DETERMINING BEST REGRESSIONAL MODEL IN PREDICTING FOETAL WEIGHT IN PHILIPS ClearVue 350 ULTRASOUND EQUIPMENT

BY

EDEM ANASTASIUS KWAMI BUAHY
(10434064)

A DISSERTATION SUBMITTED TO THE, UNIVERSITY OF GHANA, LEGON IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF MSc ULTRASONOGRAPHY DEGREE

JULY, 2014
DECLARATION

I EDEM ANASTASIUS KWAMI BUADY do hereby declare that this thesis which is being submitted in fulfillment of the requirements for the Master degree of MSc in Ultrasonography is the result of my own research performed under supervision, and that except where otherwise other sources are acknowledged and duly referenced, this work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree. I hereby give permission for the Department of Radiography to seek dissemination/publication of the dissertation in any appropriate format. Authorship in such circumstances to be jointly held between me as the first author and the project supervisors as subsequent authors.

Signed ………………………………………. Date……………………

EDEM ANASTASIUS KWAMI BUADY
(Student ID No.10434063)

Signed ………………………………………. Date……………………

DR. SAMUEL OPOKU

Signed ………………………………………. Date……………………

DR. S. ANIM-SAMPONG

Signed ………………………………………. Date……………………

DR. SAMUEL OPOKU
(Head of Department)
DEDICATIONS

But for the protection of the Almighty God, this work would have been an impossible task. I therefore dedicate this write up to the Almighty God for his wisdom, knowledge, understanding, and guidance.

Consequently, dedication of this work is extended to my ever-loving mother Mrs. Janet Yawa Komla-Buady and father Anthony Kwaku Buady who even in your sickbeds demonstrated a lot of support, encouragement and love to me but as nature has it, you have all pass on to glory. May the Almighty god protect you under his strong wing: Mum and Dad, I miss you all dearly.
ACKNOWLEDGEMENT

Firstly, I would like to acknowledge the almighty God for his immense grace towards this dissertation. My immense appreciation goes to the under mentioned personalities who helped in diverse ways to ensure the success of this work.

Dr. S.Y. Opoku, Mr. K. Bamfo-Quaicoe, Dr. E.K. Ofori, Mr. W.K. Antwi, Mr. Sulley, Mr. B.O..Botwe, Mr L. Arthur all of Department of Radiographer, School of Biomedical and Allied Health Sciences for their incalculable intellectual contributions throughout the thesis process. I would also like to thank Dr. V.K. Hewlett for his time and contribution towards this research work. Finally, Dr. S. Anim-Sampongis highly acknowledged for his tireless effort in bringing this dissertation to the successful end.

I also appreciate the cooperation of all the staff of Ussher and Mamprobi Polyclinics’ ultrasound and maternity units. To the departments of Radiography and Audiology, School of Allied Health Sciences, College of Health Sciences of the University of Ghana, I want to render many thanks for your diverse contribution for this study. In respect of their friendship and encouragement towards the completion of the thesis, I thank my course mates, Mr. Ampofo, Richard, Seth, Jonathan (Kamkpee) and Eric Saka-Boateng (Sharpest) for their advice, support and prayers.

And finally to my family and friends, especially my brother Senyo and Nana Akua Adubea your care and support in physical and financially has been really appreciated. Thanks for your unceasing love, encouragement and emotional support.
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BPD</td>
<td>Biparietal diameter</td>
</tr>
<tr>
<td>HC</td>
<td>Head circumference</td>
</tr>
<tr>
<td>AC</td>
<td>Abdominal circumference</td>
</tr>
<tr>
<td>FL</td>
<td>Femur length</td>
</tr>
<tr>
<td>AD</td>
<td>Abdominal diameter</td>
</tr>
<tr>
<td>FTA</td>
<td>Foetal trunk area</td>
</tr>
<tr>
<td>APTD</td>
<td>Anterior posterior trunk diametre</td>
</tr>
<tr>
<td>TTD</td>
<td>Trans-thoracic diametre</td>
</tr>
<tr>
<td>BW</td>
<td>Birth weight</td>
</tr>
<tr>
<td>ABW</td>
<td>Actual birth weight</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>USG</td>
<td>Ultrasonography</td>
</tr>
<tr>
<td>EFW</td>
<td>Estimated foetal weight</td>
</tr>
<tr>
<td>IUEFW</td>
<td>Intrauterine estimated foetal weight</td>
</tr>
<tr>
<td>OAUTHC</td>
<td>Obafemi Awolowo University Teaching Hospital Complex</td>
</tr>
<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>PPW</td>
<td>Pre-pregnancy weight</td>
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ABSTRACT

Background: Earlier investigations have demonstrated that the accuracy of foetal weight estimation is significantly higher if several ultrasonic foetal parameters are measured, because the total body mass depends on the size of foetal head, abdominal circumference and femur length.

Aim: This study aimed to determine the best ultrasound regression models that use the common foetal biometric measurements in predicting foetal weight for normal singleton pregnancies in ClearVue 350 ultrasound equipment, and also assess the effects of few maternal anthropometric variables on estimated foetal weight in the Greater Accra Metropolis.

Methodology: The study was quantitative, cross-sectional and quasi-experimental in nature and was carried out prospectively in which convenient sampling method was used. Forty (40) participants were scanned in the study. Foetal biparietal diameter, head circumference, abdominal circumference and femur length measurements were measured according to the established guidelines. Microsoft Excel and IBM SPSS soft-wares were used for data analysis.

Results: The study demonstrated that, all eight regression models showed no statistically significant difference with (p-value <0.05) at 95% confidence interval of their mean foetal weight estimates compared to the actual birth weight of the neonates. The mean and standard deviations were similar across the eight models.

Conclusion: Findings from this study showed that, the best regressional model is Hadlock3 model. The study further revealed that, with 87% of estimated foetal weights which were within 5% of actual birth weights, demonstrate strong correlation between EFWs and ABWs, therefore (radiologists, sonographers/radiographers)on one side and (gynaecologists, midwives) on the other side can (to a high degree) rely on estimated foetal weights generated from Philips
CleaVue350 ultrasound equipment using the common foetal biometric measurements in a 2D mode to generate meaningful reports and make important decisions such as mode of delivery respectively.
CHAPTER ONE
INTRODUCTION

1.1 BACKGROUND

Prenatal or antenatal development is the process in which a human embryo or foetus gestates during pregnancy, from fertilization until birth (Shukla, 2012). The term embryo is used to describe the developing offspring during the first 8 weeks following conception, and the term foetus is used from about 2 months of development until birth Shukla (2012).

After fertilization the embryogenesis starts. In humans, when embryogenesis finishes, by the end of the 10th week of gestational age, the precursors of all the major organs of the body have been formed and the following period, which is the foetal period, is described both topically on one hand that is by organ, and strictly chronologically on the other, by a list of major occurrences by weeks of gestational age Shukla (2012). Rapid growth occurs and the embryo's main external features begin to take form in a process called differentiation, which produces the varied cell types (such as blood cells, kidney cells, and nerve cells). At 10th week, embryo measures 30–80 millimeters in length with facial features continuing to develop that is, eyelids are more developed, head comprises nearly half of the foetus' size, the face is well formed, the limbs are long and thin, the foetus can make a fist with its fingers and genitals appear well differentiated (Shukla, 2012). It is these well-developed external features or specific parts of a foetus like the limbs, head and trunk which are measured and are known as foetal biometry.

Growth rate of foetus is linear up to 37 weeks of gestation, after which it plateaus (Daftary and Chakravarti 2011). The growth rate of an embryo and infant can be reflected as the weight per gestational age, and is often given as the weight put in relation to what would be expected by the
gestational age. Neonate within the normal range of weight for that gestational age is known as appropriate for gestational age (AGA). Those that have large or small range of weights are known as large for gestational age (LGA) and small for gestational age (SGA) respectively.

According to literature (Oken et al., 2003; NahlaSubhi et al., 2010), birth weight (BW) is a composite of foetal growth and length of gestation, each of which has different contributions and different sequel. The absence of the contribution of gestational age to BW is the first step in understanding the determinants of foetal growth. Sonographic estimated foetal weight (EFW) is a foetal biometry parameter whose calculation is based on four common foetal biometric measurements, that is, biparietal diameter (BPD), head circumference (HC), femur length (FL), abdominal circumference (AC).

Inaccuracies with EFW have been reported in several literature. In particular, it has been reported in the published literature (Colman et al., 2006; Scioscia et al., 2008) of the existence of considerable differences between the sonographic EFW and the actual birth weight ABW with a mean error of 7% to 10%, even under ideal sonographic conditions. However, despite its inaccuracies EFW has been used in clinical decisions for over thirty years (Dudley, 2005; Ben-Haroush et al., 2004). In the search to improve the ability to accurately predict BW from sonographic EFW, multiple EFW formulae have been published, but limited data exist on their comparative accuracies, and considerable variation in the EFWs occurs with different formulae using the same foetal biometric measurements (Burd et al., 2009).

Again, according to Burd et al., (2009), the large number of published EFW formulae provides clear evidence that none of them are universally accepted and unfortunately, the error of
sonographic EFW appears to be greatest at the two ends of the weight scale with most EFW formulae, having low and high BWs are overestimated and underestimated respectively (Baker et al., 1994).

During the last decade, EFW has been incorporated into the standard routine antepartum evaluation of high-risk pregnancies and deliveries (Shittu et al., 2007). For instance, management of diabetic pregnancy, vaginal birth after a previous caesarean section, and intrapartum management of foetuses with breech presentations will be greatly influenced by EFW (Sherman et al., 1998; Chauhan et al., 1998). Furthermore, in dealing with anticipated preterm delivery, prenatal counseling on likelihood of survival, the intervention undertaken to postpone preterm delivery, optimal route of delivery, or the level of the hospital where delivery should occur may be based wholly or in part on the estimation of expected BW (Shittu et al., 2007). Categorization of foetal weight into either small or large for gestational age may lead to timed obstetric interventions that collectively represent significant departure from routine antenatal care (Chauhan et al., 1998; Nzeh et al., 2000; Hanretty et al., 1990; Hendrix et al., 2000).

Previous studies have shown that the accuracy of EFW is significantly higher if several ultrasonic foetal parameters are measured. This is because the total body mass depends on the size of foetal head, abdominal circumference and femur length (Mladenović-Segedi et al., 2005). In affirmation of this observation, Chien et al., (2000) validated 4 different formulae and concluded that ultrasonic EFW at term with all the four formulae was high.
Ultrasound examination and measurements of foetal biometry have become integral to modern obstetric care and thus provide avenues for dating pregnancies or for assessment of foetal growth (Leung et al., 2008). The selection of appropriate cross-sectional reference charts is of great importance to ensuring accurate diagnosis, although some published reference charts are methodologically flawed (Leung et al., 2008). Some common associated problems include repeated measurements on the same foetuses, formation of ‘super normal’ datasets by inappropriate exclusion of complicated pregnancies, failure to identify the statistical method of analysis, and the use of statistical methods which in the opinion of Altman et al., (1994) do not consider the variability of measurements with gestational age. Consequent to this, appropriate methodologies have been published (Altman et al., 1994; Royston et al., 1998), and mathematical equations and foetal biometric charts for various populations using the correct approaches are now available in the medical literature (Chitty et al., 1994; Kurmanavicius et al., 1999; Salomon et al., 2006).

