"MATERNAL RISK FACTORS ASSOCIATED WITH CONGENITAL ANOMALIES AMONG NEW-BORN BABIES: A HOSPITAL BASED CASE – CONTROL STUDY"

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LIST OF ABBREVIATIONS USED

1	WHO	World health organization
2	MOD	March of Dimes
3	ICD-10	International Classification of Diseases, Tenth Revision
4	BDRI	Birth Defect Registry of India
5	ICMR	Indian council of Medical Research
6	RCOG	Royal College of Obstetricians and Gynaecologists
7	TOF	Tetralogy of Fallot
8	PDA	Patent Ductus Arteriosus
9	PUV	Posterior Urethral Valves
10	ASD	Atrial Septal Defect
11	HbA1c	Glycated hemoglobin
12	CMV	Cytomegalovirus
13	DNA	deoxyribonucleic acid
14	NTD	Neural Tube Defect
15	MR	Measles-Rubella
16	GIT	Gastro-Intestinal System
17	LSCS	Lower Segment Caesarean Section

18	MNHR	Maternal New-born Health Registry
19	CNS	Central Nervous System
20	CVS	Cardiovascular System
21	ICU	Intensive Care Unit
22	RCT	Randomized Control Trial
23	RR	Relative Risk
24	CPI	Consumer Price Index
25	BMI	Body Mass Index
26	MTP	Medical Termination of Pregnancy
27	ANC	Antenatal Care
28	GDM	Gestational Diabetes Mellitus
29	UA	Umbilical Artery
30	UV	Umbilical Vein
31	LBW	Low Birth Weight
32	SES	Socioeconomic status

ABSTRACT

Title: Maternal risk factors associated with congenital anomalies among new-born babies: a hospital based case – control study

Introduction:

Congenital anomalies are an important cause for neonatal mortality and morbidity. An estimated 3,03,000 new-borns die within 4 weeks of birth every year, worldwide, due to congenital anomalies. According to global report of birth defects 7.9 million births (6% of total births) occur annually worldwide with serious birth defects and 94% of these births occur in the middle- and low-income countries. According to joint WHO and MOD meeting report, birth defects account for 7 % of all neonatal mortality and 3.3 million under five deaths. The prevalence of birth defects in India is 6-7% which translates around 1.7 million birth defects annually. According to WHO, it can be defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth and sometimes may be detected later in infancy (hearing defects).

The common birth defects include congenital heart disease (8-10 per 1000 live births), congenital deafness (5.6-10 per 1000 live births) and neural tube defects

(4-11.4 per 1000 live births). Congenital anomalies can contribute to long-term disability, which may have significant impacts on individuals, families, health-care systems and societies. Risk factors for congenital anomalies as per WHO are genetic factors, socioeconomic and demographic factors, environmental factors, infections and maternal nutritional status. Some congenital anomalies can be prevented through vaccination (MR vaccine), adequate intake of folic acid and iodine through

fortification or supplementation and adequate antenatal care for early detection of congenital anomalies. Some studies also suggest that babies with single umbilical artery have an increased risk for birth defects, including heart, central nervous system and urinary- tract defects and chromosomal abnormalities.

Many studies done are cross sectional studies done on small samples. Hence, this present case control study was conducted to identify the maternal and placental risk factors associated with congenital anomalies among new-born babies. Since most of the risk factors are preventable, the present study can help in identifying the association between risk factors and congenital anomaly; hence reducing the number of babies born with congenital anomalies thereby reducing perinatal mortality and morbidity.

Objectives:

1. To know the maternal risk factors associated with congenital anomalies among new-born babies.
2. To know the placental abnormalities associated with congenital anomalies among new-born babies.

Materials and Methods:

Study design: A hospital-based case - control study.

Study period: 1st January 2020 to 31st December 2020 (12 months)

Sample size: Average number of babies born with congenital anomalies every year is approximately 100

Total Sample: 100 cases and 200 controls

Sampling technique: Cases – universal sampling. Controls will be babies born immediately after the case and will be matched with the cases for gestational age (± 2 weeks) and sex.

Study population: All live born babies born with clinically detected congenital anomalies at KLE'S Dr. Prabhakar Kore Charitable Hospital during the study period were included in the study and controls were babies born without congenital anomaly with case: control ratio 1:2

Inclusion Criteria:

1. Case: All live born babies born with clinically detectable congenital anomalies delivering at KLE'S Dr. Prabhakar Kore Charitable Hospital born during study period.
2. Control: All live born babies born without detectable congenital anomalies born immediately after the case and matched for sex and gestational age ±2 weeks at KLE'S Dr. Prabhakar Kore Charitable Hospital.

Exclusion criteria:

Chromosomal anomalies / metabolic disorders of the new-born (Even if detected) will not be included in the study and those who refuse to give consent for participation in the study.

Data collection:

All women delivering babies with congenital anomalies at Dr. Prabhakar Kore Charitable Hospital were identified. Purpose of the study was explained to the participants and after building a good rapport and confidence amongst the participants

a written informed consent was obtained from all the participants enrolled for the study. Informed consent was also translated into local languages like Kannada and Marathi. Participation in the study was completely voluntary.

Using a pre-designed pre-tested questionnaire relevant history was obtained. The questionnaire consisted of IV parts. First was regarding the socio demographic details which included details regarding address, religion, education, occupation, type of family, socio – economic class etc. Second part covered details regarding obstetric history of the mothers. Height and weight of the mother were recorded and BMI was calculated.

The third part of questionnaire was to collect details of new-born like sex of the baby, birth weight, presence of any congenital anomaly and the system involved.

In the fourth part of questionnaire, information regarding the placenta was collected.

Results:

In the present study history of consanguinity, married life of ≥5 years, un-booked cases for ANC care, parity of 2 or more, history of previous abortion, non-intake of folic acid supplementation, maternal febrile illness, history of GDM, low birth weight, low placental weight, absence of 2 umbilical arteries and single umbilical vein, history of previous congenital anomalous baby were the maternal risk factors which were found to be significantly associated with occurrence of congenital anomalies.

System wise categorization of congenital anomalies was done using ICD-10 classification. Among 100 cases with congenital anomaly, 25% had congenital anomaly of CNS, 18% had congenital anomaly of CVS, 20% had congenital anomaly of genitourinary, 9% had congenital anomaly of GIT, 7% had congenital anomaly of

multiple systems, 16% had congenital anomaly of musculoskeletal and 5% had congenital anomaly of respiratory system.

Conclusion: Out of the 100 babies born with congenital malformations, CNS (25%) and genitourinary (20%) abnormality constituted majority of cases. Mothers who had babies with congenital anomalies had risk factors like consanguinity, non – intake of folic acid, history of previous abortions or previous congenital anomalous baby. Hence, the need for screening of these high-risk groups is very vital. By improving the regular antenatal visits, postnatal diagnostic services, early interventions and faster referral services to tertiary care hospital most of these newborns can be saved. Focused change in the number of USG scan required during pregnancy and inclusion of placental findings in the report could evert birth of anomalous babies.

Keywords: Congenital anomalies, new-born babies, maternal risk factors, hospital based, case–control study

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INTRODUCTION

Congenital malformations are a prime cause of neonatal morbidity and mortality[1]. More than 3 lakh new-borns die worldwide within 28 days of birth annually due to congenital malformations[1]. As stated by the global report of birth defects, every year worldwide, 6% of total births i.e., 7.9 million births occur among which 94% are serious birth defects that occur in the low- and middle-income countries[2].

Congenital anomaly as per World Health Organization (WHO) "is structural or functional anomaly which occurs during intrauterine life. It can be detected before birth, at birth and sometimes get detected later during first year of life (hearing defects)"[1].

A joint WHO and March of Dimes (MOD) meeting report states that 3.3 million under five deaths and 7% of all neonatal mortality are due to birth defects[2]. The prevalence of birth defects in India was 6-7% which is approximately 1.7 million birth defects every year[2].

The International Classification of Diseases, Tenth Revision (ICD-10) has Chapter XVII for Congenital anomalies, deformities and chromosomal abnormalities. Various studies show different prevalence based on the study type, minor defects being included, inclusion of still births, and also follow up of the new-borns. According to the data available from Birth Defect Registry of India (BDRI), the common systems involved were found to be central nervous system in which neural tube defects were found to be the most common defects, followed by musculoskeletal system, followed by cardiovascular system[3].

The common birth defects are congenital heart disease, congenital deafness and neural tube defects which are seen in 8-10, 5.6-10 and 4-11.4 births per thousand live births respectively[2].

In India, incidence of congenital anomalies was around 2.5% which accounted for 8-15% of perinatal deaths and which also accounted for 13-16% deaths of neonates[4,5]. Indian council of Medical Research (ICMR) reported that 6.6% of neonatal deaths in urban slum communities and rural communities are accounted for by congenital malformations in their community-based study[6]. Till the past decade, the highest contributors to neonatal deaths were preterm births (34.7%), intrapartum complications (19.6%), pneumonia at 16.3% followed by neonatal sepsis at 15%. Nine percent were due to congenital anomalies making it the fifth largest cause of neonatal deaths[7].

Congenital anomalies are of importance since it may contribute to long-term disability, which in turn leaves significant impacts on individuals, their families, health-care systems and societies[1].

Occurrence of congenital anomalies in low- and middle- income countries is higher that is around 94%. Possible causes include lack of screening facilities, insufficient access to nutritious foods for pregnant women, substance abuse either in form of alcohol consumption, tobacco chewing or smoking, and also an increase in the exposure to certain environmental contaminants and other infections[1].

A recent study showed that as compared to 9% of perinatal deaths a decade back, congenital malformations now contributed to a big number, that is 13.4 %. Major malformations accounts for nearly 15% of neonatal deaths[8].

Malformations as per Royal College of Obstetricians and Gynaecologists (RCOG) are classified into lethal, severe and moderate ones. Lethal defects include anencephaly, bilateral renal agenesis, osteo-chondrodysplasia, ichthyosis congenita, giant hygroma. Severe defects include hydrocephalus, spina bifida, esophageal atresia, Tetralogy of Fallot (TOF), ectodermal dysplasia, Patent Ductus Arteriosus (PDA), Posterior Urethral Valves (PUV), Atrial Septal Defect (ASD) and moderate defects include septal deviation, choanal atresia, eyelid defects, craniosynostosis[9].

In India, congenital anomalies contributed to around 60,000 neonatal deaths in 2013, which accounted for the highest global burden of neonatal mortality due to congenital anomalies. There is no data available on the magnitude of congenital anomalies in the country which clearly shows that India lacks a national birth defects surveillance. Hence, systematic data on the magnitude of congenital anomalies, the commonest types of congenital anomalies and its impact on neonatal health and healthcare is essential [10].

Around 50% of congenital anomalies are idiopathic where they cannot be linked to a specific cause. Some of the known causes for congenital anomalies were found to be defect in a single gene, multifactorial inheritance, certain chromosomal disorders, some of the teratogens present in the environment and certain nutritional deficiencies. Genetic causes can be traced to inherited genes or from mutations. Consanguinity between the parents increases the risk of congenital anomalies and risk increases to nearly two times as much for neonatal deaths and deaths that occur early in childhood and various other health conditions in the children including intellectual disability.

As per WHO, Risk factors for congenital anomalies can be genetic factors, environmental factors, maternal nutritional status, infections and socioeconomic and demographic factors[1].

The genetic causes may be numerical, structural chromosomal defects and mosaicisms. Down's syndrome is the commonest, followed by Edwards', Patau. Structural anomalies are deletion, translocation and inversion. Turner syndrome and Klinefelter syndrome are sex chromosomal abnormalities[11]. Chromosomal abnormalities like Down's are more commonly associated with advancing maternal age[1].

Other anomalies such as haemophilia C and cystic fibrosis are more prevalent in specific ethnic communities[1]. Uncontrolled diabetes in the period of organogenesis increases the risk to the fetus up to 5-6%. High Glycated hemoglobin (HbA1c) levels in first trimester directly correlate with the incidence.

Infections like toxoplasmosis, Cytomegalovirus (CMV), Rubella, Herpes, Syphilis can cause anomalies[11]. Teratogenic drugs include thalidomide, antiepileptics, warfarin, retinoic acid. Maternal exposure to alcohol, smoking also play a role[11].

It has been proved that deficiency of folate leads to neural tube defects in foetus. Central Nervous system becomes apparent on post ovulation day 18 and by 22-28 days neural tube closure takes place. Folate deficiency leads to developmental delay as it hampers the biosynthesis of deoxyribonucleic acid (DNA) and also the methylation cycle, occurring during embryogenesis[11].

The results of some observational studies were highlighted in a recent publication on the evidence that supplementation of folic acid tablets could lower the risk of Neural tube defects affected pregnancies. A Cochrane review of 5 trials involved 6,708 births concluded that a reduction in the incidence of neural tube defects (NTDs) with periconceptional folate supplementation was detected compared with no interventions or use of placebo or supplementation of minerals and vitamins without folic acid. It was seen that folic acid also had a significant protective effect for recurrence of these defects[11].

Some preventive measures can be adopted to prevent congenital anomalies in new–born babies which include vaccination [measles-rubella (MR) vaccine], ensuring sufficient intake of folic acid and iodine either by fortification of food or by supplementation and also ensuring adequate antenatal care required for early detection of congenital anomalies[1]. Some studies also suggested that for babies born with a single umbilical artery had an increased risk for birth defects, including the heart, urinary-tract defects, central nervous system and chromosomal abnormalities[12].

Most of the studies done were cross sectional studies done on small samples. For this reason, the present case-control study was conducted to recognize the maternal and placental risk factors associated with congenital anomalies among new-born babies. Since most of the risk factors are preventable, the present study can help in identifying the association between risk factors and congenital anomalies and thereby help in reducing the number of babies born with congenital anomalies which will help in reducing perinatal mortality and morbidity.

OBJECTIVES

1. To know the maternal risk factors associated with congenital anomalies among new – born babies.
2. To know the placental abnormalities associated with congenital anomalies among new – born babies.

REVIEW OF LITERATURE

Congenital anomaly also known as birth defect, as per WHO is structural or functional anomaly. Anomalies occur during intrauterine life. Defects can be identified before birth, at birth and sometimes detected later during first year of life (hearing defects).

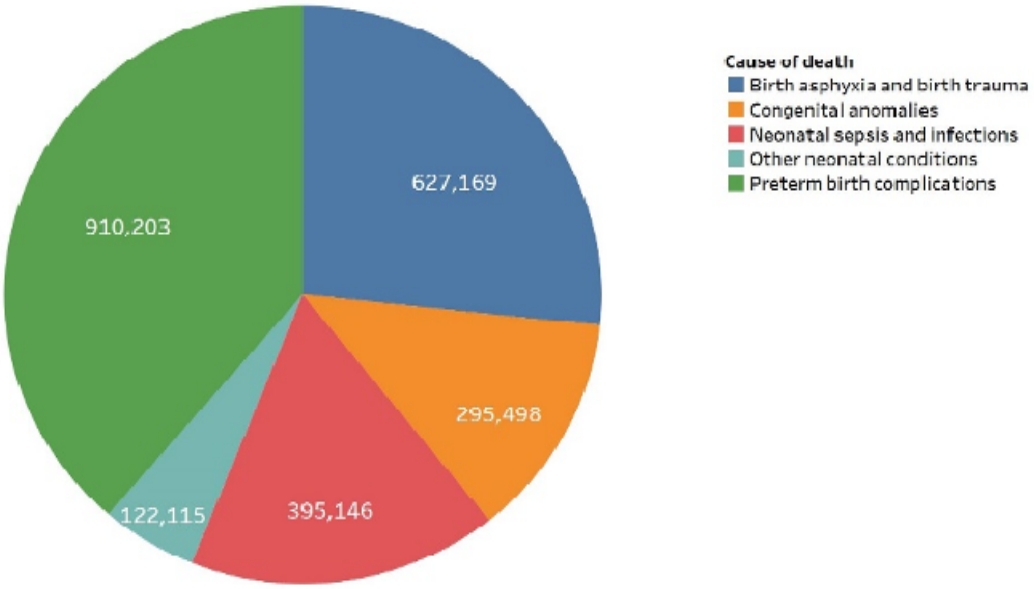
Globally, within four weeks of life, 2.95 lakh new-borns die every year due to congenital anomalies. According to Global Report on Birth Defects by MOD[13], congenital anomalies contribute to around 8 million serious birth defects yearly worldwide and nearly 95% of these births occur in middle- and low-income countries.

As per joint WHO and MOD meeting report, nearly 7% of all new-born mortality is contributed by birth defects and birth defects also account for more than 3 million under five deaths[1]. When we look at Indian statistics, prevalence of congenital anomalies varies from 61 to 69.9/1000 live births. Out of these, nearly two-third of birth defects are preventable[1].

Major Causes as well as risk factors for congenital anomalies:

Almost half of all congenital anomalies are idiopathic where a specific cause cannot be found, some of the known risk factors are genetic, environmental and other causes.

Figure 1: Major causes for deaths (numbers) of neonates globally, 2016



Genetic factors

It was found that genes play a major part in many congenital anomalies. It may be as a result of sudden change in genes, known as mutation or could be due to certain inherited genes that code for an anomaly. Hence, genetic factors perform a considerable role.

Consanguinity brings a two-fold increase in risk for neonatal death, death in early childhood, intellectual disability and other anomalies. It also raises the frequency of rare genetic congenital anomalies.

Certain rare genetic mutations namely Haemophilia C and Cystic Fibrosis are more prevalent in specific ethnic communities[1].

Socioeconomic and demographic factors

It was found that frequency of congenital anomalies was higher in resource–constrained countries and families. More than 90% of severe congenital anomalies occur in middle- and low-income countries.

Therefore, lower income could be a determinant (indirect) of congenital anomalies. This higher risk is perhaps due to lack of sufficient nutrition provided to pregnant women, and also due to increased exposure to substances like alcohol, tobacco, and infections occurring during pregnancy and poorer access to screening and other healthcare facilities. Factors commonly associated with less income may lead to an upsurge in the abnormal prenatal development.

Increasing age of the mother is also considered to be one of the potential dangers for atypical intrauterine growth of foetus. Increasing maternal age is found to be associated with higher risk of certain chromosomal abnormalities like Down's syndrome[1].

Ecological factors

Pregnant women being exposed to pesticides and chemicals, and also some of the medications taken during pregnancy, consumption of substances like alcohol, tobacco and exposure to radiation during pregnancy may cause an upsurge in the risk of having foetus or neonate being born with a congenital anomaly.

