

"A RANDOMISED CONTROLLED TRIAL TO ASSESS  
THE ROLE OF ROUTINE THIRD TRIMESTER  
ULTRASOUND IN LOW RISK PREGNANCY ON  
ANTENATAL INTERVENTIONS AND PERINATAL  
OUTCOME"

REG.NO. BJ0110002

Dissertation

Submitted to the  
KLE University, Belgaum, Karnataka

In Partial Fulfillment  
of the requirements for the degree of

MASTER OF SURGERY  
in  
OBSTETRICS AND GYNAECOLOGY

**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY,  
JAWAHARLAL NEHRU MEDICAL COLLEGE,  
BELGAUM, KARNATAKA**

**APRIL - 2013**

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**ENDORSEMENT**

This is to certify that the dissertation entitled “**A RANDOMISED CONTROLLED TRIAL TO ASSESS THE ROLE OF ROUTINE THIRD TRIMESTER ULTRASOUND IN LOW RISK PREGNANCY ON ANTENATAL INTERVENTIONS AND PERINATAL OUTCOME**” is a bonafide research work done by **THE CANDIDATE REGISTER NUMBER BJ0110002.**

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## LIST OF ABBREVIATIONS USED

AC	-	Abdominal circumference
AFI	-	Amniotic fluid index
AFV	-	Amniotic fluid volume
ANC	-	Antenatal care
APFS	-	Antepartum fetal surveillance
BPD	-	Bi-parietal diameter
CEMACH	-	Confidential Enquiry into Maternal and Child Health
CHD	-	Congenital heart disease
CI	-	Confidence interval
CS	-	Caesarean section
CTG	-	Cardio Toco graph
ECV	-	External cephalic version
EFW	-	Expected fetal weight
FL	-	Femoral length
GDM	-	Gestational Diabetes Mellitus
HC	-	Head circumference
IUGR	-	Intra Uterine Growth restriction
LMP	-	Last menstrual period
MNH	-	Maternal and Neonatal Health
NICU	-	Neonatal intensive care unit
NST	-	Non stress test
OGTT	-	Oral Glucose Tolerance Test
RCT	-	Randomized controlled trial
RR	-	Risk ratio

SGA	-	Small for gestational age
TOGV	-	Transposition of great vessels
U.K.	-	United Kingdom
U.S.A	-	United States of America
USG	-	Ultrasonography
WHO	-	World health organization

## ABSTRACT

**Background:** Although 80% of pregnancies are considered low risk antenatally, perinatal mortality is higher in them due to low index of clinical suspicion and lesser sensitivity of clinical assessment to detect high risk fetuses. Third trimester ultrasound can be used to detect conditions such as abnormalities in fetal growth, liquor & late onset fetal anomalies. This followed by appropriate antenatal interventions lead to improvement in perinatal outcome.

**Objective:** To assess the role of routine third trimester ultrasound in low risk pregnancy on antenatal interventions and perinatal outcome.

**Methodology:**

Design: Randomized controlled study.

Setting: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum.

Subjects: A total of 290 low risk pregnant women between 34- 37 weeks attending antenatal clinics and fulfilling inclusion criteria were allotted using Computer generated randomization numbers into study and control groups.

Intervention: In study group, third trimester ultrasound was performed to assess fetal growth, AFI, malpresentations, and late onset fetal anomalies. In control group, no routine ultrasound was performed, unless indicated by clinical suspicion during subsequent visits. High risk fetuses identified were managed as per the standard protocol. All women were followed to assess antenatal interventions, Intrapartum events and perinatal outcome.

**Results:** Detection of high risk fetuses antenatally in study and control group was 14.48% and 2.07% respectively. This difference was statistically significant. (p value-0.0001). Rates of antenatal interventions among study and control was 24.8% & 4.44% respectively. Prevalence of SGA fetuses among study and control was 6.9% V/s 11.03% respectively. This difference was not statistically significant. (p value- 0.253) There was no statistical difference in adverse intrapartum events, Caesarean section rate for non reassuring CTG, low APGAR score and NICU admissions among study and controls.

**Conclusion:** Routine third trimester ultrasound is a logical solution for detection of high risk fetuses in low risk pregnancies which would otherwise be missed by clinical examination. However this leads to an increase in antenatal interventions without significantly influencing the perinatal outcome.

**Key words:** Fetal growth scan; Low risk pregnancy; Perinatal outcome; Third trimester.

# *CONTENTS*

<b>SL. NO.</b>	<b>TOPIC</b>	<b>PAGE NO.</b>
1.	INTRODUCTION	1
2.	OBJECTIVES	8
3.	REVIEW OF LITERATURE	9
4.	METHODOLOGY	24
5.	RESULTS	33
6.	DISCUSSION	58
7.	CONCLUSION	67
8.	SUMMARY	69
9.	BIBLIOGRAPHY	71
10.	ANNEXURES	
	ANNEXURE I – CONSENT FORM	79
	ANNEXURE II – PROFORMA	82
	ANNEXURE III – MASTER CHART	86

## LIST OF TABLES

TABLE NO.	DESCRIPTION	PAGE NO.
1	Age distribution	34
2	Mean age	35
3	Parity	36
4	Growth abnormalities	37
5	Placental localization	38
6	Fetal malpresentations	39
7	Liquor abnormalities	40
8	Congenital anomalies	41
9	Detection of High risk fetuses	42
10	Antenatal Interventions	43
11	Intra partum events	47
12	Mode of delivery	48
13	Indications for C-section and instrumental delivery	49
14	Pregnancy outcome	50
15	Gestational age at delivery	51
16	Mean gestational age	51
17	Birth weight	52
18	Mean birth weight	53
19	Prevalence of SGA babies	54
20	APGAR score	55
21	NICU admission	56
22	Detection of SGA babies by ultrasound v/s clinical examination alone	57

## LIST OF GRAPHS

GRAPH NO.	DESCRIPTION	PAGE NO.
1	Age distribution	34
2	Parity	36
3	Growth abnormalities	37
4	Placental localization	38
5	Fetal malpresentations	39
6	Liquor abnormalities	40
7	Congenital anomalies	41
8	Detection of High risk fetuses	42
9	Antenatal Interventions	44
10	Subsequent Indicated scans	45
11	Induction of labour	46
12	Intra partum events	47
13	Mode of delivery	48
14	Indications for C-section and instrumental delivery	49
15	Birth weight	52
16	Prevalence of SGA babies	54
17	NICU admission	56
18	Detection of SGA babies by ultrasound v/s clinical examination alone	57

## LIST OF PHOTOGRAPHS

PHOTOGRAPH NO.	DESCRIPTION	PAGE NO.
1	PHILIPS HD 11 ultrasound machine	31

# Chapter 1

## Introduction



## **INTRODUCTION**

Antenatal care (ANC) is a key component of a healthy pregnancy. Regular antenatal care helps to identify and treat complications and promote healthy behavior to improve the health of the mother and the fetus.<sup>1</sup>

Improvement in perinatal outcome is an important goal of antenatal care. There are 5.9 million perinatal deaths worldwide, almost all of which occur in developing countries. Stillbirths account for over half of all perinatal deaths.<sup>2,3</sup> According to WHO global perinatal estimates for the year 2000, one third of stillbirths occur during delivery. These deaths are largely avoidable with antenatal care.<sup>4</sup>

Unexplained causes account for a significant proportion of still births. The Confidential Enquiry into Maternal and Child Health (CEMACH) statistics reveal a fairly constant rate of unexplained stillbirth among apparently anatomically and genetically normal fetuses, the incidence being approximately 1 in 200. Fetal growth restriction is an important contributor to perinatal mortality, being responsible for up to 50% of stillbirths.<sup>5</sup>

The importance of antenatal care for improving perinatal outcomes is well established. High quality antenatal care is a fundamental right of all pregnant women to safeguard their health and of their fetuses, providing opportunities for risk factor identification and appropriate interventions. The principle aim of antenatal care is the early recognition and management of high risk pregnancies.<sup>6</sup>

The antenatal period clearly presents opportunities for reaching pregnant women with a number of interventions that may be vital to their health and well-being and of their fetuses.<sup>7</sup>

In addition to the direct effect of ANC on perinatal outcomes (health benefits arising from the care itself), there may also be an indirect benefit associated with ANC, as women attending ANC are more likely to have their delivery assisted by a professional health care provider or in a health facility.<sup>7,8</sup>

The traditional approach to antenatal care which is based on European models developed in the early 1900s assumes that more is better in the care for pregnant women. Frequent routine visits are the norm and women are classified by risk category to determine their chances of complications and the level of care they need. Many developing countries have adopted this approach.

However, the Maternal and Neonatal Health (MNH) Program promotes an updated approach to antenatal care that emphasizes quality over quantity of visits. This has led to the development of a new approach called focused antenatal care. This approach recognizes two key realities. First, frequent visits do not necessarily improve pregnancy outcomes and in developing countries, they are often logistically and financially impossible for pregnant women. Second, many women who have risk factors never develop complications while women without risk factors often do. So when antenatal care is planned using a risk approach, scarce healthcare resources may be devoted to unnecessary care for "high-risk" women who may never develop complications, and "low-risk" women may be unprepared to recognize or respond to signs of complication.<sup>9</sup>

Although 80% of the pregnancies are considered antenatally to be “low risk”, large studies in Dublin and Belfast have demonstrated that perinatal mortality is higher in the apparent “low-risk” pregnancy than in the “high-risk” pregnancy.<sup>10</sup>

Although it cannot be claimed that ANC is the solution to high maternal and perinatal mortality in the developing world, however ensuring the provision of ANC may help progress to the Millennium Development Goals for maternal and child mortality.<sup>11</sup>

Antenatal care is generally thought to be an effective method of improving maternal and fetal outcomes of pregnancy.<sup>12</sup> ANC helps in identification of life threatening high risk conditions like anemia, pre eclampsia, gestational diabetes mellitus, which followed by appropriate management has shown to reduce maternal and perinatal morbidity and mortality. Immunization programmes, iron prophylaxis, early detection of preeclampsia, education, advice and preparation for transport and safe delivery are elements which may make a difference. The present system of antenatal care has stood the test of time and is widely practiced throughout the developed and much of the developing world. However the fetal risk factors like growth and liquor abnormalities cannot be picked up effectively by antenatal examination alone. During the regular antenatal visits an attempt to detect abnormal growth patterns of the fetus is done by noting maternal weight gain and assessing the fundal height. Unfortunately, these clinical methods are not as sensitive as we would wish and many growth-restricted as well as growth-accelerated fetuses slip through the clinical antenatal

net.<sup>5</sup> Further the Leopold manoeuvre has a lower sensitivity in the diagnosis of breech presentation and other malpresentations.<sup>13</sup>

Clinical assessment of fetal weight and amniotic fluid has sensitivities of less than 50% in the hands of most providers, leading to a high degree of false negative identification<sup>1</sup>. In the low risk population detection of these at risk fetuses could be missed due to low index of clinical suspicion.<sup>14</sup>

There is therefore the suggestion that if we could improve our detection rates of high risk fetuses antenatally, we would have the potential of reducing the incidence of unpredicted stillbirth.<sup>5</sup>

As medical knowledge and technology have evolved, new technologies have been added to routine antenatal care. Medical diagnostic ultrasonography, a sophisticated electronic technology, which uses pulses of high frequency sound has evolved as an important tool.

Ultrasonographic imaging during pregnancy has a major impact on prenatal care and pregnancy outcome. It is considered to be a safe method for obtaining useful information about the fetus and its environment and hence is widely used in both high and low risk pregnancies to assess fetal well being. The perceived value of indicated ultrasonography in the management of pregnancy has led to its use as an important screening tool and has also led to the incorporation of routine ultrasonography in order to improve perinatal and maternal outcome.<sup>15</sup>

In the last twenty years prenatal ultrasound imaging has shown great technological advancement and has spread widely in the entire population of pregnant women, including those at low risk. Routine ultrasonography before 24 weeks gestation is recommended for gestational age assessment detection of multiple pregnancies, fetal malformations and placental localization. These days ultrasound assessment has become the gold standard for diagnosing high risk fetuses with growth and liquor abnormalities.<sup>16</sup>

Antenatal detection of these high risk fetuses warrants an increased fetal surveillance, which would improve perinatal outcome. Antenatal interventions can be undertaken in the form of antenatal ward admissions, Antepartum fetal surveillance (APFS) with non stress test (NST), Doppler studies, indomethacin therapy for polyhydramnios, IV and oral hydration therapy for oligohydramnios, 100 gram 3 hour Oral Glucose Tolerance Test (OGTT) for suspected Gestational Diabetes Mellitus (GDM) cases with macrosomia and polyhydramnios, external cephalic version (ECV)/elective caesarean section (CS) for malpresentations, induction of labour for the compromised fetuses and so on, upon the detection of high risk fetuses by ultrasonography.

Antenatal detection of late onset structural anomalies like urinary tract, gastrointestinal, skeletal abnormalities allows decision making regarding time, place and mode of delivery leading to improved perinatal and neonatal outcome.

There is no controversy about the clinical value of using diagnostic ultrasonography in late pregnancy where there are specific clinical indications. However, the value of routine late pregnancy ultrasonography screening in

unselected or apparently low-risk pregnancies without clinical indications is still considered by many to be controversial.<sup>5</sup>

The rationale for 3<sup>rd</sup> trimester ultrasound screening would be the detection of high risk fetuses which would not have been detected by other means such as clinical examination. Subsequent management of these fetuses by appropriate antenatal interventions would improve perinatal outcome. One of the concerns is that routine ultrasonography may increase intervention with no apparent benefit in improving perinatal outcome.<sup>5</sup>

The policies for routine third trimester obstetrical ultrasound examinations differ among countries. In Canada, a routine third trimester ultrasound scan is not offered to the low-risk pregnant women but is used selectively where there are specific clinical indications that is in high risk pregnancies with known complications.<sup>17</sup>

Third trimester ultrasound seems a logical solution to identify fetuses at risk, but systematic review of evidence from randomized trials has shown that third trimester ultrasonography does not have a significant impact on reducing perinatal mortality but may increase interventions such as caesarean delivery.<sup>5</sup>

However, the evidence is difficult to interpret in the context of current obstetric practice as the evolution of ultrasound technology and rapid assimilation of newer techniques has resulted in questionable validity of the findings.<sup>5</sup>

The most modern obstetric techniques for ante partum fetal surveillance of Intra Uterine Growth restricted (IUGR) fetuses by means of Doppler

ultrasound were not used in any of the earlier studies. Such care may result in reduced perinatal morbidity and mortality by deciding the appropriate timing and mode of delivery. Further these fetuses can be strictly monitored during labor using continuous Cardio Toco graph (CTG) thereby avoiding fetal hypoxia and acidosis and improving perinatal outcome.<sup>18</sup>

Thus third trimester ultrasonography can be used to detect conditions which may not be apparent by clinical examination such as abnormalities in the fetal growth and liquor. The identification of these abnormalities followed by appropriate obstetric interventions would improve maternal and perinatal outcome.<sup>19</sup>

In view of the above, the present study was undertaken to assess the role of routine third trimester ultrasound in low risk antenatal women on antenatal interventions and to assess its impact on perinatal outcome.

# Chapter 2

## Objectives



## **OBJECTIVES**

The objectives of the present study were;

### **Primary objective**

To assess the role of routine third trimester ultrasound in low risk antenatal women on antenatal interventions.

### **Secondary objective**

To assess the role of routine third trimester ultrasound in low risk antenatal women on perinatal outcome.

