Association Between Adverse Pregnancy Outcomes and Preceding Risk Factors: an Analytical Cross-Sectional Study

Prakash Prabhakarrao Doke
  Bharati Vidyapeeth (DTU) Medical College, Pune

Sonali Hemant Palkar (✉ palkarsh@gmail.com)
  Bharati Vidyapeeth (DTU) Medical College, Pune

Jayashree Sachin Gothankar
  Bharati Vidyapeeth (DTU) Medical College, Pune

Archana Vasantrao Patil
  State Family Welfare Bureau, Government of Maharashtra

Amruta Paresh Chutke
  Bharati Vidyapeeth (DTU) Medical College, Pune

Pasad Dnyandeo Pore
  Bharati Vidyapeeth (DTU) Medical College, Pune

Aniruddha Vinayakrao Deshpande
  State Family Welfare Bureau, Government of Maharashtra

Khanindra Kumar Bhuyan
  UNICEF Maharashtra

Madhusudan Vamanrao Karnataki
  UNICEF Maharashtra

Aparna Nishikant Shrotri
  UNICEF Maharashtra

Abstract

Background: The health of women during the preconception phase though critical, is a comparatively ignored part in her life cycle. The presence of health risks is judged as hazardous to the wellbeing of women and their forthcoming progeny. The study aimed to estimate the prevalence of various pregnancy outcomes and assess the association between various risk factors and adverse outcomes.

Methods: It was a population-based cross-sectional analytical study. The study was carried out in Nashik District, having a large mountainous area. It included two randomly selected blocks, one tribal and one nontribal, in which interventions were planned in the later stage. For comparison, two adjacent blocks, one tribal and one nontribal, were also included. All women who had a pregnancy outcome in the preceding 12 months (01 April 2017 to 31 March 2018) were interviewed. Trained Accredited Social Health Activists under the direct supervision of Auxiliary Nurse Midwives and Medical Officers conducted the survey. Multivariate analysis was carried out to find the adjusted risk ratio of having a particular adverse outcome because of the specified potential risk factors.

Results: A total of 9,307 women participated in the study. The prevalence of adverse pregnancy outcomes was abortion 4.1%; stillbirth 1.6%; preterm birth 4.1%; LBW 11.2%; congenital physical defect 2.6%. Prevalence of consanguineous marriage, heavy work during the last six months of pregnancy, pre-existing illness, tobacco consumption, direct exposure to pesticides and domestic violence during pregnancy was 17.6%; 16.9%; 2.2%; 5.6%; 2.3%; and 0.8%, respectively. Risk factors that were significantly associated with abortion include existing illness at the time of conception and performing heavy work in the last six months of pregnancy. Consanguinity, tobacco consumption during pregnancy and pre-existing illness were identified as risk factors for stillbirth. Significant risk factors of LBW were heavy work in the last six months of pregnancy, pre-existing illness and residence in a tribal area.

Conclusion: The survey showed that risk factors differentially affect outcomes of pregnancy. Preconception and antenatal care should include counselling about consanguineous marriages, identifying and managing a pre-existing illness, avoiding tobacco consumption in the prenatal and natal period, and avoiding heavy work during pregnancy.

Background

India is the second-largest country in the world, and almost 70% of its population resides in the rural area. Challenges of illiteracy, malnourishment, underdevelopment and lack of basic infrastructure are faced by the rural population. Under-five mortality in the rural area is higher compared to urban [1], which may be consequent to the lack of health care facilities, apart from the socio-cultural environment [2,3]. The challenges increase further for the tribal people, who constitute 8.6 % of India's total population [4]. This socio-culturally different, underprivileged community is dissociated from the health care system. The compromised availability and access to health care leads to poor utilisation of Maternal and Child Health services [5,6]. Due to many adversities, health indicators of the tribal population are lower than the rest of the country [7,8]. For the accomplishment of targets under Sustainable Development Goal, the slogan 'Leave no one behind' has been popularised. This aptly pertains to pregnant women of these disadvantaged and marginalised groups.

A growing body of evidence suggests preconception care (PCC) in women and men prevents mortality and morbidity among mothers as well as stillbirth, newborn death, low birth weight (LBW), prematurity, and poor cognitive development in children [9]. In 2013, WHO recommended the roll-out of preconception care globally [10]. The government of India launched India Newborn Action Plan (INAP) in 2014 to reduce neonatal mortality and stillbirth rates to single-digit per 1000 total births by 2030 in India. One of the six elements included under INAP is preconception care [11]. In 2016, the Federation of Obstetric and Gynaecological Associations of India recommended the roll-out of PCC in India [12]. Despite growing evidence and supportive policy framework, PCC has not been rolled out in India systematically as yet.

