

Determinants of Congenital Anomalies in Central India: A Case-Control Study on Modifiable Maternal Risk Factors

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ABSTRACT

Background: A Congenital anomaly represents defects in morphogenesis during early foetal life. The majority have multifactorial inheritance. Some congenital anomalies can be prevented. This study assessed risk factors associated with congenital anomalies among children aged 0–6 years attending a tertiary care centre in Bhopal, Madhya Pradesh, India. **Methods:** This was a case-control study conducted at Samarpan Kendra, Bhopal, for the duration of one year. Data of 124 cases and 124 controls were collected by interviewing the mothers. Odds ratio and adjusted Odds ratio were calculated for the risk assessment. **Results:** Ten independent risk factors were statistically significant, namely duration of pregnancy, type of pregnancy, birth weight, place of delivery, order of pregnancy, irregular iron and folic Acid tablets, maternal illness, neonatal loss, and family history. These were then selected and included in the multivariate logistic regression model and adjusted odds ratios were calculated. The risk of birth defect was six times higher among preterm births (AOR= 6.001; CI= 2.524-14.264), multiple pregnancy had 12.25 times higher risk (AOR= 12.250; CI= 2.482-60.448) and low birth weight infants had 2.6 times increased risk of developing the anomaly in comparison to normal weighed infant (AOR= 2.623; CI= 1.180-5.831). **Conclusion:** Public awareness should be raised on the importance of iron and folic acid intake, regular antenatal checkups, maintaining hygienic conditions to avoid infections, nutritional care of the mother antenatally and postnatally, for the preparation for next pregnancy.

KEYWORDS

Congenital anomaly, case-control study, multivariate logistic regression, adjusted odds ratio.

INTRODUCTION

Congenital anomalies (CA) can be defined as structural or functional anomalies (e.g. metabolic disorders) that occur during intrauterine life and can be identified prenatally, at birth or later in life.(1) In 2021, the global age-standardised incidence rate of CAs was estimated at 116.36 per 100,000 live births, with a prevalence of 913.80 per 100,000.(2) Approximately 8 to 15% of perinatal deaths and 13 to 16% of neonatal deaths in India are a result of con-genital anomalies.(3) A recognizable congenital malformation is estimated to occur in one out of every 40 newborns. With decreasing mortality due to infection and nutritional disorders, congenital malformation-related deaths are increasing.(3)

Therefore, this period represents a critical window for preventive intervention strategies especially for developing countries where prevalence of birth defects is very high. First trimester is the decisive period for morphogenesis of organs, peculiarly between the 3rd and

8th weeks of gestation where any insult in any form can cause congenital abnormality.(4)

Most common and severe congenital anomalies are Congenital Heart diseases, Neural Tube Defects and Down's Syndrome.(5) Few others are cleft lip, cleft palate, autism, etc.(6) No specific aetiologies have been recognized in around 66% of major malformations and considering them have multifactorial inheritance.(7) There are plentiful factors responsible involving a wide range –some due to inherited genetic conditions, poor diet, toxic exposure of the foetus, birth injury, etc.(8) Also, maternal age, maternal infections, consanguineous marriages, type of pregnancy, maternal health, Iodine deficiency, folate insufficiency, obesity and diabetes mellitus are linked to some congenital anomalies.(9,10) Increased incidence of malformed babies is also found evident with increased use of alcohol consumption, smoking (both active and passive), irradiation.(11) Some congenital anomalies can be prevented. Vaccination of mother prior to conception particularly against rubella and chickenpox, adequate intake of folic

acid or iodine through fortification of staple foods or supplementation, and adequate antenatal care are just few examples of prevention methods.(12,13) Modern antenatal screening methods like ultrasonography, maternal serum markers, amniocentesis etc. can be used to detect congenital birth defect which can lead us for manual or therapeutic termination of pregnancy.(14) Early years of life are very crucial for the development and survival of children. To decrease the infant mortality rate and disabilities due to congenital anomalies, further research focused on primary prevention and improving Maternal and Child Health (MCH) is needed. Results of this study would help in identifying various measures to be taken to reduce the risk to be born with anomalies. Thus, the study was aimed to assess the risk factors associated with malformed babies reporting for birth defects of their children aged 0-6 years at Samarpan Kendra, Bhopal.

