Original Research

ROLE OF ANTENATAL ULTRASONOGRAPHY IN THE DETECTION OF FETAL CONGENITAL ANOMALIES: A HOSPITAL BASED OBSERVATIONAL STUDY AT A TERTIARY CARE CENTRE IN ASSAM, INDIA

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ABSTRACT

Background: Globally, congenital fetal malformations are the leading cause of perinatal morbidity and mortality. Prenatal ultrasound has become a clinically recognized first-line early non-invasive screening tool. This study was conducted at a tertiary care hospital in Assam, India, and used ultrasound screening to assess the type spectrum and prevalence of fetal malformations.

Objective: This study, a project of prenatal ultrasound screening for fetal congenital anomalies, was conducted at the Radiology Department of FAAMCH Hospital in Barpeta, Assam, India.

Methods: The paper opens with a clear statement of two core research objectives, outlines the implementation details of the entire research workflow, and adopts SPSS in conjunction with descriptive statistical analysis. All study parameters are explicitly documented, which enables the replication and traceability of the research, and aligns with the standard writing logic of medical scientific research papers.

Results: Baseline statistics of congenital fetal anomalies in the cohort of this study show that central nervous system anomalies rank first at 37.5%, followed by cardiovascular anomalies at 17.5%, gastrointestinal anomalies at 15%, and other types. Anencephaly accounts for 12.5% of all cases, lethal anomalies account for 25%, live births make up 52.5% of all pregnancy outcomes, and 20% of the cases are associated with maternal diabetes.

Conclusion: Antenatal ultrasonography remains indispensable in the early detection and characterization of fetal congenital anomalies, with CNS malformations predominating in the study population. Early and systematic anomaly scanning facilitates timely counseling, informed obstetric decision-making, and improved perinatal outcomes.

Keywords: Fetal Anomalies; Antenatal Ultrasonography; TIFFA Scan; Central Nervous System Malformations; Congenital Anomalies; Prenatal Diagnosis; Perinatal Outcomes; FAAMCH.

INTRODUCTION

This paper first establishes a standardized definition of fetal anomalies, which covers two categories of clinical conditions: lethal malformations include anencephaly and severe heart defects, while correctable malformations include cleft lip and renal pelvis dilatation [1].

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Citing data from references [2,3], congenital anomalies account for 3-4% of neonatal deaths, and cause significant neonatal morbidity and long-term disability. Drawing on data from reference [4], approximately 1 in every 33 newborns is born with a congenital anomaly. The burden of these conditions is disproportionately high in low- and middle-income countries such as India, stemming from inadequate access to prenatal screening, weak medical infrastructure, and high prevalence of risk factors. Most affected cases can benefit from early identification and early intervention.

Prenatal ultrasound has become a core pillar of modern obstetric perinatal care, and it is the

mainstream non-invasive, low-cost, highly accessible tool used for fetal assessment [5]. Since this technology was first applied in the early 1980s to reliably diagnose fetal disorders such as spina bifida and anencephaly, it has developed rapidly. At present, three-stage prenatal ultrasound examinations are routinely carried out: nuchal translucency (NT) measurement and early structural assessment at 11-13 weeks of gestation, anomaly screening scan at 18-22 weeks of gestation, and late-pregnancy fetal growth assessment scan [6]. Newly introduced technologies in recent years, including high-resolution 2D imaging, 3D/4D ultrasound, Doppler imaging, and the TIFFA protocol, have further improved the diagnostic efficacy of prenatal ultrasound [7-9].

Despite notable progress in the field of prenatal ultrasound detection of fetal malformations, many core challenges remain unresolved to achieve accurate malformation detection using this technology. According to data from reference [10], the sensitivity of ultrasound for detecting congenital malformations worldwide ranges from 53% to over 80%, and this performance is affected by five core factors: operators' professional competence, equipment quality, the gestational age at screening, fetal position, and the physical condition of pregnant women. In India, most prenatal care is delivered in resource-limited settings, leading to uneven screening quality. The country also faces three major local barriers: the inherent operator-dependent nature of ultrasound, insufficient access to the specialized TIFFA ultrasound, and an imperfect referral system. These issues often cause missed or delayed diagnoses. FAAMCH, a tertiary hospital located in Barpeta, Assam, currently provides core prenatal ultrasound services to a large number of patients from diverse backgrounds across the region.

Long lacking research data on the spectrum, prevalence, and perinatal impacts of ultrasound-detected fetal malformations in Northeast India, this paper reports on a single-center clinical study launched at FAAMCH. The study analyzed the morbidity patterns of the target population to optimize clinical diagnosis and treatment pathways, allocate medical resources, and develop region-specific prenatal screening guidelines. It also supplements evidence-based support for tertiary care centers across India to incorporate systematic prenatal ultrasound as a standard early screening service.

Objectives

This study was conducted by the FAAMCH institution, which adopted prenatal ultrasound as its core technology to set layered research objectives: the core objective is to detect and characterize fetal malformations, with a key focus on identifying abnormalities that fall within the gestational age window eligible for legal termination of pregnancy. Two additional extended objectives are also established: the first is to assess the associations between fetal malformations and maternal age, parity, and the gestational age at which the examination was performed; the second is to test whether multiple malformations belong to the same identifiable syndrome.

The first secondary objective of this study is to explore the impact of identified fetal abnormalities on four types of obstetric decisions, including termination of pregnancy. In addition, the second secondary objective is to assess the impact of three types of maternal diseases on the types and incidence of fetal abnormalities.

METHODOLOGY AND MATERIALS

Study Design and Setting

This study is a hospital-based observational obstetric ultrasound study, carried out at the Radiology Department of FAAMCH, a tertiary care teaching hospital equipped with modern imaging facilities in Barpeta District, Assam, India. This hospital serves the urban and rural prenatal populations of Barpeta and its surrounding counties and districts. The study ran from November 2023 to October 2024. All ultrasound examinations were completed by qualified radiologists following the guidelines of ICRI and ISUOG. The project has received approval from the institutional ethics committee, and all enrolled subjects have signed written informed consent forms.

Inclusion and Exclusion Criteria

- **The inclusion criteria for this study are:** 1. Pregnant women at any gestational stage whose fetuses are detected with abnormalities via ultrasound; 2. Pregnant women with a past pregnancy history of fetal congenital anomalies; 3. Pregnant women with unexplained recurrent miscarriage; 4. Pregnant women diagnosed with the specified pre-pregnancy baseline diseases; 5. Pregnant women who have long used confirmed teratogenic medications.
- **Exclusion criteria for this study are:** 1. Pregnant women with normal level-1 ultrasound findings; 2. Pregnant women diagnosed with hydatidiform mole or intrauterine fetal death; 3. Pregnant women who are unwilling to sign the informed consent form.

