

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES (MUHS)

RESEARCH PROTOCOL - TITLE & SYNOPSIS

Sr. No. Item	Guidelines
01) Title :-	Placental Thickness and Its Correlation with Advancing Gestational Age: A Predictive Marker for Small for Gestational Age (SGA) Fetuses
02) Introduction :-	<p>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.</p> <p>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. Ultrasound biometry is considered gold standard for assessing fetal weight using biometric parameters including biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), and femur length (FL).</p> <p>In certain fetal pathologies, conventional biometric parameters may not reliably predict fetal weight. 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.</p> <p>Predicting small for gestational age (SGA) neonates antenatally remains challenging. Placental thickness measurement has emerged as a potentially useful parameter for identifying fetuses at risk for being SGA. Reduced placental thickness compared to gestational age norms may indicate impaired placental function and inadequate fetal growth.</p>
3.1) Primary Research Question :-	Can two-dimensional sonographic placental measurements improve the prediction of small-for-gestational-age (SGA) infants?
3.2) Secondary Research Question 1 :-	What is the individual predictive accuracy of placental thickness measurements for identifying SGA infants with birth weight below the 10th and 5th percentiles?
3.3) Secondary Research Question 2 :-	How does the predictive performance of placental thickness compare with conventional fetal biometric parameters in identifying pregnancies at risk for delivering SGA infants?

<p>4.1) Primary Hypothesis :-</p>	<p>Null Hypothesis (H₀): There is no significant relationship between placental thickness measured at 18–23 weeks of pregnancy and the incidence of small-for-gestational-age (SGA) infants.</p> <p>Alternate Hypothesis (H₁): There is a significant inverse relationship between placental thickness measured at 18–23 weeks of pregnancy and the incidence of SGA infants, with reduced placental thickness being associated with higher incidence of SGA.</p>
<p>4.2) Other Hypothesis 1 :-</p>	<p>Null Hypothesis (H₀): Combined placental thickness and biometric measurements do not provide better predictive accuracy for SGA compared to biometric measurements alone.</p> <p>Alternate Hypothesis (H₁): Combined placental thickness and biometric measurements provide superior predictive accuracy for identifying SGA infants compared to conventional biometric parameters alone.</p>
<p>4.3) Other Hypothesis 2 :-</p>	<p>Null Hypothesis (H₀): There is no significant difference in predictive performance between placental thickness measurements and conventional biometric parameters for identifying SGA pregnancies.</p> <p>Alternate Hypothesis (H₁): Placental thickness measurements demonstrate superior predictive performance compared to conventional biometric parameters alone in identifying pregnancies at risk for delivering SGA infants.</p>
<p>05) Review of Literature :-</p>	<p>Jindal M et al (2017) conducted a prospective study to evaluate the role of two-dimensional ultrasonographic placental measurements in predicting small for gestational age (SGA) fetuses. The study found that both MaxPD and MPD were significantly smaller in SGA pregnancies ($p \leq 0.001$). The ROC curve for combined placental biometry had the maximum area under the curve (0.805), indicating strong predictive value. The authors concluded that placental measurements taken in mid-gestation are valuable predictors of SGA.</p> <p>Vachon-Marceau C et al (2017) conducted a prospective cohort study assessing the link between first-trimester placental thickness and the risk of preeclampsia or SGA neonates. 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; $p = 0.06$). The authors concluded that increased placental thickness is linked to preeclampsia, while decreased thickness is associated with SGA.</p> <p>Sovio U et al (2014) studied 3,920 nulliparous women, measuring placental thickness via ultrasound at 10–14 weeks. Higher placental thickness was linked to a lower risk of SGA-pop infants (OR = 0.80, $p = 0.01$). The authors concluded that increased placental thickness in the first trimester is associated with lower SGA risk but mainly reflects normal birth weight variation.</p>

