46)	0.95 (0.61–1.43)

Moderate/Severe vs. Normal	0.75 (0.53–1.06)	0.71 (0.50–1.03)	0.71 (0.49–1.02)	0.71 (0.50–1.03)
History of Hypertension				
Yes vs. No	1.04 (0.36–3.03)	0.96 (0.32–2.90)	1.00 (0.33–3.01)	0.98 (0.32–2.98)
Hypertension				
Pre-hypertension (120-139 mm Hg/ 0r 80-89 mm Hg) vs. Normal	1.01 (0.75–1.36)	1.01 (0.73–1.39)	0.99 (0.72–1.36)	1.01 (0.74–1.39)
Hypertension (>140/>90 mm/Hg) vs. Normal	0.65 (0.23–1.85)	0.69 (0.24–2.03)	0.72 (0.25–2.13)	0.69 (0.24–2.04)
Antenatal Checkups				
<8 visits vs. ≥ 8 visits	1.23 (0.92–1.65)	1.17 (0.85–1.60)	1.20 (0.88–1.64)	1.17 (0.85–1.60)
ASHA Home Visits During Pregnancy				
Never/Rarely vs. Occasionally/Regularly	1.11 (0.76–1.63)	0.99 (0.63–1.65)	0.82 (0.46–1.47)	
ASHA-accompanied ANC Visits				
Never/Rarely vs. Occasionally/Regularly	1.22 (0.91–1.64)	1.16 (0.82–1.65)		1.18 (0.81–1.72)
INTERACTIONS				
Class*ASHA Home Visits				
Class 1 vs. Class 4*ASHA Home Visits (Never/Rarely)			2.07 (0.45–9.53)	
Class 2 vs. Class 4*ASHA Home Visits (Never/Rarely)			4.30 (0.90–20.52)	
Class 3 vs. Class 4*ASHA Home Visits (Never/Rarely)			0.59 (0.08–4.62)	
Class 1 vs. Class 4 *ASHA Home Visits (Occasionally/Regularly)			1.20 (0.70–2.06)	
Class 2 vs. Class 4*ASHA Home Visits (Occasionally/Regularly)			**2.24 (1.29–3.92)***	
Class 3 vs. Class 4*ASHA Home Visits (Occasionally/Regularly)			0.96 (0.48–1.95)	
Class*ASHA-accompanied ANC Visits				
Class 1 vs. Class 4*ASHA-accompanied ANC Visits (Never/ Rarely)				1.11 (0.55–2.24)
Class 2 vs. Class 4*ASHA-accompanied ANC Visits (Never/Rarely)				**2.26 (1.10–4.63)***
Class 3 vs. Class 4*ASHA-accompanied ANC Visits (Never/Rarely)				0.71 (0.27–1.89)
Class 1 vs. Class 4*ASHA-accompanied ANC Visits (Occasionally/Regularly)				1.53 (0.74–3.15)
Class 2 vs. Class 4*ASHA-accompanied ANC Visits (Occasionally/Regularly)				**2.70 (1.27–5.74)***
Class 3 vs. Class 4*ASHA-accompanied ANC Visits (Occasionally/Regularly)				1.08 (0.43–2.70)

CI, confidence intervals; OR, odds ratio; Bolded point estimates indicate statistical significance at P <0.05*

Model 2: Adjusted for age, delivery location, baseline STI, history of neonatal loss or still birth, history of spontaneous abortion, history of induced abortion, passive smoking, previous low birth weight, anemia, history of hypertension, hypertension, ANC visits, ASHA home visits during pregnancy and ASHA-accompanied ANC visits.
Model 3: Adjusted for age, delivery location, baseline STI, history of neonatal loss or still birth, history of spontaneous abortion, history of induced abortion, passive smoking, previous low birth weight, anemia, history of hypertension, hypertension, ANC visits, ASHA home visits during pregnancy and interaction of classes and ASHA home visits during pregnancy.
Model 4: Adjusted for age, delivery location, baseline STI, history of neonatal loss or still birth, history of spontaneous abortion, history of induced abortion, passive smoking, previous low birth weight, anemia, history of hypertension, hypertension, ANC visits, ASHA home visits during pregnancy and interaction of classes and ASHA-accompanied ANC visits.
Class 1: “Low SES, Early Marriage, Multigravida, 1 Child or More”, Class 2 “Low SES, Later Marriage, Primigravida, No Children”, Class 3 “High SES, Later Marriage, Multigravida, 1 Child or More” and Class 4 “High SES, Later Marriage, Primigravida, No Children”