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Anatomy

FOETAL ANOMALIES: FREQUENCY AND ANATOMICAL VARIATION IN EACH TRIMESTER IN PREGNANT WOMEN VISITING RAMA MEDICAL COLLEGE, KANPUR.

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ABSTRACT **Introduction:** Foetal anomalies, known as congenital anomalies, are a significant concern for maternal and neonatal well-being due to their potential impact. A 2021 study in India documented a 1.82% frequency of major congenital anomalies among live births, with common congenital heart diseases such as atrial septal defects at 43.91 per 10,000 births and ventricular septal defects at 27.44 per 10,000 births [3]. Few studies in Uttar Pradesh have explored anomalies during gestation, prompting the current study. **Materials And Methods:** This hospital-based cross-sectional study enrolled pregnant women aged 18 years and older. Sample size calculation (n = 3560) considered a 3% prevalence of major foetal anomalies [4], applying a 95% confidence interval and a 10% non-response rate. Data collection employed a pre-designed questionnaire, and foetal anomaly detection utilized GE Varsana Essential ultrasound scans by radiologists. Data analysis utilized IBM SPSS version 26. **Results:** Of the participants, 1526 (47.1%) hailed from rural areas and 1709 (52.9%) from urban areas. Regarding age, 311 (9.6%) were under 20 years old, and 941 (29%) were over 35 years old. Educationally, 518 (16%) had education below the 10th standard. The overall incidence of foetal anomalies was 2.69%.

KEYWORDS : Foetal anomalies, antenatal OPD, Trimester, Anatomical variation.

INTRODUCTION

Foetal anomalies, also called congenital anomalies, cause a high level of concern for both the mother and the baby because of their potential impact on neonatal wellbeing and long-term implications after birth. There can be mild anomalies like cleft lip, polydactyly, and naevus, but some of them can be life-threatening defects like congenital heart disease, anencephaly, neural tube defects, and so on. A study conducted in India 2021 documented the frequency of major congenital anomalies in 1.82% of live births. [1], and a meta-analysis in 2018 showed a pooled prevalence of 184.48 per 10,000 births. [2], which shows that in our country, there is a similar incidence of major congenital anomalies occurring years apart. Hence, understanding the frequency and their anatomical variations of foetal anomalies is crucial for effective early prenatal screening, diagnosis, and management.

Organogenesis starts in 4 to 5 weeks of intrauterine life with the formation of the neural tube from the ectoderm, which eventually develops into the brain and spinal cord; the heart begins to beat; limb buds appear; as well as major organs such as the liver, kidneys, and intestines starting to develop. During 9 to 12 weeks, limb development progresses, with fingers and toes becoming distinct and facial features starting to form, including eyes, nose, and mouth. In 13 to 16 weeks, musculoskeletal structures, including bones and muscles, undergo continued growth and ossification, then until 24 weeks and by 25 weeks, organogenesis is complete and the foetus starts to gain weight. During the gestation period, foetal anomalies can be detected with the help of an advanced ultrasonographic scan. The most common congenital heart diseases, like atrial septal defects, are about 43.91 per 10,000 births, and ventricular septal defects are about 27.44 per 10,000 births. [3] Also, the other variants are very common, like anencephaly, neural tube defects, cleft lip, and mega cystitis.

There are very few studies done in Uttar Pradesh to find anomalies during the gestation period, which shows a gap in the literature; thereby, this study was planned. In this context, the frequency of foetal anomalies, their anatomical types, and associated factors were studied in pregnant women visiting Rama Medical College in Kanpur. This study aims to systematically analyse the frequency and types of foetal anomalies in each trimester, as well as the major predictors responsible for those anomalies. The outcomes of this study are anticipated to add more informative insight for healthcare providers and researchers involved in human anatomy and reproductive and child health.

MATERIAL AND METHOD

Study Design:

A hospital based cross-sectional study.

Study Setting:

The research is carried out at RAMA Medical College, a tertiary care hospital and research centre situated in Kanpur, Uttar Pradesh, India, from July 2022 to December 2023. The antenatal outpatient department (OPD) at RAMA Medical College was the place to first contact with the pregnant women for enrolling.

Study Population:

The study includes currently pregnant women aged 18 years and above who are attending the antenatal OPD at RAMA Medical College during the study period.

