

“PREVALENCE OF DISCORDANT GROWTH
IN TWIN PREGNANCIES - A CROSS
SECTIONAL STUDY”

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LIST OF ABBREVIATIONS USED

AC	-	Abdominal circumference
ACOG	-	American College of Obstetricians and Gynecologists
BPD	-	Biparitel diameter
CI	-	Confidence interval
cm	-	Centimeter
CRL	-	Crown rump length
DC	-	Dichorionic
EDD	-	Estimated date of delivery
EFW	-	Estimated fetal weight
FL	-	Femur length
FSB	-	Fresh macerated stillbirth
GDM	-	Gestational diabetes mellitus
HC	-	Head circumference
IUD	-	Intrauterine death
IUGR	-	Intrauterine growth restriction
IVF	-	In vitro fertilization
kg	-	Kilogram
KMC	-	Kangaroo mother care
LMP	-	Last menopause
LSCS	-	Lower segment caesarean section
MC	-	Monochorionic
MIN	-	Minute
n	-	Total number
NICU	-	Neonatal intensive care unit

p	-	Probability
P.I.	-	Pulsatility index
PIH	-	Pregnancy induced hypertension
PNMR	-	Perinatal mortality rate
POG	-	Period of gestation
R.I.	-	Resistance index
RDS	-	Respiratory distress syndrome
S/D	-	Systolic to diastolic ratio
SD	-	Standard deviation
TTTS	-	Twin to twin transfusion syndrome
USA	-	United States of America
USG	-	Ultrasound
vs	-	Versus

ABSTRACT

PREVALENCE OF DISCORDANT GROWTH IN TWIN PREGNANCIES- A CROSS SECTIONAL STUDY

Background and objective

A twin gestation is generally a high risk pregnancy and discordant fetal growth results in adverse perinatal outcomes. This study was undertaken to determine the prevalence of discordant growth in twin pregnancies and the perinatal outcome in twin pregnancies with discordant growth.

Methodology

This one year cross sectional study was done in the Department of Obstetrics and Gynecology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. A total 93 women with twin pregnancy were studied. Birth weight difference with >15% between twins was regarded as discordant growth.

Results

The prevalence of discordant growth in twins was 38.71%. Among the babies with discordant growth maximum babies were found to have discordancy between 15.1 to 25 percent 55.5%. Maximum numbers of (36.11%) discordant babies had birth weight between 2000-2499 grams and had apgar score of seven or more at one minute (55.56%) while at five minutes, 1% of the discordant newborns had apgar score of < 7. 41.67% of the discordant newborns required KMC while 44.44% of the discordant newborns had NICU admission and preterm delivery was the commonest cause of NICU admission in discordant

babies (76.92%) followed by RDS (17.02% and 15.39%). Perinatal Mortality was noted in 22.22% of the discordant newborns ($p=0.03$) compared to concordant group which was and significant all of which occurred with birth weight discordancy of $> 25\%$. No statistically significant association was noted between maternal age, parity status, gestational age and mode of delivery with growth discordancy ($p>0.050$) and also no statistically significant association was noted between apgar score at one minute and five minutes, KMC and NICU admission and discordancy ($p>0.050$).

Conclusion

Considering the birth weight difference of more than 15% there is higher prevalence of discordancy. The present study showed prevalence of discordancy was as high as 38.71% considering the birth weight difference of more than 15%. Prevalence of Grade –I (15.1 to 25%) discordancy was found in 55.56% and Grade-II ($>25\%$) discordancy was found in 44.44%. There was an increased incidence of perinatal mortality in discordant twins compared to concordant twins which was statistically significant. Perinatal mortality occurred only in discordant twins with Grade-II discordancy. There was no statistical significance in other neonatal outcomes including birth weight, apgar score, admission to NICU, KMC and mode of delivery between concordant and discordant groups. Presence of discordancy in twins is a risk factor for increased perinatal mortality.

Keywords:

Discordant growth; multiple pregnancies; Twin Gestation;

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INTRODUCTION

The incidence of multiple births has risen in the last 30 years. In 2009, 16 women per 1000 giving birth in England and Wales had multiple births compared with 10 per 1000 in 1980. This rising multiple birth rate is due mainly to increasing use of assisted reproduction techniques, including in vitro fertilisation (IVF). Up to 24% of successful IVF procedures result in multiple pregnancies. Multiple births currently account for 3% of live births.¹

Twin gestations when compared to singletons are associated with higher perinatal morbidity and mortality. The addition of discordant fetal growth adds the potential for further complications. Discordant fetal growth has been variously reported to occur in 15-29% of twin pregnancies.²

The incidence of twin pregnancies has increased remarkably since the late seventies because of the improved reproductive medicine and a greater proportion of older pregnant mothers who naturally have a higher incidence of multiple gestations.^{3,4} The occurrence and frequency of twinning varies across human populations. The maternal age, socio-environmental factors, increase in the use of contraceptives, the race of human population, increase in spontaneous abortion rate and seasonal variations, are among the factors that could influence twinning rate.⁵

Twin pregnancies are more prone to complications than single pregnancies. Early in pregnancy there is high risk of miscarriage and sometimes one fetus dies and is reabsorbed resulting into the vanishing twin syndrome.⁶ Other complications associated with twin pregnancy include high incidence of hypertension (pregnancy-induced hypertension, pre-eclampsia or eclampsia), gestational diabetes mellitus,

bleeding in pregnancy (placenta praevia or abruptio), preterm birth and small-for-gestational-age babies due Intrauterine growth restriction (IUGR), postpartum hemorrhage, congenital malformations, and Twin to twin transfusion syndrome (TTTS).^{7,8}

Unique to multiple gestations, discordance is the difference in the weights of the fetuses. Birth weight discordance is defined as a percentage difference in birth weight of 15% to 25%. The incidence of Discordance has been reported to occur in 15% to 29% of twin gestations. Birth weight discordance is an important contributor to adverse perinatal outcome.⁹

Discordance is defined with the larger twin as the standard of growth and is calculated by the following equation: (larger estimated or actual weight – smaller estimated or actual weight)/ larger estimate or actual weight). While acknowledging the lack of consensus on the precise threshold of discordance that is linked with complications, ACOG considers a 15-25% difference in actual weight among twins to be discordant.¹⁰

The consensus statement by the Society of Obstetricians Gynecologists of Canada, specifies that discordance is a difference of abdominal circumference (AC) of 20 mm or estimated fetal weight (EFW) difference of 20%. The Society of Obstetricians Gynecologists of Canada recommends that the EFW be derived from biparietal diameter with AC or a combination of AC and femur length.¹¹

Determination of fetal growth discordance is important, because studies have shown an association with increased mortality and morbidity when there are significant differences in birth weight. Therefore, detection of antenatal growth

discordance by ultrasound is useful in identifying twins that may require increased surveillance to prevent higher fetal/neonatal complications. Confounding factors in studies of twin growth discordance include chorionicity, gestational age at delivery, and growth restriction relative to expected birth weight, as well as suboptimal sample size. Growth discordance has been defined in several ways, with the most common being the difference in estimated fetal weight derived by ultrasound biometry.¹²

Birth weight discordance is a pathological entity, which may lead to adverse neonatal outcomes such as stillbirth, perinatal morbidity, and preterm delivery . Independently of gestational age at delivery, twins with significant birth weight discordance have poorer perinatal outcomes.¹³

According to the American College of Obstetricians and Gynecologists (ACOG) practice bulletin on multiple gestation, discordant growth is associated with increased likelihood of anomalies, intrauterine growth restriction (IUGR), preterm birth, infection(cytomegalo virus) of 1 fetus, stillbirth, umbilical arterial Ph < 7.10, admission to neonatal intensive care unit, respiratory distress, and death within 1 week of birth. Despite the known association with a multitude of adverse outcomes, what is debated about discordant twins are the following factors that decrease or predispose to discordant growth: the ability to identify abnormal growth, the threshold of discordance that significantly increases the perinatal complication rate, the comorbidities that alter the likelihood of poor outcome, and how to manage divergent growth.¹⁴

Unequal placental sharing and peripheral, ‘velamentous’ cord insertions are common in TTTS. Significant intrauterine size discordance occurs in MC twins in the absence of TTTS in approximately 10% of pregnancies. The incidence of size

discordance is as great in DC pregnancies but management of discordant growth restriction may be more difficult in MC pregnancies. Discordant fetal growth restriction may be differentiated from TTTS by the absence of polyhydramnios in one of the amniotic sacs, although the small twin may have oligohydramnios owing to placental insufficiency.¹⁵

Growth discordance has been considered as a complicating factor with higher perinatal morbidity and mortality. The high perinatal mortality rate in twins is largely associated with the increased rate of low birth weight babies from preterm deliveries and growth restricted pregnancies. For these reasons the presence of discordance has prompted preterm delivery to prevent fetal death and to decrease neonatal morbidity. Discordance alone may result in excess neonatal morbidity because of prematurity.¹⁶

However, there is a paucity of data on outcome of discordant growth in twin pregnancies especially in Indian literature. Hence the this study was undertaken to determine the prevalence of discordant growth and the association between birth weight discordance and poor perinatal outcome so as to understand the differences in the incidence of mortality between larger and smaller twins and to determine whether discordance is an independent factor for perinatal morbidity and mortality.

OBJECTIVES

The objectives of the present study were;

Primary objective

To determine the prevalence of discordant growth in twin pregnancies.

Secondary Objective

To determine the perinatal outcome in twin pregnancies with discordant growth.

REVIEW OF LITERATURE

TWIN GESTATION

The phenomenon of twinning has fascinated mankind throughout its recorded history. Twins have often been regarded as being inherently different from singletons, and societal responses to their birth have ranged from awe to fear.¹⁷

Twin fetuses commonly result from fertilization of two separate ova and are termed as double ovum, dizygotic or fraternal twins. About a third as often, twins arise from a single fertilized ovum that subsequently divides into two similar structures, each with the potential for developing into a separate individual. These twins are termed as single-ovum, monozygotic, or identical twins. All dizygotic twins and one-third of monozygotic twins have separate inner and outer sacs and are thus dichorionic-diamniotic. Two thirds of monozygotic twins have a single outer sac and two inner sacs (monochorionicdiamniotic) and about 1% of twins will share their inner sac ie. monochorionic-monoamniotic.¹⁸

In monozygotic twins, various types of chorionicity and amniocity can occur as result of when the fertilized oocyte divides. Division occurring between the first day and third day results into dichorionic-diamniotic twins accounting for about 1/3 of cases. Division between the fourth day and the eighth day results into monochorionic-diamniotic twins (about 2/3 of the cases). Division occurring late between ninth and thirteenth day after fertilization results into monochorionic-monoamniotic (about 1%). Division taking place beyond the thirteenth day results into conjoined twins.¹⁸

Twin pregnancies in general population comprise about 1% of all pregnancies, but can account for up to 10% of perinatal mortality. Low birth weight and prematurity are the main causes of high perinatal morbidity and mortality in twins, whereas malpresentation and the hazards of delivery are next in order of concern. For these reasons, twin pregnancy is considered a high-risk pregnancy; different aspects of the risk include the mode of delivery, which remains a subject of a controversy and discussion among obstetricians.⁴

The birth rate of monozygotic twins is constant worldwide (approximately 4 per 1000 births). Birth rates of dizygotic twins vary by race. The highest birth rate of dizygotic twinning occurs in African nations, and the lowest birth rate of dizygotic twinning occurs in Asia.¹⁹

The natural twinning rates in India are 9–16 per 1000 live births. However a recent study from Tumkur, Karnataka found the incidence of twin gestation rate as high as 20.3 per 1000 live births.²⁰

Multiple pregnancy is associated with higher risks for the mother and babies. Women with multiple pregnancies have an increased risk of miscarriage, anaemia, hypertensive disorders, haemorrhage, operative delivery and postnatal illness. In general, maternal mortality associated with multiple births is 2.5 times that for singleton births.¹

Twin pregnancy is considered as a high risk pregnancy. Globally, the highest burden of multiple births has been found in sub-Saharan Africa, with an average twinning rate of 20 per 1,000 deliveries compared to 10 per 1,000 deliveries in Europe or around 5-6 per 1,000 deliveries in Asia. Nigeria has the highest prevalence of

multiple births worldwide. Twinning is a multi factorial phenomenon principally attributable to genetic and environmental factors, such as advanced maternal age and increased parity. In India, twinning occurs in approximately 1% of pregnancies and has been reported to be responsible for 10% of perinatal mortality. The incidence of twins is on rise due to variety of reasons like increased use of assisted reproductive techniques and increasing number of women having pregnancy at advanced age.³¹

Fetal complications are reported to be more in monozygotic pregnancies as compared to dizygotic twins. Monochorionic twin gestations are at higher risk of preterm labour, discordant fetal growth, abnormal vascular communications, Acardiac twin (TRAP), Twin-Twin Transfusion syndrome(TTTS), fetal malformations, cord complications and stillbirths.³¹

Among the above complications fetal discordant growth is common and important fetal complication that has an impact on perinatal outcome.