Other factors like living at site close to waste sites, smelters or mines or working in such places may also prove to be a potential risk factor, especially if the

mother is already suffering from certain nutritional deficiencies or has been exposed to other environmental risk factors[1].

Infections

In low income and middle-income countries certain infections like rubella and syphilis occurring during pregnancy are one of the major causes of congenital malformations in low income and middle-income countries.

Microcephaly was found in the growing fetus as well as in the new-born if the pregnant woman was infected by Zika virus. Other complications like preterm births, fetal loss and still births were also caused due to Zika virus infection during pregnancy[1].

Maternal nutritional status

Maternal nutritional status plays a very important role, as any folate insufficiency was found to increase the risk of having a baby with a neural tube defect. Excessive intake of vitamin A may affect the embryo or fetal development adversely[1].

Classification of Congenital anomalies: According to International Classification of Diseases – XVII, Congenital Malformations are classified as:

1. Congenital malformations of the nervous system (Q00 – Q07)
2. Congenital malformations of eye, ear, face and neck (Q10 – Q18)
3. Congenital malformations of the circulatory system (Q20 – Q28)
4. Congenital malformations of the respiratory system (Q30 – Q34)
5. Cleft lip and cleft palate

6. Other congenital malformations of the digestive system (Q38 – Q45)
7. Congenital malformations of genital organs (Q50 – Q56)
8. Congenital malformations of the urinary system (Q60 – Q64)
9. Congenital malformations and deformations of the musculoskeletal system (Q65 – Q79)
10. Other congenital malformations (Q80 – Q89)
11. Chromosomal abnormalities, not elsewhere classified (Q90 – Q99)

Within this classification "congenital malformations, deformations and chromosomal abnormalities" are (Q00-Q99) but excludes "inborn errors of metabolism" (E70-E90).

BILATERAL CLEFT LIP

POLYDACTYLY

TONGUE TIE

ANENCEPHALY

Detection

Screening for congenital anomalies can be conducted during the following 3 periods which are:

Preconceptional screening: This type of screening involves taking family history along with carrier screening. In countries where consanguineous marriages are common, this type of screening is very helpful to identify people at risk for specific disorder and also people at risk of passing a disorder to their offspring[1].

Peri-conception screening: There are certain maternal risk factors that could increase risk of congenital anomalies in the new-born, and the results obtained from peri–conception screening will help in providing appropriate care as per the risk status. Screening of younger women, mothers with advancing age, screening individuals with history of exposure to substances like either alcohol or tobacco and mothers having other risk factors may be included. Placental markers can also be made use of to predict the danger of having chromosomal abnormalities and neural tube defects. For screening many of the chromosomal abnormalities free fetal DNA is also used.

Other tests such as chorionic villus sampling and amniocentesis can be used in women at risk for diagnosis of chromosomal abnormalities and infections.

Ultrasound scans done at regular intervals also play a very important role in screening of major structural abnormalities including Down's syndrome during the first trimester, and also for identifying severe fetal anomalies occurring during the second trimester[1].

Neonatal screening: This type of screening involves screening of new-borns for presence of any disorders of the blood or inborn errors of metabolism including hormone production. New-born babies are also screened for deafness and heart defects, these are done by conducting various clinical examinations. Neonatal screening facilitates early detection of congenital anomalies making it possible to provide appropriate treatment hence saving many lives as well as it helps in preventing the progression of these anomalies to some visual, physical, intellectual or auditory disabilities.

Routine screening of new-born babies for any abnormalities of the thyroid or adrenal glands is also practiced by some countries before discharge from the maternity unit[1].

STRATEGIES TO LOWER THE IMPACT OF CONGENITAL MALFORMATIONS IN INDIA

Evidence shows that number of children with birth defects is higher in India. The lack of public health backing for treatment often indicates towards lasting suffering. The reproductive and child health programmes have pre-existing preventive strategies to reduce birth defects. A programme for prevention could be started to address this unseen public health issue with a few additions. With education at community level along with health personnel education, identification of risk factors and its management, screening of the population, genetic counselling as well as availability of proper services. For a preventive service to be effective, it should have both basic reproductive health services as well as medical genetic screening[7].

PREVENTION:

Preventive strategies include primary level, secondary level and tertiary level of prevention. The following strategies can be applied at numerous stages of pregnancy that includes before conception, after conception and also during the Postnatal period[7].

Preventive public health measures are aimed to reduce incidence by preventing emergence or lowering the risk factors or by reinforcing the protective factors. Vital interventions and efforts include:

Teenage girls and pregnant women can take a healthy diet with fruits and vegetables along with supplementation of folic acid especially for adolescent girls, maintain ideal body weight, refrain from consumption of tobacco, alcohol.

Exposure of the pregnant women to harmful substances (heavy metals, pesticides) in the environment can be reduced.

Control of diabetes before pregnancy and during pregnancy through counselling, diet management, administration of insulin if required, maintaining ideal body weight, justification if medications taken and exposure to medical radiation can be done.

Infection screening especially for varicella, rubella and syphilitic infections. Vaccination for rubella virus.

Recent Literatures:

A cross-sectional study was conducted in a tertiary care government hospital at Rohtak, Haryana to establish proportion of gross congenital malformations. According to this study, gross congenital malformations was found in 16.4 per 1000 consecutive singleton births (>28weeks). The three leading congenital malformations were found to be anencephaly (44.68%) followed by talipes equinovarus (17.02%) and then meningomyelocele (10.63%). Higher number of malformed births were seen amongst un-booked (2.07%); women with education <8 years of schooling [2.14%]; gravid status of ≥ 3 (2.69%). Congenital malformations were more common in preterm babies (5.13%); higher risk of congenital malformation was found in babies delivered by cesarean section (4.36%). Mortality rate was found to be higher among babies born with congenital malformations (17.35%). The study highlighted the need for maternal nutrition especially folic acid[14].

A hospital-based cross-sectional study was conducted in the year 2015-2016 at Rajarajeswari Medical College and Hospital, Kambipura, Bangalore to study the prevalence of congenital anomalies. All babies born between 1st August 2015 and 31st July 2016 were included in the study. Among the 2,137 deliveries, 86 babies were found to have congenital malformations. Prematurity, consanguinity and increased maternal age were risk factors for congenital malformations. Cardiovascular anomalies were found to be the most common with prevalence rate of 4%[15].

A cross-sectional study was carried out between September 2011 to August 2012 in a Medical College in Kolkata which included all live born babies born during the time period in which the study was conducted. The new-borns were examined for existence of any congenital anomalies. About 12,896 babies were born during study

period. Of them, 286 (2.22%) had congenital anomalies. Majority of women (55.7%) belonged to 21-30 years age group. When compared to primipara (1.8%), congenital anomalies were more common in multipara (3.3%). Musculoskeletal system was found to be predominantly involved (33.2%) followed by gastrointestinal system (15%). The most common congenital anomaly in musculoskeletal system was Talipes (17.1%) and in gastro-intestinal system (GIT), it was cleft palate and cleft lip. According to this study, low birth weight of the new-born, prematurity, multiparity, consanguinity and cesarean delivery increased the risk of having a baby with congenital anomaly[16].

A cross-sectional study was conducted to study the contribution of congenital anomalies to perinatal mortality and also to know the prevalence of congenital malformations in a hospital in Vellore, Tamil Nadu. Sample size of 36,074 births from 2003 to 2013 were studied. Birth registers as well as medical records were used to collect data. The prevalence of congenital anomalies was 12.5/ 1000 live births. The most common were musculoskeletal disorders and then craniovertebral anomalies. Need for periconceptional folic acid supplementation and early recognition of malformations was highlighted[17].

A cross-sectional study was conducted from June 2014 to November 2014 in a tertiary care hospital in Maharashtra to study numerous new-born characteristics as well as to determine the frequency and pattern of congenital anomalies at birth. Data was collected using semi structured questionnaire and clinical examination of new-born. 24 (2.69%) babies out of 892 new-borns (livebirths and stillbirths) were found to have congenital malformations at birth. Cardiovascular system was the most common involved (29.6%)[18].

A hospital-based case-control study was conducted in North India to study the risk factors of congenital malformations. In this study, the age and sex were matched. To obtain data on exposure to risk factors, the mothers were interviewed. 203 Congenital malformation cases and 203 controls were studied. Risk factors like usage of drugs for sex selection by mother (OR=4.35), alcohol consumption by father (OR=3), smoking (OR=4.5) and tobacco chewing (OR=2.7) were significantly associated. Marriage at a younger age that is <18years and previous abortion history in the mothers were also found to be important interpreters of congenital malformations[19].

A case-control study for a period of 6 months was conducted in the year 2017 in the hospitals affiliated to Hamadan University of Medical Sciences which aimed to identify the frequency and numerous types of congenital malformations in Hamadan province. The study was targeted at new-borns from their birth to their discharge from the hospital. Neonatal cases with congenital anomalies were detected through examination. A control was allocated on the same day and hospital per each case. Matching was done with homogeneous neonatal sex, maternal age, and place of residence (city or town). The prevalence of congenital anomalies was found to be 0.85% (8.5 per thousand live births). Genitourinary system was most commonly involved (40%) followed by musculoskeletal system (25.2%) and then by ear, eye and neck (18.5%). Male child, consanguineous marriage, simultaneous contraceptive use were risk factors. The study recommended periodic prenatal examination, early diagnosis and intervention. This study also recommended creation of public awareness regarding the burden of consanguineous marriage[20].

A case-control study was conducted in southwestern Ethiopia at six hospitals from May 2016 to May 2018 to obtain related risk factors with congenital malformations. A standard checklist was made use of to evaluate neonates for existence of congenital anomalies. Risk factors like unknown medicine use early in pregnancy (AOR = 3.4), usage of surface water for drinking purpose (AOR = 2.1), exposure to pesticide during pregnancy (AOR = 3.9), exposure to passive smoking (AOR = 4.1), early supplementation of folic acid (AOR = 0.4) were significantly associated. The study recommended to provide health education on prevention of congenital anomalies and highlighted necessity to improve quality of care given to pregnant women as well as follow ups provided and supplementation of folic acid through fortification of food[21].

A retrospective study was conducted to identify the system-wise occurrence of congenital anomalies in new-born babies admitted in a tertiary hospital and the associated maternal factors. The study period was for two years conducted among all the mothers and their new-born babies with congenital anomalies who were delivered or referred to the Obstetrical Department/ Neonatology unit. The most involved system was genito-urinary system (28.5%) followed by cardiovascular system (20.5%). Diabetes (14.01%), history of previous abortions (12.7%) followed by hypothyroidism (8.7%) were significantly associated maternal risk factors. Intrauterine growth restriction (17.4%) was found to be more common in these babies. Prevention by preconceptional counselling, public awareness during adolescence, and antenatal screening were emphasized[22].

A cross–sectional study was conducted in two hospitals in Mount-Lebanon for 9 months from January to December 2009. All new-borns born during study period (n=1000) were included. It was conducted to study the prevalence, types and correlates of congenital anomalies among liveborn and stillborn neonates. New-borns were assessed for congenital malformations and neonatal data was obtained from medical records. Classification of congenital anomalies according to WHO is based upon the anatomical system affected. Out of one thousand singleton births, 24 (2.4%) were found to have birth defects. The most common system involved was Cardiovascular system followed by limb anomalies (4/1000). A substantial association of history of consanguinity (p= 0.015) and alcohol consumption by pregnant woman (p=0.027) with increased congenital anomalies rates was seen. The study highlighted need of health education through programs to prevent defects in children of consanguinity[23].

A cross sectional study was conducted from August 2015 to July 2016 in a tertiary care Hospital in Bhubaneswar, Odisha to determine proportion of congenital anomalies in live new-borns. The study population were babies who were born in the hospital (inborn) and babies who were brought to outdoor or emergency (outborn) during this period. Patients having congenital anomalies were examined by consultant pediatrician and neonatologist. Out of total 11,867 neonates, 319 (2.9%) neonates had congenital anomaly. Higher incidence was found in women who underwent lower segment caesarean section (LSCS). Male sex, multigravida, consanguineous marriage was associated with congenital defects. Musculoskeletal defects were the most common. This study recommended creation of public awareness regarding the preventable risk factors of congenital anomalies and also about early prenatal diagnosis of common anomalies[24].

A cross-sectional study was conducted to know the prevalence and types of congenital anomalies among babies being delivered at an institution in Kashmir. A neonatologist clinically evaluated new-born for diagnosis. There were 1,129 live births with 617 (53.8%) male and 529 (46.2%) female. Female: male ratio of congenital anomalies was 1.8:1. Seventeen (1.48%) new-born babies were identified to have birth defects. Central nervous system (29.41%) was the most common system to be involved followed by cardiovascular system (17.64%) followed by genitourinary system (17.64%). The study recommended regular antenatal check-ups as well as prenatal diagnosis for prevention of congenital anomalies[25].

A cross-sectional study was conducted in Jawaharlal Nehru Medical College (J N Medical College), Uttar Pradesh (UP) in which all live born babies with major congenital anomalies from January 2015 to December 2015 were included. The babies were examined for congenital malformations and incidence of congenital malformation was 2.5%. Major system to be involved was found to be musculoskeletal system (58%) followed by cardiovascular (28%) and then genitourinary system (18%). The study concluded that congenital anomalies had association with risk factors like history of spontaneous abortion, consanguinity, age of mother. The study highlighted that early diagnosis could help in better outcome of these new-born babies with congenital anomalies[26].

A retrospective study was conducted among population visiting a tertiary care hospital at Mumbai to evaluate the incidence of structural congenital anomalies. Out of 5,020 deliveries, 50 babies with congenital anomalies identified. Incidence was 0.9% with most common system being craniospinal system (44%) followed by musculoskeletal system (30%). Consanguinity was noted in 40% of cases which was

an important factor to increase risk of congenital anomalies followed by history of previous abortions. The study highlighted the need for focused screening with a level II targeted scan at 18-20 weeks and one more scan at 24 weeks. After detection of anomaly, management options can be discussed with neonatologist, pediatric surgeon and neurosurgeon. If parents are willing, pregnancy may be continued[27].

A cross-sectional study was conducted in Nishtar Hospital, Multan among all women giving birth to babies to determine the prevalence of congenital anomalies in new-born babies. A total of 611 consecutive neonates delivered were evaluated by neonatologist for diagnosis. Prevalence of congenital anomalies was found to be 2.95%. The most common anomalies involved central nervous system (38.88%), cleft lip and cleft palate (11.11%), musculoskeletal system (5.55%), ear, face and neck (5.55%), gastrointestinal tract (5.55%) and having more than one defect (33.33%). Parental consanguinity was found in 31.79% of all cases and 55.5% of cases with congenital malformations. The study highlighted the need for creating awareness regarding avoidance of consanguineous marriages[28].

A secondary data analysis of a population-based study was conducted to report on incidence of congenital anomalies from Maternal New-born Health Registry (MNHR). All deliveries between 2014 to 2018 in Chimaltenango, Guatemala were included. Cases were reported and reviewed by field staff and medically trained staff, respectively. Out of 60,142 births, 384 (63.8/10,000 births) infants had congenital anomaly. The most common malformations were of nervous system (28.8/10,000) followed by musculoskeletal system (10.8/10,000) and then cleft lip and palate (10.0/10,000). The study highlights the importance of prenatal care, family planning, healthy diet for women, control of infections in pregnancy[29].

A prospective study was conducted in a rural medical college hospital in Wardha, Maharashtra to report incidence of congenital anomalies. This study included all deliveries between 1st January 2005 and 31st July 2007 comprising of 9,386 births. The new-borns were examined for presence of congenital anomalies. Babies with congenital malformations was 179 (1.91%). Women with risk factors like prematurity, increased maternal age, increasing birth order and low birth weight baby were at higher risk. The most common malformations were seen in cardiovascular system followed by musculoskeletal and genitourinary anomalies. The study emphasized on early diagnosis and surgical correction to better the chances of survival and highlighted evaluation of cardiovascular system to rule out congenital heart disease[30].

A cross-sectional study was carried out in a rural hospital setting in Maharashtra with an objective to detect the frequency of congenital surgical malformations. 3,000 consecutive births over a study period of 9 months were included and frequency was 21.1 per thousand births. The most common systems involved were gastro-intestinal tract and genito-urinary tract (20.4% each) followed by the central nervous system (17.3%). Risk factors associated were advancing maternal age (>35 years), higher gravida mothers (>G4), maternal hypertension, consanguineous marriages and previous history of abortions[31].

A prospective study was conducted at a hospital in Hyderabad from November for a period of one year which included both intramural as well as extramural babies to know the varying pattern of congenital malformations and to study the effect of ecological risk factors on birth defects. Incidence of congenital anomalies was 2.15%. Central nervous system (CNS) with 22 % of cases was found to be the most common

system to be involved followed by GIT followed by Cardiovascular system (CVS). Congenital anomalies like Meningomyelocele, malformations of the anus and rectum and acyanotic heart diseases were most commonly seen. Term babies were most frequently having congenital malformations. New-born babies with lower weight had higher percentage of congenital malformations (2.64%). Male (2.53%) babies were found to be affected more when compared to female babies. The factors associated with increased risk were obesity in mother, parental consanguinity and history of congenital anomalies in the family[32].

A prospective study to determine the prevalence of congenital malformations at birth at a teaching institution for two and half years on 9,405 consecutive single births showed prevalence of major congenital malformations in live births was 1.6% and in 16.4% in still births. Amongst Muslims with consanguinity, the prevalence of congenital malformation was 4.6%. Open neural tube defect was the most common anomaly (31.7%) occurring at a rate of 4.7 per 1000 single births, followed by equal presence of meningomyelocoele and anencephaly. Significantly associated factors were history of concomitant medical illness, medication intake during the first trimester, history of threatened abortion, pre-eclamptic toxaemia and hydramnios in current pregnancy[33].

A cohort study was done in Pune, India to study the prevalence of congenital anomalies and its role in neonatal mortality. A cohort of pregnant women were followed up till outcome such as abortion or medical termination of pregnancy, live or stillbirth and neonatal or post-neonatal mortality. Visual examination was done for confirmation of congenital anomalies followed by other investigations. Among 1,822 births, the prevalence was 230.51/ 10,000 births. The most common system affected

was cardiovascular system (65.86/ 10,000 births) followed by neural tube defects (27.44/ 10,000 births). Congenital malformations were found to be the second leading cause of neonatal deaths.1 in 44 births in the cohort were affected by congenital anomalies. The study highlighted the need for a well-focused national programme with strategies directed towards prevention, care as well as surveillance of congenital anomalies[34].

