

MATERIALS AND METHODS

MATERIALS AND METHODS

Type of study:

An analytical epidemiological study was carried out to determine the different ultrasonographic interpretations concerned.

Study Design:

The present study was a cross sectional hospital based one conducted to determine the different parameters of the fetus.

Study Duration:

The study was conducted during the period of three and a half years from September 2005 to February 2009.

Study setting:

The study was done in the department of Anatomy in collaboration with the Department of Radiodiagnosis of North Bengal Medical college and Hospital, Sushrutanagar, Dist. Darjeeling; the only medical teaching institution in the northern part of West Bengal.

Study population:

The subset of antenatal mothers attending the Department of Radiodiagnosis of North Bengal Medical College and Hospital for assessment of their feto-placental profile.

Sampling:

The study was carried out throughout the span of three years and six months from September 2005 to February 2009. All the

subjects were chosen from the antenatal mothers attending the Department of Radiodiagnosis for ultrasonographic fetoplacental profile and having the OPD ticket along with documented 1st trimester CRL (Crown Rump Length) in previous ultrasonography report. Study subjects were selected according to the inclusion and exclusion criteria mentioned later on.

The data collection was carried out through five days span of every week i.e. from Monday to Friday, mostly from 12noon to 3 pm excluding the Government holidays and the days of leave of the investigator.

The subject who has been examined once was never repeated for participation in this study.

Maintaining the criteria of inclusion and exclusion at first 1002 antenatal mothers were approached for this study but unfortunately 63 of them denied for participation. So, finally 939 subjects included in this study.

Study Plan:

At first on the month of January 2005, the study was planned to be done. It was discussed with the then Head of the Department of Anatomy and Head of the Department of Radio diagnosis of North Bengal Medical College & Hospital and feasibility of the study was judged by a trial in the Department of Radiodiagnosis and according to the consultation of them a proforma was prepared. After that, the study proposal was submitted to the Faculty Council for Post Graduate studies in

Science & Medicine of University of North Bengal for their final approval which was sanctioned in the month of August' 2005.

After that it was placed to obtain the permission from the Chairman of Ethical Committee of north Bengal Medical College & Hospital and with the permission of Head of the Department of Anatomy and Radiodiagnosis data collection started.

Eligibility of the study population.

A. Inclusion Criteria:

1. Pregnancy having 24 weeks onwards.
2. Having documented 1st trimester CRL.
3. Uneventful pregnancy till date or without any bad obstetric history.
4. Given informed consent.

B. Exclusion Criteria:

1. Having no documented 1st trimester CRL.
2. High risk pregnancy or in emergency crisis.
3. Documented or reported any associated disorders (medical/surgical) of the mother.
4. Documented any fetal anomaly.
5. Not given the consent.

Data collection:

For data collection same machine, same probe and same observer maintained throughout the study period. In all the measurements average of three values were considered.

Tools:

1. Ultrasonography machine: Agilent Image Point Hx.

Company: H.P (Hewlett- Packard)

Model: Image Point Hx.

Serial NO.US99602612.

Screen size=14inches.



Ultrasonography Machine

Probe (Transducer): 3.5 MHz curvilinear electronic Transducer.

No.c3540.

Company: H.P (Hewlett- Packard)



Ultrasonography Probe

2. Ultrasound Gel: The gel is prepared using the following ingredients:

Carbomer ----- 10.0 gm
EDTA -----0.25 gm
Propylene Glycol -----75.0 gm
Trolamine -----12.5 gm
Distilled water ----- up to 500ml

'Medigold' ultrasound gel was used.



Ultrasound Gel

3. Predesigned proforma.

4. Pen, Pencil and eraser.

5. Digital camera: SAMSUNG, 7.2 Mega Pixels.

6. Computer: HP Pavilion, Pentium 4

Technique of data collection:

Patient was examined in the presence of a nursing staff. Transabdominal ultrasonography was done in optimally distended bladder. Ultrasound Gel was applied over the abdomen prior to probe placement and then sonography was performed.



Ultrasonography being performed for fetoplacental profile

After assessing the fetal number, viability, lie, presentation and fetoplacental anomaly, subjects were selected finally. Then Biparietal diameter (BPD), Head circumference (HC), Abdominal circumference (AC), Femoral length (FL) and Fetal kidney length (FKL) were measured to assess the gestational age.