MATERIAL & METHODS

Design and Setting of the Study: The present study was designed to assess the risk factors associated with birth defects among the children aged 0-6 years reporting to the Samarpan Kendra, District Early Intervention Centre, Bhopal, Madhya Pradesh, India. This study was a facility-based case-control study carried out at Samarpan Kendra, associated with Jai Prakash District Hospital, Bhopal, which acts as a referral centre catering to the needs of people hailing from all over the large central Indian state of Madhya Pradesh.

Characteristics of Participants: The study population consisted of children between zero to six years of age reporting for check up at the centre during the period of study. The Study was undertaken from June 2018 to May 2019 for a period of one year.

Inclusion criteria: Children aged zero to six years reporting to the above centre for the first time. Of all the children, those who were diagnosed with any type of birth defect were included in disease positive group while those without any abnormality were considered for disease negative group.

Exclusion Criteria: Those birth defect cases visiting for follow-up treatment, cases out of Bhopal district and seriously ill children requiring immediate referral.

Sampling Technique: Study population was selected using convenient sampling technique. Data collection was scheduled on two specific days per week during Outpatient Department (OPD) hours to ensure systematic sampling.

Methodology: Permission for the study was obtained from the ethical committee of Gandhi Medical college Bhopal (Letter No – 3872-74/MC/IEC/2018, dated on 30-01-2018) and concerned authority at Samarpan Kendra. Informed consent was obtained from the study participants after explaining them the nature and

purpose of the study. Data collection was done by face-to-face interview using a predesigned, pretested and semi-structured questionnaire. The questionnaire variables had information on various associated risk factors.

The study consisted of two age-matched groups:

- Group 1 (cases) - All the children diagnosed with any type of birth defect reporting to the centre during the study duration on that particular allotted day.
- Group 2 (controls) - This group consisted of children aged 0–6 years who were referred to the centre under the *Rashtriya Bal Swasthya Karyakram* (RBSK) initiative due to a suspicion of any of the '4Ds' (Defects at birth, Diseases, Deficiencies, and Developmental delays)(15). However, upon detailed clinical evaluation at the centre, these children were confirmed to have no congenital anomalies or significant developmental deficits.

The presence of birth defect was based on the diagnosis made by the clinician examining the child visiting the centre. Each study group included 124 consecutive participants. The varieties of birth defects reported were Congenital heart disease, Congenital deafness, Down's syndrome, Cleft lip/palate, Neural tube defect, Dysplastic dislocation of hip and Congenital cataract.

Data was entered in Microsoft Excel and later analysis was done with the help of Epi Info™ software (Centre for Disease Control and Prevention, Atlanta, GA, USA). Categorical variables (sociodemographic details, maternal history and birth history) were expressed as frequencies and percentages. The association between potential risk factors and the presence of congenital anomalies was initially assessed using the Chi-square test. Unadjusted Odds Ratios (OR) with 95% Confidence Intervals (CI) were calculated to quantify the strength of these associations. To control for potential confounders and identify independent predictors of congenital anomalies, a multivariate binary logistic regression model was employed. Variables that demonstrated statistical significance in the univariate analysis were included in the multivariate model. A stepwise approach was utilized to refine the model. Results are presented as Adjusted Odds Ratios (AOR) with their corresponding 95% CIs. For all statistical tests in the present study, a p-value of < 0.05 was considered statistically significant.

RESULTS

The present study included a total of 124 cases and 124 age matched controls. The majority of the children (39.5%) included were from the age group of > 1 year – ≤ 3 years followed by 27.4% from the age group of ≥ 1 month – ≤ 1 year. (Table 1).