Data Collection Procedure

This study implemented uniform standardized operating procedures. Baseline data were collected using a pre-structured proforma, which covered demographic information, medical and obstetric history, family history of congenital malformations, history of teratogen exposure, and screening results including blood type, routine blood and urine test results, and HIV status. Ultrasound examinations

used a SAMSUNG RS80 color ultrasound system fitted with a CA1-7A convex array probe; 3D ultrasound was added as a supplementary measure when necessary. Fetal assessments followed the 22 standard planes specified in the TIFFA protocol, and we recorded biological parameters including BPD and HC, as well as indicators such as amniotic fluid and placental status.

Statistical Data Analysis

In this study, all collected research data were entered into a structured database, and SPSS statistical software was used to complete all analyses. Each type of statistical method was matched to the research subjects it is applicable to. Research results are presented as absolute values plus percentages. The whole process is clear and replicable, and meets the norms of scientific research methodology.

RESULTS

This hospital-based observational study conducted at FAAMCH enrolled 40 prenatal pregnant women who met two sets of eligibility criteria over a 1-year enrollment period.

Table 1: Age Distribution of Study Participants (n = 40)

Age Group (Years)	Number of Participants (n)	Percentage (%)
< 20	5	12.5%
20–29	15	37.5%
30–39	10	25.0%
≥ 40	10	25.0%
Total	40	100%

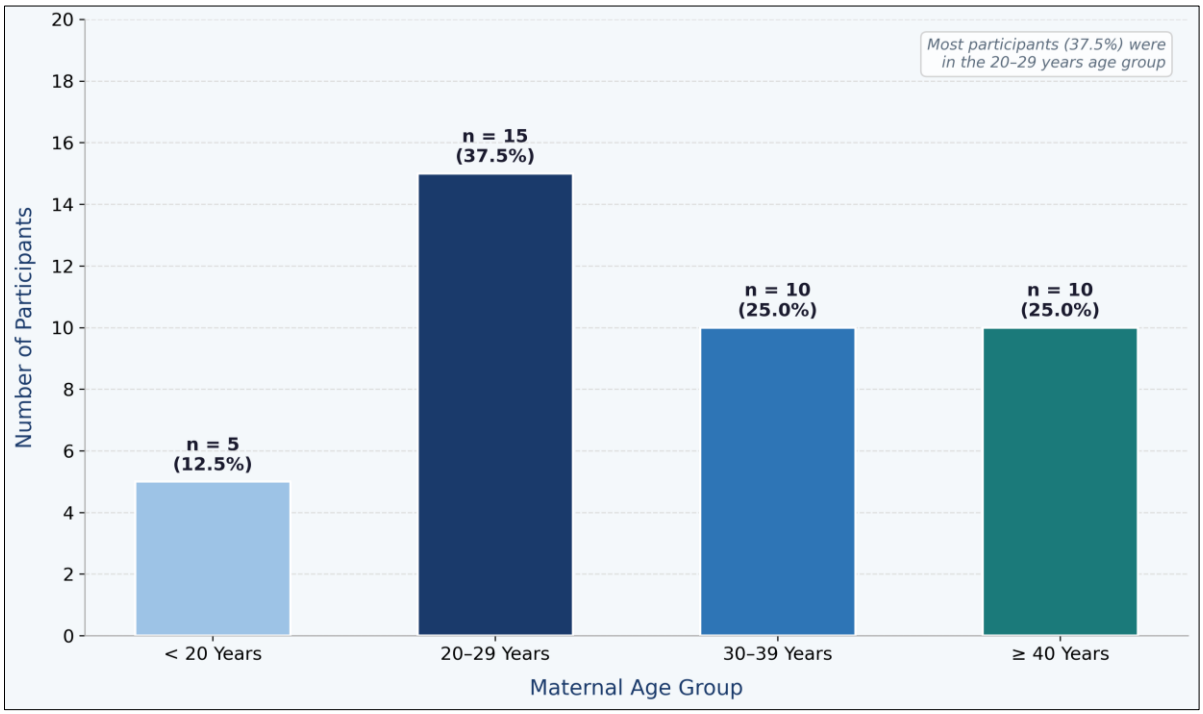

Figure 1: Age Distribution of Study Participants

The majority of study participants (37.5%) were in the 20–29 years age group, reflecting the peak reproductive age in this population. A notable 25% each were in the 30–39 and ≥40 year's groups, with the smallest proportion (12.5%) comprising women under 20 years. The high proportion of older mothers (≥40 years) is noteworthy as advanced maternal age is an established risk factor for chromosomal and structural fetal anomalies [11].

Table 2: Parity Distribution of Study Participants (N = 40)

Parity	Number of Participants (n)	Percentage (%)
Primigravida	22	55.0%
Multigravida	18	45.0%
Total	40	100%