A cross-sectional study was done in a rural hospital in Amritsar, Punjab for a period of one year to determine the prevalence of congenital anomalies. Among 859 admissions to the intensive care unit (ICU), 59 cases were diagnosed to have congenital anomalies giving a prevalence of 6.8%. The most common system involved was gastrointestinal system followed by nervous system disorders. The study recommended early diagnosis in the antenatal and postnatal periods and early referral to tertiary hospital for timely interventions[35].

A descriptive study was performed in a medical college in Davangere, Karnataka to study the incidence, clinical profile and outcome of congenital anomalies for a period of two years. All patients were assessed both clinically and radiologically for presence of congenital malformations. Using a proforma, mothers were interviewed to determine the presence of risk factors. Out of 3820 births, 95 infants had congenital anomalies and incidence was noted to be 24.8 per 1000 births. Risk factors associated were consanguinity between parents and bad obstetric history. The study emphasized on small family norms, population control, systematic examination of new-born and accurate antenatal anomaly scan[36].

A descriptive cross-sectional study was conducted in six villages of Ambala district to determine the prevalence of congenital anomaly. Children <6 years of age

were examined by investigators and traditional birth attendants and anganwadi workers were helpful in identifying externally visible malformations. Among 1371 children, the prevalence was 22/1000. The most commonly involved systems were cardiovascular system (37%) followed by musculoskeletal system (30%) and the by gastrointestinal system (23%)[37].

A meta-analysis was done to estimate the effects of folic acid supplementation on neural tube defects. A meta-analysis of three randomized control trials (RCT) from low-income countries showed that folic acid supplementation for a mother with a previous pregnancy with neural tube defects showed more than 70% reduction in recurrence and a meta-analysis of one RCT with three cohort studies showed a 62% reduction for a woman as part of primary prevention. A meta-analysis of eight observational studies gave an estimated reduction in NTD incidence of 46%. These eight studies examined folic acid food fortification. The study emphasized on folic acid food fortification which could halve the incidence of neural tube defects[38].

A retrospective study was conducted in a tertiary hospital in Ludhiana to determine the prevalence of congenital anomalies. Among 10,000 consecutive births, the prevalence was 3.6%. The study showed that although the frequency was similar among the sexes, anencephaly was more common in female and genitourinary anomalies were common in male. Risk factors observed were decreasing gestation and birth weight. A significant correlation was also seen in maternal factors like previous history of abortions, history of drug intake, fever during 1st trimester and diabetes mellitus[39].

A prospective study was done in a rural tertiary care hospital to determine the prevalence of congenital anomalies. Among 3000 consecutive births (with 14 twin deliveries), the rate of congenital malformation was seen as 27.2/ 1000 births. Risk factors observed were advanced maternal age, primi and fourth gravida mothers. Maternal factors increased rate of congenital malformation were consanguinity in parents, maternal febrile illness in first trimester and previous history of abortion[40].

A meta-analysis was done to assess the effects of preconceptional care in reducing congenital malformations among women with diabetes mellitus. The results showed that in 14 cohort studies, the pooled rate of congenital anomalies was lower in women who received preconception care at 2.1% compared to non-recipients (6.5%). In nine studies, the risk for developing anomalies was lower among women who received preconception care with relative risk (RR) of 0.32 and early first-trimester mean glycosylated haemoglobin values were also lower. The study emphasized on strategies to improve access so that adequate blood glycemic control, folic acid intake so as to improve pregnancy outcome[41].

METHODOLOGY

SOURCE OF DATA: Babies delivered at KLEs Dr. Prabhakar Kore Charitable Hospital and MRC, Belagavi city, North Karnataka during the study period.

STUDY DESIGN: A hospital-based Case-control study.

STUDY PERIOD: The study was carried out for a period of 12 months from 1st January 2020 to 31st December 2020.

STUDY POPULATION

All live born babies born with congenital anomalies at KLEs Dr. Prabhakar Kore Charitable Hospital were included in the study.

Controls were babies born immediately after the case and were matched with the cases for gestational age and sex.

INCLUSION CRITERIA

Case: All live born babies born with clinically detectable congenital anomalies delivering at KLEs Dr. Prabhakar Kore Charitable Hospital born during study period.

Control: All live born babies born without detectable congenital anomalies born immediately after the case and matched for sex and gestational age ±2 weeks at KLEs Dr. Prabhakar Kore Charitable Hospital.

EXCLUSION CRITERIA

Chromosomal anomalies/ metabolic disorders of the new-born (even if detected) will not be included in the study and those who refuse to give consent for participation in the study.

SAMPLE SIZE:

All live born babies born with clinically detected congenital anomalies at KLEs Dr. Prabhakar Kore Charitable Hospital during the study period were included in the study and controls were the babies born after the cases and without congenital anomaly. A case: control ratio 1:2 was taken for the study.

Average number of babies born with congenital anomalies every year is approximately 100. Hence Total Sample: 100 cases and 200 controls.

SAMPLING METHOD

Cases – universal sampling.

Controls will be babies born immediately after the case and will be matched with the cases for gestational age ($\pm$ 2 weeks) and sex.

METHOD OF DATA COLLECTION

Permission was obtained from the Principal, Jawaharlal Nehru Medical College, KAHER, Belagavi. Ethical Clearance was obtained from the Institutional Ethics Committee for Human Subjects Research, to conduct the study (Annexure I).

All women delivering babies with congenital anomalies at KLEs Dr. Prabhakar Kore Charitable Hospital were identified.

Purpose of the study was explained to the participants and after building a good rapport and confidence amongst the participants a written informed consent was obtained from all the participants enrolled for the study. Informed consent was also translated into local languages like Kannada and Marathi. Participation in the study was completely voluntary.

Using a pre-designed pre-tested questionnaire relevant history was obtained. The questionnaire consisted of IV parts. First was regarding the socio demographic details which included details regarding place of residence, religion, education, occupation, type of family, socio–economic class etc. Second part covered details regarding age of the mother at marriage, history of consanguinity, number of married life in years, if she was a registered case or not, obstetrics score, any history of previous abortion, still births, early neonatal death or previous congenital anomalous baby. Information regarding period of gestation, mode of delivery, history of exposure to X–rays or insecticides / pesticides during pregnancy, any history of tobacco or alcohol consumption during pregnancy, history of any drug intake except for folic acid, iron and calcium during pregnancy. If there was any history of pre conceptional folic acid consumption and if the woman consumed folic acid tablets during the first 3 months of pregnancy and for how many months, information regarding the Anomaly scan done in second trimester if it was done or not and if yes whether the present congenital anomaly was detected on scan, history of fever with rash during pregnancy, any history of gestational diabetes mellitus or pregnancy induced hypertension or other chronic conditions in the mother and any family history of congenital anomalies. Height and weight of the mother were recorded, and BMI was calculated.

The third part of questionnaire was to collect details of new-born like sex of the baby, birth weight, presence of any congenital anomaly and the system involved.

Information regarding new-born was also collected from clinical records and other appropriate investigations done.

Clinical evaluation of the new- born babies was done by the pediatrician for diagnosis of congenital malformations

In the fourth part of questionnaire, information regarding the placenta like the weight of placenta and presence of any placental abnormality like absence of any placental cotyledons, abnormal insertion of umbilical cord and any deviation from presence of 2 umbilical arteries and one umbilical vein was collected from the labour room records.

DATA ANALYSIS PLAN

The data collected using the questionnaire were coded and entered into Microsoft Excel sheet.

Results were analyzed to know the association between maternal risk factors and congenital anomalies using Chi Square Test with logistic regression (univariate/ multivariate analysis) with $P < 0.05$ as significance level.

Definition of Study variables –

Type of family

1. Joint: "It consists of number of married couples and their children who live in the same household."

2. Nuclear: "The family consisting of married couple along with their dependent children."

3. Broken family: "A broken family is one where the parents have separated, or where death has occurred of one or both the parents."

4. Problem family: "The standards of life are generally far below the accepted minimum and parents are unable to meet the physical and emotional needs of their children and the home life is utterly unsatisfactory."[42].

Socio-economic class

Modified B. G. Prasad's classification[44] was used which was obtained by:

The B.G. Prasad's scale was introduced in 1961 considering the base of Consumer Price Index (CPI) for 1960 as 100. Consumer Price Index for January 2020 was 330.

Multiplication factor = Current index value (330)/ Base index value in 2001 (100) = 3.3

The new income value is calculated using the following equation:

= multiplication factor × old income value × 4.63 × 4.93.

Here 4.63 and 4.93 are the linking factors given by the Labour Bureau of India.

So, after substituting the values, the new scale is

Socio – Economic status: Class	B. G. Prasad's classification of 1961 (monthly income in rupees)	Revised B. G. Prasad's classification for 2020 (monthly income in rupees)
I	100 and above	7533 and above
II	50 – 99	3766 – 7532
III	30 – 49	2260 – 3765
IV	15 - 29	1130 – 2259
V	Below 15	1129 and below

Educational Qualification

1. Illiterate: "Those who cannot read or write with understanding in any language."
2. Primary school: "Those who had completed one to five years of schooling."
3. High school: "Those who had completed six to ten years of schooling."
4. PUC: "Those who had completed education up to PUC."
5. Degree: "Those who had completed any graduation degree course or any postgraduation course."

Occupation

The source of their income, as self-reported by the beneficiaries, who would earn his or her living by means of it.

1. Unemployed: "Those who currently is not working or not receiving monitory benefits of any kind"
2. Employed: "Those who currently is working or receiving monitory benefits of any kind"[43].

Anthropometry

Body Mass Index (BMI): Calculation of BMI = weight in kg/ (Height in m)^2

BMI calculated was categorized as per WHO criteria for Asian population[45].

CATEGORY	BMI
Underweight	< 18.5kg/ m^2
Normal	18.5 – 22.9kg/m^2
Overweight	23 – 24.9kg/m^2
Obese	≥ 25kg/m^2

Consanguinity: "Mating between people who are related by blood. Such off springs may carry rare recessive genes. Hence marriage between first cousins is discouraged."

Still Birth: "A baby born with no signs of life at or after 28weeks gestation."

Preterm: "Birth occurring before completion of 37 menstrual weeks of gestation regardless of birth weight."

Primigravida: "Is one who is pregnant for the first time."

Gravida: "Denotes a pregnant state both present and past, irrespective of the period of gestation."

Parity: "Denotes a state of previous pregnancy beyond the period of viability."

Abortion: "Is the expulsion or extraction from its mother of an embryo or fetus weighing 500g or less when it is not capable of independent survival."

Medical termination of pregnancy (MTP): "Deliberate induction of abortion by a registered medical practitioner in the interest of mother's health and life is protected under the MTP Act" [46].

RESULTS

Congenital anomaly among new-borns was considered as outcome of interest. Those new-borns with outcome of interest were referred to as cases and those without outcome of interest were referred to as controls. Maternal socio - demographic characteristics, reproductive and obstetric history were considered as explanatory variables.

The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance. In case of zero or low frequency in some of the categories, simulated p-value was calculated wherever required. Both univariate and multivariable logistic regression analysis were performed to determine the predictors for outcome of interest. Crude and Adjusted odds ratio along with 95% CI is presented.

P value < 0.05 was considered statistically significant. RStudio Version 1.2.1093 was used for statistical analysis.

Table 1: Age wise distribution of mothers of cases and controls

Age group (in years)	Cases No (%)	Controls No (%)
19 to 24	26(26.0)	65(32.5)
25 to 29	57(57.0)	106(53.0)
≥30	17(17.0)	29(14.5)
Total	100	200

In the present study, 57% and 53% of mothers of cases and controls were aged between 25 – 29 years respectively. Least were aged ≥ 30 years.

Table 2: Distribution of mothers of cases and controls as per the place of residence

Address	Cases No (%)	Controls No (%)
Rural	62(62.0)	121(60.5)
Urban	38(38.0)	79(39.5)
Total	100	200

In the present study, 62% and 60.5% mothers of cases and controls were residents of rural area respectively and 38% and 39.5% mothers of cases and controls were residents of urban area.

Table 3: Distribution of mothers of cases and controls as per the religion

Religion	Cases No (%)	Controls No (%)
Hindu	85(85.0)	144(72.0)
Muslim	13(13.0)	48(24.0)
Christian	2(2.0)	8(4.0)
Total	100	200

In the present study, 85% and 72% of mothers of cases and controls were Hindu by religion. 13% and 24% mothers of cases and controls were Muslim by religion. Only 2% and 4% of mothers of cases and controls were Christian by religion.

Table 4: Distribution of cases and controls as per the literacy status of mothers

Education	Cases No (%)	Controls No (%)
Illiterate	10(10.0)	23(11.5)
Primary	8(8.0)	26(13.0)
High school	25(25.0)	43(21.5)
Pre-university I & II	29(29.0)	61(30.5)
Degree & >	28(28.0)	47(23.5)
Total	100	200

n the present study, 29% and 30.5% of mothers of cases and controls had education up to Pre – university I & II. Very few that is 10% and 11.5% mothers of cases and controls were illiterate.

Table 5: Distribution of cases and controls as per mothers' occupation

Occupation	Cases No (%)	Controls No (%)
Employed	58(58.0)	118(59.0)
Housewife/ Unemployed	42(42.0)	82(41.0)
Total	100	200

In the present study, 58% and 59% of mothers of cases and controls were employed. Whereas 42% and 41% of mothers of cases and controls were unemployed.

Table 6: Distribution of mothers of cases and controls according to type of family

Type of family	Cases No (%)	Controls No (%)
Joint	62(62.0)	110(55.0)
Nuclear	38(38.0)	90(45.0)
Total	100	200

In the present study, 62% and 55% of mothers of cases and controls belonged to joint family. Only 38% and 45% of mothers of cases and controls belonged to nuclear family.

Table 7: Distribution of mothers of cases and controls as per Socioeconomic status (SES)

SES	Cases No (%)	Controls No (%)
Class I	3(3.0)	13(6.5)
Class II	38(38.0)	68(34.0)
Class III	35(35.0)	73(36.5)
Class IV	22(22.0)	45(22.5)
Class V	2(2.0)	1(0.5)
Total	100	200

Among 100 mothers of cases, 3% were Class I, 38% were class II, 35% were class III, 22% were class IV and 2% were class V whereas among 200 mothers of controls, 6.5% were Class I, 34% were class II, 36.5% were class III, 22.5% were class IV and 0.5% were class V according to Modified B. G Prasad's classification.

Table 8: Distribution of cases and controls according to their mothers age at marriage

Age at marriage (in years)	Cases No (%)	Controls No (%)
≤20	45(45.0)	77(38.5)
>20	55(55.0)	123(61.5)
Total	100	200

Among 100 mothers of cases, 45% were married when they were ≤ 20 years and 55% were married when they were >20 years whereas among 200 mothers of controls, 38.5% were married when they were ≤ 20 years and 61.5% were married when they were >20 years.

Table 9: Distribution of mothers of cases and controls according to history of consanguinity

History of consanguinity	Cases No (%)	Controls No (%)
No	83(83.0)	192(96.0)
Yes	17(17.0)	8(4.0)
Total	100	200

In the present study, 17% mothers of cases had history of consanguinity and only 4% mothers of controls had history of consanguinity.

Table 10: Distribution of cases and controls according to their mothers' years of married life

Years of marriage	Cases No (%)	Controls No (%)
<5 years	58(58.0)	150(75.0)
5 years	42(42.0)	50(25.0)
Total	100	200

In the present study, among cases, 58% mothers had <5 years of married life and 42% had ≥ 5 years of married life whereas among controls, 75% mothers had <5 years of married life and 25% had ≥ 5 years of married life.

Table 11: Distribution of mothers of cases and controls according to BMI

BMI	Cases No (%)	Controls No (%)
Underweight	1(1.0)	2(1.0)
Normal	81(81.0)	162(81.0)
Overweight	16(16.0)	32(16.0)
Obese	2(2.0)	4(2.0)
Total	100	200

In the present study, among mothers of both cases and controls, 1% were underweight, 81% were normal, 16% were overweight and 2% were obese respectively.

Table 12: Reproductive and obstetrics history of mothers of cases and controls

Variables		Cases (n=100)	Controls (n=200)
ANC case	Booked	85(85.0)	185(92.5)
	Unbooked	15(15.0)	15(7.5)
Gravida	Primigravida	34(34.0)	69(34.5)
	2	37(37.0)	95(47.5)
	3	21(21.0)	30(15.0)
	≥ 4	8(8.0)	6(3.0)
Parity	0	9(9.0)	11(5.5)
	Primipara	34(34.0)	69(34.5)

	1	35(35.0)	93(46.5)
	2	16(16.0)	27(13.5)
	3	6(6.0)	0(0.0)
H/O previous abortion	No	82(82.0)	174(87)
	Medical termination	3(3.0)	0(0.0)
	Spontaneous	15(15.0)	26(13.0)
Mode of delivery	Vaginal	73(73.0)	146(73.0)
	C section	27(27.0)	54(27.0)
Folic acid tablets taken	No	26(26.0)	11(5.5)
	In 1st trimester (1 month)	34(34.0)	55(27.5)
	In 1st trimester (2 months)	40(40.0)	134(67.0)
History of fever with rash during pregnancy	No	97(97.0)	200(100.0)
	In 1st trimester	1(1.0)	0(0.0)
	In 2nd trimester	2(2.0)	0(0.0)
History of GDM	No	96(96.0)	200(100.0)
	Yes	4(4.0)	0(0.0)
Birth weight	<1kg	13(13.0)	0(0.0)
	1 to 1.5 kg	16(16.0)	11(5.5)
	1.5 to 2.5 kg	37(37.0)	151(75.5)
	>2.5kg	34(34.0)	38(19.0)
Placenta weight	<400	33(33.0)	16(8.0)
	400 to 450	45(45.0)	118(59.0)

	>450	22(22.0)	66(33.0)
Presence of 2 UA/ 1 UV	No	5(5.0)	0(0.0)
	Yes	95(95.0)	200(100.0)
History of previous congenital anomalous baby	No	84 (84.0)	200 (100.0)
	Yes	16 (16.0)	0 (0.0)

In the present study antenatal care (ANC) case was booked for 85% of mothers of cases and 92.5% of mothers of controls. 34% and 34.5% were primigravida among mothers of cases and controls respectively. 3% mothers had done medical termination and 15% had spontaneous abortion among cases whereas none (0%) had done medical termination and 13% mothers had spontaneous abortion among controls. The mode of delivery was vaginal for 73% and caesarean section for 27% among mothers of both cases and controls. It was found that 26% mothers had not taken folic acid tablet among cases whereas only 5.5% mothers of the controls hadn't taken folic acid tablets. 1% and 2% had history of fever with rash during pregnancy in 1st trimester and 2nd trimester respectively among mothers of 100 cases whereas none (0%) of the mothers had history of fever with rash among 200 controls. Approximately 4% had history of (Gestational Diabetes Mellitus) GDM among mothers of cases and none (0%) had history of GDM among controls. In the present study 13% had birth weight <1 kg among 100 cases whereas none had birth weight <1 kg among 200 controls. Placenta weight of 33% of the cases was < 400g whereas it was < 400g only for 8% of the controls. There was absence of 2 umbilical artery (UA)/ 1 umbilical vein (UV) in 5% of the cases and none (0%) in controls.