# Chapter 3

## Review of Literature



## **REVIEW OF LITERATURE**

Safeguarding the health of the mothers and their young children is one of the world's most urgent priorities. Over 130 million babies are born every year in the world and more than 10 million infants die before their fifth birthday and almost 8 million before their first.<sup>20</sup> According to World Health Organization (WHO), 2.7 million babies are born dead every year and another 3 million do not survive beyond the first week of life.<sup>21</sup>

Approximately 98% of the 5.7 million perinatal deaths suffered globally occurred in developing countries. India continues to contribute about a quarter of all global maternal and perinatal deaths.<sup>21</sup> In 2005, more than 78000 (20%) of 387200 maternal deaths and more than 1 million (31%) of 3.4 million neonatal deaths occurred in India.<sup>22</sup>

Stillbirths account for over half of all perinatal deaths. Preterm birth, low birth weight, sepsis, birth asphyxia and congenital malformation are the main causes of perinatal deaths worldwide.<sup>9</sup> About one-third of perinatal deaths in developing countries are related to intra-partum complications leading to birth asphyxia. Preterm birth, malformations and infections related to pregnancy and birth contribute to the remainder of the early neonatal deaths.<sup>21</sup>

Neonatal deaths and stillbirths stem from poor maternal health, inadequate care during pregnancy, inappropriate management of complications during pregnancy and delivery, poor hygiene during delivery and the first critical hours after birth and lack of newborn care.<sup>20</sup> Often the death of mothers is closely connected with newborn deaths as maternal mortality and morbidity have

negative impact on the survival chances of the newborn. The current perinatal mortality rate in India is 49 per 1000 live births.<sup>23</sup>

Primary obstetric causes of perinatal death include spontaneous preterm delivery and hypertensive disorders of pregnancy.<sup>24</sup> Antepartum hemorrhage, multiple pregnancy, severe intrauterine growth restriction, maternal medical diseases like chronic hypertension, diabetes, cardiovascular diseases, chronic renal disease contribute to remaining cases.<sup>24</sup> Intranatal causes include asphyxia, prolonged labour, umbilical cord complications, birth injuries and obstetric complications. Postnatal causes include prematurity, respiratory distress syndrome and congenital anomalies. The biomedical determinants of perinatal mortality include maternal factors such as age, parity, antenatal care, bad obstetric history, pregnancy-related complications and the perinatal and neonatal factors such as birth weight, gestational age, infection and congenital malformations.<sup>8</sup> The non-medical factors include financial constraints at individual level, education and occupation of the parents. High maternal age, primi-parity, high parity, smoking, low socio-economic status and being a single mother have been identified as risk factors for perinatal mortality.

Intrapartum fetal death is usually the result of fetal distress and obstructed labour. It often reflects poor access or poor quality of clinical care during delivery.<sup>25</sup> In developed countries, the majority of stillbirths occur before labour onset but this proportion is low in developing countries may be due to under reporting of cases.<sup>25,26</sup>

Intra-uterine growth restriction represents major risk factor for perinatal death.<sup>23,25,27</sup> The prevalence of small for gestational age babies in live births is about 10 to 25% and in stillbirths it is upto 41%.<sup>27</sup> Stillbirth babies were 6.8 times more likely to be small for gestational age (SGA). Antepartum fetal surveillance including Doppler velocimetry is useful in distinguishing IUGR fetuses at risk for intrauterine fetal death.<sup>27,28</sup> Absent end diastolic flow or reverse end diastolic flow in the umbilical artery is suggestive of severe fetal compromise and prompt consideration of delivery.<sup>28</sup> Antenatal identification followed by close antepartum fetal surveillance and timely decision to deliver growth restricted fetuses helps in the prevention of stillbirth.<sup>29</sup>

Reproductive health is a priority programme for all the Southeast Asia Regional countries where maternal mortality continues to be a major problem. Antenatal care, a pregnancy-related service provided to pregnant women by health professionals is among the major interventions which aims to prevent perinatal deaths and maintain the health of women during pregnancy.<sup>30</sup> A review on interventions for neonatal survival demonstrated that up to 12% of perinatal deaths could be averted by the provision of antenatal care services at 90% coverage.<sup>31</sup>

Antenatal care enables health professionals to identify potential risks for the pregnancy or for the delivery and to provide prompt treatment for women experiencing health problems during pregnancy. Through this service, women will receive assistance in developing a birth plan and be prepared for parenting after the childbirth.<sup>30</sup>

Antenatal care is the most important method for detecting high risk pregnancies and complications at the earliest. ANC is a critical element for reducing maternal and perinatal mortality and for providing pregnant women with a broad range of promotive and preventive health services. ANC is also an opportunity to inform women about the danger signs and symptoms for which immediate assistance should be sought from a health care provider.<sup>30</sup>

Pathological growth restricted fetuses are at greater risk of stillbirth, birth hypoxia, neonatal complications in the perinatal period, impaired neurodevelopment and cerebral palsy in childhood, non-insulin-dependent diabetes and hypertension in adult life. Majority of these small fetuses are not diagnosed until delivery and detecting these fetuses antenatally remains a priority of antenatal care. Methods of detecting IUGR fetuses include antenatal clinical examination, measurement of symphysis–fundal height and ultrasound-estimated fetal weight. Symphysis fundal height measurements have been shown to perform relatively poorly. A combined approach of screening with symphysis–fundal height measurement complemented with ultrasound-derived fetal abdominal circumference if IUGR is suspected has been advocated by some but still antenatal care remains a screening scenario as opposed to a diagnostic one. Many fetuses with intrauterine growth restriction remain undetected by clinical examination alone.<sup>5</sup>

Fetal urine is the major source of amniotic fluid in the latter half of pregnancy. Oligohydramnios in the absence of ruptured membranes or fetal anomalies is thought to be associated with chronic fetal compromise and this leads to redistribution of regional blood flow resulting in reduction in fetal renal

blood flow, fetal oliguria and thus less amniotic fluid. Oligohydramnios can be diagnosed by ultrasound measurement of maximum pool depth, two-diameter amniotic fluid pockets or amniotic fluid index (the sum of the vertical maximum pool depths in four quadrants) and applying the result to normal reference ranges. Clinical assessment of Amniotic fluid volume (AFV) is notoriously difficult even in the most experienced hands. If the assessment of amniotic fluid volume were to be considered of significance in the detection of fetal compromise, ultrasonography would have to be used in the majority of cases.<sup>5</sup>

In the United Kingdom and most developed countries, the structural and genetic normality of the fetus has invariably been addressed by mid-pregnancy. A mixture of biochemical screening, nuchal translucency measurement at 12 weeks and a structural scanning at 20 weeks usually means that the mother is entering the third trimester with the full knowledge of the alleged normality, or otherwise, of her fetus. However, a number of structural fetal abnormalities may manifest later in pregnancy. These include craniospinal abnormalities (microcephaly and hydrocephaly), gastrointestinal abnormalities (intestinal obstruction and atresia), urinary tract abnormalities and some skeletal abnormalities. It has been suggested that the value of detecting fetal structural abnormalities before birth allows decisions regarding prenatal consultation with a pediatric surgeon, optimal timing, place and mode of delivery leading to improved management and outcome. More importantly in the context of screening for growth restriction, fetuses may be growth restricted due to an intrinsic abnormality as opposed to placental-dysfunction-related growth restriction. Therefore the recognition of IUGR in late pregnancy must always trigger a re-evaluation of the apparent

normality of the fetus.<sup>5</sup> Third trimester ultrasound also allows determination of fetal presentation. It has been demonstrated that ultrasound is better than clinical evaluation in determining fetal presentation.<sup>32</sup> Approximately 20% of breech presentations are initially identified during active labour.<sup>33</sup> Although vaginal breech delivery is still an option<sup>34,35</sup>, most centers opt for an elective CS or offer ECV.<sup>36,37</sup> However when breech presentation is diagnosed in labour ECV may not be an option and evaluation for vaginal delivery may not be possible thus CS may be the safest option. Caesarean sections performed during labour are associated with an increased risk of maternal morbidity.<sup>38</sup> In this context it is not clear if third trimester ultrasonography would contribute to a reduction in the rate of emergency CS for malpresentations identified in active labour, if identification of a breech presentation is followed by a standardized management plan (ECV or elective CS).<sup>13</sup>

In the last four decades, ultrasonography has become a valuable and increasingly popular tool in obstetrics. A routine third trimester ultrasonography is intended to evaluate fetal size, amniotic fluid volume, placental site, late onset fetal anomalies and fetal presentation. Third trimester ultrasonography can be used to detect conditions which may not be apparent by clinical examination such as abnormalities in the fetal growth and liquor. The identification of these abnormalities followed by appropriate obstetric interventions would improve maternal and perinatal outcome.<sup>19</sup>

Third trimester obstetric ultrasonography is used to screen for late onset fetal anomalies, IUGR or macrosomia, oligohydramnios or polyhydramnios, to assess fetal presentation, placental position, and fetal well-being. The prevalence

of abnormal findings may be low in low-risk pregnancies. The resources required to provide third trimester ultrasound for the entire population are significant. It is likely that a policy of routine third trimester ultrasound would be unacceptable on the basis of cost-effectiveness. Moreover, it may increase antenatal interventions or the rate of CS. However, it is not known if a policy of routine third trimester ultrasonography followed by appropriate prenatal care would improve perinatal and maternal outcomes and thereby reduce the cost associated with neonatal and maternal complications. Ultrasonography is a screening and diagnostic tool. It is appropriate that an adequate management plan should follow the detection of an abnormality (IUGR, malformation, breech presentation, polyhydramnios or oligohydramnios) by ultrasound. When evaluating the efficacy of ultrasonography on perinatal outcome, it is important to evaluate its diagnostic accuracy for detecting fetal anomalies, estimating fetal weight and assessing fetal well-being and the abnormal diagnostic test result should be followed by specified interventions such as surveillance or treatment.<sup>13</sup>

Until recently, routine ultrasound after 24 weeks gestation in low-risk or unselected populations had not been shown to affect antenatal, obstetric or neonatal intervention or morbidity in screened v/s control groups, although placental grading was associated with a significant reduction in the stillbirth rate in the one trial that assessed it.<sup>19</sup> A Meta analysis was carried out in 2001 to assess the effects of routine late pregnancy ultrasound (defined as greater than 24 weeks) on obstetric practice and pregnancy outcome in women with low risk pregnancies. Eight trials recruiting 27,024 women, which were carried out in the late 1970s and early 1980, the most recent being the study in 1993 was included

in the Meta analysis.<sup>19</sup> The meta analysis included the following studies: The RADIUS Study (1993),<sup>39</sup> The Alesund Trial (2000),<sup>40</sup> The Trondheim Study (1984),<sup>41</sup> The Glasgow Study (1984),<sup>42</sup> The Perth Study (1993),<sup>43</sup> The Peterborough Study (1987),<sup>44</sup> The New Zealand Study (1993),<sup>45</sup> The Belfast study (2003).<sup>10</sup>

The 2001 Meta analysis concluded that routine late pregnancy ultrasonography in low risk or an unselected pregnancy does not confer benefit on mother or the fetus.<sup>19</sup>

The objective of the RADIUS Study<sup>39</sup> was “to determine whether ultrasound screening decreased the frequency of adverse perinatal outcomes.” This was the largest study included in the meta-analysis with 15151 pregnant women at low risk. Multiple pregnancies were included in this low-risk population. The ultrasound examination included assessment of placental location, amniotic fluid volume, fetal biometry, and a detailed fetal anatomical survey. In the study group, the detection rate of fetal anomaly was 34.8%. This rate was higher in the study population than in the controls (11%). Although more than 50% of fetal anomalies were diagnosed during the third trimester ultrasound, the authors concluded that routine ultrasound did not improve perinatal outcomes. However, no mention was made of any management plans following abnormal ultrasound findings such as IUGR or fetal malformation. Only the RADIUS Trial included detection of fetal anomaly as an outcome of interest. Identification of fetal malformations in the third trimester raises the critical issue of late termination of pregnancy. However, appropriate perinatal management for specific malformations such as congenital heart disease (CHD),

gastro intestinal and urogenital anomalies can improve neonatal outcomes.<sup>46</sup> In a recent retrospective study, the mean gestational age at diagnosis of transposition of great vessels (TOGV) was 25.5 weeks, well after the routine second trimester anomaly scans.<sup>47</sup> It is possible that routine third trimester ultrasound could improve both the detection rate of late onset fetal anomalies and perinatal outcomes when associated with an adequate perinatal management plan. The RADIUS Study did not show improved perinatal outcomes, although it demonstrated an increased rate of diagnosis of fetal anomalies.<sup>39</sup> However, the study population in the RADIUS study did not undergo routine 2<sup>nd</sup> trimester anomaly scan. In another study conducted in Paris<sup>48</sup> involving 7812 women who had a third trimester ultrasound, 187 (2.4%) had a fetus with at least one major anomaly, 65 (34.8%) of which were detected prenatally, with more than one half detected at the third trimester ultrasound. In contrast to the RADIUS Study,<sup>39</sup> this study demonstrated that third trimester ultrasound doubled the detection rate of fetal anomalies.

The Alesund Trial<sup>40</sup> was published in 2000. Patients were recruited between 1979 and 1981. This randomized controlled trial was designed “to detect a 50% difference in the incidence of induction for apparent post-term pregnancies between women who were screened with ultrasound and unscreened women.” The objective of this study does not match the objective of the meta-analysis.

In Trondheim Study<sup>41</sup> the sample size was calculated to be able to demonstrate a 50% reduction in post-term pregnancies. To discriminate between normal growth and suspected IUGR, the authors used “fetal biparietal diameter one standard deviation below the mean growth curve” ,which is not a sensitive

criteria to identify IUGR fetuses. Using this criterion only 25% of small for gestational age fetuses were identified antenatally. Moreover the authors of this trial noted that “two of the three sonographers had only limited experience in the technique and received two months of intensive training before the study.”

The objective of Glasgow Study<sup>42</sup> was to use ultrasound screening to reduce adverse perinatal outcomes associated with IUGR. The ultrasound examination did not include assessment of placental location, amniotic fluid volume, fetal presentation, or fetal morphology. To estimate fetal size, the authors of this study measured crown rump length and multiplied this by trunk area measured at between 34 and 36 weeks’ gestation. This method is not currently used to estimate fetal weight.

The Perth Study<sup>43</sup> evaluated the impact of serial ultrasound and Doppler studies on perinatal outcomes. The main outcome measures were prematurity rate and NICU stay. Even though this study did not show improvement in neonatal outcomes, the diagnosis of IUGR in the study group was made twice as often as in controls (relative risk 2.07; 95% confidence intervals 1.34–3.21). Although perinatal mortality rate was not one of the outcome measures, there were 10 neonatal deaths in the control group (n = 1415) compared with 3 in the study group (n = 1419). In this study, no management plan has been evaluated.

The objective of Peterborough Study<sup>44</sup> was to show an effect on pregnancy outcome when placental grading was revealed to the clinician after a third trimester ultrasound examination. The ultrasound examination did not include assessment of fetal biometry, amniotic fluid volume, fetal presentation, or

fetal morphology. Placental grading was assessed in both the study and the control groups, but was revealed only to the clinicians in the study group. The study group had a 14% decrease in adverse perinatal outcome, although this difference was not significant. The perinatal mortality rate was 5 times lower in the study group.

The New Zealand Study<sup>45</sup> evaluated the effect of routine third trimester ultrasound on the morbidity and mortality of fetuses with IUGR. The ultrasound examination did not include assessment of placental location, amniotic fluid volume, fetal presentation, or fetal morphology. The study's hypothesis was "that early diagnosis of fetal growth problems leads to more appropriate management and therefore improved outcome." The investigators found no significant difference in outcome of pregnancy between study and control group. However, "appropriate management" is not specified in the description of the study; the investigators specified only that "estimated fetal weights below the 20th percentile for gestational age were reported and additional scans were recommended but not arranged." Moreover, the 20<sup>th</sup> centile cut off value is not a standard cut off value to diagnose IUGR.

Thus ultrasound examination options differed between these trials with some offering no routine scans at any time in pregnancy to the control group, some offering routine scans to all participants earlier in pregnancy (before 24 weeks' gestation) and some offering routine scan at all stages of the trial, but only revealing results of late pregnancy ultrasound (after 24 weeks' gestation) for the study groups.<sup>19</sup>

These trials evaluated different aspects of third trimester ultrasound. Two trials (Glasgow 1984 (UK);<sup>42</sup> New Zealand 1993<sup>45</sup>) addressed ultrasound screening for small for dates. The Peterborough 1987 (UK) trial<sup>44</sup> addressed the value of placental grading as an adjunct to routine third trimester ultrasound scan.