Fetal Growth Discordance

Fetal Growth Discordance (defined as a 20% difference in EFW between fetuses of the same pregnancy) is a marker of growth abnormality and is associated with an increased risk of fetal death and neonatal mortality and morbidity. It is evident in 5% to 15% of twins and 30% of triplets and is associated with six-fold increase in perinatal morbidity and mortality. Significant risk factors for discordant growth include monochorionic placentation, preeclampsia and antepartum bleeding.²²

For the most part, twins grow at the same rate as singletons, regardless of chorionicity up to at least 32 weeks gestation. After that time, studies have described

slower rates of growth for twins. The decreased rate may be related to reduced intrauterine physical space or to uteroplacental insufficiency.²²

Abnormal growth discordance has been defined as ranging from 15% to 40%, but is generally thought to be greater than 20%. It has been reported to occur in up to 30% of twin pregnancies depending on the definition used.¹⁷

Birth weight discordance is not specific, and even at the threshold of 25%, the majority of twins do well. Risk factors include antenatal bleeding, umbilical cord abnormalities such as velamentous cord insertion, uteroplacental insufficiency, fetal issues such as chromosomal, genetic, or anatomical abnormalities, monochorionicity, and maternal complications such as chronic hypertension and pregnancy-induced hypertension.¹⁷

However, they did not seem to be at increased risk for serious neonatal morbidity and mortality. Unique to multiple gestations, discordance is the difference in the weights of the fetuses. According to the American College of Obstetricians and Gynecologists (ACOG) (2009) practice bulletin on multiple gestation, discordant growth is associated with increased likelihood of anomalies, intrauterine growth restriction (IUGR), preterm birth, infection of 1 fetus, stillbirth, umbilical arterial pH - 7.10, admission to neonatal intensive care unit, respiratory distress, and death within 1 week of birth. Despite the known association with a multitude of adverse outcomes, what is debated about discordant twins are the following factors that decrease or predispose to discordant growth: the ability to identify abnormal growth, the threshold of discordance that significantly increases the perinatal complication rate, the comorbidities that alter the likelihood of poor outcome, and how to manage divergent group.¹⁴

Expert reviews, a summary of 31 publications with 1.1 million twins indicates that the likelihood of discordance of 20% is 16% (180,302/1,130,505 twin pregnancies; range, 14–41%;). Eight publications provided evidence of discordance of at least 30%; discordance had occurred in 5% of twins (42,373/854,331 twin pregnancies; range, 3–10%. The rate of discordance, however, varied among publications with 1000 vs 1000-9999 vs 10,000 cohorts. Discordance of at least 20% was significantly higher in 15 publications from foreign countries 17%; 11,369/65,997 twin pregnancies than in 16 reports from the United States (16%; 168,933/1,064,790 twin pregnancies; odds ratio [OR], 1.10; 95% confidence interval [CI], 1.08 –1.12.¹⁰

Even among publications with 1000 cohorts, discordance of 20% occurred significantly more commonly in other countries 19%; 520/2,712 twin pregnancies than in the United States 16%; 225/1,445 twin pregnancies; OR, 1.28; 95% CI, 1.08–1.52. In 2006, there were 137,085 twin pairs born in the United States; if 16% were discordant, we estimate that there are approximately 22,000 discordant twin pairs born per year.¹⁰

Placental pathology commonly accounts for growth-discrepancy within a multiple pregnancy. Discordant fetal growth is usually defined as a 15-25% reduction in the estimated fetal weight of the smallest fetus compared to the largest. Most published studies focus on discordant growth within twin pairs and have demonstrated an association with structural malformations, perinatal mortality, fetal growth restriction, preterm delivery, caesarean delivery for nonreassuring fetal status, umbilical arterial acidaemia, NICU admission and respiratory morbidity. The prospective ESPRiT Study conducted in Ireland established that the threshold for

significant birth weight discordance, i.e. that associated with an increase in perinatal morbidity, is 18% both for dichorionic twins and for monochorionic twins without twin-twin transfusion syndrome. An anticipated difference of 18% or more between co-twin weights should therefore prompt more intensive fetal monitoring and merits consultation with a Fetal Medicine Specialist particularly before term.²¹

Uneven placental sharing of 25% was significantly different among discordant vs nondiscordant twins (56% vs 19%, respectively; $p=0.0001$). As placental share diverges, discordance increases up to 4 times. The pattern and size of vascular anastomoses that are present in monochorionic placentas is also associated with growth discordance that manifests either early or late in gestation. In a study of 178 twin pairs, placentas growth discordance at 20 weeks' with gestation had more unequally shared vessels and had an increased number of arterioarterial anastomoses with larger diameters compared with those with late-onset discordant growth. Clinically, these pregnancies experienced higher rates of Doppler abnormalities, mostly intermittent absent end diastolic blood flow in the umbilical artery, fetal death, and earlier gestational age at delivery for fetal indications (33.2 weeks gestation) compared with those pregnancies with late-onset growth discordance or concordant growth (35.2 weeks; $P=0.001$).¹⁰

The prospective multicenter cohort study in 2011 included 1,028 unselected twin pairs recruited over a 2-year period, from May 2007 to October 2009. Perinatal outcome data were recorded for 977 patients (100%). fetuses alive beyond 24 weeks, including 14 cases of twin-twin transfusion syndrome. Adjusting for gestation at delivery, twin order, gender, and growth restriction, perinatal mortality, individual morbidity, and composite perinatal morbidity were all seen to increase with birth

weight discordance exceeding 18% for dichorionic pairs (hazard ratio 2.2, 95% confidence interval [CI] 1.6–2.9, $P < .001$) and 18% for monochorionic twins without twin–twin transfusion syndrome (hazard ratio 2.6, 95% CI 1.6–4.3, $P < .001$). A minimum twofold increase in risk of perinatal morbidity persisted even when both twin birth weights were appropriate for gestational age. The threshold for birth weight discordance established by this prospective study was 18% both for dichorionic twin pairs and for monochorionic twins without twin–twin transfusion syndrome. This threshold was considerably lower than that defined by many retrospective series as pathologic. They suggest that an anticipated difference of 18% in birth weight should prompt more intensive fetal monitoring.²²

A cross sectional comparative study done in Pakistan Institute of Medical Sciences, Islamabad, from January 2005 to December 2007 with Two hundred and fifty three pairs of twins were delivered during the three years . All twin gestations delivered at > 28 weeks gestation with birth weight discordance > 20% twin birth weight difference were included. The frequency of birth weight discordance was 19% (48 verses 205 concordant twin pairs). Preterm delivery (68% vs. 25%), pre-labour rupture of membranes (33% vs. 9%) and pregnancy induced hypertension (22% vs. 12%) were significantly more frequent in birth weight discordant compared to concordant gestations. The cesarean section rate was 29% and 21% respectively. Twelve (12%) discordant and 29 (7%) concordant infants required NICU admission. There were 10 intrauterine deaths(10%) and one (1%) neonatal death among the discordant twins while 18 (4%) intrauterine deaths and 10 (2.4%) neonatal deaths occurred in concordant twins, resulting in uncorrected PNMR of 114.5 and 43.9 per 1000 births respectively.²

Alam et al. reported that adverse outcomes with a discordance of 20% is associated with abnormal growth; if the difference is at least 25%, then morbidity is associated with the route of delivery or a congenital anomaly. One potential explanation for the contradictory findings is the small sample size of most studies.³⁰

A study done in Southwest Nigeria to determine the frequency of twinning in four urban settings of Ilesha, Ile-Ife, Ogbomoso and Ado-Ekiti showed the overall average frequency of 40.2 per 1000 deliveries. The four hospitals ranked among the highest recorded rates of twin births in the world.²⁵

A study done in rural Burkina Faso to assess the prevalence, mortality and provision of obstetric care in twins, showed the overall population based prevalence of twin delivery of 1.6% and a hospital based prevalence of 2.8% out of the total 9457 deliveries recorded in the study period.²⁶

A Cross-sectional study done at Mahidol University, Bangkok, Thailand (2006) 150 twin pregnancies 28 weeks of gestation were enrolled. Discordance was found in 35 cases. Prevalence was 23.3%. No significant association between discordance and Maternal age, Maternal complications, Parity, Pregnant by assisted reproduction, Gestational age at first diagnosis, Chorionicity. Discordant twins delivered at earlier gestational age (34.4), more likely to be admitted to the NICU (34.3% vs 7.8%).²⁷

A study by Amaru and coworkers of 1318 twin pairs from 1992 to 2001 from a single institution suggests that 20% growth discordance may result in an increased risk for some adverse outcomes but not for serious morbidity and mortality. After adjusting for chorionicity, antenatal steroids, oligohydramnios, preeclampsia, and

gestational age at delivery, discordant twins independent of small-for-gestational-age status were at increased risk for very low birth weight, neonatal intensive care unit admission, neonatal oxygen requirement, and hyperbilirubinemia. However, they did not seem to be at increased risk for serious neonatal morbidity and mortality.²⁴

A retrospective study was done in American University of Beirut Medical Centre, Lebanon in 2003 ,679 twins pregnancies were recruited .Discordant twins occurred in 11.9%. Discordant twins had a significantly higher incidence of growth restriction compared to concordant twins (88.9% vs 43.5%). Discordant twins had a significantly higher incidence of hyperbilirubinemia, need for mechanical ventilation.²⁸

Hanley et al noted a high incidence of velamentous cord insertion in twins (13-21%) and reported that it is significantly more common in monochorionic, than dichorionic, twin pairs (18% vs 6%; p=0.001). Additionally, its impact on birthweight discordance is 13.5 times greater for monochorionic diamniotic twin gestations than for dichorionic diamniotic twins. Two other publications also evaluated the effect of abnormal placental cord insertion on birthweight discordance and showed similar results.²⁹

Anath and coworkers evaluated 269,287 twin births from 1995 to 1997 using the matched multiple birth file for the United States. In same sex twins, a birth weight discordance of 20%, and in different sex twins, a birth weight discordance of 40% resulted in an increased risk for abruption (relative risk 1.2 and 2.2, respectively). In twins without abruption, growth discordance of 15% in same sex twins and 30% in different sex twins resulted in a increased risk for stillbirth, neonatal deaths, and preterm births.²³

A Population based study among 384 pairs twin gestations over 20 weeks of gestation during a two-year period were retrospectively analyzed, thirteen patients were identified to have single fetal demise and fourteen patients were documented to have dead fetuses of both twin pairs. Of 357 twin gestations studied 137 (38.4%) had discordance of < 10% and 36 experienced discordance of >30% (10.1%). The frequency of low APGAR score (< 7) in women with >30% discordance was higher than that of <10% group (16.7% vs. 9.5%). Intensive care for infants was required in 30 infants with >30% birth weight discordance (41.7%) and in 24 cases with <10% birth weight discordance (8.8%). Thirty-three percent of cases with discordance of >30% experienced neonatal mortality whereas the corresponding figure for patients with <10% discordance was 1.5%.⁹

Establishing a link between twin discordance and peripartum complications is imperative because it influences management, potentially improves outcomes, and may influence study design. The difficulties in the correlation of discordance with morbidity and death are (1) the small sample size of most studies, (2) almost all reports have linked actual weights, which are unavailable until after delivery, with complications rather than sonographic estimate of weight, which is available antenatally, (3) sex, (4) presentation, (5) gestational age, (6) medical obstetric complications, (7) antenatal surveillance, (8) the use of corticosteroids, (9) suboptimal growth, (10) anomalies, (11) route of delivery and (12) the availability of neonatal intensive care unit, all of which influence outcome, regardless of discordancy.

Acknowledging the lack of consensus on the precise threshold of discordance that is associated with complications, ACOG provides a range. When the difference

among the twins' birthweight is 15-25%, there is an increased risk of morbidity and death.¹⁴

This review on discordancy permits us to gauge its rate and identify the risk factors. Considering the vagaries of estimating fetal weight with singleton fetuses, our inability to identify discordance with measurements of biometric parameters is expected. Establishing chorionicity in the first trimester is imperative because it permits early identification and treatment of certain complications. Although there are limited data on the false-negative rate for twins who undergo antenatal tests, discordant growth after fetal viability is an indication for surveillance. Preterm delivery for discordance alone should not be undertaken.

METHODOLOGY

This study was conducted in the Department of Obstetrics and Gynecology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Study design

The study design was a cross sectional study.

Study duration and period

This one year study was conducted from January 2014 to December 2014.

Place

The present study was done at Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to Jawaharlal Nehru Medical College, Belgaum.

Source of data

Pregnant woman with twin pregnancy delivered at KLE Hospital beyond 28 weeks were studied.

Sample size

A total of 93 pregnant women with twin pregnancy were included in the study.

Sampling procedure

The sample size was calculated using the formula as below.

$$n = Z^2 p q / D^2$$

Where,

n = Sample size

Z = Confidence limit = 1.96

p = Prevalence that is, 24%

q = 100 – p = 76%

d = Absolute error = 20% of P that is 10

Therefore,

$$n = (1.96)^2 \times 24 \times 76 / 10^2$$

$$n = 72$$

However during the study period 93 cases were enrolled.

Selection criteria

Inclusion

- Pregnant women with Twins delivered at KLE hospital.
- Gestational age > 28 weeks.
- Known LMP or First Trimester USG.

Exclusion

- Congenital Anomaly of one or both twins.
- IUD of one or both twins.

Ethical clearance

The ethical clearance was obtained from the Institutional Ethical committee, Jawaharlal Nehru Medical College, Belgaum prior to the commencement.

Informed Consent

The eligible women were explained about the nature of the study and a written informed consent was obtained (Annexure I).

Method of collection of data

After the enrollment information regarding demographic data, obstetric history and current pregnancy details were obtained (Annexure II).

All eligible pregnant women with twin pregnancy delivered at KLE hospital were recruited in the study. Birth weight discordancy was calculated as per the formula as described below.

$$\frac{(\text{Birth weight of larger twin} - \text{birth weight of smaller twin}) \times 100}{\text{Birth weight of larger twin}}$$

Birth weight of larger twin

Discordancy was diagnosed when the difference in the EFW of both twins was > 15 % of larger twin at any gestational age. Perinatal outcome was compared between discordant group and concordant group.

The following perinatal outcome was analysed at the time of delivery

- Gestational age
- Birth weight

- Apgar score
- Admission to NICU, KMC
- Mode of Delivery
- Perinatal mortality

Statistical analysis

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

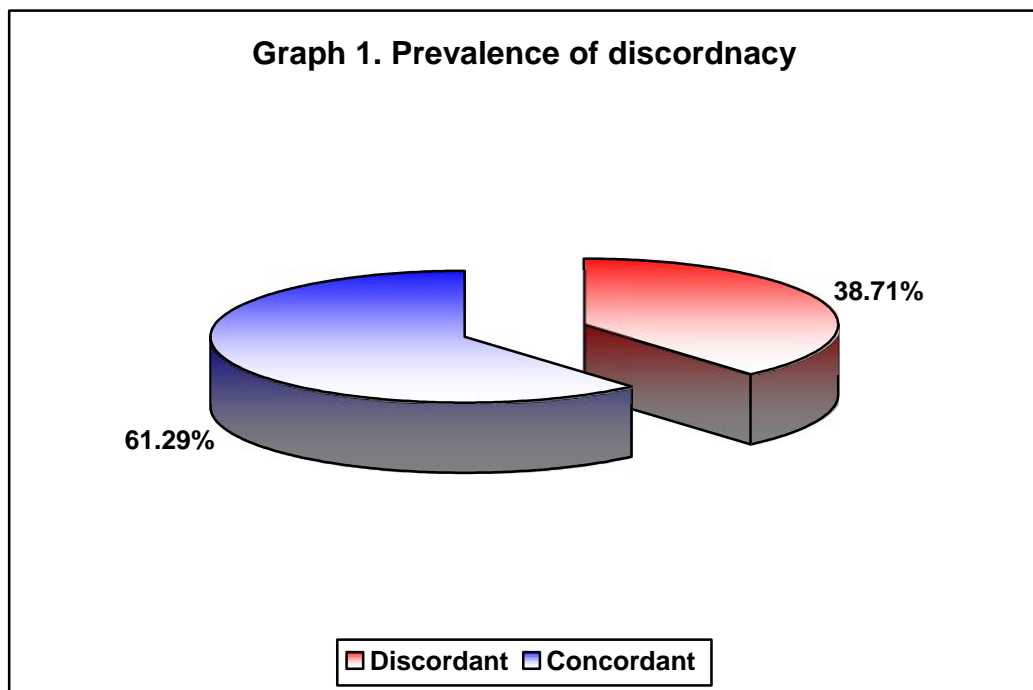
RESULTS

This cross sectional study was conducted in the Department of Obstetrics and Gynecology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. During the study period from January 2014 to December 2014 a total of 93 women fulfilled the selection criteria hence were enrolled.