1.2 PROBLEM STATEMENT

The influence of ethnicity or race on foetal biometry has been firmly established and widely published in literature (Yeo et al., 1994; Jacquemyn et al., 2000). Leung et al., (2008) established that, Hong Kong Chinese have similar reference chart as Singaporeans for all biometric measurements but differs greatly in biometric measurement with those of UK and France with respect to femur length (FL).

Several variables including ethnicity are incorporated in developing regression models for global use in ultrasound foetal biometry. However, these plethora of regression models are mostly
based on Western and European populations which might not be representative of Ghanaian’s, and thus create opportunities for deviations and errors in ultrasound foetal biometry using Philips ClearVue 350 ultrasound equipment.

Presently, there is no specific well documented evidence of regressional models of combined biometric measurements for EFW in Ghana. Thus the use of these regressional models based on Western and European populations on Ghana’s obviously presents a challenge in EFW biometry. In particular, the absence of knowledge of precise foetal weights presents additional problems of unnecessary caesarean sections and its associated complications, limit women from their preferred choice of number of children, and perturb critical interventions in cases of macrosomia and breech presentation.

Furthermore, anecdotal report has shown that enormous complaints from midwives about inconsistencies of gestational age with respect to EFW, huge gaps between approximate ABW and EFW, and the prolonged duration of EFW given at a particular date and onset of labor of an expectant mother have been reported in Mamprobi Polyclinic. These problems may have arisen from ultrasound foetal biometry using regression models unrepresentative in Ghana or due to operator inexperience.

Aside these challenges, the Ghana government through the health agencies (Ministry of Health and Ghana Health Service) has begun nationwide programme of equipping all polyclinics and district hospitals with Philips ClearVue 350 ultrasound equipment. It is known that the regressional model used in this equipment does not provide for variations of race influences in foetal biometrics. It is therefore imperative to determine regression model based on common biometric measurements most suitable for the Ghanaian population and minimize the stated problems above.
1.3 RESEARCH QUESTION/HYPOTHESES

1.3.1 Research Question: What is the best regression model(s) from Philips ClearVue 350 ultrasound equipment, using common biometric measurements in establishing EFW in utero in Greater Accra Metropolis?

1.3.2 Hypothesis:

Null Hypothesis $H_0$: There will be no significant difference between EFWs and ABWs.

Alternative Hypothesis $H_1$: There will be significant difference between EFWs and ABWs.

1.4 SIGNIFICANCE OF STUDY

Generally, simple and accurate methods of estimating intrauterine foetal weight that can be easily applied to all pregnancies are important means of reducing prenatal mortality and morbidity. These are done through early detection of faltering growth and also in managing breech presentation, macrosomia and intrauterine growth retardation at term by gynaecologists and midwives.

To buttress the point above, several investigations have shown that low EFW is associated with high prenatal mortality and morbidity according to (Mavalankar et al., 1991). Therefore, importantly, knowing the weight of a foetus and with other examinations like umbilical Doppler and laboratory tests can help clinicians significantly reduce the occurrences of prenatal morbidity, mortality and maternal deaths in some cases.
1.5 AIMS

The aim of this research study is to determine the best ultrasound regression model that uses the common foetal biometric measurements in predicting foetal weight for normal singleton pregnancies with ClearVue 350 ultrasound equipment, and also assess the effects of some few maternal anthropometric variables on EFW in the Greater Accra Metropolis.

1.6 OBJECTIVES

To determine EFWs of foetuses.

To determine ABWs of neonates.

To compare EFWs to ABWs.

To obtain records of maternal anthropometrics (height and weight) from the time of visiting antenatal for the first time and weight at the last antenatal visit.
CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

Before and after the introduction of ultrasound into obstetric work, some forms of assessing EFW were carried out globally. Earlier assessments were purely via physical examination of maternal and foetus. After the advent of ultrasound equipment, others were performed physically, in combination with ultrasonic measurements when EFW formulae were not incorporated in ultrasound equipment.

2.2 HISTORICAL REVIEW OF ESTIMATING FOETAL WEIGHT

About four decades ago, Campbell and Wilkin assessed BW prediction of foetuses, using abdominal circumference only, by ultrasonic means. This measurement showed that:

1. Accuracy of predictions varied with the size of the foetus.
2. The predicted BW and the ABW were not comparable.

For instance, at a predicted weight of 1 kg, 95% of BWs fell within 160 g, while at 2 kg, 3 kg and 4 kg, the corresponding values were 290 g, 450 g and 590 g respectively. However, according to Kearney et al., (1978), inclusion of abdominal circumference in determination of EFW cannot be overemphasized as it presents a higher percentage value for predicting BW.

To date, a lot of mathematical formulae as noted in the literature have been deduced to narrow the range of foetal weight estimation. Therefore, there is a strong evidence base of using more
than two biometric measurements to obtain accurate EFWs which will lead to the common methods in estimating foetal weight sonographically.

2.3 TACTILE ASSESSMENT OF FOETAL SIZE

Dare et al., (1990) used the tactile assessment, which is the oldest technique for assessing foetal weight. This is done via manual assessment of foetal size by obstetricians and midwives worldwide, i.e. by external palpation of the uterus and foetal parts. This method is extensively used because it is both convenient and virtually costless. However, it has long been known as a subjective method that is associated with significant predictive errors (Shittu et al., 2007). According Bossak et al., (1972), it is both patient- and clinician-dependent for its success (less accurate for obese gravidas than non-obese and significant inter-observer variation in prediction of BW even among experienced clinicians).

Maternal self-estimation of foetal weight in multiparous women shows comparable accuracy to clinical palpation in some studies for predicting abnormally large foetuses (Chauhan et al., 1992; Chauhan et al., 1998). According to Shittu et al. (2007), various calculations and formulae based on measuring uterine fundal height above symphysis pubis have been developed. For example, Ojwang et al., (1984) used the product of symphysio-fundal height and abdominal girth measurement at various levels in centimeters above the symphysis pubis in obtaining a fairly acceptable predictive value but with considerable variation from the mean. To further simplify this method, Dare et al., (1990) in OAUTHC, Ile-Ife, used the product of symphysio-fundal height and abdominal girth at the level of the umbilicus measured in centimeters and expressed the result in grams to obtain the EFW at term in-utero. The EFW correlated well with BWs.

The Johnson's formula for EFW weight in vertex presentation defined as:
\[ EFW(g) = 155nFH \]  

Where \( FH \) = fundal height, and \( n \) = \[\begin{cases} 11, & \text{vertex below ischial spine} \\ 12, & \text{vertex above ischial spine} \end{cases}\]  

If a patient weighs more than 91 kg, 1 cm is subtracted from the FH (Shittu et al., 2007).

### 2.4 FOETAL WEIGHT PREDICTIONS USING ALGORITHM DERIVED FROM MATERNAL AND PREGNANCY-SPECIFIC CHARACTERISTICS

According to Shittu et al., (2007) again, a new theoretically-defensible equation capable of predicting BWs prospectively from maternal characteristics was developed. To do this, the efficacy of 59 scientifically-justifiable terms was evaluated simultaneously, obviating any confounding co-variation and determining which of the predictions could account for variation in BW that others could not. Aside maternal race, only six maternal and pregnancy-specific variables were important in prediction of BW for otherwise normal gravidas. Using these routinely-recorded variables, an equation based on maternal demographic and pregnancy-related characteristics alone was developed to help predict BW as shown by Nahum (2003).

\[ BW(g) = d [9.36 + 0.262f_g + 0.000237\ H_mW_m + (4.81\ W_{Rm}(p + 1)] \]  

Where \( d \) = gestational age, \( f_g \) = fetal gender, \( H_m \) = maternal height, \( W_m \) = maternal weight measured at 26 weeks, \( W_{Rm} \) = maternal weight gain rate (\( W_m/d \)), \( p \) = parity. From the definition of variables, equation 2.3 can be re-written as

\[ BW(g) = d[9.36 + 0.262f_g + 0.000237\ H_mW_m + (4.81\ W_m/d (p + 1)] \]
As obesity is linked to weight gain, Nahum et al., (1995) earlier demonstrated that the effect of maternal obesity on foetal weight gain at term is small and not clinically significant. The study also shows that, foetal weight gain was only 0.6g per day greater for obese pregnant women than for those of normal weight for height and male foetuses gained weight 0.5g per day faster than females. Therefore, it presupposes that the incorporation of maternal weight gain rate into Nahum’s equation is of no significance.

2.5 OBSTETRIC ULTRASONOGRAPHY IN ESTIMATING FOETAL WEIGHT

The modern method for assessing foetal weight involves the use of foetal measurement obtained via ultrasonography and has the advantage of relying on linear and/or planar measurements of intra-uterine foetal dimensions that are definable objectively and should be reproducible (Shittu et al., 2007). However, early expectations that this method might provide an objective standard for identifying foetuses of abnormal size for gestational age was recently undermined by prospective studies that showed sonographic estimates of foetal weight to be no better than clinical palpation predictions based on algorithms using various combinations of foetal parameters, such as AC, FL, BPD, and HC (Shittu et al., 2007). These common and popular models are classified into groups depending on the combinations of foetal parameters and are used either singularly or in combination as shown in literature by (Nahum, 2003; Hadlock et al., 1985; Nzeh et al., 2000; Campbells, 1975; Comb et al., 1993; Ott et al., 1986 and Deter et al., 1985). The mathematical equations referred to as Model Reference Equations (MRE) which underpins these algorithms for calculating EFW are described by Nahum and Stanislaw, (2003) as shown below:

\[
f_g = \begin{cases} 
  -1, & \text{female} \\ 
  0, & \text{unknown} \\ 
  1, & \text{male} 
\end{cases}
\]  

(2.5)
2.5.1 Group 1: Abdominal Circumference Only

The unlisted group of equations provide for calculating EFWs using:

1. Campbell and Wilkin (in kg):
   \[ \ln EFW = -4.564 + 0.282 AC - 0.00331 AC^2 \]  
   (2.5)

2. Hadlock et al.
   \[ \ln EFW = 2.695 + 0.253 (AC) - 0.00275 AC \]  
   (2.6)

3. Jordaan
   \[ \log_{10} EFW = 0.6328 + 0.1881 (AC) - 0.0043 (AC)^2 + 0.000036239 (AC)^3 \]  
   (2.7)

4. Warsof et al.
   \[ \log_{10} EFW = -1.8367 + 0.092 (AC) - 0.000019 (AC)^3 \]  
   (2.8)

5. Higginbottom et al.
   \[ EFW = 0.0816 (AC)^3 \]  
   (2.9)

2.5.2 Group 2: Abdominal Circumference and Femur Length

These groups of equations provide for calculation of the EFWs using AC and FL only:

6. Hadlock et al
   \[ \log_{10} EFW = 1.304 + 0.05281 (AC) + 0.01938 (FL) - 0.004 (AC)(FL) \]  
   (2.10)

7. Woo et al.
   \[ \log_{10} EFW = 0.59 + 0.08 (AC) + 0.28 (FL) - 0.00716 (AC)(FL) \]  
   (2.11)

8. Warsof et al.
   \[ \ln EFW = 2.792 + 0.108 (FL) + 0.0036 (AC)^2 - 0.0027 (AC)(FL) \]  
   (2.12)
2.5.3 Group 3: Abdominal Circumference and Biparietal Diameter

