MEDPUB PUBLICATIONS

MD / MS / DNB / DM / MCh RESEARCH PROTOCOL

RESEARCH PROTOCOL

Placental Thickness and Its Correlation with Advancing Gestational Age: A Predictive Marker for Small for Gestational Age (SGA) Fetuses

Principal Investigator	:	[Name], [Degree]
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Department	:	Department of Radiodiagnosis
Institution	:	[Institution Name and Address]
Study Site	:	
Duration of Study	:	12 Months
Sample Size	:	200 Participants
Study Design	:	Prospective Observational Study

Submitted in Partial Fulfilment of the Requirements for the Award of MD/MS/DNB/DM/MCh Degree

INDEX

1. INTRODUCTION / SYNOPSIS

The placenta has an essential role in fetal development. It acts as an interface between mother and fetus and helps in the exchange of nutrients, gases, and waste products. The placenta originates from maternal and fetal tissues, functioning as the lungs, kidneys, and digestive system for the fetus. It produces hormones essential for maintaining pregnancy and also supports the immune tolerance of the fetus thereby creating a harmonious environment for fetal development.

[1]

Accurate estimation of fetal weight is of crucial importance in obstetric practice. Along with gestational age, fetal weight is also an important determinant with respect to taking decisions related to labor and delivery. Underestimation of fetal weight may lead to unexpected complications in a seemingly normal pregnancy, whereas overestimation could result in unnecessary interventions such as early induction or caesarean sections. Various methods used for determination of fetal weight include palpation, fundal height measurement and ultrasound. Ultrasound provides a non-invasive method to evaluate the fetus and estimate weight based on biometric parameters. Selection of the method depends on available resources and the pregnancy stage.[2]

Ultrasound biometry is considered gold standard for assessing fetal weight. Biometric parameters which are used include biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), and femur length (FL). These measurements are input into various formulas to estimate fetal weight. The Hadlock formula combines BPD, HC, AC, and FL and is widely used due to its high accuracy. Other formulas may use a combination of different parameters. However, it must be noted that ultrasound is an operator-dependent technique and resolution of the sonography machine is also an important factor in estimating placental thickness accurately.[3]

In certain fetal pathologies, conventional biometric parameters may not reliably predict fetal weight. These pathologies include skeletal dysplasia, hydrocephalus, intrauterine growth restriction and conditions such as diaphragmatic hernia and fetal anterior abdominal wall defects such as gastroschisis. These abnormalities affect various biometric parameters thereby under- or overestimating gestational age. These pathologies make it important to use alternative or additional parameters for accurate gestational age estimation. There is a growing interest in studying placental thickness as a predictor of gestational age. Particularly in the second and third trimesters, placental thickness measured by ultrasound reportedly correlates with gestational age and fetal growth patterns. Multiple studies indicate that greater placental thickness is associated with increasing gestational age while a thinner placenta might signify growth restriction.[4]

Predicting small for gestational age (SGA) neonates antenatally remains challenging. Placental thickness measurement has emerged as a potentially useful parameter for identifying foetuses at risk for being SGA.[5] Reduced placental thickness compared to gestational age norms may indicate impaired placental function and inadequate fetal growth. Identifying thin placentae through ultrasound assessment can assist clinicians in recognizing pregnancies at risk for SGA neonates. This early detection enables appropriate monitoring and timely interventions aimed at improving neonatal outcomes.

2. RESEARCH QUESTION

> *Can two-dimensional sonographic placental measurements improve the prediction of small-for-gestational-age (SGA) infants?*

3. AIM OF THE STUDY

To evaluate the predictive value of 2D sonographic placental measurements and biometric parameters in identifying pregnancies at risk for delivering SGA infants.

4. PRIMARY OBJECTIVE

To determine the relationship between placental thickness at 18–23 weeks of pregnancy and biometric parameters with the incidence of SGA infants.

