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DIAGNOSTIC ACCURACY OF ULTRASOUND LN PRENATAL DIAGNOSIS OF CLUBFOOT ASSOCIATED WITH FETAL ANOMALIES

Original Research

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Acknowledgement: The authors thank the radiology and obstetrics staff for their valuable support in conducting this study.

Conflict of Interest: None
Grant Support & Financial Support: None

ABSTRACT

Background: Congenital talipes equinovarus (clubfoot) is a common musculoskeletal deformity present at birth, affecting approximately 1 to 2 per 1,000 live births globally. Early prenatal identification through ultrasonography provides an opportunity for timely counseling, preparation, and intervention. However, data on the diagnostic reliability of ultrasound in lower-resource or community-level settings remain limited, warranting further investigation to establish its accuracy across diverse populations.

Objective: To evaluate the diagnostic accuracy of prenatal ultrasound in detecting clubfoot, using postnatal clinical examination as the gold standard, and to assess the influence of maternal and fetal factors on diagnostic outcomes.

Methods: A cross-sectional study was conducted over six months at the Radiology Department of a tertiary care hospital. A total of 215 pregnant women beyond 24 weeks of gestation with singleton pregnancies and sonographic suspicion of foot anomalies were enrolled. All ultrasound examinations were performed using the Voluson E10 3D imaging system. Clubfoot was diagnosed when persistent abnormal foot positioning and angles were observed in multiple views. At delivery, a pediatrician clinically confirmed the presence or absence of clubfoot, and findings were matched with prenatal ultrasound outcomes. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated using SPSS version 25.

Results: Ultrasound demonstrated a sensitivity of 77.78%, specificity of 94.12%, PPV of 77.78%, NPV of 94.12%, and an overall diagnostic accuracy of 90.70%. Diagnostic performance improved in pregnancies beyond 28 weeks and among those with normal maternal BMI and amniotic fluid index. Accuracy was reduced in mothers with diabetes or hypertension.

Conclusion: Prenatal ultrasound is a highly reliable tool for detecting clubfoot in the late second and early third trimesters, especially under optimal maternal and fetal conditions. Its routine inclusion in anomaly screening can enhance early diagnosis and newborn care.

Keywords: Amniotic Fluid Index, Clubfoot, Congenital Abnormalities, Diagnostic Imaging, Maternal Health, Prenatal Ultrasound, Sensitivity and Specificity.

INTRODUCTION

Clubfoot, medically termed congenital talipes equinovarus, is among the most common congenital musculoskeletal deformities, affecting approximately 1 to 2 per 1,000 live births globally (1). This condition is characterized by an inward and downward twisting of the foot, often leading to significant mobility issues if left untreated. While clubfoot may occur in isolation, it is not uncommon for it to be associated with other structural anomalies involving the central nervous system, musculoskeletal system, cardiovascular system, or genitourinary tract (2,3). Early and accurate detection is crucial, as timely intervention significantly improves functional outcomes and quality of life (4). Advances in prenatal imaging, particularly ultrasonography, have greatly enhanced the early detection of fetal anomalies, including clubfoot. Routine anomaly scans performed between 18 and 24 weeks of gestation are typically when clubfoot is first identified, usually by observing abnormal positioning of the fetal foot (5). The evolution of high-resolution ultrasound equipment and increasing expertise among sonographers have contributed to the enhanced visibility of such deformities (6). This early identification enables healthcare providers to counsel expectant parents more effectively, plan for postnatal management strategies such as the Ponseti method or surgical correction, and assess for the presence of additional congenital anomalies that may alter clinical decision-making (7,8).

Despite the routine use of ultrasound for prenatal screening, the sensitivity and specificity of ultrasonographic diagnosis of clubfoot remain inconsistent across studies. Reported sensitivity varies widely due to differences in gestational age at the time of screening, operator skill, and the quality of imaging equipment (9). Additionally, false-positive diagnoses may occur due to transient fetal positioning or limitations in imaging resolution, particularly in low-resource settings (10). Furthermore, while several studies have explored the utility of prenatal ultrasound in diagnosing clubfoot, few have examined its association with concurrent fetal anomalies, especially in populations from low- and middle-income countries where disparities in healthcare infrastructure persist (11). There is a paucity of literature exploring maternal risk factors such as age and their potential link to associated malformations in fetuses diagnosed with clubfoot (12,13). Moreover, many existing studies derive data from technologically advanced regions, limiting the generalizability of findings to under-resourced environments. This gap in research underscores the importance of conducting region-specific studies to better understand the spectrum of associated anomalies and refine prenatal counseling and management strategies accordingly. Given these challenges and unmet needs, this study aims to evaluate the diagnostic accuracy of prenatal ultrasonography in detecting clubfoot and to investigate the frequency and patterns of associated fetal anomalies across diverse clinical settings.