The EFW are estimated via these groups of equations using AC and BPD only:

9. Vintzileos et al.

\[ \log_{10} EFW = 1.879 + 0.084 \cdot BPD + 0.026 \cdot AC \] \hspace{1cm} (2.13)

10. Warsof et al.

\[ \log_{10} EFW = -1.599 + 0.144 \cdot BPD + 0.032 \cdot AC - 0.000111 \cdot AC \cdot (BPD)^2 \] \hspace{1cm} (2.14)

11. Shepard et al.

\[ \log_{10} EFW = -1.7492 + 0.166 \cdot BPD + 0.046 \cdot AC - 0.002546 \cdot AC \cdot (BPD) \] \hspace{1cm} (2.15)


\[ \log_{10} EFW = -1.1683 + 0.0377 \cdot AC + 0.0950 \cdot BPD - 0.0015 \cdot AC \cdot (BPD) \] \hspace{1cm} (2.16)

13. Hadlock et al.

\[ \log_{10} EFW = 1.1134 + 0.05845 \cdot AC - 0.0000604 \cdot AC^2 - 0.007365 \cdot (BPD)^2 + 0.000595 \cdot AC \cdot (BPD) + 0.16994 \cdot (BPD) \] \hspace{1cm} (2.17)

14. Woo et al.

\[ \log_{10} EFW = 1.63 + 0.16 \cdot BPD + 0.00111 \cdot AC^2 - 0.00008599 \cdot (BPD) \cdot AC^2 \] \hspace{1cm} (2.18)
15. Hsieh et al.

\[
\log_{10} EFW = 2.1315 + 0.0056544(AC)(BPD) - 0.00015515(BPD)(AC)^2 + 0.000019782(AC)^3 + 0.052594(BPD)
\] (2.19)

2.5.4 Group 4: Abdominal Circumference, Head Circumference (±Biparietal Diameter)

EFWs are derived from these groups of equations using AC, HC, and with or without BPD only:

16. Hadlock et al.

\[
\log_{10} EFW = 1.182 + 0.0273(HC) + 0.07057(AC) - 0.00063(AC)^2 - 0.0002184(AC)(HC)
\] (2.20)

17. Jordaan.

\[
\log_{10} EFW = 0.9119 + 0.0488 (HC) + 0.0824 (AC) - 0.001599 (AC)(HC)
\] (2.21)

18. Jordaan.

\[
\log_{10} EFW = 2.3231 + 0.02904 (AC) + 0.0079 (HC) - 0.0058 (BPD)
\] (2.22)

2.5.4 Group 5: Abdominal Circumference, Femur Length, and Biparietal Diameter

Using AC, FL and BPD biometrics only, the EFW can be calculated via:

19. Hadlock et al.

\[
\log_{10} EFW = 1.335 - 0.0034(AC)(FL) + 0.0316(BPD) + 0.0457(AC) + 0.1623(FL)
\] (2.23)

20. Woo et al.-7
\[ \log_{10} EFW = 1.54 + 0.15(BPD) + 0.00111(AC)^2 + 0.0000764(BPD)(AC)^2 + 0.05(FL) - 0.000992(AC)(FL) \]  
\[ (2.24) \]

21. Shinozuka et al.

\[ EFW = 0.23966 \cdot (FL)(AC)^2 = 1.6230 \cdot (BPD)^3 \]  
\[ (2.25) \]

22. Hsieh et al.

\[ \log_{10} EFW = 2.7193 + 0.0094962(AC)(BPD) - 0.1432(FL) - 0.00076742(AC)(BPD)^2 + 0.001745(FL)(BPD)^2 \]  
\[ (2.26) \]

2.5.6 Group 6: Abdominal Circumference, Femur Length, and Head Circumference

Using the AC, FL, and HC biometrics, the EFWs can be calculated via:

23. Hadlock et al.

\[ \log_{10} EFW = 1.326 - 0.00326(AC)(FL) + 0.0107(HC) + 0.0438(AC) + 0.158(FL) \]  
\[ (2.27) \]

24. Combs et al.

\[ EFW = 0.23718 \cdot (FL)(AC)^2 + 0.03312 \cdot (HC)^3 \]  
\[ (2.28) \]

25. Ott et al.

\[ \log_{10} EFW = -2.0661 + 0.04355(HC) + 0.05394(AC) - 0.0008582(AC)(HC) + 1.2594(FL/AC) \]  
\[ (2.29) \]

2.5.7 Group 7: Abdominal, Head Circumferences, Femur Length, Biparietal Diameter

The EFWs can also be calculated using AC, HC, FL and BPDs via:

26. Hadlock et al.

\[ \log_{10} EFW = 1.3596 + 0.0064(HC) + 0.0424(AC) + 0.174(FL) + 0.00061(AC)(BPD) - 0.00386(AC)(FL) \]  
\[ (2.30) \]
In-utero foetal biometric assessment made by obstetric ultrasonography use best-fit algorithms to make BW predictions (Benacerraf et al., 1988) and this provides an attractive ‘objective’ method of estimating BW. Willocks et al., (1964) were among the first to report their experience with ultrasound foetal weight estimation, and commented that clinical estimation of foetal weight is little more than guess work because of the influence of factors such as abdominal wall thickness, uterine tension, volume of amniotic fluid, and position of the foetus in utero. It was claimed that in two thirds of cases, foetal weight could be estimated to within about 2.2kg using ultrasound (Tlale, 2012).

A large number of foetal weight prediction formulae have since been suggested based on foetal biometry including head BPD, HC, FL, AC and abdominal diameters (AD) known as common foetal biometry. In particular, a retrospective study has been done by Shamley and Landon (1994), to evaluate four published equations by Sherpard et al., (1982), Hadlock et al., (1985), Rose and McCallum (1987), and Sabbagha et al., (1989), as well as clinical estimation for accuracy in determining foetal weight in labour. According to the study, Hadlock and Shepard equations were associated with lower percentages of error 6.1% and 6.2% respectively than the Sabbagha formula (7.8%; p<0.007). For all four equations, 70-79% of foetal weight predictions were within 10% of ABW. The Shepard formula, however, has limited application in labour because head descent obscures the BPD which is essential to the foetal weight calculation. The study concluded that the use of any of the four standard equations or clinical examinations provides accurate estimation of foetal weight for patients in labour, even in the presence of ruptured membranes.
In these comparisons, the percentage of predictions within 10% of the BW for ultrasound estimation ranged from 39% to 69% (Hendrix et al., 2000; Chauhan et al., 1992; Chauhan et al., 1992; Barnhard et al., 1996; Sherman et al., 1998). While ultrasound foetal weight estimation may not appear significantly better than clinical methods, a recent comparison by Peregrine et al., (2007) has shown that ultrasound estimations of foetal weight immediately before labour was more accurate than clinical estimation for low and high BW babies, where clinical estimates are known to be relatively inaccurate.

A study by Yoni et al., (1996) investigated the effect of oligohydramnios on intrapartum estimation of foetal weight, and concluded that in term patients, intrapartum sonographic prediction of BW in the presence of reduced amniotic fluid volume offered no advantage over EFW obtained by abdominal palpation. However, the presence of oligohydramnios significantly reduced the accuracy of intrapartum clinical and sonographic foetal weight estimations, therefore, it was suggested that intrapartum foetal weight estimation be obtained prior to artificial rupture of membranes (Almonem, 2015)

Although the validity and reproducibility of these formulae have been documented in clinical practice with a reported systematic error of 10% or less relative to the ABW, it is well recognized that various foetal factors may influence the accuracy of foetal weight estimations. However, there are few reports that document the effect of certain maternal characteristics, specifically maternal size and obesity, on the ability to obtain ultrasonographic foetal biometric measurements and consequently calculate reliable foetal weights (Field et al., 1995)
Newer technologies may be able to provide better foetal weight estimation, for example, three-dimensional (3-D) sonography potentially allows superior foetal weight estimation including soft tissue volume of the foetal thigh, upper arm and abdomen (Schild et al., 2000; Bennini et al., 2010). Its advantage over conventional two-dimensional (2-D) ultrasonography is that reproducible circumference and volumetric measurements become feasible by simultaneous visualization of three orthogonal foetal limb sections. However, the disadvantage is that 3-D sonography is a more time consuming process, requires technically advanced and expensive equipment, and special operator training and skills which may also be more difficult to apply during labour (Tlale, 2012). According to Lindell and Marsal (2009), it seems unreasonable to abandon the 2-D ultrasound imaging for foetal weight estimation.

2.6 MAGNETIC RESONANCE IMAGING IN ESTIMATING FOETAL WEIGHT

Magnetic resonance imaging (MRI) has recently been used for estimating foetal volume and weight in diabetic and normal pregnancy using high-resolution MRI machine combined with semi-automatic segmentation software (Shittu et al., 2007). Its use may be recommended for clinical situation where accurate estimation is essential. Its strong disadvantage is that it is expensive even where it is available (Uotila et al., 2000). However, the promising new development in foetal weight estimation by echo-planer MRI cannot be overemphasized and its advantages compared with other imaging techniques include the ability to obtain multi-planar acquisitions and therefore theoretically improved resolution (Shamar et al., 2012)

Although it is feasible to calculate MRI foetal weight in sagittal, coronal, or axial planes, (the recommended plane of imaging,) slice of thickness, and associated number of acquisitions that most accurately determine term foetal weight had not yet been established or published at the
time when Hassibi et al. (2004) presented their findings. According to (Tlale, 2012) sought to
determine whether there are differences in foetal weight calculation based on plane of imaging or
thickness by comparing sagittal 5mm, 3mm, and axial 8 mm MRI acquisitions with term BW
and sonography foetal weight calculations. Their goal was to establish an optimal, practical
protocol for foetal MRI in the prediction of foetal weight in the term infant. Calculated weights
from a 90-sec single-shot fast spin- echo sequence MRI acquisition with 8mm thick slices in the
axial plane at term were found to be better than sonographic estimates (Tlale, 2012). The
problem with these methods, according to Loffler (1967) is that, addition to its expensiveness, its
impracticability for obtaining measurements during labor. However as indicated earlier that only
measurements of foetus such as BPD, HC, AC, FL, FTA, AD, APTD, and TTD had stood the
test of time in deducing EFW which is inexpensive. Despite the discrepancies between EFW and
ABW, these equation models based on foetal biometric measurements are extensively being used
global currently.