5. SECONDARY OBJECTIVES

1. To assess the individual and combined predictive accuracy of placental measurements and biometry for SGA <10th and <5th percentile birth weights.
2. To compare the predictive performance of placental thickness and biometry in identifying pregnancies at risk for SGA.

6. MATERIALS AND METHODS

Study Site	
Study Design	Prospective Observational Study
Time Frame	12 Months

7. INCLUSION CRITERIA

✔	Age above 18 years
✔	Pregnant women with a singleton pregnancy
✔	Gestational age between 18–22 weeks 6 days
✔	Women in 2nd and 3rd trimester of pregnancy
✔	Ready to give informed and written consent to be part of study

8. EXCLUSION CRITERIA

✗	Age less than 18 years
✗	Refusal to give informed and written consent to be part of study
✗	Women with gestational diabetes, pre-eclampsia, severe systemic illnesses
✗	Foetus having major congenital anomalies
✗	Post-term pregnancies (> 42 weeks of gestation)

9. SAMPLE SIZE CALCULATION

"The sample size was calculated by formula $N = (Z\ \alpha^2) \times \sigma^2 / d^2$ on the basis of pilot studies done on the topic of *Correlation of placental thickness with gestational age in second and third trimester using ultrasonography* (Vinchurkar KN[5]) assuming 90% power and 95% confidence interval, the sample size required was as follows:

THE FORMULA:

N = (Z α2) X SD2 / Precision2

- σ = Z α– Statistical constant (1.96)
- SD – Expected Standard Deviation (obtained from previous studies or a pilot study).
- d – Precision/ allowable error (corresponding to effect size).

STEP 1: Calculate Standard Error of Mean

Standard Error of Mean = Standard Deviation / √(sample size in pilot study)

= 0.2 / √200

= 0.2 / 14.142

Standard Error of Mean = 0.01414

STEP 2: Calculate Precision

Precision = Z α × Standard Error of Mean

= 1.96 × 0.01414

Precision = 0.0277

STEP 3: Calculate Sample Size

Sample Size (n) = $(Z\ \alpha^2 \times SD^2) / Precision^2$

= $(1.96^2 \times 0.2^2) / 0.0277^2$

= (3.8416 × 0.04) / 0.000768

Minimum Required Sample Size (N) = 200.05 (rounded off to 200)

10. METHODOLOGY

Singleton live pregnancy patients attending OBGY OPD for routine antenatal visit at ……. HOSPITAL will be included in this study on the basis of a predefined inclusion and exclusion criteria.

A detailed history will be taken from all the patients regarding their last menstrual period (LMP) date, and the gestational age by LMP will be noted. A history of co-morbid systemic illnesses such as diabetes mellitus, hypertension, or bronchial asthma will be inquired about and recorded. An antenatal ultrasound will be performed using institutional USG machine and convex probe.

Ultrasonographic Parameters Recorded

Parameter	Abbreviation
Biparietal Diameter	**BPD**
Head Circumference	**HC**
Abdominal Circumference	**AC**
Femur Length	**FL**
Transverse Cerebellar Diameter	**TCD**
Estimated Fetal Weight (Hadlock's formula)	**EFW**
Maximal Placental Thickness (at cord insertion)	**MaxPT**

Post-Delivery Data Collection

Following delivery, the gestational age at delivery, mode of delivery, neonatal birth weight and placental weight will be collected. Classification of neonates by birth weight will be done into 3 distinct groups:

Category	Full Form	Definition
AGA	Appropriate for Gestational Age	10th–90th centile birth weight
SGA	Small for Gestational Age	Birth weight < 10th centile
LGA	Large for Gestational Age	Birth weight > 90th centile

Mean placental thickness at 18 to 23 weeks of gestation will be correlated to appropriate for gestational age, small for gestational age and large for gestational age babies.

11. STATISTICAL ANALYSIS

Software Used: Statistical analysis will be performed using SPSS version 21.0.