Table 13: Variables related to antenatal detection of congenital anomalies of mothers of cases and controls

Variables		Cases (n=100)	Controls (n=200)
Anomaly scan done	No	14(14.0)	5(2.5)
	Yes - In 2nd trimester	86(86.0)	195(97.5)
Diagnosis of congenital anomaly on scan	No	39(39.0)	NA
	Yes	61(61.0)	NA
Congenital anomaly	No	0(0.0)	200(100.0)
	CNS	25(25.0)	NA
Congenital anomaly	CVS	18(18.0)	NA
	Genitourinary	20(20.0)	NA
	GIT	9(9.0)	NA
	Multiple system	7(7.0)	NA
	Musculoskeletal	16(16.0)	NA
	Respiratory system	5(5.0)	NA

In the present study among cases, 16% mothers had history of previous congenital anomalous baby whereas among controls, none (0%) of the mothers had history of previous congenital anomalous baby. Anomaly scan was done in 86% of mothers of cases during 2nd trimester whereas it was done in 97.5% of mothers of controls during 2nd trimester. 61% of cases were diagnosed of congenital anomaly on scan whereas 39% congenital anomalies remained undiagnosed on scan.

In the present study among 100 cases with congenital anomaly, 25% had congenital anomaly of CNS, 18% had congenital anomaly of CVS, 20% had congenital anomaly of genitourinary, 9% had congenital anomaly of GIT, 7% had congenital anomaly of multiple systems, 16% had congenital anomaly of musculoskeletal and 5% had congenital anomaly of respiratory system

Table l4: Distribution of cases and controls as per gender of the baby

Gender of the baby	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Male	55(55.0)	110(55.0)	0.000	1	1.000
Female	45(45.0)	90(45.0)			
Total	100	200			

Figure 2: Gender of the baby in cases and controls

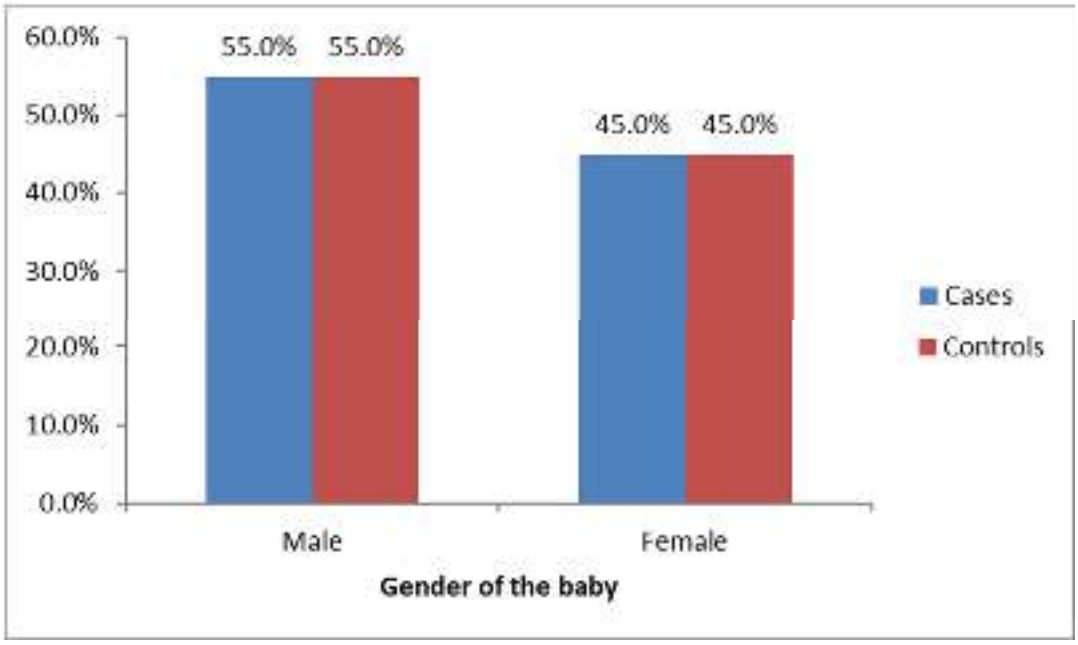
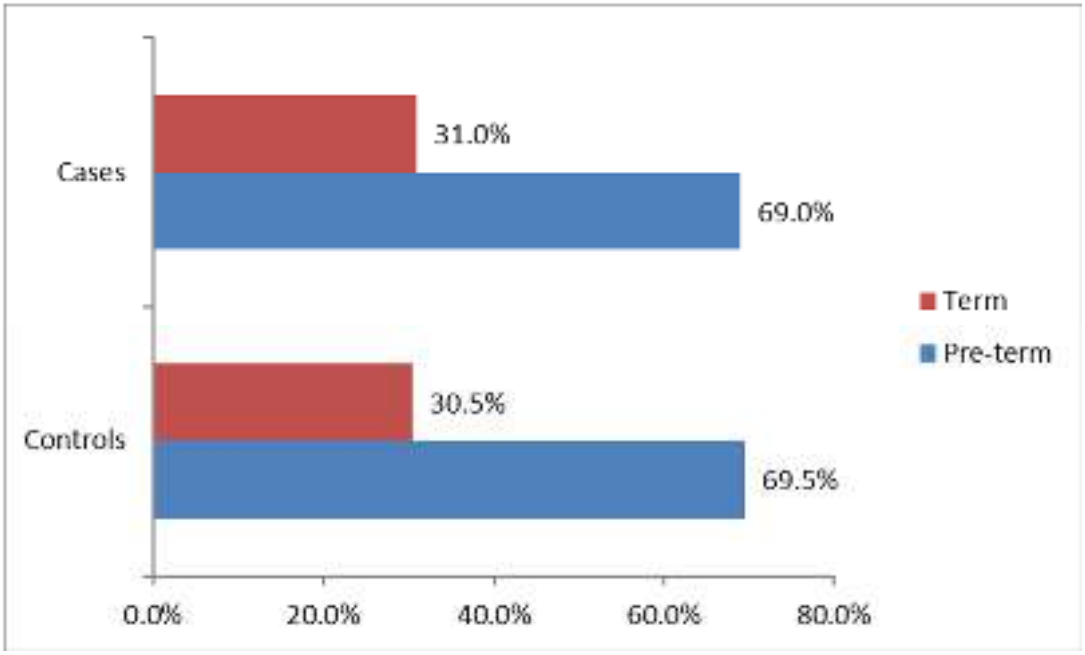


Table 15: Distribution of cases and controls as per gestational age at birth

Gestational age at birth	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Term	31(31.0)	61(30.5)	0.000	1	1.000
Pre-Term	69(69.0)	139(69.5%)			
Total	100	200			

Figure 3: Gestational age at birth in cases and controls



As gender of the new-born and age of gestation were matched, there is no significant difference between cases and controls.

Table 16: Association between age distribution of mothers of cases and controls and presence of congenital anomaly

Age group	Cases No (%)	Controls No (%)	Chi-square	df	P-value
19-24	26(26.0)	65(32.5)	1.397	2	0.497
25-29	57(57.0)	106(53.0)			
≥ 30	17(17.0)	29(14.5)			
Total	100	200			

There was statistically no significant association between age of the mothers among cases and controls and presence of congenital anomalies among new-born babies (p>0.05). Among 100 cases, 26% were between 19 to 24 years, 57% were between 25 to 29 years and 17% were ≥ 30 years whereas among 200 controls, 32.5% were between 19 to 24 years, 53% were between 25 to 29 years and 14.5% were ≥ 30 years.

Figure 4: Age wise distribution of mothers of cases and controls

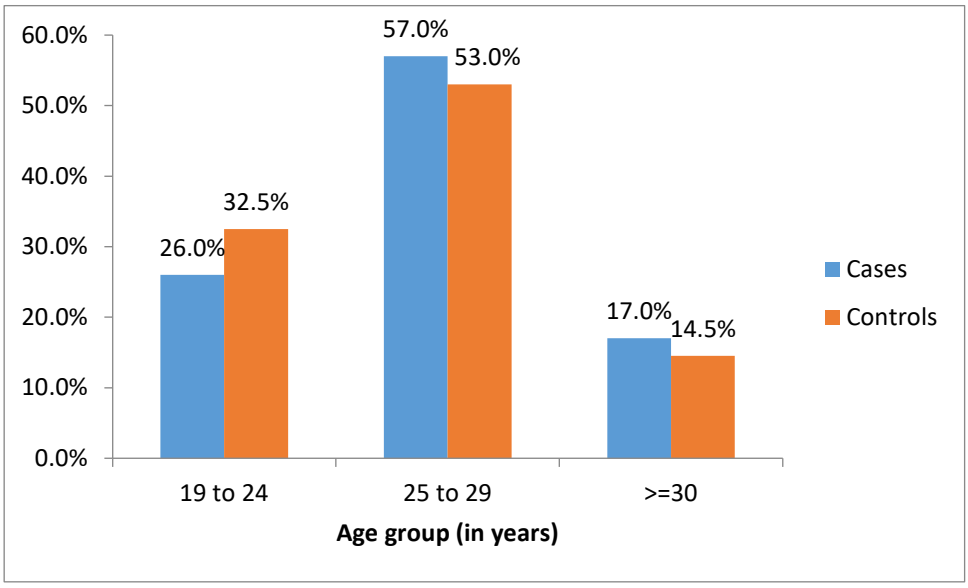


Table 17: Association between place of residence of mothers of cases and controls and presence of congenital anomalies

Place of residence	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Rural	62(62.0)	121(60.5)	0.063	1	0.802
Urban	38(38.0)	79(39.5)			
Total	100	200			

There was statistically no significant association between place of residence and presence of congenital anomalies among new-born babies ($p>0.05$). Among 100 cases, 62% lived in rural area and 38% lived in urban area whereas among 200 controls, 60.5% lived in rural area and 39.5% lived in urban area.

Figure 5: Distribution of mothers of cases and controls as per the place of residence

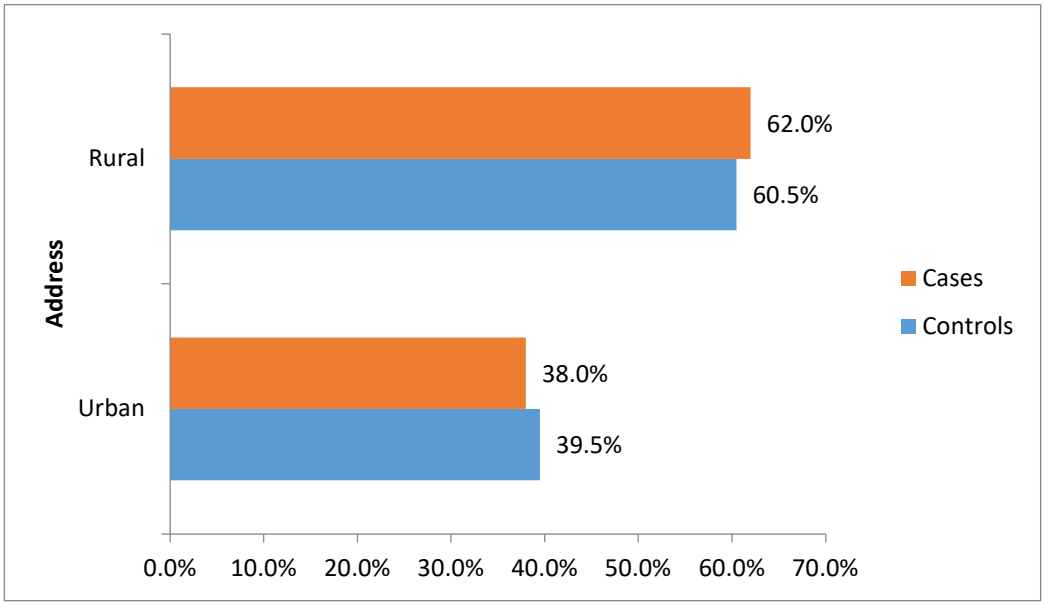


Table 18: Association between religion and presence of congenital anomalies

Religion	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Hindu	85(85.0)	144(72.0)	6.243	2	**0.044**
Muslim	13(13.0)	48(24.0)			
Christian	2(2.0)	8(4.0)			
Total	100	200			

There was statistically significant association found between religion and presence of congenital anomalies among new-born babies ($p<0.05$). Among 100 cases, 85% were Hindus, 3% were Muslim and 2% were Christian whereas among 200 controls, 72% were Hindus, 24% were Muslim and 4% were Christian.

Figure 6: Distribution of mothers of cases and controls as per the religion

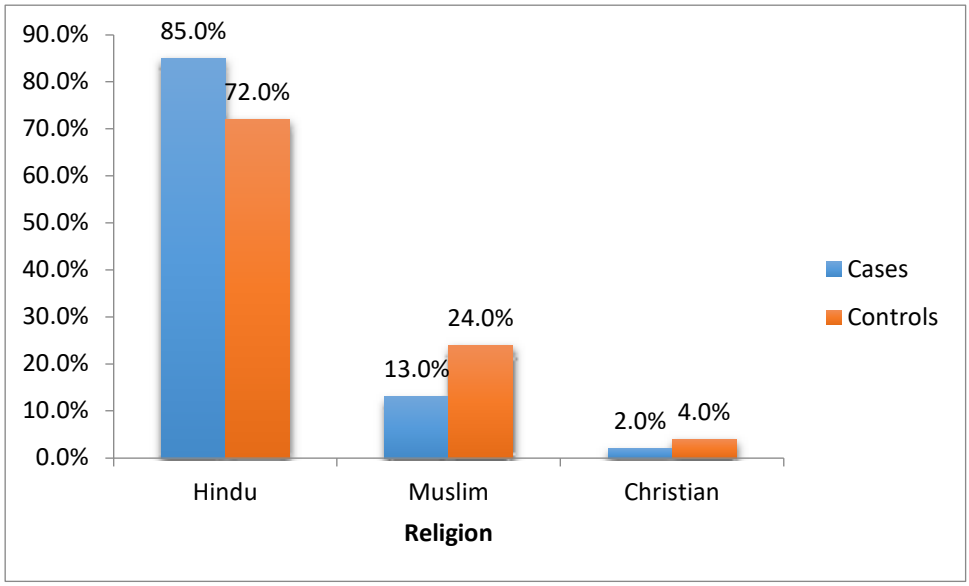


Table 19: Association between literacy status and presence of congenital anomalies

Education	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Illiterate	10(10.0)	23(11.5)	2.557	4	0.634
Primary	8(8.0)	26(13.0)			
High School	25(25.0)	43(21.5)			
Pre-university I and II	29(29.0)	61(30.5)			
Degree & >	28(28.0)	47(23.5)			
Total	100	200			

There was statistically no significant association between education and presence of congenital anomalies among new-born babies (p>0.05). Among 100 cases, 10% were illiterate, 8% had primary education, 25% had high school education, 29% had pre-university I & II education and 28% had degree or higher education whereas among 200 controls, 11.5% were illiterate, 13% had primary education, 21.5% had high school education, 30.5% had pre-university I & II education and 23.5% had degree or higher education

Figure 7: Distribution of cases and controls as per literacy status of mothers

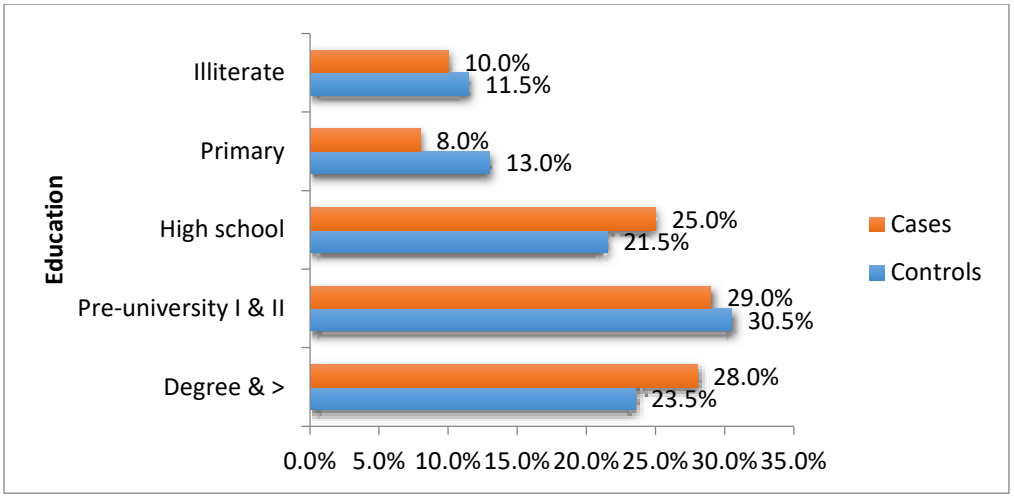


Table 20: Association between occupation and presence of congenital anomaly

Occupation	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Employed	58(58.0)	118(59.0)	0.027	1	0.868
Housewife/ Unemployed	42(42.0)	82(41.0)			
Total	100	200			

There was statistically no significant association found between occupation and presence of congenital anomalies among new-born babies ($p>0.05$). Among 100 cases, 58% were employed and 42% were housewife or unemployed whereas among 200 controls, 59% were employed and 41% were housewife or unemployed.