	<p>Omer Ahmed FAS et al (2023) studied 210 pregnant women in their second and third trimesters. The mean placental thickness increased from 12.96 mm at 12 weeks to 36.82 mm at 37 weeks. A strong positive correlation was observed between placental thickness and gestational age (12–38 weeks) and fetal weight (14–37 weeks). The authors concluded that placental thickness can serve as a reliable marker for estimating gestational age and fetal weight.</p> <p>Ki Hoon Ahn et al (2017) conducted a retrospective study involving 1,281 women examining the correlation between placental thickness-to-estimated fetal weight ratios and SGA incidence. Women with higher placental thickness-to-estimated fetal weight ratios were more likely to deliver SGA infants. The authors suggested that this ratio measured at midterm could serve as an effective adjunctive screening marker for predicting SGA status.</p>
<p>6.1) Primary Objectives :-</p>	<p>To determine the relationship between placental thickness at 18–23 weeks of pregnancy and biometric parameters with the incidence of SGA infants.</p>
<p>6.2) Other Objectives 1 :-</p>	<p>To assess the individual and combined predictive accuracy of placental measurements and biometry for SGA <10th and <5th percentile birth weights.</p>
<p>6.3) Other Objectives 2 :-</p>	<p>To compare the predictive performance of placental thickness and biometry in identifying pregnancies at risk for SGA.</p>
<p>07) Methodology :-</p>	<p>Study Design: Prospective Observational Study Study Duration: 24 Months (May 2026 to April 2028) Sample Size: 200 Participants</p> <p><u>INCLUSION CRITERIA:</u></p> <ul style="list-style-type: none"> ✓ 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 <p><u>EXCLUSION CRITERIA:</u></p> <ul style="list-style-type: none"> ✗ Age less than 18 years ✗ Refusal to give informed and written consent ✗ Women with gestational diabetes, pre-eclampsia, severe systemic illnesses ✗ Fetus having major congenital anomalies

X Post-term pregnancies (> 42 weeks of gestation)

SAMPLE SIZE CALCULATION:

Formula: $N = (Z\alpha^2) \times \sigma^2 / d^2$

Based on pilot studies assuming 90% power and 95% confidence interval:

- $Z\alpha = 1.96$ (Statistical constant)
- $SD = 0.2$ (Expected Standard Deviation)
- Precision = 0.0277

Minimum Required Sample Size (N) = 200

STUDY PROCEDURE:

Singleton live pregnancy patients attending OBGY OPD for routine antenatal visit will be included based on predefined inclusion and exclusion criteria. A detailed history will be taken regarding last menstrual period (LMP), gestational age, and co-morbid systemic illnesses.

Ultrasonographic Parameters Recorded:

- 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, gestational age at delivery, mode of delivery, neonatal birth weight and placental weight will be collected. Neonates will be classified as:

- 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

STATISTICAL ANALYSIS:

Software: SPSS version 21.0

- Quantitative data: Mean \pm Standard Deviation (SD)
- Qualitative data: Frequencies and Percentages
- Comparison of quantitative variables: One-way ANOVA + Bonferroni post-hoc correction
- Correlation analysis: Pearson's Correlation Coefficient
- Categorical variables: Chi-square test / Fisher's exact test
- **Statistical Significance: p-value < 0.05**