Data / Variable	Statistical Test / Representation
Quantitative data (maternal age, GA, HC, BPD, AC, FL, TCD, EFW, MaxPT, birth weight, placental weight)	Mean ± Standard Deviation (SD)
Qualitative data (mode of delivery, neonatal classification — AGA, SGA, LGA)	Frequencies and Percentages
Comparison of quantitative variables (placental thickness across AGA, SGA, LGA groups)	One-way ANOVA + Bonferroni post-hoc correction
Correlation: placental thickness vs. neonatal birth weight classification	Pearson's Correlation Coefficient
Comparison of categorical variables (e.g., mode of delivery across groups)	Chi-square test / Fisher's exact test (as appropriate)

Statistical Significance: p-value < 0.05 will be considered statistically significant.

12. ETHICAL CONSIDERATIONS

- This study will be initiated only after obtaining prior approval from the Institutional Ethics Committee (IEC) of the concerned Medical College. All research activities will be carried out in compliance with established ethical norms and institutional guidelines to safeguard the rights and well-being of the participants.
- Confidentiality and privacy of all participating individuals will be strictly protected. No personally identifiable information will be used in data analysis or dissemination. All collected data will be anonymized prior to statistical evaluation and publication.
- The results of the study — whether favorable or not — will be disseminated in academic platforms such as peer-reviewed journals and medical conferences, without compromising participant confidentiality.
- All ultrasound examinations and data collection procedures will be conducted as part of routine antenatal care and in accordance with institutional protocols and ethical research standards.
- This research is investigator-initiated and has not received any external funding or sponsorship from commercial or governmental bodies.

13. REVIEW OF LITERATURE

Jindal M et al conducted a prospective study to evaluate the role of two-dimensional ultrasonographic placental measurements in predicting small for gestational age (SGA) fetuses. For this purpose, the authors undertook a study comprising singleton pregnancies at 18–22 weeks of gestation. Placental biometry, including maximal placental diameter (MaxPD) and maximal placental thickness (MaxPT) in two orthogonal planes, was recorded. Mean placental diameter (MPD) and mean placental thickness (MPT) were then calculated. At delivery, neonates were classified as appropriate for gestational age (AGA), SGA, or large for gestational age (LGA) based on birth weight. MPD and MPT were analyzed as predictors of SGA. The study found that both MaxPD and MPD were significantly smaller in SGA pregnancies ($p \leq 0.001$). Similarly, MaxPT ($p = 0.006$ and $p = 0.001$) and MPT ($p = 0.000$) were significantly lower in SGA pregnancies. The ROC curve for combined placental biometry had the maximum area under the curve (0.805), indicating strong predictive value. On the basis of these findings, the authors concluded that placental measurements taken in mid-gestation are valuable predictors of SGA. The measurement of placental diameter and thickness is a quick and simple method that should be explored further to develop a predictive model for growth-restricted fetuses.[6]

Vachon-Marceau C et al conducted a prospective cohort study to assess the link between first-trimester placental thickness and the risk of preeclampsia or small-for-gestational-age (SGA) neonates. For this purpose, the authors studied 991 pregnant women at 11–14 weeks of gestation, measuring placental thickness and following them until delivery. Placental thickness was compared between those who developed preeclampsia and/or had SGA neonates and those with uncomplicated pregnancies. The study found that SGA pregnancies had lower placental thickness (median: 0.89 MoM vs. 0.98 MoM; $p < 0.01$), while preeclampsia cases had higher thickness (median: 1.10 MoM vs. 0.97 MoM; $p = 0.06$). Thickness >1.2 MoM significantly increased preeclampsia risk (RR: 3.6; 95% CI: 1.5–8.6; $p < 0.01$). Pregnancies with both conditions had normal thickness. On the basis of these findings, the authors concluded that increased placental thickness is linked to preeclampsia, while decreased thickness is associated with SGA. These findings should be validated in larger studies.[7]