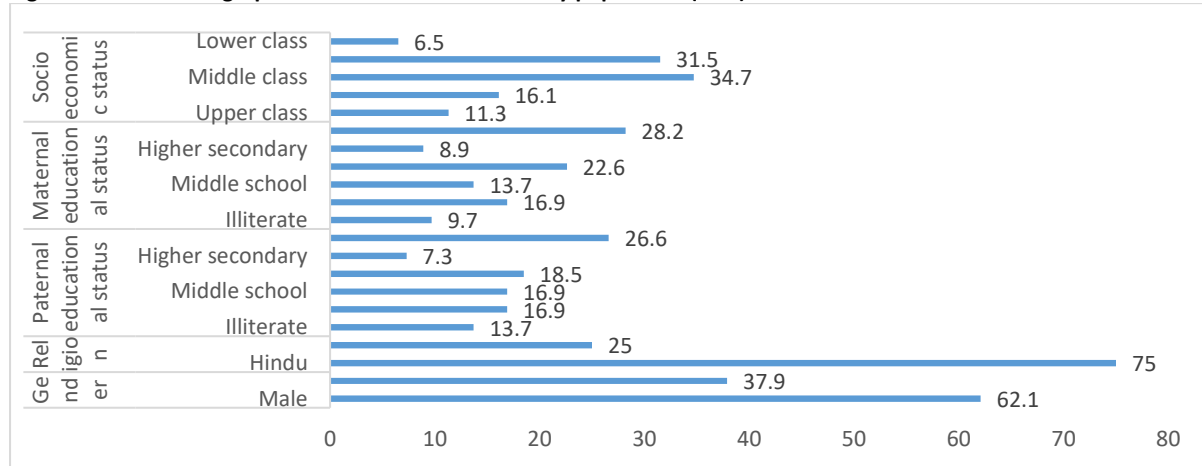
Table 1 – Distribution of Cases and Age-Matched Controls according to the age group

S No	Age Group	Cases (n = 124)	Controls (n = 124)	Total (N = 248)
1	< 1 month	12 (9.7%)	12 (9.7%)	24 (9.7%)
2	≥ 1 month – ≤ 1 year	34 (27.4%)	34 (27.4%)	68 (27.4%)
3	> 1 year – ≤ 3 years	49 (39.5%)	49 (39.5%)	98 (39.5%)
4	> 3 years – 6 years	29 (23.4%)	29 (23.4%)	58 (23.4%)
Total		124 (100.0%)	124 (100.0%)	248 (100.0%)

Analysis of the study population revealed that majority of the children (75.0%) belonged to the Hindu religion. Regarding gender distribution, a male preponderance was observed, with males accounting for 62.1% of the cases compared to 37.9% of females. Parental educational status of the study population shows that

most were educated till graduation or above. Most of the study participants included were from Middle class (34.7%) followed by Lower Middle class (31.5%) as per Modified B.G Prasad Classification for Socio economic status assessment. (Figure 1)

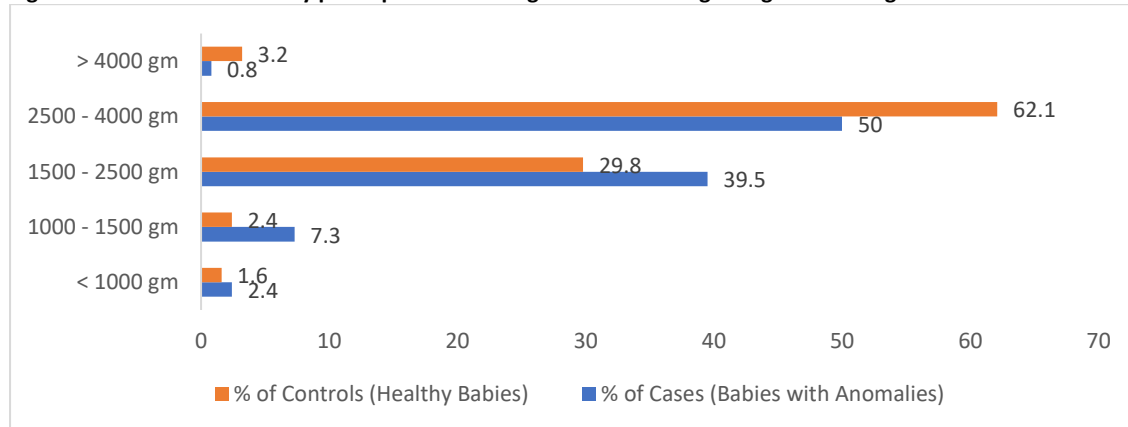
Figure 1 – Sociodemographic characteristics of the study population (in %)