2.7 GENDER-SPECIFIC ESTIMATION OF FOETAL WEIGHT

It has been previously suggested and also published in the literature that differences exist in the
accuracy of sonographic weight estimation between male and female foetuses, and that these
differences may be the result of gender-specific intrauterine growth patterns (Pang et al., 2003;
Parker et al., 1984; Pineau et al., 2003; Fields et al., 2009; Schild et al., 2004; and Schwarzler et
al., 2004). These also include gender-related differences in body composition and percent of
body fat and in ratios among various biometric indices (Fields et al., 2009; Schwarzler et al.,
2004).
Indeed, Melamed et al., (2011) have recently reported that sonographic weight estimation was consistently more accurate for male than female foetuses, irrespective of the model used. It may be reasonable to hypothesize that the use of two distinct gender-specific models, optimized for male and female foetuses, may overcome this limitation. However, the impact of such gender-specific models on the accuracy of foetal weight estimation is as yet unclear. Surprisingly, none of the widely accepted sonographic models for foetal weight estimation (Shepard et al., 1982; Hadlock et al., 1984; Hadlock et al., 1985; Warsof et al., 1986; Ott et al., 1986; and Combs et al., 1993) includes foetal gender in the equation, and the results of only one study indicated that the use of such gender-specific model may result in more accurate estimation than several widely used models (Schild et al., 2004; Siemer et al., 2008a; Siemer et al., 2008b).

Moreover, it is unknown whether such gender-related model optimization merely reflects a different set of gender-specific model coefficients or whether these gender-specific models also differ in the combination of biometric indices incorporated into the model (Melamed et al., 2012). However, the quest for simple and understandable approach of EFW deduction, other formulae have emerged recently. For instance, it has been established that gender-specificity has an effect on EFW, that male foetuses have more weight than their female counterparts for the same gestational age. Hence, as proposed by Schild et al., (2004), different models should be applied to different groups of foetuses depending on gender.

To augment Schild’s work, Siemer et al., (2008) demonstrated that Schild’s gender-specific formula had the highest degree of accuracy than those equations widely use in the weight range between 2,500 and 3,999 g where majority of BWs falls but fare poorly at the extremes with BW < 2500g and >3999g. In improving on Schild’s gender-specific model, Melamed et al., (2012) adjusted Schild’s formula and hard more accurate result. However, these gender-specific models
were associated with highest accuracy (lowest systematic error) only in the larger interquartile BW subgroup, while this advantage was not clearly observed in the extremes of BW (below the first quartile and above the third quartile) as was observed in many studies (Melamed et al., 2012).

2.8 ETHNIC AND RACIAL DIFFERENCES IN ESTIMATED FOETAL WEIGHT

The effects or impact of racial variations and ethnicity on EFW have been questioned by Richard et al., (1997) in a study on differing BWs among infants of US-born Blacks, African-born Blacks, and US-born Whites. In this research, during the past 40 years, epidemiologic research has elucidated many important associations between the socio-demographic characteristics of mothers and the BW of infants. For example, the extremes of childbearing age (Kleinman & Kessel, 1987), cigarette smoking (Fox et al., 1994), inadequate prenatal care (Murray & Bernfield., 1988), urban poverty (Collins & David, 1990) and black race (David and Collins., 1991) are well-documented risk factors for low BW. Other obstetrical risk factors account for part of the racial disparity in BW, but differences persist (Lieberman et al., 1987; Rawlings et al., 1995; Klebanoff et al., 1989; Sheehan & Gregorio, 1995). Although the incidence of low BW decreases in both blacks and whites as the number of risk factors declines, the improvement is faster among whites, resulting in a wider BW gap between blacks and whites among infants of low-risk women (Kleinman & Kessel, 1987; Collins & David, 1990). This led some investigators to believe that genetic factors associated with race influence BW. (Naylor & Myrianthopoulos 1967; Little & Sing 1987; Magnus 1984; Hulsey et al., 1991; Goldenberg et al., 1991; Wildschutt et al., 1991).
In the National Collaborative Prenatal Project, only 1% of the total variance in BW among 18,000 infants was accounted for by socioeconomic variables, leading the authors to conclude that “race behaves as a real biological variable in its effect on BW and this effect of race is presumably genetic” (Naylor & Myrianthropoulos, 1967). The assumption that black women differ genetically from white women in their ability to bear normal or large infants persists in more recent studies of foetal growth (Hulsey et al., 1991; Amini et al., 1994) one of which, for example, refers to “genetic factors affecting growth, such as neonatal gender and race” (Amini et al., 1994). Few data have been published on the BWs of infants born to African-born women in the United States. Most African Americans trace their origins to Western Africa, where the slave trade flourished in the 17th and 18th centuries (Oliver & Fage, 1988; Reed 1969). It is estimated that U.S. blacks derive about three quarters of their genetic heritage from West African ancestors and the remainder from Europeans (Reed, 1969; Chakraborty, 1991; Adams & Ward, 1973; Glass, 1953). To the extent that population differences in allele frequency underlie the observed differences in BW between blacks and whites in the United States, one would expect women of “pure” West African origin to bear smaller infants than comparable African Americans, considering the European genetic admixture in the latter (Richard et al., 1997). However, this assumption appear not to be true according to (Richard et al., 1997).

In summary, African-born black women have infants with a greater mean BW and a different birth-weight distribution than U.S. - born black women born (Richard et al., 1997). Therefore, from the literature, there is clear evidence of the effect of race and ethnicity of a particular population on EFW which clearly suggests that, research must be conducted to find out and ensure that, the most accurate regression model is used for a particular population in question.
2.9 GENETIC FACTORS

Interest in determining the relative contributions of factors that produce BW variation, namely the maternal and foetal genetic factors and the environment of the foetus have been expressed. Approximately 40% of total BW variation is due to the genetic contributions from mother and foetus (approximately half from each), and the other 60% is due to contributions from the foetal environment (Polani, 1974).

Although both parents' genes affect childhood growth and final adult size, the maternal genes have the main influence on BW as the classic horse-pony cross-breeding experiments by Walton and Hammond (1938) demonstrated the important role of the mother that foals of the maternal horse and paternal pony are significantly larger than foals of the maternal pony and paternal horse, and foals of each cross are comparable in size to foals of the pure maternal breed which clearly demonstrated the widely held study of a maternally related constraint on foetal growth.

Similar conclusions of maternal constraint to growth are reached from family studies in humans. Low and high BWs recur in families with seemingly otherwise normal pregnancies. Sisters of women with intrauterine growth restriction (IUGR) babies tend to have IUGR babies, a trend that is not seen in their brothers' babies (Johnstone & Inglis, 1974). Mothers of IUGR infants were frequently growth restricted at birth (Ounsted & Ounsted, 1966; Simpson et al., 1975).

There is also a greater similarity in BW between maternal half siblings and full siblings than between paternal half siblings and full siblings Robert and Robert (2012). Although the maternal phenotypic expression particularly maternal height may affect foetal growth, the evidence for such an influence is not convincing Robert and Robert (2012). Social deprivation has also been
associated with IUGR, a finding not explained by known physiologic or pathological factors (Wilcox et al., 199).

The one definite paternal influence on foetal growth and size at birth is the contribution of a Y chromosome rather than an X chromosome (Robert and Robert, 2012). The male foetus grows more quickly than the female foetus and weighs approximately 150g to 200g more than the female at birth (Thomson et al., 1968). There is also a suggestion that paternal size at birth can influence foetal growth, with BWs potentially increased by 100g to 175g (Klebanoff et al., 1998). Furthermore, the greater the antigenic dissimilarity between the parents, the larger the foetus. Whether it is genetically determined or not, women who were small for gestational age (SGA) at birth have double risk of reduced intrauterine growth in their foetuses (Klebanoff et al., 1997). In similar fashion, foetuses destined to deliver preterm have a higher incidence of reduced foetal growth (Bukowski et al., 2001). The role of the genetic constitution of mother or foetus in these observations is not clear.

Specific maternal genotypic disorders can cause IUGR. An example being phenylketonuria (Saugstad, 1972). Infants born to homozygously affected mothers almost always have IUGR, but whether the reason is an abnormal amount of metabolite crossing from mother to foetus or an inherent problem in the foetus is unknown Robert and Robert (2012). There is a significant association between IUGR and congenital malformations. Such abnormalities can be caused by established chromosomal disorders or by dysmorphic syndromes, such as various forms of dwarfism Robert and Robert (2012). Some of these malformations are the expression of a specific gene abnormality with a known inheritance pattern, whereas others are only presumed to be the result of a gene mutation or an adverse environmental influence Robert and Robert (2012).
Although in some reports only 2% to 5% of IUGR infants have a chromosomal abnormality, the incidence rises to 20% if IUGR and mental retardation are both present (Snijders et al., 1993). Birth weights in infants with trisomy 13, 18, and 21 are lower than normal (Chen et al., 1972, Peuschel et al., 1976). The decrease in BW is less pronounced in trisomy 21. The frequency distribution of BWs in infants with trisomy 21 is shifted to the left of the normal curve after 34 weeks of gestation, resulting in gestational ages 1 to 1.5 weeks less than normal, and BWs and lengths are less than in control infants from 34 weeks until term (Creasy et al., 2013). This effect is more marked after 37 weeks of gestation, but BWs are still only approximately 1 standard deviation from mean weight. BWs in translocation trisomy 21 are comparable to those in primary trisomy 21. Birth weights of newborns that are mosaic for normal and 21-trisomic cells are lower than normal but higher than those of 21-trisomic infants (Polani, 1974).

Newborns with other autosomal abnormalities, such as deletions (chromosomes 4, 5, 13, and 18) and ring chromosome structure alterations, also have had impaired foetal growth. Although abnormalities of the female (X) and male (Y) sex chromosomes are frequently lethal (80% to 95% result in first trimester spontaneous abortions), they could be a cause of IUGR in a newborn (Kramer, 1987). Infants with XO sex chromosomes have a lower mean BW than control infants (approximately 85% of normal for gestational age) and are approximately 1.5 cm shorter at birth. Mosaics of 45 X and 46, XX cells are affected to a lesser degree (Kramer, 1987). Although a paucity of reports prevents definite conclusions, it appears that the repressive effect on foetal growth is increased with the addition of X chromosomes, each of which results in a 200- to 300-g reduction in BW (Kramer, 1987). In general, IUGR is associated with numerous other dysmorphic syndromes, particularly those causing abnormal brain development. The overall contribution that chromosomal and other genetic disorders make to human IUGR is estimated to
be 5% to 20% and approximately 25% of foetuses with early-onset foetal growth restriction could have chromosomal abnormalities, and karyotyping via cordocentesis can be considered Robert and Robert (2012). A genetic basis should be considered strongly if IUGR is encountered in association with neurologic impairment or early polyhydramnios.

The two main methods for predicting BW in current sonographic obstetrics are:

(a) clinical techniques based on abdominal palpation of foetal parts, calculations based on fundal height in combination with some foetal biometric measurements and

(b) sonographic measures of skeletal foetal parts only which are then inserted into regression equations to derive estimated foetal weight (Hanretty et al., 1990; Hendrix et al., 2000; Raman et al., 1992).

Although some investigators consider sonographic estimates to be superior to clinical estimates, others, in comparing both the techniques concurrently, conclude that they confer similar levels of accuracy (Nzeh et al., 2000; Hanretta et al., 1990; Hendrix et al., 2000; Raman et al., 1992; Watson et al., 1988; Mehdizadeh et al., 2000; Wilcox et al., 1992; Cecattiet al., 2000; Johar et al., 1988; Hulsey et al., 1991; Richards et al., 2001; Hadlock et al., 1985, Ebomoyi et al., 1991, Ojwang et al., 1984).