Data obtained was coded and analysed. The final results and observations were tabulated as below.

Table 1. Prevalence of discordancy

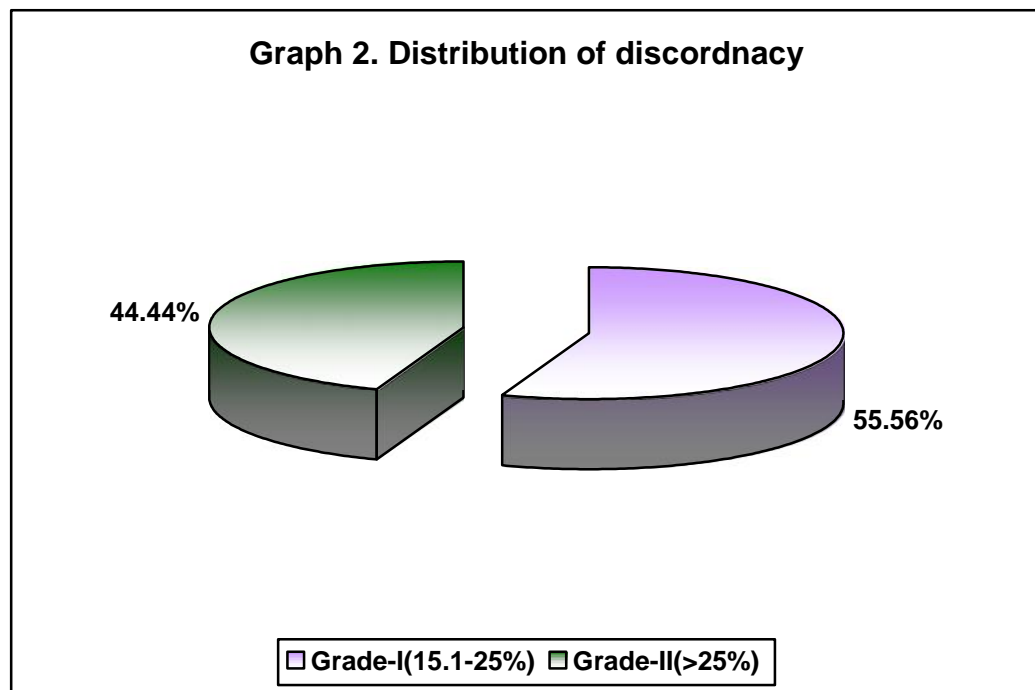
Type of twins	Distribution (n=93)	
	Frequency	Percentage
Concordant(15%)	57	61.29
Discordant(> 15%)	36	38.71



In the present study, the prevalence of discordant growth in twins was 38.71%.

Table 2. Distribution of discordancy

Discordancy (%)	Distribution (n=36)	
	number	percent
Grade -I (15.1 to 25%)	20	55.56
Grade-II (>25 %)	16	44.44

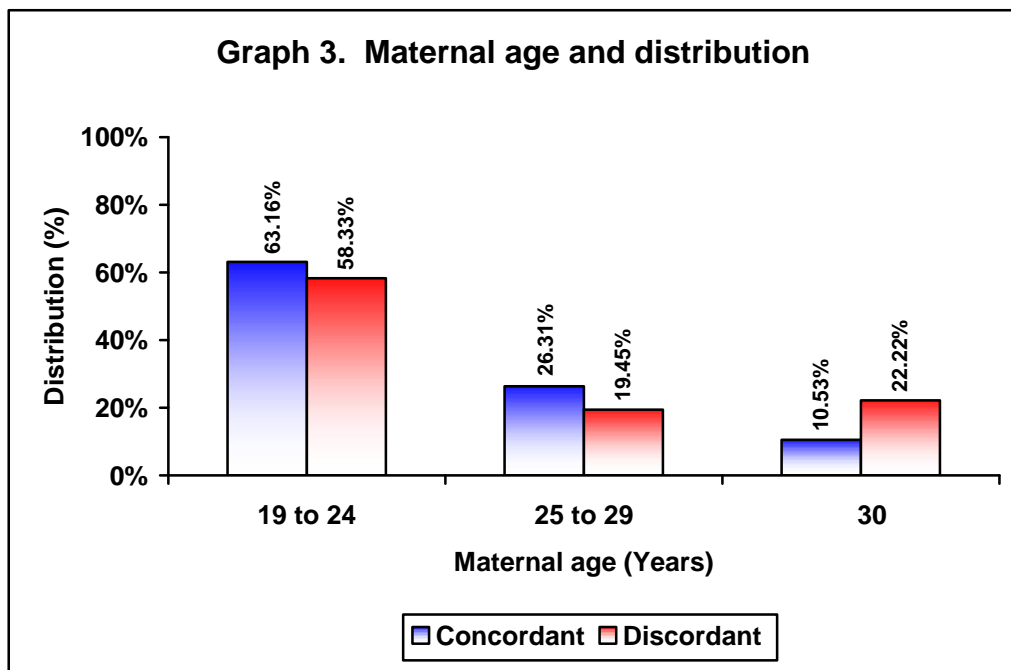


In this present study, maximum numbers of discordant twins (55.56%) had Grade -I discordancy and 44.44 % of twins had Grade-II discordancy.

Table 3. Maternal age distribution

Maternal age (years)	Concordant (n=57)		Discordant (> 15%) (n=36)		p- value
	Number	Percentage	Number	Percentage	
19 to 24	36	63.16	21	58.33	0.64
25 to 29	15	26.31	07	19.45	0.44
30	06	10.53	08	22.22	0.02

p = 0.080

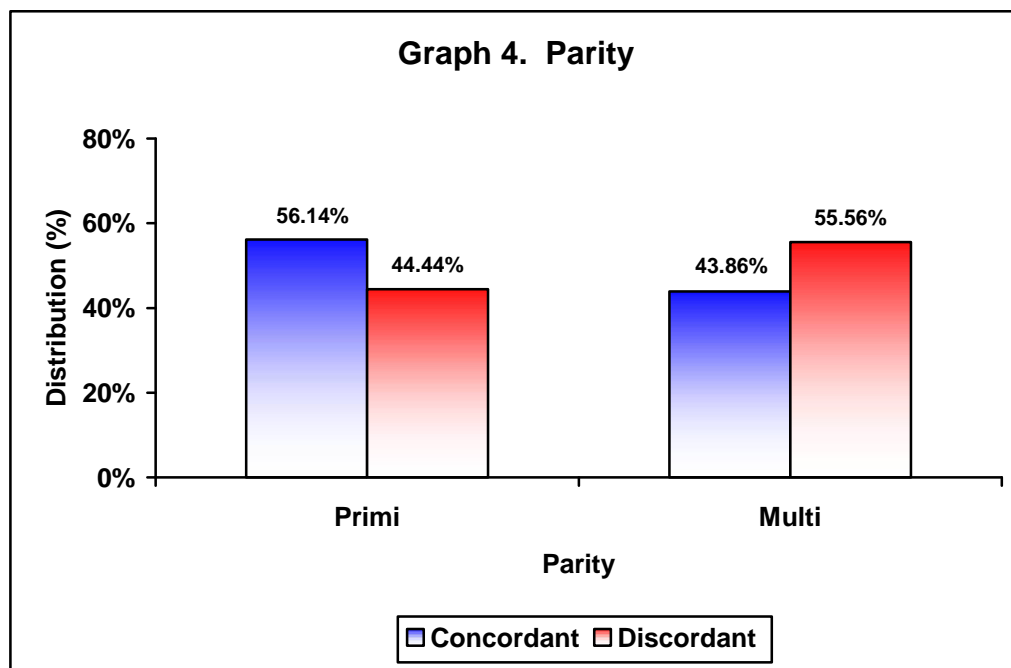


In this present study, maximum numbers of discordant twins (22.22%) were found in mothers aged >30 years which was found to be statistically significant (p=0.02) and maximum numbers of concordant twins(68.18%) were found in mothers aged 25 to 29 years which was statistically not significant .

Table 4. Parity

Parity	Concordant (15%) (n=57)		Discordant (> 15%) (n=36)		p-value
	Number	Percentage	Number	Percentage	
	Primi	32	56.14	16	
Multi	25	43.86	20	55.56	0.30

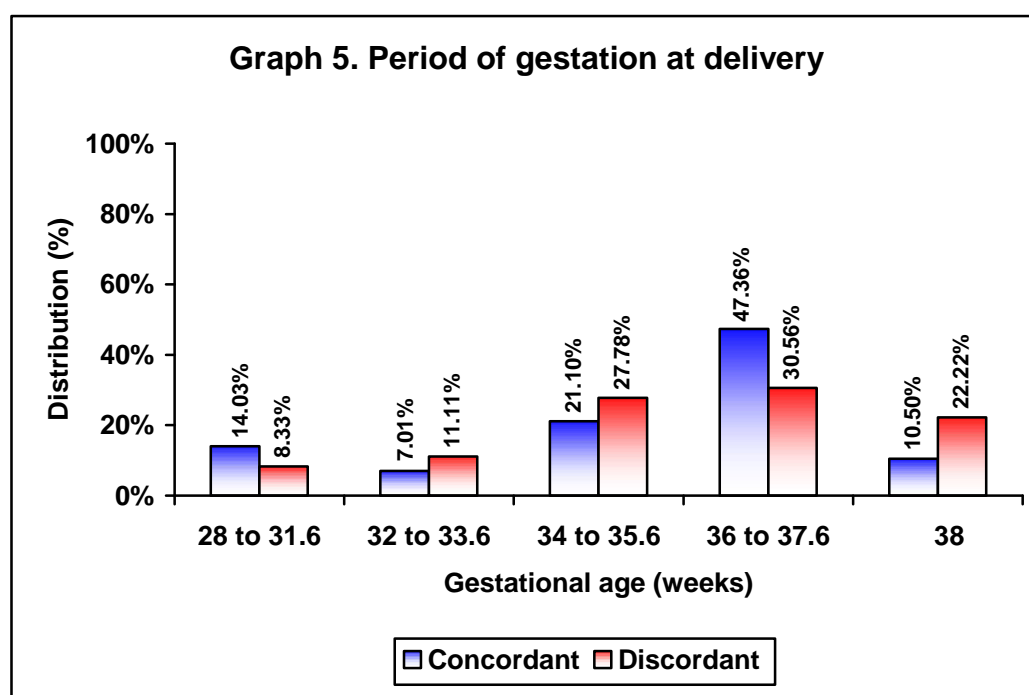
p = 0.272



In this study, maximum numbers of discordant twins (55.56%) were found in women with multi parity whereas maximum numbers of concordant twins (56.14%) were noted in women with primi parity. However, the difference was statistically not significant.

Table 5. Period of gestation at delivery

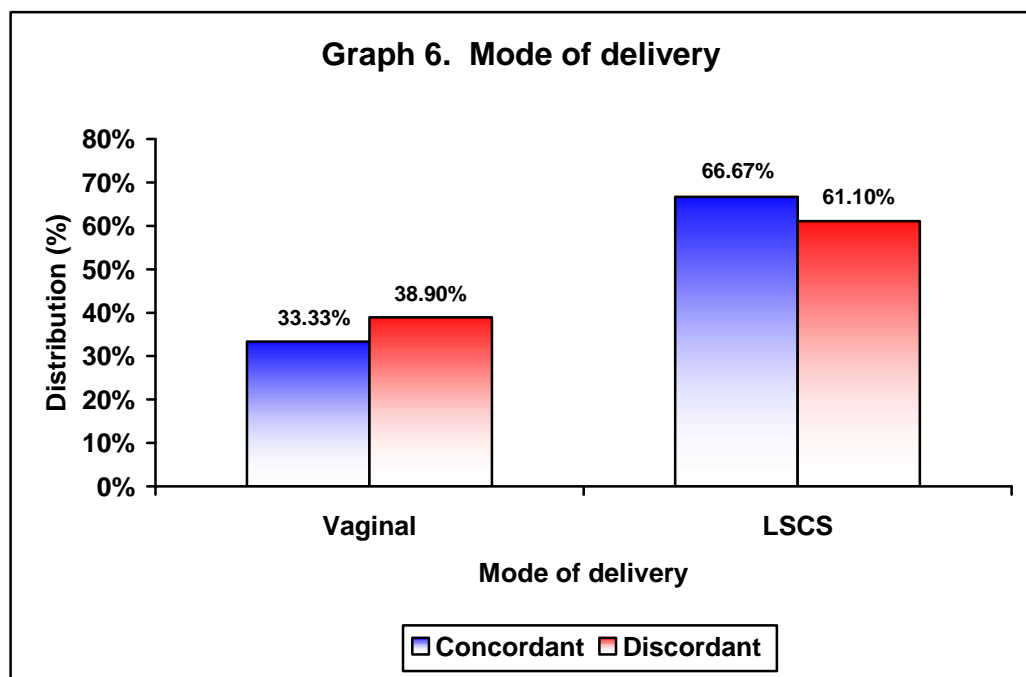
Gestational age (weeks)	Concordant (15%) (n=57)		Discordant (> 15%) (n=36)		p-value
	Number	Percentage	Number	Percentage	
28 to 31.6	08	14.03	03	08.33	0.41
32 to 33.6	04	07.01	04	11.11	0.52
34 to 35.6	12	21.10	10	27.78	0.01
36 to 37.6	27	47.36	11	30.56	0.11
38	06	10.50	08	22.22	0.13