Sample Size:

The sample size is determined considering the prevalence (3%) of major foetal anomalies reported in previous studies [4] and the desired level of allowable error 1/5th of P (as the Prevalence is low) [5] with 95% confidence interval, and 10% non-response rate comes out to be 3556 rounded off to 3560.

Study Unit:

Pregnant women visiting ANC-OPD.

Study Method:

Pregnant women, who were taking antenatal care in OBG-OPD, were included in the study. The sociodemographic and women-related factors, like weeks of trimester, were noted after taking informed consent. Data collection is carried out through a pre-formed, structured questionnaire. Ultrasonographic reports of pregnant women who have already had their ultrasound scanning done collected, for the rest participants, ultrasound scans reports were traced from the radiology department of RAMA Medical College. To detect foetal anomalies USG scan were done using the GE Varsana Essential 17.3/Convex Probe, TV/TR Probe by radiologist in the same setup. Data related to socio-demographic factors, height, weight, Body Mass Index, obstetric background, maternal well-being, and any exposure to environmental or genetic risk factors were collected.

Dependent Variables:

The primary outcome variable is the presence or absence of major foetal anomalies diagnosed during pregnancy.

Statistical Analysis:

The data were analysed using IBM SPSS (Statistical Package for the Social Sciences) version 26. Descriptive statistics are used to summarise the characteristics of the study population and the frequency of major foetal anomalies in each trimester. Univariate analysis, such as chi-square tests, is conducted to find associations between potential determinants (e.g., maternal age, parity, socioeconomic status) and the occurrence of major foetal anomalies. P-value less than 0.05 considered significant.

Ethical Considerations:
Ethical approval is obtained from the Institutional Ethics Committee of RAMA Medical College, hospital and research centre (Approval No 2022/2707) before initiating the study. Informed consent is obtained from all study participants, and confidentiality of data is maintained.

Note: The gender of the foetus was not disclosed to the pregnant women or any relatives.

RESULT

325 pregnant women were excluded from a total of 3560 due to having twin pregnancies. Hence, of the total 3235 women included in the analysis. In view of sociodemographic and clinical variables, out of which 1526 (47.1%) were from rural areas and 1709 (52.9%) from urban areas, with respect to age group, 311 (9.6%) were below 20 years of age and 941 (29%) were more than 35 years of age. 518 (16%) studied below the 10th standard; nearly the same percentage of women had completed their postgraduate degree, but most women—1272 (39.3%)—had passed high school; 216 (6.6%) women out of 3235 were employed, and the rest were housemakers; 41% of pregnant women were in their first trimester; 26.3% were in their second trimester; and 32.7% were in their third trimester. In view of parity, 1589 (49.1%) were primiparous. Consanguinity was present in 144 (4.4%) women. Body mass index calculation showed 141 (4.4%) obesity. 779 (24%) women said that they have history of miscarriage, 388 (12%) women were taking medication for diabetes, and 301 (9.3%) out of total 3235 were hypertensive diagnosed before the current pregnancy as shown in table 1.

Out of 1326 pregnant women in their first trimester, six had foetal anomalies. Detected anomalies in those women who were in their second trimester during the duration of the study were 37 out of 851, and 44 anomalies were detected in 1058 women in their third trimester, constituting 87 (2.69%) entirely, as shown in figure 1.

The frequency of anatomical variations and foetal anomalies displayed in Table 2 per trimester offers understanding into their occurrence during each stage of gestation. Among the six anomalies found in women in their first trimester, one each was anencephaly and macrocrania, but in the second trimester group, there were 13 cases of hydronephrosis, 5 cases of congenital heart diseases, and 8 cases of single umbilical arteries out of a total of 37 anomalies. In the third trimester group, 7 congenital heart defects and 15 excretory system anomalies were diagnosed.

