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Diagnostic accuracy of routine anomaly scans in identifying congenital malformations during the second trimester. A cross-sectional observational study.

Dr. Chhani Lal Narsingh Sidar[1]*, Dr. Vidya Laxmi[2]
[1]Associate Professor, Department of Radiodiagnosis, Abhishek I. Mishra Memorial Medical College and Research, Junvani, Durg, District Durg, Chhattisgarh, India.
[2]Tutor, Department of Radiodiagnosis, Abhishek I. Mishra Memorial Medical College and Research, Junvani, Durg, District Durg, Chhattisgarh, India.

Abstract

Background:
Congenital malformations remain a leading cause of neonatal morbidity and mortality worldwide. Early detection through routine anomaly scans during the second trimester is critical for timely counseling, management, and improving pregnancy outcomes. However, the diagnostic accuracy of these scans varies depending on the type of anomaly and the expertise of the examiner.

Objective:
To evaluate the diagnostic accuracy of routine second-trimester anomaly scans in detecting congenital malformations when compared with postnatal findings.

Methods:
A cross-sectional observational study was conducted among 100 pregnant women undergoing routine anomaly scans between 18 and 22 weeks of gestation. Findings were compared with postnatal examinations and confirmatory investigations. Sensitivity, specificity, predictive values, and overall diagnostic accuracy were calculated.

Results:
Out of 100 cases, routine anomaly scans detected congenital malformations in 18 fetuses (18%). Postnatal evaluation confirmed 20 malformations, including 16 true positives, 2 false positives, and 4 false negatives. Sensitivity was 80%, specificity 97.6%, positive predictive value 88.9%, negative predictive value 95.2%, and overall diagnostic accuracy 94%. Central nervous system anomalies were most common (6%), followed by cardiac (6%), skeletal (5%), renal (3%), and gastrointestinal anomalies (2%). Missed anomalies were primarily subtle cardiac and skeletal malformations.

Conclusion:
Routine second-trimester anomaly scans demonstrate high diagnostic accuracy, particularly for central nervous system and renal malformations. However, cardiac and skeletal anomalies remain challenging and require meticulous evaluation.

Recommendations:
Enhanced operator training, incorporation of advanced imaging techniques, and standardized protocols are recommended to improve detection rates of cardiac and skeletal anomalies during routine anomaly scans.

Keywords: *Congenital malformations, anomaly scan, diagnostic accuracy, prenatal screening, second trimester.*
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Corresponding Author: *Dr. Chhani Lal Narsingh Sidar*
Email: ***drcnsidar884@gmail.com***
Associate Professor, Department of Radiodiagnosis, Abhishek I. Mishra Memorial Medical College and Research, Junvani, Durg, District Durg, Chhattisgarh, India.

Introduction
Congenital malformations are a major contributor to perinatal morbidity and mortality, often leading to long-term disability and substantial healthcare burden worldwide. The global prevalence of structural anomalies is estimated at 2–3% of live births, with higher rates in low- and middle-income countries where access to specialized prenatal

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diagnostic services is limited [1]. Early and accurate detection of fetal anomalies is crucial for optimizing maternal and neonatal outcomes, as it facilitates timely parental counseling, obstetric planning, and referral to advanced care centers [2].

Second-trimester ultrasonography, particularly between 18 and 22 weeks of gestation, has become the cornerstone of routine antenatal screening. It is a non-invasive, widely accessible, and cost-effective modality for detecting a broad spectrum of structural malformations [3]. However, the diagnostic accuracy of anomaly scans is influenced by multiple factors, including operator expertise, equipment quality, fetal position, gestational age, and the specific type of anomaly under evaluation [4]. Gross malformations of the central nervous system and abdominal wall are more readily identified, whereas cardiac and subtle skeletal anomalies remain diagnostically challenging [2,4].

Evidence from both high-resource and resource-constrained settings demonstrates significant variability in detection rates, underscoring the importance of evaluating the real-world performance of routine anomaly scans across diverse populations [1,4]. In India, where congenital anomalies are an under-recognized but important contributor to perinatal mortality, systematic assessment of the diagnostic accuracy of second-trimester scans is particularly relevant [5].

The present study was undertaken to assess the diagnostic accuracy of routine second-trimester anomaly scans in detecting congenital malformations by comparing antenatal ultrasound findings with postnatal outcomes. The results are expected to provide insights into the strengths and limitations of routine anomaly scans and suggest strategies to improve detection rates, especially for anomalies that are commonly missed.