In this present study, maximum numbers of both discordant (30.56%) and concordant twins (47.36%) delivered between 36.0 to 37.6 weeks of gestations. 27.78% of discordant twins delivered between 34.0 to 35.6 weeks of gestation were found statistically significant. (p=0.01)

Table 6. Mode of deliver

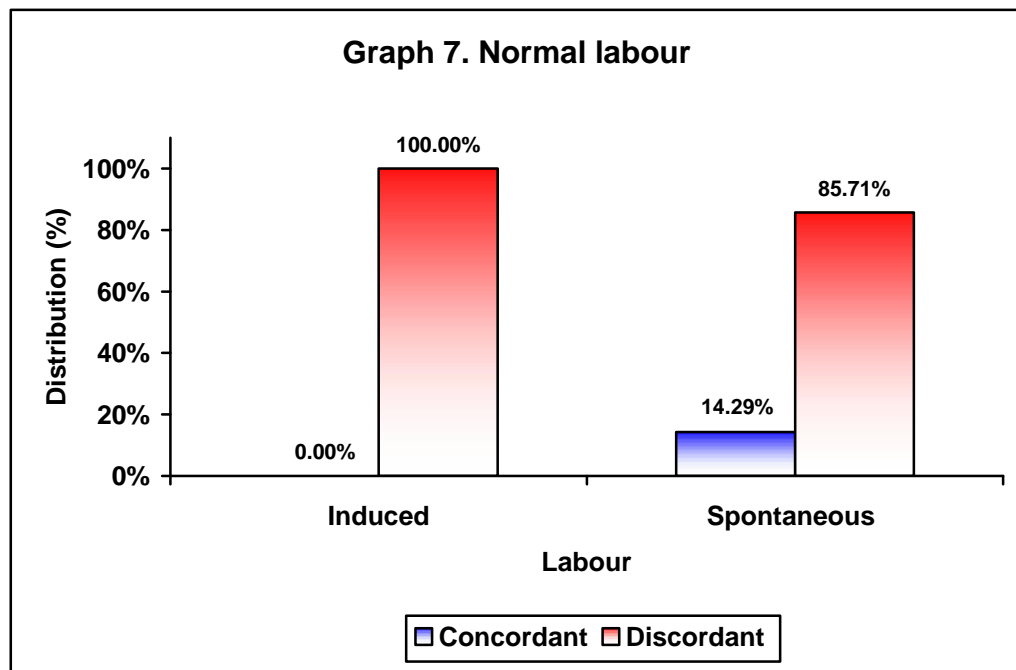
Mode of delivery	Concordant (15%) (n=57)		Discordant (> 15%) (n=36)		p-value
	Number	Percentage	Number	Percentage	
	Vaginal	19	33.33	14	
LSCS	38	66.67	22	61.10	0.58



In this present study, maximum numbers of discordant twins (38.90%) delivered vaginally whereas maximum number of concordant twins (66.67%) delivered by LSCS . However this difference was statistically not significant.

Table 7. Normal labour

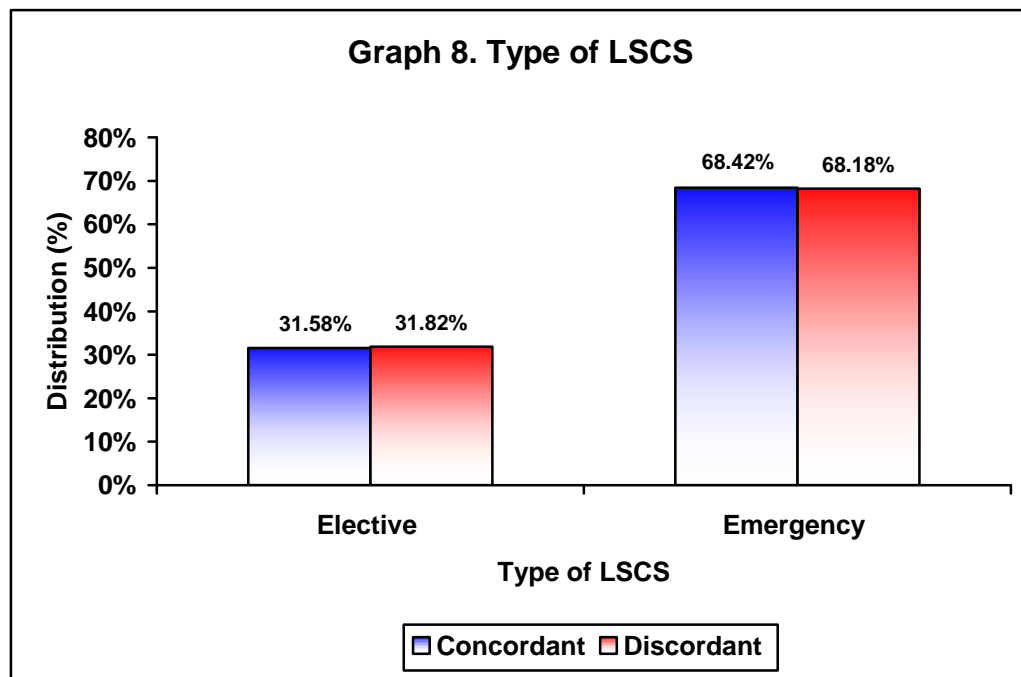
Normal Labour	Concordant (15%) (n=19)		Discordant (> 15%) (n=14)		p-value
	Number	Percentage	Number	Percentage	
Induced	0	0.00	02	14.29	0.08
Spontaneous	19	100.00	12	85.71	0.08



In this study, among the discordant twins delivered vaginally, 85.71% went into spontaneous labour compared to 14.29% of concordant babies and all discordant twins were induced, of which all of them delivered vaginally. However this difference was statistically not significant.

Table 8. Type of LSCS

Type of LSCS	Concordant (15%) (n=38)		Discordant (> 15%) (n=22)		p-value
	Number	Percentage	Number	Percentage	
	Elective	12	31.58	07	
Emergency	26	68.42	15	68.18	0.98



In the present study, 31.82% discordant twins and 31.58% of concordant twins underwent elective LSCS respectively. 68.18% discordant twins and 68.42% of concordant twins underwent emergency LSCS. However, this difference was statistically not significant.

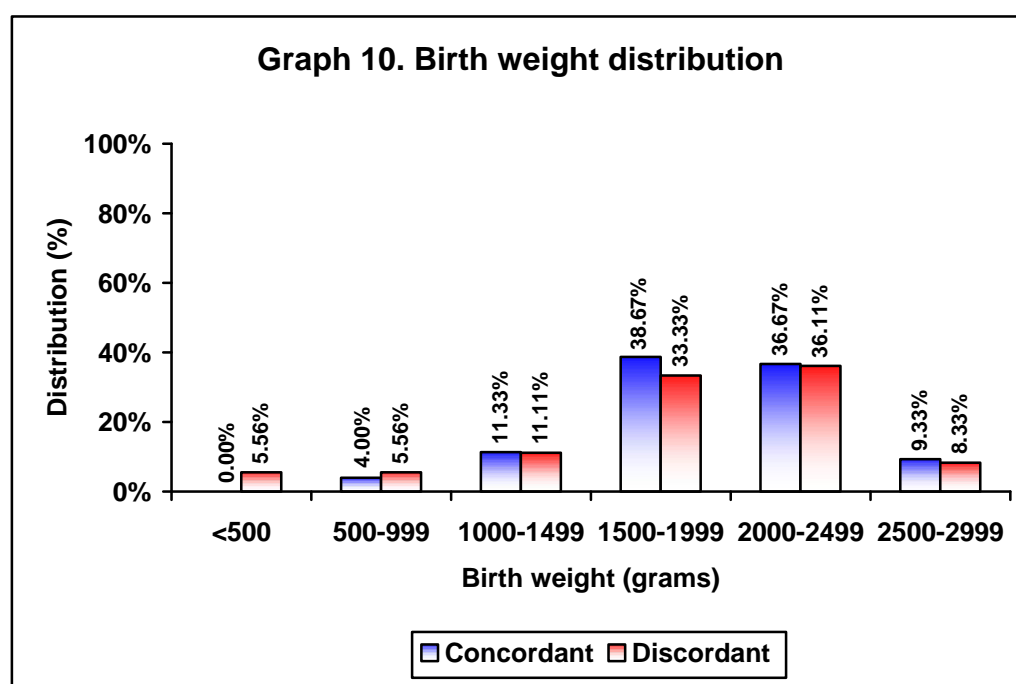
Table 9. Indications of LSCS in discordant twins

Indications	Distribution (n=22)	
	Frequency	Percentage
Previous caesarian section	03	13.60
Severe pre-eclampsia	05	22.71
Precious pregnancy with discordant growth	03	13.60
IUGR	04	18.18
Fetal distress	01	4.50
Abruption	01	4.50
Bad obstetric history with twin pregnancy	01	4.50
Transverse lie	01	4.50
First twin breech presentation	02	9.09
GDM with discordancy	01	4.50

In this study the commonest indication for LSCS was severe pre-eclampsia (22.71%) followed by Asymmetrical IUGR (18.18%) and previous caesarean section and previous pregnancy with discordant growth (13.6% each).

Table 10. Birth weight distribution

Birth weight (grams)	Concordant (15%) (n=150)		Discordant (> 15%) (n=36)		p-value
	Number	Percentage	Number	Percentage	
	<500	0	0.00	2	
500 - 999	6	4.00	2	05.56	0.68
1000 - 1499	17	11.33	04	11.11	0.97
1500 - 1999	58	38.67	12	33.33	0.55
2000 - 2499	55	36.67	13	36.11	0.95
2500 - 2999	14	09.33	3	09.72	0.82

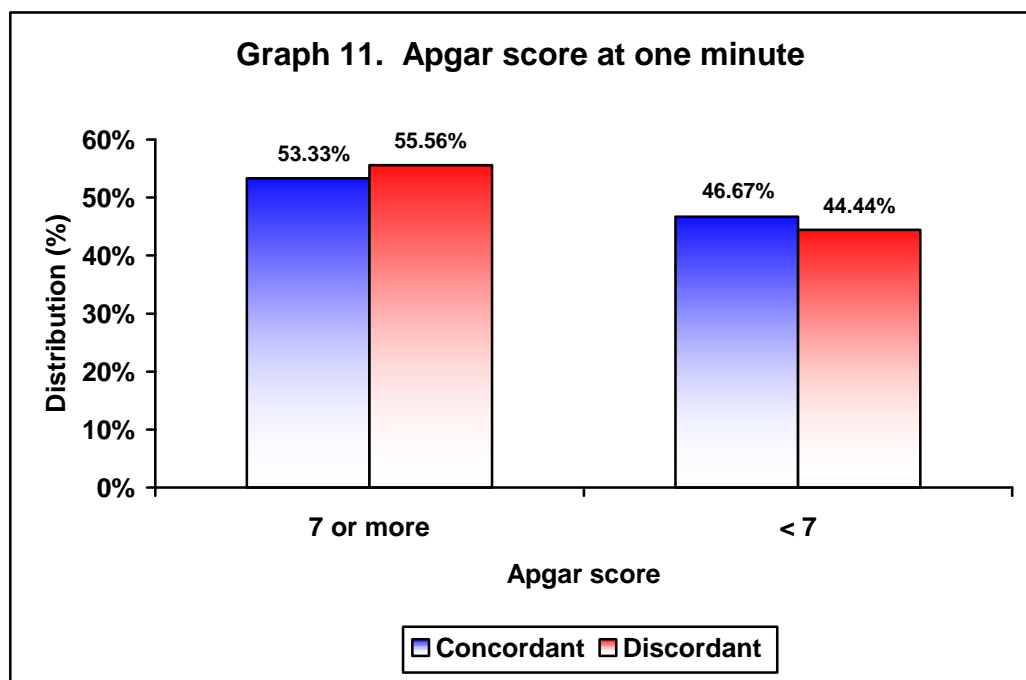


In this study, maximum numbers of (36.11%) discordant babies had birth weight between 2000-2499 grams and maximum number (38.67%) of concordant twins had birth weight between 1500-1999 grams. Birth weight of discordant babies < 500 was found statistically significant. (p=0.04)

Table 11. Apgar score at one minute

Apgar score	Concordant (15%) (n=150)		Discordant (> 15%) (n=36)	
	Number	Percentage	Number	Percentage
7 or more	80	53.33	20	55.56
< 7	70	46.67	16	44.44

p = 0.81

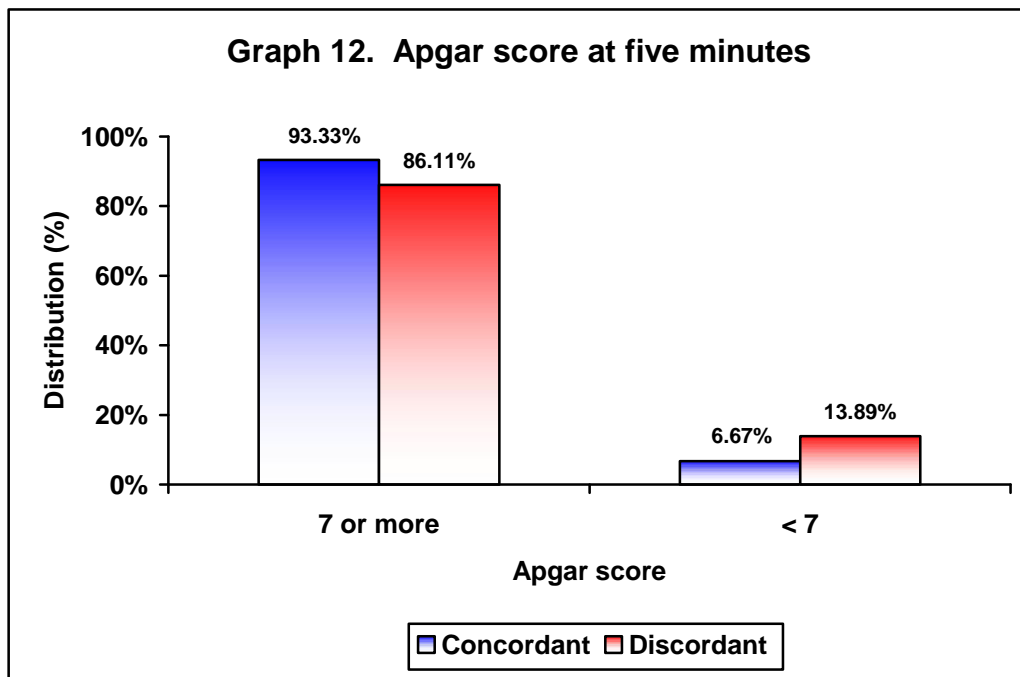


In this study, maximum numbers of discordant newborns (55.56%) and concordant newborns (53.33%) had apgar score of seven or more at one minute. However this difference was statistically not significant (p=0.81)