When the birth weights of both groups were analysed, it was observed that 62.1% of controls and 50.0% of cases were having birth weights between 2.5 - 4.0 kg, followed by 29.8% of controls and 39.5% cases with birth weights

between 1.5 – 2.5 kg. A significantly higher proportion of cases (49.2%) were low birth weight (< 2.5 kg) compared to the control group (33.9%). (Figure 2)

Figure 2 - Distribution of study participants according to the birth weight in grams among cases and controls



Among the 124 cases included in the study, a total of 138 birth defects were reported. 52 (37.7%) children reported to have congenital heart disease, followed by 23 (16.7%) children with congenital deafness. Down syndrome was

observed in 19 (13.8%) children. Congenital cataract and Developmental Dysplasia of Hip was the least observed anomaly in the present study. (Table 2)

Table 2 – Distribution of study participants according to the type of birth defect

S No	Variable	Number (N)*	% of responses
1	Congenital heart disease	52	37.7
2	Congenital deafness	23	16.7
3	Down's syndrome	19	13.8
4	Club foot	15	10.9
5	Cleft lip/ palate	14	10.1
6	Neural tube defect	7	5.1
7	DDH	2	1.4
8	Congenital cataract	2	1.4
9	Others	4	2.9
Total		138	100

*Multiple responses.

Table 3 shows various possible risk factors (foetal, paternal and maternal) which may be responsible for the abnormality. 38.7 % of cases and 15.3 % of controls were preterm, with a significant p-value. The odds of developing congenital anomaly are 3.49 times more among preterm (OR= 3.490, CI= 1.901- 6.409). 4.0% of cases and 21.7 % of controls reported multiple pregnancy indicating that those born as single pregnancy had 6.6-fold higher risk of developing defect (OR= 0.151, CI= 0.056- 0.406). 42 out of 124 of cases and 61 out of 124 controls had birth weight <2.5 kg with significant p- value of 0.014 (OR= 0.529, CI= 0.317- 0.883).

The risk was increased by 18% where paternal age was 30 years and above of having congenital anomaly but did not reach statistical significance. Neither any significance was observed for paternal smoking.

16.9 % of cases and 12.9 % of controls had positive consanguinity history between parents without any significant difference. 18.5 % of mothers among cases and 4.0 % of mothers among controls were aged 30 and above with a significant p-value. In the univariate analysis, mothers aged 30 years and above appeared to have a 5.4-fold higher risk of delivering a child with a congenital anomaly compared to younger mothers (OR = 5.419; 95% CI: 1.99–14.77; p < 0.001). However, upon controlling for potential confounders in the multivariate logistic regression model, maternal age did not retain statistical significance (AOR = 0.41; p = 0.218), indicating it was not an independent predictor in this cohort. Home delivery was reported in around 19.4 % (cases) and 1.6 % (controls) which was highly significant. Home deliveries

were 14.64 times at more risk of developing anomalies compared to hospital deliveries (OR= 14.64, CI=3.377-63.453). Majority (46.8%) of mothers of malformed children had their second or third parity (OR= 6.408, CI= 1.827-22.471). 36.3 % of mothers accompanying malformed children gave history of irregular intake of Iron and Folic Acid tablets (IFA) during their antenatal period. Babies born to these mothers reported 17.1-times higher risk of developing the defect with a highly significant difference of p- value <0.01 (OR=17.088, CI= 5.912-49.389). Maternal illness during pregnancy did also present with statistically significant difference (p<0.01). The odds of developing birth defect were 6.31 times higher among those reporting with the illness (OR= 6.314, CI= 2.675-14.901).