The government of Maharashtra, with the support of UNICEF, implemented a comprehensive

PCC in the state. A tribal block having a marginalised population (Peint) and one nontribal block (Sinnar) in the Nashik district of Maharashtra were selected for the intervention, and adjacent one tribal & nontribal block from the same district were taken as a comparison. It is implied that the assessment of the impact of the comprehensive PCC in reducing adverse pregnancy outcomes is indispensable. Accordingly, this cross-sectional analytical study was conducted among all women who had a pregnancy outcome in the preceding 12 months in the two intervention and two comparison blocks to estimate the prevalence of adverse pregnancy outcomes and associated risk factors.

The potential risk factors included in the study are the ones which are commonly seen in rural and tribal pregnant women, which included consanguineous marriage, performing heavy work during the last six months of pregnancy, consumption of tobacco, consumption of alcohol during pregnancy, exposure to pesticides, and domestic violence during pregnancy. All these potential risk factors for adverse pregnancy outcomes are modifiable through health advocacy/ awareness programs.

The evidence generated from this baseline study is expected to provide baseline estimates, which will help design interventions as well as for comparison with post-intervention outcomes, which will influence the policy and programming for preconception care in India.

Objectives

1. To estimate rates of adverse pregnancy outcomes (abortion, stillbirth, preterm, low birth weight, congenital physical defect and neonatal deaths) in Nashik district, India.
2. To compare the estimates between the study and control blocks, as well as between tribal and nontribal blocks.
3. To assess the association between risk factors (consanguinity, heavy work in the last six months of pregnancy, tobacco consumption, alcohol consumption, exposure to the pesticide, domestic violence, existing illness and residence in the tribal area) and adverse pregnancy outcomes.

Methods

Study design

It was a population-based study conducted before the initiation of interventions. It was an analytical cross-sectional study.

Study setting

It was carried out in the Nashik district. It included two intervention blocks in which intervention was planned, one tribal (Peint) and one nontribal (Sinnar). It also included two adjacent comparison blocks, one tribal (Trimbakeshwar) and one nontribal (Niphad). Nashik district is located high on the Deccan Plateau; it is surrounded by the Sahyadri range of mountains. The selected tribal blocks are hilly, difficult to reach and are having high annual rainfall. The population of these four blocks as per the last census (2011) is 1,19,838 for Peint; 3,46,390 for Sinnar; 1,68,423 for Trimbakeshwar and 4,93,251 for Niphad [4]. The block-wise map of the district is given in Fig. 1.

Study period

The study was carried out in 2018-19. Actual data was collected from May to July 2018.

Tools and Data collection

The consultative process was adapted for designing the interview schedule. This predesigned tool was validated by experts, translated in the local language (Marathi) and pre-tested before it was used in the field. The questionnaire included demographic information, details of pregnancy, its outcome and risk factors associated with adverse pregnancy outcome. Rigorous training was conducted on these tools for Accredited Social Health Activists (ASHA) who collected the data and Auxiliary Nurse Midwife (ANM) who supervised the activity. If a woman was not present during the home visit, she was visited later within the next month.

Participants

All women in the reproductive age group in these blocks were contacted. Women who had pregnancy outcome in the last 12 months, i.e., 01 April 2017 to 31 March 2018, were included in the study provided they met the inclusion criteria of being resident of the area (residing or intends to reside for more than six months). Those women who were unable to understand Marathi, Hindi or English or unable to respond due to psychotic illness were excluded.

Variables

The variables were of three types. The first type included the following demographic variables; age, family type, education, occupation, and place of usual residence. The second type included the following potential risk factors; consanguinity, heavy work in the last six months of pregnancy, tobacco consumption, alcohol consumption, exposure to a pesticide, domestic violence, existing illness. The outcome variables were abortion, stillbirth, preterm birth, low birth weight, congenital physical defect, and neonatal death. Standard definitions were used. Information about all these variables was based on responses given by the participants.

Sample size estimation

As per District Level, Household Survey 4, stillbirth and abortion rate for the rural area in Nashik District was 1.3% and 6.1%, respectively [13]. For estimation of the stillbirth rate with 95% confidence and an accepted difference of 0.26%, 7,600 pregnant women were required to be surveyed. In the year 2016-17 and 2017-18, each year, more than 22,000 pregnancies were registered in these four blocks [14]. Hence authors conducted a survey covering entire rural areas of these four blocks.

Data Analysis

Statistical analysis was conducted using a Statistical Package for Social Sciences version 25.0. Chi-square test was applied wherever applicable. We first carried out the univariate then multivariate analysis. The authors preferred calculation of the adjusted risk ratio (ARR) to adjusted odds ratio because of relating a particular adverse outcome to the presence of the known potential risk factors prior to the outcome. The level of significance was decided at $P<0.01$.