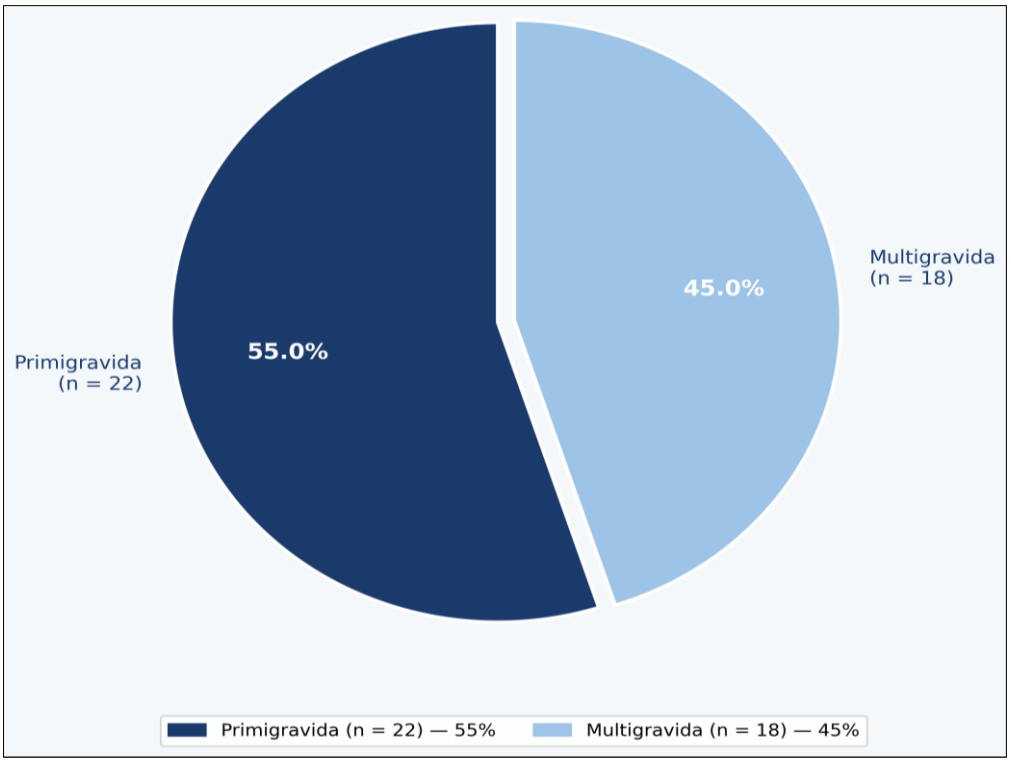

Figure 2: Parity Distribution (Primigravida Vs. Multigravida)

Among enrolled participants, 55% were primigravida and 45% were multigravida. The slight preponderance of primigravida women is consistent with reports from other tertiary centres in India [4,12].

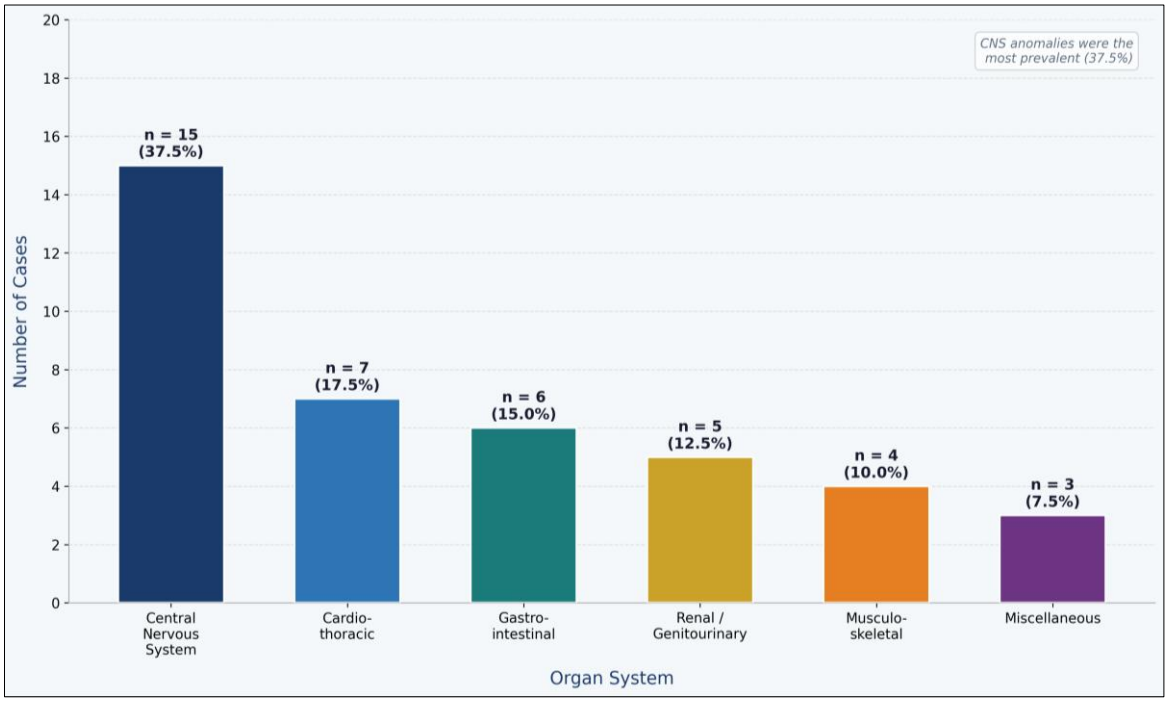

Figure 3: Distribution of Fetal Anomalies by Organ System (N = 40)

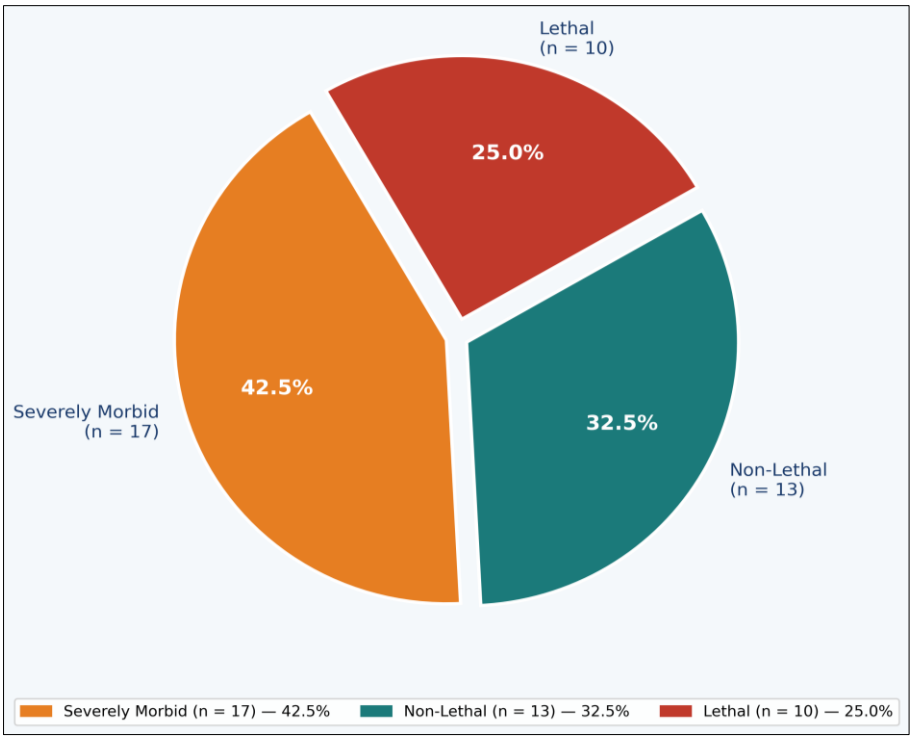

Figure 4: Lethality Classification of Detected Fetal Anomalies (N = 40)

Lethality analysis revealed that 25% of anomalies were classified as lethal, 42.5% as severely morbid, and 32.5% as non-lethal. Among lethal anomalies, anencephaly accounted for the majority. The high proportion of lethal anomalies underscores the importance of timely prenatal detection.