Methodology

Study Design and Setting

This hospital-based cross-sectional observational study was conducted in the Department of Radiodiagnosis, Abhishek I. Mishra Memorial Medical College & Research, Junvani, Durg, District Durg, Chhattisgarh, India, over a period of twelve months from April 2024 to March 2025. The institution is a tertiary care teaching hospital catering to both urban and semi-rural populations across central Chhattisgarh, with an average annual delivery rate exceeding 3,500. The Radiodiagnosis Department is equipped with high-resolution ultrasound scanners and functions as a regional referral center for antenatal imaging.

Study Population

Pregnant women attending the antenatal clinic who underwent routine second-trimester anomaly scans between 18 and 22 weeks of gestation were included. A total of 100 consecutive eligible participants were recruited during the study period.

Sample Size Determination

The minimum required sample size was calculated using the formula for estimating proportions:

$$n = Z^2 \times P \times (1 - P) / d^2,$$

Where Z represents the standard normal deviate at 95% confidence level (1.96), P is the expected prevalence of congenital malformations detectable on anomaly scans (assumed 20% based on prior hospital-based data [4,6]), and d is the desired precision (0.08). Substituting these values, the calculated sample size was 96. Allowing for potential loss to follow-up, a total of **100 participants** were recruited to ensure adequate statistical power.

Inclusion Criteria

Singleton pregnancies between 18 and 22 weeks of gestation.
Women are willing to undergo antenatal anomaly scans and postnatal follow-up.

Exclusion Criteria

Multiple gestations.
Pregnancies with uncertain gestational age.
Women lost to follow-up or with incomplete records.

Data Collection Procedure

All participants underwent a standardized anomaly scan performed by experienced radiologists using high-resolution ultrasound equipment. Each fetus was systematically evaluated for structural anomalies involving the central nervous system, cardiovascular system, genitourinary tract, gastrointestinal system, and musculoskeletal structures. Findings were recorded in a structured proforma. After delivery, neonates were examined clinically by pediatricians, and suspected anomalies were confirmed by appropriate investigations (echocardiography, neuroimaging, renal scans, or surgical exploration where indicated). Antenatal ultrasound findings were compared with postnatal outcomes for accuracy assessment.

Outcome Measures

Diagnostic performance of anomaly scans was evaluated in terms of:
Sensitivity
Specificity
Positive predictive value (PPV)
Negative predictive value (NPV)
Overall diagnostic accuracy

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Bias and Quality Control

To minimize observer bias, all ultrasound examinations were performed by two senior radiologists with more than five years of experience, following a standardized anomaly scan protocol. Inter-observer variability was reduced through consensus reading in ambiguous cases. Selection bias was minimized by including consecutive eligible antenatal cases attending routine scans within the study period. Information bias was mitigated by maintaining uniform data recording using predesigned proformas and blinded postnatal verification by pediatricians unaware of antenatal findings.

Statistical Analysis

Data were compiled in Microsoft Excel and analyzed using SPSS version 26. Categorical variables were presented as frequencies and percentages. Diagnostic indices were calculated using 2×2 contingency tables, with statistical significance considered at $p < 0.05$.

Ethical Considerations

Approval was obtained from the Institutional Ethics Committee of Abhishek I. Mishra Memorial Medical College & Research. Written informed consent was secured from all participants, and confidentiality was maintained.

Results

Participant Screening and Recruitment

During the study period from April 2024 to March 2025, a total of 112 pregnant women between 18 and 22 weeks of gestation attended the antenatal clinic for routine anomaly scans. Of these, 107 women were initially assessed for eligibility. Five participants were excluded due to multiple gestations (n = 3) and uncertain gestational age (n = 2). The remaining 102 eligible women consented to participate; however, two were lost to postnatal follow-up, resulting in a final analytical sample of 100 participants included in the study. The detailed screening and recruitment process is illustrated in Figure 1.

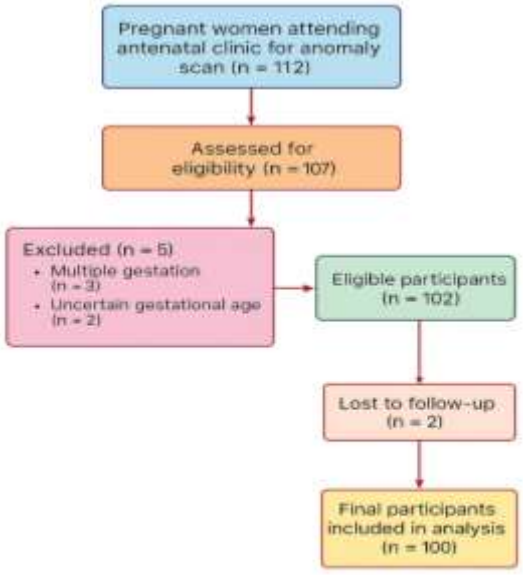

Figure 1: Flow diagram showing screening, eligibility assessment, exclusions, and final inculusion of *of* study participants who underwent routine second-trimester anomaly scans.