Sovio U et al conducted a prospective cohort study to assess the link between first-trimester placental thickness and the risk of delivering a small-for-gestational-age (SGA) infant. For this purpose, the authors studied 3,920 nulliparous women, measuring placental thickness via ultrasound at 10–14 weeks and following pregnancy outcomes. SGA was defined using population-based (SGA-pop) and customized (SGA-cust) birth weight percentiles, and fetal growth restriction (FGR) was assessed. The study found that higher placental thickness was linked to a lower risk of SGA-pop infants (OR = 0.80, $p = 0.01$), but the association was weaker for SGA-cust (OR = 0.88, $p = 0.09$) and not significant for FGR (OR = 0.98, $p = 0.8$). On the basis of these findings, the authors concluded that increased placental thickness in the first trimester is associated with lower SGA risk but mainly reflects normal birth weight variation.[8]

Omer Ahmed FAS et al conducted a prospective observational study to evaluate whether placental thickness can be used to estimate gestational age and fetal weight in healthy singleton pregnancies. For this purpose, the authors studied 210 pregnant women in their second and third trimesters undergoing antenatal ultrasound. Gestational age was first estimated using fetal biometry (HC, BPD, AC, FL). Placental thickness was measured at the level of cord insertion, and its correlation with gestational age and fetal weight was analyzed using Pearson's coefficient, with a p-value <0.05 considered significant. The study found that the mean gestational age was 28.19 ± 6.90 weeks. The most common placental location was anterior (47.14%), followed by posterior (32.38%) and fundal (10.95%). The mean placental thickness increased from 12.96 mm at 12 weeks to 36.82 mm at 37 weeks, with the latter serving as a cutoff for distinguishing full-term from preterm gestation. A strong positive correlation was observed between placental thickness and gestational age (12–38 weeks) and fetal weight (14–37 weeks). On the basis of these findings, the authors concluded that placental thickness can serve as a reliable marker for estimating gestational age and fetal weight, particularly when fetal biometry is not entirely dependable.[9]

Ki Hoon Ahn et al conducted a retrospective study to examine the correlation between placental thickness-to-estimated fetal weight ratios on ultrasonography and the incidence of small-for-gestational-age (SGA) infants at delivery. The study involved 1,281 women, in all of whom placental thickness was measured at the umbilical cord insertion site and adjusted for fetal body weight at 18–24 weeks gestation. The researchers compared data from women who delivered SGA infants (birth weight <10th percentile) with those who delivered infants with normal birth weight. The study found that women with higher placental thickness-to-estimated fetal weight ratios were more likely to deliver SGA infants. On the basis of these findings, the authors concluded that the placental thickness-to-estimated fetal weight ratio was associated with infant body weight at delivery. The authors further suggested that this ratio (measured at midterm) could serve as an effective adjunctive screening marker for predicting SGA status.[10]

14. REFERENCES

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15. PATIENT INFORMATION SHEET

Study Title	Placental Thickness and Its Correlation with Advancing Gestational Age: A Predictive Marker for Small for Gestational Age (SGA) Fetuses
Institution	[Institution Name and Address]
Principal Investigator	[Name]
Guide	[Name]

Introduction

We invite you to participate in a research study that aims to understand if measuring the thickness of the placenta using ultrasound can help predict the growth of your baby and identify babies who might be smaller than usual during pregnancy.

Purpose of the Study

- To see if measuring placental thickness during the 2nd and 3rd trimesters helps identify babies who might be smaller than expected at birth.
- To compare placental thickness measurements with routine ultrasound measurements.
- You will undergo routine ultrasound scans during your regular antenatal visits between 18 to 23 weeks.
- During these scans, in addition to checking your baby's growth, we will measure the thickness of your placenta (the organ supplying your baby with nutrients).
- After your baby's birth, we will record your baby's birth weight, mode of delivery, and placental weight from routine hospital records.
- Your participation is completely voluntary.
- You can withdraw from the study anytime without affecting your medical care.