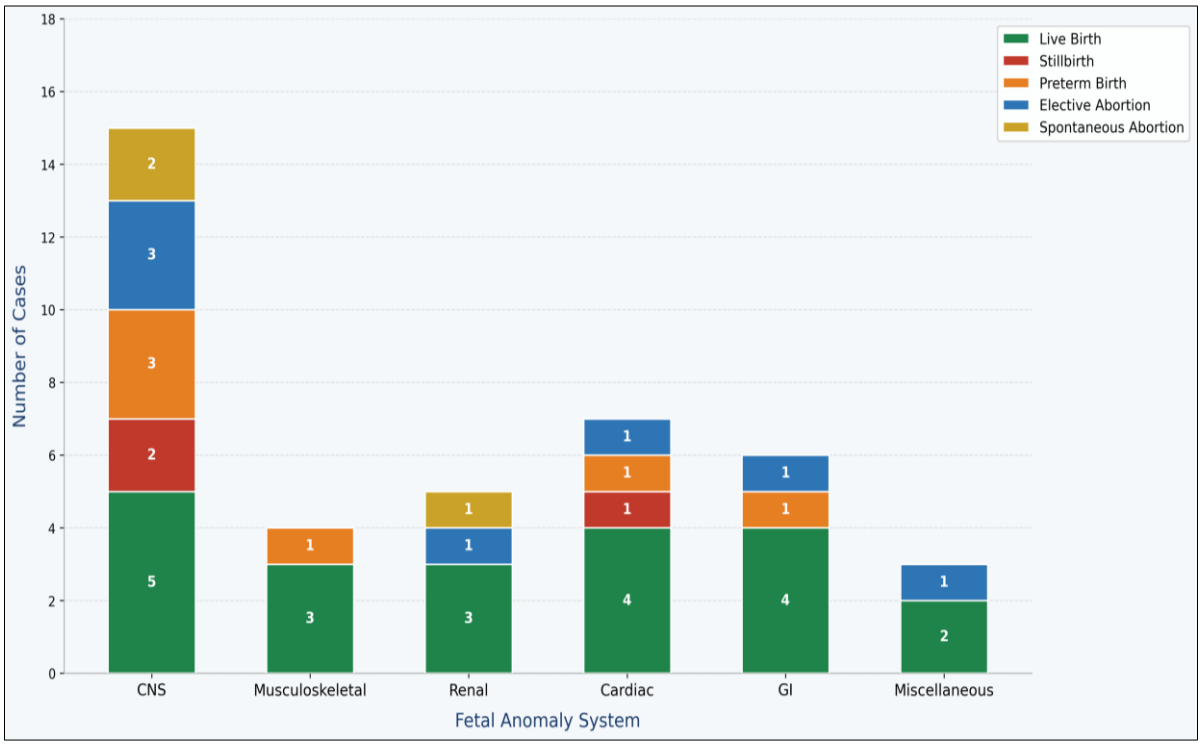

Figure 5: Perinatal Outcomes by Fetal Anomaly System (N = 40)

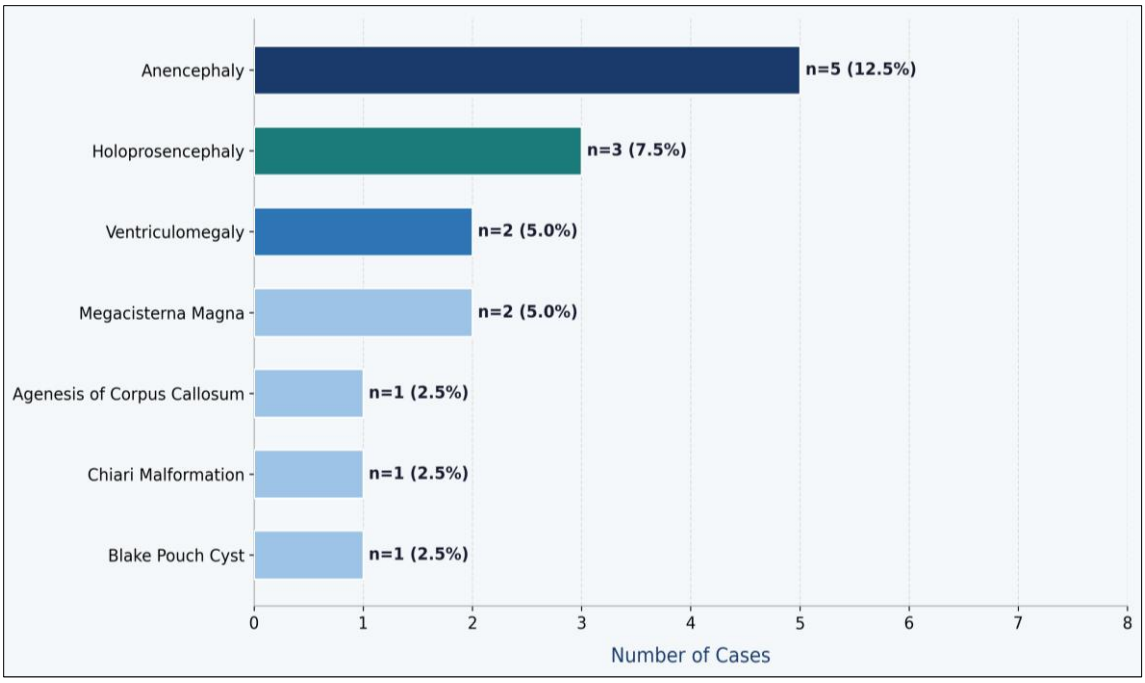

Figure 6: Cns Anomaly Subtypes Detected By Ultrasonography

CNS anomalies comprised the largest proportion (37.5%), including anencephaly (12.5%), holoprosencephaly (7.5%), ventriculomegaly (5%), megacisterna magna (5%), agenesis of corpus callosum (2.5%), Chiari malformation (2.5%), and Blake pouch cyst (2.5%). Cardiothoracic anomalies (17.5%) included tetralogy of Fallot (7.5%), diaphragmatic hernia (5%), extralobar pulmonary sequestration (2.5%), and congenital pulmonary airway malformation (2.5%). Gastrointestinal anomalies (15%) comprised omphalocele and gastroschisis (5% each), duodenal atresia, and esophageal atresia (2.5% each). Renal anomalies (12.5%) included bilateral pyelectasis (5%), posterior urethral valve (5%), and multicystic dysplastic kidney (2.5%). Musculoskeletal anomalies (10%) included thanatophoric dysplasia (5%), congenital talipes equinovarus (2.5%), and hemimelia (2.5%).