	<p><u>ETHICAL CONSIDERATIONS:</u></p> <ul style="list-style-type: none"> • Study will be initiated only after obtaining prior approval from the Institutional Ethics Committee (IEC) • Confidentiality and privacy will be strictly protected • All data will be anonymized prior to analysis and publication • All procedures will be conducted as part of routine antenatal care • This research is investigator-initiated with no external funding
<p>08) Reference Style :-</p>	<p>AMA / Vancouver Style (Numbered sequential citation with DOI where available)</p> <p>Example References:</p> <ol style="list-style-type: none"> 1. Jindal M, Gupta S. Fetal placental biometry for prediction of small for gestational age fetuses in low resource setting. Int J Reprod Contracept Obstet Gynecol. 2017;6:5266-71. 2. Vachon-Marceau C, Demers S, Markey S, et al. First-trimester placental thickness and the risk of preeclampsia or SGA. Placenta. 2017;57:123-128. doi: 10.1016/j.placenta.2017.06.016. 3. Ahn KH, Lee JH, Cho GJ, et al. Placental thickness-to-estimated fetal weight ratios and small-for-gestational-age infants at delivery. J Obstet Gynaecol. 2017;37(7):883-887. doi: 10.1080/01443615.2017.1312306.
<p>09) Timeline / Gantt Chart :-</p>	<p>Total Study Duration: 24 Months (May 2026 to April 2028)</p> <p>Months 1-2 (May-Jun 2026): Protocol finalization, IEC approval submission and acquisition, literature review completion</p> <p>Months 3-18 (Jul 2026 - Oct 2027): Patient recruitment, data collection, ultrasound examinations at 18-23 weeks, follow-up till delivery</p> <p>Months 19-21 (Nov 2027 - Jan 2028): Data compilation, database management, statistical analysis, results interpretation</p> <p>Months 22-24 (Feb - Apr 2028): Thesis writing, review and corrections, final submission, manuscript preparation for journal publication</p> <p>Detailed Gantt Chart: Please refer to Annexure VI (separate landscape page).</p>
<p>10) Annexures :-</p>	<p>The following documents are attached as annexures:</p> <p>Annexure I: Patient Information Sheet</p> <p>Annexure II: Informed Consent Form</p> <p>Annexure III: Data Collection Form / Case Record Form (CRF)</p> <p>Annexure IV: IEC Approval Letter (to be obtained)</p> <p>Annexure V: Plagiarism Report / Originality Certificate</p> <p>Annexure VI: Detailed Gantt Chart (Landscape Format)</p>

ANNEXURE I

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.

WHAT WILL HAPPEN IF YOU PARTICIPATE

- You will undergo routine ultrasound scans during your regular antenatal visits between 18 to 23 weeks of pregnancy.
- 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 (18-23 weeks)
- Willing to provide written informed consent

WHO CANNOT PARTICIPATE?

- Women below 18 years of age
- 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:

Name: _____

Mobile Number: _____

ANNEXURE II
INFORMED 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: _____

WITNESS DECLARATION

Witness Name: _____

Date: _____

Witness Signature: _____

INVESTIGATOR'S DECLARATION

I confirm that I have explained the nature, purpose, and procedures of this study to the participant.

Investigator's Name: _____

Date: _____

Investigator's Signature: _____

ANNEXURE III

DATA COLLECTION FORM / CASE RECORD FORM (CRF)

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	<input type="checkbox"/>	<input type="checkbox"/>
Hypertension	<input type="checkbox"/>	<input type="checkbox"/>
Bronchial Asthma	<input type="checkbox"/>	<input type="checkbox"/>
Others (Specify): _____	<input type="checkbox"/>	<input type="checkbox"/>

D. ULTRASONOGRAPHIC DATA (AT ENROLLMENT)

Ultrasound Date	_____
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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) - grams	_____
Maximal Placental Thickness (MaxPT) at cord insertion - cm	_____

E. DELIVERY & NEONATAL INFORMATION

Date of Delivery	_____
Gestational Age at Delivery (weeks/days)	_____
Mode of Delivery: NVD <input type="checkbox"/> Assisted <input type="checkbox"/> LSCS (Elective <input type="checkbox"/> / Emergency <input type="checkbox"/>)	_____
Birth Weight (grams)	_____
Placental Weight (grams)	_____
Neonatal Classification: AGA <input type="checkbox"/> SGA <input type="checkbox"/> LGA <input type="checkbox"/>	_____

Remarks / Additional Observations:

Investigator's Signature: _____ Date: _____