Table 12. Apgar score at five minutes

Apgar score	Concordant (15%) (n=150)		Discordant (> 15%) (n=36)	
	Number	Percentage	Number	Percentage
7 or more	140	93.33	31	86.11
< 7	10	06.67	05	13.89

p = 0.15

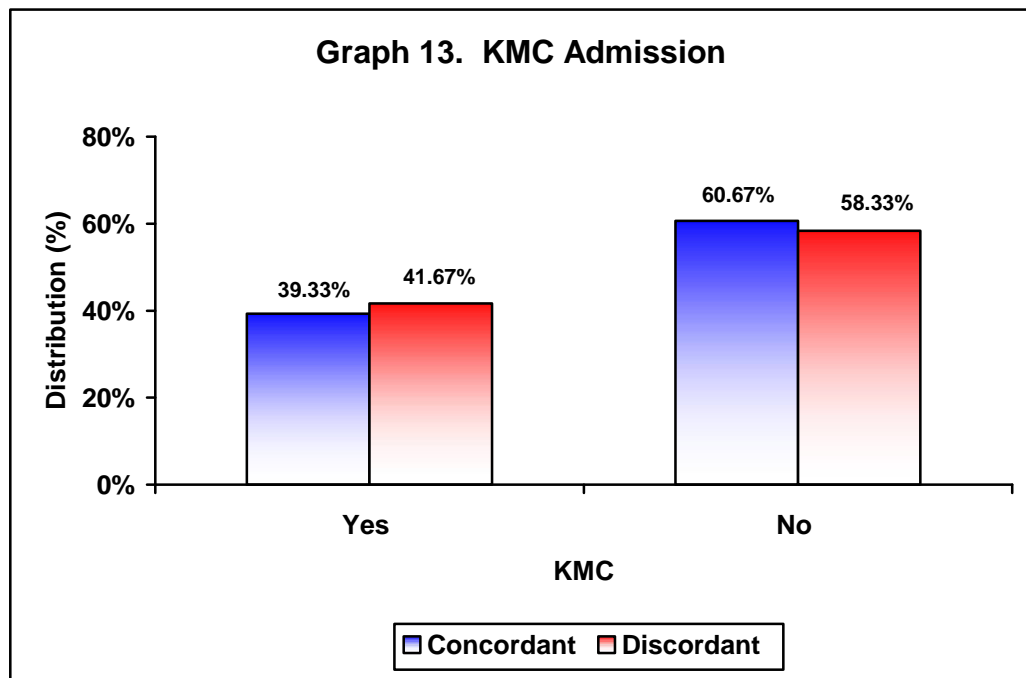


In this study, at five minutes, maximum numbers of both discordant newborns (86.11%) and maximum numbers of concordant newborns (93.33%) had apgar score 7 or more. However the difference was statistically not significant (p=0.15)

Table 13. KMC Admission

KMC	Concordant (15%) (n=150)		Discordant (> 15%) (n=36)	
	Frequency	Percent	Frequency	Percent
Yes	59	39.33	15	41.67
No	91	60.67	21	58.33

p=0.94

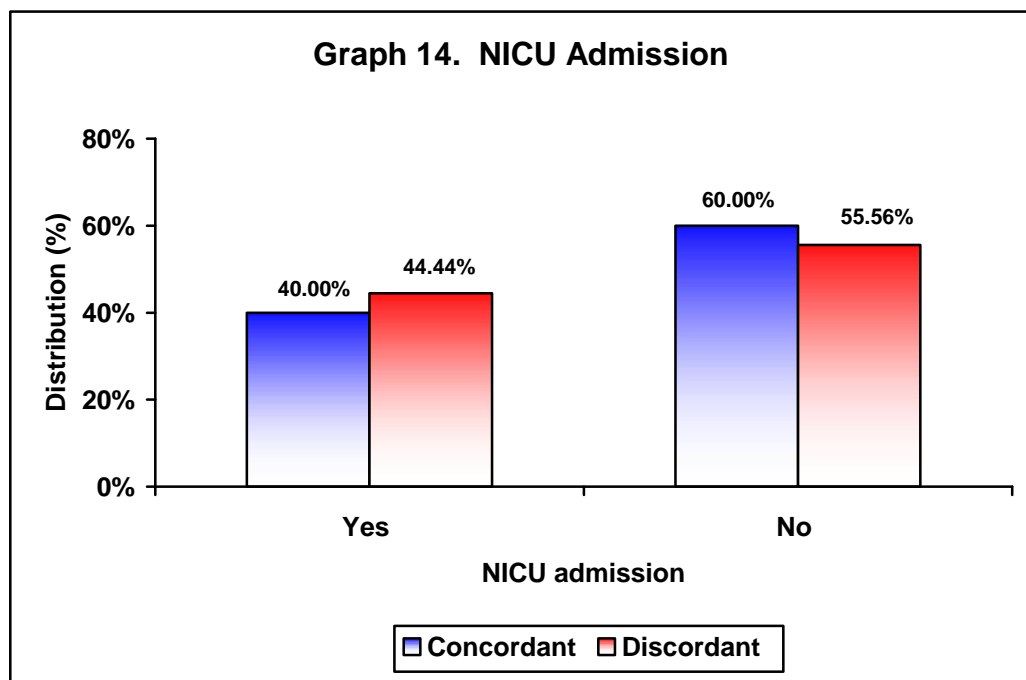


In this study, maximum numbers (41.67%) of the discordant newborns required KMC compared to 39.33% of the concordant newborns. However the difference was statistically not significant (p=0.94)

Table 14. NICU Admission

NICU	Concordant (15%) (n=150)		Discordant (> 15%) (n=36)	
	Frequency	Percent	Frequency	Percent
Yes	60	40.00	16	44.44
No	90	60.00	20	55.56

(p=0.542)



In this study, 44.44 % of the discordant newborns and 40.00 % concordant newborns required NICU admission but the difference was statistically not significant (p=0.542).

Table 15. Causes of NICU admission

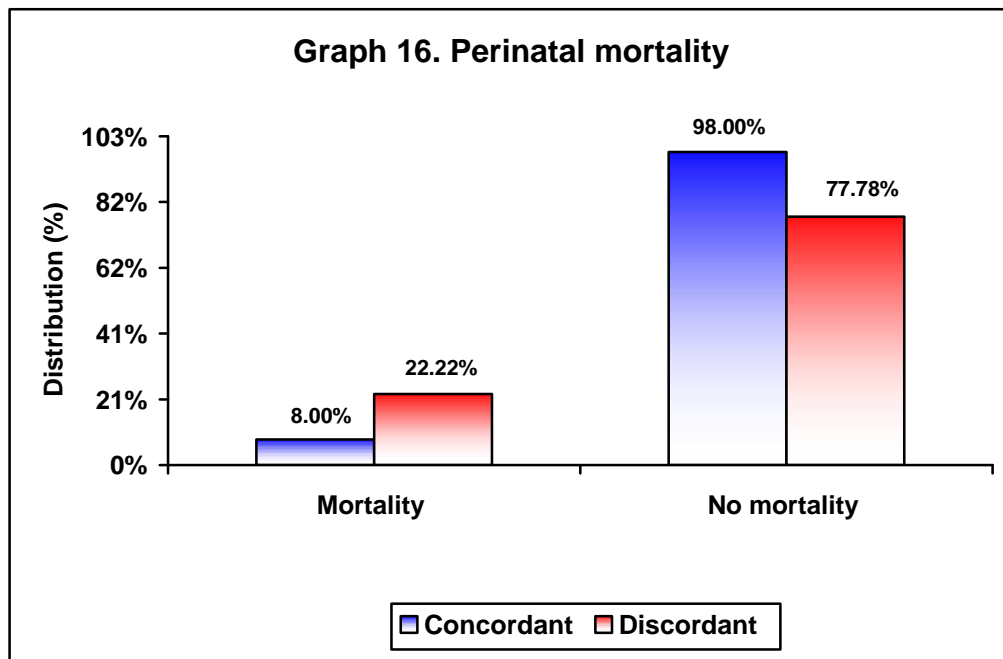
Causes	Concordant (15%)		Discordant (> 15%)	
	Frequency	Percent	Frequency	Percent
	N= 47		N=26	
Preterm	37	78.72	20	76.92
RDS	8	17.02	4	15.39
Birth asphyxia	1	02.13	2	07.69
Hypoglycemia	1	02.13	0	00.00

Table 12 shows causes of NICU admission among concordant and discordant babies. It was observed that, preterm delivery was the commonest cause of NICU admission in concordant (78.72%) and discordant babies (76.92%) followed by RDS (17.02 % and 15.39 % respectively).

Table 16. Perinatal mortality

Outcome	Concordant (15%) (n=150)		Discordant (> 15%) (n=36)	
	Frequency	Percent	Frequency	Percent
Mortality	12	8.00	08	22.22
No mortality	138	92.00	28	77.78

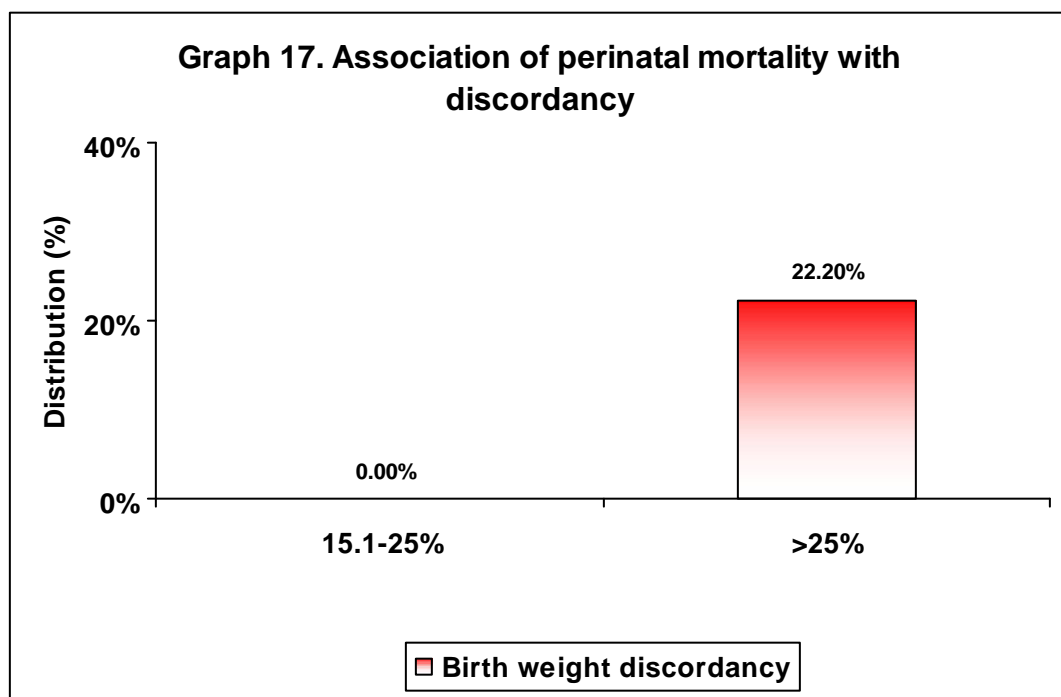
p=0.03



In this study, significant higher perinatal mortality (22.22 %) was found in discordant newborns (p=0.03).

Table 17. Association of perinatal mortality with discordancy

Discordancy	Distribution (n=36)	
	Frequency	Percentage
Grade –I (15.1 to 25 %)	00	00.00
Grade- II (> 25 %)	08	22.2%



In the present study, the perinatal mortality in discordant twins was found 22.2%, all of which occurred in Grade –II (> 25%) discordancy. There was no perinatal mortality in Grade –I (15.1 to 25%) discordancy.

DISCUSSION

The rate of multiple pregnancy is increasing worldwide. A twin gestation is generally considered to be a high risk pregnancy, the addition of discordant fetal growth adds the potential for further complications. Unequal size of twin infants could be a sign of pathologic growth in one fetus and is most often defined by using the larger twin as the standard for growth. As the weight difference of a twin pairs increases perinatal mortality and morbidity also increases. Discordant twin growth of more than 15% may be an important contributor to the adverse perinatal outcomes. This study was aimed to determine the prevalence of discordant growth in twin pregnancies and the perinatal outcome in twin pregnancies with discordant growth.

The present cross sectional study was carried out in the Department of Obstetrics and Gynecology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total 93 women with twin pregnancy who fulfilled the selection criteria from January 2013 to December 2013 were studied.

In the present study, of the 93 twins pregnancies, 57 had delivered with birth weight difference of 15% and among the 36 the birth weight difference of > 15% was noted. Hence, the prevalence of discordancy was as high as 38.71%.

The worldwide prevalence of discordancy is 16% as reported by Miller J et al in 2012 and there wide variation in the prevalence rates across the regions. The prevalence varies between 12 to 41%. Lower rates that is 12% is reported by Foley et al in 2000 from USA, Kalish et al in 2003 from USA and Usta et al in 2005 from Lebanon. Higher prevalence rates are reported by Grobman and Parilla in 2005 from USA. However the prevalence of discordancy observed in the present study was

comparable with a study done by Grobman and Parilla in 2005 from USA who reported higher prevalence of discordant growth in 41%.¹⁰ However most of the studies have estimated the prevalence by defining discordant growth at cut of 20% while the present study estimated the prevalence using a cut of value 15%.¹⁰

A cross-sectional study conducted in 2006 at Mahidol University, Bangkok, Thailand with 150 twin pregnancies 28 weeks of gestation, reported prevalence of discordance as 23.3%.²⁷

A retrospective study done in Croatia in 2004 with 351 twins pregnancies reported discordant growth among 58 twins(16.5%).¹⁶

In 2003, a retrospective study from Lebanon reported discordant twins occurred in 11.9% of all twin pregnancies.²⁸

Degree of birth weight discordance of the twin pairs is shown in Table 2. Discordancy was diagnosed when the difference in the birth weight of both twins was > 15% of larger twin at any gestational age.