The available techniques for imaging can be broadly classified under prediction of equations of BW by ultrasonography (USG) and MRI (Shittu et al., 2007). For imaging purposes, ultrasound EFW is commonly used worldwide and less expensive. In addition, acquisition of ultrasound equipment is far affordable compare to other imaging modality such as magnetic resonance imaging MRI, which is highly expensive. Thus, the aim of the present study was to determine
which of the commonly used sonographic model provide better accuracy or precision of foetal weight estimation, and to provide a better understanding of the reasons why that/those formulae should be used in deducing foetal weight estimation.
CHAPTER THREE
METHODOLOGY

3.1 INTRODUCTION

Research methods are approaches or techniques employed in conducting research operations using scientific and systematic ways in answering a research question. This section therefore presents the methodology employed in conducting this study and describes key aspects such as the study design, study population and study sites, and experimental procedure.

3.2 STUDY DESIGN

A quantitative study which is cross-sectional and quasi-experimental in nature was adopted for this study. Numeric figures were produced and analyzed for the study to become conclusive.

For a study to be quantitative, Babbie (2010) enumerated that, quantitative methods emphasize objective measurements and the statistical, mathematical, or numerical analysis of data collected through polls, questionnaires, and surveys, or by manipulating pre-existing statistical data using computational techniques. Furthermore, quantitative research focuses on gathering numerical data and generalizing it across groups of people or to explain a particular phenomenon (Muijs, 2010). This study adopted a research design that required a quantitative documentation of foetal biometric measurements and neonatal weights.

Quantitative studies are conducted to determine the relationship between an independent variable and a dependent or outcome variable within a population associated with an experiment (subjects measured before and after delivery) (Babbie, 2010). As descriptive study
establishes only associations between variables, an experimental study establishes causality (Babbie, 2010). Therefore, the study ultrasonically measured foetal biometry, compute EFWs and correlate with the actual BWs.

Quantitative research deals in numbers, logic, and an objective stance and focuses on numeric and unchanging data and detailed, convergent reasoning rather than divergent reasoning (Brains, 2011) i.e., the generation of a variety of ideas about a research problem in a spontaneous, free-flowing manner (Brians, 2011). Therefore, this study accordingly, compares EFWs to ABWs in line with the aim and objectives of this study.

As much as the study was quantitative, with assumption that there was not going be differences in experimentation and the outcome values, it was cross sectional in nature as well since all the experimental work was performed on a certain group of people during a particular period and was carried out prospectively in which convenient sampling method was applied. Convenient sampling method was used based on the fact that participants in this study must be in their latent phase during labor which is associated with a lot of pains and discomfort resulting in participants’ unwillingness to partake in the study.

Ultrasound scans for EFW were scheduled within thirty minutes on arrival to the delivery ward after medical histories such as previous antenatal ultrasound and laboratory particulars i.e. antenatal folders which include their entire previous ultrasound scan and laboratory reports have been received. The period between the time of arrival and the scheduled time for scanning became very important due to empirical evidence that, almost 95% of expectant mothers arrived at the labour-ward in the late latent phase of labour.
Foetal biometrics such as BPD, HC, AC and FL measurements were taken according to the established guidelines (Loughna et al., 2009). All examinations were performed trans-abdominally using Philips ClearVue 350 equipment, one day prior to vaginal or normal delivery and within a maximum of one day prior to induction of labour. Birth weights were measured using properly calibrated Salter scale (model 914) digital weighing scale of maximum range of 20kg.

3.3 STUDY SITES

The research was conducted at the Mamprobi Polyclinic (M-PC) in the Greater Accra Region of Ghana. This study site was selected based on the following factors:

1. Out-patients records suggested that patients from all the geo-regional groupings in Ghana residing in Accra attend this polyclinic for antenatal and delivery services.
2. M-PC has a large antenatal and delivery base.
3. M-PC is equipped with the new Philips ClearVue 350 ultrasound equipment.

3.4 STUDY POPULATION

The study included all pregnant women laboring with singleton pregnancies and had been admitted for birth deliveries at the study site within the stipulated period of four months of data collection. An anecdotal report from the study site showed one thousand two hundred and sixty-seven, (1,267) deliveries per year. Therefore, during the four months of data collection period, an estimated four hundred and twenty-two, (422) expectant mothers went ultrasound examination for the purpose of this study and biometric measurements, BPD, HC, AC and FL of foetuses were taken.
3.5 SAMPLE SIZE

Knowing the population size and using finite population correction factor, a sample size $n$ was determined via the equation according to courses.wcupa.edu;

$$n = \frac{n_o \cdot N}{n_o + (N - 1)}$$  \hspace{1cm} (3.1)

Where $n_o = \text{sample size without considering the finite population correction factor}$

$N = \text{Population size}$

Assuming $N = 442$ and $n_o = 100$ then Equation (3.1) yields a sample size of

$$n = \frac{n_o \cdot N}{n_o + (N - 1)} = \frac{(100)(442)}{100 + (442 - 1)} = 78$$  \hspace{1cm} (3.2)

Therefore, the actual sample size from finite population size of four hundred and forty-two (442) was seventy-eight, (78) participants.

At the study site, estimated numbers of seventy-eight 78 expectant mothers were expected to undergo the scanning examination during the data collection period. Participants were selected according to the inclusion and exclusion criteria, taking into account patient’s right not to partake in the research, the pain and discomfort level depending on the labour phase (active or latent) which made few participants to decline in participation and the time duration of completion of the study.

Based on the reasons given above, seventy-five, 75 participants took part in the study. However due to, late referrals of some of the participants to tertiary facilities on account of prolong latent phase of labor, indication of macrosomia and breech presentations, a sample size of 40 participants was arrived at for the study.
3.6 INCLUSION AND EXCLUSION CRITERIA

3.6.1 Inclusion Criteria

Participants were selected taking into account the following:

Expectant mothers with viable singleton pregnancies with cephalic presentations and admitted for birth delivery at the study sites

Expectant patient’s presenting with pain and discomfort level on the labour phase (active or latent).

3.6.2 Exclusion Criteria

Patients presenting the condition below were excluded from the study:

Expectant mothers with polyhydramnios, pre-term labour, ruptured membranes, abnormal lie and presentation, multiple pregnancies, antepartum haemorrhage, eclampsia, obvious congenital abnormalities, oligohydramnios, anteriorly-inserted placenta, and poor visualization of foetal part

Expectant mothers with no contraction and amniotic rapture was excluded from the study.

3.7 EQUIPMENT/INSTRUMENT CAPABILTY

A Salter scale (model 914) digital weighing scale of maximum range of 20kg and reading up to 6 decimal places was used for the weight measurements of the neonates. Using dry cells as source of electrical power, makes Salter scale very light in weight and can be moved around with less effort.

A Philips ClearVue 350 ultrasound imaging equipment was utilized for the study. The technical specifications of the equipment are listed in Table 3.1.
Table 3.1: Technical specifications of Philips ClearVue 350 ultrasound equipment

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Screen width</th>
<th>Control panel height</th>
<th>Monitor width</th>
<th>Monitor height</th>
<th>Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>51.8 cm</td>
<td>83.4 cm</td>
<td>43.2 cm</td>
<td>138.4 cm</td>
<td>58.6 cm</td>
</tr>
</tbody>
</table>

Probe: C5-2: Abdominal, obstetrics/gynaecological, pediatric, vascular, and urological curvilinear transducer

Gray scales: 255 in 2-D, M-mode, and Doppler

Components Scale lines: Up to 1,024 scan lines, transducer and mode dependent

Input signals: Low-level ECG, Four-port transducer receptacles

Electrical parameters: AC 100-240V ±10%

The advantages of this equipment over others in terms obstetric work is based on the following factors which have been incorporated into the operational function of this equipment.

3.7.1 Ultrasound Equipment Suitability for Obstetric Work

The suitability of the ultrasound equipment for obstetric work in this study was established by verification of these factors:

1. **Amniotic Fluid Index measurement**: This factor provides for calculating the amniotic fluid in each quadrant ($Q1+Q2+Q3+Q4$) to give the total amniotic fluid index (AFI) value which is immediately compared to an already provided reference range between 8.1 to 18.0cm (Rutherford et al., 1987).

2. **Biophysical profile**: An important factor that defines foetal wellbeing and expressed as

   \[ \text{Biophysical profile} = \text{movement} + \text{tone} + \text{breathing} + \text{amniotic fluid index volume} \]
It ranges from 0 to 2 or ‘Not Applicable’ which indicates that the category will not contribute to the biophysical profile total (Manning et al., 1990).

3. Selecting of number of foetus in twin, triplets and quadruplets gestations to produce separate reports on each of the foetuses. In selecting the number of foetuses, typically, the foetus closest to the cervix is labeled ‘A’ and the others are designated sequentially as they are seen moving up to the fundus as B, C, and D.

4. **Colour and power Doppler incorporation.** This is done for easy study of arterial and venous systems of the foetus especial in the foetal brain, umbilical cord and renal vessels.

5. **B and M-modes:** These mode combinations are used in displaying foetal heart movements leading to estimation of foetal heart beat and the gradient of the wave produced.

These obstetrics properties of the ultrasound equipment in addition to others like electrocardiogram, small parts and vascular imaging, and 3-D functions coupled with very clear quality images produced on a large plasma screen, makes the equipment highly functional.

### 3.8 QUALITY ASURANCE TESTS ON THE EQUIPMENT/INSTRUMENT

Quality assurance and control was carried out before this study started. The ultrasound equipment was upgraded by the engineers at the start of the study as biennial routine maintenance contract to make sure the equipment perform at its maximum operational capacity. After the upgrading of equipment, an operator manual was used to set its functions to their optimal level to produce superior image quality for accurate and precise measurements to be taken.

The Scaler scale was each time set to the zero mark before each neonate was weighed and the dry cell use to power it was changed at start of work every day.
Additionally, a wheel chair was provided to transfer patients from the ward to the scanning room due to the distance between these two destinations and patients’ unstable condition at this period. Wooden stair was provided for smooth climbing to the scanning bed and very long screen was used to partition the room to provide privacy to the patients.

3.9 ASSESSMENT OF RELIABILITY OF THE MEASUREMENTS

Before the commencement of the study, pilot survey was done to test the reliability of measurements on the sonographic images. Twenty patients were used in the pilot assessment of accurate and precise measuring of foetal biometry. The result shows 98% accuracy after scanning each participant three times and finds their arithmetic means.

The participants did not pay for participating in both the piloting and main research work.

3.10 REGRESSION MODELS

As mentioned in Chapter 2, several regression models can be applied to the calculation of EFW using ultrasonography. The regression models adopted in this study are presented here.