The RADIUS 1993 (USA) trial<sup>39</sup> was the only study which reported in detail, detection of fetal abnormalities at routine third trimester ultrasound scan. The Perth 1993 (Australia) trial<sup>43</sup> combined repeated ultrasound scan for fetal biometry and amniotic fluid assessment with Doppler ultrasound.

Childhood developmental outcomes were measured in the Perth 1993 study<sup>43</sup>, Alesund<sup>40</sup> and Trondheim trials.<sup>41</sup>

The 2001 Meta analysis<sup>19</sup> concluded that there were no differences between the study and control groups in the rates of women having further ultrasound scans, in antenatal admissions or in other tests of fetal wellbeing. Neither was there a significant difference in obstetric interventions, such as induction of labour and instrumental deliveries. There was a slightly increased caesarean section rate in the study compared with the control group and this finding approached statistical significance (15% Vs. 14%, risk ratio (RR) 1.06, 95% confidence interval (CI): 1.00–1.13, p=0.07). Study groups were less likely to deliver post-term (after 42 weeks' gestation) (3% vs. 4%, RR 0.69, 95% CI: 0.59–0.81). Preterm delivery rates and birth weight data were similar in the study and control groups. In general, perinatal mortality including or not including congenital abnormalities was no different. There was also no difference in perinatal mortality of twins. Only two studies (Glasgow 1984 (UK);<sup>42</sup>

Peterborough 1987 (UK)<sup>44</sup> reported separate data for stillbirths and neonatal deaths in congenitally normal fetuses or neonates. The Peterborough trial<sup>44</sup> suggested a reduction in the stillbirth rate if placental grading is incorporated into routine third trimester ultrasound scan. Neonatal interventions such as resuscitation, ventilation and admission to special care were no different in study versus control groups. Neither was there a difference in the 5-min Apgar scores.

The only study (RADIUS 1993, USA)<sup>39</sup> reporting moderate and severe neonatal morbidity showed no difference between the two groups. Of the three trials that reported long-term outcomes(Perth, Alesund and Trondheim trial) there were no differences between study and control groups for any childhood development outcomes measured at 8–9 years including physical development, language, speech and intelligence. The findings from these studies have not been combined in meta-analysis as outcomes were measured at different time points or using different tools, or both. There was some evidence of increased non-right-handedness for children exposed to ultrasound in the follow-up from the Norwegian trials, but as these findings have not been replicated they may have occurred by chance. Psychological and other maternal outcomes were not reported in any of the included studies.<sup>19</sup>

There were no differences between the two groups in the rates of women having additional scans, antenatal admissions, preterm delivery, induction of labour and instrumental deliveries although the rate of caesarean section increased slightly with study group.<sup>19</sup>

Parameters of perinatal outcome like birth weight, APGAR score interventions such as resuscitation and admission to NICU were similar between the groups. Infant survival with or without congenital abnormalities, was no different with and without routine ultrasound screening and childhood development at 8-9 years was similar in the three trials that measured it.<sup>19</sup>

The Belfast 2003 trial examined the impact of two third trimester scans which assessed liquor volume, fetal weight and placental maturity. The introduction of two biophysical ultrasound examinations at 30–32 and 36–37 weeks gestation to assess placental maturity, amniotic fluid volume and estimated fetal weight in a low-risk antenatal population showed that the proportion of fetuses assessed as small for dates at birth was smaller in the study group (6.9% vs. 10.4%;  $p=0.008$ ), with a corresponding increase in obstetric interventions (31.3% vs. 16.9%;  $p<0.001$ ).<sup>10</sup>

Thus, the Belfast trial (2003) done to evaluate the effect of routine third trimester ultrasound in a low risk pregnancy concluded that routine third trimester ultrasound may reduce the risk of a growth restricted fetuses and increases the antenatal interventions. Rates of admission to neonatal care unit were not significantly affected.<sup>10</sup>

A meta-analysis in 2008<sup>13</sup> reviewed the 2001 meta-analysis in detail including the Belfast study<sup>10</sup> and concluded that the meta-analysis (2001)<sup>19</sup> used outdated diagnostic techniques and ultrasound technologies in the late 1970s and early 1980s. None of the trials included in the meta-analysis evaluated the effect of routine third trimester ultrasound on perinatal outcome in low risk

pregnancies, when ultrasound assessment was followed by an appropriate perinatal management plan. None of the studies included were designed to answer the specific question: **“Does routine third trimester ultrasound in a low-risk population, followed by an adapted perinatal management plan, improve perinatal outcomes?”**. So at present, since there are no adequately designed studies, it cannot be concluded that routine third trimester ultrasound does not improve perinatal outcome.

The meta-analysis<sup>13</sup> further suggested the need for a randomized controlled trial by using the current ultrasound technologies to perform routine third trimester ultrasound evaluation, followed by appropriate obstetric interventions to answer the question raised in the meta-analysis.

This puts in question the contemporary validity of the conclusion of the 2001 meta-analysis. In fact, the 2001 meta-analysis has been recently been withdrawn by the authors.<sup>13</sup>

Thus a randomized controlled trial is required using the current technologies to assess the role of routine third trimester ultrasound in the diagnosis of high risk fetuses followed by appropriate obstetric management to evaluate its impact on perinatal outcome.<sup>13</sup>

Improvement in perinatal outcome requires timely detection of high risk fetuses followed by appropriate interventions, for which a third trimester ultrasound seems a logical solution, as the diagnosis of high risk fetuses particularly in the presumed low risk pregnancy would otherwise be missed by clinical examination alone.

# Chapter 4

## Methodology



## **METHODOLOGY**

The present study was conducted in the Department of Obstetrics and Gynecology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, KLE university teaching hospital attached to Jawaharlal Nehru Medical College, Belgaum.

### **Study design**

The study design was a randomized controlled trial.

### **Study period**

This study was conducted during the period from September 2010 to September 2011.

### **Source of data**

Low risk pregnant women between 34 to 37 completed weeks of gestation attending antenatal clinic for routine antenatal checkups were included in the study.

### **Sample size**

A total of 290 women were included in the study.

### **Sampling technique**

The sample size was calculated considering two sample proportions, for the incidence of antenatal interventions<sup>10</sup> using the formula as below,

$$n = \frac{(Z + Z)^2 p(1-p)}{(p_1 - p_2)^2}$$

Where,

$p_1 =$  Rate among scan group = 31.3%

$p_2 =$  Rate among the control = 16.9%

$p =$   $(p_1 + p_2) / 2$

$=$  0.05

$=$  0.2 (for 80% power of detection)

$Z =$  1.96

$Z =$  0.84

Considering the above formula the minimum sample size was calculated as 140 in each group. However during the study period 145 women fulfilled the selection criteria and same were included in the study.

### **Selection criteria**

#### ***Inclusion criteria***

- Singleton pregnancy
- Gestational age assigned by LMP and/or first trimester ultrasound and/or second trimester anomaly scan
- Normal midtrimester anomaly scan
- Gestational age from 34 to 37 completed weeks

***Exclusion criteria***

- High risk antenatal women like;
  - Gestational diabetes mellitus
  - Cardiac disease
  - Hypertensive disorders in pregnancy
  - Severe anemia
  - Intra uterine growth retardation
  - Oligohydramnios
  - Polyhydramnios
  - Macrosomia
  - Placenta previa
  - Rh isoimmunised pregnancy
  - Known fetal abnormality
  - Clinically suspected growth and liquor abnormalities and malpresentations
- Previous intra uterine fetal demise/ early neonatal death/ recurrent abortions

**Ethical clearance**

Prior to the commencement of the study ethical clearance was obtained from the Institutional Ethical committee, Jawaharlal Nehru Medical College, Belgaum.

**Informed Consent**

Pregnant women between 34 -37 completed weeks of gestation attending antenatal clinic for routine antenatal checkups were screened for eligibility by

detailed history, routine antenatal examination and investigations by trained residents in the department of obstetrics and gynecology. Women fulfilling selection criteria were explained about the purpose of the study and the need for randomization. A written informed consent was obtained from all the participants before the enrollment (Annexure I).

### **Method of collection of data**

After the enrollment demographic data, obstetric history and current pregnancy details were obtained. All the eligible pregnant women were clinically assessed by the standard antenatal care protocol. The data was recorded on a predesigned and pretested proforma (Annexure II).

### **Randomization**

Based on the computer generated randomization chart these women were randomized into groups as below.

- Study group (n=145): In addition to the routine antenatal care, women in this group were subjected to routine obstetric ultrasonography (USG) at the time of randomization.
- Control group (n=145): Women in this group were not subjected to routine obstetric ultrasonography at the time of randomization.

### **Procedure**

The eligible women were randomly allotted to the study group or the control group using a computer generated randomization chart. The women

randomized to the study group underwent routine obstetric ultrasonography in addition to the routine antenatal care. Ultrasonography was performed using the 3.5 MHz curvilinear probe of PHILIPS HD 11 machine to assess fetal growth, expected fetal weight and amniotic fluid volume by the trained Obstetricians and Gynecologists.

Fetal growth was assessed using the fetal parameters like Bi-parietal diameter (BPD), Head circumference (HC), abdominal circumference (AC), and femoral length (FL).

BPD was measured from the outer to inner margins of the fetal skull table perpendicular to the falx cerebri and in the plane incorporating the septum cavum pellucidum. HC was measured along the entire periphery of the outer osseous border of the cranium. AC was measured around a circular view of the fetal abdomen incorporating the portoumbilical vein complex and fetal stomach and excluding the kidneys and thorax. FL was calculated as the total length of the bone not including thin elongations at the cranial ends indicating the cartilaginous neck.

Expected fetal weight (EFW) was assessed using all these fetal parameter. The fetal biometric parameters and EFW values were plotted on a growth chart to obtain the centiles using SONOCARE software.

Amniotic fluid volume was quantified by the standard four quadrant technique. Amniotic fluid volume was calculated using amniotic fluid index, which is derived by the sum of the maximum vertical depth of the deepest

amniotic fluid pocket free of fetal parts and cord in each of the four uterine quadrants.

During the ultrasound evaluation, fetal malpresentations and late onset anomalies were also noted.

The values of EFW and / AC for gestational age was categorized as:

- < 10<sup>th</sup> percentile, for IUGR.
- 10- 20<sup>th</sup> percentile, for borderline IUGR.
- 80- 90<sup>th</sup> percentile, for borderline macrosomia.
- >90<sup>th</sup> percentile, for macrosomia.

The values of AFI were categorized into 5 groups:

- <5 cms, for oligohydramnios.
- 5-8 cms, for borderline oligohydramnios(less liquor).
- 20-24 cms, for borderline polyhydramnios (excess liquor).
- 25 cms, for polyhydramnios.

Borderline growth and liquor abnormalities were also noted as they could influence a change in antenatal management and pregnancy outcome.

Any abnormalities related to fetal growth and liquor abnormalities, late onset fetal anomalies and malpresentations detected on ultrasonography in the study group at the time of randomization were subjected for subsequent indicated ultrasound examination based on the abnormality detected. No scan was offered to the patients in control group at the time of randomization. However during

subsequent antenatal visits, women in the control group and women with normal ultrasound findings in the study group at the time of randomization were subjected to ultrasound evaluation based on clinical indications only. The number of such subsequent scans and the indication for the scans were noted.

The high risk fetuses thus identified were managed as per the standard management protocol by the treating obstetrician. All women were followed up to assess antenatal interventions, events during labour and perinatal outcome.

The various antenatal interventions recorded were –antenatal ward admissions, subsequent indicated scans (number and indication), ante-partum fetal surveillance like daily fetal kick count, Non stress test and Doppler studies, 100 grams, 3 hour oral glucose tolerance test, oral and intravenous hydration therapies, external cephalic version, Amnioreduction, decision for induction of labour/ C-section.

Intrapartum events like –non reassuring Cardio- Toco Graph (CTG), meconium stained amniotic fluid, continuous CTG monitoring were also noted in all cases.

The perinatal outcome of all the cases was recorded in terms of:

- Live birth/still birth/early neonatal deaths
- Gestational age at delivery
- Birth weight
- APGAR score at 1 minutes and 5 minutes
- Mode of delivery
- NICU admission



**Photograph 1. PHILIPS HD 11 ultrasound machine**

### **Statistical analysis**

The data obtained was coded and entered into Microsoft Excel Worksheet. The categorical data was expressed as rates, ratios and proportions and continuous data was expressed as mean  $\pm$  standard deviation (SD). The data was analysed using chi-square test and Fischer's exact test. A probability value ('p' value) of less than or equal to 0.05 was considered as statistically significant.

# Chapter 5

## Results



## **RESULTS**

This one year randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, KLE University's teaching hospital attached to Jawaharlal Nehru Medical College Belgaum, during the period from September 2010 to September 2011.

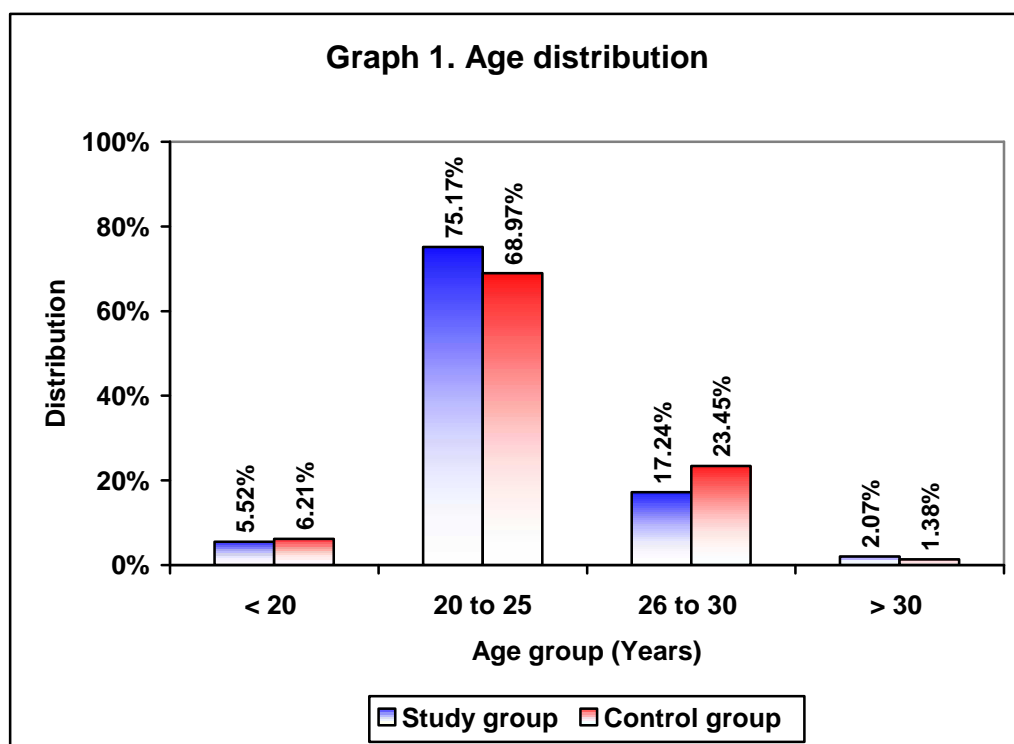
A total of 290 low risk pregnant women between 34 to 37 completed weeks of gestation attending antenatal clinic for routine antenatal checkups were included in the study. Based on the computer generated randomization chart these women were randomized into groups as below.

- Study group (n=145): In addition to the routine antenatal care women in this group were subjected to routine obstetric ultrasonography at the time of randomization.
- Control group (n=145): Women in this group were not subjected to routine obstetric ultrasonography at the time of randomization

The data obtained was coded and entered into Microsoft Excel Worksheet and the data was analyzed and results were tabulated as below.