Ten out of 124 cases (8.1%) and one out of 124 controls (0.8%) reported previous history of neonatal loss with a statistical significance. Mothers with positive history had 10.7 times more risk of having a child born with congenital anomaly compared to those without any such history. Also, the risk of delivering a newborn with anomaly (where positive family history was present) was 20.89 times higher than those with no such history (OR= 20.886, CI= 2.742-159.09).

Risk factors such as history of intake of abortion pills, any unprescribed medications, herbal supplements during antenatal period; presence of oligohydramnios; previous abortions/ still births; maternal smoking or alcohol intake and delivery via. caesarean section was found to be insignificant (Table 3).

Table 3 – Association of Foetal, Paternal, and Maternal Risk Factors with Outcome (Cases vs. Controls)

Risk Factor (Category)	Risk Factor Present	% in Cases (N=124)	% in Controls (N=124)	Odds Ratio (OR)	95% Confidence Interval (CI)	χ ² -value	p-value
1. Fetal Risks							
Duration of pregnancy	<37 weeks	38.7	15.3	3.49	1.901–6.409	17.198	<0.001*
Type of pregnancy	Multiple	4	21.8	0.151	0.056–0.406	17.365	<0.001*
Gender of child	Male	62.1	61.3	1.034	0.620–1.726	0.017	0.896
Birth weight	<2.5 Kg	33.9	49.2	0.529	0.317–0.883	5.994	0.014*
2. Paternal Risks							
Paternal age	≥30 years	41.1	37.1	1.184	0.711–1.974	0.423	0.515
Paternal smoking	Yes	12.1	10.5	1.175	0.534–2.584	0.161	0.688
3. Maternal Risks							
Consanguinity	Yes	16.9	12.9	1.376	0.680–2.783	0.794	0.373
Maternal age	≥30 years	18.5	4	5.419	1.988–14.774	13.044	<0.001*
Place of delivery	Home	19.4	1.6	14.64	3.377–63.453	20.795	<0.001*
Mode of delivery	Caesarean section	31.5	26.6	1.265	0.730–2.193	0.704	0.401
Order of pregnancy	Gravida >3	13.7	2.4	6.408	1.827–22.471	10.659	0.001*
Irregular Iron folic acid consumption	Yes	36.3	3.2	17.088	5.912–49.384	42.753	<0.001*
Maternal illness	Yes	27.4	5.6	6.314	2.675–14.901	21.302	<0.001*
Abortion pills	Yes	4	2.4	1.695	0.396–7.250	0.516	0.472
Oligohydramnios	Yes	8.1	4.8	1.725	0.607–4.902	1.069	0.301
Still birth / Previous abortion	Yes	16.1	10.5	1.642	0.777–3.468	1.712	0.190
Neonatal loss	Yes	8.1	0.8	10.789	1.359–85.624	7.705	0.005*
Family history	Yes	14.5	0.8	20.886	2.742–159.090	16.472	<0.001*
Intake of Unprescribed medication	Yes	5.6	8.9	0.614	0.230–1.641	0.958	0.327
Herbal supplements	Yes	3.2	0.8	4.1	0.451–37.215	1.837	0.175

Smoked/ tobacco	smokeless	Yes	4.8	3.2	1.525	0.419–5.544	0.416	0.518
Maternal alcohol		Yes	2.4	0.8	3.049	0.312–29.728	1.016	0.313

**Indicates significant value; Note: % - Percentage, OR- Odds ratio, CI- Confidence Interval, χ^2 - Chi square*

Table 4 presents the results of the stepwise multivariate binary logistic regression analysis, which identified independent predictors of congenital anomalies after adjusting for potential confounders. Among modifiable maternal factors, irregular consumption of Iron Folic Acid (IFA) demonstrated a strong association with the occurrence of anomalies (AOR = 14.71; 95% CI: 4.29–50.00; $p < 0.001$). Similarly, children born via home deliveries were at significantly higher risk compared to those born in institutional settings (AOR = 10.10; 95% CI: 1.96–52.63; $p = 0.006$).