3.10.1 Campbell and Wilkin Approach for EFW (AC) only

The Campbell and Wilkin (1975) regression model for computing AC only is expressed as

$$\ln \text{EFW (kg)} = -4.564 + 0.282 \cdot AC - 0.00331 \cdot AC^2$$

(3.1)

3.10.2 Hadlock Approaches for EFW Calculations: (AC, FL) only

The Hadlock et al., (1985) approach can be applied for computing AC and FL fetal biometrics via

$$\log_{10} \text{EFW} = 1.304 + 0.05281 \cdot (AC) + 0.1938 \cdot (FL) - 0.004 \cdot (AC)(FL)$$

(3.2)
In particular, the system determines 2 standard deviation ranges based on EFW via the expression

\[ EFW = \pm (0.154 * EFW) \]  

(3.3)

### 3.10.3 Hadlock Approaches for EFW Calculations: (AC, BPD) Only

In respect of EFW calculations using AC and BPD fetal biometrics only, the Hadlock regressions is represented as

\[
EFW = \log_{10} (1.11 + 0.05845(AC) - 0.000604(AC)^2 - 0.007365(BPD)^2 + 0.000595(BPD \times AC) + 0.1694(BPD))
\]

(3.4)

With a corresponding standard deviation ranges based on EFW as

\[ EFW = \pm (0.182 * EFW) \]

(3.5)

### 3.10.4 Hadlock Approaches for EFW Calculations: AC, FL and HC Only

Based on AC, FL, and HC variables, the Hadlock regression for EFW calculations is expressed as

\[
EFW = \log_{10} (1.326 - 0.00326 (AC)(FL) + 0.0107 (HC) + 0.0438 (AC) + 0.158 (FL))
\]

(3.6)

The system determines two standard deviation ranges based on EFW for this calculation as follows:

\[ EFW = \pm (0.148 * EFW) \]

(3.7)

### 3.10.5 Hadlock Approaches for EFW Calculations (AC, BPD, FL)

\[
EFW (g) = \log_{10} (335 - 0.034 \times AC \times FL - 0.0316 BPD + 0.0457 AC + 0.1623 FL)
\]

(3.8)

The EFW formula via Hadlock et al., (1985) using AC (cm), BPD (cm), and FL (cm) is: The system determines two standard deviation ranges based on EFW for this calculation as follows:

\[ EFW = \pm (0.146 EFW) \]

(3.9)

### 3.10.6 Hadlock Approaches for EFW Calculations (BPD, HC, AC, FL)
The formula for the EFW via Hadlock et al., (1985) using AC (cm), BPD (cm), FL (cm), and HC (cm) is shown below. Normal ranges are broken up by EFW as percent of EFW and a gram offset.

\[
EFW = \log_{10} \left\{ 1.3596 - 0.00386(AC)(FL) + 0.0064(HC) + 0.0061(BPD)(AC) + 0.0424(AC) + 0.174(FL) \right\}
\]

(3.10)

### 3.10.7 Osaka Approach for EFW Calculations (BPD, FTA, FL)

The EFW via Osaka University (Nobuaki et al., 1990) using BPD (range: 3.1 to 10.0cm), fetal trunk abdominal area (range: 20 to 180.0cm²), and FL (range: 1.0 to 8.0cm) is:

\[
EFW(g) = 1.25647(BPD) + 3.50665(FTA)(FL) + 6.30994
\]

(3.11)

### 3.10.8 Tokyo Approach for EFW Calculations (BPD, AD, FL)

The EFW formula via Tokyo University (Mizuno et al., 1989), using BPD (range: 3.1 to 10.0cm), AD (AP, range: 5.0 to 15.0cm), AD (transverse: range: 5.0 to 15.0cm), and FL (range: 1.0 to 8.0cm) is:

\[
EFW(g) = 1.07(BPD)^3 + 3.42 \times AD_{ap} \times AD_{trv} \times FL
\]

(3.12)

Where \( ap \) and \( trv \) are antero-posterior and transverse.

### 3.10.9 Shephard Approach for EFW Calculations (AC, BPD)

The Shephard (1982) formula for EFW using AC, (range: 15.0 to 40.0cm), and BPD (range: 3.1 to 10.0cm) is:

\[
EFW(g) = 1000 \times 10(-1.7492 + 0.166_BPD + 0.046_Ac - 0.002646 \times AC \times BPD)
\]

(3.13)

The system determines one standard deviation range based on EFW for this calculation according to the following:

\[
EFW < 2,500g = \pm 218g \\
2,500 \leq EFW \leq 3,500g = \pm 405g \\
EFW > 3,500g = \pm 566g
\]

(3.14)
3.10.10 **Shinozuka Approach for EFW Calculations (AC, BPD, FL)**

The formula for EFW via (Shinozuka *et al.*, 1996), using AC (cm) (range: none), BPD (cm) (range: none), and FL (cm) (range: none) is:

\[
EFW (g) = (1.07 \times BPD^3) + (0.30 \times AC^2 \times FL)
\]  
(3.15)

3.10.11 **Shinozuka Approach for EFW Calculations (APTD, TTD, BPD, FL)**

The Shinouzuka (1989) formula for EFW using AP trunk diameter (cm) (range: none), transverse trunk diameter (cm) (range: none), BPD (cm) (range: none), and FL (cm) (range: none) is:

\[
EFW (g) = (1.07 \times BPD^3) + 3.42 \times APTD \times TTD \times FL
\]  
(3.16)

Therefore from the immediate groups of equations above, the equations used in this study are presented in Table 3.2.
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Formulae</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campbell</td>
<td>1975</td>
<td>( \ln EFW (kg) = -4.564 + 0.282 AC - 0.00331 AC^2 )</td>
</tr>
<tr>
<td>Hadlock1</td>
<td>1984</td>
<td>( \log_{10} EFW = 1.304 + 0.05281 (AC) + 0.1938 (FL) - 0.004 (AC)(FL) )</td>
</tr>
<tr>
<td>Hadlock6</td>
<td>1985</td>
<td>( EFW = \log_{10} \left{ 1.11 + 0.05845(AC) - 0.000604(AC)^2 - 0.007365(BPD)^2 \right} + 0.000595(BPD \times AC) + 0.1694(BPD) )</td>
</tr>
<tr>
<td>Hadlock3</td>
<td>1985</td>
<td>( EFW = \log_{10} \left{ 1.326 - 0.00326(AC \times FL) + 0.017(HC) + 0.0438(AC) \right} + 0.158(FL) )</td>
</tr>
<tr>
<td>Hadlock7</td>
<td>1985</td>
<td>( EFW = \log_{10} \left{ 1.335 - 0.034 \times AC \times FL + 0.0316BPD + 0.0457AC \right} + 0.1623FL )</td>
</tr>
<tr>
<td>Hadlock4</td>
<td>1985</td>
<td>( EFW = \log_{10} \left{ 1.3596 - 0.00386(AC)(FL) + 0.0064(HC) + 0.00061(BPD)(AC) \right} + 0.0424(AC) + 0.174(FL) )</td>
</tr>
<tr>
<td>Shephard</td>
<td>1982</td>
<td>( EFW (g) = 1000 \times 10(-1.7492 + 0.166BPD + 0.046AC - 0.002646 \times BPD \times AC) )</td>
</tr>
<tr>
<td>Shinozuka2</td>
<td>1989</td>
<td>( EFW (g) = (1.07 \times BPD)^3 + (0.30 \times AC^2 \times FL) )</td>
</tr>
</tbody>
</table>
3.11 PROCEDURE FOR DATA COLLECTION

Expectant mother made to lie on the scanning bed in a supine position with the abdomen exposed, a coupling gel is applied on it and a probe used to search for foetal parts like head, abdomen and femur length and various measurements were made.

The BPD measurements were done for each foetus by obtaining a longitudinal section of the foetus using small sliding movements of the transducer on each side of the foetal spine and tracing the head along the spine. On locating the head, the transducer was moved to the vertex. In this manner, the probe was slid to the lateral side of the foetal head facing anteriorly which at this point looks ovoid in shape.

At this position, the probe was adjusted until strong midline echo with the cavum-septum pellucida is demonstrated. When the section was not the required ovoid shape, minor rotational adjustments were made until the shape was correct. Slight up and down movements of the transducer on the maternal abdomen located the correct section, which was then frozen. The BPD was measured by placing the horizontal component of the on-screen calipers on the outer aspects of the echoes from the foetal skull. This was done at right angles to the midline and at widest diameter of the ovoid head shape (Figure 3.1).
Figure 3.1: BPD measurement  
Source: Field data (2014)

Foetal AC was measured by scanning the foetus in a longitudinal plane until the foetal aorta was visualized in its course, through the foetal chest and abdomen. The probe was rotated through 90° at the level of the lower end of the foetal ribs, with the ribs showing posterior acoustic shadowing. A minor adjustment was then made by moving the transducer up or down the foetal body through maternal abdomen until the section was obtained. The section appeared almost a perfect circle, containing only a short section of the umbilical vein in the anterior third of the foetal abdomen.
For HC measurements, ellipsoidal tracing was made by drawing a line at the outer perimeter around the exact image used in measuring BPD (Figure 3.3). The FL measurement was obtained by scanning the foetus in longitudinal plane and the spine traced to its tapering end. The probe was then rotated through small angles to locate a single long bone lying almost horizontal on the monitor, producing a clean posterior acoustic shadow (Figure 3.4).
Figure 3.3: HC measurement  
Source: Field data (2014)

Figure 3.4: FL measurement  
Source: Field data (2014)
Maternal height and weights were obtained from participants antenatal records which are retrospective in nature. The participants first visit weight is referred to as initial weight and the last weight before onset of labour is final weight.

3.12 DATA MANAGEMENT

All procedures were carried out with strict adherence to standard protocols. Cross checking of data entries were made to ensure accurate data capture for accurate statistical analysis adhered to. Participants were given codes for identification. Data collecting sheets were store in safe cabinet and electronic data is stored in a password protected database. The outcome of the study will be disseminated to the Department of Radiography, School of Biomedical and Allied Health Science, College of Health Sciences, University of Ghana. Articles of this study will be published in Scientific Journals. The study reports shall be presented in various seminars and conferences.

3.13 STATISTICAL ANALYSIS

The data was entered using Microsoft Excel software package and was exported onto SPATA software package for all data analysis. Linear regression and Box and Whisker were used to show the relationship between the various EFWs and the ABWs and correlation coefficient was used to show the relationship between maternal heights, various weights and ABWs.

3.14 ETHICS

The study conformed to the guidelines for human experimentation in the Helsinki Declaration “Ethical Principles for Medical Research Involving Human Subjects”. Approval was obtained
from Ethics and Protocol Review Committee of the School of Biomedical and Allied Health Sciences. Informed consent was obtained before the study after adequate explanation. Informed written consents were obtained from the workers prior to scanning (Appendix III). Objectives and examination procedure of the study were made available for the expectant mothers (Appendix VI). Confidentiality of participants was maintained in accordance with the conditions of ethical approval from the above-named ethics committee and privacy was ensured by keeping the identity of the participants anonymous (Appendix V).

3.14.1 Standard Protocol Adopted for the Study

To prevent the re-occurrence of medical abuse of human subjects, the study was carried out with strict adherence to the following protocol guidelines:

1. Voluntary participation was read to each participant, explanation given and their consent obtained.

2. The researcher showed respect for participants and treated each of them as autonomous agents.

3. Participants were given the right to decline participation in the research at any material stage.

4. Their privacy was respected and their well-being protected.

5. Participants’ integrity was safeguarded.

6. Participants were protected from mental, physical, and emotional harm.
CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This Chapter presents the results of the study conducted to determine the best formula for estimating foetal weight. The results are presented in accordance with stated objectives of the study and included key aspects such as demographics characteristic, biometric measurements obtained ultrasonically, computation of EFW by the chosen regression equations, weighing of neonates and comparison of EFW and ABWs.