**Table 1. Age distribution**

Age group (Years)	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
< 20	08	5.52	09	6.21
20 to 25	109	75.17	100	68.97
26 to 30	25	17.24	34	23.45
> 30	03	2.07	02	1.38
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>



In the present study 75.17% of the pregnant women in study group and 68.97% women in control group were aged between 20 to 25 years.

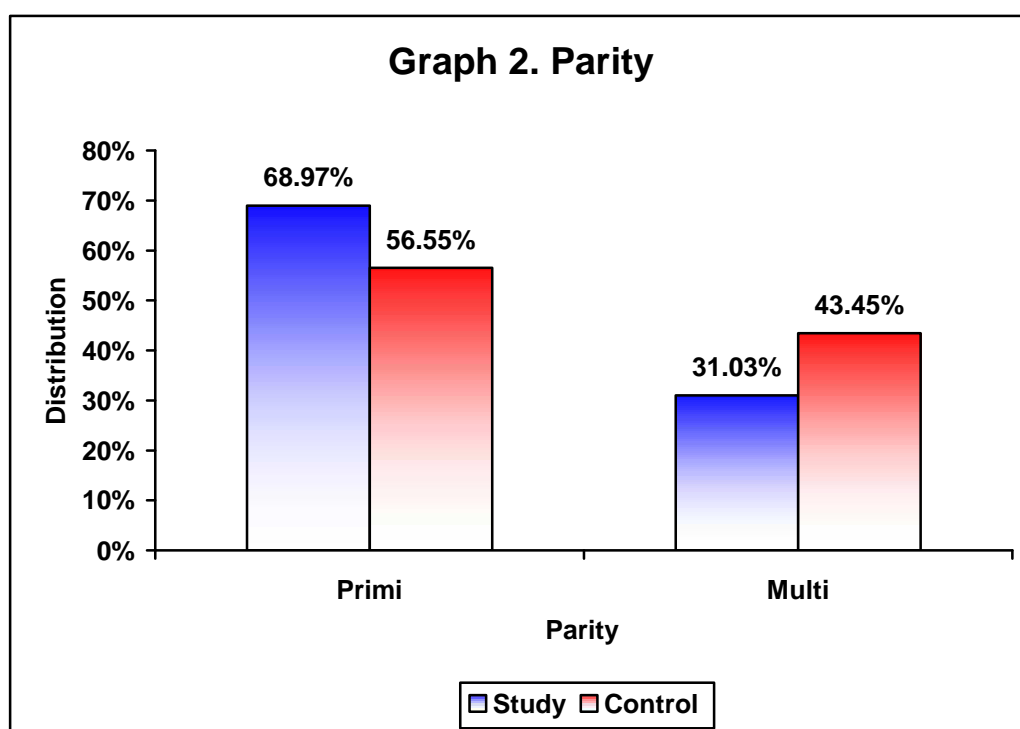
**Table 2. Mean age**

<b>Age (Years)</b>	<b>Study group (n=145)</b>	<b>Control group (n=145)</b>
Mean	23.06	23.48
SD	3.14	2.85
Median	23.00	23.00
Maximum	37.00	33.00
Minimum	18.00	19.00

The mean age in study group was  $23.06 \pm 3.14$  years and the median age was 23 years with range being 18 to 37 years. In control group the mean age was  $23.48 \pm 2.85$  years and the median age was 23 years with range between 19 to 33 years.

**Table 3. Parity**

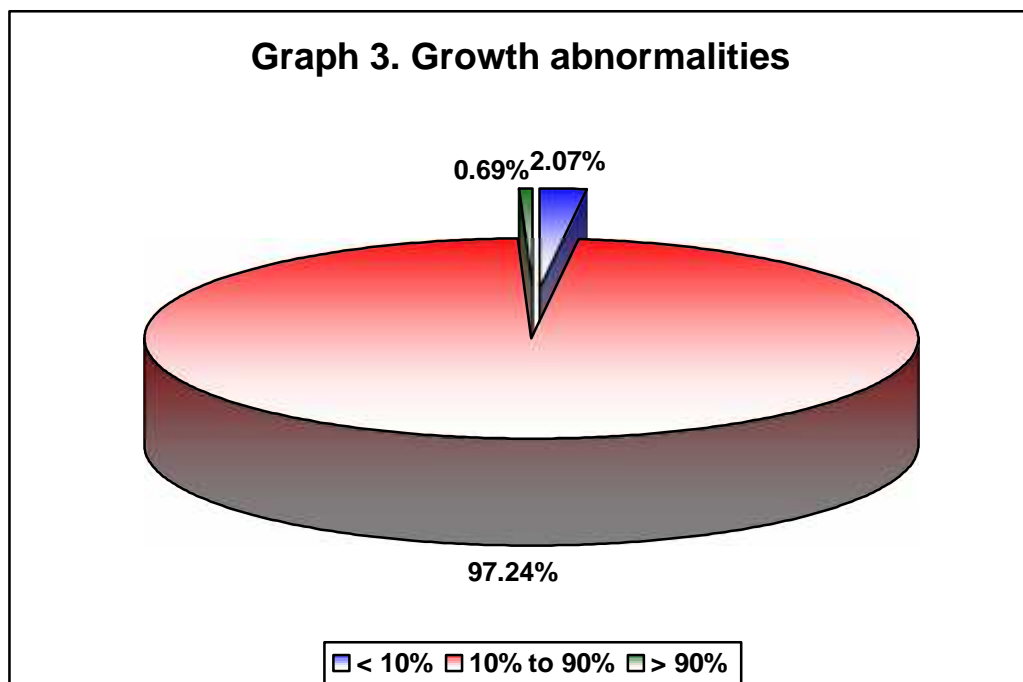
Parity	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
Primi	100	68.97	82	56.55
Multi	45	31.03	63	43.45
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>



In the present study 68.97% of the pregnant women in the study group and 56.55% of the pregnant women in the control group were primigravida.

**Table 4. Growth abnormalities**

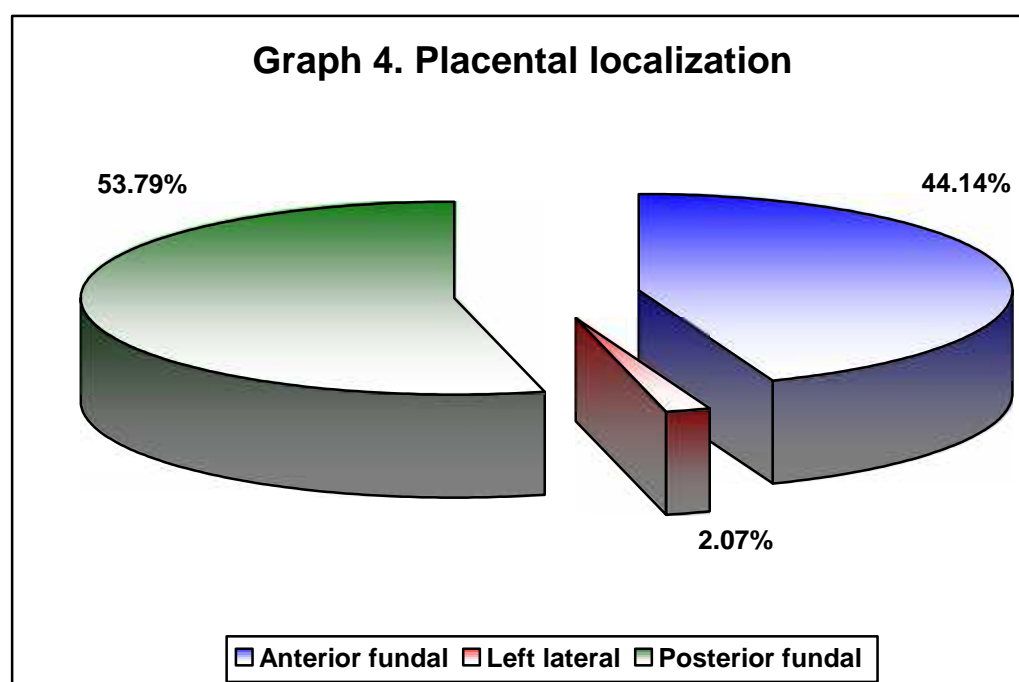
USG findings	Study group (n=145)	
	Number	Percent
< 10% (IUGR)	03	2.07
10% to 90%	141	97.24
> 90%(macrosomia)	01	0.69
<b>Total</b>	<b>145</b>	<b>100.00</b>



In the present study, USG in the study group detected 2.07% of the pregnant women with AC<10%( IUGR), 0.69% of the pregnant women with AC>90%(macrosomia), and 97.24% of the pregnant women had AC between 10%-90%.

**Table 5. Placental localization**

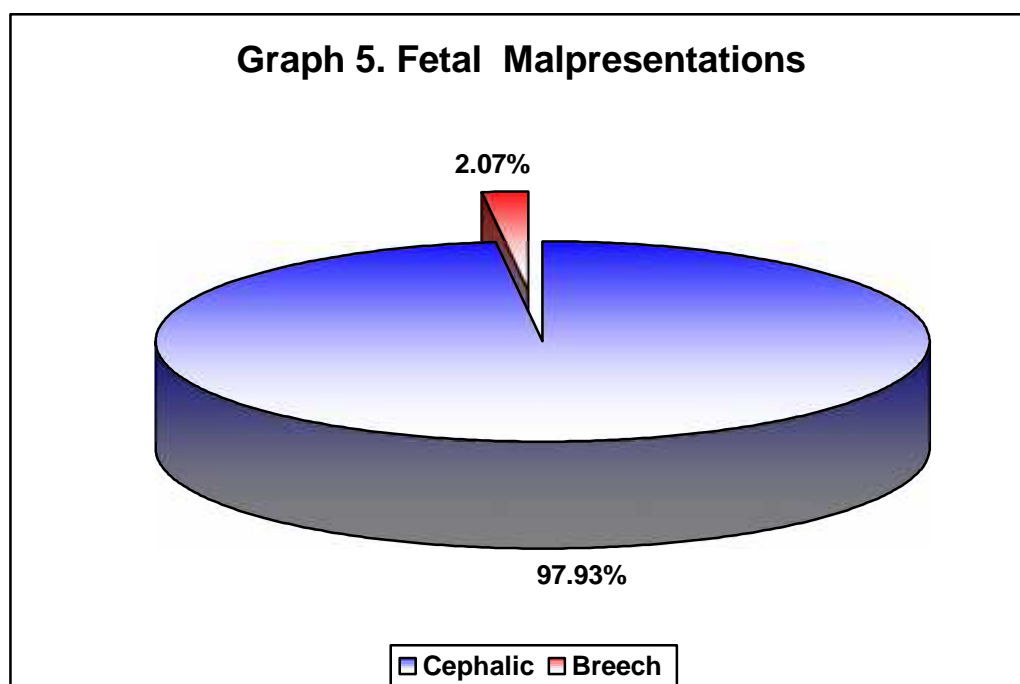
USG findings	Study group (n=145)	
	Number	Percent
Anterior fundal	64	44.14
Left lateral	03	2.07
Posterior fundal	78	53.79
<b>Total</b>	<b>145</b>	<b>100.00</b>



In the present study, USG for placental localization showed 53.79% of the pregnant women had anterior fundal placenta, 44.14% had posterior fundal placenta and 2.07% had left lateral placentation.

**Table 6. Fetal malpresentations**

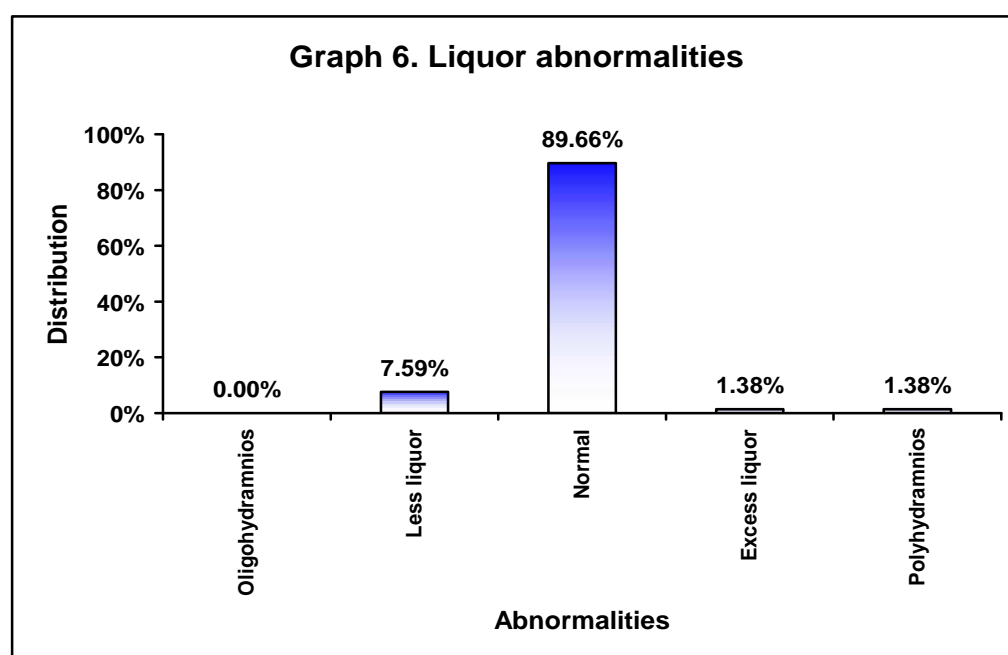
USG findings	Study group (n=145)	
	Number	Percent
Cephalic	142	97.93
Breech	03	2.07
<b>Total</b>	<b>145</b>	<b>100.00</b>



In the present study, USG in the study group detected 2.07% of the pregnant women with breech presentation and 97.93% of the pregnant women had cephalic presentation.

**Table 7. Liquor abnormalities**

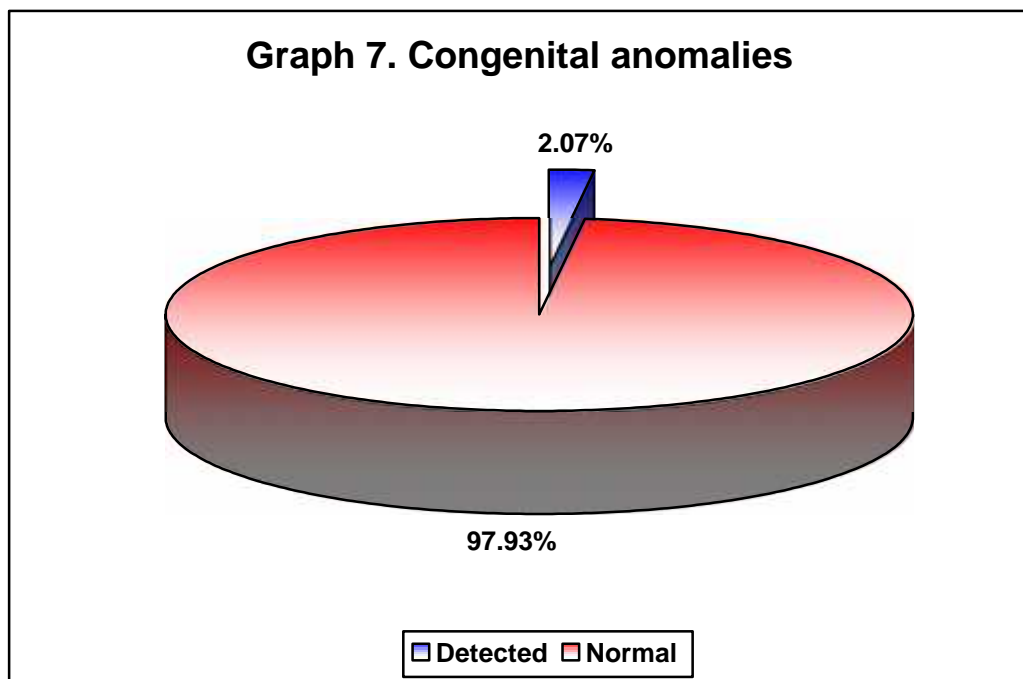
AFI (Cms)	Study group (n=145)	
	Number	Percent
Oligohydramnios (<5)	00	0.00
Less liquor (5-8)	11	7.59
Normal (8 - 20)	130	89.66
Excess liquor (20 - 25)	02	1.38
Polyhydramnios (>25)	02	1.38
<b>Total</b>	<b>145</b>	<b>100.00</b>



In the present study, USG in the study group detected no pregnant women with oligohydramnios, but detected 7.59% of the pregnant women with less liquor, 1.38% of the pregnant women with excess liquor, and 1.38% of the pregnant women with polyhydramnios. 89.66% of the pregnant women had normal liquor.