Bivariate analysis with a chi-square test was conducted to find the relationship between independent variables and foetal anomalies. The results suggest a sturdy correlation of foetal anomalies with pregnant women from the upper-middle class, indicated by an odds ratio (OR) of 0.31 (95% CI: 0.13 to 0.74), as well as with those from the middle class, with an OR of 0.30 (95% CI: 0.14 to 0.63). Maternal age also showed a significant association, particularly for individuals aged 21 to 35 years, with an OR of 4.71 (95% CI: 1.15 to 19.4), and those over 35 years old, with an OR of 4.39 (95% CI: 1.03 to 8.6). Furthermore, there was a sizeable correlation with BMI, primarily for individuals classified as obese, with an odds ratio of 47.2 (95% CI: 22 to 99). Other significant associations included consanguinity (OR 2.98, 95% CI: 1.74 to 5.09), smoking (OR 7.45, 95% CI: 2.11 to 26.1), previous history of pregnancy loss (OR 1.70, 95% CI: 1.08 to 2.67), over-the-counter drug use (OR 3.01, 95% CI: 1.94 to 4.62), and lack of folic acid tablet intake during the first trimester (OR 19.1, 95% CI: 9.5 to 38.1), P-values for the mentioned variables came out to be less than 0.05.

A multivariate analysis with multiple regression tests was conducted to look for the influence of confounding variables. The analysis showed that anomalies were not associated significantly with women in the middle-class economy, with an adjusted odds ratio aOR 0.17 (0.11 to 0.93) and P-value 0.11. Maternal age showed no association for individuals aged 21 to 35 years, with aOR of 1.61 (95% CI: 0.29 to 6.11) and P-value 0.002, but a significant association was found for those over 35 years old, with aOR of 3.92 (95% CI: 1.01 to 11.5) and P-value <0.001. Similarly, BMI is associated with individuals classified as obese, with an adjusted odds ratio of 5.87 (95% CI: 2.03 to 31.7) and a P-value <0.001. Other significant associations hold similar to univariate analysis, like consanguinity (aOR 1.54, 95% CI: 1.16 to 3.80) and P-value 0.002, smoking (aOR 3.71, 95% CI: 1.88 to 5.91) and P-value 0.04, previous history of pregnancy loss (aOR 1.21, 95% CI: 1.15 to 1.89) and P-value 0.01, over-the-counter drug use (aOR 1.24, 95% CI: 1.01 to 2.09) and P-value <0.001, and lack of folic acid tablet intake during the first trimester (aOR 6.16, 95% CI: 2.96 to 11.5) and P-value <0.001. In contrast to this, there was a strong association of foetal anomalies with those women who were taking antidiabetic drugs, which were not associated in univariate analysis (OR 1.24 CI: 1.16 to 1.81) and a P-value 0.01.

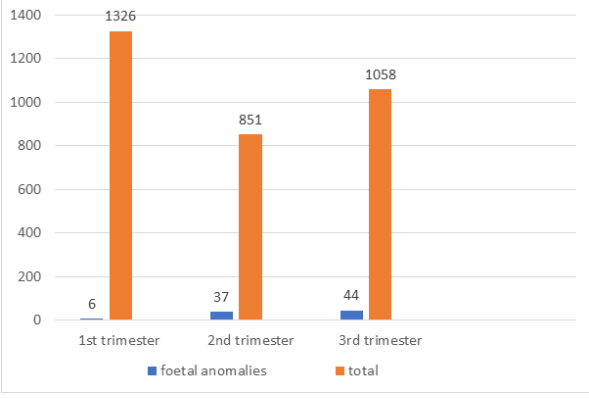

Figure 1 *Trimester wise frequency of detected anomalies.*

Table 1: Trimester Wise Frequency Of Predictors

Predictors	Description	1st trimester n/N	2nd trimester n/N	3rd trimester n/N
Area of residence	Urban	910/1326	434/851	365/1058
	Rural	416/1326	417/851	693/1058
Socio-economic status (as per modified B G Prasad Classification October 2023)	Upper class	168/1326	108/851	134/1058
	Upper middle class	215/1326	138/851	172/1058
	Middle class	336/1326	216/851	267/1058
	Lower middle class	537/1326	345/851	427/1058
	Lower class	70/1326	44/851	58/1058
Maternal age	<20 years	107/1326	94/851	110/1058
	21-35 years	696/1326	681/851	606/1058
	>35 years	523/1326	76/851	342/1058
Education	<10th standard	311/1326	91/851	116/1058
	High school	295/1326	276/851	701/1058
	Intermediate	78/1326	25/851	128/1058
	Graduate	421/1326	192/851	80/1058
	Post graduate.	221/1326	267/851	33/1058
Occupation	Employed	110/1326	29/851	77/1058
	Unemployed	1216/1326	822/851	981/1058
Religion	Hindu	998/1326	671/851	709/1058
	Muslim	328/1326	179/851	347/1058
	Other	0/1326	1/851	2/1058
Parity	Primiparous	670/1326	39/851	880/1058
	Multiparous	656/1326	812/851	178/1058