Results

In the study area, 9,307 (tribal=3298, non-tribal 6009; study=4766, control=4541) women reported pregnancy outcome in the aforesaid period. The non-response rate was less than 10% except for birth weight and gestation at the time of delivery; it was about 15% and 37.26%, respectively.

Their socio-demographic details are shown in Table 1. The overall mean age was 23.91±3.23 years. The age group distribution among tribal and nontribal women was different. The age of tribal women ranged from 17-45 years with a mean of 23.72 (SD ± 3.21), and for the nontribal area, age ranged from 17-43 years with a mean of 24.02 (SD ± 3.23). Many women were married before the legal age. Teenage pregnancy was more in the tribal block. Most of the women (70.03%) from both areas were living in a joint family. Overall, 26.02% of women had completed their Secondary School Certificate (SSC); 13.32% were illiterate, and only 2.18% were postgraduate or having a professional degree. Educational status was significantly different in both study and control group as well tribal and nontribal blocks; however, the educational status of women from tribal blocks was less compared to nontribal, and the difference was highly significant (p<0.001). Almost 80.0% of tribal women were working, whereas 50% of nontribal women were homemakers (p<0.001). The majority of tribal

women were involved in farming. Very poor educational status in Peint block and better in Niphad block and similarly majority women working from Peint block and not working in Niphad block, influenced the block performance.

Details of adverse outcomes are given in Table 2. Overall, abortion was reported by 4.28% of women. We did not differentiate whether abortion was spontaneous or induced. The difference was observed across all the blocks. It was least in Peint Block and maximum in Niphad Block. Stillbirth was reported by 1.70% of women; preterm birth by 4.32%; low birth weight by 15.16%; congenital physical defect by 2.84%, and neonatal death by only 0.59%. In tribal blocks, three maternal deaths were reported, and none by nontribal block. The exact duration of gestation in weeks could not be told by 37.30% of women.

The association of the potential risk factors during pregnancy and with adverse pregnancy outcomes are given in Table 3 and Table 4, respectively. The distribution of risk factors among women in study and control areas as well as among women from tribal and nontribal areas is given in Table 3. There were differences between the study and control area to some extent, but the distributions of all risk factors between tribal and nontribal areas were profoundly different. Excepting existing illness, all risk factors were more among women from tribal areas.

We have calculated the adjusted risk ratio. Abortions were reported by 5.83% of women performing heavy work in the last six months of pregnancy as against 3.74% who were not performing it. Only 3.82% of women who did not have any pre-existing illness experienced abortion against 15.20% who had an illness. Both heavy work in the last six months and pre-existing illness were identified as significant risk factors for abortion. Consanguineous marriage and consumption of tobacco or alcohol were not associated with abortion. More abortions were reported from the nontribal area as compared to tribal (5.08% vs 2.33%).

Among 3.55% of tobacco consumers, stillbirth was reported compared to 1.56% among non-consumers. In women having a pre-existing illness, 6.36% had stillbirth compared to 1.59% among those who did not have any such illness. Other factors were not associated with stillbirth.

The proportion of preterm birth was 2.73% among tribal and 4.76% among nontribal women. It was 4.94% among women performing heavy work in the last six months of pregnancy, compared to 4.03% among those who did not perform heavy work.

Low birth weight (LBW) was reported by 17.03% of mothers performing heavy work in the last six months of pregnancy, compared to 12.09% who did not perform heavy work. It was also reported by 23.33% of women having pre-existing illness as against 13.03% who did not have any such illness. LBW was reported by 17.57% tribal and 11.00% nontribal women.

The congenital physical defect was observed among 4.86% of off-springs from consanguineous marriages and 2.15% of non-consanguineous marriages. The proportion of congenital physical defect was higher (4.43% vs 2.28%) among mothers having a history of performing heavy work in the last six months of pregnancy. It was observed that among women consuming tobacco, 5.21% of babies were having congenital physical defect, whereas the proportion was 2.62% among non-consumers.

Early neonatal death was reported by 0.8% tribal and 0.5% nontribal women. None of the potential risk factors mentioned above was found to be associated with early neonatal death.

Discussion

Adverse pregnancy outcomes can be influenced by various factors that are present prior to or emerged during pregnancy. The present study was a survey carried out for measuring the prevalence of pregnancy outcomes and its association with potential risk factors.