**Table 8. Congenital anomalies**

Congenital anomalies	Study group (n=145)	
	Number	Percent
Detected	03	2.07
Normal	142	97.93
<b>Total</b>	<b>145</b>	<b>100.00</b>



In the present study, USG in the study group detected 2.07% of the pregnant women with congenital anomalies. 97.93% of the pregnant women had no congenital anomalies.

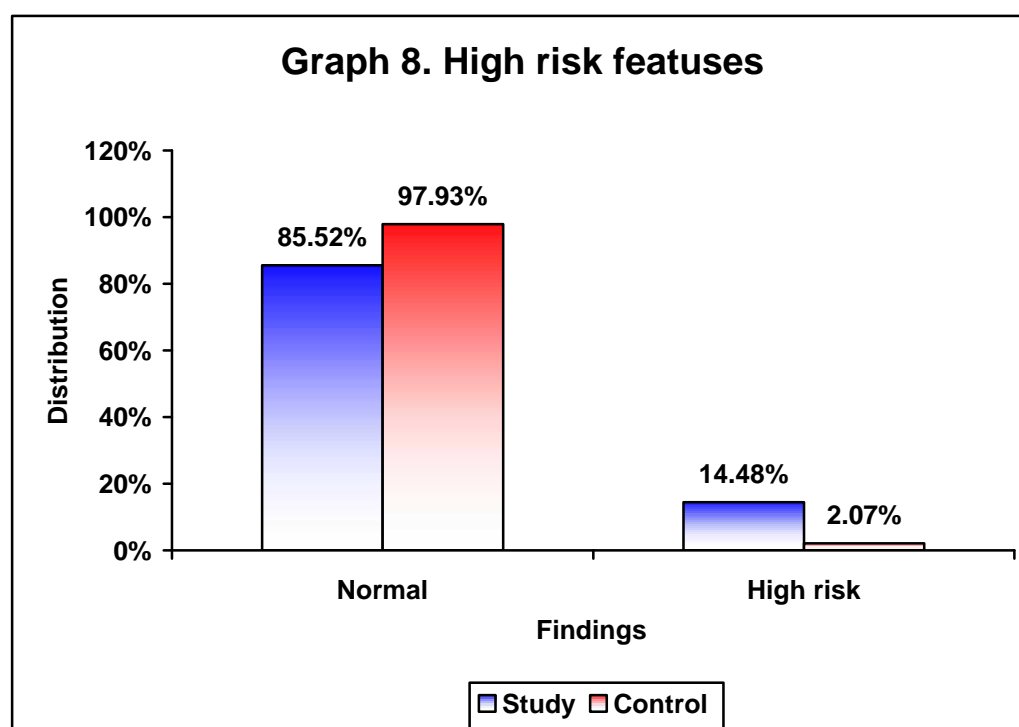
**Table 9. Detection of High risk fetuses**

Findings	Study group (n=145)		Control group (n=145)	
	Number	Percent	Number	Percent
Normal	124	85.52	142	97.93
High risk	21	14.48	03	2.07
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>

$$\chi^2 = 14.727$$

$$DF = 1$$

$$p = 0.0001$$

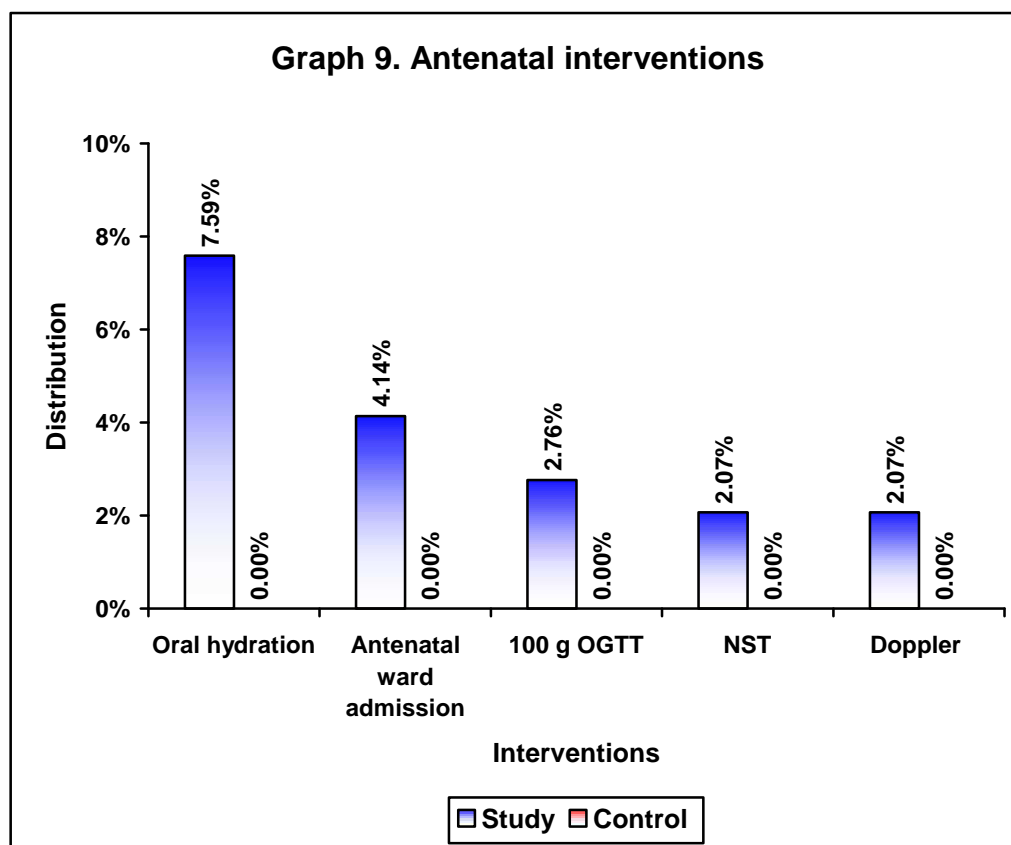


In the present study, USG in the study group detected 14.48% of the pregnant women with high risk fetuses, whereas in the control group 2.07% of the pregnant women had high risk fetuses. This difference was statistically significant. (p value- 0.0001)

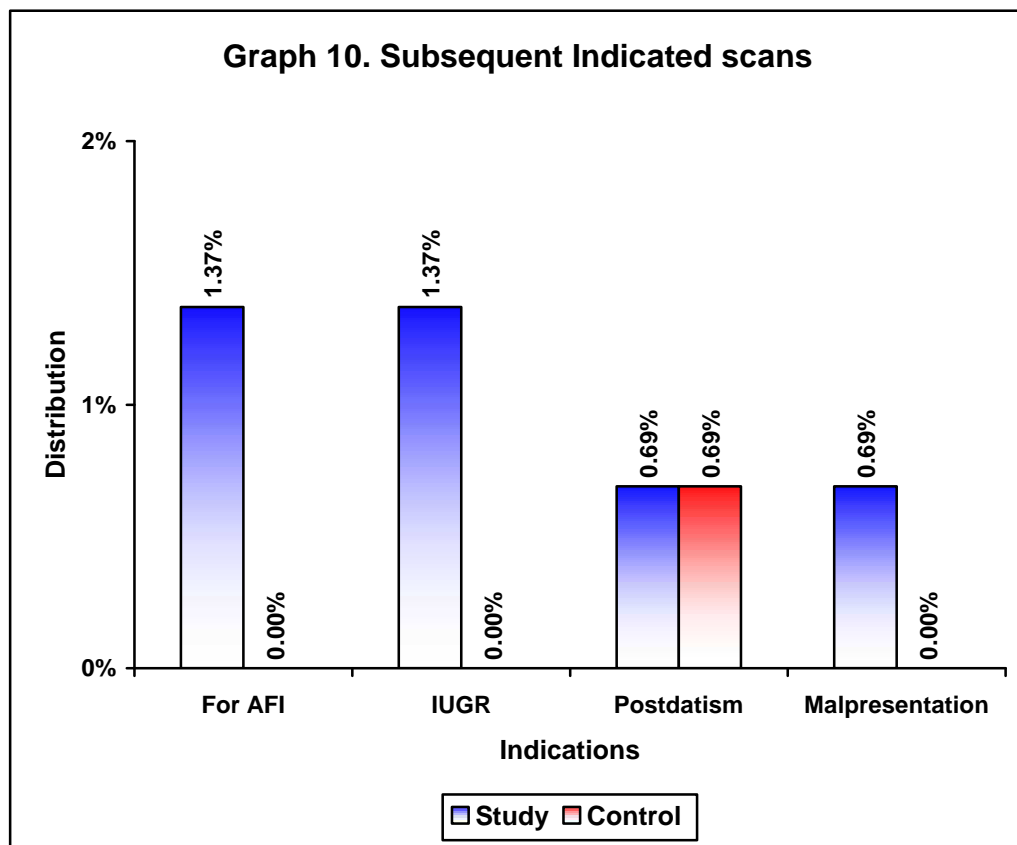
**Table 10. Antenatal Interventions**

Antenatal Interventions	Study group (n=145)		Control group (n=145)		p value
	No	%	No	%	
Antenatal ward admission	06	4.14	00	0	0.029
NST	03	2.07	00	0	0.247
Doppler	03	2.07	00	0	0.247
100 grams 3 hour OGTT	04	2.76	00	0	0.122
Oral hydration therapy	11	7.59	00	0	0.002
Total Induction of labour	08	5.52	03	2.07	0.124
• <i>Induction for High risk fetuses</i>	04	2.76	03	2.01	1.000
○ <i>IUGR fetuses</i>	03	2.07	03	2.07	1.000
○ <i>Oligohydramnios</i>	01	0.69	00	0	1.000
• <i>Induction for Post datism</i>	04	2.76	00	0	0.122
Subsequent indicated scans	06	4.14	01	0.69	0.500
• <i>For AFI</i>	02	1.37	00	0.00	0.498
• <i>IUGR</i>	02	1.37	00	0.00	0.498
• <i>Post datism</i>	01	0.69	01	0.69	1.000
• <i>Malpresentation</i>	01	0.69	00	0.00	1.000

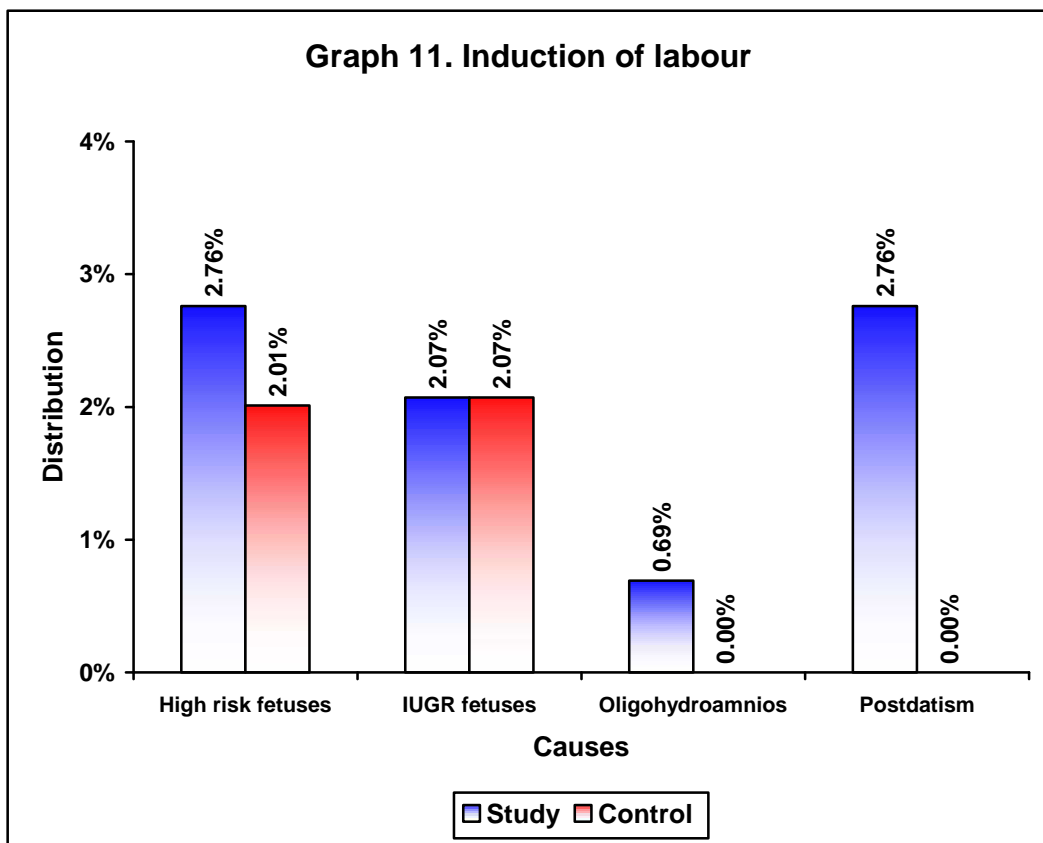
\* Fisher exact test



In the present study, 4.14% of the pregnant women in the study group were advised antenatal ward admission after detection of high risk fetuses on USG for further management and to none among the control group. After the detection of IUGR on USG, Doppler and NST was performed in 2.07% of the pregnant women in the study group and none among the control group. Oral hydration therapy after detection of less liquor by USG was advised in 7.59% of the pregnant women in the study group and to none among the control group. 100 grams, 3 hour OGTT after detection of polyhydramnios and macrosomia by USG was done in 2.76% in the study group and none in the control group. Statistically significant difference was noted in the antenatal ward admission (p value- 0.029) and oral hydration therapy (p value- 0.002) among the study and control group.



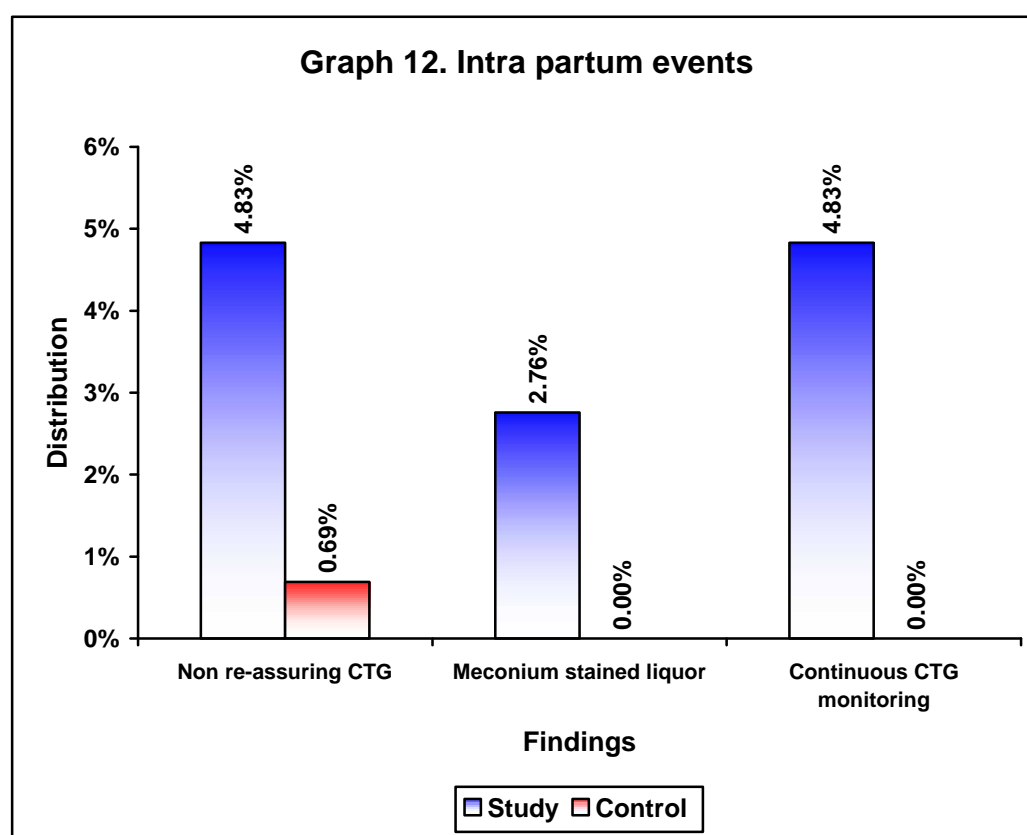
Subsequent indicated scans in the study group were done in 4.14% of the pregnant women. Among these, 2 cases (1.38%) underwent scan for determination of AFI after oral hydration therapy, 1 case (0.69%) for determination of malpresentation, 2 cases (1.38%) underwent subsequent scan with Doppler upon detection of IUGR and 1 case (0.69%) underwent scan in view of post datism. In the control group, only 1 case (0.69%) underwent subsequent indicated scan in view of post datism (0.69%).