METHODS

This cross-sectional validation study was conducted in the Department of Radiology at Sharif Medical and Dental College, Lahore, over a period of six months following approval of the research synopsis by the Institutional Review Board (IRB). Ethical considerations were strictly observed, and written informed consent was obtained from all participants prior to enrollment. The study aimed to assess the diagnostic accuracy of prenatal ultrasonography in detecting clubfoot, with clinical examination at birth serving as the reference standard. A total of 215 pregnant women were recruited using a non-probability consecutive sampling technique. The sample size was calculated using the diagnostic accuracy formula, assuming a clubfoot prevalence of 58.3%, an ultrasound sensitivity of 85%, a specificity of 90%, and a 7% margin of error at a 95% confidence level. Inclusion criteria consisted of women aged between 18 and 40 years, with singleton pregnancies in their second or third trimesters, and considered low-risk for complications. Eligible participants exhibited sonographic indicators suggestive of fetal constraint or abnormal foot positioning, such as restricted limb movements or suspected structural anomalies. Women were excluded if they experienced intrauterine death, early neonatal death, stillbirth, or if the neonate was found to have complex congenital anomalies not related to clubfoot on ultrasound.

All participants were referred from the outpatient department to radiology after fulfilling the inclusion criteria. Baseline demographic and clinical data were recorded, including maternal age, gestational age, body mass index (BMI), amniotic fluid index (AFI), parity, antenatal care booking status, family history of clubfoot (in first-degree relatives), maternal diabetes, and hypertension. Each participant underwent a 3D obstetric ultrasonographic scan using the Voluson™ E10 system by GE Healthcare (2021), performed by the principal investigator. Ultrasound findings were categorized as clubfoot positive or negative based on predefined diagnostic criteria. Following

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delivery, all neonates were examined by a pediatrician blinded to the ultrasound findings, and clinical diagnosis of clubfoot was documented (14,15). Neonatal data, including gender and presence of clubfoot, were recorded. Management of confirmed clubfoot cases was carried out according to institutional protocols. Statistical analysis was performed using SPSS version 25. A Shapiro-Wilk test was used to assess the normality of continuous variables. Descriptive statistics for continuous variables such as maternal age, gestational age, BMI, and AFI were presented as mean ± standard deviation. Categorical variables, including parity, antenatal booking, previous family history of clubfoot, diabetes, hypertension, and neonatal gender, were summarized using frequencies and percentages. Diagnostic performance of ultrasound—including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy—was determined using a 2×2 contingency table, with clinical examination at birth considered the gold standard. Stratified analyses were performed across various maternal and fetal factors to evaluate consistency in diagnostic performance.

RESULTS

The analysis included data from 215 pregnant women who met the inclusion criteria. The mean maternal age was 27.5 ± 4.5 years, with an average gestational age of 32.1 ± 3.2 weeks at the time of ultrasonographic examination. The average body mass index (BMI) was 26.4 ± 3.1 kg/m², and the mean amniotic fluid index (AFI) was 12.6 ± 2.5 cm. All participants were multiparous, with parity less than five. Of the total, 8.37% (n=18) had a family history of clubfoot, while 11.63% (n=25) were diabetic and 10.23% (n=22) had a diagnosis of hypertension. Antenatal care booking was recorded in 83.72% (n=180) of cases. Prenatal ultrasound identified clubfoot in 45 fetuses (20.93%), and clinical examination after delivery confirmed clubfoot in an equal number of neonates (20.93%), indicating good agreement between prenatal and postnatal findings. Among these, true positives (TP) were observed in 35 cases, true negatives (TN) in 160 cases, false positives (FP) in 10 cases, and false negatives (FN) in 10 cases. The sensitivity of prenatal ultrasound for detecting clubfoot was calculated at 77.78%, reflecting its ability to correctly identify affected fetuses. Specificity was 94.12%, indicating strong reliability in ruling out unaffected cases. The positive predictive value (PPV) was 77.78%, and the negative predictive value (NPV) was 94.12%. Overall diagnostic accuracy of the ultrasound modality was found to be 90.70%. Further stratified analysis showed that gestational age beyond 28 weeks was associated with improved diagnostic accuracy, yielding sensitivity and specificity of 80% and 95% respectively. A normal BMI was linked to slightly higher sensitivity (82%) and specificity (93%). Similarly, an AFI within normal range showed sensitivity of 78% and specificity of 92%. Ultrasound sensitivity was higher in the absence of maternal diabetes (79%) and hypertension (81%), with specificity consistently at 94% in both subgroups. This indicates that the presence of maternal comorbidities might slightly reduce the predictive performance of prenatal sonographic evaluation.