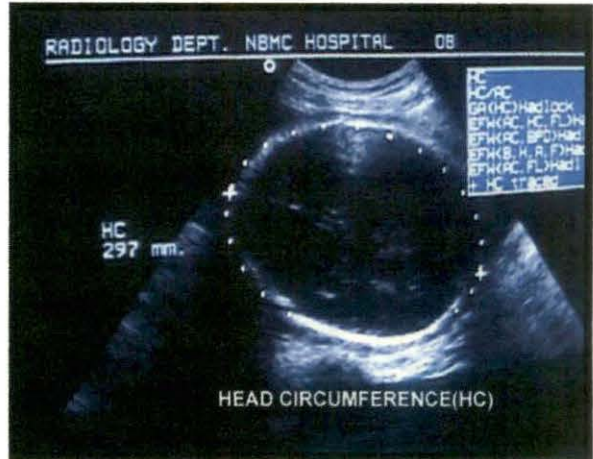
A fetus in the womb, viewed on ultrasonogram.
SP = Spine, PL= Placenta

Biparietal diameter (BPD) was measured from the transaxial sonogram of fetal head at the level of paired thalami and cavum septum pallucidum. BPD was measured from the outer edge of the cranium nearest the transducer to the inner edge of the cranium farthest from the transducer. Distance between these two points was defined as BPD and was expressed in millimeter (mm).



Sonographic measurement of fetal Biparietal diameter

With the help of electronic ellipse available in ultrasound scanner the cranial circumference was also measured at the same level of measurement of BPD which was defined as **Head circumference (HC)** and was expressed in millimeter (mm).



Sonographic measurement of fetal Head circumference

Abdominal circumference (AC) was obtained by placing electronic calipers at the outer perimeter of the fetal abdomen measured on transverse scan at the level of stomach and intrahepatic portion of umbilical vein. This measurement of **AC** was expressed in millimeter (mm).



Sonographic measurement of fetal Abdominal circumference

For the purpose of measurement of **Femoral length (FL)**, fetal spine was traced up to the sacrum and transducer moved to image femur. The length of entire femur was measured by placing electronic calipers at two ends of the femur excluding the thin bright reflection of cartilaginous epiphysis. This measurement of FL was expressed in millimeter (mm).



Sonographic measurement of fetal Femoral length

Last of all, it was approached to document the **Fetal kidney length (FKL)**. At first the transducer (probe) was placed in such manner that the longitudinal view of the fetal spine becomes prominent. Then the probe was moved along paravertebral plane until the long axis of fetal kidney was visualized. At first the left kidney was approached and in case its view was not clear, the right kidney was approached. The kidney lies lateral to the spine and dorsolateral to the abdominal great vessels. With the use of caliper first point



Sonographic measurement of Fetal kidney length

was taken on the outer most point on the proximal curved border and the second point was taken on outer most point on the distal most curved border along the long axis of the kidney. The distance of these two points was noted in millimeter (mm).