The socio-demographic profile of women is certainly different for women residing in the tribal and nontribal area. This is important to note because the outcomes are also influenced by these factors. Although rarely practised in western countries, consanguineous marriages are seen throughout India. As shown by the India Human Development Survey (IHDS, 2004-2005) data, they were predominant in the Southern States ranging from 28% to 38% [15]. Prevalence in Maharashtra was also high (28%). In the present study, the prevalence of consanguineous marriage was 17.6% which is lower than the reported studies from rural South India, ranging from 20.3 to 36% [16,17,18]. This lower prevalence in the present study may be due to a declining trend consequent to education and modernisation.

In the present study, only 5.6% of women reported tobacco consumption during pregnancy which is less than other studies [19,20,21]. Amongst all forms of tobacco, women from India indulge more in applying Mishri (roasted tobacco) on gums and teeth, which was also observed in this study. Alcohol consumption in Indian women is less compared to women from western countries, which decreases further in pregnancy [22,23]. Alcohol consumption was very less in the study, which was lower than the consumption reported by Bellad MB et al. from India [16].

Farming is a major occupation in rural and tribal parts of India, and various pesticides are commonly used to protect the crops. Pesticide spraying on grapes is a highly prevalent seasonal work in the area. Exposure to various pesticides during pregnancy has been identified as a risk factor for adverse pregnancy outcomes; however, results are not consistent [24,25,26,27]. Association was dependent on various factors like the type of pesticide, the period of gestation, duration and amount of exposure. In this study, only 2.3% of women reported direct exposure to pesticides during pregnancy. The reason may be the non-involvement of women in the actual spraying of pesticides. This exposure to pesticides was not found associated with any of the adverse pregnancy outcomes.

Domestic violence during pregnancy was reported by only 0.8% of women, which was lower than previous reports from different states of India that ranged from 7.1% - 18% [28,29,30,31]. Considering Indian culture, women do not divulge such information, so that these figures may be just the tip of the iceberg. The pre-existing illness like endocrine abnormalities, heart disease, liver disease, etc., in the pregnant woman, can have adverse pregnancy outcomes over and

above risk to maternal health [32,33,34]. In the present study, 2.2% of women had reported pre-existing illness; however, there is a dearth of information about the prevalence of pre-existing illness in pregnant women in the community.

When the distribution of these potential risk factors was compared in tribal versus nontribal area, consanguineous marriage, heavy work in the last six months of pregnancy, tobacco and alcohol consumption, exposure to pesticides, and domestic violence were significantly more in the tribal area, which maybe because of the socio-cultural differences in these areas. Some studies have compared the socio-demographic profile of women from the tribal and nontribal area; however, a comparison of the distribution of such potential risk factors in these two groups of women are extremely rare. Alcohol consumption was higher in tribal women, which is similar to the observation of Mohan D et al. [35] who categorised tribal women in the high-risk group for alcohol consumption. Only pre-existing illness at the time of conception was more in nontribal area than tribal which may be because of better availability and accessibility of health care services in nontribal area than tribal which has led to more detection of existing illnesses.

Abortion

In the present study, 4.1% of women reported abortion which is consistent with estimated 47·0/1000 women abortions in India in 2015 [36]. Performing hard manual work, including lifting heavy weights during early pregnancy, is associated with abortion which is once again confirmed in this study. In the present study, existing maternal illness had three times the risk of abortion, which was also identified as a risk factor for abortion in other studies [37,38,39]. More abortions occurred in the nontribal area compared with tribal (5.1% vs 2.3%), and the difference was statistically significant. Residence in the tribal area has a protective factor. This may be due to more availability of various means of abortion like access to abortifacient medicines, health facilities, and affordability to avail these facilities. However, this could not be confirmed, as we did not differentiate between spontaneous and induced abortion. It was not consistent with observation reported by Niswade A et al. for tribal and rural communities from Maharashtra, India [40]. Consanguineous marriage was not associated with abortion in the present study; however, few studies observed an association between consanguineous marriage and abortion [16,17]. Whereas no association was observed in one study [18]. Studies have shown an association of alcohol consumption during pregnancy, especially the first trimester, with an increased risk of abortions [41,42]. A review by Henderson et al. 2007 did not find consistent evidence for increased risk of spontaneous abortion with light to moderate prenatal alcohol exposure [43]. Association of alcohol consumption with abortion was not seen in this study.