Figure 8: Distribution of cases and controls as per occupation of mothers

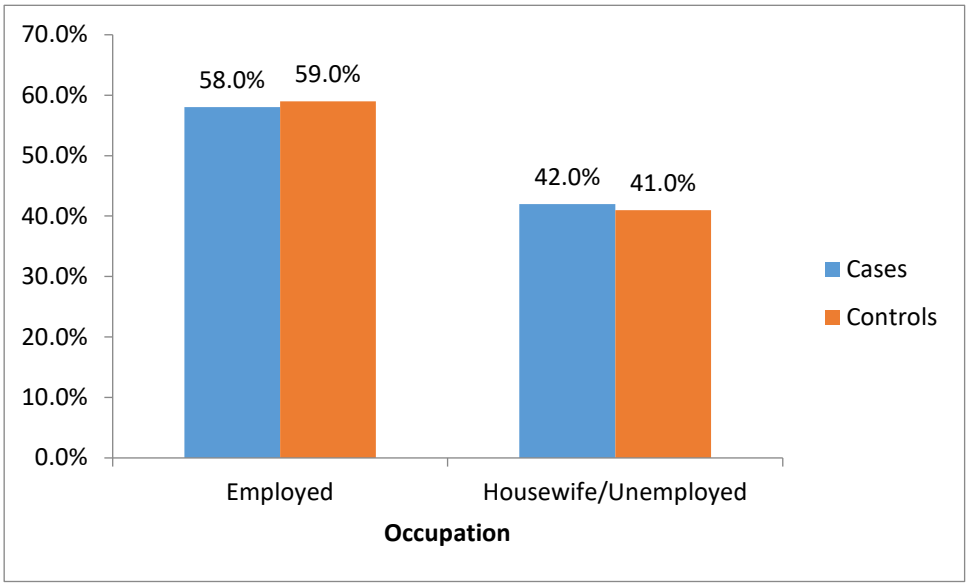


Table 21: Association between type of family and presence of congenital anomaly

Type of family	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Joint	62(62.0)	110(55.0)	1.335	1	0.248
Nuclear	38(38.0)	90(45.0)			
Total	100	200			

There was statistically no significant association found between type of family and presence of congenital anomalies among new-born babies (p>0.05). Among 100 cases, 62% had joint family and 38% had nuclear family whereas among 200 controls, 55% had joint family and 45% had nuclear family.

Figure 9: Distribution of mothers of cases and controls according to type of family

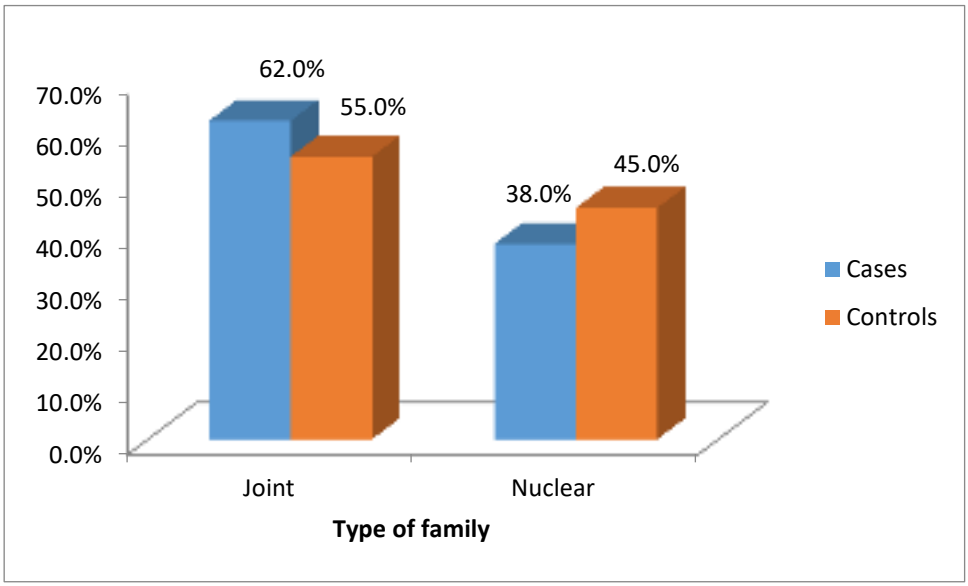


Table 22: Association between SES and presence of congenital anomaly

SES	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Class I	3(3.0)	13(6.5)	3.382	4	0.496
Class II	38(38.0)	68(34.0)			
Class III	35(35.0)	73(36.5)			
Class IV	22(22.0)	45(22.5)			
Class V	2(2.0)	1(0.5)			
Total	100	200			

There was statistically no significant association between socioeconomic status and presence of congenital anomalies among new-born babies ($p>0.05$). Among 100 cases, 3% were Class I, 38% were class II, 35% were class III, 22% were class IV and 2% were class V whereas among 200 controls, 6.5% were Class I, 34% were class II, 36.5% were class III, 22.5% were class IV and 0.5% were class V.

Figure 10: Distribution of mothers of cases and controls as per SES

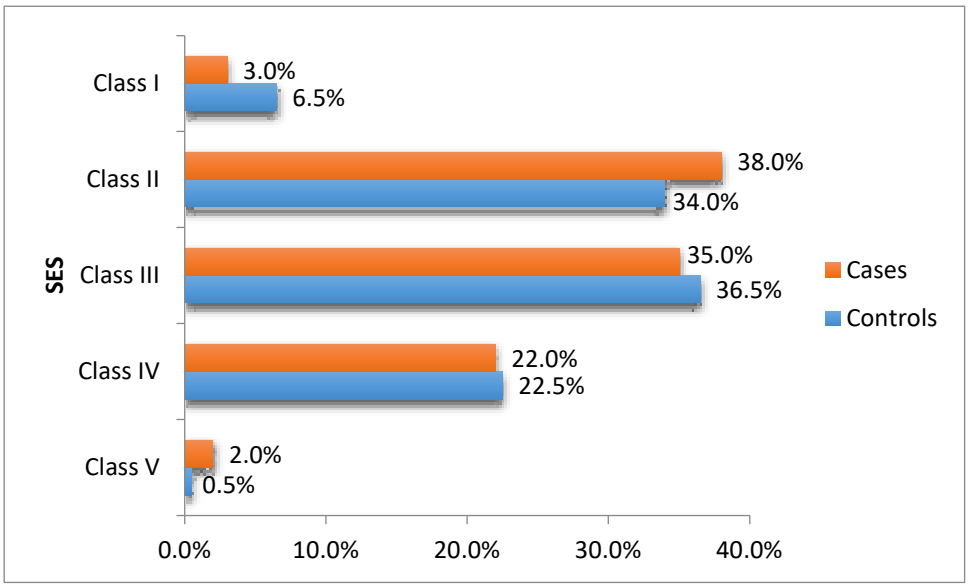


Table 23: Association between age at marriage (in years) and presence of congenital anomaly

Age at marriage	Cases No (%)	Controls No (%)	Chi-square	df	P-value
≤20	45(45.0)	77(38.5)	0.280	1	0.280
>20	55(55.0)	123(61.5)			
Total	100	200			

There was statistically no significant association found between age at marriage and presence of congenital anomalies among new-born babies (p>0.05). Among 100 cases, 45% married when they were ≤ 20 years and 55% married when they were >20 years whereas among 200 controls, 38.5% married when they were ≤ 20 years and 61.5% married when they were >20 years.

Figure 11: Distribution of mothers of cases and controls according to age at marriage

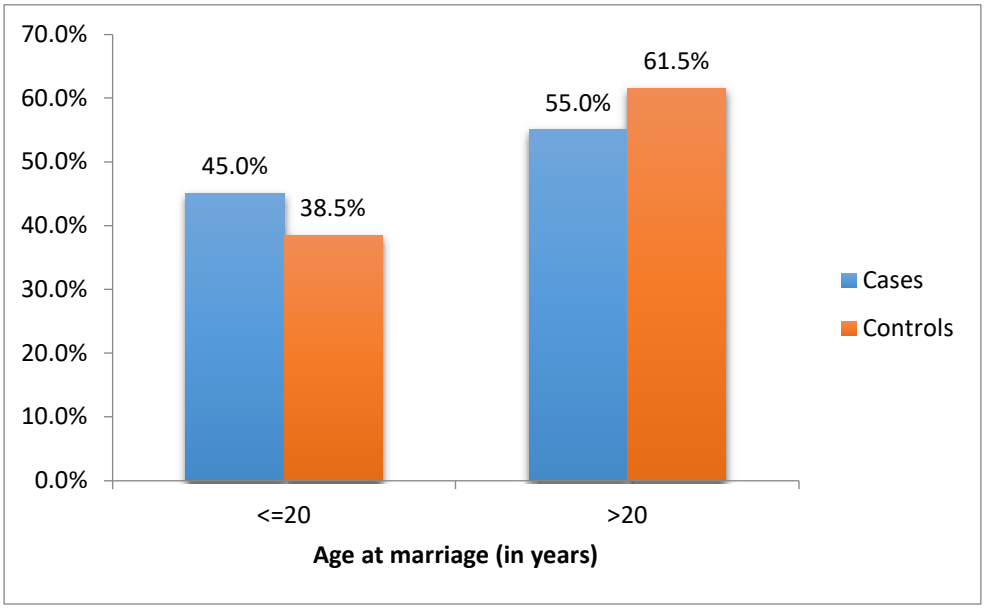


Table 24: Association between history of consanguinity and presence of congenital anomaly

History of consanguinity	Cases No (%)	Controls No (%)	Chi-square	df	P-value
No	83(83.0)	192(96.0)	14.749	1	**<0.001**
Yes	17(17.0)	8(4.0)			
Total	100	200			

Since 17% had history of consanguinity among case and only 4% had history of consanguinity among controls, there was statistically significant association between history of consanguinity and presence of congenital anomalies among new-born babies ($p<0.05$).

Figure 12: Distribution of mothers of cases and controls according to history of consanguinity

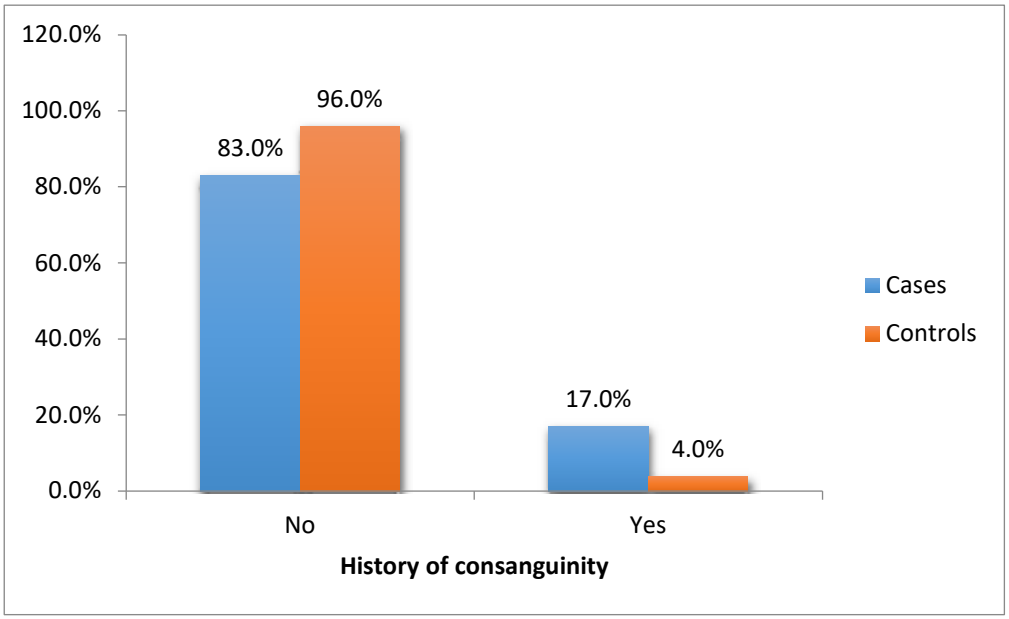


Table 25: Association between years of married life of mothers of cases and controls and presence of congenital anomaly

Years of marriage	Cases No (%)	Controls No (%)	Chi-square	df	P-value
<5 years	58(58.0)	150(75.0)	9.061	1	**0.003**
≥ 5 years	42(42.0)	50(25.0)			
Total	100	200			

Years of marriage and presence of congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$). Among cases, 58% had <5 years of marriage and 42% had ≥ 5 years of marriage whereas among controls, 75% had <5 years of marriage and 25% had ≥ 5 years of marriage.

Figure 13: Distribution of mothers of cases and controls according to years of married life

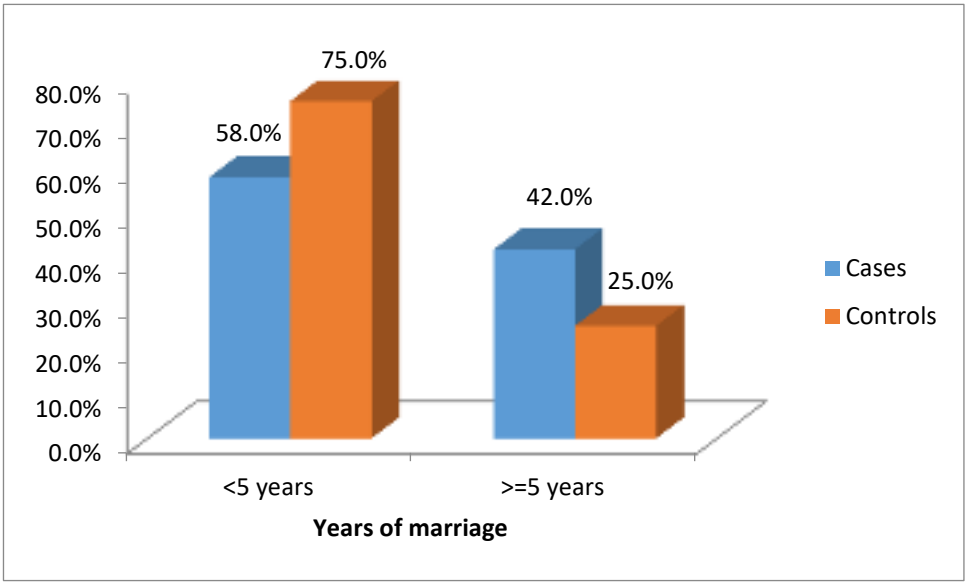


Table 26: Association between BMI distribution of mothers of cases and controls and presence of congenital anomaly

BMI	Cases No (%)	Controls No (%)	Chi-square	df	P-value
Underweight	1(1.0)	2(1.0)	0.000	3	1.000
Normal	81(81.0)	162(81.0)			
Overweight	16(16.0)	32(16.0)			
Obese	2(2.0)	4(2.0)			
Total	100	200			

There was statistically no significant association between BMI and presence of congenital anomalies among new-born babies (p>0.05). Among both cases and controls, 1% were underweight, 81% were normal, 16% were overweight and 2% were obese each.

Figure 14: Distribution of mothers of cases and controls according to BMI

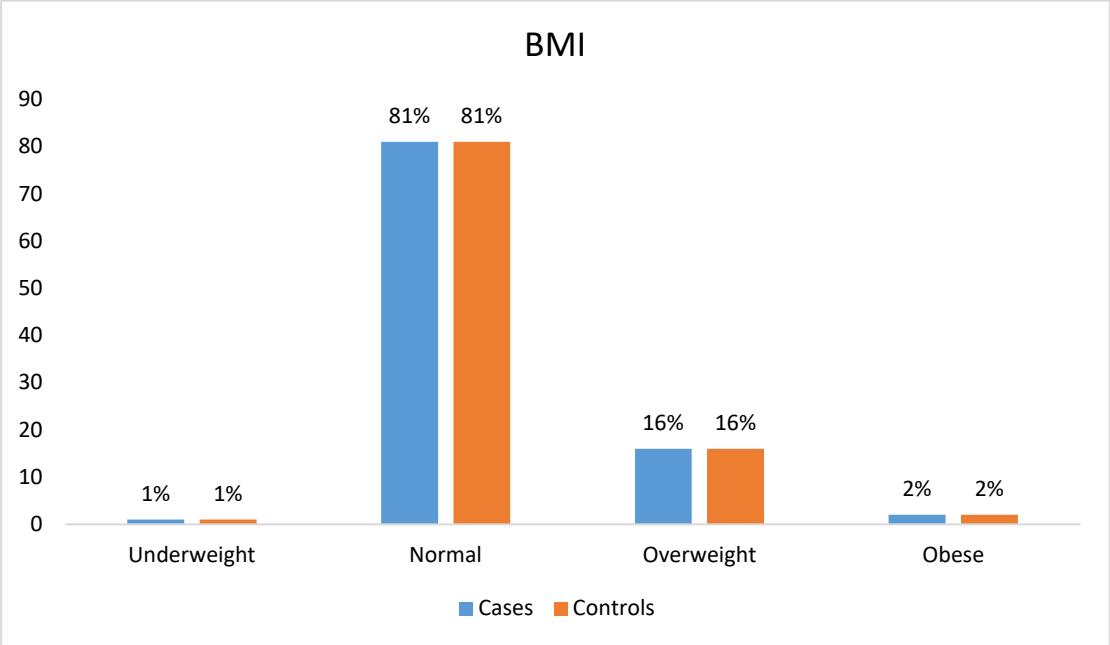


Table 27: Association between reproductive and obstetrics history and presence of congenital anomaly

Variables		Cases (n=100)	Controls (n=200)	Chi-square	df	P-value
ANC case	Booked	85(85.0)	185(92.5)	4.167	1	**0.041***
	Unbooked	15(15.0)	15(7.5)			
Gravida	Primigravida	34(34.0)	69(34.5)	6.659	3	0.084
	2	37(37.0)	95(47.5)			
	3	21(21.0)	30(15.0)			
	≥ 4	8(8.0)	6(3.0)			
Parity	0	9(9.0)	11(5.5)	15.587	4	**0.004***
	Primipara	34(34.0)	69(34.5)			
	1	35(35.0)	93(46.5)			
	2	16(16.0)	27(13.5)			
	3	6(6.0)	0(0.0)			
H/O previous abortion	No	82(82.0)	174(87)	6.390	2	**0.047***
	Medical termination	3(3.0)	0(0.0)			
	Spontaneous	15(15.0)	26(13.0)			
Mode of delivery	Vaginal	73(73.0)	146(73.0)	0.000	1	1.000
	C section	27(27.0)	54(27.0)			
Folic acid tablets taken	No	26(26.0)	11(5.5)	32.045	2	**<0.001***
	In 1st trimester (1 month)	34(34.0)	55(27.5)			
	In 1st trimester (2 months)	40(40.0)	134(67.0)			
History of fever with rash during pregnancy	No	97(97.0)	200(100.0)	6.061	2	**0.035***
	In 1st trimester	1(1.0)	0(0.0)			
	In 2nd trimester	2(2.0)	0(0.0)			
History of	No	96(96.0)	200(100.0)	8.108	1	**0.011***

GDM	Yes	4(4.0)	0(0.0)			
Birth weight	<1kg	13(13.0)	0(0.0)	56.185	3	**<0.001***
	1 to 1.5 kg	16(16.0)	11(5.5)			
	1.5 to 2.5 kg	37(37.0)	151(75.5)			
	>2.5kg	34(34.0)	38(19.0)			
Placenta weight	<400	33(33.0)	16(8.0)	30.665	2	**<0.001***
	400 to 450	45(45.0)	118(59.0)			
	>450	22(22.0)	66(33.0)			
Presence of 2 UA/ 1 UV	No	5(5.0)	0(0.0)	10.169	1	**0.003***
	Yes	95(95.0)	200(100.0)			
H/O previous congenital anomalous baby	No	84(84.0)	200(100.0)	33.803	1	**<0.001***
	Yes	16(16.0)	0(0.0)			

Note: * Statistically significant (p<0.05)

There was significant association between ANC case and presence of congenital anomalies among new-born babies (p<0.05) since ANC case was booked for 85% of the cases and it was booked for 92.5% of the controls. 34% and 34.5% were primigravida among cases and controls respectively. Parity and presence of congenital anomalies among new-born babies was statistically significantly associated (p<0.05) as the proportion of para 2 and para 3 was higher in cases as compared to controls. There was significant association between history of previous abortion and presence of congenital anomalies among new-borns since 3% had done medical termination and 15% had spontaneous abortion among cases whereas none (0%) had done medical termination and 13% had spontaneous abortion among controls. The mode of delivery was vaginal for 73% and caesarean section for 27% among both cases and controls. Folic acid tablets taken and presence of congenital anomalies among new-born babies

was statistically significantly associated ($p<0.05$) since 26% had not taken folic acid tablet among cases whereas only 5.5% of the controls hadn't taken folic acid tablets. There was significant association between history of fever with rash during pregnancy and presence of congenital anomalies among new-born babies ($p<0.05$) as 1 (1%) and 2 (2%) had history of fever with rash during pregnancy in 1st trimester and 2nd trimester respectively among 100 cases whereas none had history of fever with rash among 200 controls. Since, 4% had history of GDM among cases and none had history of GDM among controls, there was significant association between history of GDM and presence of congenital anomalies among new-born babies ($p<0.05$). Birth weight and congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$) since 13% had birth weight <1 kg among 100 cases whereas none had birth weight M 1 kg among 200 controls. Placenta weight and presence of congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$) as the placenta weight of 33% of the cases was <400g whereas it was <400g only for 8% of the controls. Since, there was absence of 2 UA/ 1 UV in 5 (5%) of the cases and none in controls, there was significant association between presence of 2 UA/ 1 UV and presence of congenital anomalies among new-born babies ($p<0.05$).