Consanguinity	Present Absent	40/1326 1286/1326	104/851 747/851	127/1058 931/1058
History of previous abortion	Present Absent	91/1326 1235/1326	190/851 661/851	498/1058 560/1058
History of addiction	Yes No	2/1326 1324/1326	19/851 832/851	0/1058 1058/1058
History of over-the-counter drugs	Present Absent	441/1326 885/1326	112/851 739/851	200/1058 858/1058
Diabetes	Yes No	177/1326 1149/1326	87/851 764/851	124/1058 934/1058
Hypertension	Yes No	129/1326 1197/1326	60/851 791/851	112/1058 946/1058
BMI	Normal Overweight Obese	803/1326 401/1326 122/1326	634/851 207/851 10/851	673/1058 376/1058 9/1058

Table 2: Frequency And Anatomical Variations Of Anomalies.

Anatomical variate	**1st trimester**	**2nd trimester**	**3rd trimester**	**Total.**
Central nervus system				
Anencephaly	1	0	0	1
Neural tube defect	0	2	0	2
Macro crania	1	0	0	1
Cardiovascular system				
Atrial septal defect	0	2	5	7
Ventricular septal defect	0	1	4	5
Valvular defect	0	2	1	3
Gastrointestinal system				
Duodenal atresia	1	0	0	1
Oesophageal atresia	0	2	4	6
Omphalocele	0	0	2	2
Face and neck				
Increase nuchal fold				
Cleft lip	1	2	2	5
Cystic hygroma	0	1	2	3
Micrognathia	0	2	2	4
Respiratory system				
Diaphragmatic hernia	0	0	1	1
Skeletal system				
Short long bones	0	1	0	1
Polydactyly				
Excretory system				
Renal cyst	0	0	2	2
Hydronephrosis	0	13	11	24
Mega-cystitis	0	1	1	2
Pelvic kidney	0	0	1	1
Other				
Single umbilical artery	2	8	6	16
Total	6	37	44	87

Table 3: Association Of Anomalies With Predictors

Predictors	**Foetal anomalies**	**OR**	**P-value**	**aOR**	***P value**
Socio-economic status					
Upper class	19/410	Ref	0.007	Ref	
Upper middle class	08/525	0.31 (0.13 to 0.74)	0.001	0.89 (0.37 to 1.61)	0.03
Middle class	12/819	0.30 (0.14 to 0.63)	0.09	0.17 (0.11 to 0.93)	0.10
Lower middle class	38/1309	0.61 (0.35 to 1.08)	0.55	0.42 (0.09 to 1.32)	0.06
Lower class	10/172	1.2 (0.58 to 2.80)		1.73 (0.51 to 2.09)	0.16
Maternal age					
<20 years	2/311	Ref		Ref	
21-35 years	59/1983	4.71 (1.15 to 19.4)	0.03	1.61 (0.29 to 6.11)	0.002
>35 years	26/941	4.39 (1.03 to 18.6)	0.04	3.92 (1.01 to 11.5)	<0.0001
BMI					
Normal	11/2110	Ref		Ref	
Overweight	48/984	9.71 (5.61 to 18.9)	<0.001	1.78 (1.01 to 7.86)	0.005
Obese	28/141	47.2 (22 to 99)	<001	5.87 (2.03 to 31.7)	<0.001
Parity			0.79		0.81
Primiparous	36/1589	Ref		Ref	
Multiparous	51/1646	1.37 (0.61 to 2.45)		1.39 (0.44 to 3.18)	
Consanguinity					
Present	18/271	2.98 (1.74 to 5.09)	0.001	1.54 (1.16 to 3.80)	0.002
Absent	69/2964	Ref		Ref	
History of previous abortion					
Yes	29/779	1.70 (1.08 to 2.67)	0.02	1.21 (1.15 to 1.89)	0.01
No	58/2456	Ref		Ref	
History of smoking/alcohol					
Yes	3/21	7.45 (2.11 to 26.1)	0.001	3.71 (1.88 to 5.91)	0.04
No	84/3214	Ref		Ref	