Stillbirth

Stillbirth was reported by 1.6% of mothers, which is similar to Doke P et al., who reported stillbirth of 1.55% from rural Maharashtra, India [44]. Other studies from India have reported a stillbirth rate ranging from 10-20 per 1000 birth [45,46]. In the present study, consanguineous marriage was identified as a significant risk factor for stillbirth, consistent with Bellad MB et al. and Kulkarni ML et al.[16,47]. Tobacco consumption increased the risk of stillbirth by two times which is consistent with other studies [48,49,50]. The meta-analysis by Marufu TC et al. 2015 reported maternal smoking during pregnancy increased the risk of stillbirth by 47% and confirmed a strong dose-response effect [51]. Many studies have identified alcohol consumption during pregnancy as a risk factor for stillbirth, which was not seen in this study [52,53]. It may be because of a small number of women consuming alcohol in the present study. Existing maternal illnesses like thyroid dysfunction or diabetes mellitus are associated with stillbirth, which is similar to the present study [37,42,54]. Domestic violence was not associated with stillbirth, which is not consistent with previous studies [28,55].

Preterm

In the present study, reported preterm birth was 4.1% which was lower than the range of 9% to 18% reported by various Indian studies [55,56,57], and the global estimate of 10.6% [58]. One of the reasons may be that these studies are either past studies or not from a progressive state. The reporting of the preterm birth rate was less than expected, which may be because of the recall bias and inability of mothers in reporting the exact pregnancy duration. An overall high proportion of women (37.26%) were unable to quantify the period of gestation in weeks, and particularly among women from tribal areas, the proportion was 46.63%. Less preterm births were reported in tribal women compared to nontribal; the difference was statistically significant. Although the non-response rate was more among tribal women, the explicit reasons for the lower prevalence of preterm babies could not be elicited.

Consanguineous marriage has been found associated with preterm births in previous studies; however, it was not observed in the present study [59,60]. In the present study, heavy work during the last six months of pregnancy was identified as a risk factor for preterm birth. Knudsen IR et al. from Denmark reported an increased risk of preterm birth in mothers performing heavy work like lifting heavy loads during pregnancy but not in women performing physically strenuous work [61]. Snijder CA et al. from Netherland did not find consistent significant associations between physically demanding work and low birth weight or preterm delivery [62].

Studies have shown the association of tobacco consumption or smoking during pregnancy with preterm birth which is due to various obstetric factors [63,64]. Risk is shown to increase with the amount of smoke [65]. Quitting smoking, especially early in pregnancy, decreases the risk of preterm birth [65]. However, in the present study, tobacco consumption was not associated with preterm birth. The role of alcohol consumption in preterm birth is controversial, and no association was found in this study [43,65]. Few studies have identified exposure to pesticides as a risk factor for preterm birth; however, findings are not consistent [24,66,67]. The present study did not find any association of exposure to pesticides with preterm birth. A meta-analysis by Shah PS et al. 2010 reported a 46% risk of preterm birth in women exposed to domestic violence during pregnancy; however, it was not observed in the present study [68]. Existing maternal illnesses like diabetes mellitus or liver disorder are found to be associated with preterm birth, but no such association was found in the present study [32,39,69].

Low Birth Weight

The study reported 11.2% LBW, which was lower than the global estimate of 14.6% [70], and the range of 17% to 36.8% reported from rural or tribal settings of India [71,72,73]. Performing heavy work during the last six months of pregnancy was associated with LBW, which was similar to the observation made by Kumar M et al.[71]. Use of any form of tobacco, including smokeless tobacco, was associated with harmful effects in the form of LBW; however, this study did not find such association [63,74]. Similarly, in the present study, no association of maternal alcohol consumption during pregnancy was found with LBW. Like premature birth, exposure to various pesticides during pregnancy has been identified as a risk factor for LBW; however, results are not consistent [24,25]. This study also did not find such an association. The association between pesticides and LBW depends on various factors like the type of pesticide, the period of gestation, duration and amount of exposure.

Gebremedhin M et al., in their study, had observed five times the risk of LBW in women having chronic medical illness during pregnancy [75]. In the present study, such a risk was 1.8 times high. Domestic violence was found to be associated with LBW in some studies; however, it is not observed in this study [70,76]. Residence in the tribal area was identified as a risk factor for LBW, which was similar to the finding of Niswade A et al.[40]. This may be because of various socio-demographic and environmental factors like maternal age, education, nutrition, Ante Natal Care (ANC) visits, availability and accessibility of health care facility etc.

Congenital Physical Defect

Congenital physical defects were present in 2.6% of babies, which is slightly more than the estimated national pooled prevalence of 184.48 per 10,000 births reported by Bhide P et al. 2018 in his meta-analysis [76]. In the present study, the perception of women about congenital physical defects pertained mostly to physical defects. Actual assessment of genetic or metabolic physical defects is difficult to assess in the field. Similar to previous studies, the present study found consanguineous marriage as a risk factor for a congenital physical defect in the baby [47,77,78]. The proportion of congenital physical birth defects may be reduced by creating awareness about the effects of consanguineous marriages. This intervention is not attempted and probably may require minimal resources. Moreover, it will have collateral benefits on biochemical and functional congenital anomalies.