Table 28: Comparison of variables related to antenatal detection of congenital anomalies between case and control

Variables		Cases	Controls	Chi-square	df	P-value
Anomaly scan done	No	14(14.0)	5(2.5)	14.862	1	**<0.001***
	Yes - In 2nd trimester	86(86.0)	195(97.5)			
Diagnosis of congenital anomaly on scan	No	39(39.0)	200(100.0)	153.138	1	**<0.001***
	Yes	61(61.0)	0(0.0)			

Note: * Statistically significant (p<0.05)

Among cases, 16% had history of previous congenital anomalous baby whereas among controls, none (0%) had history of previous congenital anomalous baby. Anomaly scan was done in 86% of the cases during 2nd trimester whereas it was done in 97.5% of the controls during 2nd trimester. 61% cases were diagnosed of congenital anomaly on scan whereas none (0%) controls were diagnosed of it.

Table 29: Maternal risk factors of congenital anomalies among new-born babies

Variables	Univariate model	Multivariable model

		cOR(95%CI)	P-value	aOR(95%CI)	P-value
Age (in years)		1.05 (0.97-1.13)	0.225	1.16 (0.87-1.55)	0.305
Address	Rural (Reference)				
	Urban	0.94 (0.57-1.54)	0.802	0.82 (0.43-1.59)	0.560
Religion	Hindu (Reference)				
	Muslim	0.46 (0.24-0.9)	**0.022***	0.49 (0.21-1.16)	0.105
	Christian	0.42 (0.09-2.04)	0.284	0.72 (0.11-4.77)	0.732
Education	Illiterate (Reference)				
	Primary	0.71 (0.24-2.1)	0.533	0.56 (0.13-2.40)	0.435
	High school	1.34 (0.55-3.26)	0.523	2.48 (0.68-9.05)	0.168
	Pre-university I & II	1.09 (0.46-2.59)	0.839	2.58 (0.57-11.77)	0.220
	Degree & >	1.37 (0.57-3.30)	0.482	3.2 (0.57-17.96)	0.185
Occupation	Employed (Reference)				
	Housewife/Unemployed	1.04 (0.64-1.70)	0.868	1.26 (0.46-3.47)	0.649
Type of family	Joint (Reference)				
	Nuclear	0.75 (0.46-1.22)	0.248	0.61 (0.29-1.30)	0.198
SES		1.07 (0.82-1.41)	0.612	1.12 (0.69-1.82)	0.650
Age at marriage		0.96 (0.87-1.05)	0.348	0.83 (0.60-1.14)	0.255
History of consanguinity	No (Reference)				
	Yes	4.92 (2.04-11.84)	**<0.001***	6.83 (2.29-20.41)	**0.001***
Years of marriage	<5 years (Reference)				
	>=5 years	2.17 (1.30-3.62)	**0.003***	1.19 (0.38-3.69)	0.762
BMI	Normal (Reference)				
	Underweight	1.00 (0.09-11.19)	1.000	3.10 (0.23-41.89)	0.394
	Overweight	1.00 (0.52-1.93)	1.000	1.10 (0.47-2.56)	0.822

	Obese	1.00 (0.18-5.57)	1.000	1.93 (0.27-13.80)	0.510
ANC case	Booked (Reference)				
	Unbooked	2.18 (1.02-4.66)	**0.045***	1.35 (0.50-3.63)	0.548
Gravida	Primigravida (Reference)				
	2	0.79 (0.45-1.38)	0.410	0.50 (0.21-1.16)	0.106
	3	1.42 (0.71-2.84)	0.320	0.99 (0.31-3.14)	0.981
	≥ 4	2.71 (0.87-8.42)	0.086	0.78 (0.12-5.18)	0.798
Parity	1 (Reference)				
	Primigravida	1.31 (0.74-2.30)	0.350		
	2 or 3	2.17 (1.09-4.29)	**0.027***		
	0	2.17 (0.83-5.69)	0.114		
H/O previous abortion	No (Reference)				
	Yes	1.47 (0.76-2.83)	0.250	1.21 (0.48-3.05)	0.683
Mode of delivery	Vaginal (Reference)				
	C section	1.00 (0.58-1.72)	1.000	0.86 (0.43-1.72)	0.670
Folic acid tablets taken	No (Reference)				
	Yes, in 1st trimester (1 month)	0.26 (0.11-0.60)	**0.001***	0.31 (0.11-0.85)	**0.023***
	Yes, in 1st trimester (2 months)	0.13 (0.06-0.28)	**<0.001***	0.14 (0.05-0.36)	**<0.001***
Placenta weight		0.98 (0.97-0.99)	**<0.001***	0.98 (0.97-0.99)	**<0.001***
Anomaly scan done	No (Reference)				
	Yes, in 2nd trimester	0.16 (0.05-0.45)	**0.001***	0.13 (0.04-0.46)	**0.002***

Note: * Statistically significant (p<0.05); cOR: Crude Odds Ratio; aOR: Adjusted Odds Ratio

Table 4 shows the results from binary logistic regression analysis for congenital anomalies among new-born babies. Some of the variables were re-categorized in the logistic regression due to zero/low frequency in certain categories. Variables such as history of fever with rash during pregnancy, history of GDM, presence of 2 UA/ 1 UV, history of previous congenital anomalous baby and diagnosis of congenital anomaly on scan were not taken in the analysis because of 0 frequencies in the controls. Both univariate and multivariable binary logistic regression were used to examine the factors associated with congenital anomalies among new-born babies. Parity was not included in the multivariable model due to multicollinearity problem. Both univariate and multivariable models showed that history of consanguinity, folic acid tablets taken, placenta weight and anomaly scan done were significant predictors of congenital anomalies among new-born babies. Religion, years of marriage, ANC case and parity were also found to be significant in univariate analysis.

From multivariable model, new-borns with mothers having history of consanguinity were 6.83 times (aOR 6.83, 95% CI 2.29-20.41) more likely to develop congenital anomalies as compared to new-borns with mothers without history of consanguinity. New-borns with mothers taking folic acid tablets in 1st trimester for 1 month were 69% (aOR 0.31, 95% CI 0.11-0.85) less likely to develop congenital anomalies as compared to new-borns with mothers taking no folic acid tablets. Similarly, new-borns with mothers taking folic acid tablets in 1st trimester for 2 months were 86% (aOR 0.14, 95% CI 0.05-0.36) less likely to develop congenital anomalies as compared to new-borns with mothers taking no folic acid tablets. With each gram increase in placenta weight, the odds of congenital anomalies in new-borns

decreased by 2% (aOR 0.98, 95% CI 0.97-0.99). New-borns with mothers who had done anomaly scan in 2nd trimester were 87% (aOR 0.13, 95% CI 0.04-0.46) less likely to develop congenital anomalies as compared to new-borns with mothers who hadn't done anomaly scan.

DISCUSSION

The present study sought to know the maternal risk factors associated with congenital anomalies and also to know the placental abnormalities associated with congenital anomalies among new–born babies, delivered in a tertiary Hospital. This one-year hospital-based study was conducted between the period of January 2020 and December 2020 in the labour rooms of Dr Prabhakar Kore Hospital Belagavi. A total of 100 cases met the inclusion criteria and controls were selected with 1:2 ratio. The cases and controls were studied and analyzed.

Socio – demographic Characteristics of mothers of cases:

Table 1 shows distribution of mothers of cases and controls according to their age. Among 100 cases, 26% were between 19 to 24 years, 57% were between 25 to 29 years and 17% were >=30 years whereas among 200 controls, 32.5% were between 19 to 24 years, 53% were between 25 to 29 years and 14.5% were >=30 years. Mean age of mothers of cases was found to be 26.93 ± 4.35 and for controls, it was 26.37 ± 4.34.

The mean maternal age of mothers in a retrospective cross-sectional study which was carried out in 2 hospitals of Mount-Lebanon was found to be 25.97±9.7[23].

In another study which was carried out for one year in a tertiary care hospital of Odisha, it was found that 68.75% mothers were aged between 20-35 years while only 12.5% were < 20 years of age[24].

In a hospital-based cross-sectional study which was done in Kolkata, it was seen only 10% of the women were more than 30 years of age and majority of the women were between 20 and 30 years of age[16].

In a hospital-based cross–sectional observational study which was conducted in J N Medical College, Aligarh for a period of one year, it was found that more than half of the women (53%) were less than 30 years of age, and 47% women were more than 30 years of age[26].

Table 2 shows distribution of cases and controls as per their mothers' place of residence. Among 100 cases, 62% lived in rural area and 38% lived in urban area whereas among 200 controls, 60.5% lived in rural area and 39.5% lived in urban area.

Similar to the present study, a descriptive study was conducted in a rural hospital in Amritsar which included new-borns from both urban and rural setting being admitted to the hospital during the study period[35].

In a prospective cohort study which was carried out at four hospitals in Pune, India to study the prevalence of congenital anomalies, only women from urban setting were included in the study[34].

Table 3 shows distribution of mothers of cases and controls as per religion. Among 100 cases, 85% were Hindus, 3% were Muslim and 2% were Christian whereas among 200 controls, 72% were Hindus, 24% were Muslim and 4% were Christian.

In a hospital-based cross–sectional observational study which was conducted in a Neonatology section, Department of pediatrics, J N Medical College, Aligarh for

a period of one year, it was found that 62% of the mothers were Muslim by religion and 38% were Hindu by religion[26].

Table 4 shows literacy status of mothers of cases and controls. Among 100 cases, 10% were illiterate, 8% had primary education, 25% had high school education, 29% had pre-university I & II education and 28% had degree or higher education whereas among 200 controls, 11.5% were illiterate, 13% had primary education, 21.5% had high school education, 30.5% had pre-university I & II education and 23.5% had degree or higher education.

Another study which was done in the Department of Obstetrics and Gynaecology at a tertiary care hospital in Odisha also showed comparable results where majority of mothers of cases were educated and very few were uneducated[24].

Table 5 shows employment status of mothers of cases and controls. Among 100 cases, 58% were employed and 42% were homemaker or unemployed whereas among 200 controls, 59% were employed and 41% were homemaker or unemployed.

In contrast to the present study, another hospital records-based study in Mount-Lebanon showed that majority of mothers were homemakers and very few were employed[23].

Table 6 shows the distribution of mothers of cases according to type of family. Among 100 cases, 62% had joint family and 38% had nuclear family whereas among 200 controls, 55% had joint family and 45% had nuclear family.

Table 7 in the present study shows the distribution of mothers of cases according to their socio – economic status. Among 100 cases, 3% were Class I, 38% were Class II, 35% were Class III, 22% were Class IV and 2% were Class V whereas

among 200 controls, 6.5% were Class I, 34% were Class II, 36.5% were Class III, 22.5% were Class IV and 0.5% were Class V.

In another study which was done in a tertiary care hospital in Odisha, India for a period of one year, 59.38% belonged to lower class, 34.37% belonged to middle class and 6.25% belonged to upper class[24].

Table 8 shows distribution of cases and controls according to their mothers' age at marriage. Among 100 cases, 45% married when they were <=20 years and 55% married when they were >20 years whereas among 200 controls, 38.5% married when they were <=20 years and 61.5% married when they were >20 years.

Table 9 shows distribution of cases and controls according to their mothers' history of consanguinity. Nearly 17% had history of consanguinity among cases and only 4% had history of consanguinity among controls.

In a descriptive study which was conducted in a medical college in Davangere, Karnataka, it was observed that 45.2% mothers had no history of consanguinity and 54.7% had history of consanguinity[36].

Table 10 shows distribution of mothers of cases and controls according to years of marriage. Among cases, 58% had <5 years of marriage and 42% had >=5 years of marriage whereas among controls, 75% had <5 years of marriage and 25% had >=5 years of marriage.

Table 11 shows distribution of mothers of cases and controls according to Body mass index. Among both cases and controls, 1% were underweight, 81% were normal, 16% were pre-obese and 2% were obese each.

Table 12: Comparison of reproductive and obstetrics history of mothers of cases and controls

Booked vs un-booked mothers

In the present study, 85% of the cases were booked and 15% were unbooked and among controls 92.5% were booked and 15% were unbooked.

In a one-year hospital-based study which was done in Odisha, it was found that unbooked mothers without any antenatal care were 62.5 % and booked mothers were 37.5%[24].

In a cross-sectional descriptive study which was conducted in a teaching hospital, it was observed that 98.9% mothers of babies born without congenital anomalies and 1.01% mothers of babies born with congenital anomalies were booked where as 98% mothers of babies born without congenital anomalies and 2% mothers of babies born with congenital anomalies were unbooked[14].

Parity

In the present study, 9% mothers among cases and 11% mothers among controls were nulliparous. 34% were primigravida among cases and 34.5% were primigravida among controls. Proportion of para 2 and para 3 was higher in controls (60%) as compared to cases (57%).

In a hospital-based cross–sectional observational study which was conducted in a Neonatology section, Department of pediatrics, J N Medical College, Aligarh for a period of one year, it was found that 59% of mothers were multipara and 41% mothers were primipara[26].

In a retrospective study which was carried out in a hospital in Mumbai, Maharashtra, it was found that 64% of mothers were multipara and 36% of the mothers were primipara[27].

In a study which was done in a medical college in Vellore. 53.5% women were nulliparous women, and 46.6% mothers were para 2 or more[17].

History of previous abortion

In the present study, 3% had done medical termination and 15% had spontaneous abortion among cases whereas none (0%) had done medical termination and 13% had spontaneous abortion among controls.

In a study which was done at a medical college in Vellore, it was seen that 86.7% mothers had no history of abortion and 13.3% mothers had history of previous abortions[17].

Mode of delivery

In the present study, 73% of mothers delivered by normal vaginal delivery and 27% mothers delivered by C-section among both cases and controls.

In a cross-sectional study which was carried out in a tertiary care hospital of Maharashtra for a period of 6 months, it was seen that 65.6% had normal vaginal delivery and 34.4% had C-section[18].

In a retrospective study which was carried out in two Lebanese Hospitals, it was seen that (63.2%) had normal vaginal delivery and 36.8% had cesarean section[23].

In a hospital-based cross–sectional observational study which was conducted in a Neonatology section, Department of pediatrics, J N Medical College, Aligarh for a period of one year, it was found that 54% mothers had normal vaginal delivery and 46% mothers had LSCS[26].

In a study which was conducted at a medical college in Vellore, it was found that 74.9% of the mothers had delivered by normal vaginal delivery and 15.4% mothers had undergone LSCS[17].

Folic acid tablets

In the present study, 26% had not taken folic acid tablet among cases whereas only 5.5% of the controls had not taken folic acid tablets.

Fever with rash

In the present study, 1 (1%) and 2 (2%) had history of fever with rash during pregnancy in 1st trimester and 2nd trimester respectively among 100 cases whereas none had history of fever with rash among 200 controls.

A study which was done in a tertiary care centre in Maharashtra showed that 8% of the mothers had history of fever during pregnancy[18].

Gestational diabetes mellitus

In our study, 4% of the mothers of cases had history of GDM and none of the mothers of controls had history of GDM.

A study which was conducted in a tertiary care centre in Mumbai showed that 6% of the mothers had history of gestational diabetes mellitus[27].

Birth weight of new-born

In the present study, 13% had birth weight <1 kg among 100 cases whereas none had birth weight <1 kg among 200 controls.

In a hospital-based study carried out in Mumbai, 75.4% new born babies had birth weight ≥ 2.5kg and 24.6% new born babies had birth weight ≤ 2.5kg[27].

In a hospital-based cross–sectional observational study which was conducted in a Neonatology section, Department of pediatrics, J N Medical College, Aligarh for a period of one year, it was found that 51.5% new born babies had birth weight of > 2.5kg, 38.5% had birth weight between 2.5–1.5kg, 8% had birth weight between 1.5–1kg and 2% had birth weight of <1kg[26].

In the present study, the placental weight of some of the cases was <400g whereas it was <400g only for few of the controls. There was absence of 2 Umbilical artery and 1 Umbilical Vein in 5% of the cases and none in controls.