In this present study, maximum babies (55.56%) were found to have Grade-I discordancy (15.1 to 25 %) followed by Grade- II (>25 %) (44.44%). In a study from Croatia the prevalence of discordant twins was 23.3%, defined as more than 20% difference in birth weight. Of these, 12.6% showed 20-25% discordance and 10.7% showed more than 25% discordance.¹⁶

A retrospective population-based cohort study in Lebanon showed that the rate of discordance was 19.6%, 7.7% had 20-25% discordance and 11.9% had more than 25% discordance.²⁸

A study done in the United States, the rate of discordance was 15%, 6.9% had 20-25% discordance and 8.1% had more than 25% discordance.³²

Another study done by Texas, the rate of discordance was 15%; 7% had 20-25% discordance and 8% had more than 25% discordance.² The difference in reported rate might be due to different populations and the definition used.

In the present study, maternal age distribution as shown in Table 3. majority of discordant twins (22.22%) were found in mothers aged >30 years which was statistically significant (p= 0.029) and maximum numbers of concordant twins (68.18%) were found in mothers aged 25 to 29 years which was not statistically significant. (p=0.282)

A study from Croatia in 2004 also reported significantly higher number of mothers with preterm discordant twin in the age group of 36–40 years old (38.4% vs. 16.5%; p<0.050).¹⁶

Another study done by Demissie. K et .al. showed that maternal age > 30 years was associated with significant (29%) discordance fetal growth.²³

In this study, parity distribution as shown in table 4. prevalence of discordancy was high in women with multi parity (55.56%) where as maximum numbers of concordant babies (56.14%) were noted in women with primi parity but no statistically significant association was observed (p=0.272). In contrast a study from Croatia in 2004 reported significantly higher number of nulliparous mothers with preterm discordant twins (62.5% vs. 55.8%; p<0.050)¹⁶. Another study by Cohen *et al.* reported on association of extreme birth weight discordancy (75.8%) with

primiparity³³. However, Amaru et al' did not find any significant associated factors for discordant twins similar to the present study.²⁴

In the present study, with regard to gestational age at delivery as shown in table 5. maximum numbers of both discordant (30.56%) and concordant twins (47.36%) delivered between 36.0 to 37.6 weeks of gestations . 27.78% of discordant twins delivered between 34.0 to 35.6 weeks of gestation were found statistically significant. (p=0.01) A study from Croatia demonstrated that discordant twins delivered at significantly earlier gestational age compared to concordant twins.¹⁶ A study by Cohen et. al.showed that twin pregnancies with extreme discordance may reach gestational age of 36 weeks .³³

In the present study, mode of delivery as shown in table 6. 38.90% discordant twins delivered vaginally compared to 33.33% of concordant twins(p- 0,58) and 61.10% discordant twins underwent LSCS compared to 66.67% of concordant twins (p-0.58).However, the difference statistically not significant.

In the present study, as shown in table 7. 14 (38.90%) discordant twins delivered vaginally compared to 19 (33.33%) of concordant babies ,out of these 14, 12(85.71%) discordant twins went into spontaneous labour compared to (14.29%) of concordant babies and all discordant twins were induced ,of which all of them delivered vaginally. However this difference was statistically not significant (p=0.172).

In the present study, as shown in table 8. 31.82% of discordant twins and 31.58% of concordant twins underwent elective LSCS respectively and 68.18% discordant twins and 68.42% of concordant twins underwent emergency LSCS . However, this difference was statistically not significant.(p=0.602).

In this study , as shown in table 9 .Out of 22 (36.67%) LSCS in discordant growth,,indications of LSCS are as follow: 7 woman underwent Elective LSCS - 3 (42.8%) woman conceived after infertility treatment and had birth weight discordancy more than 20%, 1 (22.17%) woman had severe PIH, 1 (14.2%) woman had previous LSCS with discordancy > 25%, 1 (14.2%) woman had GDM on insulin with discordancy >25% and went preterm spontaneous labour, 3 (21.4%) woman underwent term spontaneous labour, 2 (14.2%) woman were induced at term. Overall the rate of discordancy was high in normal deliveries compared to LSCS but the difference was statistically not significant (p=0.585). Similar to the findings of this study a study form Thailand also reported that both discordant and concordant groups had a similar rate of cesarean delivery.²⁷

For the analysis of neonatal outcome the larger baby in the discordant twins was included in the concordant group.

In this study, birth weight distribution as shown in table 10. In this study, maximum numbers of 12 (36.11%) discordant babies had birth weight between 2000-2499 grams and maximum number 58 (38.67%) of concordant twins had birth weight between 1500-1999 grams. However this difference was statistically not significant (p=0.655).

A study done in Thailand showed that discordant twins had significant lower birth weight than those of concordant twins (1698g and 2153g,p=0.001) .²⁷ In contrast to study done in Croatia showed that there were significant discordant babies in 2000-2499 (30.59%) p=<0.001 comparable to present study.¹⁶

In this study, apgar score at one minute as shown in table 11, maximum numbers of discordant newborns (55.56%) and concordant newborns (53.33%) had apgar score of seven or more at one minute. However this difference was statistically not significant ($p=0.81$).

In this study, apgar score at five minutes as shown in table 12, maximum numbers of both discordant newborns (86.11%) and maximum numbers of concordant newborns (93.33%) had apgar score 7 or more at five minutes. However the difference was statistically not significant ($p=0.15$). However no statistically significant difference was observed with regard to apgar score at one minute and five minutes in concordant and discordant babies.

In contrast, a study from Croatia reported that, term discordant babies had significantly higher incidence of low Apgar scores compared to concordant babies.¹⁶ A study from Lebanon did not find any statistically difference in apgar scores in both groups.²⁸

A study from turkey found low apgar score in discordant babies with birth weight difference $>30\%$ compared to concordant babies (16.7% vs 9.5%).⁹

In this study further KMC admission as shown in table 13. Maximum numbers (41.67%) of the discordant newborns required KMC compared to 39.33% of the concordant newborns. However the difference was statistically not significant ($p=0.94$).

In this study further NICU admission as shown in table 14. 44.44 % of the discordant newborns and 40.00 % concordant newborns required NICU admission but the difference was statistically not significant ($p=0.542$).

In contrast a study from Croatia the authors found that neonatal NICU admission increased significantly among those discordant pairs, in both larger and smaller infants.¹⁶

A study from turkey, NICU admission found in discordant babies (41.7%) compared to (8.8%) of concordant babies⁹

However no statistically significant association was noted between KMC and NICU admission ($p>0.050$) suggesting comparable perinatal outcome in both the subsets. . It was observed that, preterm delivery was the commonest cause of NICU admission in concordant (78.72%) and discordant babies (76.92%) followed by RDS (17.02 % and 15.39 % respectively).

In this study, as shown in table 16.17. Significant higher perinatal mortality (22.22 %) was found in discordant newborns. ($p=0.03$) The perinatal mortality in discordant twins was found 22.2%, all of which discordant twins occurred in Grade –II(> 25%) discordancy. There was no perinatal mortality in Grade –I (15.1to 25%) discordancy. Significantly higher mortality was noted in babies who had birth weight discordancy of > 25% (100%; $p=0.002$). No mortality found in larger babies in discordant growth.

Cohen et al. showed that twin pregnancies with extreme discordance may reach gestational age of 36 weeks with fair neonatal outcomes³³.

Similar observations were reported in a cross-sectional study from Thailand where no significant association was found between discordance and various factors, including maternal age, maternal complications, parity, pregnant by assisted reproduction, gestational age at first diagnosis, chorionicity.²⁷ However, discordant

twins delivered at earlier gestational age and were more likely to be admitted to the NICU. A retrospective study from Croatia in 2004 with 351 twins pregnancies reported discordant growth among 58 twins. Study showed higher incidence of low apgar scores, major malformations, early abnormal neurological signs, intraventricular haemorrhage, sepsis and anaemia.¹⁶ ^s In 2003, a retrospective study from Lebanon reported significantly higher incidence hyperbilirubinemia, need for mechanical ventilation and a longer nursery stay²⁸.

Based on the current findings of our study, the presence of growth discordance of >25% is associated with increased perinatal mortality and is definitely a high risk factor in twin pregnancies.

CONCLUSION

The present study showed prevalence of discordancy was as high as 38.71% considering the birth weight difference of more than 15%. Prevalence of Grade –I (15.1 to 25%) discordancy was found in 55.56% and Grade-II (>25%) discordancy was found in 44.44%. There was an increased incidence of perinatal mortality in discordant twins compared to concordant twins which was statistically significant. Perinatal mortality occurred only in discordant twins with Grade-II discordancy. There was no statistical significance in other neonatal outcomes including birth weight, apgar score, admission to NICU, KMC and mode of delivery between concordant and discordant groups. Presence of discordancy in twins is a risk factor for increased perinatal mortality.

SUMMARY

A twin gestation is generally considered to be a high risk pregnancy and addition of discordant fetal growth adds potential for further complications. Discordant twin growth of >15% may results in adverse perinatal outcome. This study was undertaken to determine the prevalence of discordant growth in twin pregnancies and the perinatal outcome in twin pregnancies with discordant growth.

This one year cross sectional study was done in the Department of Obstetrics and Gynecology, KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. A total 93 women with twin pregnancy were studied. Birth weight difference with >15% between twins was regarded as discordant growth.

The prevalence of discordant growth in twins was 38.71%. Among the babies with discordant growth maximum babies were found to have Grade-I discordancy (15.1 to 25%) 55.5% and Grade –II discordancy was found in 44.44%. The prevalence of discordancy was high in women who were aged more than 30 years (22.22%; p=0.029). Also the rate of discordancy was high in babies with gestational age between 34.0 to 36.0 weeks (p=0.010). Maximum numbers of (36.11%) discordant babies had birth weight between 2000-2499 grams and had apgar score of seven or more at one minute (55.56%) while at five minutes, 86.11% of the discordant newborns had apgar score of >7. 41.67% of the discordant newborns required KMC while 44.44 % of the discordant newborns had NICU admission and preterm delivery was the commonest cause of NICU admission in discordant babies (76.92%) followed by RDS (15.39%). Perinatal Mortality was noted in 22.22% of the discordant newborns (p=0.03) compared to concordant group which was significant, all of which

occurred with birth weight discordancy of $> 25\%$. No statistically significant association was noted between parity status and mode of delivery with growth discordancy ($p>0.050$) and also no statistically significant association was noted between apgar score at one minute and five minutes, KMC and NICU admission and discordancy ($p>0.050$).

The present study showed higher prevalence of discordancy in our hospital settings considering the birth weight difference of more than 15%. Prevalence of Grade -I (15.1 to 25%) discordancy was found in 55.56% and Grade-II ($>25\%$) discordancy was found in 44.44%. There was an increased incidence of perinatal mortality in discordant twins compared to concordant twins which was statistically significant. Perinatal mortality occurred only in discordant twins with Grade-II discordancy.

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ANNEXURE I – ETHICAL CLEARANCE



K.L.E.SOCIETY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELGAUM-590010 (KARNATAKA-INDIA)
(Affiliated to KLE University, Belgaum)

Website: <http://www.jnmc.edu>
E-Mail : domejnmc@sancharnet.in
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Ref: MDC/DOME/ ೧೩

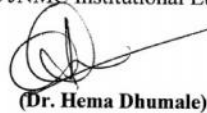
Date: 06/12/2013

To,

PG student in M.S OBG,
J.N.Medical College,
BELGAUM.

Sub: Institutional Ethical Clearance for changed research proposal.

With reference to the above, we wish to inform you that your proposed research project, which was cleared earlier by the institutional ethical committee was titled "**To determine the perinatal outcome of twin pregnancies with Discordant growth**". The title of this earlier proposed research project has been changed to "**PREVALANCE OF DISCORDANT GROWTH IN TWIN PREGNANCIES**", without any change in the methodology. Therefore this proposed research project with the new title is ethical and justifiable. The research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.


(Dr. Hema Dhumale)

Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.


(Dr. Ganga Pilli)

Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.

ANNEXURE II – CONSENT FORM

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled –“**PREVALANCE OF DISCORDANT GROWTH IN TWIN PREGNANCIES -A CROSS-SECTIONAL STUDY.**” conducted by Dr._____, Post Graduate in M.S. Obstetrics & Gynaecology under the guidance of Dr. _____ Professor , Department of Obstetrics & Gynaecology, J.N. Medical College, Belgaum under KLE university, Belgaum.

Respected Madam we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

The purpose of research:

To determine the preterm birth in twin pregnancies with discordant growth .This study proposes to study the impact of discordant growth in twin pregnancies and to know its related perinatal outcome.

Procedure Involved:

If you agree to enroll yourself in my study, you will be interviewed regarding your some personal information and obstetric history relevant to the study. You will be subjected to ultrasonography to diagnose the presence of discordant growth . The

following perinatal outcome will be analysed at the time of delivery:- Gestational age, Birth weigh , Apgar score, Admission to NICU, Mode of Delivery, Perinatal mortality.

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.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E.S hospital.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is

obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. If you are injured, you may contact Dr. _____, at Department of Obstetric & Gynaecology, KLES Hospital& MRC or by Ph. No: _____.

Questions:

In case you have any questions related to the study, in future or in case of study related, you can contact Dr. _____, at Department of Obstetric & Gynaecology , KLES Hospital and MRC, Ph. No. _____ or phone number: _____ or Dr. _____, Professor, Dept. Of Obstetric & Gynaecology , KLES Hospital and MRC, Belgaum.