Table 3: Gestational Age at Time of Ultrasound (N = 40)

Gestational Age (Weeks)	No. of Participants (n)	Percentage (%)
< 20	4	10.0%
20–24	6	15.0%
25–28	8	20.0%
29–32	8	20.0%
33–36	8	20.0%
≥ 37	6	15.0%
Total	40	100%

Table 4: Maternal Medical History (N = 40)

Medical Condition	No. of Participants (n)	Percentage (%)
Diabetes mellitus	8	20.0%
Hypertension	5	12.5%
Heart disease	3	7.5%
Epilepsy	2	5.0%
Psychiatric illnesses	2	5.0%
No known condition	20	50.0%
Total	40	100%

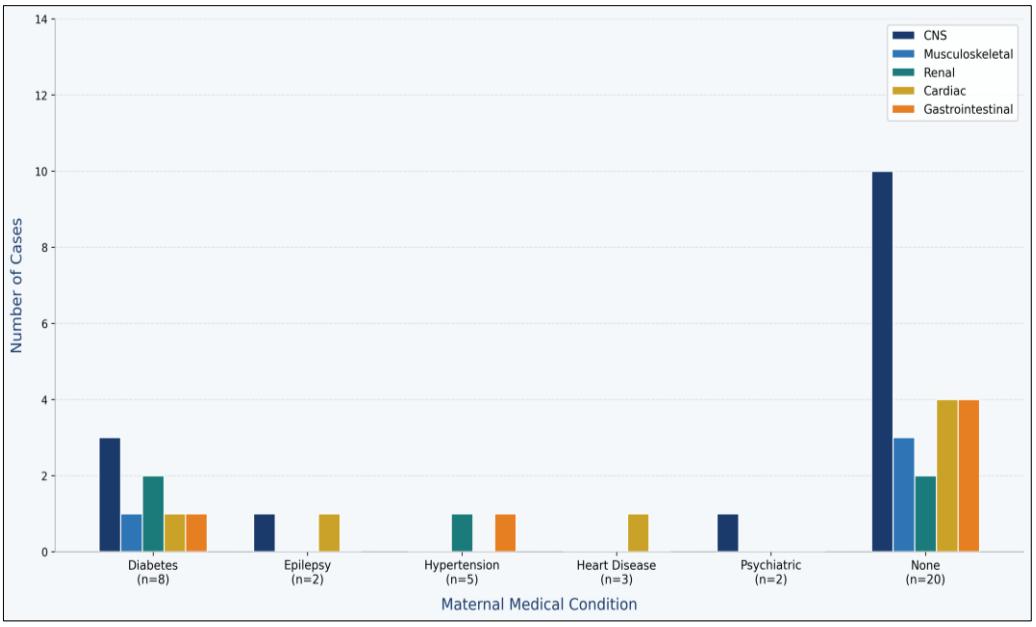

Figure 7: Association between Maternal Medical Conditions and Fetal Anomaly Types

Half of the study participants (50%) had no known pre-existing medical conditions. Diabetes mellitus was the most prevalent comorbidity (20%), followed by hypertension (12.5%). Maternal diabetes is a well-established teratogenic risk factor, particularly for CNS and cardiac malformations [14, 15].

Table 5: Distribution of Fetal Anomalies by Organ System (N = 40)

System Affected	No. of Cases (n)	Percentage (%)
Central Nervous System (CNS)	15	37.5%
Cardiovascular / Cardiothoracic	7	17.5%
Gastrointestinal	6	15.0%
Renal / Genitourinary	5	12.5%
Musculoskeletal	4	10.0%
Miscellaneous	3	7.5%
Total	40	100%

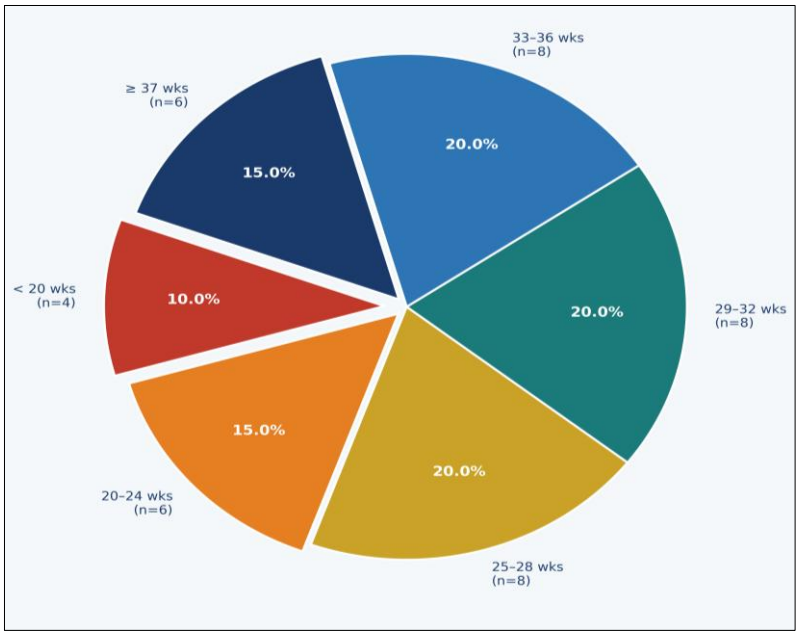

Figure 8: Gestational Age Distribution at Time of Ultrasound (N = 40)

Among the participants enrolled in this study, only 10% completed prenatal scans before 20 gestational weeks, while 75% attended their medical visits between 20 and 36 gestational weeks. This distribution stems from the referral regulations for tertiary A hospitals: completing an early scan before 20 gestational weeks is a necessary condition to meet the statutory requirements for pregnancy termination after a confirmed diagnosis of lethal fetal anomalies [13].

This study found that among perinatal cases, live births accounted for 52.5%, preterm births made up 15%, and all other adverse outcomes including stillbirths totaled the remaining 47.5%; the rate of adverse outcomes was the highest for central nervous system malformations, while musculoskeletal and gastrointestinal malformations had relatively better prognoses [11]; the observed correlations between maternal high-risk factors are consistent with the previous conclusions stated and the overall malformation rate of primiparas (55%) was higher than that of multiparas (45%).