Obstetric and biological factors also showed significant independent associations. Multiple pregnancies (AOR = 12.25) and preterm births (AOR = 6.00) were strong predictors of congenital anomalies. A positive family history of birth defects (AOR = 47.62) and a history of maternal illness during pregnancy (AOR = 6.10) also remained statistically significant in the final model. Conversely, while maternal age (≥ 30 years) and multiparity were significant in the univariate analysis, they did not retain statistical significance ($p > 0.05$) after adjustment in the multivariate model (Table 4).

Table 4 - Stepwise logistic regression analysis results for the determinants affecting the presence of birth defects (Multivariate, binary logistic regression)

Independent Variables	Adjusted OR (AOR)	95% CI (Lower – Upper)	p-value
Duration of pregnancy (< 37 weeks)	6	2.52 – 14.26	< 0.001*
Type of pregnancy (Multiple)	12.25	2.48 – 60.45	0.002*
Birth weight (< 2.5 Kg)	2.62	1.18 – 5.83	0.018*
Irregular IFA consumption (Yes)	14.71	4.29 – 50.00	< 0.001*
Place of delivery (Home)	10.1	1.96 – 52.63	0.006*
Maternal illness (Yes)	6.1	2.22 – 16.67	< 0.001*
Family History (Yes)	47.62	4.10 – 500.00	0.002*
Neonatal loss (Yes)	12.82	1.04 – 166.67	0.047*
Maternal Age (≥ 30 yrs)	0.41	0.10 – 1.70	0.218
Order of pregnancy (Gravida >3)	0.21	0.02 – 2.00	0.177

Note: OR- Odds ratio, CI- Confidence Interval

DISCUSSION

In current study, among foetal factors, preterm birth showed statistically significant risk of birth defect with six times higher chance of defect among preterm births. This is in agreement with the findings of Cosme et al.(16) where the risk was 2.39 times higher among preterm with OR = 2.39, CI= 2.30-2.49 and Gandhi et al.(17) showed highly significant difference for developing malformed babies in preterm deliveries ($p < 0.001$).

Result of recent study shows that 4.0 % of cases were twin pregnancies. Multiple pregnancies had 12.25 folds higher risk than single pregnancy of developing the defect. In agreement to our results, Cosme et al.(16) revealed that twin pregnancy and triplet or more is a risk factor for CAs with OR= 1.28 and 2.68 respectively. In a study by Vinodh et al.(18) with similar observations, 2.4 % deliveries were twin delivery among CA births. Likewise, a study by Pattnaik et al.(19) observed multiple pregnancies in 2% of malformed births.

In our study, low birth weight infant had 2.6 times increased risk of developing the defect. This is in agreement with a study by Cosme et al.(16) revealed that low birth weights were 3.35 times at higher risk of developing congenital anomalies. Also, study by Rasheed and Haseeb(20), reported significant difference ($p < 0.05$) among low birth weights for the development of malformations.

Our univariate analysis suggested an increased risk among mothers aged ≥ 30 years, a finding consistent with studies by Abdou et al.(21) and Cosme et al.(16) However, this association lost significance in our multivariate

model. This suggests that the apparent risk of advanced maternal age in our study population may have been mediated by other correlated factors, such as multiparity or maternal illness, rather than age itself.

Our study revealed that home deliveries were 14.64 times at more risk of developing anomalies compared to hospital deliveries. In agreement with this, Sridhar(22), also reported 82.27% were institutional deliveries while 17.73% delivered at home. The reason for this significance may lie in the fact that frequency of structural defects at birth such as club foot, hip anomalies, etc. may increase at home deliveries which is usually may be conducted by untrained birth attendants. Also, it can be perceived that if a female delivers at institution, then the family may be vigilant enough for proper antenatal care of mother.