If you have any queries about your rights as a study subject, you may call Dr. _____, Prof. & Head of Pathology as Chairman of J. N. Medical College Institutional Ethical Committee of Human Subjects Research, Phone No. _____ at J. N. Medical College, Belgaum

Consent for participation in research trial

I, _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read form in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject : _____ Date:

Witness Name : _____ Signature: _____ Date :

Investigators Name: _____ Signature: _____ Date:

Place : _____

ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ಪತ್ರ

ಶ್ರೀಮತಿ -----

ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ವ್ಯಾಸಂಗ ಮಾಡುತ್ತಿರುವ ಡಾ||
ನಿಕಿತಾ, ಇವರು ಪ್ರಾಧ್ಯಾಪಕರು, ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀ ರೋಗ
ಶಾಸ್ತ್ರ, ಕೆ.ಎಲ್.ಇ. ವಿಶ್ವವಿದ್ಯಾಲಯದ ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯ ಅವರ
ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ಮಾಡಿರುವ **“ಅವಳ ಮಕ್ಕಳ ಗರ್ಭಧಾರಣೆಯಲ್ಲಿ ಮಕ್ಕಳ ಅಸಂಗತ
ಬೆಳವಣಿಗೆಯ ಬಗ್ಗೆ ಮಾಡಿರುವ ಒಂದು ವಿಭಾಗೀಯ ಅಧ್ಯಯನ”** (Prevalance of
Discordant Growth in Twin Pregnancies – A Cross Sectional Study) ದಲ್ಲಿ
ಭಾಗವಹಿಸಲು ಆಮಂತ್ರಿಸುತ್ತಿದ್ದೇವೆ.

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅರ್ಹರಾಗಿರುವುದರಿಂದ ನಿಮ್ಮ ಹೆಸರನ್ನು
ನೊಂದಾಯಿಸಲು ನಿಮ್ಮನ್ನು ವಿನಂತಿಸುತ್ತೇವೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸದ್ಯ ನೀವು
ಅನುಭವಿಸುತ್ತಿರುವ ತೊಂದರೆಗಳ ಬಗ್ಗೆ ಕೆಲವು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲಾಗುವುದು, ಅವುಗಳಿಗೆ ನೀವು
ನಿಮ್ಮ ಗೊತ್ತಿರುವ ಮಾಹಿತಿಯ ಮೇರೆಗೆ ಉತ್ತರಿಸಬಹುದು.

ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ವೈಯಕ್ತಿಕವಾಗಿದ್ದು, ನೀವು ಇದರಲ್ಲಿ
ಭಾಗವಹಿಸಿದರೂ ಅಥವಾ ಭಾಗವಹಿಸದಿದ್ದರೂ ಜೆ.ಎನ್. ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯದ
ಜೊತೆಗಿರುವ ನಿಮ್ಮ ಸಂಬಂಧ ಮೇಲೆ ಯಾವುದೇ ಪರಿಣಾಮ ಉಂಟಾಗುವುದಿಲ್ಲ. ನೀವು
ಭಾಗವಹಿಸಲು ಇಚ್ಛಿಸಿದರೂ ಸಹ, ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಇದರಿಂದ
ಹೊರಹೋಗಬಹುದು.

ಈ ಸಂಶೋಧನೆಯ ಮುಖ್ಯ ಉದ್ದೇಶ:

ಅಸಂಗತ ಬೆಳವಣಿಗೆಯ ಅವಳ ಮಕ್ಕಳ ಗರ್ಭಧಾರಣೆ ಮಾಡಿದ ಮಹಿಳೆಯಲ್ಲಿ ಅವಧಿಪೂರ್ವ
ಪ್ರಸವದ ಬಗ್ಗೆ ನಿರ್ಧರಿಸುವುದು ಹಾಗೂ ಅಸಂಗತ ಬೆಳವಣಿಗೆ ಹೊಂದಿದ ಅವಳ ಮಕ್ಕಳ
ಗರ್ಭಧಾರಣೆಯಲ್ಲಿ ಆಗುವ ಪರಿಣಾಮಗಳು ಮತ್ತು ಅದಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಪ್ರಸವೋತ್ತರ
ಫಲತಾಂಶಗಳನ್ನು ಕಂಡು ಹಿಡಿಯುವುದು ಈ ವಿಭಾಗೀಯ ಅಧ್ಯಯನದ ಮುಖ್ಯ
ಉದ್ದೇಶವಾಗಿರುತ್ತದೆ.

ಅಧ್ಯಯನವು ಒಳಗೊಂಡಿರುವ ವಿಧಾನ:

ನೀವು ಸದರಿ ಅಧ್ಯಯನದಲ್ಲ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೋಂದಾಯಿಸಲು ಒಪ್ಪಿಕೊಂಡರೆ, ನಿಮ್ಮ ವೈಯಕ್ತಿಕ ಮಾಹಿತಿ ಹಾಗೂ ಪ್ರಸೂತಿ ಇತಿಹಾಸದ ಬಗ್ಗೆ ಒಂದು ಸಂದರ್ಶನ ನಡೆಸಲಾಗುವುದು ಮತ್ತು ನಿಮ್ಮ ಗರ್ಭದಲ್ಲ ಅವಳಿ ಮಕ್ಕಳ ಅಸಂಗತ ಬೆಳವಣಿಗೆಯನ್ನು ತಿಳಿದುಕೊಳ್ಳಲು ಅಲ್ಟ್ರಾಸೋನೋಗ್ರಾಫಿ ಟೆಸ್ಟ್ ಮೂಲಕ ವೈದ್ಯಕೀಯ ಪರೀಕ್ಷೆ ನಡೆಸಲಾಗುವುದು. ಮತ್ತು ಈ ಕೆಳಗಿನವುಗಳ ಬಗ್ಗೆ ಪ್ರಸೂತಿಯ ವೇಳೆಯಲ್ಲಿ ಉಂಟಾಗುವ ಪ್ರಸವಪೂರ್ವ ಫಲಿತಾಂಶಗಳ ಬಗ್ಗೆ ವಿಶ್ಲೇಷಣೆ ಮಾಡಲಾಗುವುದು:- ಗರ್ಭಧಾರಣೆಯ ವಯಸ್ಸು, ಜನನ ವೇಳೆಯಲ್ಲಿ ಮಗುವಿನ ತೂಕ, ಎನ್‌ಬಿಸಿಯು ದಲ್ಲ ದಾಖಲೆ, ಪ್ರಸೂತಿಯ ವಿಧಾನ, ಪ್ರಸವಪೂರ್ವ ಸಾವಿನ ಪ್ರಮಾಣ, ಇತ್ಯಾದಿ.

ಅಪಾಯ ಮತ್ತು ಪ್ರಯೋಜನಗಳು:

ಈ ಅಧ್ಯಯನದಲ್ಲ ಯಾವುದೇ ಗಮನೀಯ ಅಪಾಯಗಳಿರುವುದಿಲ್ಲ. ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲ ಭಾಗವಹಿಸುವುದರಿಂದ ನಿಮಗೆ ಯಾವುದೇ ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಧನಗಳನ್ನು ಕೊಡಲಾಗುವುದಿಲ್ಲ.

ಸ್ವಯಂ ಪ್ರೇರಿತ ಭಾಗವಹಿಸುವಿಕೆ/ಹೊರ ಹೋಗುವುದು:

ಈ ಅಧ್ಯಯನದಲ್ಲ ಭಾಗವಹಿಸುವುದು ಸಂಪೂರ್ಣ ವೈಯಕ್ತಿಕವಾಗಿರುತ್ತದೆ. ನೀವು ಇದರಲ್ಲ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೋಂದಾಯಿಸದಿದ್ದರೂ ಸಹ ನೀವು ಇದರಲ್ಲ ಭಾಗವಹಿಸಿದರೂ ಅಥವಾ ಭಾಗವಹಿಸದಿದ್ದರೂ ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆಯ ಜೊತೆಗಿರುವ ನಿಮ್ಮ ಸಂಬಂಧ ಮೇಲೆ ಯಾವುದೇ ಪರಿಣಾಮ ಉಂಟಾಗುವುದಿಲ್ಲ.

ಪರ್ಯಾಯ/ಬದಲಿ:

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲ ಭಾಗವಹಿಸದಿದ್ದರೂ, ನಮ್ಮ ದಿನ ನಿತ್ಯದ ನಿರ್ವಹಣೆಯಲ್ಲಿ ಯಾವುದೇ ವ್ಯತ್ಯಾಸವಾಗುವುದಿಲ್ಲ.

ಗೌಪ್ಯತೆಯ ರಕ್ಷಣೆ:

ನಿಮ್ಮ ಬಗೆಗಿನ ವಿವರಗಳು ಸಂಶೋಧನಾ ತಂಡದವರಿಗೆ ಮಾತ್ರ ತಿಳಿದಿರುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲ ನೀವು ಒದಗಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು (ಈ ಕೆಳಗಿನ ಸಂದರ್ಭಗಳನ್ನು ಬಿಟ್ಟು) ನಿಮ್ಮ ಅಜಿತ ಪರವಾನಿಗೆ ಇಲ್ಲದೇ ಬೇರೆಯವರಿಗೆ ಕೊಡಲಾಗುವುದಿಲ್ಲ.

- 1) ನಿಮ್ಮ ಹಕ್ಕು ಮತ್ತು ಹಿತರಕ್ಷಣೆ ಸಲುವಾಗಿ ತುರ್ತು ಸಂದರ್ಭಗಳಲ್ಲಿ
- 2) ಕಾನೂನಿನ ಪ್ರಕಾರ ಯಾವುದೇ ಮಾಹಿತಿ ಒದಗಿಸಬೇಕಾದ ಸಂದರ್ಭದಲ್ಲಿ

ಅಧ್ಯಯನದ ಫಲತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸುವ ಅಧಿಕಾರ:

ಈ ಸಂಶೋಧನೆಯ ಫಲತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸಿದಾಗ ಅಥವಾ ಚರ್ಚಿಸುವಾಗ ನಿಮ್ಮ ಯಾವುದೇ ವೈಯಕ್ತಿಕ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಕೊಡಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುವುದು.

ಭಾಗವಹಿಸುವುದರಿಂದ ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಗಳು:

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮ ಹೆಸರನ್ನು ನೋಂದಾಯಿಸಿದರೆ ನಿಮಗೆ ಯಾವುದೇ ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಗಳನ್ನು ಕೊಡಲಾಗುವುದಿಲ್ಲ. ಇದನ್ನು ಕೇವಲ ಸಂಶೋಧನೆಗಾಗಿ ಮಾಡಲಾಗುವುದು ಮತ್ತು ಇದರ ಎಲ್ಲ ಖರ್ಚುಗಳನ್ನು ಸಂಶೋಧಕರೇ ಭರಿಸುತ್ತಾರೆ.

ಪರಿಹಾರ:

ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಪಟ್ಟಂತೆ ನಿಮಗೆ ಯಾವುದೇ ಗಾಯಗಳಾದರೆ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ. ವತಿಯಿಂದ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುವುದು. ಈ ರೀತಿಯ ವೈದ್ಯಕೀಯ ಚಿಕಿತ್ಸೆಗೆ ಯಾವುದೇ ಪರಿಹಾರಧನ ಕೊಡಲಾಗುವುದಿಲ್ಲ. ನಿಮಗೆ ಯಾವುದೇ ಗಾಯವಾದ ಸಂದರ್ಭದಲ್ಲಿ ನೀವು ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ. ಇವರನ್ನು ಅಥವಾ ಮೊಬೈಲ ನಂ.: ಮೂಲಕ ಸಂಪರ್ಕಿಸಬಹುದು.

ಪ್ರಶ್ನೆಗಳು:

ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಬೇಕಾಗಿದ್ದರೆ, ನೀವು ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ., ಫೋನ್: ಅಥವಾ ಮೊಬೈಲ ನಂ.: ಅಥವಾ ಡಾ|| ಯೆಶಿತಾ ಬಿ. ಪೂಜಾರಿ, ಪ್ರಾಧ್ಯಾಪಕರು, ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕೆ.ಎಲ್.ಇ.ಎಸ್. ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಮ್.ಆರ್.ಸಿ. ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

4

ಈ ಅಧ್ಯಯನದಲ್ಲ ಪ್ರಯೋಗಾರ್ಥಿಯಾಗಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ, ನೀವು ಡಾ|| ಪ್ರಾಧ್ಯಾಪಕರು ಮತ್ತು ಪೆಥಾಲಾಜಿ ವಿಭಾಗದ ಮುಖ್ಯಸ್ಥರು, ಚೇರಮನ್ ಜೆ.ಎನ್. ಮೆಡಿಕಲ್ ಕಾಲೇಜ್ ಇನ್‌ಸ್ಟಿಟ್ಯೂಷನಲ್ ಎಥಿಕ್ಸ್ ಕಮಿಟಿ ಆನ್ ಹ್ಯೂಮನ್ ಸಬ್ಜೆಕ್ಟ್ಸ್ ರಿಸರ್ಚ್, ಮೊಬೈಲ್ ನಂ.: 9 _____ ಮೂಲಕ ಸಂಪರ್ಕಿಸಬಹುದು.

ಈ ಸಂಶೋಧನಾ ಪ್ರಯೋಗದಲ್ಲ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ

ಈ ಕೆಳಗೆ ಸಹಿ ಮಾಡಿದ _____ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿ ಈ ಅಧ್ಯಯನದಲ್ಲ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಂಡಿರುತ್ತೇನೆ. ಈ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಮಾಡುವುದರಿಂದ ನಾನು ನನ್ನ ಯಾವುದೇ ಕಾಯದೇಬದ್ಧ ಹಕ್ಕುಗಳನ್ನು ಬಿಟ್ಟುಕೊಟ್ಟಿರುವುದಿಲ್ಲ. ನಾನು ಯಾವುದೇ ಸಂದರ್ಭದಲ್ಲ ಈ ಅಧ್ಯಯನದಿಂದ ಹೊರಹೋಗಬಹುದು. ನಾನು ಈ ಅಧ್ಯಯನವು ಒಳಗೊಳ್ಳುವ ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳು ಹಾಗೂ ಪ್ರಶ್ನೆಗಳಿಗೆ ನಾನು ಕೊಟ್ಟಿರುವ ಉತ್ತರಗಳನ್ನು ನನ್ನ ಮಾತೃಭಾಷೆಯಲ್ಲಿ ಓದಿ, ತಿಳಿದುಕೊಂಡು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ಕೊಟ್ಟಿರುತ್ತೇನೆ.