Representative Clinical Images

The following ultrasound images represent key cases of fetal anomalies identified at FAAMCH during the study period. These are original images obtained using the SAMSUNG RS80 ultrasound machine at the Department of Radiology, FAAMCH.

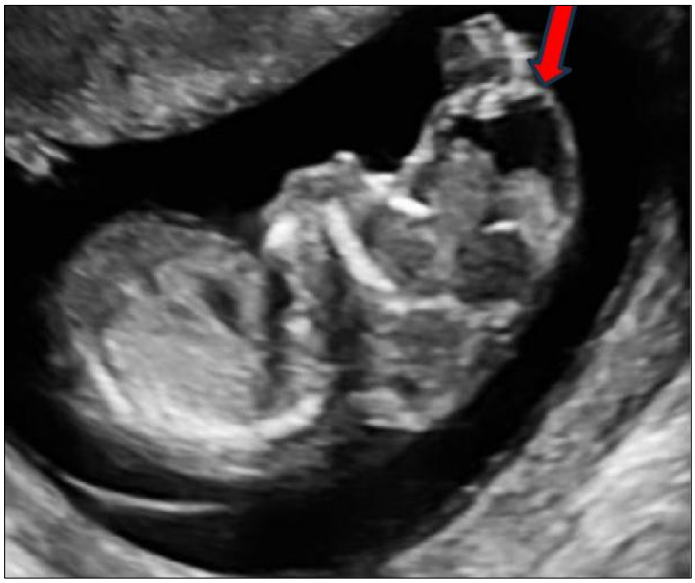

Figure 9: Case of Exencephaly Showing absent Cranial Vault and Herniation of Brain Parenchyma into Amniotic Cavity

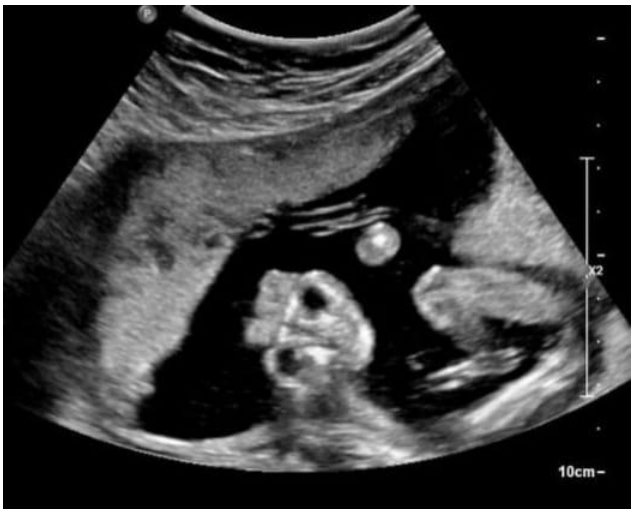

Figure 10: Case of Anencephaly Showing Absent Cranial Vault and Brain Parenchyma with Bulging Orbits Resembling "Frog Eye Sign"

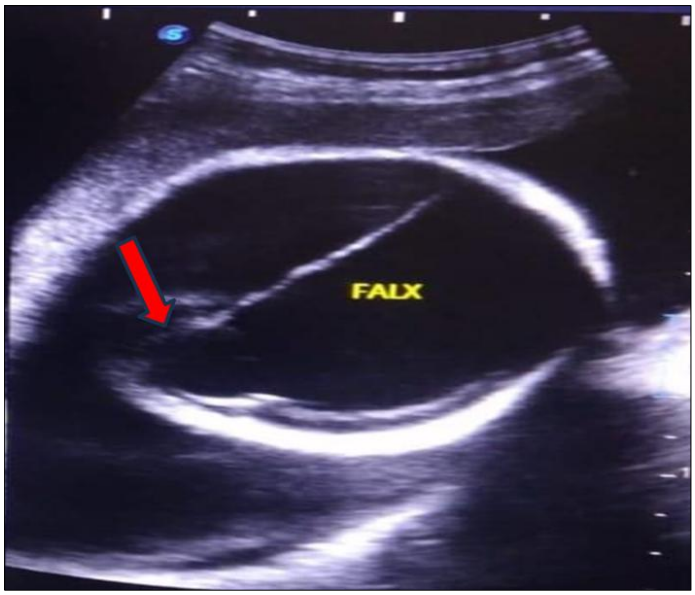

Figure 11: Case of Lobar Holoprosencephaly Showing Deficient Falx Cerebri Anteriorly in a Small Portion