Induction of labour on detection of high risk fetuses was done in 2.76% and 2.01% of the pregnant women among the study and control group respectively.

**Table 11. Intra partum events**

Interventions / Advice	Study group (n=145)		Control group (n=145)		p value
	Number	Percent	Number	Percent	
Non reassuring CTG	07	4.83	01	0.69	0.066
Meconium stained liquor	04	2.76	00	0.00	0.122
Continuous CTG monitoring	07	4.83	00	0.00	0.014



In the present study 4.83% in the study group and 0.69% in the control group had non reassuring CTG. Meconium staining of liquor was noted in 2.76% in the study group and none in the control group. Continuous CTG monitoring was done in 4.83% in the study and none among the control group. Statistically significant difference was noted only in continuous CTG monitoring. (p value-0.014) among the study and control group.

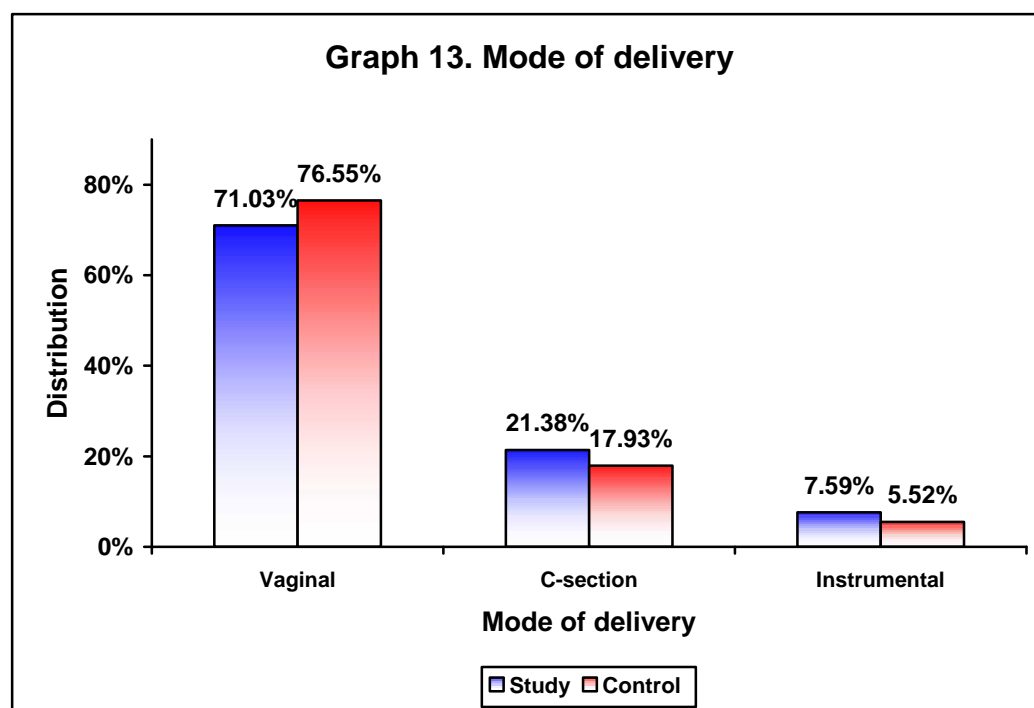
Table 12. Mode of delivery

Mode of delivery	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
Vaginal	103	71.03	111	76.55
C-section	31	21.38	26	17.93
Instrumental	11	7.59	08	5.52
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>

$$\chi^2 = 1.212$$

$$DF = 2$$

$$p = 0.548$$

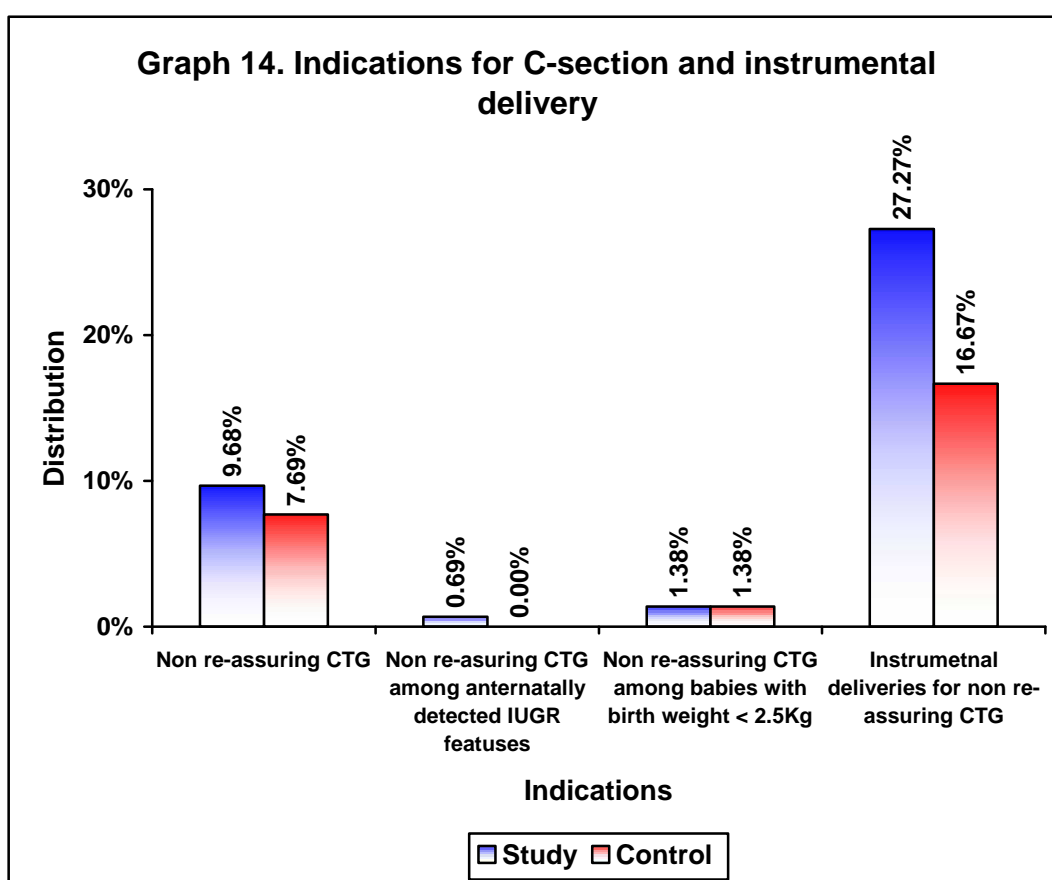


In the present study, 71.03% of the pregnant women in the study group and 76.55% of the pregnant women in the control group had vaginal delivery. 21.38% of the pregnant women in the study group and 17.93% of the pregnant women in the control group had C- section. Instrumental deliveries among the study group and the control groups were 7.59% and 5.52% respectively. However, this difference was not statistically significant (p value-0.548).

**Table 13. Indications for C-section and instrumental delivery**

Indications	Study group (n=145)		Control Group (n=145)		P value
	Number	Percent	Number	Percent	
Non re-assuring CTG (n=31)	03	9.68	02	7.69	1
Non re-assuring CTG among antenatally detected IUGR fetuses	01	0.69	00	0.00	1
Non re-assuring CTG among babies with birth weight < 2.5 Kg	02	1.38	02	1.38	1
Instrumental deliveries for non reassuring CTG	03	27.27	01	16.67	0.602

\* Fisher exact test



In the present study, 9.68% of the pregnant women in the study group and 7.69% of the pregnant women in the control group underwent C- section for non reassuring CTG. 27.27% of the pregnant women in the study group and 16.67% in the control group underwent instrumental deliveries for non reassuring CTG. Non re assuring CTG among antenatally detected IUGR fetuses in the study group was noted among 0.69%. Non reassuring CTG noted among babies with Birth weight <2.5 kg in the study group and the control group was 1.38%.

**Table 14. Pregnancy outcome**

Pregnancy outcome	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
Live birth	145	100.00	145	100.00
Fresh macerated stillbirth	0	0.00	0	0.00
Macerated still Birth	0	0.00	0	0.00
Early neonatal death	0	0.00	0	0.00
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>

In the present study, there were no perinatal deaths in both the study and the control group.

**Table 15. Gestational age at delivery**

Gestational age (Weeks)	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
< 37	00	0.00	04	2.76
37 to 41	141	97.75	140	96.55
> 41	04	2.75	01	0.69
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>

$\chi^2$  with Yate's correction = 2.28      p = 0.131

In the present study, 97.75% of the pregnant women in the study group and 96.55% of the pregnant women in the control group had gestational age at the time of delivery between 37-41 weeks.

**Table 16. Mean gestational age**

Gestational age (weeks)	Study	Control
Mean	38.89	38.97
SD	1.11	1.24
Median	39.00	39.00
Maximum	41.00	42.00
Minimum	37.00	35.00

The mean gestational age at delivery in the study group was  $38.89 \pm 1.11$  weeks and the median was 39 weeks with range between 37-41 weeks. In the control group, mean gestational age at delivery was  $38.97 \pm 1.24$  weeks and the median was 39 weeks with range between 35-42 weeks.

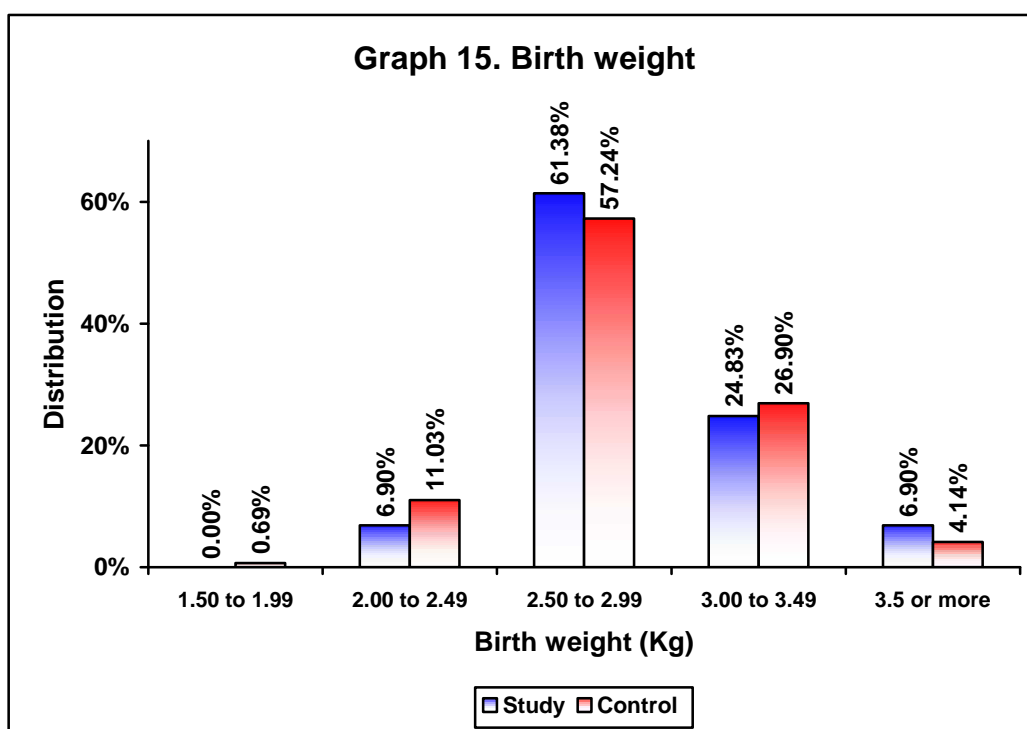
Table 17. Birth weight

Birth weight (Kg)	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
1.50 to 1.99	0	0.00	01	0.69
2.00 to 2.49	10	6.90	16	11.03
2.50 to 2.99	89	61.38	83	57.24
3.00 to 3.49	36	24.83	39	26.90
3.5 or more	10	6.90	06	4.14
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>

$$\chi^2 = 3.144$$

$$DF = 3$$

$$p = 0.370$$



In the present study, 61.38% of the pregnant women in the study group and 57.24% in the control group had babies with birth weight ranging between 2.5- 2.99 kgs. However, this difference was not statistically significant (p value- 0.370).

**Table 18. Mean birth weight**

<b>Birth weight (Kg)</b>	<b>Study</b>	<b>Control</b>
Mean	2.84	2.80
SD	0.32	0.34
Median	2.80	2.75
Maximum	3.70	3.90
Minimum	2.15	2.10

The mean birth weight in the study group was  $2.84 \pm 0.32$  kgs and the median birth weight was 2.80 kgs with range between 2.15 to 3.70 kgs. In the control group, mean birth weight was  $2.84 \pm 0.34$  kgs and the median was 2.75 kgs with range between 2.10 to 3.90 kgs. However this difference was not statistically significant (p value-0.370).

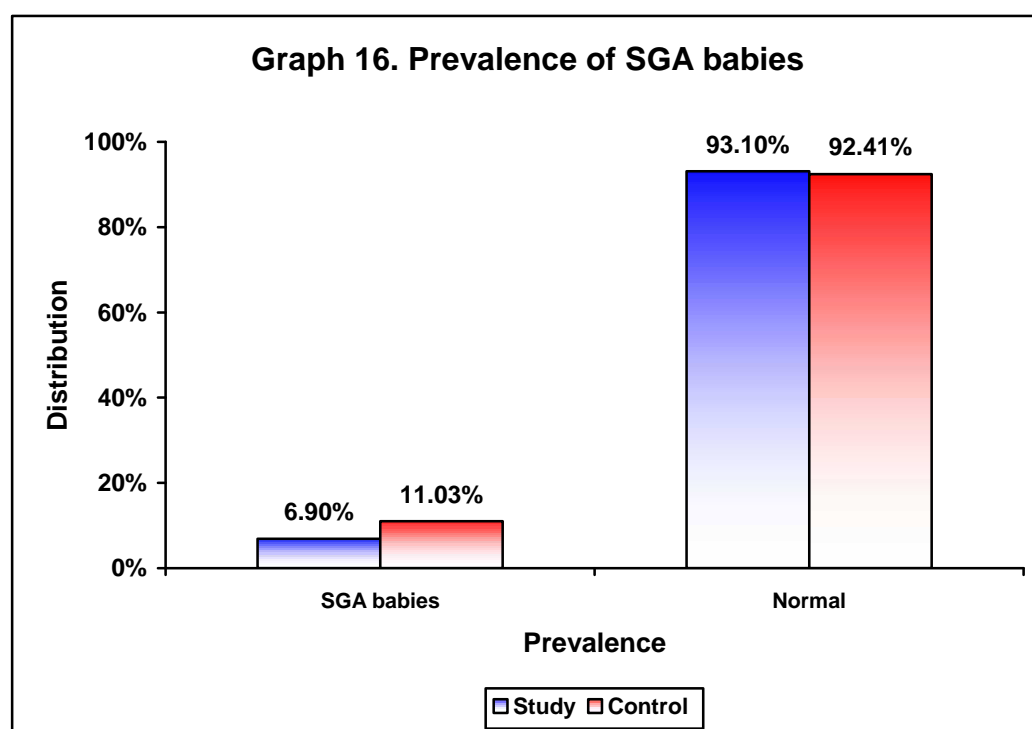
**Table 19. Prevalence of SGA babies**

Prevalence	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
SGA babies	10	6.90	16	11.03
Normal	135	93.10	134	92.41
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>150</b>	<b>103.45</b>

$$x^2 = 1.301$$

$$DF = 1$$

$$p = 0.253$$



In the present study, prevalence of SGA babies in the study group was 6.90% in the study group and 11.03% in the control group. This difference was not statistically significant (p value-0.253).