It was also found to be associated with heavy work during the last six months of pregnancy. Tobacco consumption was identified as a risk factor for a congenital physical defect. A meta-analysis by Little J et al. 2004 has reported an association of maternal smoking with congenital oro-facial clefts [79], whereas Hackshaw A et al., in his systematic review, has found a significant association with many other birth defects like a heart defect, musculoskeletal defect, oro-facial clefts etc.[80]. Alcohol consumption during pregnancy was identified as a risk factor for a congenital physical defect in off-springs [81,82]; however, it was not observed in this study. Existing illness in pregnant women has been identified as a risk factor for congenital physical defects in a few studies but was not seen in this study [77,83].

Early Neonatal Death

Early neonatal death was 0.59% which was lower than the estimated early neonatal death rate of 20 per 1000 live births in India for the year 2017 [84]. This may be due to lower rates of preterm deliveries and low birth weight babies and a high rate of institutional deliveries in the study area. Ahmed et al. reported a 2.3 times high risk of neonatal mortality among mothers who experienced violence during pregnancy [28]. No such association was found in the present study.

Strengths And Limitations

It was a large study involving more than nine thousand women from four blocks. It included various adverse pregnancy outcomes as well as various risk factors. It was conducted with the help of existing health care workers. However, the overall prevalence of socio-demographic characteristics and risk factors considered in the present study may not be a true reflection of the community in general because 35% of the women in the study were from tribal area. It also implies that it is pertinent for states having a high tribal population. Although the non-response rate was more among tribal women, the explicit reasons for the lower prevalence of preterm babies could not be elicited. Details regarding pre-existing illness were not studied. The details of abortion were not collected.

Conclusion

The present study confirms a higher rate of consanguineous marriage, heavy work during the last six months of pregnancy, tobacco and alcohol consumption among tribal women. The existing illnesses were more common in the nontribal area. Of the studied potential risk factors, performing heavy work during the last six months of pregnancy was associated with abortion, preterm birth, LBW and congenital physical defect. The pre-existing maternal illness was associated with abortion, stillbirth and LBW. Thus, there is clear evidence that pre-existing illness is associated with adverse pregnancy outcomes, but unfortunately, there is a dearth of information about the prevalence of existing illness in the preconception period in the community. Consanguineous marriage and tobacco consumption during pregnancy were associated with stillbirth and congenital physical defect.

Mass awareness regarding the adverse effects of consanguineous marriage should be done to avoid such marriages in future. This study high lights the need for physical examination and necessary investigations of women in the preconception period. Advocacy of prevention of tobacco consumption in prenatal and natal period is very important and should be included in preconception care. Advice regarding adequate rest and not performing heavy work during pregnancy should be given to the pregnant women by health care provider during the ANC visits.

Abbreviations

PCC: preconception care; INAP: India Newborn Action Plan; ASHA: Accredited Social Health Activists; ANM: Auxiliary Nurse Midwife; ARR: adjusted risk ratio; LBW: Low birth weight; SSC: Secondary School Certificate; IHDS: India Human Development Survey; ANC: Ante Natal Care; PG: Post Graduate; HSC: Higher

Secondary-school Certificate; ITI: Industrial Training Institute

Declarations

Ethics approval and consent to participate

Approval from the Institutional Ethics Committee Bharati Vidyapeeth (Deemed to be University) Medical College, Pune [DCGI Regd. No. ECR/518/Inst/MH/2014/RR-17] was obtained before initiation of the study vide letter no. BVDUMC/IEC/11 dated 30th April 2018. Informed written consent for participation was obtained from all the participant women. All methods were performed in accordance with the relevant guidelines and regulations (Declaration of Helsinki).

Consent for publication

Not Applicable.

Data availability data and material

Data used in the analysis are available from the corresponding author on reasonable request.

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Tables

Table 1 Socio-demographic profile of women in Nasik district, India, 2017-18							
	Study		χ²	Residence		χ²	Total*
	Study	Control	(p)	Tribal	Non-tribal	(p)	
Age							
15-19	232	207		192	247		439
20-24	2674	2370		1793	3251		5044
25-29	1408	1402	9.84	928	1882	31.35	2810
30-34	206	209	(0.08)	119	296	(<0.001)	415
35-39	38	32		31	39		70
40-44	9	3		6	6		12
Type of family							
Nuclear	840	883		597	1126		1723
Joint	3563	3305	5.94 (0.051)	2355	4513	3.68 (0.158)	6868
Other	47	52		25	74		99
Education							
PG/ Professional	98	98		25	171		196
Graduation	176	237		43	370		413
HSC/ ITI	1009	912		386	1535		1921
SSC	1170	1099	20.76	531	1738	1067.8	2269
7th pass	860	738	(0.002)	671	927	(<0.001)	1598
>7th pass	623	538		630	531		1161
Illiterate	578	583		716	445		1161
Occupation							
Working	3195	2333	224.43	2624	2904	985.58	5528
Homemaker	1441	2025	(<0.001))	521	2945	(<0.001)	3466