Our study denotes that mothers with parity three and above were 6.4 times more likely to develop the anomaly which was also the finding of study by Miraje et al.(23) and Mashhadi Abdolahi et al.(24) where three or more birth order was associated with 18.16%, 19.17% and 17% of the anomalies respectively. In contrast to Pattnaik et al.(19), our study found that 42% of mothers of anomalous babies were gravida four or higher.. Risk of congenital anomaly was 1.86 times higher among multigravida as compared to primigravida, Abdou et al.(21)

Results of present study explain that 36.3 % of mothers accompanying malformed children gave history of irregular intake of IFA tablets during their antenatal period. Babies born to mothers on irregular intake had

17.1-fold higher risk of developing malformation with a highly significant difference of p-value <0.01. Inadequate IFA supplementation was observed in 34.24%, a study by Miraje *et al.* (23). Similarly, in a study by Prema *et al.* (25), maternal periconceptional folic acid was present in 31.4% of the cases while 62.8% of controls. Several studies show that ensuring maternal folic acid supplementation during the periconceptional period can lower the incidence of these anomalies (26,27). Hence the intake of periconceptional folic acid has a preventive role in congenital anomalies and the association between the two is statistically significant.

In this study, 27.4% of cases and 5.6% of controls verified presence of maternal illness during pregnancy. The odds of developing the anomaly were 6.31 times higher among those reporting the illness in comparison to those without any illness. Miraje *et al.* (23) noted that history of fever with rash was present in 26.02% and history of TORCH infection in 20.54% during the antenatal period. Similar results were observed in studies by Prema *et al.* (25), Buhasan *et al.* (28) and Kaneko *et al.* (27). reporting importance of various risk factors such as maternal fever, diabetes, intake of antiepileptic drugs, etc.

18 out of 124 cases (14.5 %) and one out of 124 controls (0.8 %) reported history of any type of birth defect in the family, according to our study. The risk of delivering a newborn with anomaly (where positive family history was present) was 20.89 times higher than those with no such history (OR= 20.886, CI= 2.742- 159.09). Similar findings were seen in a study Miraje *et al.* (23), Bastola *et al.* (4), Sridhar (22). Also, in a study by Abdou *et al.* (21) the risk was increased by 82 % among those with positive family history. In a country like India, women belonging to low and middle socio-economic group usually present with under-reporting of consumption of various substances due to social beliefs and customs.

A primary limitation of the present study is the potential exclusion of birth defects in newborns who died shortly after birth or those with mild anomalies that were not yet clinically apparent at the time of the first visit. Additionally, the reliance on convenience sampling and doctor-dependent diagnoses at a single referral centre may result in observer bias and limit the generalizability of the findings to the broader population. We found wide confidence intervals for some of the significant risk factors, namely family history of congenital anomalies (AOR = 47.62) and home deliveries (AOR = 10.10). This is a statistical phenomenon and is likely to be due to the small number of events in these subgroups among the controls (e.g. only one control had a positive family history). While the association is statistically significant and there is no doubt about the direction of risk, the exact size of the odds ratios should be taken with caution. Larger population-based studies would be necessary to narrow these intervals and increase the precision of these risk estimates.

CONCLUSION

Congenital anomalies among this Central Indian population had a strong correlation with modifiable maternal and obstetric risk factors. The study found irregular consumption of iron and folic acid (IFA) during pregnancy and non-institutional (home) deliveries were

found to be significant independent predictors of birth defects. Other important determinants included preterm birth, low birth weight and multiple pregnancy and history of maternal illness and neonatal loss. Notably, although the advanced maternal age was found as a risk factor in univariate analysis, the same was not confirmed as an independent predictor after adjustment for confounders.

RECOMMENDATION

These findings highlight the importance of strengthening services at the community level for antenatal services. Public health interventions therefore need to be focused on strict compliance with periconceptional IFA supplementation and the promotion of institutional deliveries to ensure skilled monitoring. Additionally, focused counselling and surveillance are indicated for mothers with a history of neonatal loss or intercurrent maternal illnesses to optimize outcomes in subsequent pregnancies.

AUTHORS CONTRIBUTION

All authors have contributed equally.

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Nil

CONFLICT OF INTEREST

There are no conflicts of interest.

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DECLARATION OF GENERATIVE AI AND AI ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

The authors haven't used any generative AI/AI assisted technologies in the writing process.

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