Table 13: Variables related to antenatal detection of congenital anomalies between cases and controls

Previous congenital anomalous baby

In the present study among cases, 16% had history of previous congenital anomalous baby whereas among controls, none (0%) had history of previous congenital anomalous baby

In another study which was done in a tertiary care hospital of Odisha, history of previous congenital malformation baby was found only in one patient. The baby was born with polydactyly of 5th finger[24].

Similarly, in another hospital-based study which was done in Mumbai, 4% mothers had history of previous congenital anomalous baby[27].

Anomaly scan

In the present study, anomaly scan was done in 86% of the cases during 2nd trimester whereas it was done in 97.5% of the controls during 2nd trimester. 61% cases were diagnosed to have congenital anomalous baby on scan.

In a retrospective descriptive study, which was carried at SGRDIMSR, Vallah, Amritsar which is a rural tertiary care teaching hospital, 67.7% mothers had reports of fetal ultrasonography and only 17.5% cases of congenital anomaly were confirmed antenatally[35].

Congenital anomaly: In the present study, Central Nervous system (25%) was found to be most commonly involved, followed by the genitourinary system (20%), cardiovascular system (18%), Musculoskeletal system (16%), multiple system involvement (7%) and respiratory system being least involved (5%).

An epidemiological study conducted in 6 villages of Ambala district showed that the most common system involved was Cardiovascular malformations (37%), second most common system was musculoskeletal (30%), followed by gastrointestinal (23%), followed by central nervous system (13%), followed by genitourinary (6.6%)[37].

A cross-sectional study was done in a hospital in Kolkata to study the pattern of congenital anomalies in the study, the most common system involved was musculoskeletal system (33.2%), second most commonly involved system was the gastro-intestinal tract (GIT) (15%), followed by Central nervous system (11.2%),

followed by genitourinary (10.5%) and cardiovascular system (9.1%), least common to be involved was skin (8.7%)[16].

Another prospective cohort study was undertaken at four hospitals in Pune where in women reporting for first antenatal checkup (ANC) were included. The study showed that most prevalent congenital anomalies were congenital heart defects, musculoskeletal system was second most common system to be involved, followed by urinary system anomalies[34]. Similar to our study, digestive system, respiratory system and genital organs were less commonly involved.

Table 14 shows that there was no significant association between gender of the new–born babies and presence of congenital anomalies as in the present case-control study matching was done for sex in all new-born babies born with congenital anomalies.

A hospital-based study which was carried out in Mount-Lebanon showed that there was no significant association between sex of the new-born babies and occurrence of congenital anomalies[23].

A descriptive study was done in a medical college in Davangere, showed that there was significant association between sex of the new–born babies and occurrence of congenital malformations as the incidence was found to be higher in male babies[36].

Table 15 shows that there was no significant association between gestational age of the new–born babies and presence of congenital anomalies as in the present case-control study matching was done for gestational age in all new-born babies born with congenital anomalies.

A cross-sectional study which was done in a hospital in Kolkata showed that gestational age was significantly associated with occurrence of congenital anomalies as incidence was found to be higher among preterm babies[16].

A retrospective descriptive study which was carried at SGRDIMSR, Vallah, Amritsar showed that there was significant association between gestational age and occurrence of congenital anomalies among new–born babies as the incidence was found to be higher among term babies as compared to preterm babies[35].

Table 16 shows that age of mothers had no significant association with presence of congenital anomalies among new-born babies as in the present study majority of the mothers were between 25–29 years of age for both cases and controls.

A cross–sectional study was done in a medical college in Vellore where it was found that age of the mother was not significantly associated with occurrence of congenital anomalies[17].

In a hospital-based cross-sectional observational study which was conducted in Aligarh, UP from January 2015 to December 2015 showed that lower maternal age was associated with congenital anomalies[26].

In contrast to the present study, a study which was done in Mumbai, Maharashtra which showed advanced maternal age was associated with increased risk of congenital anomalies[27].

Table 17 shows that place of residence of mothers was not significantly associated with presence of congenital anomalies among new-born babies as majority of the mothers were residents of rural area for both cases and controls.

Table 18 shows that religion of the mother was significantly associated with presence of congenital anomalies among new-born babies ($p<0.05$).

This is similar to another hospital-based cross-sectional observational study which was conducted in J N Medical College, Aligarh, UP where mothers' religion was found to be associated with occurrence of congenital anomalies[26].

Table 19 shows that education status of the mother was not significantly associated with presence of congenital anomalies among new-born babies as majority of the mothers were educated up to pre–university I and II for both cases and controls.

Table 20 shows that occupation of the mothers was not significantly associated with presence of congenital anomalies among new-born babies as in our study, majority of the mothers were employed for both cases and controls.

Similar to the present study, in a hospital-based study done in Mount-Lebanon, it was found that there was no significant association between mother's working status and presence of congenital anomalies($p>0.05$)[23].

Table 21 shows that type of family was not significantly associated with presence of congenital anomalies among new-born babies as majority of the mothers in our study belonged to joint family.

Table 22 shows that socioeconomic status was not significantly associated with presence of congenital anomalies among new-born babies.

This finding is in contrast to another study which was done in a tertiary centre in Odisha in which lower or middle socioeconomic class of mothers was associated with occurrence of congenital anomalies[24].

Table 23 shows that age at marriage was not significantly associated with presence of congenital anomalies among new-born babies as in our study, majority of mothers were married after the age of 20 years for both cases and controls.

This is in contrast to a case-control study conducted in PGIMER, Chandigarh where it was seen that marriage at an early age that is <18 years was associated with occurrence of congenital malformations[19].

Table 24 shows that history of consanguinity was not significantly associated with presence of congenital anomalies among new-born babies as in our study, 17% had history of consanguinity among cases and only 4% had history of consanguinity among controls.

These findings were similar to a study carried out in Mount-Lebanon where they found that parents' consanguinity was associated with a higher risk of congenital malformation. ($p = 0.015$)[23].

A hospital-based cross-sectional observational study which was conducted in Aligarh, UP showed that congenital anomalies in new-borns was associated with maternal factors like history of consanguinity[26].

A study conducted at a tertiary care centre in Mumbai showed comparable results where consanguinity was found to be the single most important factor which was associated with increased risk of congenital anomalies[27].

In another hospital-based cross-sectional study carried out in Kolkata, history of consanguinity was significantly associated with the presence of congenital anomalies ($p < 0.001$)[16].

Table 25 shows that years of marriage and presence of congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$). Among cases, 58% had <5 years of marriage and 42% had >=5 years of marriage whereas among controls, 75% had <5 years of marriage and 25% had >=5 years of marriage.

Table 26 shows that BMI of the mothers was not significantly associated with presence of congenital anomalies among new-born babies as in our study, most of the mothers had normal body mass index for both cases and controls.

Table 27 shows that ANC case being booked versus unbooked was significantly associated with presence of congenital anomalies among new-born babies ($p< 0.05$).

Another cross-sectional study carried out in a tertiary care hospital in Haryana showed similar results where association was found between unbooked mothers and presence of congenital anomalies[14].

This finding is similar to another study which was conducted in a hospital in Odisha where there was association between unbooked mothers and presence of congenital anomalies[24].

Table 27 shows that parity and presence of congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$).

Similar to the present study, a hospital-based cross-sectional study which was conducted in Kolkata showed that parity of the mother was significantly associated with presence of congenital anomalies[16].

This was in contrast to another study done in a secondary hospital in Vellore where they found that there was no significant association between the parity of the mother and presence of congenital anomalies ($p > 0.05$)[17].

Table 27 shows that there was significant association between history of previous abortion and presence of congenital anomalies among new-borns as in our study, many mothers of cases had history of previous abortion and very few mothers of controls had history of previous abortions.

A case-control study which was carried out at a hospital in Chandigarh found history of previous abortion to be most significantly associated with congenital malformations[19].

In a retrospective study which was done on 10,000 consecutive births, it was found that maternal factors like history of previous abortions was significantly associated with occurrence of congenital malformations.

This was in contrast to a study conducted in secondary hospital at Vellore where there was no significant association between history of previous abortions with occurrence of congenital malformations[17].

Another case-control study was conducted at a hospital in Chandigarh showed similar results where there was significant association between previous history of abortion and presence of Congenital anomalies[19].

Table 27 shows that mode of delivery was not significantly associated with presence of congenital anomalies as majority of the mothers in our study had vaginal delivery.

In a observational study which conducted at a hospital in Bhubaneswar, it was found that there was significant association between mode of delivery and presence of congenital anomalies as cesarean section was more commonly associated than normal delivery with presence of congenital anomalies in this study[24].

In a cross-sectional study conducted in Kolkata, mode of delivery was also significantly associated with congenital anomaly ($p = 0.005$) and it was more in case of cesarean deliveries[16].

Table 27 shows that non-intake of folic acid tablets and presence of congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$) since many mothers had not taken folic acid tablets among cases whereas only very few had not taken folic acid tablets among controls.

Another study conducted in a medical college at Vellore showed similar results with higher incidence of neural tube defects, which is known to be prevented by intake of adequate folic acid[17].

Another hospital-based case-control study was done in Chandigarh which showed similar results where there was significant association between non intake of folic acid tablets during pregnancy and presence of congenital anomalies ($p= 0.0013$)[19].

A study by Blencowe et al concluded that folic acid supplementation and fortification are effective in reducing neonatal mortality from neural tube defects[38].

Table 27 shows that there was significant association between history of fever with rash during pregnancy and presence of congenital anomalies among new-born babies ($p<0.05$).

Similar to the present study, a retrospective study which was conducted on 10,000 consecutive births, it was found that maternal factors like fever during first trimester was not significantly associated with presence of congenital malformations[39].

According to Chaturvedi P et al, it was seen that fever during first trimester was found to be significantly associated with occurrence of congenital malformation[40].

In contrast to the present study, a study which was conducted in a medical college in Davangere showed that maternal febrile illness during first trimester was not significantly associated with occurrence of congenital malformations[36].

Table 27 shows that history of GDM was significantly associated with presence of congenital malformations among new-born babies ($p<0.05$).

Similar to the present study, a retrospective study done on 10,000 consecutive births from showed that there was a significant correlation between maternal diabetes mellitus and congenital malformations in the baby[39].

A metanalysis conducted in Canada by Ray et al stated that outpatient preconception care probably reduces risk of major congenital anomalies among women with pregestational diabetes mellitus[41].

In contrast to the present study, a study which was conducted at a medical college in Davangere showed that maternal diabetes mellitus was not significantly associated with presence of congenital anomalies[36].

Table 27 shows that birth weight and congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$).

A cross-sectional descriptive study was carried out in the neonatal care unit of R. G. Kar Medical College and Hospital which showed similar results where low birth weight (LBW) was associated with increased risk of congenital malformations[16].

Another hospital-based cross-sectional observational study conducted in J N Medical College, Aligarh Muslim University showed that low birth weight was associated with increased risk of congenital malformations[26].

Similar results were found in another prospective cohort study which was undertaken in 2017 in Pune, India[34].

A retrospective cross-sectional study which was conducted in Mount-Lebanon showed that low birth weight of the baby was significantly associated with occurrence of congenital anomalies ($p=0.027$)[23].

In another cross-sectional study which was carried out in Kolkata, it was found that low birth weight was significantly associated with presence of congenital anomalies ($p=0.000$)[16].

Table 27 shows that placenta weight and presence of congenital anomalies among new-born babies was statistically significantly associated ($p<0.05$) as the placenta weight of many of the cases was found to be <400 grams whereas very few controls had placental weight <400 grams.

Table 27 shows that presence of 2 UA/ 1 UV was significantly associated with presence of congenital malformations among new-born babies ($p<0.05$) as there was absence of 2 UA/ 1 UV in 5% of the cases and none in controls.

Table 28 shows that there was significant association between history of previous congenital anomalous baby and presence of congenital anomalies.

Similar to the present study, a case-control study was conducted in Chandigarh. This study among matched subjects showed that history of having previous congenital anomalous baby was significantly associated with increased risk of having a baby with congenital malformation[19].

In a hospital-based study conducted in Lebanon, it was found that there was no significant association between siblings' congenital malformation and presence of congenital anomalies ($p>0.05$)[23].

Table 28 shows that even though anomaly scan was done in 86% of the cases and 97.5% of the controls, there was significant association between anomaly scan being done and presence of congenital anomalies.

Table 28 shows that 61% cases were diagnosed of congenital anomaly on scan. Hence, in our study, there was significant association between diagnosis of congenital anomaly on scan and presence of congenital anomalies.

Table 28 shows that among 100 cases with congenital anomaly, 25% had congenital anomaly involving the Central nervous system, followed by CVS (18%), genitourinary system (20%), GIT (9%), 7% had congenital anomaly of multiple systems, 16% had congenital anomaly of musculoskeletal and 5% had congenital

anomaly of respiratory system hence according to the present study type of system involved was significantly associated with presence of congenital anomalies.

Table 29 shows univariate analysis where religion (cOR = 0.46), history of consanguinity (cOR = 4.92), years of marriage (cOR = 2.17), unbooked ANC (cOR = 2.18), parity 2 or 3 (cOR = 2.17), non-intake of folic acid tablets, anomaly scan (cOR = 0.16) were the maternal risk factors that were found to be significantly associated with occurrence of congenital anomalies.

Table 29 shows multivariate analysis where history of consanguinity (aOR = 6.83), non-intake of folic acid tablets (aOR = 0.31), placental weight less than 400 grams (aOR = 0.98) and anomaly scan not done (aOR = 0.13) were the risk factors found to be significantly associated with occurrence of congenital anomalies.

In the present study, maternal risk factors like history of previous still birth, history of early neonatal death, history of exposure to radiation during pregnancy history of any drug intake during pregnancy, history of pre-conceptional intake of folic acid, history of use of tobacco during pregnancy, history of alcohol consumption during pregnancy, vaccination status of mother, history of pregnancy induced hypertension, history of exposure to insecticides/ pesticides during pregnancy, family history of congenital anomalies were not significantly associated with occurrence of congenital malformations.

Similarly, in another study which was conducted at a tertiary care centre in Odisha, no significant association was found between history of drug addiction, smoking, or exposure to radiation during pregnancy[24].

In contrast to the present study, a case-control study which was conducted in Chandigarh showed that family history of congenital malformation, contraceptive use, history of any medications taken during pregnancy, history of traditional drug usage were maternal risk factors found to be significantly associated with occurrence of congenital anomalies[19].

CONCLUSION

Out of the 100 babies born with congenital malformations, CNS (25%) and genitourinary (20%) abnormalities constituted majority of cases. Mothers who had babies with congenital anomalies had risk factors like consanguinity, non–intake of folic acid, history of previous abortions or previous congenital anomalous baby. Hence, the need for screening of these high-risk groups is vital.

The incidence of congenital malformations was higher among women with history of consanguineous marriage which can be related to increased practice of inbreeding especially seen in this part of country. So, to bring down the incidence of congenital anomalies consanguineous marriages should be avoided.

Interventions like periconceptional supplementation of folic acid should be included.

Anomaly scan done at 18 – 20 weeks of pregnancy plays a particularly important role in early detection of congenital anomalies. Once an anomaly is detected on scan, various management options can be discussed with the parents which will help in reducing the associated mortality and morbidity.

By improving the regular antenatal visits, postnatal diagnostic services, early interventions and faster referral services to tertiary care hospital most of these new-borns can be saved.

Focused change in the number of USG scan required during pregnancy and inclusion of placental findings in the report could evert birth of anomalous babies.

RECOMMENDATIONS

1. Community level

ASHA workers / health worker (female)

- Early registration of pregnancy and folic acid prophylaxis to be emphasized.
- Advise to community – to avoid consanguineous marriages.

Pregnant women

- Health education on folic acid prophylaxis

Community

- Avoiding consanguineous marriages.

2. Programme managers/ policy makers

A. Periconceptional folic acid prophylaxis to be implemented.

B. Guidelines for Antenatal USG scan.

- Anomaly scan between 18 – 22 weeks to be made compulsory for all antenatal cases.
- Placental condition to be mentioned in USG scan report.

LIMITATIONS

As it is a hospital-based study done in a single tertiary care hospital, generalizability is a problem for which population-based studies are necessary or study involving more hospitals can be done.

In the present study, stillborn babies and abortions were not included because, often, the gross congenital malformations are not very obvious and are difficult to detect and most of the cases would require a pathological autopsy which may not be feasible.

Only the gross anatomy of placenta was considered and not the pathological aspect while finding association between placental factors and congenital anomaly.

As it is a case-control study, recall bias on exposure is also a limitation of the study.

SUMMARY

Congenital anomalies are one of the major causes of neonatal as well as infant morbidity and mortality.

A hospital-based case–control study was conducted for a period of one year from January 2020 to December 2020 at Prabhakar Kore Hospital, Belagavi. The objective of the study was to know the maternal risk factors associated with congenital anomalies among new-born babies.

During the study period of one year, a total of 100 live born babies having congenital anomalies and who fit into the eligibility criteria were identified. They were matched with controls who did not have congenital anomalies for gestational age and sex in the ratio of 1:2.

Out of the 100 cases, majority of the mothers of the cases belonged to age group of 25 – 29 years. About 62% of mothers hailed from rural area and 85% were Hindu by religion. Majority that is 58% of the mothers were homemakers and 90% mothers had minimum of primary schooling, among which 32.2% had completed their pre–university I and II. Majority of the mothers of cases belonged to class II according to Modified B. G. Prasad classification. About 62% of them belonged to joint families.

Out of the 200 controls that is babies born without congenital anomalies majority, of the mothers belonged to 25 – 29 years age group. 41% of the mothers were homemakers and 88.5% had minimum of primary schooling among which 34.5% had completed their pre – university I and II. Majority of the mothers of

controls belonged to class III according to Modified B. G. Prasad classification. About 55% of them belonged to joint families.

History of consanguinity, married life of ≥5 years, un-booked cases for ANC care, parity of 2 or more, history of previous abortion, non-intake of folic acid supplementation, maternal febrile illness, history of GDM, low birth weight, low placental weight, absence of 2 umbilical arteries and single umbilical vein, history of previous congenital anomalous baby were the maternal risk factors which were found to be significantly associated with occurrence of congenital anomalies.

System wise categorization of congenital anomalies was done using ICD-10 classification. Among 100 cases with congenital anomaly, 25% had congenital anomaly of CNS, 18% had congenital anomaly of CVS, 20% had congenital anomaly of genitourinary, 9% had congenital anomaly of GIT, 7% had congenital anomaly of multiple systems, 16% had congenital anomaly of musculoskeletal and 5% had congenital anomaly of respiratory system.