History of over-the-counter drugs					
Yes	41/753	3.01 (1.94 to 4.62)	0.0001	1.24 (1.01 to 2.09)	<0.001
No	46/2482	Ref		Ref	
Diabetes					
Yes	13/388	1.29 (0.71 to 2.36)	0.39	1.24 (1.16 to 1.81)	0.01
No	74/2847	Ref		Ref	
Hypertension			0.36		0.07
Yes	14/301	1.37 (0.73 to 2.33)		1.26 (0.97 to 3.11)	
No	73/2934	Ref		Ref	
Folic acid in first trimester			<0.001		<0.001
Yes	9/302	Ref		Ref	
No	78/2933	19.1 (9.5 to 38.1)		6.16 (2.96 to 11.5)	

DISCUSSION

From the original group of 3560 pregnant women, 325 were not included due to twin pregnancies, likely to prevent potential complications linked to multiple pregnancies. The research encompassed participants from both rural 1526 (47.1%) and urban 1709 (52.9%) settings, ensuring a balanced representation across locations near RAMA Medical College. The age range was diverse, with a significant portion under 20 years old (311; 9.6%) and over 35 years old (941; 29%). Educational levels varied widely, with a notable percentage below the 10th standard of 518 (16%) and a comparable number holding postgraduate degrees. Most women had completed high school in 1272 (39.3%), which can influence their understanding of health matters and decision-making during pregnancy. Employment was limited, with 216 women (6.6%) employed and the majority engaged in homemaking, a factor that can impact access to healthcare and socioeconomic aspects of pregnancy.

The Overall incidence of foetal anomalies was 2.69% which was similar with the study done by Bhinde et al., 2016 and Indian academy of paediatrics guideline 2021[2,6]. In the first trimester group, the identification of six anomalies is notable. Specifically, the presence of anencephaly and macro crania, albeit in small numbers, highlights the severity and complexity of certain anomalies that can manifest early in pregnancy. In the second trimester group, the increase in anomalies, with 13 cases of hydronephrosis, 5 cases of congenital heart diseases, and 8 cases of single umbilical arteries among the total 37 anomalies, suggests a transition in the types of anomalies observed. This shift could be related to the developmental stages of various organs and systems during the second trimester, leading to a different spectrum of anomalies being detected. In the third trimester, the diagnosis of 7 congenital heart defects and 15 excretory system anomalies further delineates the evolving nature of foetal anomalies throughout pregnancy.

Overall heart defects were 15 (17.2%), which was lower than the national average recently published in 2022 by Manojkumar Rohit[7] is of particular concern due to their potential long-term impact on the health and well-being of the newborn.

The multivariate analysis revealed significant correlations between foetal anomalies and several factors, including socioeconomic status (middle class), maternal age (particularly those over 35), BMI (specifically obese individuals), consanguinity, smoking, previous history of pregnancy loss, over-the-counter drug use, and lack of folic acid intake during the first trimester as studied by Prema N et.al.,2016[8], Singhal et.al.,2020[9].

CONCLUSION

This study finds foetal anomalies in each trimester in pregnant women getting antenatal care at RAMA Hospital in Kanpur, India. Most anomalies were anomalies of the excretory system, followed by the cardiovascular system. There was a lower risk of congenital heart disease than the national average. The study also found associated factors with anomalies, like sociodemographic and maternal variables. A major factor in lowering the burden of foetal deformity is early screening, over-the-counter drug restriction, and antenatal diagnosis by ultrasonography.

Limitation

Acknowledging the study's limitations is crucial because this cross-sectional study cannot clearly measure the causes of foetal anomalies [10]. Potential biases, like recall bias in self-reported data, and since the study participants were individuals who voluntarily visited the hospital, the findings may not be generalizable to the community[11].

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Conflict Of Interest

Nill

Ethical Considerations:

Ethical approval is obtained from the Institutional Ethics Committee of RAMA Medical College, hospital and research centre (Approval No 2022/2707) before initiating the study. Informed consent is obtained from all study participants, and confidentiality of data is maintained.

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