**Table 20. APGAR score**

APGAR score	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
At 1 Min				
< 7	01	0.69	01	0.69
> 7	144	99.31	144	99.31
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>
At 5 Min				
< 7	02	1.38	01	0.69
> 7	143	98.62	144	99.31
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>

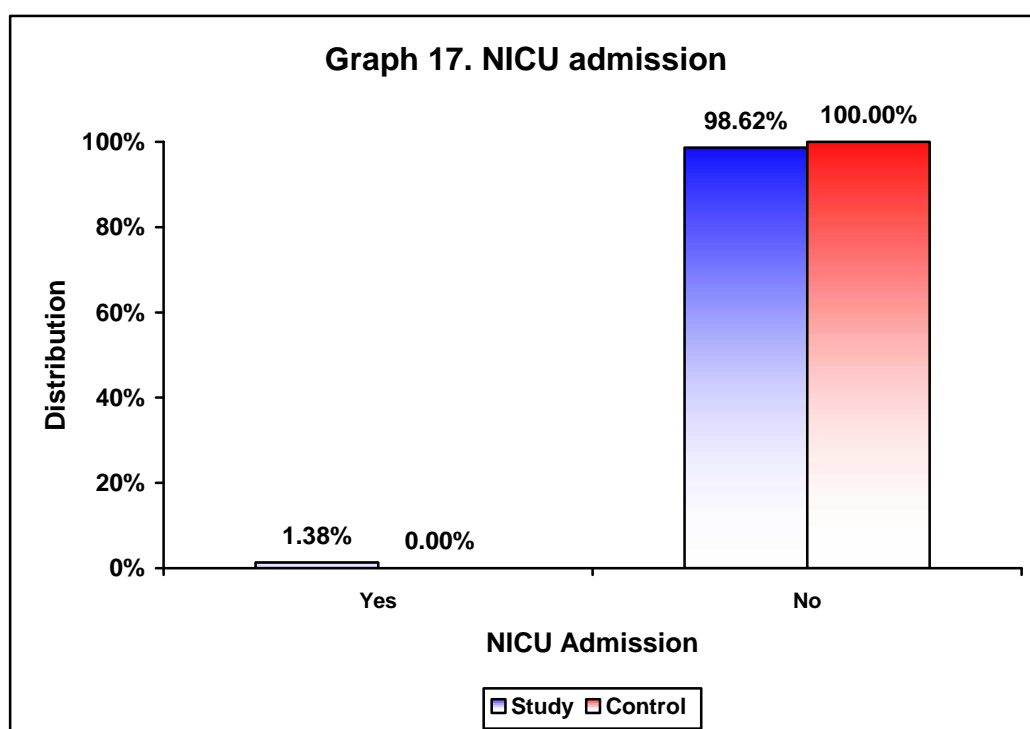
**Fisher exact (p=1)**

In the present study, Apgar score at 1 min < 7 was noted in 0.69% in both study and control group. Apgar score at 5 min <7 was noted in 1.38% in the study group and 0.69% in the control group. However the difference was not statistically significant (P value=1).

Table 21. NICU admission

NICU admission	Study group (n=145)		Control Group (n=145)	
	Number	Percent	Number	Percent
Yes	02	1.38	00	0.00
No	143	98.62	145	100.00
<b>Total</b>	<b>145</b>	<b>100.00</b>	<b>145</b>	<b>100.00</b>

Fisher exact p = 0.498

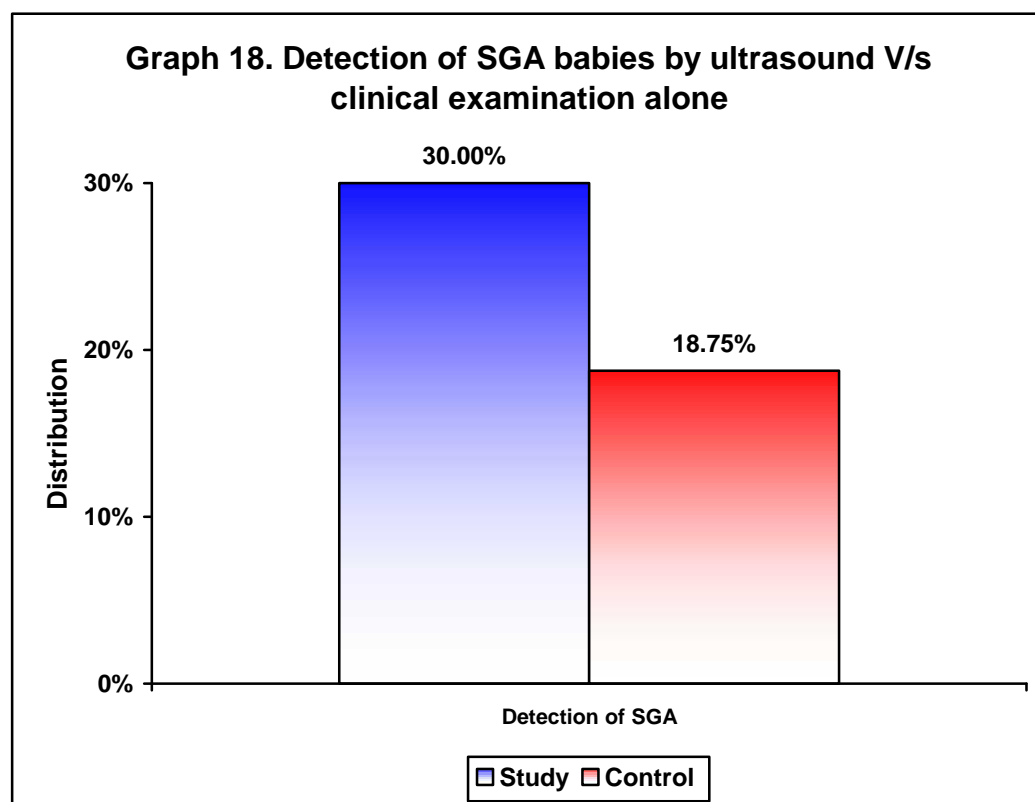


In the present study, NICU admissions in the study group were 1.38% and none in the control group. This difference was not statistically significant (p value-0.498).

**Table 22. Detection of SGA babies by ultrasound v/s clinical examination alone**

	Study	Control
Detection (%)	30.00%	18.75%

**Fisher exact p = 0.644**



In the present study, detection rate of SGA babies by USG (birth weight < 2.5 kgs) in the study group was 30% and 18.75% by clinical examination alone in the control group. However this difference was not statistically significant (p value- 0.644).

# Chapter 6

## Discussion



## **DISCUSSION**

There has been no controversy regarding the use of third trimester ultrasonography in high risk pregnancies because of the well-recognized perinatal risks that can be assessed by ultrasonography. Thus detection of high risk fetuses followed by appropriate management would reduce perinatal mortality and morbidity. However the usefulness of a routine third trimester ultrasonography in low risk pregnancies for the detection of high risk fetuses (growth and liquor abnormalities) where there are no indications has been a controversial topic.

Various trials have also concluded that routine third trimester ultrasound in low risk antenatal women does not confer benefit, but may increase interventions<sup>5,18,19</sup> Belfast study (2003) concluded that routine third trimester ultrasonography reduces the risk of a growth restricted fetuses and increase the antenatal interventions.<sup>10</sup> Meta-analysis (2001) results suggested that routine ultrasound, after 24 weeks gestation, in low-risk or unselected women does not provide any benefit for the mother or the fetus.<sup>19</sup> But, the meta-analysis in 2008 reviewed the 2001 meta-analysis in detail including the Belfast study and recommended the need for RCT to prove the hypothesis.<sup>13</sup>

Hence, the present study was undertaken to assess the role of routine third trimester ultrasound in low risk antenatal women on antenatal interventions and to assess its impact on perinatal outcome.

This one year randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of September 2010 to

September 2011. A total of 290 low risk pregnant women between 34 to 37 completed weeks of gestation attending antenatal clinic for routine antenatal checkups were included in the study. Based on the computer generated randomization chart these women were randomized into study group (n=145) which underwent routine third trimester ultrasonography in addition to the routine antenatal care at the time of randomization and control group (n=145) in which women were offered routine antenatal care only and were not subjected to routine third trimester ultrasonography at the time of randomization.

In the present study ultrasonography in the study group detected 2.07% of the pregnant women with AC <10% (IUGR) and 0.69% of the pregnant women with AC>90% (macrosomia), while the rest 97.24% of the pregnant women had AC between 10%-90%. In the control group, the detection of fetuses with IUGR based on clinical assessment only and later confirmed by indicated USG was also 2.07%. However no cases of macrosomia were detected on clinical assessment in the control group. The detection rate of IUGR fetuses by ultrasonography in the study group was 30% and in the control group the detection rate of IUGR fetuses by clinical examination alone was 18.75%. Thus the detection of IUGR fetuses by routine ultrasonography was higher compared to clinical assessment alone; however this difference did not reach statistical significance (p value-0.644). This finding was comparable to the result of the study conducted in 1996 which concluded that around 16% of IUGR fetus will be detected by routine obstetric examination.<sup>14</sup> Another study also had similar conclusion that routine third trimester ultrasonography performed better than clinical evaluation in the detection of IUGR.<sup>49</sup> In the Perth study (1993), there

was an unexpected finding of significantly higher IUGR in the serial ultrasound group (intensive group). The detection rate of IUGR fetuses was twice as high in the study group as it was in controls. The authors stated that this could be a chance finding or due to frequent exposure to serial ultrasound which would have influenced fetal growth and stressed the need for further investigation of the effects of frequent ultrasound on fetal growth.<sup>43</sup>

The detection of a macrosomic fetus in an uncomplicated pregnancy ranges from 15% to 79% with sonographic estimates of birth weight and from 40% to 52% with clinical estimates. Among diabetic patients the probability of identifying a newborn weighing >4000 g clinically and sonographically is over 60%.<sup>50</sup> In our study, ultrasonographic detection of macrosomic fetuses with the criteria of AC > 90<sup>th</sup> centile was 0.69% and none were detected by clinical examination alone. This finding was similar to the observation of a study<sup>51</sup> which concluded that clinical estimation of birth-weight is as accurate as routine ultrasonographic estimation, except in low-birth-weight babies. Therefore when the clinically estimated expected fetal weight suggests weight is less than 2,500 grams, subsequent sonographic evaluation is recommended to yield a better prediction of fetal weight and to further evaluate fetal well-being. There is clearly a role for clinical estimation of birth weight as a diagnostic tool suggesting that clinical estimation is sufficient to manage labour and delivery in low risk term pregnancies. Even in estimating the weight of macrosomic fetuses for making decision regarding trial of labour, there appears to be no benefit in obtaining a routine sonographic birth-weight. Therefore ultrasonographic estimation of birth weight appears to have a role only when clinically estimated fetal weight is less

than <2,500 grams. In such cases subsequent sonographic estimation would yield a better prediction of fetal weight and further necessitate to assess such fetuses for the type of IUGR, congenital malformations and to assess the well being of the fetus by biophysical profile and Doppler studies. In the low birth-weight (<2,500 grams) group, the mean errors of sonographic estimates were significantly smaller and significantly more sonographic estimates (66.7%) were within 10% of actual birth-weight than those of the clinical method (41.7%). No statistically significant difference was observed in all the measures of accuracy for the normal birth-weight range of 2,500-<4,000 grams and in the macrosomic group ( >4,000 grams) except that, while the ultrasonographic method underestimated birth-weight, the clinical method overestimated it. The mean absolute percentage error of the clinical method was smaller than that of the sonographic method and the number of estimates within 10% of actual birth weight for the clinical method (70%) was greater than for the sonographic method (68%); however the difference was not statistically significant.<sup>51</sup>

In our study, ultrasonography detected breech presentation among 2.07% in the study group and no cases of breech presentation was detected/ missed in the control group. This finding is similar to study<sup>18</sup> which demonstrated that ultrasound is better than clinical evaluation in determining fetal presentation. Ultrasonography identified non-cephalic presentation in 8% women, comprising 16.3% with breech and 1.7% with transverse or oblique lie.

In our study, congenital anomalies were detected by ultrasonography in 2.07% in the study group. This observation was not comparable to the results of the RADIUS study<sup>6</sup>, in which 22% of anomalous fetus was detected among

ultrasound group and 6.5% among the control group which was statistically significant. In a study conducted in the Parisian population,<sup>48</sup> 2.4% had a fetus with at least one major anomaly, 34.8% of which were detected antenatally with more than half detected in the third trimester. The higher rate of detection of congenital anomalies by third trimester ultrasonography in these studies was because of the fact that the study population were not subjected to routine 2<sup>nd</sup> trimester anomaly scan. However in our study, patients in both the study and control groups had undergone a routine 2<sup>nd</sup> trimester anomaly scan and this could be the reason for lower percentage of congenital anomaly detection during the third trimester ultrasonography.

In our study, ultrasonography detected 7.59% of the pregnant women in study group with less liquor, 1.38% of the pregnant women with excess liquor, 1.38% of the pregnant women with polyhydramnios and no pregnant women with oligohydramnios. There are no similar studies which have assessed amniotic fluid parameters with which these results could be compared. However a study<sup>52</sup> concluded that the routine use of third trimester ultrasonography for the detection of liquor abnormalities is likely to lead to increased obstetric intervention without improvement in perinatal outcomes.

Overall, USG in the study group detected significantly higher number of pregnant women with high risk fetuses (14.48%) in the form of IUGR, breech presentation, congenital anomalies, less liquor, excess liquor and polyhydramnios, whereas in the control group only 2.07% of the pregnant women with high risk fetuses in the form of IUGR were detected antenatally (p value - 0.0001).

In the present study, 4.14% of the pregnant women in the study group were advised antenatal ward admission after detection of high risk fetuses on USG for further management and to none among the control group. After the detection of IUGR on USG, Doppler and NST was performed in 2.07% of the pregnant women in the study group and none among the control group. Oral hydration therapy after detection of less liquor by USG was advised in 7.59% of the pregnant women in the study group and to none among the control group. 100 grams, 3 hour OGTT after detection of polyhydramnios and macrosomia by USG was done in 2.76% in the study group and none in the control group. Statistically significant difference was noted in the antenatal ward admission (p value- 0.029) and oral hydration therapy (p value- 0.002) among the study and control group.

Subsequent indicated scans in the study group were done in 4.14% of the pregnant women. Among these, 2 cases (1.38%) underwent scan for determination of AFI after oral hydration therapy, 1 case (0.69%) for determination of malpresentation, 2 cases (1.38%) underwent subsequent scan with Doppler upon detection of IUGR and 1 case (0.69%) underwent scan in view of post datism. In the control group, only 1 case (0.69%) underwent subsequent indicated scan in view of post datism.

Induction of labour on detection of high risk fetuses was done in 2.76% of the pregnant women in the study group and 2.10% of the pregnant women in the control group.

This observation was similar to the Belfast study<sup>10</sup> in which rates of antenatal interventions were significantly higher among the study group (31.3%) than among the control group (16.9%).