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ANNEXURE I – ETHICAL CLEARANCE LETTER

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed to be University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/DOME/ 236 **Date: 24/12/2019**

To,

Dr.
PG student in Community Medicine,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"MATERNAL RISK FACTORS ASSOCIATED WITH CONGENITAL ANOMALIES AMONG NEW BORN BABIES: A HOSPITAL BASED CASE- CONTROL STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE II - INFORMED CONSENT

TITLE: MATERNAL RISK FACTORS ASSOCIATED WITH CONGENITAL ANOMALIES AMONG NEW BORN BABIES: A HOSPITAL BASED CASE-CONTROL STUDY

Investigator: DR.
Postgraduate,
Department Of Community Medicine,
J N Medical College,
KAHER, Belagavi.

Guide: DR.
Professor
Department of community medicine
J N Medical College,
KAHER, Belagavi.

INTRODUCTION

Congenital anomalies are an important cause for neonatal mortality and morbidity. An estimated 303000 newborns die within 4 weeks of birth every year, worldwide, due to congenital anomalies. Congenital anomalies can contribute to long-term disability, which may have significant impacts on individuals, families, health-care systems, and societies. The most common, severe congenital anomalies are heart defects, neural tube defects and Down syndrome. As per WHO, genetic factors, socioeconomic and demographic factors, environmental factors, infections, maternal nutritional status are some of the risk factors associated with congenital anomalies in new born babies.

Some congenital anomalies can be prevented through vaccination, adequate intake of folic acid, iodine through fortification of staple foods or supplementation, and adequate antenatal care for early detection of congenital anomalies are examples of preventive methods. Therefore, this study is being conducted to identify the maternal risk factors associated with congenital anomalies among new born babies and since

most of the risk factors are preventable it can help in reducing the number of babies born with congenital anomalies thereby reducing perinatal mortality and morbidity. Participation in this study is completely voluntary.

EXPLANATION OF PROCEDURES

In this study, once the consent has been obtained from the participant, the participants will be interviewed Using a pre designed pre tested questionnaire. To obtain relevant history regarding socio demographic factors, antenatal and past history of any illness, treatment etc.

Some information regarding new borns will be collected from clinical records, USG etc. Diagnosis of congenital anomalies will be based on clinical evaluation of the new born by the pediatrician and other appropriate investigations.

POSSIBLE BENEFITS

The investigator does not promise or guarantee that you will receive direct benefit by being in this study. It will benefit the whole community because by this study, we will be able to determine the maternal risk factors associated with congenital anomalies among new born babies and since most of the risk factors are preventable it can help in reducing the number of babies born with congenital anomalies in future.

POSSIBLE RISKS

There is no risk associated with participation in this study.

CONFIDENTIALITY

Your identity will not be revealed. All information will be collected, coded and anonymized so that no one will know the identify.

WITHDRAWAL

Participation in this study is voluntary. If you do not wish to participate in this study, you will not lose benefits to which you are entitled.

COSTS OF PARTICIPATION

The cost of the study will be borne by the investigator. There will be no additional cost to you for participating in this study.

PAYMENT OF PARTICIPATION

There will be no incentives to you for participating in this study.

AUTHORIZATION TO PUBLISH RESULTS

The investigators may use the information gathered from this study for presentation in scientific journals. However, your identity will not be disclosed in such presentation or publication.

LEGAL RIGHTS

By signing this consent form, you are not waiving any of your legal rights.

QUESTIONS

If you have any questions about this study, you may contact **Dr. _____ Dr. _____** If you have any questions about your rights as a study participant, you may contact **Dr. Roopa M Bellad, Chairman,** JNMC Institutional Ethics Committee on human subjects' research at 0831-2741701.

CONSENT STATEMENT

"I have been explained all the contents of this consent form in my local language and have understood and clarifies all my queries about the study to the best of my knowledge. Furthermore, I recognize that I have the complete right to withdraw the consent at any point during the study. I understand that the information given by me will be confidential and will be used for research purpose only. Further, I am aware that the result of this research will be presented/published without disclosing any personal identification of the participants.

I hereby give my voluntary consent for participation in this study. I do sign the informed consent form in front of an eyewitness whom I recognize."

Name of the participant: _____Signature/ left thumb impression

Name of the eyewitness: _____Signature/ left thumb impression

Name of the investigator: _____Signature

Signature of the guide:

Date:

ANNEXURE III – QUESTIONNAIRE

MATERNAL RISK FACTORS ASSOCIATED WITH CONGENITAL ANOMALIES AMONG NEW BORN BABIES: A HOSPITAL BASED CASE CONTROL STUDY

PART-I SOCIO-DEMOGRAPHIC ASPECTS

Name of the mother:

Age: _____ years

IP number:

Address:

Contact number:

1. Religion: a. Hindu b. Muslim c. Christian d. Others (specify)
2. Education: a. Illiterate b. Primary school c. High school
   d. Pre-university I & II e. Degree &>
3. Occupation: a. House wife b. Employed
4. Type of Family: a. Joint b. Nuclear c. Broken family d. Problem family
5. a. Monthly income of the family:
   b. Total number of family members:
   c. Monthly per capita income:
6. Socio-economic status – Modified B.G. Prasad classification
   a. Class I b. Class II c. Class III d. Class IV e. Class V

PART II – OBSTETRIC HISTORY

7. Age at marriage ____Years
8. H/o Consanguinity? Yes / No

9. Married life ____Years

10. ANC case: a. Booked b. Unbooked

11.Gravida: a. Primigravida b. 2 c. 3 d. ≥ 4

12.Parity: a. Primipara b. 2 c. 3 d. ≥ 4

13. H /o of previous abortion? Yes / No

If yes: specify whether

i. Spontaneous ii. Medical termination (with reason)

14. H/o previous still birth? Yes / No

15. H/o early neonatal death? Yes / No

16. H/o previous congenital anomalous baby? Yes / No

17. Period of gestation: a. Term b. Preterm

18. Mode of delivery: a. Normal b. C- Section

19. H/o exposure to X - rays during pregnancy? Yes / No

20. H/o any drug intake (except folic acid, iron & calcium)?

Yes / No

If yes: specify which month

21. H/o pre conceptional intake of folic acid? Yes / No

21. Folic acid tablets taken? Yes / No

If yes: Mention the trimester -

How many months -

22. H/o use of tobacco during pregnancy? Yes / No

If yes: In which form -

Frequency of use -

23. H/o alcohol consumption during pregnancy? Yes / No

If yes: Quantity -

Frequency -

24. H/o fever with rash during pregnancy? Yes / No

If yes: specify the trimester

25. Vaccination status of the mother during MR campaign: Yes / No

26. Anomaly scan done? Yes / No

If yes: Which trimester –

27. Diagnosis of congenital anomaly on scan? Yes / No

28. H/o GDM /overt diabetes? Yes / No

29. H/o PIH? Yes / No

30. Exposure to insecticides/ pesticides during pregnancy? Yes / No

31. Family history of congenital anomalies? Yes / No

ANTHROPOMETRIC MEASUREMENTS OF THE MOTHER:

Height: Weight: BMI:

PART III - DETAILS OF NEWBORN

32. Sex of baby: a. Male b. Female

33. Birth weight: ____kg

34. Congenital anomaly if any -

35. Investigations if any -

PART IV – PLACENTA DETAILS

36. Weight of the placenta:

37. All placental cotyledons present? Yes / No

38. Position of insertion of umbilical cord?

a. Normal b. Abnormal

39. Presence of 2 umbilical arteries and 1 umbilical vein? Yes/ No (If any deviation mention)

ANNEXURE IV - KEY TO MASTER CHART

1. AGE – ACTUAL AGE IN YEARS

2. ADDRESS:

RURAL – 1

URBAN – 2

3. RELIGION:

HINDU – 1

MUSLIM – 2

CHRISTIAN – 3

OTHERS – 4

4. EDUCATION:

ILLITERATE – 1

PRIMARY SCHOOL – 2

HIGH SCHOOL – 3

PRE - UNIVERSITY I & II – 4

DEGREE & > - 5

5. OCCUPATION:

HOUSEWIFE/ UNEMPLOYED – 1

EMPLOYED – 2

6. TYPE OF FAMILY:

JOINT – 1

NUCLEAR – 2

BROKEN – 3

PROBLEM – 4

7. SOCIO ECONOMIC STATUS:

CLASS I – 1

CLASS II – 2

CLASS III – 3

CLASS IV – 4

CLASS V – 5

8. AGE AT MARRIAGE – ACTUAL AGE IN YEARS

9. HISTORY OF CONSANGUINITY:

YES – 1

NO – 2

10. MARRIED LIFE – ACTUAL IN YEARS

11. ANC CASE:

BOOKED – 1

UNBOOKED – 2

12. GRAVIDA:

1 -1

2 - 2

3 - 3

4 - ≥ 4

13. PARITY:

1 – 1

2 – 2

3 – 3

4 - ≥4

5 – PRIMIGRAVIDA

14. HISTORY OF PREVIOUS ABORTION:

1 – YES

2 – NO

11 – YES, SPONTANEOUS

12 – YES, MEDICAL TERMINATION

15. HISTORY OF PREVIOUS STILL BIRTH:

1 – YES

2 – NO

16. HISTORY OF EARLY NEONATAL DEATH:

1 – YES

2 - NO

17. HISTORY OF PREVIOUS CONGENITAL ANOMALOUS BABY:

1 – YES

2 – N0

18. PERIOD OF GESTATION:

1 – TERM

2 – PRETERM

19. MODE OF DELIVERY:

1 – VAGINAL

2 – C – SECTION

20. HISTORY OF EXPOSURE TO X – RAYS DURING PREGNANCY:

1 – YES

2 – NO

21. HISTORY OF ANY DRUG INTAKE (EXCEPT FOLIC ACID, IRON AND CALCIUM):

1- YES

2 – NO

11 – YES ANTIEMETICS

12 – YES ANALGESICS

13 – YES ANTIBIOTICS

14 – YES OTHERS

22. HISTORY OF PRE CONCEPTIONAL-INTAKE OF FOLIC ACID:

1 – YES

2 – NO

23. FOLIC ACID TABLETS TAKEN:

1 – YES

2 – NO

111 – YES, IN FIRST TRIMESTER FOR 1 MONTH

112 – YES, IN FIRST TRIMESTER FOR 2 MONTHS

113 – YES, IN FIRST TRIMESTER FOR 3 MONTHS

121 – YES, AFTER 1^{ST} TRIMESTER FOR 1 MONTH

122 – YES, AFTER 1^{ST} TRIMESTER FOR 2 MONTHS

123 – YES, AFTER 1^{ST} TRIMESTER FOR 3 MONTHS

24. HISTORY OF USE OF TOBACCO DURING PREGNANCY:

1 – YES

2 – NO

25. HISTORY OF ALCOHOL CONSUMPTION DURING PREGNANCY:

1 – YES

2 – NO

26. HISTORY OF FEVER WITH RASH DURING PREGNANCY:

1 – YES

2 – NO

11- YES, IN 1ST TRIMESTER

12 – YES, IN 2ND TRIMESTER

13 – YES, IN 3RD TRIMESTER

27. VACCINATION STATUS OF MOTHER (IF VACCINATED IN MR CAMPAIGN):

1 – YES

2 – NO

28. ANOMALY SCAN DONE:

1 – YES

2 - NO

11 – YES, IN 1ST TRIMESTER

12 – YES, IN 2ND TRIMESTER

13 – YES, IN 3RD TRIMESTER

29. DIAGNOSIS OF CONGENITAL ANOMALY ON SCAN:

1 – YES

2- NO

30. HISTORY OF GDM

1 – YES

2- NO

31. HISTORY OF PIH:

1 – YES

2 – NO

32. EXPOSURE TO INSECTICIDES/ PESTICIDES DURING PREGNANCY:

1 – YES

2 – NO

33. FAMILY HISTORY OF CONGENITAL ANOMALIES:

1 – YES

2 – NO

34. BMI: ACTUAL BMI OF THE PREGNANT WOMAN

35. SEX OF BABY:

1 – MALE

2- FEMALE

36. BIRTH WEIGHT:

1 - <1KG

2 – 1 – 1.5 KG

3 – 1.5 – 2.5KG

4 - > 2.5 KG

37. CONGENITAL ANOMALY:

1 – YES

2 – NO

11 – CNS

12 – GENITOURINARY

13 – CVS

14 – MUSCULOSKELETAL

15 – GIT

16 – RESPIRATORY SYSTEM

17 – MULTIPLE SYSTEM INVOLVED

38. WEIGHT OF PLACENTA – ACTUAL WEIGHT IN GRAMS

39. ALL PLACENTAL COTYLEDONS PRESENT:

1 – YES

2 – NO

40. POSITION OF INSERTION OF UMBILICAL CORD:

1 – NORMAL

2 – ABNORMAL

41.PRESENCE OF 2 UMBILICAL ARTERIES AND 1 UMBILICAL VEIN:

1 – YES

2 - NO

42. CODING FOR CASES AND CONTORLS:

1 – CASES

2 - CONTROLS

ANNEXURE V – MASTER CHART

SL NO	AGE	ADDRESS	RELIGION	EDUCATION	OCCUPATION	TYPE OF FAMILY	SES	AGE AT MARRIAGE	CONSAG	MARRIED LIFE	ANC CASE	GRAVIDA	PARITY	H/O PREVIOUS ABORTION	H/O S.B	H/O N.D	H/O PREV C. A BABY	PERIOD OF GESTN	MODE OF DELIVERY	H/O X RAY	H/O DRUG INTK	H/O PRE CONCP F.A	FOLLIC ACID	TOBACCO	ALCOHOL	FEVER WITH RASH	VACCINATION OF MOTHER	ANOMALY SCAN	DIAGNOSIS OF C.A ON SCAN	GDM	PIH	INSCTICIDES	FAMILY H/O C.A	BMI	SEX OF BABY	BW	C.A	WT OF PLACENTA	PLACENTAL COTYLDN	UMB CORD	PRESENCE OF 2 UA/ 1 UV	CASES / CONTROL
1	41	1	1	1	1	1	4	20	2	21	1	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	12	1	1	2	2	2	19.7	1	3	12	400	1	1	2	1
2	22	1	1	1	1	1	4	17	2	5	1	2	1	2	2	2	1	2	1	2	2	2	2	2	2	2	12	1	2	2	2	2	21.9	1	3	17	380	1	1	1	1
3	19	1	1	2	1	1	4	18	2	1	1	1	5	2	2	2	2	2	1	2	2	2	112	2	2	2	2	12	1	2	2	2	2	23.8	1	1	13	350	1	1	1	1
4	32	2	3	3	2	2	2	28	2	4	1	2	NA	11	2	2	2	2	2	2	2	2	112	2	2	2	2	12	1	2	2	2	2	24.1	1	1	11	300	1	1	2	1
5	21	2	1	3	2	2	3	19	2	2	1	2	1	2	2	2	2	2	1	2	2	2	112	2	2	2	2	12	1	2	2	2	2	29.6	1	4	16	420	1	1	1	1
6	35	2	1	3	2	2	2	26	2	9	1	2	1	2	2	2	2	2	1	2	2	2	112	2	2	2	2	12	1	2	2	2	2	22.8	1	3	14	380	1	1	1	1
7	23	1	2	3	1	1	4	19	2	4	2	3	2	2	2	2	1	2	2	2	2	2	112	2	2	2	2	12	1	2	2	2	2	24	1	3	17	420	1	1	1	1
8	22	2	1	2	1	1	5	19	2	3	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	12	1	2	2	2	2	2	21.4	1	1	13	350	1	1	1	1
9	23	2	1	3	2	1	3	22	2	1	2	1	5	2	2	2	1	2	1	2	2	2	111	2	2	12	2	12	1	2	2	2	2	23.1	1	3	12	400	1	1	1	1
10	24	2	1	2	1	1	4	20	2	4	1	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	12	1	2	2	2	2	22.5	2	1	11	350	1	1	1	1
11	25	1	1	4	2	1	2	20	2	5	2	2	1	2	2	2	2	2	2	2	2	2	111	2	2	2	2	12	1	1	2	2	2	21.8	2	1	13	280	1	1	1	1
12	32	2	1	3	2	2	2	26	2	6	1	1	5	2	2	2	1	2	1	2	2	2	111	2	2	2	2	12	2	2	2	2	2	18.7	1	4	16	380	1	1	1	1
13	30	1	1	3	2	2	3	22	2	8	1	4	3	2	2	2	2	2	1	2	2	2	112	2	2	2	2	12	2	2	2	2	2	24.4	1	3	16	410	1	1	2	1
14	26	2	1	4	2	2	2	20	1	6	1	3	1	11	2	2	2	2	1	2	2	2	2	2	2	2	2	12	1	2	2	2	2	22.1	1	4	12	420	1	1	1	1
15	28	2	1	1	1	1	5	24	1	4	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	12	1	2	2	2	2	21.7	1	3	14	410	1	1	1	1
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286	27	1	2	4	2	1	3	24	2	3	1	2	NA	11	2	2	2	1	1	2	2	2	112	2	2	2	2	2	2	2	2	2	2	22.8	2	3	2	430	1	1	1	2
287	28	1	1	4	2	1	2	24	2	4	1	2	1	2	2	2	2	1	1	2	2	2	112	2	2	2	2	12	2	2	2	2	2	20.5	2	3	2	456	1	1	1	2
288	29	2	1	5	2	2	1	24	2	5	1	3	2	2	2	2	2	2	1	1	2	2	111	2	2	2	2	12	2	2	2	2	2	23.8	2	3	2	440	1	1	1	2
289	26	1	1	4	2	1	3	22	2	4	2	2	1	2	2	2	2	2	1	2	2	2	111	2	2	2	2	12	2	2	2	2	2	24.2	2	3	2	480	1	1	1	2
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293	30	2	3	5	2	2	1	25	2	5	1	3	2	2	2	2	2	2	1	1	2	2	112	2	2	2	2	12	2	2	2	2	2	25	1	3	2	410	1	1	1	2
294	26	1	1	4	1	1	4	22	2	4	1	2	1	2	2	2	2	2	1	1	2	2	112	2	2	2	2	12	2	2	2	2	2	20.8	1	3	2	460	1	1	1	2
295	28	1	1	5	2	2	3	25	2	3	1	2	1	2	2	2	2	2	1	2	2	2	112	2	2	2	2	12	2	2	2	2	2	21.3	2	3	2	486	1	1	1	2
296	27	1	1	4	2	1	3	25	2	2	1	1	5	2	2	2	2	2	1	2	2	2	2	2	2	2	2	12	2	2	2	2	2	26.4	2	3	2	490	1	1	1	2

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