Seventy-five, 75 expectant mothers reporting for normal delivery at the study site initially consented to participation following adherence to study protocols and ethics requirements out of calculated sample size of seventy-eight, 78. However, only forty, 40 participants were used in the study due to late referral of patients on suspicion of macrosomia, prolonged latent phase of labour and breech presentations. Therefore, 96% response rate was achieved for the study.

4.2 DEMOGRAPHICS

The age and body mass index (BMI) demographics of the participants are shown in Table 4.1. The mean age of the population was 26.93±6.06 years. The initial median BMI of the participants at their first visit in the first trimester was 23.31 and an inter-quartile range (IQR) of 5.15, and 27.80 (IQR=5.33) at third trimester.
Table 4.1: Maternal Demographics (N=40)

<table>
<thead>
<tr>
<th>Maternal age (years)</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean ± s.d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>17</td>
<td>38</td>
<td>26.93 ± 6.06</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Median</th>
<th>Inter-quartile range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial BMI</td>
<td>23.31</td>
<td>5.15</td>
</tr>
<tr>
<td>Final BMI</td>
<td>27.80</td>
<td>5.33</td>
</tr>
</tbody>
</table>

Statistical analysis was performed to establish correlation between maternal weight, height, initial and final BMI, and neonates’ weights (ABWs). The results are presented in Table 4.2.

Table 4.2: Correlation coefficient between maternal demographics and neonates’ ABWs

<table>
<thead>
<tr>
<th>Demographic variables</th>
<th>Correlation coefficient ($R^2$)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial maternal weight (kg) vrs. ABW (kg)</td>
<td>0.0251</td>
<td>0.8777</td>
</tr>
<tr>
<td>Final maternal weight (kg) vrs. ABW (kg)</td>
<td>0.1785</td>
<td>0.2705</td>
</tr>
<tr>
<td>Initial maternal BMI vrs. ABW (kg)</td>
<td>0.0502</td>
<td>0.7586</td>
</tr>
<tr>
<td>Final Maternal BMI vrs. ABW (kg)</td>
<td>0.2043</td>
<td>0.2061</td>
</tr>
<tr>
<td>Maternal height (cm) vrs. ABW (kg)</td>
<td>-0.0856</td>
<td>0.5996</td>
</tr>
</tbody>
</table>

Source: Field data (2014)

The range of computed correlated coefficients {weight: $R^2 = 0.0251-0.1787$; BMI: $R^2 = 0.0502-0.2043$; height: $R^2=-0.0856$} and p-values {0.2061-0.8777 > 0.05} within 95% confidence
intervals established significant differences between maternal anthropometrics and neonates ABWs.

4.3 FETAL BIOMETRICS

Table 4.3 below shows the results of the sonographically determined fetal biometric data.

Table 4.3: Mean and standard deviation of BPD, HC, FL, and AC (N=40)

<table>
<thead>
<tr>
<th>Fetal biometric measurements</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Mean ± s.d</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPD</td>
<td>8.99</td>
<td>9.28</td>
<td>9.13 ± 0.45</td>
</tr>
<tr>
<td>AC</td>
<td>34.91</td>
<td>36.42</td>
<td>35.67 ± 2.37</td>
</tr>
<tr>
<td>HC</td>
<td>31.94</td>
<td>33.16</td>
<td>32.56 ± 1.91</td>
</tr>
<tr>
<td>FL</td>
<td>7.44</td>
<td>7.71</td>
<td>7.58 ± 0.43</td>
</tr>
</tbody>
</table>

Source: Field data (2014)

Fetal weights determined via the eight regression models (Campbell & Wilkin 1975, Hadlock 2, 7, 4, 3, 6, 1985, Shephard, 1982, Shinozuka 2 1996) were compared with ABWs of 40 neonates. For normal delivery at term, 35, (87.5%) newborns had BWs between 2.5kg and 3.9kg (Table 4.4)

Table 4.4: Birth weights at term

<table>
<thead>
<tr>
<th>Birth weight at term (kg)</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2.5</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td>2.5 – 3.9</td>
<td>35</td>
<td>87.5</td>
</tr>
<tr>
<td>&gt; 3.9</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: Field data (2014)

The mean ABW ranged from 3.0kg –3.3kg with a mean of 3.2 ± 0.46kg.
4.4 **HYPOTHESIS**

As hypothesized that there will be no significant difference between EFWs and ABWs, all the eight equations or regression models present p-values<0.05 significance level. Therefore, the study failed to reject the null hypothesis.

![Figure 4.1: Scatter plot of ABW against regresional models](image)

Source: Field data (2014).

A scatter plot in Figure 4.1 showed a linear trend among all the 8 regression models with outliers and their statistical measures as shown in table 4.5 below.
Table 4.5: Comparison between EFW generated by the regression models to ABWs

<table>
<thead>
<tr>
<th>ABW &amp; regression models</th>
<th>EFWs</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower limit</td>
<td>Upper limit</td>
</tr>
<tr>
<td>ABW (N = 40)</td>
<td>3.03</td>
<td>3.33</td>
</tr>
<tr>
<td>Eqn_1: Campbell 1975</td>
<td>3.44</td>
<td>3.69</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.52</td>
<td>-0.26</td>
</tr>
<tr>
<td>Eqn_2: Hadlock 1 1885</td>
<td>3.03</td>
<td>3.33</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.52</td>
<td>-0.26</td>
</tr>
<tr>
<td>Eqn_3: Hadlock 6 1885</td>
<td>3.03</td>
<td>3.33</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.31</td>
<td>-0.30</td>
</tr>
<tr>
<td>Eqn_4: Hadlock 3 1885</td>
<td>3.53</td>
<td>3.57</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.50</td>
<td>-0.23</td>
</tr>
<tr>
<td>Eqn_5: Hadlock 7 1885</td>
<td>3.54</td>
<td>3.58</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.52</td>
<td>-0.25</td>
</tr>
<tr>
<td>Eqn_6: Hadlock 4 1885</td>
<td>3.53</td>
<td>3.57</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.50</td>
<td>-0.24</td>
</tr>
<tr>
<td>Eqn_7: Shephard 1982</td>
<td>3.36</td>
<td>3.73</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.52</td>
<td>-0.22</td>
</tr>
<tr>
<td>Eqn_8: Shinozuka 2 1996</td>
<td>3.55</td>
<td>3.59</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.52</td>
<td>-0.25</td>
</tr>
</tbody>
</table>

Source: Field data (2014)
With exception of the Hadlock31985 regression model, the results showed that the absolute mean difference between the ABWs and the EFWs in all the regressions models were statistically significant \([p\text{-value}=0.0001<0.05, \text{ with a 95\% CI, -0.52 to -0.23-0.26}].\) The absolute mean difference between the ABW and Hadlock31985 EFW was also statistically significant \([p\text{-value} = 0.02 < 0.05 \text{ with a 95\% CI of -0.31 to -0.30}],\) showing no difference between the mean ABW and the mean EFW.

In Table 4.5 Hadlock3 i.e. equation 4 shows a narrow interval of limits around the estimated mean and the smallest standard deviation.

The Box and Whisker plot illustrating distinctly the relationship between the ABWs and EFWs generated by the regression models and the associated distribution of the z-scores (median, minimum, maximum, first quartile, third quartile and inter-quartile ranges) is shown in Figure 4.2 below.
Figure 4.2: Box and Whisker distribution of ABW and EFWs  
Source: Field data (2014)
CHAPTER FIVE

DISCUSSION

5.1 INTRODUCTION

This Chapter discusses the findings of the study in relationship with reviewed literature. The findings were presented in relationship to the stated objectives of the study under various themes.

5.2 RESPONSE RATE

A response rate of 75, (96%) out of 78, (100%) was achieved for this study. However, only 40, 53% out of 75 expectant mothers were used in the study. The low final figure of 40 was attributed to late referral of 35, (47%) patients to tertiary (Specialist) centres on suspicion of macrosomia, prolong latent phase of labour and breech presentations. Follow up on these participants by telephone yielded no result in one week of hospitalization. This scenario even present higher percentage comparable to study by Fernandez et al., (2009) in which the study reported that, about 15% of participants were lost to follow up after 6 weeks post hospitalization.

5.3 DEMOGRAPHICS

The ages of the 40 expectant mothers ranged from 17-38 years with a mean of 26.93± 6.1 years. An initial and final median BMI of 23.31 and 27.80kg/m² and their corresponding IQR of 5.15 and 5.33 were also obtained respectively. The mean age of the population is representative of the reproductive age group in Ghana and comparable to a mean age of 27.01±5.40 years reported by Kumarasiri et al. (2013) in an EFW study conducted on singleton pregnancies in Sri Lanka. However the BMI and IQR in this study are in sharp contrast with the work of Kumarasiri et al. (2013), which reported a median BMI of 20kg/m² and an IQR of 2.2. Additionally, statistical
significance was established between all groups of maternal anthropometric and ABW \([p\text{-values}>0.05]\) i.e. range of computed correlated coefficient \(R^2\)-values and \(p\)-values (> 0.05) within 95% confidence intervals established significant differences between maternal anthropometrics (Weight, Height, BMI) and neonates ABWs as shown in Table 4.2.

On the contrary, a study by Ojha & Malla (2007) indicated that low maternal anthropometric (weight, height and BMI) are some risk factors that contribute to low BW, as confirmed by Jananthan et al., (2009), that a strong correlation existed between maternal anthropometric and ABW. Additionally, in WHO publication (Backstrand, 1995) of the Mexico Nutrition CRSP research project in six Leishmann villages in the rural Solis Valley of central Mexico during 1984-1986 also established that weight and BMI showed the highest association with BW while the effect of maternal height on ABW was insignificant. The contrast of the findings of this study with the literature might be due to large sample size of those previous studies. However, findings from this study are consistent with (Nahum et al., 1995).

### 5.3 FOETAL BIOMETRICS

All the 40 uncomplicated singleton pregnancies seen during the study period were between 35⁰ and 40⁶ weeks of gestation. Foetal weights determined via the 8 regression models were compared with ABWs of 40 neonates. The mean duration from ultrasound scan to delivery was 1 day (range 0-2). For normal delivery at term, most of the newborns \((n=35, 87.5\%)\) had BWs in the range of 2.5 and 3.9kg, while 7.5\% \((n=3)\) weighed more than 3.9kg. Only 5\% \((n=2)\) weighed less than 2.5kg. According to WHO, low and high BW limits are defined as BW less than 2.5 kg and greater than 3.9kg respectively. Comparatively, the results obtained in this study are consistent with the WHO limits.
According to Nahum et al., (1995) in Gerard et al., (2002), the daily rate of foetal growth is 13.0g for boys and 12.4g for girls respectively. Hence for term deliveries of 270 days, these figures translate into 3.51kg for boys and 3.35kg for girls. The EFWs obtained in this study are in agreement with Nahum et al., (1985) and Gerard et al., (2002) as the mean EFW of all the models is 3.46±0.65 and ABW ranged from 3.0kg –3.3kg with a mean of 3.2 ± 0.46kg.

From figure 4.2, the findings in this study confirmed many studies which concluded that most EFW models generally overestimated foetal weight. Heer et al., (2008) established that, among all known influencing factors, only a time interval of more than 7 days between EFW and delivery had a negative impact on foetal weight estimation. Therefore, the principle of foetal weight compensation from scan time to delivery time was therefore ignored in this study as it presents no clinical significance of affecting neonates ABWs.