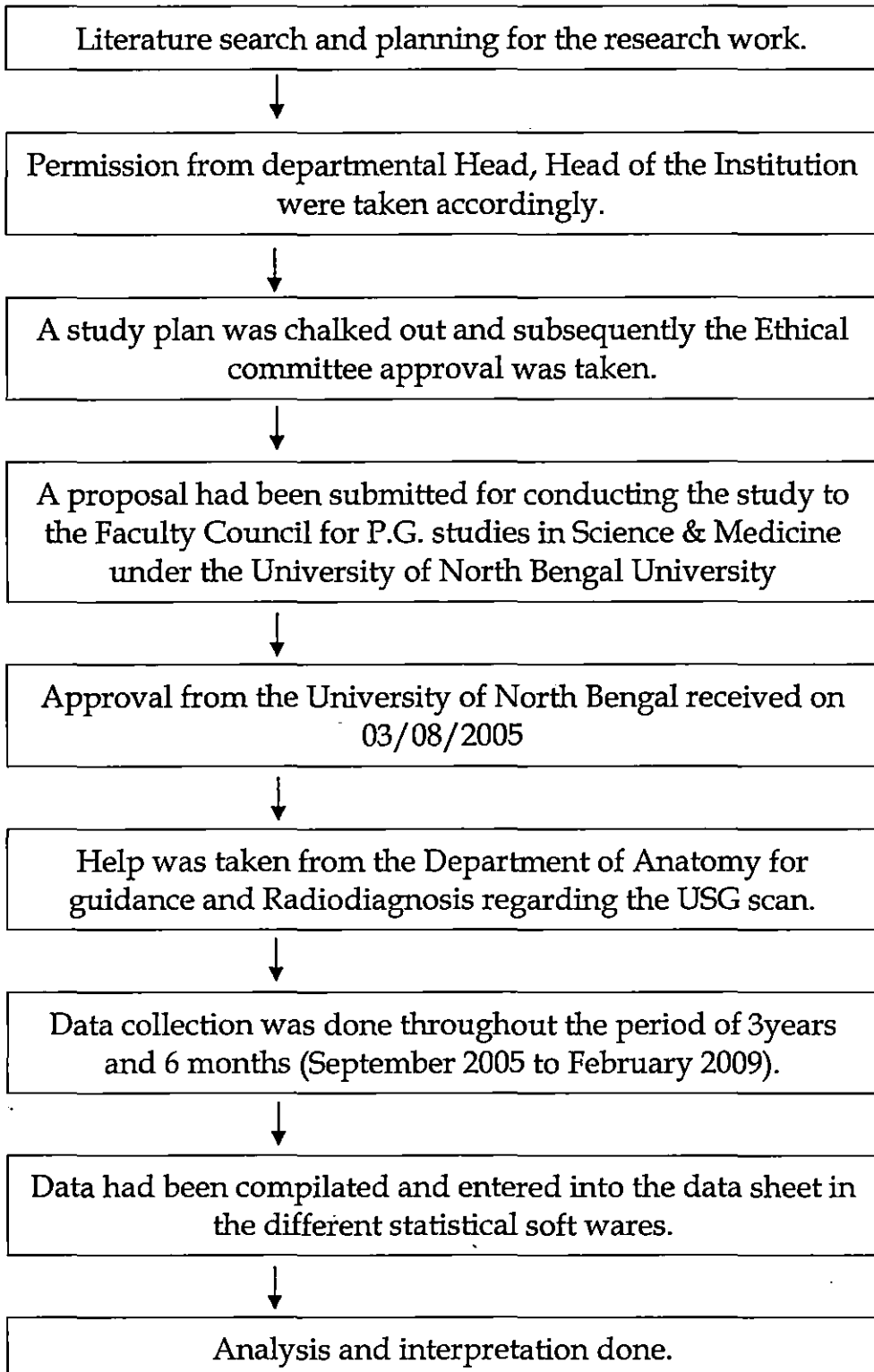
Variables used:

1. **Age of the mother:** Age of the mother was noted in completed years.
2. **Gravida:** Noted as the times of conception. Subjects were classified as “primi” having first time conception and “multi” those have conceived more than once.
3. **Biparietal diameter (BPD):** The fetal Biparietal diameter noted in millimeter(mm), as measured from ultrasonogram.
4. **Head circumferences (HC):** The fetal Head circumferences noted in millimeter(mm), as measured from ultrasonogram.
5. **Abdominal circumference (AC):** The fetal Abdominal circumference noted in millimeter (mm), as measured from ultrasonogram.
6. **Femoral Length (FL):** The fetal Femoral Length noted in millimeter (mm), as measured from ultrasonogram.
7. **Fetal kidney length:** Fetal kidney length noted in millimeter (mm), as measured from ultrasonogram.
8. **Gestational age:** Gestational age was calculated as per pre-existing documented first trimester CRL (Crown Rump Length) and noted in weeks.

Scheme of analysis:

These data were noted on the space schedule in the master sheet previously made ready. Variables were explored and analysed using appropriate statistical methods. The data those entered in Excel data sheet were compiled and converted to different codes and finally analysed by using the Epi-info 3.5.1 and SPSS (Stastical Package for Social Science) 12 version. Various parametric and non-parametric statistical analysis methods were used like Students T test, Chi-square test, Regression analysis and other suitable methods where applicable accordingly.

FLOW CHART SHOWING DIFFERENT STAGES OF THE STUDY:



Limitations of study:

1. The machine used for this study shows measurement of fetal biometric parameters in centimeter and its fractions. So, during data tabulation the first decimal of the fraction of a centimeter was taken into consideration for the purpose of expression of the data in millimeters.
2. All measurements though taken as average of 3 values but definitely not beyond subjective error.
3. The data collected and analysed in this study was solely dependent on antenatal mothers of a particular region i.e. North Bengal zone of India. To generalise the findings there is a strong need to conduct the study among the representative population of wide area and should not be confined in a particular region.
4. Intra-observer variations also could not be eliminated.