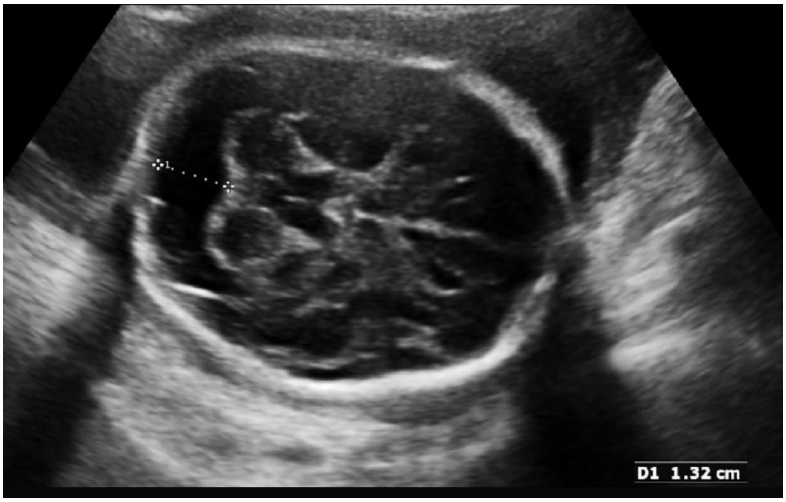

Figure 12: Case of Megacisterna Magna

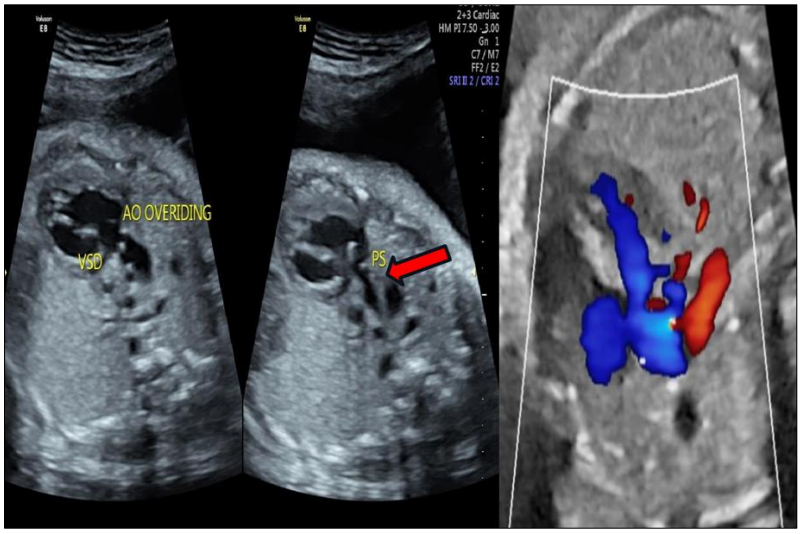

Figure 13: Case of Tetralogy of Fallot Showing Overriding Of Aorta over A VSD, Right Ventricular Hypertrophy and Pulmonary Stenosis

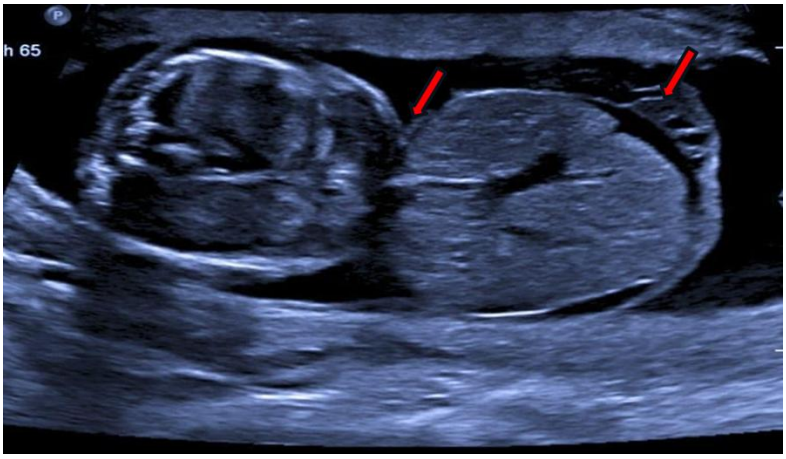

Figure 14: Case of Omphalocele Showing Herniation of Liver into Amniotic Cavity through a Midline Anterior Abdominal Wall Defect (Covered By Membrane)

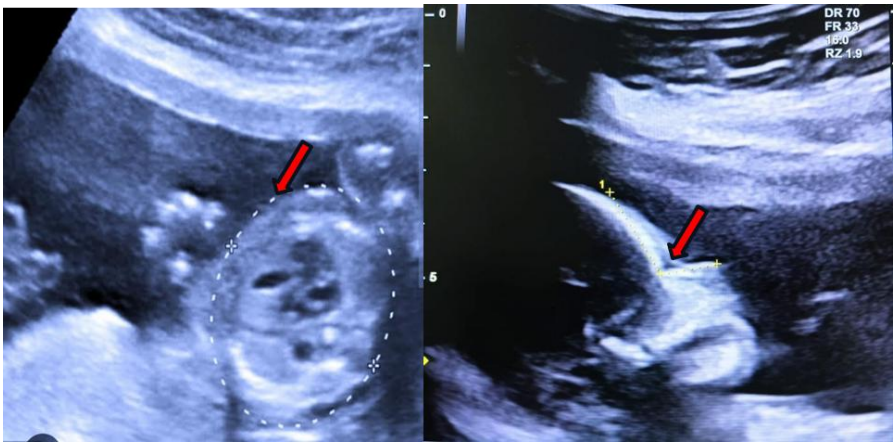

Figure 15: Case of Thanatophoric Dysplasia Showing Bent Femur and Short Humerus

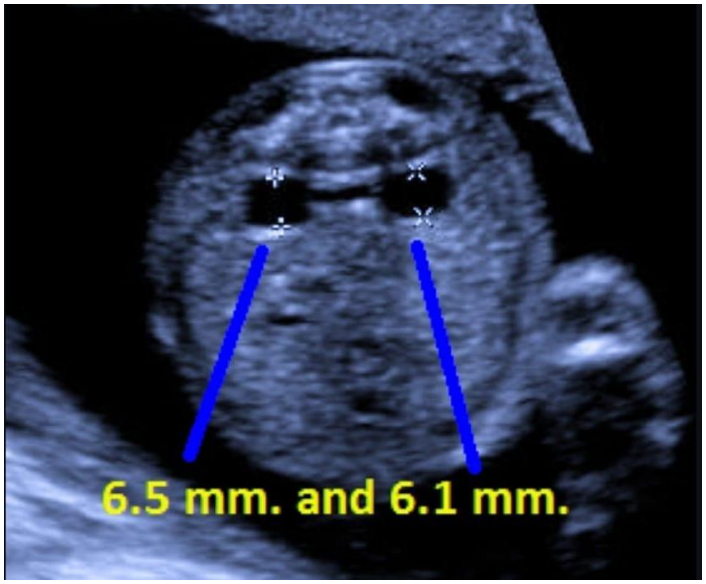

Figure 16: Case of Thanatophoric Dysplasia Showing Narrow Thorax and Frontal Bossing

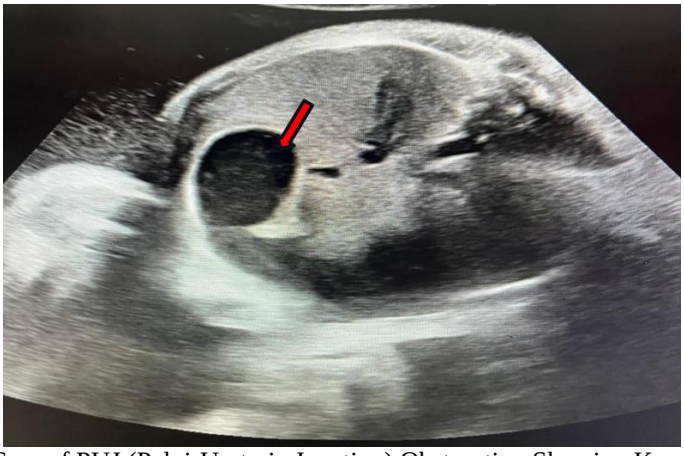

Figure 17: Case of PUJ (Pelvi-Ureteric Junction) Obstruction Showing Key Whole Sign