Luria et al., (2004) concluded that, there is a very good correlation between ultrasound EFW and ABW. However, limits of agreement are fairly wide, thus ultrasound estimates of BW turn to overestimate the neonatal weight by an average of 52g. Differences in anthropometry during pregnancy appear to be related to BW. It was found that the smallest infants were those whose mothers had a relatively lower pre-pregnancy weight (PPW) and early pregnancy weight, and who subsequently failed to gain much weight by the third trimester (Backstrand, 1995) was also established by this study.

Arguably, no previous study has been done in Ghana to assess the accuracy of using established regression models in predicting EFW. This present study showed that the regression models established no significant differences in predicting ABWs. The means and standard deviations
within 95% CI of the 4 foetal biometrics (BPD, HC, FL and AC) were very close, indicating the precision of the theoretical models in determining ABWs in this study. However, inconsistent with Kearney et al., (1978), who reported that inclusion of AC in estimating BW is the only biometric measurement that can positively influence accuracy of EFW as it present the highest standard deviation value of ± 2.37 around its mean compared standard deviation value of ± 0.43 for (FL) shown in Table-3.3. The disagreement might stem from the fact that, foetal abdominal circumference in other populations differs greatly from that of Ghanaian one or differences in accurate measurements.

A linear trend was noticed among all the 8 regression models with outliers. This means that, individual point estimates as well as differences in estimates between any of the regression models was a precise measure of the ABW. Per the earlier hypothesis, that there will be no statistically significant difference between the ABWs and any of the 8 regression models. This study indeed demonstrated that all the regression models showed no statistically significant difference at \((p-value =0.0001)\) in their mean EFWs compared to the neonates ABWs. This study demonstrated that 87% of EFWs are within 5% of ABWs agreed with studies by Harlev et al., (2006), Shittu et al., (2007) and Atalie et al., (2006) which reported that about 75% of EFWs were within 10% of ABWs. The 87% of EFW within 5% of ABWs compared to 75% of EFWs within 10% of ABWs indicated how superior i.e. accuracy and precision of measurements in this study as compared to others.

The 8 regression models adopted in this work are typically based on western populations and hence does not account for racial and ethnic differences which present diversities in anthropometrics. Further to this, regression analysis was used in the comparisons.
On the contrary, Altman and Bland (1983) questioned the appropriateness of using regression analysis in such comparisons, suggesting that many factors influenced the accuracy of EFWs. Kumarasiri et al., (2013) also concluded that operator experience played an important role in accurate estimations of foetal weight among others. In this study, the mean BWs at term among the Ghanaian population (3.53± 0.05kg - 3.57± 0.08kg) was comparable to the reference range of 3.08 ± 0.4kg derived from the global reference range based on WHO surveys of mean BW at term (Mikolajczyk, 2011) who also used regression analysis.

In conclusion, all the 8 regression models predicted high accuracies of estimating foetal weights within 5% of ABWs. With the exception of the Hadlock6(1985) regression model which had $p$-value of 0.02, the results showed that the absolute mean difference between the ABWs and the EFW in all the regression models were statistically significant with $p$-values = 0.0001. This is suggestive that all the regressions models can be apply to Ghanaian population. However, measuring BPD in labour period becomes less accurate as the head distends into the pubic bone which turns to masked the foetal head from complete visualization and accurately measurement coupled with narrow interval of limits around the estimated mean and the smallest standard deviation, this study projects Hadlock3 i.e. equation 4 as regressional model which does not depend on BPD for EFW, to be the best regressional model to be use in Ghanaian population at term for estimating foetal weight.
CHAPTER SIX

CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

6.1 INTRODUCTION

The study on the accuracy of ultrasound regression models for predicting foetal biometrics for normal singleton pregnancies has been conducted. It was aimed at determining the best ultrasound regression models using common foetal biometric measurements in EFW predictions using the ClearVue 350 ultrasound equipment. The study included assessing records of maternal anthropometrics (height and weight) from the time of first antenatal visit and weight at the last antenatal visit, accurate measurements of foetal biometrics (BPD, HC, FL, and AC) as input data into 8 established regression models, weight measurements of neonates within 1 hour of delivery, comparisons of EFWs generated by the regression models to ABWs.

A summary of the present findings, conclusions, recommendations and limitations arising from this research study are presented in this Chapter.

6.2 CONCLUSIONS

Comparisons of EFWs and ABWs have been investigated in various populations like that of (US, Europe, Latin Americas and Africa) and by different methods. The findings of the study showed that:

- all the 8 regression models with the exception of the Hadlock7 which had (p-value = 0.02), established \( p \)-values = 0.0001 < 0.05 level of significance. Therefore, the best
ultrasound regressional model in predicting foetal weight in Philips ClearVue 350 ultrasound equipment is/are all the 8 models as there $p$-values <0.05 significant level.

- the regression models predicted 87% of all EFWs in 5% of ABWs within 95% confidence interval demonstrating high degree of accuracy and consistency.

Per these findings, gynaecologists, radiologists, sonographers/radiographers and midwives can rely on EFWs produced from the Philips CleaVue ultrasound equipment using common foetal biometric measurements in a 2D mode.

Prenatal care is essential for preventing foetal and/or maternal mortality and other complications. However, timely interventions for patients at risk are required to prevent these complications. As a result, if the method used for identification of patients at risk lacks sensitivity and specificity, the trial of any intervention will not yield good results. It is therefore a challenge to estimate actual foetal and BWs using ultrasound scans. Despite the limitations of ultrasound EFWs, the modality remains the key basis for decisions amongst clinicians in many countries including Ghana.

### 6.3 RECOMMENDATIONS

As noted from the study, it was only conducted in a microcosm population. Therefore, geographical zones and country wide study should be done for better generalization. Radiographers, sonographers, radiologists, gynaecologists, and midwives (professionally trained and qualified to scan) should be trained every six months on emerging scan procedures and produce accurate images and EFWs to enable good clinical decisions to be taken.
The findings from this study have clearly shown that, with 87% of EFWs were within 5% of ABW. Hence, radiographers, sonographers, gynecologists, radiologists, and midwives can, to a high degree of accuracy rely on EFWs generated from the Philips ClearVue ultrasound equipment using the common foetal biometric measurements in a 2D mode. Caution must however be exercised especially in suspected large for date foetuses as all models appear to slightly overestimated ABW.

6.3 LIMITATIONS OF THE STUDY

- The major limitation as far as this study is concerned was the large number of referrals from the study site to tertiary facilities after scanning. This has greatly affected the sample size of this study.

- Midwives in the labour-wards, most often, did not call the researcher when patients came for delivery.

- The scanning site was far from the labour-ward making it difficult for patients to walk in.
REFERENCES


Courses.wcupa.edu; Publication retrieved from www. Courses.wcupa.edu on 17th March 2014


CrossRef | Web of Science | Medline


APPENDICES

APPENDIX I

PARTICIPANTS INFORMATION SHEET

DETERMINING BEST REGRESSIONAL MODEL IN PREDICTING FOETAL WEIGHT IN PHILIPS ClearVue 350 ULTRASOUND EQUIPMENT

Purpose of the Study
You are being asked to participate in this study in order to test for the best regression model (Equation) for predicting birth weight (BW).

Study Procedure and General Information.
If you agree to be part of this study, ultrasound scanning will be performed on your abdomen to measure the head, abdomen, and thigh bone of your foetus.

Risk to the Patient
Patient lying on the examination bed for longer period can cause unnecessary discomfort due to the pressure exerted on both the aorta and inferior vena cava. Therefore, the examination must be done quickly with precision.

Additionally, although there is no risk associated with the use of ultrasound waves, however the principle of ALARA (AS LOW AS REASONABLE ACHIEVABLE) with respect to ultrasound dose will be strictly adhere to.

Patient’s Right
Any patient has the right to partake or withdraw at any time during study. All participants will be fairly treated equally with no patient paying for the examination throughout the period of the study. Any ethical violation by the investigator can be reported to the SAHS Ethical and protocol review committee, College of Health Sciences, University of Ghana.

All participants shall be identified by codes. The following under listed names who are members of the Dissertation Advisory Team (DAT) can be contacted for any concerns you have with respect to this study:
APPENDIX II INFORMED CONSENT FORM

Department of Radiography, School of Biomedical and Allied Health Sciences, College of Health Sciences, University of Ghana

Title of Project: Determining Best Regressional Model in Predicting Foetal Weight in Philips Clearvue 350 Ultrasound Equipment

Purpose of Research: In Partial Fulfilment of MSc Degree

Name of Researcher: EDEM ANASTASIUS KWAMI BUADY

Name of Supervisors: DR. SAMUEL OPOKU, DR. ANIM-SAMPONG

CONFIDENTIALITY: All data will be anonymously and confidentially handle.

I…………………………………………………………………………………………. agree to take part in the above research and I consent to my participation. I understand that my participation is entirely voluntary and that there is no personal benefit that I will derive by participating in this study.

If you have any concern about this study and wish to contact someone independently, you may contact the supervisors below. SIGNATURE………………………………………………

DR. SAMUEL OPOKU                  DR. ANIM-SAMPONG
Dept. of Radiography                Dept. of Audiology
SBAHS                                SBAHS
University of Ghana                  University of Ghana
P.O. Box KB 143                      P.O. Box KB 143
Korle-Bu                             Korle-Bu
Tel: 0246909286/0207934650           Tel: 0207774000
APPENDIX III
DATA COLLECTION SHEET

SECTION A: MATERNAL DEMOGRAPHIC INFORMATION

A. Code number…………………………
B. Age………………………………years.
C. Height…………………………...cm
D. Weight…………………………...kg
E. Weight Difference………………...kg

SECTION B: FOETAL BIOMETRIC MEASUREMENTS

BPD……………………………………...cm
AC……………………………………...cm
HC……………………………………...cm
FL……………………………………...cm
APPENDIX IV ETHICAL CLEARANCE

SCHOOL OF ALLIED HEALTH SCIENCES
COLLEGE OF HEALTH SCIENCES
UNIVERSITY OF GHANA
ACADEMIC AFFAIRS

Phone: +233-0302-687974/5
Fax: +233-0302-688291

My Ref. No. SAHS/ 10434064
Your Ref. No.

Mr. Edem A. K. Buady,
Dept. of Radiography,
SAHS,
Korle Bu.

Dear Mr. Buady,

ETHICS CLEARANCE


Following a meeting of the Ethics and Protocol Review Committee of the School of Allied Health Sciences held on Monday 24th March, 2014, I write on behalf of the Committee to approve your research proposal as follows:

TITLE OF RESEARCH PROPOSAL: "Ultrasound Accuracy of Combining Biometric Measurements in Establishing Faetal Weight"

This approval requires that you submit six-monthly review reports of the protocol to the Committee and a final full review to the Committee on completion of the research. The Committee may observe the procedures and records of the research during and after implementation.

Please note that any significant modification of the research must be submitted to the Committee for review and approval before its implementation.

You are required to report all serious adverse events related to this research to the Committee within seven (7) days verbally and fourteen (14) days in writing.

11th April, 2014.
P. O .Box KB 143
Korle Bu
Accra
Ghana