Table 1: Baseline Characteristics of Study Participants (n = 215)

Variable	Mean ± SD / Frequency (%)
Age (years)	27.5 ± 4.5
Gestational Age (weeks)	32.1 ± 3.2
BMI (kg/m²)	26.4 ± 3.1
Amniotic Fluid Index (cm)	12.6 ± 2.5
Parity <5	215 (100%)
History of clubfoot	18 (8.37%)
Diabetes (BSR >200 mg/dl)	25 (11.63%)
Hypertension (BP ≥140/90)	22 (10.23%)
Antenatal Booking Done	180 (83.72%)

Table 2: Prenatal Ultrasound and Postnatal Findings for Clubfoot

Finding	Frequency (n)	Percentage (%)
Clubfoot detected on ultrasound	45	20.93%
Clubfoot confirmed after birth	45	20.93%

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Table 3: Diagnostic Accuracy of Prenatal Ultrasound for Clubfoot

Diagnostic Outcome	Count (n)
True Positives (TP)	35
True Negatives (TN)	160
False Positives (FP)	10
False Negatives (FN)	10

Table 4: Calculated Diagnostic Accuracy Measures

Measure	Value (%)
Sensitivity	77.78%
Specificity	94.12%
Positive Predictive Value	77.78%
Negative Predictive Value	94.12%
Diagnostic Accuracy	90.70%

Table 5: Stratified Analysis of Diagnostic Accuracy

Stratification Factor	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Gestational age >28w	80	95	78	96	91
Normal BMI	82	93	76	97	90
Normal AFI	78	92	74	95	89
No maternal diabetes	79	94	77	96	90
No hypertension	81	94	80	95	91