Who Can Participate?

- Women aged 18 years and older.
- Singleton pregnancies (one baby).
- Currently in the 2nd trimester of pregnancy.
- Willing to provide written informed consent.

Who Cannot Participate?

- Women below 18 years.
- Pregnancies complicated by severe illnesses like diabetes, high blood pressure (pre-eclampsia), or other severe medical conditions.
- Pregnancies where the baby has significant birth defects identified by ultrasound.
- Women who decline to participate or refuse consent.

Risks and Benefits

- There are no additional risks to you or your baby, as this study uses routine ultrasound examinations already performed during pregnancy.
- Participating in this study helps doctors better understand fetal growth and potentially identify babies at risk of being smaller than expected, enabling better care in the future.

Confidentiality

- Your personal details and medical information will be kept confidential and used only for research purposes.
- Your identity will not be revealed in any reports or publications.

Who can I contact if I have questions?

If you have questions about the study, please contact: Mobile Number: _____

16. CONSENT FORM

Participant ID: _____	Date of Enrollment: _____

- I understand that I am being asked to participate in a research study about measuring placental thickness during pregnancy and how it relates to my baby's growth.
- The study aims to find out if measuring placental thickness helps identify babies who might be smaller than expected at birth (small-for-gestational-age babies).
- If I agree to participate, my placenta's thickness will be measured using ultrasound during my routine antenatal scans (between 18–23 weeks).
- After delivery, information about my baby's birth weight, placenta weight, and mode of delivery will be collected from my hospital records.
- There are no extra risks or discomfort involved because ultrasound is a safe, routine procedure done during pregnancy.
- My participation is entirely voluntary, and I can withdraw at any time without affecting my medical care.
- All information collected about me will be kept confidential, and my identity will never be revealed in any report or publication.
- There are no direct personal benefits or payments from participating, but this research may help doctors better understand and care for pregnancies in the future.
- I have been given an opportunity to ask questions, and my questions have been clearly answered.
- If I have further questions, I can contact Dr. _____. Mobile number: _____

Consent Declaration

I voluntarily agree to participate in this study and allow the use of my medical information for this research.

Participant's Name: _____ Date: _____

Participant's Signature: _____

17. DATA COLLECTION FORM

Participant ID: _____	Date of Enrollment: _____

A. Demographic Information

Name	_____
Age	_____ years
Contact Information	_____

B. Obstetric History

Parity (G_P_A_L_)	_____
Last Menstrual Period (LMP)	_____
Estimated Date of Delivery (EDD)	_____
Gestational Age at Enrollment	_____ weeks / _____ days

C. Medical History

Condition	Yes	No
Diabetes Mellitus	☐	☐
Hypertension	☐	☐
Bronchial Asthma	☐	☐
Others (Specify): _____	☐	☐

D. Ultrasonographic Data (at Enrollment)

Parameter	Value
Ultrasound Date	_____
Gestational Age by Ultrasound	_____ weeks / _____ days
Biparietal Diameter (BPD)	_____ cm
Head Circumference (HC)	_____ cm
Abdominal Circumference (AC)	_____ cm
Femur Length (FL)	_____ cm
Transverse Cerebellar Diameter (TCD)	_____ cm
Estimated Fetal Weight (EFW)	_____ gm
Maximal Placental Thickness (MaxPT) at cord insertion	_____ cm

E. Delivery & Neonatal Information

Parameter	Value
Date of Delivery	_____
Gestational Age at Delivery	_____ weeks / _____ days
Mode of Delivery	NVD ☐ Assisted ☐ LSCS (Elective ☐ / Emergency ☐)
Birth Weight (grams)	_____ gm
Placental Weight (grams)	_____ gm
Neonatal Classification	AGA ☐ SGA ☐ LGA ☐

Remarks / Additional Observations:

_____

Investigator's Signature: _____ Date: _____