DISCUSSION

This study compiles original cohort data on fetal congenital malformations detected via prenatal ultrasound screening at FAAMCH, a tertiary hospital in Assam, India. The proportion of each type of malformation, listed in descending order of prevalence, is: central nervous system (CNS) malformations 37.5%, cardiovascular malformations 17.5%, gastrointestinal malformations 15%, renal malformations 12.5%, musculoskeletal malformations 10%, and other malformations 7.5%. The most common single malformation is anencephaly, accounting for 12.5% of all cases. The conclusion of high prevalence of CNS malformations is consistent with the conclusions of published cohorts from India and other developing countries cited in references [7, 4, 16, and 19]. This pattern arises from the high rate of periconceptional folate deficiency and the low coverage of pre-pregnancy folate supplementation among rural populations, which aligns with the model of similar studies conducted at local tertiary centers across India.

The global incidence of congenital heart disease (CHD) is 8 per 1000 live births. The detection rate of CHD via routine prenatal ultrasound ranges from 30% to 80%, and it is heavily influenced by a treatment center's clinical protocols and the operator's skill level [20, 21]. In the cohort of this study, the incidence of cardiovascular malformations was 17.5%, among which tetralogy of Fallot, the most common malformation in this group, accounted for 7.5%. TIFFA scanning can detect rare malformations including tetralogy of Fallot, diaphragmatic hernia, and extra lobar pulmonary sequestration. The combined view set it requires the four-chamber view plus the left ventricular outflow tract (LVOT) and right ventricular outflow tract (RVOT) views can significantly improve the detection rate of outflow tract malformations [10]. The overall incidence of internal medical comorbidities in this cohort was 50%, with diabetes accounting for 20% of these cases. Among fetuses of mothers with diabetes, central nervous system malformations made up 7.5%, renal malformations 5%, and digestive tract malformations 2.5%. Combining this observation with the established conclusion that pregestational diabetes is a recognized independent risk factor for multiple congenital malformations [14,15], this study recommends that all pregnant women with diabetes undergo targeted Grade II prenatal anomaly screening between 18 and 22 weeks of gestation.

Perinatal outcome analysis from this study of a prenatal diagnosis and care cohort for fetal anomalies in Northeast India shows that 25% of the fetal abnormalities were lethal, which pushed the cohort's stillbirth rate to 7.5% and its rate of selective pregnancy termination to 17.5%, highlighting the necessity of timely prenatal detection. India's Medical Termination of Pregnancy (MTP) Act only permits legal termination of pregnancy for cases in which a fetal anomaly is diagnosed before 20 weeks of gestation. In this study, only 10% of participants completed their ultrasound scan within this time limit. This critical problem stems from systemic flaws in the local referral system. Integrating amniocentesis, chorionic villus sampling (CVS), and chromosomal microarray analysis can improve diagnostic accuracy, and this study confirms the core clinical value of prenatal ultrasound for the region.

Limitations of the Study

This study has several core limitations, which are detailed as follows: First, only 40 samples were included, leading to insufficient statistical power and limited generalizability of the study's conclusions; the observed trends require verification in larger-scale, multicenter cohorts. Second, this study was conducted at a single-center tertiary care hospital, which introduced selection bias. Most of the study's participants were high-risk pregnant people referred from peripheral medical institutions, which may have led to an overestimation of community prevalence. Third, the three types of confirmatory genetic tests amniocentesis, chorionic

villus sampling, and chromosomal microarray were not performed, which may have resulted in missed diagnoses or misclassification of some abnormal subtypes. Fourth, the study lacked long-term postpartum follow-up data, so it was not possible to assess the true prognostic value of prenatal abnormalities, nor to verify the correlation between prenatal ultrasound findings and postpartum outcomes. Fifth, this study was an observational study based on routine clinical scans, so its results were affected by inter-operator variability in ultrasound interpretation. Future research should adopt a multicenter design, add genetic verification, implement a standardized TIFFA process with inter-observer reliability assessment, and carry out comprehensive postpartum follow-up, to generate more robust research evidence.

ACKNOWLEDGMENT

We extend our gratitude to the Department of Radiology and the Department of Obstetrics and Gynecology at Fakhruddin Ahmed Medical College and Hospital (FAAMCH) in Barpeta, Assam, India, for providing institutional coordination and platform support for this study. We thank all voluntary prenatal pregnant participants who agreed to share their personal clinical data, as well as the hospital's sonographers, nursing staff and administrative personnel for their assistance with data collection and patient coordination. This study was approved and supervised by the hospital's institutional ethics committee, received no external funding, has no conflicts of interest to declare, and meets the compliance requirements for international academic publication.

CONCLUSION

This study confirms that prenatal ultrasound is an indispensable tool for the early diagnosis of congenital fetal anomalies in tertiary care settings in Assam, India, and can effectively achieve the early detection and systematic classification of congenital fetal anomalies. Among the spectrum of anomalies detected during the study period, central nervous system anomalies accounted for the highest share at 37.5%, followed in order by anomalies of the cardiovascular system, gastrointestinal system, renal system, and musculoskeletal system. Fatal anomalies made up 25% of all detected cases; the adverse perinatal outcomes linked to these anomalies, including induced labor, stillbirth, and preterm birth, highlight the significance of early diagnosis. Comorbidities in pregnant people such as maternal diabetes and advanced maternal age are associated with a higher disease burden of specific anomalies, which aligns with established pathophysiological mechanisms. TIFFA scans conducted at FAAMCH can detect all categories of anomalies, a conclusion supported by reference [25].

Against the current state of the prenatal screening system in India's northeastern region, the authors of this paper propose a tiered upgrade framework to advance the system: In the short term, the framework addresses infrastructure gaps by increasing the number of radiologists trained in TIFFA, upgrading ultrasound equipment at district, county and township-level medical institutions, and establishing standardized referral pathways. It also calls for improving the diagnostic system: integrating genetic testing into the prenatal diagnosis process, pairing it with precision genetic counseling services, building a regional registry of congenital anomalies, and rolling out three core public health interventions: folic acid supplementation for women during the peri-conception period, management of maternal diabetes, and public outreach on early prenatal screening. In the long term, the framework lays out plans to launch multi-center research that integrates fetal MRI and AI-assisted image analysis, to improve the accuracy of anomaly detection under conditions of limited resources.

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