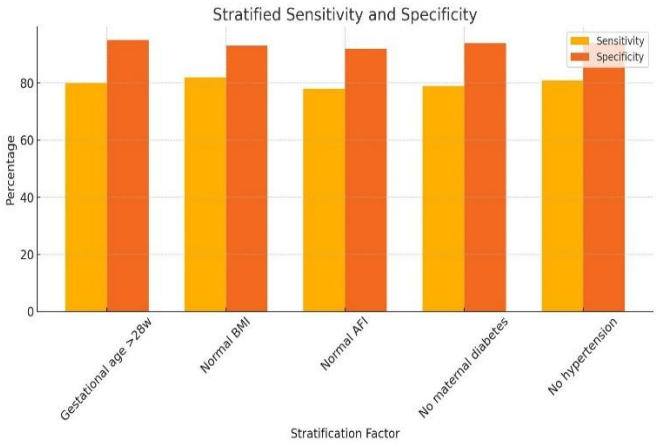

Figure 1 Stratified Sensitivity and Specificity

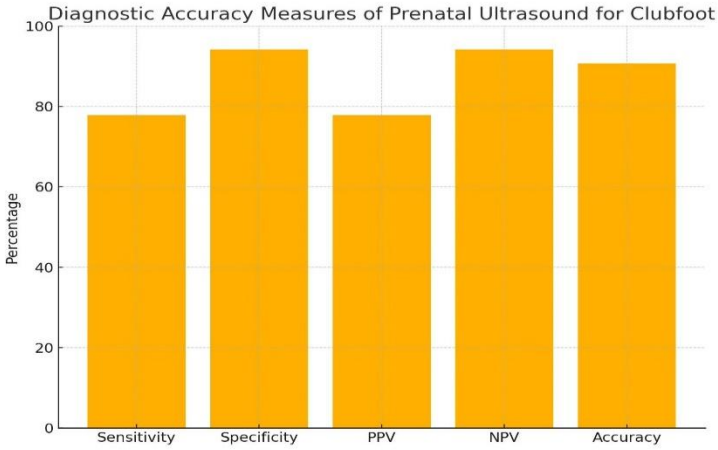

Figure 2 Diagnostic Accuracy Measure of Prenatal ultrasound for Clubfoot

DISCUSSION

The findings of this study demonstrated that prenatal ultrasound achieved a sensitivity of 77.78%, specificity of 94.12%, positive predictive value (PPV) of 77.78%, negative predictive value (NPV) of 94.12%, and an overall diagnostic accuracy of 90.70% for the detection of congenital talipes equinovarus. These metrics reflect a high level of diagnostic reliability when ultrasonography is performed during the late second or early third trimester. Comparable outcomes have been reported in earlier research, where similar or slightly higher specificity was achieved in tertiary centers using standardized protocols and experienced sonographers (15,16). The diagnostic specificity observed in this study reinforces the clinical utility of ultrasound as a non-invasive and readily accessible tool for antenatal

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screening of clubfoot, especially in settings where advanced genetic testing may not be available. The PPV observed in the current study was marginally lower than values reported in other regional and international datasets, possibly attributable to sample characteristics such as variations in parity, BMI, and gestational age at the time of imaging (17,18). Nevertheless, a PPV of over 75% still holds clinical value, enabling clinicians to offer timely counseling and management guidance to expectant parents. A particularly notable strength of this study was the inclusion of a stratified analysis, which showed improved diagnostic metrics in cases evaluated beyond 28 weeks of gestation. This improvement aligns with physiological developments such as increased fetal skeletal mineralization and better positioning for sonographic visualization in later gestation, factors also confirmed by prior literature (19,20).

Maternal and fetal characteristics had a marked influence on diagnostic performance. Normal maternal BMI and AFI were associated with higher sensitivity and NPV, likely due to improved sonographic window and reduced attenuation of acoustic signals. Conversely, maternal comorbidities such as diabetes and hypertension were linked to decreased diagnostic clarity, echoing previously reported associations where vascular and placental insufficiencies altered fetal development patterns and posed interpretative challenges for ultrasonography (20,21). This study, therefore, supports the position that optimizing maternal health and imaging conditions can significantly impact the effectiveness of prenatal diagnostics. All participants in this study received antenatal care from booking until delivery, which may have contributed positively to the consistency of findings and follow-up assessments. Early detection of structural deformities like clubfoot allows families and clinical teams to anticipate postnatal interventions such as the Ponseti method, facilitating better outcomes. However, a significant limitation of the study was its focus on isolated clubfoot. While some studies have shown that clubfoot may occur as part of syndromic or chromosomal anomalies, particularly involving neuromuscular or central nervous system disorders, this study did not explore the presence or absence of additional anomalies, nor did it utilize advanced imaging or genetic analyses to rule them out (21,22). This limits the ability to generalize findings to more complex or syndromic presentations.

Another limitation was the reliance on operator-dependent ultrasonography and the absence of standardized inter-observer assessments. Although all scans were conducted using high-end equipment and by trained personnel, variability in interpretation could not be entirely excluded. Moreover, the diagnostic performance was assessed only in a single center, potentially affecting external validity. Nonetheless, the study's strength lies in its prospective design, adequate sample size, use of well-defined diagnostic criteria, and postnatal clinical confirmation, which collectively enhance its methodological robustness. In resource-constrained environments, where genetic screening may not be feasible, reliable ultrasound practices become especially important. The implementation of a standardized diagnostic protocol for clubfoot using 3D or 4D ultrasonography, combined with continued education and training for sonographers and obstetricians, can significantly enhance diagnostic accuracy. Future studies should aim to integrate genetic testing, multicenter data, and the evaluation of associated anomalies to develop a more comprehensive understanding of prenatal clubfoot and improve perinatal care strategies.

CONCLUSION

This study concluded that prenatal ultrasound is a reliable and effective tool for detecting congenital talipes equinovarus, particularly when performed after 28 weeks of gestation and in mothers without complicating health conditions. The findings underscore the importance of timely antenatal care and suggest that clubfoot screening should be routinely integrated into standard anomaly scans. By identifying the condition early, healthcare providers can offer appropriate counseling, prepare for postnatal interventions, and reduce the emotional and clinical burden on families. Future research linking ultrasound findings with postnatal outcomes and genetic profiles will be essential to refine diagnostic accuracy and improve neonatal care strategies.

AUTHOR CONTRIBUTION

Author	Contribution
Halima Bashir*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Rafia Irum	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Hamna Mazhar	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published

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