* Total does not tally because of non-response by the participants

PG=Post Graduate; HSC=Higher Secondary-school Certificate; ITI=Industrial Training Institute

Table 2 Prevalence of adverse outcomes in Nasik district, India, 2017-18

		Study			Residence			
		Study	Control	χ² (p)	Tribal	Non-tribal	χ² (p)	Total*
Abortion	Yes	140	242	33.79	77	305	40.64 (<0.001)	382
	No	4626	4299	(<0.001)	3221	5704		8925
Still Birth	Yes	62	87	6.34	61	88	1.545	149
	No	4564	4212	(0.012)	3160	5616	(0.214)	8776
Preterm Birth	Yes	141	101	2.67	48	194	12.73 (<0.001)	242
	No	2961	2636	(0.102)	1712	3885		5597
Low Birth weight	Yes	538	502	0.47	458	582	66.06 (<0.001)	1040
	No	3626	3232	(0.492)	2148	4710		6858
Congenital birth defect	Yes	116	129	2.07	94	151	0.567	245
	No	4484	4138	(0.15)	3106	5516	(0.451)	8622
Neo-natal deaths	Yes	22	30	1.90	25	27	3.25	52
	No	4604	4269	(0.168)	3196	5677	(0.071)	8873

* Total does not tally because of non-response by the participants

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Table 3 Potential risk factors during pregnancy and residence in Nasik district, India, 2017-18

		Study			Residence			Total
		Study	Control	χ² (p)	Tribal	Non-tribal	χ² (p)	
Consanguinity	Yes	794	848	8.12	651	991	22.3	1642
	No	3771	3446	(0.004)	2418	4799	(<0.001)	7217
Heavy work in last 6 Months	Yes	708	869	36.57	882	695	453.6	1577
	No	3664	3206	(<0.001)	1919	4951	(<0.001)	6870
Tobacco	Yes	234	283	7.64	406	111	443.4	517
	No	4523	4257	(0.006)	2892	5888	(<0.001)	8780
Alcohol	Yes	26	18	1.15	27	17	12.5	44
	No	4668	4488	(0.283)	3271	5885	(<0.001)	9156
Exposure to pesticides	Yes	78	131	16.57 (<0.001)	93	116	7.8	209
	No	4671	4389		3184	5876	(<0.001)	9060
Domestic violence	Yes	32	42	1.90 (0.167)	48	26	25.6	74
	No	4683	4445		3239	5889	(<0.001)	9128
Existing illness	Yes	95	109	1.57 (0.209)	40	164	23.9	204
	No	4591	4409		3258	5742	(<0.001)	9000

*Total does not tally because of non-response by the participant

Table 4 Adverse pregnancy outcomes and potential risk factors in Nasik district, India, 2017-18

		Abortion*		ARR (95% CI)	p	Still Birth*		ARR (95% CI)	p	Preterm Birth*		ARR (95% CI)	p	Low Birth Weight*		ARR (95% CI)	p	Co Ph de
		Yes	No			Yes	No			Yes	No			Yes	No			Ye
Consanguinity	Yes	65	1577	1.0	0.76	39	1538	1.5	0.03	36	950	1.0	0.81	180	1215	0.9	0.41	76
	No	302	6915	(0.8-1.4)		102	6813	(1.0-2.3)		200	4483	(0.7-1.4)		819	5341	(0.8-1.1)		14
Heavy Work in last 6 mths.	Yes	92	1485	1.9	0.00	37	1438	1.4	0.10	48	924	1.4	0.04	211	1028	1.3	0.00	65
	No	257	6613	(1.5-2.5)		102	6511	(0.9-2.1)		182	4336	(1.1-2.0)		726	5279	(1.1-1.5)		15
Tobacco	Yes	10	507	0.5	0.06	18	489	2.1	0.01	16	311	1.5	0.13	73	345	1.2	0.23	26
	No	371	8409	(0.3-1.0)		131	8278	(1.2-3.6)		226	5279	(0.9-2.6)		964	6509	(0.9-1.5)		21
Alcohol	Yes	1	43	0.5	0.53	2	41	1.5	0.59	2	22	1.6	0.50	7	26	1.2	0.56	1
	No	370	8786	(0.1-3.7)		144	8642	(0.4-5.9)		239	5507	(0.4-6.4)		1022	6765	(0.6-2.4)		24
Exposure to pesticides	Yes	10	199	1.0	0.95	4	195	0.8	0.76	4	98	0.9	0.85	28	149	1.0	0.90	17
	No	371	8689	(0.5-2.0)		144	8545	(0.3-2.6)		238	5473	(0.4-2.4)		1005	6688	(0.7-1.5)		22
Domestic violence	Yes	2	72	0.6	0.52	1	71	0.5	0.54	2	43	1.0	0.98	11	41	0.9	0.84	6
	No	362	8766	(0.2-2.5)		144	8622	(0.8-3.9)		238	5493	(0.2-3.9)		1019	6754	(0.5-1.8)		23
Existing illness	Yes	31	173	3.1	0.00	11	162	3.0	0.00	7	104	1.0	0.97	35	115	1.8	0.00	5
	No	344	8656	(2.0-4.9)		138	8518	(1.4-6.4)		230	5415	(0.4-2.7)		998	6661	(1.3-2.5)		23
Residence in tribal area	Yes	77	3221	0.5	0.00	61	3160	1.1	0.71	48	1712	0.6	0.00	458	2148	1.5	0.00	94
	No	305	5704	(0.4-0.7)		88	5616	(0.7-1.6)		194	3885	(0.4-0.8)		582	4710	(1.3-1.7)		15