In the present study 4.83% in the study group and 0.69% in the control group had non reassuring CTG. Meconium staining of liquor was noted in 2.76% in the study group and none in the control group. Continuous CTG monitoring was done in 4.83% in the study and none among the control group. Among the intranatal events, statistically significant difference was noted in study group only for continuous CTG monitoring (p value-0.014). However there are no similar studies which have included and assessed the intranatal events. Hence the results of intranatal events could not be compared.

In this study, 71.03% and 76.55% of the pregnant women in study and control group had vaginal delivery respectively. The C section rate in the study group and the control group was 21.38% and 17.93% respectively. The rates of instrumental deliveries in the study group and the control group were 7.59% and 5.52% respectively. However for all these variables difference was not statistically significant (p value- 0.548) between the study and control group.

In the present study, 9.68% of the pregnant women in the study and 7.69% in control group underwent C- section for non reassuring CTG. 27.27% in the study group and 16.67% in the control group underwent instrumental deliveries for non re- assuring CTG. Non reassuring CTG among antenatally detected IUGR fetuses in the study group was noted among 0.69%. Non

reassuring CTG noted among babies with BW < 2.5 kg in the study group and the control group was similar i.e., 1.38%.

In the present study, there was no perinatal mortality in both the groups. 97.75% of the pregnant women in the study and 96.55% in the control group had gestational age at the time of delivery between 37-41 weeks. The mean gestational age at delivery in the study group was  $38.89 \pm 1.11$  weeks and in control group it was  $38.97 \pm 1.24$  weeks.

In the present study, 61.38% in the study group and 57.24% in the control group had birth weight between 2.5- 2.99 kgs. The mean birth weight in the study group was  $2.84 \pm 0.32$  kgs and in the control group, it was  $2.84 \pm 0.34$  kgs. However this difference was not statistically significant (p value-0.370).

In this study, prevalence of SGA babies in the study group was 6.90% and 11.03% in the control group (p value-0.253). This observation was similar to the Belfast study<sup>10</sup> in which the proportion of infants assessed as SGA in the study was 6.9% compared with control 10.4%.

Perinatal outcomes measured using variables like live birth rates, gestational age at delivery, low birth weights, mode of delivery, low APGAR scores at 1 and 5 mins and NICU admissions were not statistically significant.

This finding is similar to the conclusion of 2001 Meta analysis<sup>19</sup> which stated that routine third trimester ultrasound in low risk pregnancies does not confer benefit on the mother or the fetus. The results of another study<sup>18</sup> also states that routine third trimester ultrasound for detection of IUGR fetuses has not

significantly reduced the incidence of the most extreme cases of IUGR, perinatal or infant mortality, APGAR score < 7 at 5 min, or the rate of C section/instrumental delivery.

This could be explained by the non significant difference in prevalence of IUGR in the study and control group. Since IUGR is the most significant factor in determining perinatal outcome in an otherwise low risk antenatal women, there was no statistically significant difference in perinatal outcome between the two groups. The comparable perinatal outcome in both groups i.e. routine V/s indicated third trimester ultrasound in low risk antenatal women, in spite of the higher prevalence of high risk fetus in routine ultrasound group could also be due to the result of appropriate antenatal and intranatal interventions.

# Chapter 7

**Conclusion**



## **CONCLUSION**

Overall the present study detected significantly higher number of high risk fetuses by routine third trimester ultrasonography in the low risk pregnant women in the study group (14.48%) compared to the control group (2.07%). The high risk fetes thus identified included IUGR (2.07%), macrosomia (0.69%), breech presentation (2.07%), congenital anomalies (2.07%), less liquor (7.59%), excess liquor (1.38%) and polyhydramnios (1.38%).

Based on these USG findings, the rates of antenatal interventions in the low risk antenatal women were higher in the study group (24.8%) than in the control group (4.44%). The antenatal interventions in the study group were in the form of antenatal ward admission (4.14%), Doppler studies (2.07%), oral hydration therapy for less liquor (7.59%), 100 grams, 3 hours OGTT to evaluate the cases of polyhydramnios and macrosomia (2.76%) and subsequent indicated scans (4.14%). In control group none of these ante natal interventions were undertaken based on clinical assessment except subsequent indicated scans (0.69%).

There was also no statistically significant difference in the intra natal events observed (non re assuring CTG, meconium staining of liquor and use of continuous CTG monitoring) among the study and control group.

The perinatal outcome in both the groups did not vary with regard to perinatal mortality, birth weight, prevalence of SGA babies, APGAR score at one minute and five minutes and NICU admissions.

Routine third trimester ultrasound seems to be a logical solution for the detection of high risk fetus in low risk pregnancies which would otherwise be missed by clinical examination. Though it leads to a statistically significant increase in the identification of high risk fetuses followed by a statistically significant increase in antenatal interventions, there is no significant improvement in perinatal outcome.

Indicated third trimester ultrasound in low risk pregnancies although leads to lesser identification of high risk fetus and lesser antenatal interventions, the perinatal outcome is not significantly different when compared to low risk antenatal women undergoing routine third trimester ultrasound. Therefore routine third trimester ultrasound in low risk antenatal women does not improve perinatal outcome as compared to indicated third trimester ultrasound based on clinical assessment.

Hence, a regular antenatal care and meticulous obstetric examination obviate the need for a routine third trimester ultrasound in low risk antenatal women.

# Chapter 8

## Summary



## SUMMARY

The present study was undertaken to assess the role of routine third trimester ultrasound in low risk antenatal women on antenatal interventions and to assess its impact on perinatal outcome.

This one year randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of September 2010 to September 2011. A total of 290 low risk pregnant women between 34 to 37 completed weeks of gestation attending antenatal clinic for routine antenatal checkups were included in the study. Based on the computer generated randomization chart these women were randomized into study group (n=145) which underwent routine third trimester ultrasonography in addition to the routine antenatal care at the time of randomization and control group (n=145) in which women were offered routine antenatal care only and were not subjected to routine third trimester ultrasonography at the time of randomization.

Overall the present study detected significantly higher number of high risk fetuses by routine third trimester ultrasonography in the low risk pregnant women in the study group (14.48%) compared to the control group (2.07%). Based on these USG findings, the rates of antenatal interventions in the low risk antenatal women were higher in the study group (24.8%) than in the control group (4.44%). There was also no statistically significant difference in the intra natal events observed (non re assuring CTG, meconium staining of liquor and use of continuous CTG monitoring) among the study and control group. The perinatal

outcome in both the groups did not vary with regard to perinatal mortality, birth weight, prevalence of SGA babies, APGAR score at one minute and five minutes and NICU admissions.

Routine third trimester ultrasound seems to be a logical solution for the detection of high risk fetus in low risk pregnancies which would otherwise be missed by clinical examination. Though it leads to a statistically significant increase in the identification of high risk fetuses followed by a statistically significant increase in antenatal interventions, there is no significant improvement in perinatal outcome.

# Chapter 9

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# Annexures

## Annexure I



## **ANNEXURE I**

### **INFORMED CONSENT FORM FOR PARTICIPATION IN THE RESEARCH STUDY**

**TITLE: A RANDOMIZED CONTROLLED TRIAL TO ASSESS THE  
ROLE OF ROUTINE THIRD TRIMESTER ULTRASOUND ON  
ANTENATAL INTERVENTIONS AND PERINATAL OUTCOME IN  
LOW RISK PREGNANCY.**

#### **Objective/ Purpose of the study**

We request you to participate in a study conducted by Dr. \*\*\*\*\*  
\*\*\*\*\*, Mob No: \*\*\*\*\* \*\*\*\*\*, Postgraduate in the Department of Obstetrics  
and Gynaecology, KLE University's Teaching Hospital, Belgaum, under the  
direct supervision and guidance of Dr. Mrs. \*\*\*\*\*, Associate Professor,  
Department of Obstetrics and Gynaecology, KLE University's Teaching  
Hospital, Mob No: \*\*\*\*\*. The study is an attempt to find out the role of  
routine third trimester ultrasound on antenatal interventions and perinatal  
outcome. Routine third trimester ultrasound would detect abnormalities in the  
fetus, liquor, placenta, congenital anomalies, malpresentations, which may not be  
detected by clinical examination and the identification of these followed by  
appropriate obstetric interventions would improve perinatal outcome. Patients  
who fulfill the eligibility criteria will be included in the study. Your participation  
in the study will help us to derive a conclusion which will be beneficial to the  
larger population.

## **Procedures**

You will be asked to provide some personal identification information and obstetric history relevant to the study. You will then be randomized into either study or control group. Women in study group will undergo a third trimester ultrasound to detect abnormalities in the fetal growth and liquor. No scan will be done in control group. No scan in the control group will in no way alter the conventional treatment protocol as, presently routine third trimester scan is not done in low risk antenatal women and scan is done only when clinically indicated.

## **Risks and benefits**

There are no additional risks involved in the procedure. There will be no financial incentives for being a part of the study.

Your participation in the study is purely voluntary. Your decision will not affect your relationship with the institute or in the standard of care provided to you. You are free to withdraw at any time during the study.

## **Privacy and confidentiality**

Every effort will be made to protect the confidentiality of the information provided by you. Results of the study may be published for scientific purposes, but your name will not be used.

If you have any questions about the study, you can contact Dr. Mrs. \*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*, Associate Professor, Department of Obstetrics and Gynaecology.

In case you need any further information regarding your rights as a study participant, you may please contact Principal and Chairman of J.N.M.C, Institutional Ethics Committee, Mob no: \*\*\*\*\* \*\*\*\*\*.

I, volunteer and consent to participate in the study. I have read the consent or has been read to me. The study has been fully explained to me and I was given an opportunity to ask questions and receive answers.

Signature/ thumb impression of participant :

Signature/ thumb impression of witness :

Signature of the investigator :

Date :

# Annexures

## Annexure II



**ANNEXURE II**

**DATA COLLECTION INSTRUMENT**

**TITLE: A RANDOMIZED CONTROLLED TRIAL TO ASSESS THE  
ROLE OF ROUTINE THIRD TRIMESTER ULTRASOUND ON  
ANTENATAL INTERVENTIONS AND PERINATAL OUTCOME IN  
LOW RISK PREGNANCY .**

SLNO: DATE: \_\_\_\_\_

--	--	--	--	--	--	--	--

GROUP: OPD NO: \_\_\_\_\_

--	--	--	--	--	--	--	--

IPDNO:

--	--	--	--	--	--

UNIT: \_\_\_\_\_

PATIENT'S NAME: \_\_\_\_\_

AGE: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CONTACT NO (RESIDENCE/MOBILE): \_\_\_\_\_

OBSTETRIC INDEX: G \_P\_ L\_ A \_ D\_

OBSTERTIC HISTORY:

L.M.P:

--	--	--	--	--	--	--	--

E.D.D:

--	--	--	--	--	--	--	--

CORRECTED E.D.D

--	--	--	--	--	--	--	--

PERIOD OF GESTATION: \_\_\_\_\_

EXAMINATION FINDINGS:

PR: \_\_\_\_\_ BP: \_\_\_\_\_ PALLOR: \_\_\_\_\_

FUNDAL HEIGHT: \_\_\_\_\_ wks.

IS THE CARDIOVASCULAR SYSTEM NONMAL?

YES: NO:

WAS THE CONSENT GIVEN?

YES: NO:

IF YES, RANDOMISATION NO: ALLOCATION GROUP: \_\_\_\_\_

## ULTRASOUND FINDINGS:

DATE:		
POG:		
Study group	In weeks	In centiles
BPD		
HC		
AC		
FL		
EFW in grams		
Placental localisation		
Presentation		
Congenital anomalies		
AMNIOTIC FLUID INDEX		
Q1		
Q2		
Q3		
Q4		
TOTAL		

DATE:		
POG:		
Subsequent scan	In weeks	In centiles
BPD		
HC		
AC		
FL		
EFW in grams		
Placental localisation		
Presentation		
Congenital anomalies		
AMNIOTIC FLUID INDEX		
Q1		
Q2		
Q3		
Q4		
TOTAL		

**ANTENATAL OBSTETRIC INTERVENTIONS:**ANTENATAL ADMISSIONS :  ORALHYDRATION: DAILY FETAL KICK COUNT :  IV HYDRATION: NON STRESS TEST :  AMNIO REDUCTION: DOPPLER :

ORAL GLUCOSE TOLERANCE TEST:

EXTERNAL CEPHALIC VERSION :

INDUCTION OF LABOR :

IF YES, INDICATION : \_\_\_\_\_

SUBSEQUENT ANTENATAL SCAN:

IF YES, INDICATION : \_\_\_\_\_

**INTRAPARTUM EVENTS:**

FETAL DISTRESS :

MECONIUM STAINED LIQUOR :

CONTINUOUS CTG MONITORING :

**PERINATAL OUTCOME:**

LIVE BIRTH/ FSB/ MSB/ EARLY NEONATAL DEATH

GESTATIONAL AGE AT DELIVERY: \_\_\_\_\_

BIRTHWEIGHT: \_\_\_\_\_

MODE OF DELIVERY

VAGNIGAL:

VENTOUSE:

FORCEPS:

C-SECTION

C-SECTION: ELECTIVE/EMERGENCY

APGAR SCORE: 1 MIN:

5 MIN:

NICU ADMISSION : \_\_\_\_\_

INDICATION: INDICATION: \_\_\_\_\_



































MASTER CHART - CONTROL GROUP

Serial Number	Randomization Number	Patient Number	Date of randomization	Age (Years)	Parity	Previous LSCS	POG at randomization	BPD	HC	AC	FL	EFW (gms)	Placental localisation	Presentation	Congenital anomalies	AFI (Cms)	Detection of high risk fetus	Antenatal ward admission	Daily fetal kick count	Non stress test	Doppler	Oral glucose tolerance test	Oral hydration	Intravenous hydration	Amnioreduction	External cephalic version	Induction of labour	Subsequent indicated scans	Non re-assuring CTG	Meconium stained liquor	Continuous CTG monitoring	Live births	Fresh Still Birth	Macerated still Birth	Early neonatal death	Gestational age at delivery (weeks)	Birth weight (Kg)	1 Minute	5 Minute	APGAR score	NICU admissions	Yaginal delivery	Caesarean section section	Ventouse delivery	Forceps delivery	Remarks
145	298	1684912	22/09/2011	23	0	0	35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	40	2.5	7	8	0	1	0	0	0			

# Annexures

**Annexure IV**



**ANNEXURE IV – MASTER CHART**

AB	- Abruption
AC	- Abdominal circumference
AF	- Anterior fundal
AFI	- Amniotic fluid index
BPD	- Bi parietal diameter
BR	- Breech
CD	- Cervical dystocia
CTG	- Cardio-tocograph
CTL	- Changed to transverse lie
EFW	- Estimated fetal weight
EL	- Eclampsia
FC	- Femur length
FD	- Fetal distress
gm	- Grams
HC	- Head circumference
HDR	- Hydronephrosis
IUGR	- Intrauterine growth retardation
Kg	- Kilogram
LL	- Left lateral
LLQ	- Less liquor
LSCS	- Lower segment caesarean section
MC	- Macrosomia
MIS	- Missed

MLQ	- More liquor
M	- Multi
MSL	- Meconium stained liquor
NICU	- Neonatal intensive care unit
NP LV IS	- NP living issue
NPL	- Non progress of labour
NST	- Non stress test
NWVBAC	- Not willing for vaginal birth after delivery
P LSCS	- Previous lower segment caesarean section
PDFD	- Induced for postdatism fetal distress
PD	- Post datism
PF	- Posterior fundal
PMBD	- Poor maternal bearing down
POG	- Period of gestation
P	- Primi
PPROM	- Preterm premature rupture of membranes
PTVD	- Preterm vaginal delivery
PU OB	- Pelvi ureteric junction obstruction
RA	- Renal anomaly
RT	- Right
S NST	- Suspicious NST
SD	- Scar dehiscence
TMC	- Thick meconium