A total of 100 pregnant women who underwent routine anomaly scans during the second trimester were included in the study. The mean maternal age was 26.8 ± 4.2 years, with the majority being primigravida (54%). The mean gestational age at the time of the anomaly scan was 20.4 ± 1.8 weeks. Consanguinity was noted in 7% of cases, and a positive family history of congenital malformations was present in 3% (Table 1).

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Table 1. Baseline Characteristics of the Study Population (n = 100)

Parameter	Value (Mean ± SD / n, %)
Maternal age (years)	26.8 ± 4.2
Gestational age at scan (weeks)	20.4 ± 1.8
Gravida distribution	Primigravida – 54 (54%) Multigravida – 46 (46%)
Family history of malformations	3 (3%)
Consanguinity	7 (7%)

Routine anomaly scans detected congenital malformations in 18 fetuses (18%). Postnatal follow-up and confirmatory investigations identified 20 true congenital malformations, indicating that four cases were missed antenatally, while two were falsely reported. Based on this, the diagnostic accuracy parameters of the anomaly scan were calculated. The sensitivity was 80%, specificity 97.6%, positive predictive value 88.9%, negative predictive value 95.2%, and overall diagnostic accuracy 94% (Table 2).

Table 2. Diagnostic Performance of Routine Anomaly Scan

Parameter	Value
True Positives (TP)	16
False Positives (FP)	2
True Negatives (TN)	80
False Negatives (FN)	4
Sensitivity	80%
Specificity	97.6%
Positive Predictive Value	88.9%
Negative Predictive Value	95.2%
Overall Accuracy	94%

The distribution of anomalies by organ system is summarized in Table 3. Central nervous system malformations were the most frequently identified (6 cases), followed by cardiac (6 cases), skeletal (5 cases), renal (3 cases), and gastrointestinal anomalies (2 cases). While most anomalies were correctly detected antenatally, cardiac and subtle skeletal abnormalities accounted for the majority of missed diagnoses.

Table 3. Spectrum of Congenital Malformations Detected

System Involved	Antenatally Detected (n)	Confirmed Postnatally (n)
Central Nervous System	6	6
Cardiac	4	6
Renal/Genitourinary	3	3
Gastrointestinal	2	2
Skeletal	3	5
Total	**18**	**20**

Analysis of error patterns revealed four false negatives and two false positives (Table 4). The missed cases included two cardiac malformations (ventricular septal defect and transposition of great vessels) and two skeletal anomalies (clubfoot and mild limb shortening). False positives included one suspected hydronephrosis that resolved spontaneously and one suspected diaphragmatic hernia that was not confirmed postnatally.

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Table 4. Missed and Falsely Reported Anomalies

Category	Number of Cases	Details
False negatives	4	2 cardiac anomalies (VSD, TGA) 2 skeletal anomalies (clubfoot, mild limb shortening)
False positives	2	1 suspected hydronephrosis (resolved) 1 suspected diaphragmatic hernia (normal postnatal exam)

Discussion

In this hospital-based observational study of 100 pregnant women, routine second-trimester anomaly scans demonstrated high diagnostic accuracy for detecting congenital malformations, with a sensitivity of 80%, specificity of 97.6%, and overall accuracy of 94%. These findings confirm the importance of anomaly scans as a vital component of antenatal care for identifying major structural abnormalities.

The prevalence of congenital malformations in our study was 20%, which is higher than that reported in community-based studies but comparable to referral hospital series where high-risk pregnancies are overrepresented. Central nervous system malformations were the most frequently identified, followed by cardiac and skeletal anomalies. This distribution is consistent with international data indicating that routine ultrasonography is most reliable for detecting gross central nervous system and renal malformations, whereas anomalies such as facial clefts, subtle skeletal defects, and cardiac malformations are more often missed [6,7].

This study's results also highlight that while major abnormalities like anencephaly and hydrocephalus are readily detected, cardiac defects continue to pose diagnostic challenges, reflecting limitations in sensitivity even in well-equipped centers. Similar concerns have been emphasized in guidelines for second-trimester scans, where operator expertise and systematic protocols are critical for improving detection [8]. Variability in detection rates across different regions and healthcare systems has also been reported, underscoring the influence of infrastructure and population-specific factors [9,10].