ಪ್ರಯೋಗಾರ್ಥಿಯ ಹೆಸರು : _____

ಪ್ರಯೋಗಾರ್ಥಿಯ ಸಹಿ: _____ ದಿನಾಂಕ: _____

ಸಾಕ್ಷಿಯ ಹೆಸರು: _____ ಸಹಿ: _____ ದಿನಾಂಕ: _____

ಸಂಶೋಧಕರ ಹೆಸರು: _____ ಸಹಿ: _____ ದಿನಾಂಕ: _____

ಸ್ಥಳ: _____

शोध (निकाल) - प्रसिध्द करण्याचा अधिकार :-

जेव्हा संशोधनाचा निकाल प्रसिध्द केला जाईल किंवा सभेमध्ये चर्चा केली जाईल, त्यावेळी तुमची ओळख पटेल अशी कोणती ही माहिती दिली जाणार नाही. या अभ्यास क्रमादरम्यान जी माहिती मिळविलेली आहे आणि ज्याची तुमच्याकडून ओळखलेली आहे ती गुप्त राहिल.

सहभागा करिता प्रेरणा :-

रुग्णांचे नांव नोंदणी करिता आर्थिक सहाय्य दिले जाणार नाही. हे कार्य पुर्णपणे संशोधनाकरीता आहे आणि संशोधनाचा पूर्ण खर्च संशोधकांकडून केला जाईल.

नुकसान भरपाई :-

अभ्यासक्रमा वेळी कांही दुखापत झाल्यास, के.एल.ई. हॉस्पिटल व एम.आर.सी. बेळगांव कडून उपचार केले जातील. कायद्या प्रमाणे अशा वैद्यकीय उपचाराला कोणतीही नुकसान भरपाई अथवा खर्च देणे नाही. जर तुम्हाला दुखापत झाली असल्यास तुम्ही डॉ. - स्त्री रोग व प्रसुती विभाग, के.एल.ई. हॉस्पिटल किंवा एम.आर.सी. बेळगांवकडे संपर्क साधू शकता. नं.

प्रश्न :-

जर तुम्हाला अभ्यास क्रमा बदल भविष्यात कांही प्रश्न असल्यास तुम्ही डॉ. - स्त्री रोग व प्रसुती शास्त्र विभाग, के.एल.ई. हॉस्पिटल किंवा एम.आर.सी. बेळगांव नं. किंवा नं. किंवा डॉ., अध्यापक - स्त्री रोग व प्रसुती शास्त्र विभाग, के.एल.ई. हॉस्पिटल किंवा एम.आर.सी. बेळगांव कडे संपर्क साधू शकता.

जर तुम्हाला अभ्यासक्रमाचा विषय असल्या बदल हळू विषयक कांही प्रश्न असल्यास तुम्ही डॉ., -अध्यापक व रोग निदान शास्त्राचे प्रमुख चेअरमन जे.एन.मॅडीकल कॉलेज इनस्टीट्यूशनल येथील कमिटी ह्युमन सबजेक्ट्स रिसर्च फोन नं. जे.एन.मॅडीकल कॉलेज बेळगांव यांना संपर्क साधू शकता.

संशोधन अभ्यासाकरिता सहभागासाठी संमतीपत्र

श्री./श्रीमती/कुमारी -----आम्ही तुम्हाला विनंती करतो की आपण आमचा अभ्यासक्रम “**जुळ्या गरोदरपणातील विसंगत वाढीचा फैलाव - प्रतिनिधीक अभ्यासक्रम**” करिता नोंद करून घ्यावे.

डॉ. पोस्ट ग्राजुएट एम.एस. (प्रसुतीशास्त्र व स्त्रीरोग) यांनी डॉ. येशीता व्ही. पुजार, अध्यापक स्त्रीरोग व प्रसुतीशास्त्र जे.एन. मेडीकल कॉलेज, बेळगांव के.एल.ई युनीव्हर्सिटी, बेळगांव यांच्या मार्गदर्शना खाली संचालित केलेला आहे.

आदरणीय मॅडम आम्ही तुम्हाला विनंती करतो की, आपण आमच्या अभ्यासक्रमामध्ये सहभाग होण्याकरिता नोंद करावी कारण आपण या अभ्यासक्रमामध्ये भाग घेण्याकरता पात्र आहात. या अभ्यासक्रमा दरम्यान तुम्हाला तुमच्या सद्य परिस्थितीस तक्रारी बद्दल प्रश्न विचारले जातील आणि तुम्ही तुमचा चांगल्या माहिती प्रमाणे त्याची उत्तरे द्यावयाची आहेत.

तुमचा संशोधनातील सहभाग हा स्वइच्छेने आहे. तुमचा संशोधनात सहभागी होण्याचा अगर न होण्याचा तुमच्या व जे.एन. मेडिकल कॉलेजचा संबंधावर कांही परिणाम होणार नाही. जर तुम्ही सहभागाचा निर्णय घेतला तरी कोणत्याहीवेळी तुम्ही तो निर्णय बदलण्याचे आपणास स्वातंत्र्य आहे.

संशोधनाचा हेतू :-

जुळ्या गरोदरपणातील वेळेपूर्वी विसंगत वाढीने होणारे जन्म याबाबत विचार करणे. ह्या अभ्यासक्रमात मुळे जुळ्या गरोदरपणातील मुलांचे विसंगत वाढीने होणारे परिणाम याचा अभ्यास करण्यास सहाय्य होईल.

समाविष्ट कार्यपध्दती :-

जर तुम्ही अभ्यासक्रमामध्ये भाग घेण्याकरता तयार असाल तर, या अभ्यासक्रमास आवश्यक असलेल्या वैयक्तिक माहिती बाबत व प्रसुती इतिहासाबद्दल तुम्हाला प्रश्न विचारले जातील व त्याच बरोबर तुम्हाला विसंगतवाढीचा शोध घेण्याकरता अल्ट्रा-सोनोग्राफी करावी लागेल., प्रसुतीच्यावेळी खालील स्त्री

जन्मापासुनच्या परिणामाचा निष्कर्ष काढला जाईल. गर्भधारणेचा काळ, जन्मावेळेचे वय, NICU मध्ये दाखल करणे, प्रसुतीची पध्दत, स्त्रीजन्मापासुनचे प्राणघातक रोग.

जबाबदारी व फायदे :-

या काळात कोणतीही अधिक जबाबदारी नाही. या अभ्यास क्रमाचा सहभागाबद्दल कोणतेही आर्थिक सहाय्य मिळणार नाही.

स्वेच्छा सहभाग/माघार :-

या अभ्यासक्रमातील सहभाग हा स्व-इच्छेनुसार आहे. तुम्ही या अभ्यास क्रमामध्ये भाग घेण्याचा निर्णय घेवू शकता. तुमच्या निर्णयाचा के.एल.ई. मधुन दिल्या जाणाऱ्या सद्य व भविष्यातील आरोग्य सुविधांवर कांही परिणाम होणार नाही.

पर्याय :-

जरी तुम्ही सहभागाकरिता नकार दिला तरी तुम्हाला रोजच्या व्यवस्थेतील सुविधा उपलब्ध असतील.

गुप्तता व विश्वास :-

तुम्ही संशोधनाचा भाग असल्याचे फक्त संशोधन गटाच्या सदस्यांना माहीत असेल. खाली दिलेल्या दोन मुद्यांन व्यतिरीक्त तुमच्या बदल व संशोधना दरम्यान तुम्ही दिलेल्या माहिती बदल कोणास ही तुमच्या लेखी सम्मती शिवाय माहिती दिली जाणार नाही.

- १) तुमचे हक्क व स्वास्थ्य रक्षण करण्यासाठी बिकट प्रसंग असल्यास.
- २) जर कायदाने घावे लागल्यास.

शोध (निकाल) - प्रसिध्द करण्याचा अधिकार :-

जेव्हा संशोधनाचा निकाल प्रसिध्द केला जाईल किंवा सभेमध्ये चर्चा केली जाईल, त्यावेळी तुमची ओळख पटेल अशी कोणती ही माहिती दिली जाणार नाही. या अभ्यास क्रमादरम्यान जी माहिती मिळविलेली आहे आणि ज्याची तुमच्याकडून ओळखलेली आहे ती गुप्त राहिल.

सहभागा करिता प्रेरणा :-

रुग्णांचे नांव नोंदणी करिता आर्थिक सहाय्य दिले जाणार नाही. हे कार्य पुर्णपणे संशोधनाकरीता आहे आणि संशोधनाचा पूर्ण खर्च संशोधकांकडून केला जाईल.

नुकसान भरपाई :-

अभ्यासक्रमा वेळी कांही दुखापत झाल्यास, के.एल.ई. हॉस्पिटल व एम.आर.सी. बेळगांव कडून उपचार केले जातील. कायद्या प्रमाणे अशा वैद्यकीय उपचाराला कोणतीही नुकसान भरपाई अथवा खर्च देणे नाही. जरी तुम्हाला दुखापत झाली असल्यास तुम्ही डॉ. - स्त्री रोग व प्रसुती विभाग, के.एल.ई. हॉस्पिटल किंवा एम.आर.सी. बेळगांवकडे संपर्क साधू शकता. नं.

प्रश्न :-

जर तुम्हाला अभ्यास क्रमा बदल भविष्यात कांही प्रश्न असल्यास तुम्ही डॉ. - स्त्री रोग व प्रसुती शास्त्र विभाग, के.एल.ई. हॉस्पिटल किंवा एम.आर.सी. बेळगांव नं. किंवा नं. किंवा डॉ. ; , अध्यापक - स्त्री रोग व प्रसुती शास्त्र विभाग, के.एल.ई. हॉस्पिटल किंवा एम.आर.सी. बेळगांव कडे संपर्क साधू शकता.

जर तुम्हाला अभ्यासक्रमाचा विषय असल्या बदल हळू विषयक कांही प्रश्न असल्यास तुम्ही डॉ. - अध्यापक व रोग निदान शास्त्राचे प्रमुख चेअरमन जे.एन.मॅडीकल कॉलेज इनस्टीट्यूशनल येथील कमिटी ह्युमन सबजेक्ट्स रिसर्च फोन नं. जे.एन.मॅडीकल कॉलेज बेळगांव यांना संपर्क साधू शकता.

संशोधनातील सहभागाकरिता सम्मती पत्र

मी-----

स्वइच्छेने संशोधनाच्या अभ्यासा करीता विषय म्हणुन सहभागी होण्यासाठी तयार आहे. हे सम्मती पत्र सही करुण मी माझे कुठलेही कायदेशीर हक्क सोडुन दिले नाहीत. मी कोणत्याही क्षणी विषय म्हणुन अभ्यास क्रमामधुन माघार घेवु शकते. तसेच या अर्जातील सर्व जबाबदारी व फायदे समजुन घेवुन व सर्व प्रश्नांची उत्तरे जाणुन मी हा सम्मती अर्ज वाचुन अथवा माझ्या भाषेत वाचुन घेवुन समजुन सही केलेला आहे.

विषयाचे नांव : -----

सही अथवा हा.डा.अं. -----

दि :-----

साक्षीदाराचे नांव :-----

सही ----- ता:-----

संशोधकाचे नांव :-----

सही ----- ता:-----

स्थळ :

दिनांक :

ANNEXURE III – PROFORMA

**TITLE: Prevalence of discordant growth in twin pregnancies –
A cross-sectional study.**

SLNO: _____ DATE:

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

GROUP: _____

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:

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

GESTATIONAL AGE: WEEKS

--	--

 DAYS

--	--

WAS THE CONSENT GIVEN?

YES:

--	--

 NO:

--	--

ULTRASOUND FINDINGS:

T₁ SCAN:

DATE:				
				POG:
				CRL:
				EDD:
DATE:				
POG:				
Study group	In cm / weeks	In percentiles	In cm /weeks	In percentiles
BPD				
HC				
AC				
FL				
EFW in grams				
DATE:				
POG:				
Study group	In cm /weeks	In percentiles	In cm /weeks	In percentiles
BPD				
HC				
AC				
FL				
EFW in grams				

DOPPLER FINDINGS: TWIN - A

Date	1	2	3
R.I			
P.I			
S/D RATIO			

DOPPLER FINDINGS: TWIN -B

Date	1	2	3
R.I			
P.I			
S/D RATIO			

PERINATAL OUTCOME: TWIN -A TWIN - B

GESTATIONA L AGE :

BIRTH WEIGHT (kgs):

Less than 1 kg	<input type="text"/>	<input type="text"/>
1 – 1.5 kg	<input type="text"/>	<input type="text"/>
1.5 – 2.0 kg	<input type="text"/>	<input type="text"/>
2.0 – 2.5 kg	<input type="text"/>	<input type="text"/>
2.5 – 3.0 kg	<input type="text"/>	<input type="text"/>
> 3.0 kg	<input type="text"/>	<input type="text"/>

DISCORDANCY : :

SEX: M F

APGAR SCORE : 1 MIN :
5 MIN :

NICU ADMISSION YES No

INDICATION :

NEONATAL COMPLICATIONS :

MODE OF DELIVERY :

VAGINAL :

SPONTANEOUS	<input type="text"/>
INDUCED	<input type="text"/>

VENTOUSE:

FORCEPS:

C-SECTION:

ELECTIVE / EMERGENCY

INDICATION: _____

ANNEXURE IV – KEY TO MASTER CHART

-	-	Absent
+	-	Present
CS	-	Caesarean section
CTG	-	Cardiotocography
EDD	-	Estimated date of delivery
EL	-	Elective
ELSCS	-	Emergency lower segment caesarean section
EM	-	Emergency
GA	-	Gestational age
GDM	-	Gestational diabetes mellitus
IN	-	Induced
IUGR	-	Intrauterine growth restriction
IUI	-	Intrauterine insemination
Kgs	-	Kilogram
KMC	-	Kangaroo mother care
LBW	-	Low birth weight
LL	-	Lower limb
LMP	-	Last menopausal date
MCDA	-	Monochorionic diamniotic
NICU	-	Neonatal intensive care unit
PIH	-	Pregnancy induced hypertesion
PROM	-	Prerupture of membrane
PV	-	Per vaginal

RDS	-	Respiratory distress syndrome
SP	-	Spontaneous
UA	-	Uterine artery
VG	-	Vaginal

8123180937 Mahadev