*Total does not tally because of non-response by the participants

Figures
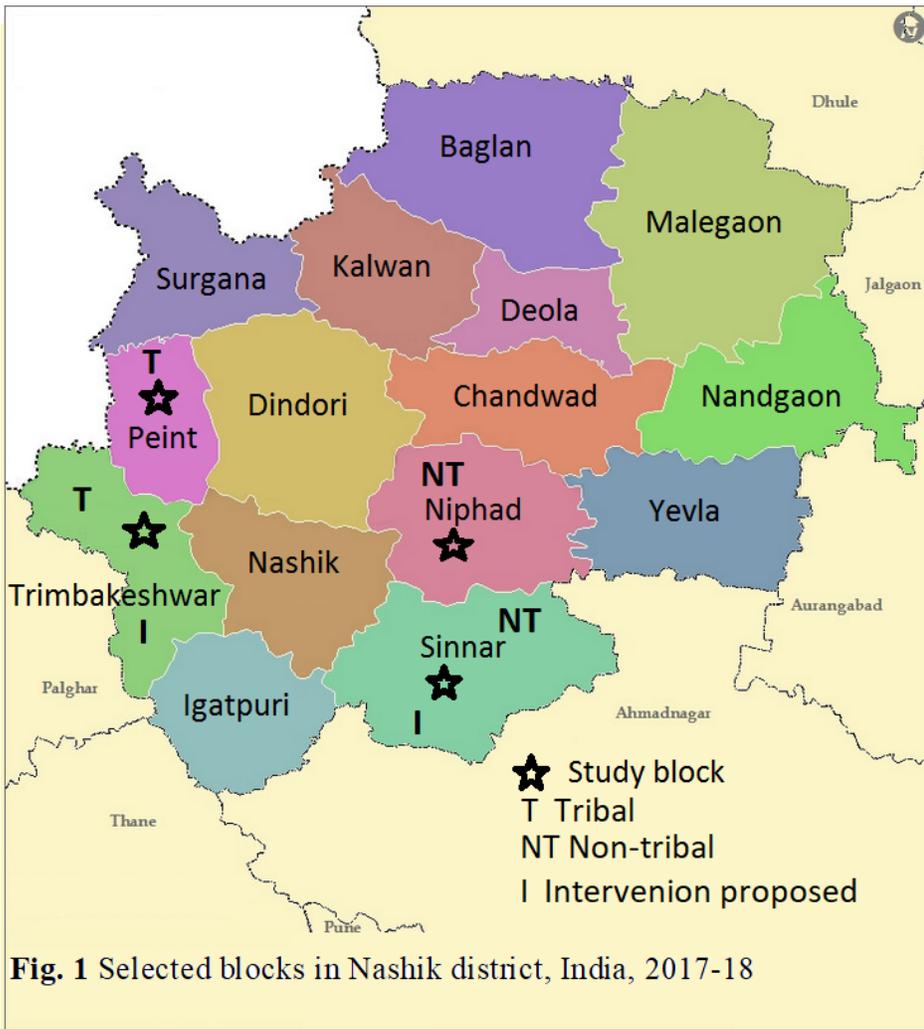
Fig. 1 Selected blocks in Nashik district, India, 2017-18

Figure 1

Note: The designations employed and the presentation of the material on this map do not imply the expression of any opinion whatsoever on the part of Research Square concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. This map has been provided by the authors.