Advances in imaging modalities such as three-dimensional and four-dimensional ultrasonography, as well as artificial intelligence–assisted models, are emerging as promising tools for enhancing diagnostic accuracy, particularly for congenital heart disease [11]. Additionally, studies comparing early versus late mid-trimester scans suggest that the timing of screening may affect sensitivity, with later scans offering higher detection rates for certain anomalies [12].

Overall, these study findings reinforce the pivotal role of routine second-trimester anomaly scans in prenatal care while highlighting the need for improved protocols, specialized training, and selective integration of advanced imaging modalities to strengthen diagnostic yield.

Generalizability

Although this was a single-center study, the findings are likely applicable to similar tertiary healthcare settings in low- and middle-income countries where routine second-trimester anomaly scans are part of standard antenatal care. The diagnostic accuracy observed in this study reflects real-world conditions using standard ultrasound equipment and protocols, thereby enhancing external validity. However, variations in operator expertise, population risk profile, and resource availability may influence detection rates in other regions, warranting multicentric validation studies.

Conclusion

Routine second-trimester anomaly scans proved to be a reliable tool for prenatal detection of congenital malformations, demonstrating high specificity and overall diagnostic accuracy. Central nervous system and renal anomalies were identified with greater consistency, whereas cardiac and subtle skeletal anomalies were more frequently missed, reflecting known limitations of ultrasound screening. Despite a small proportion of false-positive findings, anomaly scans remain invaluable for guiding obstetric decision-making, parental counseling, and neonatal preparedness. The findings underscore the importance of strengthening radiologist training, adopting standardized scanning protocols, and integrating advanced imaging modalities to enhance early detection, ultimately improving maternal and neonatal health outcomes.

Limitations

However, this study **had** certain limitations. Being a cross-sectional observational study, it could not establish long-term outcomes or causal associations between antenatal findings and neonatal morbidity. The relatively small

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sample size and single-center design may limit the generalizability of results. Furthermore, advanced imaging modalities such as fetal echocardiography or 3D/4D ultrasonography were not used, which might have improved detection rates of complex anomalies, particularly cardiac defects.

Recommendations

Based on the study findings, routine second-trimester anomaly scans should be emphasized as a standard component of antenatal care. Training programs for radiologists, incorporation of structured protocols, and selective use of advanced imaging for high-risk pregnancies are recommended to enhance diagnostic accuracy. Establishing national guidelines and conducting multicenter longitudinal studies would provide stronger evidence to improve prenatal screening practices and reduce perinatal morbidity and mortality.

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List of Abbreviations

CNS – Central Nervous System
VSD – Ventricular Septal Defect
TGA – Transposition of the Great Arteries
PPV – Positive Predictive Value
NPV – Negative Predictive Value
SPSS – Statistical Package for the Social Sciences

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Conflict of Interest

The authors declare no conflict of interest.

Author contributions

CLNS-Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.**VL**-Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation.

Data availability

Data is available upon request

Author Biography

Dr. Chhani Lal Narsingh Sidar is currently serving as an Associate Professor in the Department of Radiodiagnosis at Abhishek I. Mishra Memorial Medical College & Research, Junvani, Durg, Chhattisgarh (India) since March 2024.
He completed his MBBS in 1992 from Gajra Raja Medical College, Gwalior (Madhya Pradesh) under Jiwaji University, and subsequently obtained his MD in Radiodiagnosis in 1998 from the same institution. Following his graduation, he worked as a Resident Medical Officer in the Radiology department at Pandit Jawaharlal Nehru Hospital and Research Centre, Bhilai, from July 1994 to April 1995.
Dr. Sidar has extensive teaching and clinical experience. He served as a Senior Resident from April 2017 to April 2018 and later worked as an Assistant Professor in Radiodiagnosis at Bharat Ratna Late Shri Atal Bihari Vajpayee Memorial Medical College, Rajnandgaon, Chhattisgarh, from February 2019 to March 2024.
With over two decades of clinical exposure and academic involvement, Dr. Sidar has contributed significantly to radiodiagnostic education and patient care. His areas of expertise include diagnostic imaging, ultrasound, and cross-sectional radiology. He is actively engaged in undergraduate and postgraduate teaching and continues to serve as a guide and mentor for medical students. **ORCID ID:**https://orcid.org/0009-0009-5508-1112
Dr. Vidya Laxmi is working as a Tutor in the Department of Radiodiagnosis at Abhishek I. Mishra Memorial Medical College & Research, Junvani, Durg, Chhattisgarh, India. She is actively involved in academic teaching and clinical radiology, with a special interest in diagnostic imaging and ultrasound.

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